ABSTRACT

THE RELATIONSHIP BETWEEN HEALTH LITERACY, SELF-EFFICACY, AND QUALITY OF LIFE AMONG HEART FAILURE PATIENTS

By Mark T. Weidemann

Heart failure (HF) is a growing healthcare concern nearing epidemic numbers. The prevalence of HF was 5.8 million in 2006, with an annual incidence rate of 10 per 1000 after age 65. Mortality rates are high, as HF accounts for 282,754 deaths annually. In 2005, annual healthcare costs associated with HF were approximately $35 billion. These costs are estimated to increase to over $39.2 billion in 2010.

Quality of life (QOL) has been found to be a predictor of hospital readmissions and mortality in persons with HF. Inadequate health literacy and low self-efficacy have both been found to be related to poorer health outcomes, including lower QOL, yet few studies have examined these concepts together among HF patients. The purpose of this pilot study is to examine the possible relationships between health literacy, self-efficacy, and QOL among patients with HF. Bandura’s (1986) Social Cognitive Theory is utilized as the guiding theoretical framework for this study.

A non-experimental, cross-sectional, correlational design was utilized. A convenience sample of 5 inpatients with a primary diagnosis of HF was obtained from a hospital located in Northeast Wisconsin. The Newest Vital Sign instrument was used to measure health literacy; Self Efficacy for Managing Chronic Disease 6-Item Scale measured perceived self-efficacy; and QOL was measured using the Minnesota Living with Heart Failure Questionnaire. Data were analyzed using Pearson’s r and descriptive statistics.

The study demonstrated a highly significant relationship between self-efficacy and QOL ($r = -0.965, p = 0.01$). The relationships between health literacy and self-efficacy, as well as health literacy and QOL, were not found to be significant. All patients were found to have a high likelihood of having inadequate health literacy, had a moderately high level of self-efficacy and moderately low QOL.

The results demonstrate the need to be aware of the prevalence of inadequate health literacy in patients with HF and to seek interventions aimed at improving patients’ self-efficacy and QOL. The use of Bandura’s (1986) social cognitive theory may help advanced nurse practitioners discover interventions that will improve the overall QOL among HF patients.

Replication of this study with a larger sample size in multiple locations is warranted to improve the statistical power, as well as the generalizability, of the results. An experimental design would allow for causal inferences.
THE RELATIONSHIP BETWEEN HEALTH LITERACY, SELF-EFFICACY, AND QUALITY OF LIFE AMONG HEART FAILURE PATIENTS

by

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This paper is dedicated to the people in my life who supported me through the last 4 years, as I worked to fulfill a major goal in my life. To my wife, Cathy, who has made numerous sacrifices and given me all the support that I needed. To my children Anna and Andrew, who had to sacrifice play time with Daddy and let me have quiet time for studying when needed. To my mom, who took time out of her days to watch the children while I had to be at clinical, classes, or study. This journey has been long and hard. It would not have been possible without the support of my friends and family. Thanks!
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>LIST OF TABLES</th>
<th>vi</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIST OF FIGURES</td>
<td>vii</td>
</tr>
</tbody>
</table>

## CHAPTER I – INTRODUCTION

- Introduction .................................................. 1
- Significance to Nursing ........................................ 4
- Statement of the Problem ...................................... 5
- Purpose of the Study ............................................ 6
- Research Question ............................................. 6
- Definitions of Terms .......................................... 6
  - Conceptual Definitions ...................................... 6
  - Operational Definitions .................................... 7
- Assumptions .................................................... 7
- Chapter Summary .............................................. 8

## CHAPTER II – THEORETICAL FRAMEWORK AND REVIEW OF LITERATURE

- Theoretical Framework ......................................... 9
- Case Study Application ........................................ 13
- Literature Review .............................................. 16
  - Self-Efficacy .................................................. 16
  - Health Literacy .............................................. 17
  - Quality of Life .............................................. 20
  - Health Literacy and Self-Efficacy .......................... 22
  - Self-Efficacy and Quality of Life ......................... 23
  - Health Literacy and Quality of Life ....................... 24
  - Health Literacy, Self-Efficacy, and Quality of Life .... 25
- Chapter Summary .............................................. 26
TABLE OF CONTENTS (Continued)

<table>
<thead>
<tr>
<th>CHAPTER III – METHODOLOGY</th>
<th>27</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design of Study</td>
<td>27</td>
</tr>
<tr>
<td>Population, Sample, and Setting</td>
<td>27</td>
</tr>
<tr>
<td>Data Collection Instruments</td>
<td>28</td>
</tr>
<tr>
<td>Demographical Questionnaire</td>
<td>28</td>
</tr>
<tr>
<td>Newest Vital Sign</td>
<td>28</td>
</tr>
<tr>
<td>Self-Efficacy for Managing Chronic Disease 6-Item Scale</td>
<td>29</td>
</tr>
<tr>
<td>The Minnesota Living with Heart failure Questionnaire</td>
<td>29</td>
</tr>
<tr>
<td>Data Collection Procedures</td>
<td>30</td>
</tr>
<tr>
<td>Data Analysis Procedures</td>
<td>31</td>
</tr>
<tr>
<td>Limitations</td>
<td>32</td>
</tr>
<tr>
<td>Chapter Summary</td>
<td>32</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CHAPTER IV – RESULTS AND DISCUSSION</th>
<th>33</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>33</td>
</tr>
<tr>
<td>Demographic Data</td>
<td>33</td>
</tr>
<tr>
<td>Results</td>
<td>36</td>
</tr>
<tr>
<td>Research Question</td>
<td>36</td>
</tr>
<tr>
<td>Health Literacy and Self-Efficacy</td>
<td>36</td>
</tr>
<tr>
<td>Health Literacy and Quality of Life</td>
<td>36</td>
</tr>
<tr>
<td>Self-Efficacy and Quality of Life</td>
<td>36</td>
</tr>
<tr>
<td>Discussion of Findings</td>
<td>37</td>
</tr>
<tr>
<td>Chapter Summary</td>
<td>39</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CHAPTER V – SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS</th>
<th>41</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>41</td>
</tr>
<tr>
<td>Conclusions</td>
<td>43</td>
</tr>
<tr>
<td>Limitations of the Study</td>
<td>44</td>
</tr>
<tr>
<td>Implications for Advanced Practice</td>
<td>44</td>
</tr>
<tr>
<td>Recommendations for Future Studies</td>
<td>45</td>
</tr>
<tr>
<td>Chapter Summary</td>
<td>45</td>
</tr>
</tbody>
</table>
TABLE OF CONTENTS (Continued)

APPENDIXES

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix A</td>
<td>Demographical Survey</td>
<td>47</td>
</tr>
<tr>
<td>Appendix B</td>
<td>Newest Vital Sign Instrument</td>
<td>49</td>
</tr>
<tr>
<td>Appendix C</td>
<td>Self-Efficacy for Managing Chronic Diseases 6-Item Scale</td>
<td>52</td>
</tr>
<tr>
<td>Appendix D</td>
<td>Minnesota Living With Heart Failure Questionnaire</td>
<td>54</td>
</tr>
<tr>
<td>Appendix E</td>
<td>Permission to Use the MLHFQ Instrument</td>
<td>56</td>
</tr>
<tr>
<td>Appendix F</td>
<td>University of Wisconsin IRB Approval Letter</td>
<td>58</td>
</tr>
<tr>
<td>Appendix G</td>
<td>Aurora Health Care IRB Approval Letter</td>
<td>60</td>
</tr>
<tr>
<td>Appendix H</td>
<td>Consent for Participation Form</td>
<td>64</td>
</tr>
</tbody>
</table>

REFERENCES | 72 |
## LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1.</td>
<td>Frequency and Percentage of Demographic Characteristics</td>
<td>34</td>
</tr>
<tr>
<td>Table 2.</td>
<td>Descriptive Statistics -- Instruments</td>
<td>36</td>
</tr>
<tr>
<td>Table 3.</td>
<td>Correlations Between Health Literacy, Self-Efficacy, and Quality of Life</td>
<td>37</td>
</tr>
</tbody>
</table>
LIST OF FIGURES

Figure 1. Social Cognitive Theory – Causal Structure Model.......................... 11
CHAPTER 1

INTRODUCTION

Introduction

Heart failure (HF) is a growing health care concern nearing epidemic numbers (Cutilli, 2007). While many of the cardiovascular disease rates have leveled off or decreased, HF rates continue to rise (Anderson et al., 2006). This is likely due to the aging population and improving technology that has increased the patient survival rate after suffering heart attacks (Speros, 2004). The prevalence of HF was 5.8 million in 2006, with an annual incidence rate of 10 per 1000 after the age of 65, and the HF mortality rate is estimated at 282,754 deaths per year (Donald et al., 2009).

Recently, HF has been cited as the most common discharge diagnosis among patients over the age of 65 years and attributes to around 11 million office visits and 3.5 million hospitalizations annually (Anderson et al., 2006). Among the Medicare population, readmission rates are reported at 24.5%, which is highest among all medical diagnoses (Anderson et al., 2006). One third of persons hospitalized with HF are readmitted in 3 to 6 months after discharge (Anderson et al., 2006).

Financial issues are a concern as well, especially in today’s crisis involving health care costs. Patients with HF usually require costly emergency visits and hospitalizations (Murray et al., 2009). In the United States (U.S.), health care costs associated with HF exceed $34.8 billion dollars. In 2004, HF was the second highest expense billed for Medicare, accounting for 5.8% of Medicare’s total expenditures (Murray et al., 2009). Episodes of hospitalizations, including emergency visits for HF, were found to be preventable in about 40% of cases (Anderson et al., 2006).
Many factors that impact the outcomes in patients with HF have been explored. Quality of life (QOL) has been found to be a factor in various chronic disease outcomes, including HF, such as in hospital readmissions (Mejhert, Kahan, Persson, & Edner, 2006), mortality (Rodriguez-Artalejo et al., 2005), depression (Goldney, Fisher, Phillips, & Wilson, 2004), and health care costs (Eisner et al., 2002).

Quality of life is a measurement that is commonly used to indicate the physical, social, and psychological functioning of patients (Arnold et al., 2005). Physical functioning can be affected by symptoms such as shortness of breath, peripheral edema, fatigue, and difficulty sleeping. Psychological functioning can be affected by symptoms such as anxiety and depression. Finally, social functioning can be affected by ability to earn a living, visiting friends or relatives, as well as performing sexual activities (Rector & Cohn, 2005).

In persons with HF, QOL has been found to be a predictor of hospital readmissions and mortality (Mejhert et al., 2006; Rodriguez-Artalejo et al. 2005). Sub-domains of QOL, such as pain, sleep, anxiety, and physical mobility, also have been found to predict not only readmissions, but lower physical, social, and psychological functioning among HF patients (Mejhert et al., 2006).

It is important to discover ways for health care providers to help persons with HF improve their QOL. Researchers have discovered that both health literacy and self-efficacy have been positively associated with QOL in chronic diseases, including HF (Joekes, Elderen & Schreurs 2007; Lavoie et al., 2008; Mancuso & Rincon, 2006; Tokuda, Doba, Butler & Paasche-Orlow, 2009).

Self-efficacy, defined as a person’s confidence or belief that they can competently perform a particular behavior (Bandura, 1986), appears to be linked to
health outcomes and QOL. Tsay and Chao (2002) reported that patients who have confidence in their abilities to modify their health behaviors will be more likely to actually perform those tasks. A positive correlation was found between self-efficacy and higher levels of functional status among HF patients, therefore, resulting in improved health behaviors (Tsay & Chao, 2002). Their results were consistent with findings from previous cardiac studies from Joekes et al. (2007) and Arnold et al. (2005), where a significant positive relationship between self-efficacy and QOL among cardiac patients was demonstrated.

Health literacy is a relatively new and emerging concept defined as the degree of ability that an individual has to obtain, process, and understand health information and services required to make sufficient health decisions (Speros, 2004). Patients with poor health literacy levels have difficulties with reading labels on pill bottles, food labels, and dosing schedules, as well as with comprehending appointment schedules and educational brochures (Speros, 2004). The effects and prevalence of health literacy has received a greater amount of attention over the past 5 years. One of the objectives for the nation in Healthy People 2010 is improving the health literacy skills of the U.S. population (U.S. Department of Health and Human Services, 2000). The Institute of Medicine (IOM) also has recognized health literacy as an important factor in health care delivery, as it is listed as 1 of 20 priority areas of quality improvement (IOM, 2004).

A meta-analysis of 85 studies related to health literacy between the years of 1963 to 2004 indicated a prevalence of 46% for low and marginal health literacy (Paasche-Orlow, Parker, Gazmararian, Nielsen-Bohlman & Rudd, 2005). Gazmararian, Williams, Peel, and Baker (2003) found that 81% of English speaking patients over the age of 60 had inadequate health literacy. Among the Medicare population, 30% of
enrollees do not have adequate health literacy skills (Gazmararian et al., 2003). This is concerning, as the Medicare population of 65 years of age and older carries the greatest burden of chronic diseases such as HF (Gazmararian et al., 2003).

Health literacy has been associated with poorer health status, lower self-care abilities, less health care knowledge, higher hospitalization rates, and higher health care costs, as well as lower QOL (Dan et al., 2006). Persons with chronic disease and low health literacy have less knowledge of their disease and self-management skills than people of adequate literacy (Gazmararian et al., 2003). Therefore, it is important to identify people with inadequate health literacy skills due to its potential impact on self-efficacy and QOL.

Few studies examining the relationship between health literacy, self-efficacy, and QOL among HF patients have been identified. It is reasonable to postulate that individuals who have low health literacy skills may have a low self-efficacy due to their perceived inadequacies, and that patient's QOL and health outcomes may be directly related to their self-efficacy and health literacy. Therefore, it is important to discover whether these concepts are related, as it may provide a target for inventions that may positively impact QOL in persons with HF.

Significance to Nursing

Heart failure is a chronic disease that requires collaboration with the patients, family members, and health care providers. Advanced practice nurses (APN) are prominent in the health care field and are responsible for the management of patients with chronic disease. As the population of people with HF rises, the importance of the APN’s role increases, as well.
Education has been considered a fundamental part of nursing practice. It is essential for nursing to continue to evolve its education practice to help with the challenges of global health. Advanced nurse practitioners promote holistic care, as well as self-efficacy, to provide the patients with tools to modify their own behavior. This may become difficult without being familiar with the concept of health literacy. The effects and prevalence of health literacy has received a greater amount of attention over the past 5 years. One of the objectives for the nation in Healthy People 2010 is improving the health literacy skills of the U.S. population (U.S. Department of Health and Human Services, 2000). Having the fundamental knowledge of health literacy will help identify potential interventions that may impact self-efficacy and ultimately QOL.

Statement of the Problem

The incidence and prevalence of HF continues to grow, as does the hospital readmission rates (Donald et al., 2009; Murray et al., 2009). Agencies are looking for ways to reduce costs from preventable hospitalizations of HF patients (Rodriguez-Artalejo et al., 2005). Quality of life has been shown to be a predictor of hospital readmissions (Rodriguez-Artalejo et al., 2005), and therefore, exploring ways to improve QOL may be a possible avenue to reduce hospitalization and costs. Quality of life is a multi-factorial concept involving physical, social, and psychological functioning. Self-efficacy has been correlated with QOL; however, self-efficacy itself is a multi-factorial concept, as well. Health literacy may impact a person’s self-efficacy and ultimately impact their QOL; yet, these concepts are not well studied together in the HF population.
Purpose of the Study

The purpose of this pilot study was to examine the relationships between health literacy, self-efficacy, and QOL among patients with HF. The results may help determine if higher health literacy and self-efficacy may be correlated to higher QOL and, therefore, help discover interventions that may be utilized to improve the QOL in HF patients.

Research Question

What are the relationships between health literacy, self-efficacy, and QOL among heart failure patients?

Definitions of Terms

Conceptual Definitions

*Health literacy:* Health literacy is the degree of ability that an individual has to obtain, process, and understand health information and services required to make sufficient health decisions (Speros, 2004).

*Heart failure (HF):* Heart failure is a chronic clinical disease caused by the reduced ability of the heart to pump blood throughout the body. The disease is usually caused by coronary artery disease (CAD), hypertension, and diabetes. Symptoms of HF include of dyspnea, fatigue, and lower extremity edema (Ross et al., 2008).

*Quality of life (QOL):* Quality of life is a measurement that is commonly used to indicate the physical, social, and psychological functioning of patients (Arnold et al., 2005).
Self-efficacy: Self-efficacy is a person’s belief about their abilities to perform certain actions in events that affect their lives. It is not their skill, but the process of how they feel, think, motivate themselves and their decision process (Bandura, 1994).

Operations Definitions

Health literacy: Health literacy will be quantified using The Newest Vital Sign (NVS) assessment tool (Stanford Patient Educational Research Center, 2009).

Heart failure patients: For the purpose of this study, a HF patient will include any person between the ages of 18 and 89 years, who is hospitalized with ICD-9 diagnostic code of 428.0 or 428.9 (HF).

Quality of life: Quality of life will be quantified by utilizing the Minnesota Living with Heart Failure Questionnaire (MLHFQ).

Self-efficacy: Self-efficacy will be quantified using the Self-Efficacy for Managing Chronic Diseases 6-Item Scale (SEMCDS), which will measure their confidence level in performing various tasks related to their chronic disease of HF.

Assumptions

1. Patients will answer the questionnaires truthfully.
2. The NVS assessment tool will be a valid and reliable measure of health literacy.
3. Patients with HF have inadequate health literacy level.
4. Self-efficacy is influenced by an individual’s health literacy level.
5. Self-efficacy is an important determinant for behavior.
6. There is a dynamic, continuous interaction between the individual, environment and behavior.
Chapter Summary

Heart failure is approaching epidemic numbers and attributes to almost $35 billion in health care costs for the U.S. alone. This has prompted various agencies to look for ways to reduce costs, including factors impacting hospitalizations. Quality of life is a predictor of health status and hospital readmissions in HF. Identifying targets for intervention that may positively impact QOL is crucial.

Self-efficacy is also a concept that can affect health behaviors. Lower self-efficacy has been found to result in lower patient outcomes and QOL (Arnold et al., 2005; Joekes et al, 2007; Tsay & Chao 2002). Health literacy has gained much attention throughout the health care industry. The prevalence of inadequate health literacy is alarmingly high (Paasche-Orlow et al., 2005). Lower health literacy has been found to negatively impact health behaviors. Lower health literacy and perceived self-efficacy have been shown to be associated with poorer QOL, as well as increased readmissions; yet, few studies were identified that explore all three concepts within the same sample of persons with HF. Therefore, the purpose of this study is to examine the relationships between health literacy, self-efficacy and QOL.
Theoretical Framework

The theory of self-efficacy describes an individual's perception in their capabilities to perform challenging tasks. In 1986, Bandura conceptualized self-efficacy. He then went on to determine that strong efficacy will enhance human accomplishment, while a weak sense of efficacy will weaken commitment to difficult tasks (Bandura, 1994).

Self-efficacy is based upon Bandura's Social Cognitive Theory, which is a way to view human functioning. Bandura (1986) describes how cognition, vicarious experiences, self-regulatory, self-reflective processes, and social environment play a central role to the construction of self-efficacy beliefs. Behavior self-efficacy can be influenced by factors such as past personal accomplishments, vicarious and emotional experiences, and coping abilities, as well as, the way one cognitively processes the experiences (Bandura, 1977). Also, social settings can influence self-efficacy behavior and vice versa. An individual with a lower level of self-efficacy may choose environments that are less threatening, where an individual with higher level of self-efficacy may choose environments where they can get involved in activities (Bandura, 1977).

Bandura believed that cognitive thought was a missing element in other social theories. As a result, human functioning is viewed as a dynamic triadic reciprocity of personal factors, behavior, and environment influences (Bandura, 1986). The Causal Structural model of Social Cognitive Theory depicts the reciprocal interaction between
the three determinants (Figure 1). The theory provides a means to understand and predict human behavior. Bandura (1986) describes the determinants as follows:

1. **Personal:** The concept of personal factors is described as determinants, such as cognitive abilities, expectations, beliefs, self-perceptions, emotions, sex, ethnicity, and genetic predisposition. These factors influence the personal beliefs, coping abilities, problem solving abilities, and decisions, which all affect a human’s learning process, and self-efficacy behaviors (Bandura, 1986).

2. **Environment:** Environment refers to external social and physical factors that affect a person’s behavior. Social environment may include family, friends, and colleagues, while the physical environment includes factors such as living accommodations, availability of foods, temperature, electricity and plumbing (Bandura, 1986).

3. **Behavior:** Behavior refers to the resulting actions of the individual (Bandura, 1986).
*Cognitive abilities include health literacy, the ability to perform basic reading, writing, and numerical tasks.

Figure 1. Social Cognitive Theory – Causal Structure Model (Bandura, 1986) (*adapted to include concept of health-literacy and self-efficacy).
The reciprocal interaction between the concepts is dynamic and bi-directional. Personal factors influence both behavior and the environment. In this interaction, a person who is upset while the APN attempts to educate him or her may create a negative environment that can ultimately affect the teaching an APN provides, as well as the ability the person has to learn. These personal and environment factors may then impact the subsequent behavior. This may result in a negative behavior, which then may negatively affect personal factors, as well as the environment. This dynamic model provides a means to explain and predict behaviors and can help APNs identify areas to intervene in order to promote positive patient outcomes. The reciprocal model shows how dynamic a person’s self-efficacy is and how it can be affected. Past personal and vicarious experiences and supportive social environments all can contribute to both higher personal goals and the belief that he or she can successfully achieve their goals (Bandura, 1986).

Bandura’s theory of self-efficacy suggests that an individual’s confidence in their abilities to perform health behaviors will influence their actual performance and adherence of those behaviors (Urmimala, Sadia & Mary 2009). Therefore, a belief in one’s ability to successfully perform health behaviors can directly impact health outcomes. The Social Cognitive Theory provides a framework to help develop strategies for improving a person’s self-efficacy by influencing personal factors, environmental factors, or behaviors. The concept of health literacy is related to Bandura’s concept of personal factors as it involves cognition capability (See Figure 1). Health literacy is the degree of ability that an individual has to obtain, process, and understand health information and services required to make sufficient health decisions (Speros, 2004). Thus, health literacy may directly impact the personal factor within the Causal Structure.
Model and thus, via triadic reciprocality, will ultimately determine the resultant behavior. These relationships may either foster or inhibit self-efficacy.

Both self-efficacy and health literacy are related to the concepts in Bandura’s Social Cognitive Theory and, therefore, may be associated with a patient’s QOL. Quality of life is a measurement that is commonly used to indicate the physical, social, and psychological functioning of patients (Arnold et al., 2005). Quality of life has been used as an overall measure of well-being in persons with chronic diseases (Arnold et al., 2005; McAuley et al., 2006). Since self-efficacy and health literacy both influence a person’s ability to perform and adhere to health behaviors (Mancuso & Rincon, 2006; Urmimala et al., 2009), they can potentially influence QOL.

Case Study Application

Mr. Marvin Lee is a 72-year-old widowed gentleman who was admitted to the hospital for nocturnal dyspnea and pulmonary rales. He had worked as a machinist with various employers and retired 7 years ago from John Deere after 18 years of employment. One year ago, Marvin had severe heartburn that turned into crushing chest pain. He was brought to the hospital via ambulance and had emergency coronary artery bypass graft surgery, where four grafts were placed. This was an unsettling experience for him, as he felt dependencies that he never had before. Six months ago, he came to the emergency department with symptoms of shortness of breath and was admitted with a diagnosis of HF. Prior to discharge, Marvin was given a booklet about HF and a list of medications he needed to take once he returned home. The nurse had told him he could only have 2,000 milligrams (mgs) of salt a day and needed to weigh himself each morning. Marvin looked through the HF booklet, but didn’t understand why
he had to take the medications, or why he had to weigh himself each morning. This describes the personal factors that impact Marvin’s confidence in his ability to carry out healthy behaviors. Specifically, Marvin’s inadequate health literacy inhibited him from fully understanding his written educational materials and medication regime.

Upon returning home, Marvin found the medication regimen was overwhelming for him. Some medications were to be taken only when needed, other medications needed to be taken once a day, and still others were twice a day. He then began to give up on taking a few of the newer medications and wished that his wife was still alive, as he knew that she would be able help him. He canceled appointments with his ANP and did not following a low salt diet, as he did not see the benefit in doing these things. The environmental factors of being a widow without social support not only impacted his personal factors, but his perceptions and cognition (i.e. inadequate health literacy), ultimately influenced his behavior.

For a short period of time, Marvin did okay at home; therefore, his behaviors reinforced his personal factors and environment. However, 2 months later, Marvin began to gain weight, feel short of breath, and could not function like was able to in the past. This resulted in a decreased QOL. He felt that he was no longer able to manage his health, creating a negative environment, and finally began to give up on trying to adhere to his medication and exercise regimen.

He was admitted to the hospital again with a diagnosis of HF with the same symptoms. At the time of discharge, the nurse went over the risks of his current health management decisions and strongly encouraged Mr. Lee to adhere to his discharge instructions. His world seemed to come crashing down even further. He felt he would not be able to live his life as he had earlier, as he has been told that he will need to
make many changes, including checking daily weights, taking six more medications, and
eating low sodium and low fat foods. This was all overwhelming for him, so he
reluctantly decided to visit his APN the following day after his discharge.

His APN had reviewed his records and decided to have a “heart-to-heart”
discussion with Mr. Lee regarding his disease and hospital readmissions to find out what
might be causing his current health outcomes. In the beginning of the visit, Mr. Lee’s
health literacy was assessed and was found to be low. Mr. Lee did not fully understand
his disease (personal factor); the required medication, diet, and health management
regimen (personal factor); lives alone and never had to learn how to cook heart healthy
meals (personal factor and environment); lacked confidence in his abilities to perform
and meet the needed tasks and goals (self-efficacy); and had been unable to perform
activities or visit relatives (QOL).

Mr. Lee was setup to see a nurse and dietitian to review his disease and health
management program. The staff encouraged Mr. Lee that he was fully capable of
managing his disease and that they just need to help him better understand his disease
management. They reviewed educational materials with him, which were written at an
appropriate literacy level that he could understand. This created a positive learning
environment for Marvin. At the end of the appointment, Mr. Lee felt more confident in his
ability to manage his disease and began to follow-up with his health care provider on a
regular basis. Currently, Mr. Lee has been adhering to his disease management plan
and, as a result, has not been hospitalized again. He is finally able to perform activities
he enjoys, such as walking in the woods, visiting relatives, and working on his 1930 Ford
Model A coupe. In summary, through better cognitive ability, self-perception, and a
positive environment, he felt more prepared to meet the tasks needed to adopt a healthy
lifestyle and adhere to his management plan. This led to a better self-efficacy and QOL, and he did not get readmitted to the hospital.

This case study describes Bandura’s Social Cognitive Theory and model, which helps explain Mr. Lee’s behaviors through the interaction between self-efficacy and health literacy and their impact on QOL.

Literature Review

This review of literature focuses on the concepts of healthy literacy, self-efficacy, and QOL, as well as how they are related to each other.

Self-Efficacy

Self-efficacy is defined as a person’s confidence or belief that they can competently perform a particular behavior (Bandura, 1986). Self-efficacy has been studied across many chronic disease states and has been found to be positively correlated with physical and psychological health outcomes (Lavoie et al., 2008; Tsay & Chao, 2002; Urmimala et al., 2009).

Tsay and Chao (2002) explored the relationships between self-efficacy, functional status, and depression in 100 chronic HF patients using a non-experimental, correlational design. A significant positive correlation between perceived self-efficacy and functional status ($r = 0.55, p < 0.001$) was found, while a significant negative correlation between self-efficacy and depressive symptoms ($r = -0.61, p < 0.001$) was demonstrated. This study suggests that HF patients with high levels of perceived self-efficacy have a higher level of functional status, therefore, indicating that self-efficacy plays a strong role in the maintaining both good physical and emotional function in HF patients.
Urmimala et al. (2009) studied the relationship between self-efficacy and health status in patients with coronary heart disease. They utilized a non-experimental, cross-sectional prospective design. A sample of 1,024 outpatients with coronary heart disease (CHD) was recruited over a period of 2 years. The mean age of the participants was 67 years. Eighty-seven percent of them graduated from high school, while 47% of them had an income of less than $20,000. Lower self-efficacy scores were independently associated with lower health status outcomes, greater physical limitation, diminished QOL, and lower overall health. The researchers had found that self-efficacy was strongly predictive of overall health status. The results, therefore, suggest that interventions to improve self-efficacy can assist in improving overall outcomes.

Health Literacy

Only recently has the health care community begun to recognize health literacy as a problem of significant magnitude. Health literacy is defined as the degree of ability that an individual has to obtain, process, and understand health information and services required to make sufficient health decisions (Speros, 2004). The American Medical Association (AMA) published its first paper related to health literacy in 1999 (American Medical Association Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, 1999). Since then, the IOM, the Agency of Healthcare Research and Quality, and the Joint Commission of Accreditation of Health Care Organizations have begun to state and address the issue of health literacy (Safeer, Cooke & Keenan, 2006).

A meta-analysis of 85 U.S. studies related to health literacy between the years of 1963 to 2004 indicated that 46% of persons in the U.S. have low or marginal health literacy (Paasche-Orlow et al., 2005). Gazmararian et al. (2003) found that 81% of English-speaking patients over the age of 60 had inadequate health literacy. Among the
Medicare population, 30% of enrollees did not have adequate health literacy skills (Gazmararian et al., 2003). This is concerning, as the Medicare population of 65 years of age and older carries the greatest burden of chronic diseases, such as HF (Gazmararian et al., 2003). Furthermore, HF is the second highest expense billed for Medicare, accounting for 5.8% of Medicare’s total expenditures (Murray et al., 2009).

The relationships between inadequate literacy skills and health outcomes are now recognized and better understood. Having inadequate health literacy has been found to result in poor medication adherence (Chew, Bradley, Flum, Cornia & Koepsell, 2004); lower QOL (Mancuso & Rincon, 2006); and increased health care costs (Howard, Gazmararian & Parker 2005; Weiss & Palmer, 2004). Inadequate health literacy negatively affects health-promoting behaviors, history taking, and explanations concerning diagnoses and treatment (AMA, 1999). Powell, Hill and Clancy (2007) found that lower health literacy was associated with poorer disease knowledge in patients with diabetes. Corroborating these findings, Schillinger et al. (2002) examined the association between health literacy with diabetes outcomes. They found that patients with lower health literacy significantly predicted poor glycemic control in diabetics.

Wolf, Gazmararian, and Baker (2005) investigated the relationship between health literacy and functional health status among older adults. The study was a cross-sectional survey of 2,923 participants. Health literacy was measured with the Test of Functional Health Literacy in Adults (TOFHLA) instrument, while functional status was measured using the Medical Outcome Study 36-Item Short Form Health Survey. The results of the study indicated that individuals with inadequate health literacy had lower physical functioning (67.7 versus 78.0, p < 0.001). Furthermore, individuals with inadequate health literacy were more likely to report difficulties with activities of daily
living (OR, 1.79; 95% CI, 1.39 – 2.32). They concluded that, among the older adult participants, inadequate health literacy was independently associated with lower functioning health status. This study also compared the HF rates among individuals with inadequate health literacy with those with adequate health literacy. The comparison indicated that individuals inadequate health literacy had significantly higher rates of HF (6.1% versus 3.8%, p = 0.05). A limitation of the study was that the functional status was a measurement of the participants self-report.

Murray et al. (2009) studied the factors associated with exacerbation of HF, as well as, the relationship between the number of hospitalizations and emergency room visits and health literacy, functional status, and demographics, including age, race, sex, and education. The researchers measured a comprehensive set of independent variables in a randomized sample of 192 HF patients at 6 months and 12 months. The median age of the participants was 62.6 years. Seventy-one percent of participants were found to have adequate health literacy, as measured by the Short Test of Functional Health Literacy in Adults (STOFHLA). The results indicated that patients with adequate health literacy had 64% fewer hospital admissions for HF (Incident ratio – 0.35; 95% confidence interval, 0.15 – 0.76). Quality of life was measured using the Chronic Heart Failure Questionnaire. Participants with higher QOL scores had 34% less emergency visits (incident ratio 0.71; 95% CI, 0.50 – 1.01). The study suggests that health literacy skills are a key factor in managing costly health care. Finally, they found that participants who are older, less educated, and of a race other than White have both lower STOFHLA scores and QOL. A limitation of this study was that the sample was recruited from a largely indigent population and, therefore, may not represent the
general population. Another limitation was that the numbers were sparse for HF-specific events and will need further studies to confirm their results.

Gazmararian et al. (2003) examined the relationship between health literacy and chronic disease knowledge among patients with a hypertension, diabetes, HF, and asthma. The study was non-experimental and utilized the STOFHLA and chronic disease knowledge questionnaires instruments for their assessment. They determined that participants with inadequate health literacy had significantly less knowledge about their disease than participants with adequate health literacy. Similar to Murray et al. (2009), demographic variables, such as age, education level, and race were associated with health literacy skills and QOL.

Dan et al. (2006) investigated the relationship between health literacy and demographic information, including age, race, education, and gender among HF patients. The sample consisted of 314 middle-aged and older adults who were diagnosed with HF and were taking at least one HF medication. Health literacy was measured with the STOFHLA instrument. Twenty-eight percent of the participants had either inadequate or marginal health literacy. The results of the study indicated that age was negatively associated with health literacy \( r = -0.11, p < 0.05 \). Education was also found to be independently associated with health literacy, while race and gender explained very little variance in literacy. A limitation of the study was that the sample consisted of only White and African-American participants, which limits generalizability to other ethnicities.

Quality of Life

Quality of life is a measurement that is commonly used to indicate the physical, social, and psychological functioning of patients (Arnold et al., 2005). Physical
functioning includes shortness of breath, fatigue, peripheral edema, and difficulty sleeping, as well as psychological symptoms, such as anxiety and depression. Social functioning includes ability to work, go places, and doing things with family and friends. Finally, psychological function includes concentration, memory, and self-control (Rector, 2005). The concept of QOL has been extensively studied in literature in relation to health outcomes and has been found to be a factor in various chronic disease outcomes, such as hospital readmissions (Mejhert et al. 2006), mortality (Rodriguez-Artalejo et al., 2005), depression (Goldney et al, 2004), and health care costs (Eisner et al., 2002).

The overall prognosis of HF is poor, and mortality has been shown to exceed that of many other diseases. Heart failure accounts for approximately 65% to 75% of the total health care costs due to the complexities related to the disease (Mejhert et al., 2006). Quality of life has been found to be related to the New York Heart Association (NYHA) functional class, sex, and marriage status (Cline, Willenheimer, Erhardt, Wiklund & Israelsson, 1999; Rivas, Permanyer-Miralda, Brotons, Anzar & Sobreviela, 2008). Therefore, finding a way to improve the QOL is essential in helping to control health care costs and improve outcomes for persons with HF.

Cline et al. (1999) studied health-related quality of life (HRQL) in elderly patients with HF. They explored the correlations between QOL and the NYHA functional class, as well as with age, marriage status and sex. The results indicated that higher NYHA functional class was associated with poorer QOL. Women were found to be associated with poorer QOL. Age was found to have a weak association until age 80. Finally, married patients were associated with higher QOL compared to single patients. In addition, they concluded that HRQL in the elderly is adversely affected by HF functional status.
Mejhert et al. (2006) studied the relationship between QOL and hospital readmissions among HF patients. Their research consisted of a prospective study consisting of 208 HF patients who were 60 years of age and older. Quality of life was measured by utilizing the Nottingham Health Profile (NHP), a non-disease specific, 38-item questionnaire. The participants were followed for 18 months. A univariate analysis revealed that readmissions were predicted by poor QOL (169 versus 83, p < 0.001), while mortality was also predicted by poor QOL (183 versus 142, p < 0.05).

**Health Literacy and Self-Efficacy**

Wagner, Semmler, Good, and Wardle (2009) explored the relationship of health literacy and self-efficacy in regards to patients participating in colorectal screening. The sample consisted of 96 participants between the ages of 50 and 69 years. Health literacy was measured with the TOFHLA instrument, while self-efficacy was measured with a 4-item questionnaire. The results of the study demonstrated a significant positive association between health literacy and self-efficacy (r = 0.33, p < 0.001). A limitation to this study was the relatively small sample size.

Torres and Marks (2009) studied the relationships between health literacy and self-efficacy among patients needing to make decisions regarding their post menopausal health. The sample consisted of women between the ages of 45 and 65. Pearson’s r correlation indicated a strong positive relationship between health literacy and self-efficacy (r = 0.69, p < 0.01). Again, this study had a relatively small sample size and consisted of only female participants.

Conversely, Sakar, Fisher, and Schillinger (2006) explored the relationship between self-efficacy and health literacy among diabetic patients and found no relationship. They also found that the self-efficacy scores did not differ significantly
across race. The sample size of 408 participants consisted of six different races. One possible reason for the results may be a relatively young population, with a mean of 58.1 years. Also, over half of the participants were managed with oral medications or diabetic diet alone.

_Self-Efficacy and Quality of Life_

McAuley et al. (2006) explored the relationship between self-efficacy and QOL among older adults. The sample consisted of 249 adults with a median age of 68.12 years. Self-efficacy was measured with the Exercise Self-efficacy Scale and QOL with the Satisfaction with Life Scale. The results of the study indicated a positive relationship between self-efficacy and QOL ($r = 0.35$, $p < 0.05$). This is important, as it indicates that a person’s confidence in their abilities has implications to their health outcomes. Limitations to this study included a small sample size and that the participants were all women.

Lavoie et al. (2008) investigated the relationship between self-efficacy and QOL among patients with asthma. The sample consisted of 557 asthma adult patients. Self-efficacy was measure using the Asthma Self-Efficacy Scale and QOL using the Asthma Quality of Life Questionnaire. The results of the study indicated a moderate to strong positive correlation between self-efficacy and QOL ($r = 0.62$, $p < 0.001$). Other results of the study indicated that age, lower education, unemployment, and being non-White were associated with lower self-efficacy and QOL. Although the sample size was adequate, results may not be generalizeable to community settings, as the sample was drawn form a tertiary clinic. Another limitation was that self-report instruments were utilized and, therefore, may be subject to recall bias.
Joekes et al. (2007) studied the relationship between self-efficacy and QOL in 41 patients with HF. Self-efficacy was strongly associated with QOL, as a positive correlation between self-efficacy and QOL was demonstrated. Therefore, higher self-efficacy scores were correlated with better QOL. This study confirms the importance of enhancing self-efficacy in HF patients in order to help improve their QOL. Limitations to this included a fairly small homogeneous sample.

Arnold et al. (2005) used a cross-sectional study to explore the relationship between self-efficacy and QOL among outpatients with chronic obstructive pulmonary disease and HF. Sixty-five HF patients participated in the study. Quality of life was measured using the Rand 36-item Health Survey, which measures the three domains of physical, psychological, and social functions. Self-efficacy was measured with Sullivan’s Self-efficacy Scale. Self-efficacy was significantly related to QOL ($r = 0.50, p < 0.001$). Patients with higher self-efficacy reported better physical functioning.

**Health Literacy and Quality of Life**

Bautista, Glen, Shetty and Wludyka (2009) explored the association between health literacy and QOL among 140 adult patients with epilepsy. The researchers determined that inadequate health literacy scores were associated with lower QOL scores. Health literacy was measured utilizing only three questions from the STOHFLA instrument rather than the standard 36-item questionnaire. This may have affected the reliability and validity of this measure.

Tokuda et al. (2009) had also found a relationship between health literacy and QOL. A sample of 1,040 participants was collected from a national on-line survey in Japan. Quality of life was measured by utilizing the physical and psychological domains of the World Health Organization Quality of Assessment-BREF (best technique available
reference notes). A one-item screening question was used to determine health literacy. Individuals with inadequate health literacy had significantly lower mean scores on their physical well-being scores compared to those with adequate health literacy (60.6 versus 71.7, 95% CI -14.0 to -8.3). They had also found similar results with psychological well-being scores (59.7 versus 68.3, 95% CI -11.4 to -5.7). A limitation to this study was that the researchers were unable to utilize the more validated tools for measuring health literacy, such as the TOFHLA or Rapid Estimate of Adult Literacy in Medicine (REALM) due to difficulties with translation into the Japanese language. However, the 1-item screening question was validated against REALM and STOFHLA.

*Health Literacy, Self-Efficacy, and Quality of Life*

Mancuso and Rincon (2006) explored the relationship between health literacy, self-efficacy, and QOL in adults with asthma. Health literacy was measured with the TOFHLA instrument, QOL with the Asthma Quality of Life Questionnaire (AQLQ), and self-efficacy with the Asthma Self-Efficacy Scale. Of the 175 patients, 18% had marginal or inadequate health literacy. A statistically significant relationship between lower health literacy and lower QOL was demonstrated. The correlation between health literacy and self-efficacy was found to be non-significant ($r = 0.05$, $p = 0.66$). The relationship between QOL and self-efficacy was not explored. This study suggests that health literacy may be related to self-efficacy. However, limitations of the study included lack of generalizability, as the study was conducted in an urban practice. Also, only two questions were used to measure the concept of self-efficacy, which may have reduced the reliability and validity of this measure.
Chapter Summary

In this chapter, the theoretical framework of Bandura’s Social Cognitive Theory was presented, along with relevant literature related to the concepts of self-efficacy, health literacy, HF, and QOL were presented. A review of the Bandura’s Social Cognitive Theory and model demonstrates how self-efficacy, health literacy, and QOL may be related.

The individual concepts are well documented in the literature, but there were a limited number of studies that have examined the associations between self-efficacy, health literacy, and QOL, particularly among individuals with HF. Therefore, a need exists to examine these associations. Exploring the possible relationships between self-efficacy, health literacy, and QOL may identify targets for intervention that can impact and improve QOL in persons with HF.
CHAPTER III
METHODOLOGY

The purpose of this study was to examine the relationships between health literacy, self efficacy, and QOL among HF patients. In this chapter, the design, population, sample, setting, data collection instruments, data analysis procedures, and limitations will be presented.

Design of the Study

The study utilized a nonexperimental, descriptive, correlational design. A correlational design was used to determine if a relationship exists between health literacy, self-efficacy, and QOL.

Population, Sample, and Setting

The target population for this study was inpatients with a diagnosis of HF in northeast Wisconsin. The sample for this study was a convenience sample with the following inclusion criteria: (a) current inpatients on the telemetry floor with a ICD-9 diagnostic code of 428.0 or 428.9 (congestive HF), (b) 18 to 89 years of age, (c) willingness to participate in the brief surveys, (d) ability to speak, write, and read English, (e) medically able to participate, with stable vital signs, and (f) must be approached within 1 to 2 days after each telemetry unit admission. Exclusion criteria consisted of any HF patients who were unstable, in the intensive care unit (ICU), or who had an active health behavior problem.
Data Collection Instruments

Four instruments were used for this study: (a) demographical questionnaire (Appendix A), (b) the NVS measured health literacy (Appendix B), (c) the SEMCDS measured self-efficacy (Appendix C), and (d) the MLHFQ (Appendix D) measured QOL.

Demographical Questionnaire

This data collection instrument was developed by the principle investigator (PI) to include information about age, sex, race, marital status, educational level, and income.

Newest Vital Sign

This instrument was developed to be a quick and accurate assessment tool for health literacy in health care setting and is also available in both English and Spanish versions (Weiss et al., 2005). This instrument assesses understanding and application of words, forms, and numeracy, which are all defined by health literacy. The NVS consists of a single ice cream nutrition label, where the PI asks the participant six questions that should take about 3 minutes of time to complete. There is only one correct answer for each question, and the interviewer is to check whether the answer was correctly answered or not. The participant’s health literacy is based on the total number of correct answers. A score of four or more correct answers indicates adequate health literacy; two to three correct answers indicates possible limited health literacy; and zero to one correct answer suggests a high likelihood (50% or more) of limited health literacy (Weiss et al., 2005). The English version was used for this research study.

Weiss et al. (2005) studied the reliability, validity, and accuracy of the NVS. A sample of 250 English-speaking adults was recruited from three outpatient clinics. The
internal consistency was adequate, with a Cronbach alpha of 0.76, as was the criterion validity \( r = 0.59, P < 0.001 \). The receiver operating characteristic (ROC) curve indicated that a final patient score of less than 2 had a sensitivity of 72% and a specificity of 87% for predicting limited literacy, while a score of less than 4 had a sensitivity of 100% and a specificity of 64%. The TOFHLA, one of the most widely used instruments to assess health literacy, was found to strongly correlate with the NVS.

**Self Efficacy for Managing Chronic Disease 6-Item Scale**

This tool was developed and tested by the Stanford Patient Education Research Center (Stanford Patient Educational Research Center, 2009). The SEMCDS is recommended and utilized over the original instrument, “Chronic Disease Self-Efficacy Scale,” that consisted of 33 questions, as it is less burdensome for the participants. The 6-item scale is a self-administered instrument that covers several domains common across many chronic diseases, including symptom control, emotional functioning, role function, and communicating with physicians. There are six questions where participants rate their confidence from 1 (not confident at all) to 10 (totally confident), in intervals of 1. Higher numbers indicate higher self-efficacy. This instrument has been tested on 605 participants with chronic diseases, with an internal consistency reliability of 0.91, a mean score of 5.17, and a standard deviation of 2.22 (Stanford Patient Educational Research Center, 2009).

**The Minnesota Living with Heart Failure Questionnaire**

This instrument was designed to measure the effects of HF and its treatments on a person's QOL. The 21-item instrument measures the four dimensions of QOL, which includes physical, emotional, mental, and social status, using a 6-point Likert scale ranging from 0 to 5. Zero indicates no effect and 5 indicates very much effect (Rector &
Cohn, 2005). The higher the overall score, the lower overall QOL is due to HF. The average Cronbach's alpha of 0.93 was obtained from a sample of 2000 participants (Rector & Cohn, 2005). There was a high internal consistency, which suggests that the MLHFQ measures a single construct (Rector & Cohn, 2005). Permission to use the MLHFQ was received from the author (Appendix E).

**Data Collection Procedures**

The researcher obtained permission from the University of Wisconsin Oshkosh Institutional Review Board (IRB) (Appendix F) and the participating hospital's IRB (Appendix G) prior to the data collection. All data were collected in accordance with the Health Insurance Portability and Accountability Act.

The setting was at one hospital in Northeast Wisconsin. During the data collection portion of the study, the PI searched the medical records of current patient population on the telemetry unit to identify potential study participants per inclusion and exclusion criteria. Once a potential candidate was identified, the PI asked the patient's nurse to obtain permission for the PI to meet with the patient at a convenient time to discuss the study and consent for participation (Appendix H). If the potential participant was agreeable, they were approached by the PI. After a complete description of the study was given to the patient, questions were answered, and informed consent was obtained, the patient was given a demographic questionnaire, the SEMCDS, and the MLHFQ to complete. The NVS was administered to the participant by the PI. If the potential participant told the nurse that they were not interested in learning more about participating in a research project, they were not approached by the principle investigator.
The surveys and interview were given at the time of consent or at the patient’s convenience prior to discharge. If a participant became fatigued during the interview, the data collection was stopped temporarily and then resumed when the patient’s tolerance improved.

The questions minimized any possible emotional risk. The researcher was very attentive if the participants would happen to have any emotional distress. If any fatigue or emotional distress occurred, the survey administration was stopped and postponed. If the patient wanted to stop and not finish the survey, the data collection would have been stopped immediately. If the patient wanted to stop and resume completion of the survey at another time during their hospitalization, a follow-up meeting was set up between the patient and investigator to complete the survey.

Data were only collected on those patients who completed the consent process. Review of the medical record included information regarding identification of HF patients only. There was no identifiable information stored anywhere. All data collected was kept in a locked file cabinet at the PI’s home. Each participant was assigned a number, which, again, is not traceable to any identifiable information.

Data Analysis Procedures

Descriptive statistics were used to describe the sample, including the range, mean, median, and standard deviation. Pearson’s r was utilized to examine the strength and direction of the relationships between, health literacy, self-efficacy, and QOL.
Limitations

The use of a convenience sample may have affected the ability to generalize the results to the HF population. The population in the sample area was predominately White, which may also limit generalizability. The small sample size weakens the power of this pilot study. Finally, the non-experimental design does not allow for exploring causal relationships.

Chapter Summary

A non-experimental, descriptive, correlational design was used to examine the relationship of health literacy, self-efficacy, and QOL among HF patients. A demographical questionnaire, the NVS instrument, the SEMCDS6-Item questionnaire, and the MLHFQ for measuring QOL were used to collect the data in the telemetry floor at one mid-western hospital. A convenience sample was obtained from newly admitted hospitalized patients with a diagnosis of HF. Descriptive statistics and Pearson’s r correlation was used to analyze the data.
CHAPTER IV
RESULTS AND DISCUSSION

Introduction

The purpose of this study was to examine the relationships between health literacy, self-efficacy and QOL. This chapter reports the statistical findings and provides a discussion of the results.

Demographic Data

Five participants participated in this descriptive study over a 1-month period of time. Two participants were males and three were females. The average age was 81.8 years (SD = 4.97, range 75-88). All participants were White, two were married (40%), two were widowed (40%), and one was divorced (20%). A majority of the participants were high school graduates (60%), one did not graduate from high school (20%), and one had a vocational degree (20%). Sixty percent of the participants reported income levels between $11,000 and $20,000 annually, while the remaining 40% of participants reported an annual income of less than $11,000. Demographic characteristics are summarized in Table 1.
Table 1

*Frequency and Percentage of Demographic Characteristics (n = 5)*

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<thead>
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<th>Percent</th>
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<tr>
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<tr>
<td>Advanced Degree</td>
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</tr>
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<td>$61,000 -- $75,000</td>
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</tr>
</tbody>
</table>
The NVS was used to measure the health literacy level of the participants. The highest possible score was 6, with the higher scores indicating adequate health literacy. A score of 4 or more correct answers indicates adequate health literacy, two to three correct answers indicates possible limited health literacy, and zero to one correct answer suggests a high likelihood of limited health literacy (Weiss et al., 2005). The total scores ranged from 0 to 1, with a mean of 0.20 (S.D. = 4.97). The resulting mean indicated that this sample of participants with HF, overall, had limited health literacy.

The SEMCDS was used to measure the participants’ self-efficacy levels in relation to their chronic disease of HF. Scores on the SEMCDS range from 0 to 10, with higher scores indicating greater self-efficacy. The mean score within the sample was 6.57 (S.D. = 1.13), indicating that, overall, participants possessed a moderate level of confidence in their abilities to manage their HF. The Cronbach’s alpha for the SEMCDS was 0.42 within this study. This is lower than the value of 0.91 found by the developer of the instrument (Stanford Patient Educational Research Center, 2009). The lower reliability of this instrument within this study may be due to the small sample size.

The MLHFQ was used to measure the participants’ QOL related to their HF. Scores on the MLHFQ range from 0 to 105, with higher scores indicating lower QOL. The mean score within the sample was 74.20 (S.D. = 27.45), a moderately low overall QOL among the participants; although, the sample did have a large amount of variance between the scores. The Cronbach’s alpha for the MLHFQ scores was 0.96 within this study. This is comparable to the Cronbach’s alpha value of 0.93 found by the author of this instrument (Rector & Cohn, 2005). Table 2 summarizes the scores of the three instruments.
Table 2

*Descriptive Statistics – Instruments (n = 5)*

<table>
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<th></th>
<th>Mean</th>
<th>SD</th>
<th>Range of Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>NVS</td>
<td>0.20</td>
<td>0.45</td>
<td>0 -- 1</td>
</tr>
<tr>
<td>SEMCDS</td>
<td>6.57</td>
<td>1.13</td>
<td>1 -- 10</td>
</tr>
<tr>
<td>MLHFQ</td>
<td>74.20</td>
<td>27.45</td>
<td>41 -- 96</td>
</tr>
</tbody>
</table>

NVS = Newest Vital Sign, SEMCDS = Self-Efficacy for the Managing Chronic Disease 6-Item Scale; MLHFQ = Minnesota Living with Heart Failure Questionnaire; SD = standard deviation

Results

*Research Question*

What are the relationships between health literacy, self-efficacy, and QOL among heart failure patients? Pearson’s r was used to explore these possible relationships.

*Health Literacy and Self-Efficacy*

No statistically significant correlation was found between health literacy and self-efficacy within this sample (r = -0.28, p = 0.65). Therefore, the level of self-efficacy a person has does not appear to be related to their health literacy level.

*Health Literacy and Quality of Life*

No statistically significant correlation was found between health literacy and QOL (r = 0.40, p = 0.50). Therefore, the level of health literacy a person has does not appear to be related to their level of QOL.

*Self-Efficacy and Quality of Life*

A statistically significant negative correlation was demonstrated between self-efficacy and QOL scores within this sample (r = -0.97, p = 0.01). As higher MLHFQ scores indicate lower QOL, and higher SEMCDS score indicate higher self-efficacy, this
finding indicates that as self-efficacy improves, so does QOL; however, lower self-efficacy is related to lower QOL. Table 3 presents the correlations of the three concepts.

Table 3

*Correlation is significant at the 0.01 level (2-tailed)

<table>
<thead>
<tr>
<th>NVS</th>
<th>SEMCDS</th>
<th>MLHFQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson coefficient</td>
<td>-0.28</td>
<td>0.40</td>
</tr>
<tr>
<td>p-value</td>
<td>0.65</td>
<td>0.50</td>
</tr>
<tr>
<td>SEMCDS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pearson coefficient</td>
<td>-</td>
<td>-0.97*</td>
</tr>
<tr>
<td>p-value</td>
<td>-</td>
<td>0.01</td>
</tr>
</tbody>
</table>

NVS = New Vital Sign; SEMCDS – Self-Efficacy for Managing Chronic Disease 6-Item Scale; MLHFQ – Minnesota Living with Heart Failure Questionnaire

Discussion of the Findings

The results of this study indicated that all participants had a high likelihood of having inadequate health literacy (M = 0.2; S.D = 0.45). Only one participant had one question correct, while the other four answered none of the questions correctly. This was an important finding, which is supported by other studies demonstrating high levels of inadequate health literacy among several populations, including the Medicare population in the U.S. (Paasche-Orlow et al., 2005; Gazmararian et al., 2003).

The overall QOL among this sample of inpatients with HF was also moderately low (M = 74.20; S.D. = 27.45). The concept of QOL has been extensively studied in literature in relation to health outcomes and has been found to be a factor in various chronic disease outcomes, such as hospital readmissions (Mejhert et al. 2006), mortality (Rodriguez-Artalejo et al., 2005), depression (Goldney et al., 2004), and health care costs (Eisner et al., 2002). As the participants within this sample were admitted with a
diagnosis of HF, it is not surprising to find that overall QOL was moderately low within this sample.

While QOL measures appeared to be moderately low, measures of self-efficacy within this sample appeared to be moderately high (M = 6.57; S.D. = 1.13). Self-efficacy has been studied across many chronic disease states and has been found to be positively correlated with physical and psychological health outcomes (Lavoie et al., 2008; Tsay & Chao, 2002; Urmimala et al., 2009). Due to the small sample size within this study, it is difficult to interpret and explain this finding.

This study also revealed a relationship between self-efficacy and QOL among HF patients (r = -0.97, p = 0.01). However, these statistically significant results must be interpreted with caution due to the small sample size. These results are similar to other studies that examined the relationships between self-efficacy and QOL within several populations, including older adults, persons with asthma, and persons with HF (Arnold et al., 2005; Lavoie et al., 2008; Joekes et al., 2007; McAuley et al., 2006). Various instruments were used to measure self-efficacy and QOL amongst these studies, yet the relationship between the two concepts continued to be statistically significant, as in the current study.

In examining the relationships between health literacy and self-efficacy, as well as between health literacy and QOL, results from this study revealed no statistically significant relationships. There are two likely reasons for this -- the first being that there was limited variability in the participant scores of the NVS instrument, which limits the ability to find statistically significant correlations, and the second was that the statistical power of this study was low due to the very small sample size.
The lack of detecting significant relationships between these concepts within the current study contrasts previous studies, where a significant correlation between health literacy and QOL was found (Bautista et al., 2009; Tokuda et al., 2009).

Other studies have found a statistically significant correlation between health literacy and self-efficacy (Wagner et al., 2009; Torres & Marks, 2009). While Sarkar et al. (2006) found no significant relationship, this may have been because the mean age of their participants was 58.1 years. Again, lack of power to detect statistically significant relationships is the probable explanation for these differences.

Chapter Summary

The purpose of this pilot study was to examine the relationships between health literacy, self-efficacy, and QOL among patients with HF. The results may help determine if higher health literacy and self-efficacy may be correlated to higher QOL and, therefore, help discover interventions that may be utilized to improve the QOL in HF patients.

A non-experimental, descriptive, correlational design was used to determine if a relationship exists between health literacy, self-efficacy, and QOL among participants hospitalized with a diagnosis of HF. A convenience sample of 5 White participants, two males and three females, with an average age of 81.8 years was used. Descriptive statistics were used to describe the sample, and Pearson’s r was used to explore the possible relationships between self-efficacy, health literacy, and QOL. The overall health literacy level of the sample was inadequate. Quality of life measures indicated a moderately low level of QOL, yet self-efficacy score were moderately high.

The results of the study demonstrated a statistically significant negative correlation between self-efficacy and QOL. A lower level of self-efficacy was correlated
with a lower level of QOL. Health literacy and self-efficacy, as well as health literacy and QOL, were not found to have statistically significant correlations. This pilot study was underpowered for parametric testing due to a lack of variability and small sample size. Therefore, these findings must be interpreted with caution.
CHAPTER V
SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Introduction

Heart failure is nearing epidemic numbers (Cutilli, 2007). While many of the cardiovascular disease rates have leveled off or decreased, HF rates continue to rise (Anderson et al., 2006). The prevalence of HF was 5.8 million in 2006, with an annual incidence rate of 10 per 1000 after age 65, and the HF mortality rate is estimated at 282,754 deaths per year (Donald et al., 2009). Heart failure is the most common discharge diagnosis among patients over the age of 65 years and attributes to approximately 11 million office visits and 3.5 million hospitalizations annually (Anderson et al., 2006). In the U.S., health care costs associated with HF exceed $34.8 billion. In 2004, HF was the second highest expense billed for Medicare, accounting for 5.8% of Medicare's total expenditures (Murray et al., 2009).

Quality of life has been found to be a predictor of hospital readmissions and mortality in persons with HF. Inadequate health literacy and low self-efficacy have been found to be related to poorer health outcomes, including lower QOL, yet few studies have examined these concepts together among HF patients.

The purpose of this pilot study was to examine the possible relationships between health literacy, self-efficacy, and QOL among patients with HF. A non-experimental, descriptive, correlational design was used to determine if a relationship exists between the three concepts.

Bandura’s (1986) Social Cognitive Theory was utilized as the framework for this study. The theory suggests that an individual’s confidence in their abilities to perform health behaviors will influence their actual adherence of those behaviors. The social
cognitive theory provides a framework to help develop strategies for improving a person’s self-efficacy by influencing personal factors, environmental factors, and/or behaviors. Human functioning is viewed as a dynamic triadic reciprocality of personal factors, behavior, and environment influences (Bandura, 1986). The Causal Structural model of Social Cognitive Theory depicts the reciprocal interaction between the three determinants (see Figure 1).

The concept of health literacy is related to Bandura’s concept of personal factors, as it involves cognition capability. Thus, health literacy may directly impact the personal factor within the Causal Structure Model and thus, via triadic reciprocality, between personal factors, environmental factors, and behaviors will ultimately determine the resultant behavior. These relationships may either foster or inhibit self-efficacy. As self-efficacy has been found related to QOL (Arnold et al. 2005; Joekes et al., 2007; 2006; Lavoie et al. 2008; McAuley et al.), exploring concepts impacting self-efficacy (i.e. health literacy) may help to identify areas for intervention in improving QOL. Unfortunately, this study did not provide statistical support for this assumption. However, due to its small sample size, replication is warranted to further explore the concepts with Bandura’s theory and the possible impact health literacy may have on self-efficacy.

A convenience sample of five inpatients with a diagnosis of HF from a northeastern hospital in Wisconsin was employed. A demographical questionnaire and three instruments were used: (a) the NVS, (b) SEMCDS, and (c) the MLHFQ. Descriptive statistics were used to describe the sample, and Pearson’s r statistics were used to answer the research question -- What are the relationships between health literacy, self-efficacy, and QOL among heart failure patients.
A significant finding within this study was that all five participants had inadequate health literacy measured via the NVS. Only one participant answered one question correct, while the others had no correct answers. The mean score was 0.20 (SD = 0.45), with the highest score possible on the NVS being 6. Quality of life measures indicated a moderately low level of QOL, yet self-efficacy score were moderately high.

The results also demonstrated a statistically significant relationship between self-efficacy and QOL, which suggests that as a person’s self-efficacy improves, so does their QOL. The relationships between health literacy and self-efficacy, as well as health literacy and QOL, were not found to be statistically significant. Given the small sample size, these results must be interpreted with caution.

Conclusions

The study was conducted to determine the relationships between health literacy, self-efficacy, and QOL among heart failure patients. The following conclusions are drawn from the study:

1. Heart failure patients within this sample had inadequate health literacy.
2. Heart failure patients within this sample had a moderately high level of self-efficacy.
3. Heart failure patients within this sample had a moderately low level of QOL.
4. There was a significant relationship between self-efficacy and QOL among HF patients within this sample, indicating that as self-efficacy improved, QOL measures improved as well.
5. No significant relationship between health literacy and self-efficacy was found in this study.
6. No significant relationship between health literacy and QOL was found in this sample of patients with HF.

Limitations of the Study

Limitations within this study include small sample size, reduced statistical power, a homogeneous sample that is not generalizeable to the general population, and lack of experimental design that does not allow for causal inferences.

Implications for Advanced Practice

Advance practice nurses are in a key position to positively influence patients’ QOL. Education has been a fundamental part of nursing practice. Within this study, patients with HF were found to have inadequate health literacy. In fact, within this small sample, the range of correct answers from the NVS was zero to one. This not only substantiates the high prevalence of inadequate health literacy levels in the U.S., but emphasizes the need for APNs to be aware of this concept and ensure that health literacy levels are assessed and considered when caring for persons with HF. The NVS instrument is a reliable and valuable tool that can be used to screen patients in approximately 3 minutes. Having a fundamental knowledge of health literacy will help ANPs identify potential interventions necessary to improve the overall QOL in HF patients.

A statistically significant relationship was found between self-efficacy and QOL within this sample. Self-efficacy in this study is the confidence that a person has in their abilities to perform tasks related to their chronic disease of HF. Thus, interventions
aimed at improving self-efficacy may help to improve the QOL in persons with HF.

Recommendations for Future Studies

The following recommendations are warranted, based in the findings of this study:

1. Replication of this study utilizing a larger sample size to achieve adequate power to detect statistically significant findings.

2. Replication of this study to include a more ethnically diverse population to improve the generalizability of the findings.

3. Replication of this study in multiple locations around the U.S. to improve the generalizability of the findings.

4. Utilizing a prospective interventional study with an educational intervention specifically aimed to improve health literacy and evaluating the impact on health literacy levels and QOL in persons with HF.

Chapter Summary

The incidence and prevalence of HF continues to grow. Morbidity and mortality rates are high within this population, and health care costs are rising annually. The concept of QOL has been found to impact several outcomes in persons with HF, including mortality, hospital readmissions, and health care costs (Eisner et al., 2002; Mejhert et al., 2006; Rodriguez-Artalejo et al., 2005; Soledad 2005). It is important to discover ways for health care providers to help persons with HF improve their QOL.

Findings from this study, including inadequate health literacy and a statistically significant relationship between self-efficacy and QOL, demonstrate the need to be aware of the prevalence of inadequate health literacy in patients with HF and to seek
interventions aimed at improving patients’ self-efficacy in order to positively impact QOL. Nurse practitioners are in a key position to help discover interventions to counter this issue. The use of Bandura’s (1986) social cognitive theory may help ANPs discover interventions that will improve the overall QOL among HF patients.

Further research is needed to determine factors that influence QOL among persons with HF in order to improve health outcomes in this population. Recommendations for future research include:

1. Replication of the study with a larger sample size in multiple locations to improve the statistical power, as well as the generalizability, of the results.

2. A prospective interventional study with an educational intervention specifically aimed to improve health literacy and evaluation of the impact on health literacy levels and QOL in persons with HF.
APPENDIX A

Demographical Survey
The following questions will help us examine the results of the survey and will not identify you in any way. Please Circle the Answers

1. Gender:
   Male    Female

2. What is your race?
   Asian-American    African-American    Hispanic-American
   Caucasian        Native-American

3. What is your age? _________

4. What is your highest grade you completed in school?
   Less than High School    Vocational School
   GED/HSED                  Some college – no degree
   High School graduate     Advanced degree

5. Marital status:
   Never married    Married    Separated
   Divorced         Widowed    With companion

6. What is annual income level?
   Less than $10,000    $11,000-$20,000    $21,000-$30,000
   $31,000-$40,000    $41,000-$60,000    $61,000-$75,000
   More than $75,000

Thank You for Participating In This Study!
APPENDIX B

Newest Vital Sign Instrument
### Score Sheet for the Newest Vital Sign Questions and Answers

**READ TO SUBJECT:** This information is on the back of a container of a pint of ice cream.

1. **If you eat the entire container, how many calories will you eat?**
   **Answer:** 1,000 is the only correct answer

2. **If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have?**
   **Answer:** Any of the following is correct: 1 cup (or any amount up to 1 cup), Half the container. Note: If patient answers "two servings," ask "How much ice cream would that be if you were to measure it into a bowl?"

3. **Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?**
   **Answer:** 33 is the only correct answer

4. **If you usually eat 2500 calories a day, what percentage of your daily value of calories will you be eating if you eat one serving?**
   **Answer:** 10% is the only correct answer

**READ TO SUBJECT:** Pretend that you are allergic to the following substances: Penicillin, peanuts, latex gloves, and bee stings.

5. **Is it safe for you to eat this ice cream?**
   **Answer:** No

6. **(Ask only if the patient responds "no" to question 5): Why not?**
   **Answer:** Because it has peanut oil.

### Interpretation

<table>
<thead>
<tr>
<th>Number of correct answers:</th>
</tr>
</thead>
</table>

Score of 0-1 suggests high likelihood (50% or more) of limited literacy
Score of 2-3 indicates the possibility of limited literacy.
Score of 4-6 almost always indicates adequate literacy.
# Nutrition Facts

**Serving Size**  
½ cup

**Servings per container**  
4

<table>
<thead>
<tr>
<th>Amount per serving</th>
<th></th>
<th>Fat Cal</th>
<th>120</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calories</td>
<td>250</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Fat</td>
<td>13g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saturated Fat</td>
<td>9g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol</td>
<td>28mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium</td>
<td>55mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Carbohydrate</td>
<td>30g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dietary Fiber</td>
<td>2g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sugars</td>
<td>23g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein</td>
<td>4g</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

**Ingredients:** Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.
APPENDIX C

Self-Efficacy for Managing Chronic Diseases 6-Item Scale
Self-Efficacy for Managing Chronic Disease 6-Item Scale

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?
   - not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

2. How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?
   - not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

3. How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?
   - not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

4. How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?
   - not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce you need to see a doctor?
   - not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

6. How confident are you that you can do things other than just taking medication to reduce how much you illness affects your everyday life?
   - not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the scale is the mean of the six items. If more than two items are missing, do not score the scale. Higher number indicates higher self-efficacy.
APPENDIX D

Minnesota Living with Heart Failure Questionnaire
MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

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

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APPENDIX E

Permission to Use the MLHQF Instrument
Re:         U/M Docket 94019, License # A20100923

License #  9/29/2009  8:37 AM

Dear Mr. Weidemann:

The University has received and accepts your Copyright Users Agreement to use the Minnesota Living With Heart Failure Questionnaire for the purpose of -- A student or teacher who will use the Work only for a student project(s) or didactic purposes as identified in Article 6.1.1.

MAPI research Institute provides translations of the questionnaire for a nominal fee. Please contact cberne@mapigroup.com for further information.

Thank you for choosing MLHF Questionnaire

Rachel

****

Office for Technology Commercialization
University of Minnesota
1000 Westgate Drive
Suite 160
St. Paul, MN 55114-8658
APPENDIX F

University of Wisconsin Oshkosh IRB Approval Letter
Mr. Mark Weidemann

Dear Mr. Weidemann:

On behalf of the UW Oshkosh Institutional Review Board for Protection of Human Participants (IRB), I am pleased to inform you that your application has been approved for the following research: The Relationship Between Health Literacy, Self-Efficacy, and Quality of Life Among Heart Failure Patients.

Your research has been categorized as NON-EXEMPT, which means it is subject to compliance with federal regulations and University policy regarding the use of human participants as described in the IRB application material. Your protocol is approved for a period of 12 months from the date of this letter. A new application must be submitted to continue this research beyond the period of approval. In addition, you must retain all records relating to this research for at least three years after the project’s completion.

Please note that it is the principal investigator’s responsibility to promptly report to the IRB Committee any changes in the research project, whether these changes occur prior to undertaking, or during the research. In addition, if harm or discomfort to anyone becomes apparent during the research, the principal investigator must contact the IRB Committee Chairperson. Harm or discomfort includes, but is not limited to, adverse reactions to psychology experiments, biologics, radioisotopes, labeled drugs, or to medical or other devices used. Please contact me if you have any questions (PH# 920/424-1058 or e-mail: koker@uwosh.edu).

Sincerely,

Dr. Frances Rauscher
IRB Chair

cc: Dr. Kim Udlis
1713
APPENDIX G

Hospital IRB Approval Letter
17 December 2009

Mark Weidemann, RN, BSN

RE: #69-2255E: The Relationships Between Health Literacy, Self-Efficacy, and Quality-of-Life Among Heart Failure Patients

Dear Mr. Weidemann:

I am pleased to inform you that the [IRB] Biomedical has found that the above named protocol and informed consent/authorization document (IRB approved consent final version date 12/14/2009), as well as submitted surveys, questionnaires, recruitment, and written materials to include diary cards and clinical trial cards, meet the IRB's criteria for approval as modified and have been given expedited review (category #5 & 7) and approval effective 15 December 2009. You will receive a stamped copy of all approved recruitment and written materials to be seen by subjects for your research record.

The approval period commences on 15 December 2009 and expires on 14 December 2010. The internal IRB tracking number assigned to your research study is 09-2255E. Please be sure to reference that number in any future correspondence with the IRB.

Please keep in mind that you, as principal investigator, have the following obligations as outlined in the IRB policies and procedures ("SOPs") (forms and SOPs are available on the [RSP] web site

Communications: Investigators are obligated to maintain communication with the [IRB] for the duration of the research according to federal regulations and [IRB] SOPs in order to ensure adequate protection of research subjects.

Conduct of study: It is the Investigator's responsibility to ensure that he/she and his/her research staff are fully trained and aware of all scientific, protocol, human subjects, privacy and ethical matters related to the conduct of the research. If an Investigator is uncertain of any of these areas, please refer questions to the RSP office before undertaking the research.

Quality assurance activities: The [IRB] Community Quality & Compliance Specialist, operating within the RSP, will conduct quality assurance protocol assessments to ensure that the best possible research practices are used in human subject research at [RSP]. Assessments will be conducted on IRB approved protocols to ensure compliance with the protocol, [IRB] SOPs, accreditation standards, applicable federal regulations and guidance, ICH Good Clinical Practice (GCP) Guidelines as adopted by the FDA, and according to [FEDERAL] Assurance with DHHS, as well as applicable state and local law. You will be notified if this protocol is selected for assessment.

Status changes to studies: An investigator must immediately notify the IRB (using Form RR-403-C) in writing whenever a protocol is placed on hold or suspended by the sponsor for any reason, or if the study is temporarily or permanently closed to subject accrual.

Continuing Review and Completion or Termination, reporting requirements: The investigator must submit Form RR-404-A for the study as required by [FEDERAL] and federal regulations [45CFR46.109(e) and
21 CFR 56.109(f), no less than annually. If continuing review is required more often than annually, it is noted in the second paragraph of this approval letter. The IRB office will send Form RR 404-A to the investigator at least two (2) months prior to the date of expiration. The protocol will expire without further notice if the investigator fails to provide the requested information prior to the anniversary of the date of approval (this date can be found in the second paragraph of this letter). There is no "grace period" extending the conduct of the research beyond the period of approval. In the event of termination or completion of the study or the investigator's part of the study, submit a final report to the IRB within 14 days using Form RR 404-A.

Protocol and Informed Consent Document revisions: Any changes to the protocol and/or informed consent/authorization document must be reviewed and approved by the IRB prior to implementation (using Form RR 403-C). External agencies (i.e., pharmaceutical companies, device vendors, etc.) may provide information to assist in the process, but have no authority to grant approval for alterations or deviations from the original protocol or informed consent/authorization document. Although there is no regulatory timeframe for reporting changes to a research study, the IRB requires any changes that may affect a subject's willingness to participate or continue participation in a research study be submitted promptly, but in no case greater than 90 days after notification from the sponsor.

Problems that Require Prompt Reporting to the IRB: The Investigator must report significant problems that occur during the conduct of the research to the IRB no more than 10 working days after discovery. Examples of these problems can be found in IRB Policy RR 403. The IRB will determine which of the reported problems are Unanticipated Problems Involving Risks To Subjects Or Others, and therefore necessitate reporting to external agencies (per IRB Policy RR 408).

Addition or deletion of co-Investigators: Notify the IRB (using Form RR 403-C) of the addition or deletion of co- or sub-investigators during the course of the study, or if the principal investigator changes.

Informed consent document: Unless other arrangements have been approved by the IRB and noted in this approval letter, it is the study coordinator's responsibility to file a copy of the signed consent form in the subject's medical record if the study involves patients or outpatients. This document will become part of the subject's permanent medical record. In all cases, the original should be kept in your research files and a signed copy should be given to the subject.

Verification of consent: The case history for each individual shall document that informed consent/authorization was obtained prior to participation in the study (21 CFR 50, 21 CFR 312.62(b), and 21 CFR 812.140(a)(3)(i)). This documentation may consist of a chronological record of the events establishing that informed consent/authorization was obtained prior to a procedure required by the investigation, or that informed consent/authorization was obtained prior to the time the first study-related procedure was performed on the prospective subject. This must be done to demonstrate that the appropriate discussion took place with the prospective subject about the elements of informed consent/authorization and that the prospective subject's questions were answered.

Disclosure of investigation to the media: The investigator must obtain IRB approval prior to disclosing information about the investigation to the media.

Recruitment and written materials: Any materials to be viewed by research subjects or potential subjects (advertisements, letters, internet postings, any other media for subject recruitment, other written materials) require IRB review and approval prior to taping, publication, distribution, or posting (using Form RR 403-C). Each document that has been approved by the IRB will bear a stamp of IRB approval and an approved copy will be returned to you for your regulatory binder.

Notification of Medical Malpractice Insurance Carrier: The investigator must notify his/her medical malpractice insurance carrier that he/she will be conducting this research study to verify coverage under his/her policy. In addition, the investigator must participate in the Wisconsin Patient's Compensation fund (Wis. Stat. § 655.27) to conduct research at any facility.
Responsible Conduct of Research Training Programs: Those involved in research activities at Aurora are encouraged to take advantage of training programs offered by the Department of Clinical Research. A schedule of classes for employed study coordinators can be accessed through the Learning Connection via Connect. Study coordinators not employed by Aurora can access the schedule of classes for more information, please contact the Department of Clinical Research at [Contact Information].

Please direct questions regarding any aspect of your human subject research to [Manager, Research Subject Protection Program, [Contact Information]].

Sincerely,

[Signature]

Senior Chair

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7 Aurora IRB Compliance Statement: The Aurora Health Care Institutional Review Board (Aurora IRB) comply with all applicable laws, guidelines, and federal regulations that govern the operation of Institutional Review Boards, including those set forth in 45CFR and 21CFR 50 and 56, which include Good Clinical Practice guidelines (GCPs). The Aurora IRB use due-process to ensure compliance with federal requirements for diversity, have written procedures for initial and continuing review of clinical trials, prepare written minutes of convened meetings, and retain records pertaining to the review and approval process. In accordance with these regulations (45CFR46.102d) and 21CFR56.102d, the Aurora IRB prohibit any member from participating in the IRB's initial or continuing review of any study in which the member has a conflicting interest, except to provide information requested by the IRB. Our policy is to require a voting member of the IRB to leave the room for final discussion and voting on a protocol in which the member is an investigator, or has any conflict of interest. In addition, the Aurora IRB have received FULL accreditation by AAHRPP (valid until September 2013).
APPENDIX H

Consent for Participation Form
INFORMED CONSENT/AUTHORIZATION TO PARTICIPATE IN A RESEARCH STUDY

Study Title

The Relationships between Health Literacy, Self-Efficacy, and Quality-of-Life among Heart Failure Patients

What are your rights if you take part in this study?
This is a research study. A research study is an organized activity to learn more about a problem or answer questions. Many different kinds of research studies are conducted. For example, a study may test a new drug or medical device to see if it’s safe and effective. A study may be done to determine the best way to treat an illness, or how to prevent an illness. A “subject” is an individual who agrees to participate in research. A subject can be either a healthy person or a patient. The subject’s participation helps the researchers learn more about the problem or answer the questions asked by the study. You can choose whether or not you want to participate in the study. The information in this informed consent form will help you decide if you want to be part of the study or not. Please take your time to decide, and talk about this study with your personal doctors, family members, and friends if you like. If you decide you do not want to sign this consent form, you cannot take part in this research study; however, other options are available to you (see the section in this form called “What are your options if you don’t take part in this research study?”).

You are being asked to take part in a research study.
You are being asked to voluntarily take part in a research study to help explore if a relationship exists between health literacy (ability to understand instructions given by healthcare providers), self-efficacy (how confident a person is in their ability to perform various tasks related to their disease), and quality of life (patient’s ability to enjoy normal activities) among heart failure patients. You are being asked to take part because you have an admitting diagnosis of heart failure and fall within the targeted age group of 18-89 years old.

The purpose of this research study is to determine more about how health literacy and self-efficacy may impact quality of life and hospital readmissions.

This study is being done by Mark Weidemann, RN, BSN and graduate nursing student. This person is called the principal investigator in this study. Other healthcare personnel may assist Mark Weidemann in conducting this study.

Where is this study being done?

Subject Initials ___
How many people will take part in this study?
About 16 people will take part in this study.

What is involved in the study?
Screening procedures: In order to see if you were eligible to be in the study, you will be asked to answer questions about your health. If your answers tell us that you are eligible, you will be asked to take part in the testing portion of the study. If you are not eligible, your answers will be shredded so they cannot be seen or used again.

If you agree to be in this study, you are an active participant and need to follow the directions of the principal investigator. If you decide to participate in this study, the investigator will ask you to do the following things: take part in a 15-20 minute interview to measure your health literacy; answer a 6 item self-efficacy questionnaire; and answer a 21 item quality of life questionnaire. Finally, a demographic questionnaire will be given that will include questions regarding information about age, sex, ethnicity, marital status, educational level, and income bracket.

This study uses questionnaires. Some of the questions are about personal and sensitive things such as gender, race, age, confidence in your ability to manage your disease as well as assess your health literacy. Your answers to the questions will be kept with your research records. Answering these questions will have no impact on the care you receive while in the hospital.

You will have responsibilities as a research subject, which include:
- Completing the questionnaires

How long will you be in this study?
If you choose to participate in this study, your participation is going to last about 15-20 minutes. The whole study, outside of the time you will directly participate, is expected to last for about 5 months. If at any time you become fatigued or are unable to continue with answering the questions, the interview will be stopped. The interview can be restarted at your convenience throughout your hospital stay.

What are the risks to you from participating in this study?
There is potential for discomfort due to the personal nature of some of the questions. If you begin to feel uncomfortable at any time you may discontinue the participation either temporarily or permanently and may decline to answer any questions.

Are there benefits to you from participating in this study?
You will not benefit by being in this study. It is my hope to discover new information that will contribute to a better understanding of how to improve the care we provide to our heart failure patients.

What are the costs to you for participating in this study?
There is no cost to you for participating in this study. You will not be paid for being in this research study.
What are your rights if you take part in this study?
This study has been reviewed and approved by the Institutional Review Board (IRB). An IRB is made up of a group of people (both scientists and lay persons) who review and approve research studies. This IRB checks that the research being done follows federal regulations for human subject research. IRB approval of a research study only means that everything is okay according to the federal regulations to start the study. The IRB wants you to know that only you can decide if being in this study is the right decision. I am a graduate student at the University of Wisconsin Oshkosh, working on a research project for my master’s degree in nursing. The study has been reviewed and approved by the UW Oshkosh IRB in addition to the IRB.

Being in this study is your choice and only you can decide if being in this study is the right decision for you. Because you volunteer to be in this study, you may also choose to leave this study at any time. If you do not want to participate, or if you later leave this study, you will not be treated differently, your health care will not be affected in a negative way, and you will not lose any benefits you would normally receive.

You can have access to your research records at any time during this research study or upon its completion.

For general questions, concerns, or complaints about the study, contact the principal investigator, Mark Weidemann, at telephone number: [Redacted]. If the principal investigator or research staff cannot be reached, contact the Human Protections Administrator in the Research Subject Protection Program office at [Redacted] or toll-free at [Redacted] (outside the area).

If you want to talk to someone not part of this study about your rights as a human subject, or to address concerns, complaints, or input about the study, contact the Human Protections Administrator in the Research Subject Protection Program office at [Redacted] or toll-free at [Redacted].

For general information regarding Oshkosh’s Research Subject Protection Program, go to: [Redacted]. For general information regarding human subject research at Oshkosh, go to: [Redacted].
For Medical Record Use

Subject Medical Record Number: ____________

Information about Confidentiality and HIPAA

The Health Insurance Portability and Accountability Act (HIPAA) sets standards for the privacy and security of health information records. HIPAA limits how health insurance plans, pharmacies, hospitals and others can use your personal research information. HIPAA protects medical records and other health information, whether on paper, in computers, or communicated orally.

What about the confidentiality of my personal research information?

We are asking you to allow access to your health information that is otherwise protected by law. This information ("protected health information") is part of your medical record and is kept confidential. If you do not want your information to be used in this study, and do not want to participate, you will not be treated differently, your health care will not be affected in a negative way, and you will not lose any benefits you normally receive.

What protected health information is going to be used as part of the research studies?

We will be collecting the following:

- Your age, race, gender
- Diagnosis
- Dates of previous admissions and discharges to the hospital in past year
- Number of times you were admitted to the hospital to treat your heart failure in the last year

Why is this protected health information being collected and who is going to see it?

Mark Weidemann may have access to your protected health information for research purposes. Protected health information gathered during the study will be kept in your medical and research records at __________. No information, such as your medical record number, and social security number will be collected. Only your name will be assigned a code number. All study-related information will be recorded, and tracked through that code. Your name will be linked to the code in the files of Mark Weidemann, and that link will be kept on file in a locked cabinet in his office for 8 months or once the study is completed and then will be destroyed.

In addition, by signing this consent/authorization, you are allowing employees or agents of the entities listed below direct access to your original medical records maintained at __________. The purpose of the direct access is for verification of the research procedures and data, and to ensure your safety. Access to your original medical and research records may be provided to the following to the extent permitted by the applicable laws and regulations and upon request:

- Members of the __________ Institutional Review Board (IRB), consultants, and staff of __________. (The purpose is to ensure adequate protection of research subjects.)
- Staff and agents of __________. (to bill third party payers and for business purposes related to research when necessary.)

Subject initials ___

Page 4 of 7

INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY
• Organizations involved in the regulation of research and accreditation of research programs or hospitals. (The purpose of this disclosure is for research compliance and to obtain and maintain accreditation.)

Protected health information about you will be kept as confidential as possible, but we cannot promise complete confidentiality. You protected health information will be used and disclosed as described above and as required or permitted by law. However, once the information leaves our possession, we will not be able to control how it is used because the information is no longer covered by federal or state law and may be disclosed again. If the research-related records are kept in medical records, only those medical records that are related to the research will be released to the entities listed above. This does include parts of your medical record related to your eligibility to participate in this research study.

Except when required or permitted by law, you will not be identified personally (by name, street address, social security number, etc.) in any information disclosed outside of your records, in any report that might be published, no information will be included that will make it possible to identify you.

**During what period of time will the entities listed above have access to your protected health information?**

Access to your protected health information related to this study will begin as soon as you sign this consent/authorization. This authorization expires when the study is finished, all data analysis has been completed, and the research records have been destroyed.

**What if you change your mind about allowing access to your protected health information?**

You may withdraw your authorization for us to use your protected health information, but you must do so in writing to the investigator. If you withdraw this authorization, you will no longer be able to take part in this research study. If you drop out of this study, the investigator will continue to use and disclose any information about you that was gathered before you dropped out to preserve the integrity of the research study.
THIS STUDY HAS BEEN EXPLAINED TO ME BY:

Print name and title of person obtaining consent

______________________________
Signature of person obtaining consent

______________________________
Telephone

______________________________
Date

I, ____________________________, have read, or have had read to me, this informed consent document and have had my questions answered. I know that I can ask more questions any time today or in the future. I agree to take part in this research study as it is described. I have been told about the potential risks and benefits of this research study. I have been told that I will be given a copy of this informed consent document after it has been signed but before I participate in this study. I can also ask for another copy at any time. A signed copy of this document will be put in my medical record at __________________. Finally, I understand that the principal investigator can limit or stop me from being in this study if the principal investigator thinks it is best for me.

I will be told about new things the investigator(s) learns during the study that may affect my health, or my willingness to stay in the study, as soon as possible. If I want to have this information sent to my personal doctor, I should tell the principal investigator. I can ask the principal investigator to send me a copy of the results of this study when they're published.

______________________________
Signature of subject

______________________________
Date

______________________________
Signature of witness [Use only if appropriate**]

______________________________
Date

**The signature of a witness is not required when the subject reads and is capable of understanding the consent document, as outlined in 21 CFR 50.27(b)(1). When the subject is unable or has no opportunity to read the consent document to verify the accuracy and completeness of the information provided, the signature of a witness is required, 21 CFR 50.27(b)(2). The intended purpose is to have the witness present during the entire consent interview and to attest to the accuracy of the presentation and the apparent understanding of the subject.
DOCUMENTATION OF RISK/BENEFIT/ALTERNATIVES DISCUSSION

An investigator in the research study must conduct the consent interview unless he or she delegates his or her responsibility for conducting the informed consent interview to another individual who is both knowledgeable about the research study and under the investigator’s direct supervision. However, if the research study involves a medical treatment or intervention in which consent is normally obtained in the clinical setting and the medical records will be maintained at a facility, state law requires documentation that a physician who is the principal investigator or a sub-investigator in the study, has informed the patient (subject) about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. It is the IRB’s position such discussion should take place prior to the initiation of any research related activity, and any attempt to delegate this responsibility to another individual (e.g., a non-physician study coordinator) would constitute a breach of the physician’s duty to provide informed consent under state law. However it is ultimately the principal investigator’s decision.

This is to verify that I (print name) ___________________________ have explained to and discussed with the subject, or the subject’s Legally Authorized Representative, Legal Guardian, Health Care Agent, or Parent, as appropriate, the following items related to the above procedure(s) before the initiation of the research-related intervention:

- The nature of the research
- Potential risks, benefits, drawbacks
- Potential problems related to recuperation (if applicable)
- Possible results of research
- Known side effects or complications of the research
- The availability of all alternate viable modes of treatment and the benefits and risks of such treatments, if applicable.

SIGNATURE and TITLE of individual providing this information ___________________________ DATE ___________________________

A SIGNED COPY OF THIS FORM MUST BE FILED IN THE INSTITUTION'S PATIENT MEDICAL RECORD
(If applicable). The original must be kept in the Investigator’s research records.

Form IC 701A v 6/11/09
REFERENCES


