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THE IMPACT OF TELEMONITORING ON SELF-EFFICACY, EMOTIONAL WELL-BEING, AND CLINICAL OUTCOMES IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE OR HEART FAILURE

by

Jaclyn West-Frasier

A Dissertation
Submitted to the
Faculty of The Graduate College
in partial fulfillment of the
requirements for the
Degree of Doctor of Philosophy
Interdisciplinary Health Studies
Dr. Nickola Nelson, Advisor

Western Michigan University
Kalamazoo, Michigan
June 2008
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Jaclyn West-Frasier
2008
This work is dedicated in loving memory to those individuals in my life who were impacted directly by COPD or HF

My daughter Kailah Marie Frasier (5/12/91–10/2/91)
My mother-in-law Ruth Frasier
My uncle Edward Maloney
ACKNOWLEDGMENTS

The doctoral program and dissertation process has been an arduous but rewarding journey along the path of my life’s work. As I reflect on the past six years, and the preceding years, I wish to recognize, and express my deepest appreciation, to all who have contributed to this journey and influenced the direction my path has taken.

I thank God for the provisions made to me so that I could serve in healthcare for the past 34 years, first as a paraprofessional, next as a clinician, then as an educator, and now as a researcher and scholar.

I wish to thank my immediate and extended family, those that make up the fabric of my life—my husband Al and our beautiful children Isaac and Jordyn, my parents and siblings, my in-laws, nieces and nephews, and our family friends. My husband and children shared me with the doctoral program for six years. They grew accustomed to the site of me hunched over my computer and became self-sufficient performing laundry and other household chores and “self-serve” meals. Our extended family and friends, while not impacted as directly by my decision to pursue a doctorate, provided us with verbal and moral support. I want to give particular thanks to our dear friends Karen and Mike Gray. Karen helped me maintain balance by making sure I got out to ski and snowshoe in the cold season, and out on the water to kayak during the warm season. Mike constructed the database for the parent study and steadfastly stood by our family through good times and bad.
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Jaclyn West-Frasier
THE IMPACT OF TELEMONITORING ON SELF-EFFICACY, EMOTIONAL WELL-BEING, AND CLINICAL OUTCOMES IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE OR HEART FAILURE

Jaclyn West-Frasier, Ph.D.
Western Michigan University, 2008

Telemonitoring is the remote monitoring of patients’ health status using telecommunications and information processing technologies. This pilot study analyzed data collected through a parent study that randomized 46 home health patients to either standard care (SC) or standard care with the addition of telemonitoring (TM). The telemonitoring device used in this study provided daily transmission of physiologic data and patients responses to questions about their disease and symptom management.

Data analysis was completed to address the question whether telemonitoring, as part of standard home care for patients with chronic obstructive pulmonary disease (COPD) and patients with heart failure (HF), has an effect on patients’ perception of self-efficacy (confidence) for managing their disease, overall emotional well-being, and clinical outcomes. Independent variables were diagnosis (COPD or HF) and treatment group (SC or TM). Dependent variables for this pilot study were measures of self-efficacy (SE); emotional well-being (EWB); and data collected on mortality, emergency room use, and hospitalization. Data also were analyzed to identify significant relationships among 3-month variables.
By 3 months, patients in COPD-TM showed greater improvement in SE to evaluate effectiveness of strategies to relieve symptoms and a significant positive relationship between EWB and SE when compared to patients in COPD-SC. There were no differences between the groups on the other measures. Patients in HF-SC showed greater improvement on EWB and a significant positive relationship between EWB and SE, and a significant negative relationship between EWB and hospitalization, and EWB and emergency room use, when compared to the HF-TM patients. Patients in HF-TM reported more hospitalization than patients in HF-SC. There were no differences between the HF groups on the other measures.

For patients with COPD, TM was associated with improved SE for evaluating strategies used to relieve symptoms, and a positive relationship between SE and EWB. For patients with HF, TM did not have an effect other than an association with greater patient-reported hospitalization.
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CHAPTER I

INTRODUCTION

Telemonitoring is the remote monitoring of patients’ health status using audio, video, and other electronic information processing technologies to monitor patient status from a distance (Committee on Evaluating Clinical Applications of Telemedicine & Institute of Medicine, 1996). Systems range from simple mechanisms that use patient call-in of physiologic data for receipt by a computerized voice-answering system to more complex systems installed in the patient home, using video and audio data collection technology (Burgiss & Dimmick, 2003). Systems installed in the home may also include computerized disease-management educational programs (LaFramboise, Todero, Zimmerman, & Agrawal, 2003).

This study addressed the question whether telemonitoring, as part of standard home care for patients with heart failure (HF) and patients with chronic obstructive pulmonary disease (COPD), has an effect on patients’ perception of self-efficacy (confidence) for managing their disease and on their emotional well-being. Health outcomes also were compared for patients randomly selected to receive either standard care (SC) or standard care with the addition of telemonitoring (TM).

This study was conducted with patients with COPD and patients with HF recruited from patients receiving services from a home health agency in southwest Michigan who agreed to participate in this dissertation research study in addition to the
parent study. Patients in the parent study were randomized into SC (usual) care (SC) or SC+TM (TM) and were followed for 12 months. Standard care included assessment, establishment of treatment goals in collaboration with patient and family, education to patient and family on disease management, and coordination of care with the primary physician.

The telemonitoring technology device used in this study is called the Health Buddy®. It is a device that allows daily transmission of physiologic data and the recording of patient response to disease management questions. The questions relate to physiologic information such as shortness of breath, knowledge of the disease process, symptom recognition, and symptom management.

This chapter begins with definitions of key concepts and background on COPD, HF, and telemonitoring. The purpose and conceptual framework for the study are described, followed by the research questions and study design. The potential value of the study is discussed, as well as study limitations. The chapter concludes with a summary.

Definitions

**Telehealth**: The broadest term for the use of information technology in the delivery of healthcare and in the promotion of health.

**Telemonitoring**: A process that uses a device for home monitoring of patients via phone line or broadband connection. Medical attachments include items such as stethoscope, blood pressure cuff, and glucometer. The device may also include computerized disease management education.
Chronic obstructive pulmonary disease (COPD): A group of diseases characterized by air flow obstruction that is typically associated with breathing-related problems such as chronic coughing, shortness of breath, sputum production, and wheezing. COPD is often undetected until the latter stages. It is managed with medications and lifestyle changes.

Heart failure (HF): A disorder whereby the heart loses its ability to pump blood efficiently. HF is a chronic, long-term condition that is managed with medications and lifestyle changes.

Self-care management: Behaviors undertaken by patients to promote health and well-being.

Home health: Provision of health services by health care professionals directly in the patient’s home.

Standard care: Diagnostic and treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance.

Self-efficacy (SE): Degree of confidence an individual has in his or her ability to effectively perform a specific behavior. In this study, self-efficacy is measured with the confidence component scores from the Self-Care of Heart Failure Index (SCHFI) (Riegel, Carlson, & Glaser, 2000).

Emotional well-being (EWB): Individual’s overall perception of satisfaction with his or her quality of life, including happiness and pleasant emotions, and the perceived ability to meet personal goals and fulfill important life roles. In this study, EWB is measured with the SF 36 Mental Component Summary Scale (MCS) (Ware, 2005).
Clinical outcome: Impact an intervention has on the health and/or well-being of patients. Outcomes commonly measured include physiologic parameters, mortality, physical and/or mental health, ability to carry out daily activities (function), and utilization of healthcare resources. In this study, clinical outcomes were defined as mortality, emergency room use, and hospital admissions using frequency counts based upon patient/family report and data retrieved through a regional health care system.

Statement of Problem

Chronic obstructive pulmonary disease (COPD) and heart failure (HF) are among the top four causes of death in the U.S. COPD includes emphysema and chronic bronchitis. It is the most common form of lung disease, with annual costs (direct and indirect) in the U.S. estimated to exceed $30 billion. Hospitalization is the largest contributor to direct costs. COPD mortality rates continue to climb, perhaps related to the tendency for late diagnosis and lack of prevention as compared to the other diseases such as coronary artery disease, cancers, and stroke (Briggs, 2004; Feifer, Aubert, Verbrugge, & Khalid, 2002; Pauwels, Buist, Calverley, Jenkins, & Hurd, 2001; Thom et al., 2006). COPD is the only major disease continuing to show an increase in prevalence, morbidity, and mortality (Miller, George, & Halbert, 2005).

HF is one of the most serious cardiac problems in the United States, with over 50,000 new cases each year. It is the leading reason for hospitalizations for patients over 65, with a readmission rate of 44% within 6 months. HF is also the most costly reason for hospital admission; with the annual cost over $20 billion. The increasing size of the aging population has resulted in greater numbers of patients with this condition, and these
numbers are continuing to rise (J. Anderson, 2002; Thom et al., 2006; Hunt et al., 2001). The seriousness and prevalence of these two conditions (COPD and HF) make it essential that health care practitioners develop interventions that can reduce the negative consequences of these diseases.

Healthcare providers need to look beyond historic, traditional methods of working with HF and COPD to develop and implement interventions designed to address the barriers to effective self-management and to critically evaluate the impact of those interventions. Studies show that multidisciplinary management, patient education, and home-based monitoring improve mortality and may reduce medical care use and related expenditures for HF and COPD (Cleland, Louis, Rigby, Janssens, & Balk, 2005; Finkelstein et al., 2004; Goldberg et al., 2003).

Telemonitoring is a relatively new intervention in the area of home health care. This technology permits home monitoring of patients using a special device connected to a phone line or broadband technology. Interest and utilization of telemonitoring technology has increased due to rising healthcare costs; advances in communication technology; and low-cost, user-friendly devices (Burgiss & Dimmick, 2003; Meystre, 2005).

HF telmonitoring studies have focused on areas such as acceptability to patients and providers, hospitalizations and mortality, and cost-effectiveness (Louis, Turner, Gretton, Baksh, & Cleland, 2003). A review by Louis et al. suggested that telemonitoring reduces hospital utilization and may play an important role in the delivery of health care for HF patients. The review also indicated that further studies, especially large
randomized clinical trials, are needed to evaluate the usefulness of this method, including benefits and cost-effectiveness.

Pilot studies using telemonitoring with COPD have reported positive results in terms of acceptability to patient and clinician and reliability of transmitted physiological data (Finkelstein et al., 2004; Lusignan et al., 2000; Rice & Doughty, 2004). As with HF, randomized clinical trials are needed to evaluate the cost/benefit of telemonitoring and the impact on clinical outcomes of patients with COPD. Medical management and technology, while valuable, are not enough to minimize the effects of chronic disease. Patients must make substantial changes in their personal health behaviors.

Effective HF management requires major lifestyle adjustments by patients, including adherence to a complex medical regimen and symptom monitoring (Thom et al., 2006; Hunt et al., 2001). Poor adherence to treatment recommendations is a considerable problem in HF patients. It is estimated that up to one third of hospitalizations are related to nonadherence (Bennett et al., 1998; Hong, Morrow-Howell, & Enola, 2004; Michalsen & Thimme, 1998). Studies have shown that poor adherence is associated with greater morbidity and poorer quality of life (Evangelista & Dracup, 2000).

Effective management of COPD also requires adherence to a complex medical regimen and significant lifestyle adjustments by patients, with smoking cessation as the most significant in terms of reducing mortality. Several studies have shown problems with adherence to medical regimen such as broncho-dilators and recommended lifestyle adjustments (Gallefoss & Bakke, 1999; Make, 2003).
Barriers to effective self-care management in HF are numerous and include lack of knowledge (Horowitz, Rein, & Leventhal, 2004; Riegel & Carlson, 2002; Sneed & Paul, 2003), problems with symptom recognition and management (Bennett, Cordes, Westmoreland, Castro, & Donnelly, 2000; Francque-Frontiero, Riegel, Bennett, Sheposh, & Carlson, 2002), low confidence in ability to manage care (B. Carlson, Riegel, & Moser, 2001), and negative physical and emotional symptoms (Bennett et al., 2000; Riegel & Carlson, 2002). In addition, patients with HF display a high rate of depression and anxiety, which are associated with poor clinical outcomes and higher mortality (Freedland & Carney, 2000; Jiang et al., 2001; Richardson, 2003).

In contrast to the literature on HF, there is very little in the COPD literature on factors that contribute to nonadherence/poor self-management in this population. Turner, Wright, Mendella, Anthonisen, and Group (1995) analyzed data collected from 985 patients in five U.S. sites. They found that age, marital status, education, symptom severity, and race acted as predictors of adherence to nebulizer. George, Kong, Thoman, and Stewart (2005) performed a cross-sectional study ($N = 525$) in Australia to explore COPD patient perspectives on adherence. Investigators found that patient beliefs, experiences, and behaviors were more powerful than sociodemographic and clinical factors in predicting adherence to medical regimen.

In order to address issues of nonadherence, healthcare providers must develop an awareness of the factors that contribute to noncompliance. Once those factors are understood, healthcare providers may be better equipped to determine if strategies, such as telemonitoring, might improve compliance with recommended treatment and lifestyle modifications, and improve patients’ confidence in their ability to recognize symptoms.
Purpose of the Study

The primary purpose of this study was to examine the impact of telemonitoring on SE, EWB, and clinical outcomes of mortality, emergency room use, and hospitalization in patients with COPD and HF. The secondary purpose was to determine if there was a relationship among the variables of telemonitoring, self-efficacy, emotional well-being, clinical outcomes, and diagnosis.

Conceptual Framework

Bandura’s (1986) theory of self-efficacy informed the study hypothesis that telemonitoring, enhanced with an educational component and in combination with standard care, would produce changes in the level of patients’ self-efficacy and emotional well-being. Bandura’s assertion that self-efficacy predicts health-related self-care has found support in studies of chronic illness and the cardiac population (Carroll, 1995; Kempen, Sanderman, Miedema, Meyboom-de Jong, & Ormel, 2000; Perkins & Jenkins, 1998). Bandura (1998) also hypothesized that self-efficacy impacts emotional and physical well-being due to the “mind-body” connection in the autonomic nervous system.

The mind-body connection has also been studied in the COPD and HF population to clarify the relationship between disease severity and depression (Joynt, Whellan, & O’Connor, 2004; Michalsen & Thimme, 1998; Richardson, 2003). Research has demonstrated that there is a strong association between depression and mortality in patients with COPD and HF (Freedland & Carney, 2000; Jiang et al., 2001; Richardson, 2003; Yohannes, Baldwin, & Connolly, 2005) Less is known about reciprocal
relationships between emotional well-being and survival, and specifically, whether the addition of telemonitoring can influence either or both. Although randomized studies with HF patients have shown that the use of telemonitoring is associated with reduced mortality and increased survival (Benatar, Bondmass, Ghitelman, & Avitall, 2003; Cleland et al., 2005; Goldberg et al., 2003; Jerant, Azari, Martinez, & Nesbitt, 2003), no prior studies were located that closely examined the factors that might explain this effect.

This study was based on a theoretical assumption that, with the addition of telemonitoring, patients would learn to manage their disease effectively and therefore would increase self-efficacy. As confidence increases, patients should experience a corresponding increase in emotional well-being, because of a greater sense of control and satisfaction in their ability to manage their health and perform role-related activities. Further, if patients increase both self-efficacy and emotional well-being (as an indicator of improved disease management), they should improve their health and clinical outcomes as shown by reduced emergency room visits and/or hospitalization, and by lower mortality.

In this study, the experimental intervention involved a three-way interchange among patient, nurse, and telemonitoring device (TD). A study investigator, either a nurse or occupational therapist, introduced the device and provided initial training to the patient. Patients then had the responsibility to utilize the TD on a daily basis to complete daily physiologic measures and respond to disease management questions. It was expected that this process would facilitate patients to develop proficiencies and habits in monitoring physiologic measures related to their condition. They also received positive and constructive feedback from the TD as they responded to disease management
questions. This educational process was expected to allow patients to develop a greater understanding of their condition, reinforce appropriate disease management behavior, and build confidence in their ability to manage COPD or HF.

The TD unit automatically transmitted daily physiologic data and patient responses to questions to a secure webpage. The home health nurse assigned to the patient may have used the TD information to adjust standard education content provided during routine home visits so as to address the most pertinent learning needs of the individual patient. TD information may have been used to notify the primary care physician of any negative trends in the physiologic data, which may have resulted in more timely medical intervention.

Figure 1 illustrates a simple model of the theorized relationships among variables that were evaluated in this study.

Figure 1. Impact of telemonitoring on self-efficacy, emotional well-being, and clinical outcomes.
Research Questions and Hypotheses

Primary Research Question

Do patients who receive telemonitoring (TM), in addition to standard homecare, show differential improvement when compared with those who receive standard care only (SC) in the following outcome variables: (a) self-efficacy for disease management; (b) sense of emotional well-being; and (c) clinical outcomes of mortality; emergency room use, and hospitalization?

Secondary Research Question

Is there a significant relationship among the variables of self-efficacy, emotional well-being, and clinical outcomes at 3-months post index hospital discharge?

Experimental Hypotheses

The following hypotheses were examined within this study:

$H_1$: Patients with HF or COPD who are randomly assigned to receive standard care plus telemonitoring, compared with patients with HF or COPD who receive standard care only, will demonstrate greater improvement in the following variables:

a. Self-efficacy as measured by Section C (SCI-C) from the Self-Care of Heart Failure/COPD Index at 3-months post hospital discharge compared to baseline.
b. Emotional well-being as measured by the SF 36 Version One Mental Health Component Score (MCS) at 3-months post hospital discharge compared to baseline.

c. Clinical outcomes of mortality, emergency room use, and hospital admissions at 3-months post hospital discharge, with the TM group experiencing less mortality, emergency room use, and hospitalization.

\[ H_2: \] Three-month scores in self-efficacy and emotional well-being will correlate positively with each other, and negatively with 3-month clinical outcomes of emergency room use and hospitalization; the relationships will be of greater magnitude in the TM versus SC groups.

Design of Study

This was a randomized controlled trial to study the difference between standard care (control), and standard care plus telemonitoring (experimental) in terms of patient perception of self-efficacy and emotional well-being, and clinical outcomes. Data to conduct this study were gathered as part of a larger project (HSIRB approved protocol #05-02-22) in which home health patients recruited from a Midwestern home health agency had been randomly assigned to either the control or experimental group and followed over a 12-month period. The goal for the larger study was to recruit 200 subjects each to participate in the HF and COPD arms of the main study, and it is those subjects whose baseline and 3-month data were analyzed in this study.

Dependent variables analyzed in this study were self-efficacy, emotional well-being, and clinical outcomes. The tool used to measure self-efficacy is the Confidence
Component score (SCI-C) from the Self-Care of Heart Failure Index (SCHFI). The tool used to collect data on emotional well-being is the SF-36 Mental Component Summary (MCS) scale. Utilization rates for hospital and emergency services were derived from data retrieved from medical records and from structured patient interview. Mortality was determined by review of hospital records and other valid sources, such as family report.

Study Value

As the incidence of COPD and HF increases, there can be little question that better, more cost-effective treatments are essential. Although medical management of both diseases has evolved, hospitalization episodes and use of emergency services continue at high rates. Research on chronic disease has demonstrated association between compliance to disease regimen and positive clinical outcomes. Health care providers need to explore ways to improve adherence in patients with COPD and HF. This research will add to the growing knowledge base of telemonitoring and individualized patient education and the combined effect they may have on self-efficacy, emotional well-being, and clinical outcomes. This research will provide an early “glimpse” (3 months) of the effect of telemonitoring and help to identify similarities and differences between patients with COPD and HF on the dependent variables and relationships among those variables at baseline and at 3 months.

Patients

Prior research findings suggest that telehealth technology may improve the effectiveness of treatment for patients with chronic disease (Liss, Glueckauf, & Ecklund-
Johnson, 2002). Recent studies have shown that HF patients who received telemonitoring had lower hospitalization and improved survival compared to those who received standard care (Cleland et al., 2005; Goldberg et al., 2003). Comparable studies for COPD were not found. This study may add evidence about whether patients with COPD or HF may receive a significant health benefit from telemonitoring.

Practitioners

An important aspect of care to those with chronic disease is education. Research has indicated that despite the emphasis on education, knowledge and skill “gaps” exist in the HF and COPD populations. Clinicians need to assess for barriers, design education that takes these barriers into account, and consider incorporating newer aids to learning such as computer-based, telecare and telemonitoring supports (Strömberg, 2005a). Practitioners involved in HF and COPD education include physicians, nurses, pharmacists, dieticians, social workers, and rehabilitation professionals. Insights gained from this study may help practitioners across disciplines improve the effectiveness of patient education programs.

Policy Makers

Advances in healthcare and healthcare technology provide opportunities to increase access and accessibility to patients with chronic disease. Policymakers need empirical evidence on the effectiveness of telehealth interventions to help guide healthcare policy decisions (Liss et al., 2002). Knowledge gained from this study may add to the growing empirical evidence that supports telemonitoring effectiveness. Such
information will be utilized by policy makers as they make decisions on coverage, providers and reimbursement.

Limitations

This study has several limitations that should be considered when interpreting the results. These limitations are:

1. The number of participants may not be sufficient to demonstrate differences between control and treatment groups.

2. The duration of intervention (30-60 days) may not be sufficient to improve self-efficacy, emotional well-being, and ability to self-manage disease.

3. Self-efficacy and emotional well-being are subjective concepts, due to diverse intrinsic and extrinsic influences, and thus problematic to measure.

Additional issues may impact the ability to attribute causality by contributing to contamination of the control group. This is a randomized study. However, some of the nurses who provided care to the TM may have also provided care to those in the SC group. Due to the nature of the parent study, it was not possible to blind the nursing care providers to the SC and TM condition. It is possible that the type of education provided under the SC model was altered as a result of nurses working under both conditions, affected by their attitudes toward the addition of the TM technology. On the other hand, nurses were not systematically assigned to one group or the other. Thus, any effect of the participating nurses may have been spread across the two groups.
Summary

This chapter provided an overview of the literature on COPD and HF and telemonitoring. Both diseases are debilitating chronic illnesses that affect a significant number of elderly individuals in the United States. Medical advances in the treatment of both have been made, but optimal disease management has not been attained due to factors at least partially related to insufficient self-care management in this population.

Few studies of COPD and HF, including those that used telemonitoring, have directly examined the relationship between self-efficacy (SE) and emotional well-being (EWB). The current study was designed to determine whether TM would have a significant effect on either SE or EWB. Additionally, this study was designed to examine the nature of the relationship between SE and EWB and provide a preliminary glimpse into the ability of TM to increase positive health outcomes and reduce negative ones.
CHAPTER II

REVIEW OF THE LITERATURE

Heart failure (HF) and Chronic obstructive pulmonary disease (COPD) are chronic medical conditions that require systematic monitoring of intricate treatment regimens. Treatment consists of both pharmacological and nonpharmacological methods. The patient must comply with lifestyle changes in addition to following prescribed medical therapies so as to achieve optimal disease management. Both conditions are associated with high medical costs and mortality, with patient noncompliance related to both of those factors. Additional support mechanisms, such as telemonitoring combined with patient education, may help improve patient adherence to treatment and have a favorable impact on outcomes. Operational descriptions of the key concepts addressed in this study are provided below.

Defining Key Concepts

*Chronic obstructive pulmonary disease* (COPD) is a disease state characterized by airflow limitation that is not fully reversible. The airflow limitation is a result of chronic bronchitis or emphysema and is usually progressive and associated with airway hyperreactivity to noxious particles or gasses. Chronic cough and sputum production often precede airflow limitation, sometimes by years. Clinical symptoms include unusual shortness of breath and increased forced expiratory time as displayed on spirometry.
Function and quality of life are negatively affected as symptoms progress (American Thoracic Society: Medical Section of the American Lung Association, 1995; National Heart, Lung, and Blood Institute & World Health Organization, 2001).

*Heart failure* (HF) is a complex medical condition that results from inefficiency in the ability of the left ventricle to fill with, or eject, blood. The primary manifestations of this disease are fatigue and dyspnea (shortness of breath), which can interfere with exercise tolerance and create fluid retention. Fluid retention may lead to pulmonary congestion and peripheral edema, with associated weight gain. These symptoms have a negative impact on function and quality of life. Symptoms may affect individuals differently. Some may have significant fatigue but little edema, or vice versa. Many, but not all, patients present with pulmonary congestion; therefore, the term *heart failure* is preferred over *congestive heart failure*, although both terms are used in the literature to refer to similar conditions (Hunt et al., 2001).

*Compliance* is the degree to which a patient follows through on recommendations from health care providers. Some practitioners suggest that the term *compliance* should not be used due to the paternalistic overtones. A more germane term is *adherence*, which implies that patients take a more active role in making informed decisions regarding their care (Haynes, 1979) Although the two terms are often used interchangeably in the literature, the term *adherence* will be used throughout this paper.

*Self-care* has been defined as an active cognitive process that a patient uses to maintain health or manage his or her disease process. Self-care in HF and COPD involves adherence to lifestyle changes, such as smoking cessation, proper diet, regular exercise, as well as adherence to medication regimen. Patients must be able to recognize subtle
symptoms that signal a change in their condition, formulate a response to the signals, and evaluate if the response has achieved the desired effect. This additional decision-making process is described as *self-care management* (B. Carlson et al., 2001).

*Emotional well-being* is described here as a state of positive emotion, including happiness and vitality, as well as the ability to function fully in life roles. This subjective state is related to basic need satisfaction and social relatedness. Daily experiences of autonomy, competence, and relatedness contribute to the prediction of happiness and vitality (Ryan & Deci, 2001).

*Telemonitoring* is a specific term used to describe the practice of remote monitoring of patients from a distance through the use of information technology such as audio and video. Telemonitoring uses special devices that transmit information, such as physiological data, via standard telephone lines, cable-networks or broadband technology. These devices allow monitoring on a daily or continuous basis and may contain “alarm” features that notify healthcare providers if the physiological data exceed preset parameters (Bondmass, Bolger, Castro, & Avitall, 1999; Louis et al., 2003; Meystre, 2005). Telemonitoring devices may also include educational components and collect data on patient response to disease management questions (Cordisco, Beniaminovitz, Hammond, & Mancini, 1999; Goldberg et al., 2003; LaFramboise et al., 2003).

*Self-efficacy* was defined by theorist Albert Bandura (1997) as people's belief in their capability to organize and execute the course of action required to manage a prospective situation. He believed that efficacy beliefs had an influence on how people think, feel, motivate themselves, and how they act. Self-efficacy is developed through mastery experiences (success), vicarious experiences (observing others succeed), social
persuasion (encouragement from others), and is influenced by physical and emotional state (physical capability and positive mood state) (Bandura, 1997).

Review Methods

A review of the literature on key concepts, including those described in the above section, was conducted using articles selected through a search of the MEDLINE and CINAHL databases for the time period January 1995–February 2008. Search terms included the following used in various combinations: heart failure, congestive heart failure, chronic obstructive pulmonary disease, telemonitoring, monitoring, treatment, disease management, intervention, self-management, self-care, adherence/nonadherence, compliance/noncompliance, self-efficacy, mental health, emotional well-being, psychosocial, quality of life, patient education, home care, home health, hospitalization, rehospitalization, and clinical outcomes. Additional articles were identified by reviewing article reference lists to ensure that all relevant articles were gathered.

Articles selected for preliminary review were those that pertained directly to the search topic and provided theoretical insights, reported an original data-based study, or synthesized results of multiple studies. Program evaluation studies were excluded. The National Advisory Panel guideline titled the "Guide to Reading Research Articles" was used to conduct the article critique (Forrest & Miller, 2001). This guide provided a basic framework for assessing the quality of article content based on the purpose of the study, the investigative methods used, results and conclusion, and applicability to theory or practice. Articles that did not include a full explanation of areas identified in this guide were excluded from review.
COPD Description and Risk Factors

COPD is a progressive disorder characterized by a chronic inflammation in the lungs which narrows the bronchi and produces symptoms of dyspnea, chronic cough, sputum production, and wheezing. It develops over time, is typically referred to as chronic bronchitis, chronic emphysema, and the severity is often described by the degree of lung impairment. As the condition worsens, patients cannot exhale efficiently, especially during exertion, trapping air, which reduces inspiratory capacity, and so they become short of breath. The damage to lung tissue is irreversible (Booker, 2005; Briggs, 2004). The primary risk factor is tobacco use, which contributes to 80–90% of cases. Another risk factor is a specific genetic abnormality that explains 1% of cases. The remaining cases may be explained by other risk factors, such as passive smoking, air pollution, occupational airborne toxins, and hyperresponsive airways such as with asthma (National Heart, Lung, and Blood Institute & World Health Organization, 2001; Pauwels et al., 2001).

HF Description and Risk Factors

HF is a chronic progressive disorder due to myocardial dysfunction that results in the inability of the heart to deliver enough oxygenated blood to meet the metabolic requirements of the body. HF is classified as either systolic or dystolic dysfunction, with
systolic the most common (Fletcher & Thomas, 2001). Heart failure presents with symptoms of dyspnea and fatigue in the individual’s medical history and specific signs of rales (lung sounds heard through stethoscope that indicate fluid) and/or edema during the physical exam. Risk factors associated with HF include hypertension; diabetes; hypercholesterolemia; coronary, valvular, or peripheral vascular disease; exposure to cardiotoxic agents; rheumatic fever; and chest irradiation (Hunt et al., 2001).

**Impact of COPD and HF**

*Epidemiology.* COPD is the fourth leading cause of death in the United States and the mortality rate is increasing. Over 10.2 million or 5.9% of the adult population have COPD, with estimates of 4–6% in males and 1–3% in females. Actual prevalence is higher because COPD is usually not diagnosed in the early stages (Mannino, 2003). Mortality is low for those under 45 but then increases with age, and is the fourth leading cause of death in those over the age of 65. The increased mortality rate may be related to past smoking trends. Smoking is decreasing so it is hoped that the mortality trend will reverse (Pauwels et al., 2001).

HF is a growing problem in the United States and is one of the most serious diagnoses encountered in primary care (Thom et al., 2006). Mortality rates for other cardiovascular disorders have decreased, but the incidence and prevalence of HF continues to rise (J. Anderson, 2002). Currently almost 5 million Americans (2.3%) have HF, with 550,000 new cases diagnosed each year. Mortality rate within 5 years of the initial diagnosis is 50% (Thom et al., 2006).
HF is more common in the elderly, and projected increases in the aging population make a corresponding increase in HF a near certainty. One in 1,000 people over the age of 65 currently have HF. This diagnosis represents the most common Medicare hospital discharge diagnosis. The incidence of HF is increasing, despite better medical management, due in part to improved mortality for other cardiac conditions such as myocardial infarction (Thom et al., 2006). Current population trends project a population of 75 million Americans, with 20% of the population over the age of 65, by the year 2040. If the HF trend continues, the 2040 population would produce 1.5 million new cases of HF per year (Masoudi, Havranek, & Krumholz et al., 1997).

Exacerbations. Both conditions are characterized by periods of relative stability or remission, interspersed with episodes of acute symptoms, or exacerbations. In COPD, exacerbations are defined as any worsening of symptoms. A major exacerbation includes all of the symptoms of increased dyspnea, sputum volume and sputum purulence, alone or in combination with cough, wheezing, or upper respiratory infection. Less severe exacerbations include at least one of the major symptoms, alone or in combination with cough, wheezing and/or upper respiratory infection. Exacerbations are a causative factor in morbidity and mortality. Although many episodes are unreported by patients, major exacerbations are an important cause of emergency room visits and hospital readmissions, and have significant impact on quality of life and activities of daily living. Exacerbations are also associated with physiologic deterioration and airway inflammatory changes (Cross, 2005; Kim et al., 2004; Wedzicha & Donaldson, 2003).

HF exacerbation is a worsening of heart failure and may include a variety of symptoms. Major HF relapse typically presents as pulmonary edema, with symptoms of
shortness of breath, profound fatigue, hypotension, or gross edema. HF worsening is also a contributing factor to other acute conditions such as myocardial infarction, pneumonia, dysrhythmia, uncontrolled hypertension, worsening angina, sodium retention, infection, and metabolic problems. As with COPD, HF exacerbations have serious consequences in terms of morbidity and mortality, typically resulting in hospital readmissions, and with a negative impact on patient quality of life and activities of daily living (Bennett et al., 1998; Feenstra, Grobbee, Jonkman, Hoes, & Stricker, 1998).

Hospitalization and Emergency Department Visits

The number of hospital admissions/discharges is used frequently as a primary outcome variable for studies on chronic illness, and in particular for the COPD and HF population. Although less represented in the published literature, emergency room admissions are also an indicator of exacerbations that are too serious to be treated on an outpatient basis.

Chronic obstructive pulmonary disease. Acute exacerbation is a major cause of emergency room visits and hospital admissions for COPD patients (Kim et al., 2004). During 2000, COPD was responsible for 1.5 million emergency department visits and 726,000 hospitalizations in the United States (Mannino, Homa, Akinbami, Ford, & Redd, 2002). COPD patients who seek medical care in the emergency room have a high (up to 25%) relapse rate within days to weeks after receiving care (Kim et al., 2004). Forty to 50% of hospitalized patients are readmitted within 12 months, with the majority of admissions occurring within the first 3 months after hospital discharge (Bourbeau et al., 2003; Cao, Ong, Eng, Tan, & Ng, 2006). Cao et al. found hospital admission rates similar
to other studies and also comparable factors associated with frequent readmissions which included disease duration greater than 5 years, forced expiratory volume in 1 second ($\text{FEV}_1$) less than $50\%$ predicted, psychotropic drugs usage, and vaccination status (Cao et al., 2006). Garcia-Aymerich et al. (2001) identified risk factors for admissions as patients with three or more admissions the previous year, lower $\text{FEV}_1$, and underprescription of long-term oxygen therapy.

Hospitalization usually occurs in the later disease stages and so is associated with mortality (Garcia-Aymerich et al., 2001). Almagro et al. (2002) found mortality rates of $22\%$ by 12 months after hospital admission for acute exacerbation, a rate comparable to similar studies. They also found that readmission was significantly related to previous hospitalizations, hypercapnia (elevated CO2 in the blood) at discharge, and lower quality of life scores.

Only one of the previous studies (Garcia-Aymerich et al., 2001) examined compliance to medical regimen as a variable, and a significant association to hospitalization was absent. However, self-management programs that emphasize adherence to medications and lifestyle changes have been found to reduce hospital admissions and emergency department visits (Bourbeau et al., 2003), suggesting that adherence may be a factor in hospitalization.

*Heart failure.* Rehospitalization after hospital discharge also is a common concern with the HF population, and Medicare surveillance data indicate this is a national problem. In 1996, HF readmissions accounted for $8\%$ of all readmissions at a rate of $212.8$ per $1,000$. This was the most common cause for readmission in the Medicare
population. Nearly 50% of patients with a discharge diagnosis of HF were readmitted within 6 months (Masoudi et al., 2002).

Krumholz et al. (1997) evaluated all HF Medicare admissions in Connecticut during the years 1991 through 1994 to identify patient and hospital characteristics associated with a higher tendency toward readmission. This study demonstrated that 44% of HF patients were readmitted within 6 months of the index admission, and that 18% of those admissions were directly related to HF. These rehospitalization rates are similar to those found by other researchers (Hamner & Ellison, 2005; Schwartz & Elman, 2003).

Bennett et al. (1998) analyzed 1992 HF admissions to a Veteran Affairs medical center and a tertiary care university medical center. Results indicated that of the 496 patients with HF, 79% were admitted due to worsening HF with sodium retention as the leading factor (55%) in decompensation (deterioration). These factors did not change with socioeconomic status. Noncompliance with HF meds and sodium restrictions seemed to contribute to fluid overload, which leads to decompensation (Bennett et al., 1998). Similar studies conducted in the U.S. and Germany found a significant relationships between adherence and readmission rates (Hong et al., 2004; Michalsen & Thimme, 1998).

In summary, both COPD and HF have been associated with the highest hospital readmission rate in the United States (Shipton, 1996), with admissions related to worsening of symptoms and nonadherence to treatment regimen. Recent study results suggest that despite the advancement in disease management, rehospitalization in the U.S. remains a critical factor.
Disease Management

The Disease Management Association of America defines disease management as coordinated healthcare interventions and communication systems for populations with conditions that require significant patient self-care efforts. This process emphasizes the patient/provider relationship and prevention of exacerbations through the use of evidence-based practice guidelines and patient empowerment (DMAA: The Care Continuum, n.d.).

Disease management of HF and COPD includes both pharmacologic and nonpharmacologic therapies. Pharmacologic therapies use medication to reduce the effects of the disease. Other medical interventions for HF include surgery such as angioplasty and bypass; heart transplants are considered as last resort. Other medical interventions for COPD include assisted ventilation, oxygen therapy, secretion mobilization, lung resection, and lung transplants in certain advanced cases. Nonpharmacologic nonsurgical disease management for both diseases includes interventions such as rehabilitation and counseling, and lifestyle changes that are to be made by patients in order to prevent or minimize disease-related symptoms.

The goals of disease management are to reduce symptoms, slow disease progression, and improve quality of life (Leidy, Rentz, & Zyczynski, 1999). Both pharmacologic and nonpharmacologic methods are disease management interventions addressed in the 2001 Guidelines for the Evaluation and Management of Heart Failure published jointly by the American College of Cardiology (ACC) and the American Heart Association (AHA) (Hunt et al., 2001), the Global Initiative for Chronic Obstructive Lung Disease by the National Institutes of Health (National Heart, Lung, and Blood
Institute & World Health Organization (2001), and the American Thoracic Society’s Standards for the Diagnosis and Care of Patients with Chronic Obstructive Lung Disease (GOLD) (American Thoracic Society, 1995; Pauwels et al., 2001).

Nonpharmacological Disease Management

The goals of nonpharmacologic disease management for COPD are to reduce symptoms, improve quality of life, and increase the ability to participate in activities of daily living. Pulmonary rehabilitation, long-term oxygen therapy, and surgery are the methods used to achieve those goals. Pulmonary rehabilitation is a multidisciplinary approach that offers exercise training, nutrition counseling, and education to address issues such as physical deconditioning, social isolation, altered mood such as depression, and weight loss.

The American Thoracic Society Standards (ATSS) provide a comprehensive evidence-based description of the components of pulmonary rehabilitation including recommended disciplines, education, exercise training, psychosocial support, and breathing retraining. The GOLD document provides Level A recommendations for therapy including nonpharmacologic interventions of smoking cessation, patient education and counseling, long-term oxygen therapy, and exercise training. Both GOLD and ATSS provide guidelines for disease severity/stage-specific intervention, and pulmonary rehabilitation is integrated into the overall approach to disease management (American Thoracic Society, 1995; Pauwels et al., 2001).

The goal of nonpharmacologic disease management for HF is to prevent or minimize the consequences of HF through ancillary services such as rehabilitation,
dietetics, counseling, and associated changes in patient lifestyle. Patients are advised to reduce sodium intake, eliminate smoking, reduce/eliminate alcohol and caffeine, and exercise on a regular basis (J. Anderson, 2002). In addition to lifestyle changes, patients are advised to monitor and report HF symptoms to healthcare providers, manage stress, and seek treatment for depression (Centers for Disease Control and Prevention, 2006).

ACC/AHA HF practice guidelines list recommended stage-specific lifestyle modifications. However, specific methodologies are not provided. The guidelines do not contain language related to the use of ancillary services such as rehabilitation, counseling or psychotherapy; nor is depression on the list of potential comorbid conditions. However, they do contain a general recommendation to use multidisciplinary disease management programs. “Multidisciplinary disease-management programs for patients at high-risk for hospital admission or clinical deterioration are recommended to facilitate the implementation of practice guidelines, attack different barriers to behavior change, and reduce the risk of subsequent hospitalization for HF” (Hunt et al., 2001). This recommendation has been assigned a Class One rating. An ACC/AHA Class One rating indicates a condition for which there is evidence and/or agreement among expert practitioners that a procedure or therapy is beneficial and effective (Hunt et al., 2001).

Successful COPD and HF disease management requires that the medical provider and the patient adhere to evidence-based practice guidelines for both pharmacologic and nonpharmacologic interventions. A requirement of successful nonpharmacologic intervention is patient understanding and adherence with the prescribed treatment regimen and recommended lifestyle changes. Other professionals, such as nurses, dieticians, pharmacists, psychologists, and rehabilitation professionals can supplement
patient education provided by the primary care physician. Because the focus of this study was on factors related to self-management and quality of life, the next sections will provide a detailed overview on factors related to lifestyle changes and self-management required by individuals diagnosed with COPD or HF.

Patient Perspective of Disease

There is an abundance of published research on both COPD and HF from a biomedical perspective. It seems that less research has been devoted to exploration of the patients' perspective on the impact of these chronic diseases upon their daily lives. In order to understand why patient adherence to medical regimen is suboptimal, insight into disease impact at the individual level is crucial. If health professionals have a greater awareness of these factors, intervention programs can be tailored to address these issues and to have a positive impact on patients adherence and ability to self-manage their disease process. Fortunately several studies have been completed that give insight into patient perspectives on living with COPD or HF. For this section, studies were reviewed that examined the patient perspective, organized into main categories suggested by the content, and summarized under two headings: symptoms and impact on daily lives.

Reported Symptoms

Symptoms identified most frequently by patients with COPD were dyspnea (breathlessness) and fatigue (R. Arnold, Ranchor, Koëter, Jongste, & Sanderman, 2005; Bailey, 2004; Barnett, 2005; Breslin et al., 1998; Caroci & Lareau, 2004; Costi, Brooks, & Goldstein, 2006; Jonsdottir, 1998; Kapella, Larson, Patel, Covey, & Berry, 2006; Small
& Lamb, 1999) Additional symptoms include cold symptoms, changes in sputum color or volume, and cough (Costi et al., 2006).

Symptoms identified most frequently by patients with HF were dyspnea and fatigue (R. Arnold, Ranchor, Koëter, et al., 2005; Bosworth et al., 2004; Caroci & Lareau, 2004; Lainscak & Keber, 2003). Other symptoms included chest pain, coughing and congestion, difficulty sleeping, dry mouth, and ankle and leg swelling (Bekelman et al., 2007).

Perception of the Impact of Disease

The literature review identified various descriptors of disease impact on daily living and quality of life. Based on content of the literatures the investigator identified the following categories: physical ability, social roles, and emotional, economic, and cognitive issues.

COPD patients commonly reported that COPD directly impacted physical ability and activity of daily living performance (Breslin et al., 1998; Jonsdottir, 1998; Small & Lamb, 1999). Impaired physical performance also affected patient ability to carry out role-related activities such as home management, vocational activities, socialization, as well as physical intimacy with partners (Barnett, 2005; Breslin et al., 1998; Small & Lamb, 1999).

Associated with the loss in role performance were feelings of inadequacy (Bailey, 2004) and the perception that others did not understand what they were experiencing and how it affected their physical abilities (Jonsdottir, 1998). Other emotions commonly described by patients included anxiety, panic, fear, frustration, irritability, depressed
mood, and resignation. (Barnett, 2005; Breslin et al., 1998; Kapella et al., 2006; Small & Lamb, 1999). Additional problems reported included sleep disturbances (Kapella et al., 2006), pain (Jonsdottir, 1998), and difficulty concentrating (Small & Lamb, 1999).

Many COPD patients described the fear of reoccurrence of exacerbations. Other fears related specifically to dyspnea or breathlessness and described the fear of disease progression and of suffocation and death during severe episodes (Kessler et al., 2006). COPD patients also recognized the breathlessness-anxiety-breathlessness cycle and felt emotionally vulnerable due to a perceived lack of control over the cycle. Patients avoided situations that could provoke significant emotion that could worsen symptoms of breathlessness, and thus tended to isolate themselves socially during exacerbations (Bailey, 2004).

HF patients also reported problems performing customary ADL’s and felt limited physically (Lainscak & Keber, 2003; Martensson, Karlsson, & Fridlund, 1998). Patients reported limitation in role performance including social, family and work roles (Bosworth et al., 2004; Lainscak & Keber, 2003; Martensson, Karlsson, & Fridlund, 1997, 1998). Loss of income due to difficulty performing work roles was an additional stressor. Both genders experienced a loss of sexual intimacy with partners (Bosworth et al., 2004).

Patients reported many negative emotions related to the disease experience, including stress, anxiety, depression, denial, and guilt (Bosworth et al., 2004; Lainscak & Keber, 2003). Other emotions described included a sense of powerlessness and resignation (Martensson et al., 1997, 1998), hopelessness and low self-worth. Patients also described anxiety and fear related to what they perceived as an unpredictable course
of the disease (Bosworth et al., 2004). Other issues included sleep disturbance and impaired cognition (Bosworth et al., 2004; Lainscak & Keber, 2003).

It is evident from the above review that there are similarities between COPD and HF symptoms and the impact of those symptoms on quality of life. Although the etiology of the lung dysfunction between the disorders is different, many of the physical symptoms are comparable. The symptoms of fatigue and breathlessness interfere with both patient groups’ ability to perform routine daily activities. Problems in performing role-related activities and the reality of living with a progressive disorder generate negative emotions such as fear and anxiety, depressed mood and lowered self-esteem. How does disease management take into account the impact on quality of life and the negative emotions associated with these diseases?

**Biopsychosocial Factors**

In the medical model, the focus is typically on the diagnosis and treatment of the physical symptoms, not on associated psychosocial issues. However, practitioners “know” that psychosocial issues impact patient outcomes, even if formal assessment is not provided. Factors such as patient emotional and cognitive status, support systems, coping abilities, and adaptability are all issues that may be informally noted but not addressed directly in the treatment plan.

When compared to the normal population, considerably higher rates of anxiety and depression are found in the COPD (Andenæs & Kalfoss, 2004; Yohannes, 2005) and HF (Friedmann et al., 2006; T. Rutledge, Reis, Linke, Greenberg, & Mills, 2006) population. The link between these psychological factors and mortality and morbidity is
significant and may be referred to as psychologic morbidity (Dracup et al., 2003) or psychiatric comorbidity (Mikkelsen, Middelboe, Pisinger, & Stage, 2004). Unfortunately, psychological distress is underdiagnosed and undertreated in both COPD (Lacasse, Rousseau, & Maltais, 2001) and HF (Ferketich & Binkley, 2005) even though studies repeatedly demonstrate the connection between psychological factors and disease outcome (T. Rutledge et al., 2006). In the previous section, the review identified similar negative emotions reported by COPD and HF patients. Although physical symptoms and related quality of life issues seem similar, how do the psychosocial factors impact mortality and morbidity between the two populations?

**Relationship to Disease Process, Morbidity, and Mortality and Other Factors**

Mikkelsen et al. (2004) reviewed the literature on COPD and found indications of high psychiatric morbidity with prevalence of anxiety ranging from 2–50% with corresponding levels of depression. Other studies suggested that both psychological and organic factors may play a role. Dyspnea, hyperventilation, and panic are symptoms shared by individuals with COPD and panic disorder. It is felt that people with COPD may develop a dyspnea-anxiety-increased dyspnea cycle similar to a panic attack and in reaction to a fear of suffocation. Biologic factors such as smoking, hypoxia, exacerbations, and untreated depression may contribute to comorbid depression and neurocognitive deterioration. (Mikkelsen et al., 2004).

Hunninen, Breitve, Wiborg, Pallesen, and Nordhus (2005) reviewed the literature to examine psychological characteristics of COPD patients and associations among psychosocial factors. They concluded a high prevalence of anxiety and depression existed
in this population and that neuropsychological impairment is detrimental to day-to-day function and to overall quality of life. Although the majority of findings indicated correlation between variables, no conclusions could be reached about causal factors. The authors proposed that emotional distress, loss of function, reduced quality of life and severity of the disease might have multiple connections with one another. Several recent studies have found depression to be predictive of mortality and morbidity in COPD patients (Almagro et al., 2002; Cao et al., 2006; Yohannes et al., 2005).

Richardson (2003) performed a review of the literature to address depression in the HF population. Growing evidence suggests that HF patients are more likely to be depressed compared to the general population, and unlikely to be treated for depression. Studies have shown rates of major depression as high as 36% and minor depression as high as 21% in HF (Richardson, 2003). This suggests that a reciprocal percentage of only 43% or less of HF patients experience a sense of emotional well-being.

Research shows the negative impact of depression on cardiovascular disease. Depression is an independent risk factor in coronary heart disease (CHD) and a strong predictor for recurrence of cardiac episodes. Studies show increased mortality in CHD with depression, including HF. Psychiatric comorbidity, with the most common coded disorder as depression, also contributes to increased admission rates (Richardson, 2003; Sayers et al., 2007). In a study of 374 patients, Jiang et al. (2001) found that 35.3% had a Beck Depression Inventory score of 10 or higher and 13.9% had symptoms of major depression. Odd ratios indicated that depression was associated with increased risk for hospital readmissions and mortality, independent of NYHA level, age, and ischemic etiology of congestive heart failure (Jiang et al., 2001). Other researchers have found that
depression increases as patients advance to NYHA class 3 and 4 (Freedland & Carney, 2000).

Joynt et al. (2004) reviewed the literature regarding the link between depression and heart failure. Early studies indicated that complex neuron-hormonal changes that occur in both HF and depression could produce HF in susceptible individuals and hasten the progression in those who already have the disease (Joynt et al., 2004). In their 2005 review, Konstam, Moser, and De Jong addressed the concern that psychological factors have been neglected by researchers and clinicians. They summarized existing literature on anxiety, depression and HF, including research supporting the physiologic interaction between negative emotions and poor clinical outcomes in HF. Additionally they identified the behavioral mechanism whereby negative emotions, especially depression, impacts patient adherence. Nonadherence to medical regimen has been shown to increase morbidity and mortality in patients with HF. Patients with both chronic illness and depression are three times more likely to be nonadherent compared to patients without depression.

T. Rutledge et al. (2006) performed a meta-analysis of research published prior to September 2005 on the associations between depression and HF to identify prevalence of depression and the magnitude of impact on clinical outcomes. Their review indicated that depression occurs at a moderate-to-high prevalence and that HF patients with depression have higher mortality and morbidity than those without. Prevalence rates varied widely in published studies, with an aggregate rate of 21.6%, which is a rate 2 to 3 times higher than the general population. Aggregate results also indicated that there is a substantially worse prognosis in terms of mortality and morbidity, as well as higher rates of
rehospitalization and health care use. Aggregate results indicated more than a two-fold risk for mortality and clinical events for HF patients with depressive symptoms or a diagnosis of depression. HF patients with depression had more than a two-fold risk of using emergency room services and overall 29% increase in overall health care costs (T. Rutledge et al., 2006).

Other studies have identified additional predictors of mortality/morbidity, such as social isolation, lower emotional well-being, avoidance coping behavior, lack of emotional support, and nonadherence (Bennett, Pressler, Hays, Firestine, & Huster, 1997; Carels et al., 2004; Evangelista et al., 2002; Friedmann et al., 2006). In the review of patient perspectives, disease impact on patient ability to carry out life roles and related activities was a significant issue reported by patients. How do these psychosocial factors impact QOL and is there an association with morbidity and mortality as there seems to be with anxiety and depression?

Quality of Life

Researchers and health care administrators are interested in determining the impact of interventions on nonmedical patient factors, such as quality of life. Quality of Life (QOL) is a broad term that covers an individual’s satisfaction with areas of life such as work; leisure; relationships; love; spirituality; finances; and physical, emotional, and social health (Johansson, Dahlström, & Broström, 2006). A concept used to measure more specific health concepts in health care studies is health-related quality of life (Hr-QOL). Leidy et al. (1999) defined Hr-QOL as “a multidimensional concept describing the patient’s physical, social and psychological health.” They asserted that to effectively
evaluate Hr-QOL, the evaluator must measure various domains, including discomfort related to disease, physical function and social function, and emotional well-being. The patient is the chief informant and responds to tools such as surveys or interviews (Leidy et al., 1999).

**Measurement of QOL**

Approaches to measuring Hr-QOL include global measures and condition-specific measures. The utility of global measures is that comparisons can be made across diagnostic categories. These measures typically evaluate the impact of an intervention on overall quality of life and well-being. Examples of global tools are the Medical Outcomes Study 36-item Short Form (SF-36) and the Nottingham Health Profile (NHP). The most widely used generic outcome tool in research of chronic disease is the SF36 (Johansson, Agnebrink, Dahlstrom, & Brostrom, 2003; Kaplan & Ries, 2005; Leidy et al., 1999). Because COPD and HF were included in the parent study, the SF36 was chosen as the Hr-QOL measure to allow comparisons between the two diagnoses.

**Impact of COPD and HF on Quality of Life**

Disease severity and symptoms, functional limitations, and psychological distress have been found to be associated with lower quality of life in patients with COPD and HF (De Jong, Moser, & Chung, 2005; Hu & Meek, 2005; Johansson et al., 2006; Juenger et al., 2002). Hospitalization and mortality has been found to have a strong association with lower quality of life in both diagnoses (Domingo-Salvany et al., 2002; Fan, Curtis, Tu,

In COPD, the perception of breathlessness was associated with anxiety and feelings of hopelessness, and impacted quality of life scores—in particular the mental health component (Hu & Meek, 2005). Hu et al. found that breathlessness, physical impairment and ADL limitations impacted the physical health component Hr-QOL scores, and the mental health component was impacted by hopelessness and anxiety, negative affective states (fear, anger, nervousness) and breathlessness. Fatigue is a common complaint with COPD and greater perceptions of fatigue are associated with greater impairment in QOL (Breslin et al., 1998).

HF studies comparing HF QOL to the normal population have found patients with HF to have significantly lower QOL, higher levels of anxiety and depression, and QOL scores dropping as disease severity increased (De Jong et al., 2005; Juenger et al., 2002) Individuals with HF experience limitations in physical and social activities, ADLs, role-related activities, sexual activity, and in community mobility, which further impacts social interactions with family and friends (Johansson et al., 2006)

Impact of Intervention

Leidy et al. performed a systematic review of HF research published between 1990 and 1998 that used Hr-QOL as an outcomes measure. Analysis of the literature indicated that both pharmacological and nonpharmacological interventions can have a positive impact on Hr-QOL. Forty-four studies were included in the review analysis. Findings suggested that the functional aspects (physical performance) of Hr-QOL were
impacted to a greater degree by intervention than other domains measured. It was suggested that due to chronicity of the disease, recovery of mental health domains, such as emotional well-being, may be a longer process, occurring only as patients feel they are able to be more independent (Leidy et al., 1999). A comparable review of the COPD Hr-QOL literature was not found.

Quality of Life as a Predictor

Faller et al. (2007) conducted a prospective study and followed 231 subjects for 986 days. They found that both the generic (SF36) and disease-specific tools (Kansas City Cardiomyopathy Questionnaire) predicted survival on univariate analyses. After adjustment for prognostic factors, such as age, gender, disease severity and function, only the disease-specific Hr-QOL and the mental health component of the SF36 remained significant. When depression was added, both tools lost predictive significance, indicating that the prognostic value of QOL may be confounded by level of depressive symptoms and severity of the disease.

In summary, QOL studies document lower QOL in COPD and HF, and a relationship among QOL and factors such as disease severity and depressive symptoms. Studies on patient perspectives lend insight to the complexity that chronic illness imposes upon the lives of patients and challenges they confront while performing day-to-day activities, trying to maintain life-role responsibilities, and coping psychologically and emotionally with the reality of living with a progressive disorder. The medical profession is concerned by nonadherence in COPD and HF patients, and by the negative impact nonadherence has upon disease severity and, ultimately, upon survival of the patient.
What impact does the "reality" of the disease, as perceived by patients, have upon their ability to adhere to a complex self-management regimen?

Adherence: Multiple Perspectives

Adherence can be defined as: the extent to which a person's behaviors such as taking medication, following a diet, and/or executing lifestyle changes, corresponds with recommendations from a health care provider (Sabate, 2003).

The World Health Organization (WHO) has identified lack of adherence to medical recommendations as a global problem of significant consequence. Research has shown that average adherence to treatment regimen in chronic disease patients in developed countries is only 50%, and even less in undeveloped countries. Low adherence has a negative impact on patient health, overall population health and health economics. It stands to reason that improving adherence and self-management will have a positive impact on patient health and general health of the population, and may ease the economic burden of health care.

Adherence is not only a patient problem. Health care systems need to share the responsibility by finding methods that improve patient adherence. Other factors, such as family and community support, can make a difference in adherence levels. Adherence is a long-term, dynamic process involving intense interaction between health care provider and patient, and requiring a match between a patient's level of readiness for information, and the process by which that information is made available to that patient (Sabate, 2003)
Adherence in COPD and HF

Studies that measure compliance in COPD and HF have found low levels of compliance in both populations (Corden, Bosley, Rees, & Cochrane, 1997; George et al., 2005; Michalsen & Thimme, 1998; Turner et al., 1995). A literature search produced relatively few HF studies that directly examined compliance/adherence as a variable, despite the association with rehospitalization. Evangelista and Dracup (2000) conducted a systematic literature review designed to increase understanding of compliance in the HF population. They found 11 HF studies published between 1988 and 1998 that included a compliance measure as a variable. The review indicated that there seems to be an association between compliance and rehospitalization and that lower compliance may have a negative impact on mortality and quality of life. The reviewers concluded that further research is needed to examine strategies that may enhance patient compliance. However, they cautioned that no single strategy would be effective, due to the complexity of compliance behavior in patients with a chronic disease.

Leventhal, Riegel, Carlson, and De Geest (2005) conducted a literature review to provide an overview of research on HF adherence issues and to highlight remaining issues and questions. Their review identified studies that have found adherence problems (with some portion of the medical regimen) ranging from 20%–65%. Issues related to patient compliance included knowledge, beliefs, attitudes, perceptions and expectations that influence the individual’s willingness to learn about the disease and to change health behaviors. As complexity of the medical regimen increases, adherence decreases. Fewer
studies exist that examine adherence in the COPD population and no review articles were found comparable to the one by Evangelista and Dracup (2000).

To summarize findings across studies that examined factors that appear to influence adherence and self-management in COPD and HF patients, Figures 2 and 3 present content based on the current review of the literature, and divided further by factors that promote adherence, and those that hinder adherence. Figure 2 summarizes factors that support adherence, and Figure 3 summarizes factors that are perceived as barriers. The main concepts identified in the review and placed in the figures were common between the two disorders. The few items not included in the figures were specific to differences in symptoms and symptom management unique to each diagnosis. To be included in the figure, each concept had to be identified in more than one study, suggesting that these findings may be generalized to the larger population.

As indicated by the above figures, adherence is a multidimensional issue that spans knowledge of the disease, coping ability, symptom burden and management, social support, self-confidence, motivation, mental health, quality of life, and environmental factors such as healthcare insurance. Quite often healthcare providers are frustrated, and often mystified, by the tendency toward nonadherence.

Self-Management in COPD and HF

The terms self-care and self-management describe the self-initiated and self-directed action of participating in ADLs and other activities so as to maintain physical, emotional, and social wellness (Orem, 1985). More specific to patients with COPD, active participation of the patient in his or her disease management and is based on
Facilitators to Adherence/Self-Management
Supported by Studies of COPD or HF or Both

Knowledge of disease and treatment/management 1 2 3

Acceptance of disease and changes to self 1 4

Belief in effectiveness of treatment 1 3

Experience in self-management 2 5 6 7 8 9

Symptoms provide opportunity for learning; experiencing positive results from treatment/self-management

Routinization of medication/lifestyle changes 1 5

Example: environmental cues/structure to facilitate healthy behaviors

Willingness to learn and motivation to change behaviors 7 8 10 11

Fear of dying; desire to stay healthy; avoid hospitalization; maintain control over life and health

Confidence/self-efficacy for disease self-management 2 12

Support from health care providers/good relationship 1 4 5 10

Social support from family, friends, and peers 4 7 8 10 13

Quality of life 5 8 12 13

Remain positive and adjust to changes; avoid depression and negative impact; maintain balance between disease and desired life activities

Positive environment: community, health care system 2 7 13


Figure 2. Facilitators to adherence/self-management.
Barriers to Adherence/Self-Management
Supported by Studies of COPD or HF or Both

Lack of knowledge/confusion/distrust/low belief in effectiveness of disease management/less symptom experience 1–5

Symptom burden 4–10

Negative symptoms: Shortness of breath, fatigue, pain, weakness, sleep difficulties, poor concentration, memory loss, cognitive changes comorbidities

Slower to initiate self-management strategies 5 7

Low self-confidence in ability to make correct decision; slow to recognize significance of symptoms

Complexity of treatment regimen and/or fitting into routine 3 8 11 12

"Cost" outweighs perceived "benefit

Lack of social support 1 3 7 13

Putting others first/caregiver tasks; not wanting to complain or alter routines that would affect others; others not understanding limitations; others not supporting healthy behaviors

Motivational factors: 1 6

Lack of energy; low self-control; difficulty dealing with changes in routine

Emotional distress/depression 1 3 8 14

Low satisfaction with health care/relationship with providers 1 7

Environmental issues 3 4 7

Insurance problems; difficulty accessing health care system when symptoms worsen; low income; lack of transportation

1 (Cicutto, Brooks, & Henderson, 2004) 2 (Francque-Frontiero et al., 2002) 3 (Gary, 2006)
4 (Horowitz et al., 2004) 5 (Riegel & Carlson, 2002) 6 (Evangelista et al., 2003) 7 (Jaarsma et al., 2000)
8 (Leventhal et al., 2005) 9 (Rockwell & Riegel, 2001) 10 (Bourbeau et al., 2004)
11 (Dowson, Town, Frampton, & Mulder, 2004) 12 (Schnell et al., 2006) 13 (R. Arnold et al., 2006)
14 (Strömberg, 2006)

Figure 3. Barriers to adherence/self-management.
effective coping, compliance with inhaled medications, monitoring changes in disease state, and using adequate inhalation technique (Worth, 1997).

Related to the HF population, Riegel et al. (2000) described self-care as a cognitive process involving compliance with recommended lifestyle practices, such as proper diet, exercise and adherence to prescribed medications. Self-care requires the cognitive components of learning, perceiving, interpreting, reasoning, and responding (Dickson, Tkacs, & Riegel, 2007). When self-care also involves monitoring and responding to disease symptoms with the proper behavior, then evaluating the impact of the behavior change on the disease symptom, self-care management has occurred (Gantz, 1990).

To organize results of the literature review of studies that examined patient perception of behaviors needed to manage their disease, the main concepts identified in the review that were common between the two disorders are placed in Figure 4. The few items specific to differences in symptoms and symptom management were not included. Content from multiple articles was used to construct the figures and each concept in the figure was identified in more than one study.

In the studies cited in the Figure 4, behaviors/strategies used with the most frequency were adherence to medications, seeing a physician on a regular basis, obtaining an annual flu shot, and planning and modifying activities according to energy level. Activities related to lifestyle change included exercise and diet and symptom monitoring such as daily weights. These were performed with less frequency, and seemed to be related to knowledge deficits/misperceptions of symptoms and appropriate management.
strategies. Patients who have had the disorder for longer periods had greater proficiency in symptom monitoring and management.

<table>
<thead>
<tr>
<th>Patient-Identified Behaviors for Self-Care Management</th>
<th>Supported by Studies of COPD or HF or Both</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical Regimen/Lifestyle:</strong> 1-11</td>
<td>Take medications/treatments as prescribed; keep doctor appointments; obtain annual flu shot; smoking cessation/alcohol reduction; perform breathing exercises; follow recommended diet; participate in regular exercise/physical activity</td>
</tr>
<tr>
<td><strong>Monitor/respond to Symptoms:</strong> 1-5 7-11</td>
<td>Monitor changes in status:</td>
</tr>
<tr>
<td>COPD: breathing, cough, sputum color and consistency</td>
<td>HF: shortness of breath, cough, nocturnal dyspnea, edema, weight gain, fatigue, nausea, fluid intake/output</td>
</tr>
<tr>
<td>Perform the following:</td>
<td>Obtain daily weight; plan and pace activities; rest when tired; ask for help or use assistive devices; call doctor for increased symptoms; adjust medication dose (COPD&amp;HF), oxygen (COPD only) and/or diet/fluid (HF only) in response to symptoms; use strategies to improve breathing</td>
</tr>
<tr>
<td><strong>Adjustment/Support:</strong> 1 2 5 7 9-11</td>
<td>Maintain a positive attitude; acceptance of disease and resultant changes; emotional adjustment and coping; avoid depression; obtain support from family, friends, peers and professionals; balance “living” as normally as possible, with “disease management”; may use distracting or normalizing strategies</td>
</tr>
</tbody>
</table>


*Figure 4.* Patient-identified behaviors for self-care management.
Information gained from qualitative studies highlighted the psychosocial issues related to living with chronic disease. In those studies patients emphasized the importance of maintaining a positive attitude, and in adjusting both physically and emotionally to the changes in their lives. Importance of social support was identified, along with the give-and-take process used to maintain quality of life as they tried to adhere to the recommended lifestyle changes and medical regimen advocated by health care professionals.

Disease Management Programs

How do patient-identified self-management strategies compare to those advocated and “taught” by professionals in disease management programs that are designed to improve adherence and self-management? To answer that question, this author reviewed the literature for published studies on this topic. Program components identified in the published studies were also organized into categories and summarized. Similar to previous figures, content in each category was identified in more than one article for each diagnosis. The content was then organized into topic areas of medical regimen/lifestyle, monitoring and responding to disease symptoms, and adjustment/support. All programs identified in the research provided education content related to the disease process, symptoms and symptom management, but only a portion of those addressed psychosocial aspects such as stress management. Figure 5 provides the detail of that review.
### Self-Care Management Program Components

**Used in Studies of COPD or HF or Both**

**Medical Regimen/Lifestyle:** 1–8

- Understand disease process, symptoms, treatment; understand medical regimen, proper use of medications and treatment, and importance of adherence;
- prevent/recognize exacerbations; annual flu shot; smoking cessation/alcohol reduction; breathing exercises; low sodium diet/fluid restrictions for HF; adequate nutrition for COPD; exercise program/physical activity

**Monitor/respond to Symptoms:** 1–9

**Monitor changes in status:**

- COPD: breathing, cough, sputum color and consistency, chest pain; HF: shortness of breath, cough, nocturnal dyspnea, edema, weight gain, fatigue, nausea, fluid intake/output, chest pain

**Weight monitoring:**

- HF-daily to check for gain; COPD-weekly to check for loss

**Energy conservation techniques:**

- Proper positioning during activity; planning and pacing; rest when tired

**Other strategies:**

- Asking for help or using assistive devices; call doctor for increased symptoms; when to seek emergency help; adjust medication dose (COPD&HF), oxygen (COPD only) and/or diet/fluid (HF only) in response to symptoms; breathing strategies

**Adjustment/Support:** 1 3–5 7

- Stress management and coping; support from family, peers, professionals

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1 (Bourbeau et al., 2004) 2 (DeWalt et al., 2006) 3 (Flynn et al., 2005) 4 (Gallefoss & Bakke, 2002) 5 (Jaarsma, Abu-Saad, Dracup, & Halfens, 1999) 6 (McGeoch et al., 2006) 7 (Monninkhof, van der Valk, van der Palen, van Herwaarden, & Zielhuis, 2003) 8 (Wright et al., 2002) 9 (Worth, 1997)

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Figure 5. Self-care management program components.
Comparison of Disease Management Factors

More similarities than differences are evident for the two conditions across the figures. Gaps are evident between what patients do and view as important for self-care management and what is provided by the formal disease management programs. For instance, a primary goal of disease management programs is to increase patient understanding of the disease process and medical regimen, as well as to instruct patients to monitor and adjusting the regimen based upon symptoms. Patients placed greater emphasis on adhering to the treatment regimen, monitoring and reporting symptoms, and making simple adjustments in medication and/or diet, versus developing a thorough understanding of the disease process and rationale to the treatment regimen. This comparison seems to support other studies that have identified a “knowledge” gap with patient ability to understand the disease and the meaning of symptoms, which is needed in order to make the appropriate adjustments to treatment regimen.

Another difference noted was in the emphasis patients place upon the importance of accepting the reality of having a chronic disease and maintaining a positive attitude, avoiding negative emotions such as depression, and grappling with the challenge of balancing a “normal” life with a life that is directed by the necessity of living with and managing chronic disease. Patients consistently identified these factors in the reviewed studies, whereas only a few of the disease management programs placed significant emphasis on this content, and some omitted education on psychosocial factors entirely. Overall, disease management programs seem to place only minor emphasis on the
psychosocial factors that patients indicate are of significant importance to self-management.

Healthcare providers routinely provide education to patients and families. It is often assumed that an increase in knowledge will produce the required behavioral changes needed for effective disease management. If behavior changes do not occur as a result of education, that behavior is considered nonadherence. Despite customary education, a significant knowledge gap often remains for patients, and this disparity interferes with successful self-care management (Horowitz et al., 2004; Riegel & Carlson, 2002; Sneed & Paul, 2003). Additionally, patients identify psychosocial factors as important to adherence and self-management, but only minimal content from formal education programs is directed toward such areas of concern. Despite the differences identified in the above comparison, how effective are formal disease management programs?

*Outcomes of Self-Management Component of Disease Management Programs*

In a review of randomized controlled trials on COPD self-management programs by Bourbeau et al. (2003) found that 8 of the 10 programs analyzed included content on lung and COPD, and 5 also addressed exacerbation and action planning. Four of the programs were fairly comprehensive and covered all of the areas in the above figure but did not include content on coping or balancing quality of life with disease management. The remaining 6 programs covered 2–4 items listed in the disease management or disease monitoring areas of the figure.
Four of the studies in the Bourbeau (2003) review showed an improvement in health status compared to the control. Two of the six that measured health resources found a reduction in physician visits and one found a reduction in emergency room visits compared to control. Some of the studies showed improvement in patients' knowledge of their disease and care but did not necessarily lead to improved behaviors or improved health outcomes. The analysis indicated that self-management programs can improve health status and reduce physician visits and hospital use.

In a meta-analysis of randomized controlled trials of patients with HF, Jovicic, Holroyd-Leduc, and Straus (2006) summarized the content of the six self-management programs described in studies that qualified for their review. Content typically included education on HF process and symptoms, importance of daily weights, and compliance to medications and dietary restrictions. Only one study focused on the interrelationship between these content areas and healthy behaviors. Outcome of the analysis indicated that self-management programs resulted in reduction in all-cause hospital admissions and HF readmissions. Adherence to medical regimen improved but no significant difference in functional capabilities, quality of life, or symptoms were supported. All studies that compared costs showed cost savings.

Patient Education

Patient education is defined as the process of improving knowledge and skills so that patients can manage their disease appropriately. Patient education may include therapeutic education, general health education, and clinically based health promotion. Patient education is usually a key feature of multidisciplinary disease management.
programs (Strömberg, 2005a). Although patient education seems to be a key component in disease management programs, studies have shown that a knowledge gap exists and that patients feel they are not well informed (M. L. Carlson, Ivnik, Dierkhising, O’Byrne, & Vickers, 2006; Frattini, Lindsay, Kerr, & Park, 1998; Strömberg, 2005a). Strömberg (2005a) suggested that clinicians should carefully assess for barriers, design educational delivery methods that take into account these barriers, and consider incorporating newer aids to learning, such as computer-based educational delivery, telecare and telemonitoring.

Lack of knowledge, misconceptions, and difficulty applying knowledge to self-care management is a reported concern in both COPD and HF population (Artinian et al., 2002; M. L. Carlson et al., 2006; Horowitz et al., 2004; Riegel & Carlson, 2002; Sneed & Paul, 2003; Strömberg, 2005b). To answer this question as to how this deficiency has been addressed in practice, several investigators conducted systematic reviews of published research.

Devine and Pearcy (1996) conducted a meta-analysis on 65 studies to examine the effect of education, exercise and/or psychosocial support in COPD adults. Publication dates ranged from 1954 to 1994. The meta-analysis indicated that education-only programs provided limited benefit for COPD patients. Greatest benefit was achieved through pulmonary rehabilitation programs that included education, large muscle exercise, breathing training, relaxation training, physical and occupational therapy, psychosocial support, nutritional education, and vocational counseling. The authors concluded that comprehensive pulmonary rehabilitation programs improve multiple measures of function and well-being in the COPD population.
Blackstock and Webster (2007) completed a systematic review of publications from 1966–2005 to examine changes in QOL, self-efficacy, physical function, psychological function, and resource utilization in trials comparing disease-specific patient education and usual care for COPD. A total of 13 articles were included in the review. The authors concluded that a didactic approach alone had minimal effect on outcomes and is not the recommended delivery method. Education emphasizing self-management showed positive results on clinical outcomes, QOL and resource utilization, but results did not reach significance and sample sizes were insufficient to detect a significant effect.

Gillespie (2001) reviewed the literature to examine the impact of educational intervention or disease management program on HF patients. Results of the studies were fairly positive in that 13 of the 17 programs that tracked rehospitalization reported decreased admissions. Other positive results included improvement in function, higher QOL, improved knowledge, and increased adherence to treatment guidelines.

The review completed by D. Rutledge, Donaldson, and Pravikoff (2001) indicated that HF management programs with a strong educational component can empower patients with the knowledge and skills needed for successful self-care management. The majority of programs reviewed were not theoretically based, but used methods developed within the medical model and managed care environment. Rutledge et al. recommended that delivery methods need to be designed to address the learning barriers of an older, frailer population, and be modified to suit the delivery context—from ICU to home.
Relationship of Education, Adherence, and Self-Management

The review of the literature on COPD and HF identified many themes related to adherence and self-management. The World Health Organization (WHO) utilized research from chronic disease on adherence and described adherence as a "multidimensional phenomenon" involving five factors that interplay among each other. Their concept emphasized the fact that patient factors are only part of the adherence picture. Healthcare providers need to be cognizant of all that may impact patient adherence. The themes identified by this author's review on COPD and HF adherence and self-management are consistent with the five-factor/dimensions identified by WHO, which are summarized below.

1. Social economic factors: Low income may cause a patient to have to choose between competing priorities such as health care, food, rent, clothing, or allocating limited resources to children or parents under their care. Other factors that influence adherence include illiteracy, low level of education, poor social support, transportation issues, distance from treatment facilities, cost of medication, cultural and laymen beliefs and perception about disease and treatment, and unstable family situation.

2. Health care team and system-related factors: Good relationship between patient and health care provider may improve adherence. Factors that seem to have a negative impact on adherence include: poorly developed health services, inadequate reimbursement by insurance, suboptimal training/staffing in chronic disease for health care providers, limited consultation time, weak systems for providing education and
follow-up, difficulty establishing social support and self-management abilities, lack of
knowledge on contributors to adherence and methods to improve it.

3. *Condition-related factors*: These are factors that the patient directly
experiences from the disease and include symptom severity, disability, progression and
disease severity, and availability of effective treatments. Each patient may be impacted
differently depending upon their individual situation. Comorbidity complicates adherence
because the patient must simultaneously monitor and manage more than one chronic
medical condition.

They include complexity of the medical regimen, especially when comorbidities exist,
length of treatment, treatment failures, changes in treatment, positive response to
treatment, side-effects, and amount and availability of health care provider support.

5. *Patient-related factors*: Patient factors that impact adherence include the
individual’s knowledge, resources, attitudes, beliefs, perceptions and expectations. Other
factors that impact adherence are motivation, self-efficacy to manage the disease,
expectations regarding outcomes of treatment/self-management and of the consequences
of poor self-management (Sabate, 2003).

This author’s review of the literature and the WHO position paper on adherence
elucidate the multidimensionality of adherence and self-management. Key internal factors
include patient knowledge of the disease condition and beliefs in medical treatment
regimen, confidence in effecting change themselves by monitoring symptoms and making
adjustments in medications, motivation to do so in the face of complexity and challenges,
and making lifestyle changes which involve breaking old habits and establishing new ones.

Living with chronic disease requires patient adjustment to physical and emotional changes and the awareness of behaviors needed to maintain optimal health and to slow disease advancement. Patients need to make adaptive changes to manage the disease and to maintain social relationships, emotional balance, and self-esteem, despite the inevitable changes provoked by the disease process. Patients learn from health care providers, from others who share the disease, and from their own experience with managing symptoms—both successes and failures. Patients may benefit from a teaching/learning model that encompasses the biopsychosocial factors illustrated by the review of the literature.

Self-Efficacy

Self-efficacy theory was developed within Bandura’s (1986) framework of the social-cognitive theory of behavioral change. Social-cognitive theory is based on the assumption that people are able to self-reflect and self-regulate and can influence the environment actively rather than react to the environment passively (Maddux, 1995). Personal efficacy, or the individual’s belief that his or her actions will produce the desired effect, is the foundation for action or behavior. If people lack belief, they lack incentive to act. Self-efficacy influences activity choice, effort put forth, perseverance against obstacles and failure, and resiliency toward adversity. Self-efficacy influences positive or negative thought processes, level of stress with environmental factors, and level of accomplishment (Bandura, 1997).
Bandura (1986) believed that multiple areas of influence could impact people’s beliefs about their efficacy. Among these factors are previous experiences of mastery, experiences related to modeling (watching others who have mastered the activity, perform it) and persuasion (from others who want them to be successful in the task). People also rely on their physiological and emotional reaction to help reach a judgment regarding their capabilities. They may judge fatigue and pain as a sign of physical dysfunction, which results in perceived ineffectiveness. Positive mood enhances self-efficacy and negative mood diminishes self-efficacy. Ultimately, people’s perceived self-efficacy influences choice of goals, amount of effort exerted, and persistence when confronted with challenges and barriers. Self-efficacy theory proposes that the individual’s self-confidence in his or her capability to perform an activity will determine what activities will be performed, how long it will continue, and how much effort will be put forth, especially if the activity is complex or conditions change unexpectedly (Bandura, 1986).

In interpreting Bandura’s work, Lenz, Shortridge-Baggett, and Shortridge-Baggett (2002) emphasized that self-efficacy is not of a general nature, such as a personality trait. Self-efficacy is thought to be task-specific. An individual may have a high self-efficacy for some tasks, and low self-efficacy for other tasks. Self-efficacy may be then considered to be of a more temporary nature, susceptible to influence, and situation and task specific. Because efficacy beliefs are task specific, each domain of interest needs its own efficacy measure. Self-efficacy measures rate the determinants of behaviors and/or the means by which they produce effects. Traditional measures of self-efficacy ask that the individual rate the degree of confidence they have related to the performance of specific tasks. In
this study, the measure of self-efficacy will be taken from Riegel’s Self-Care of Heart Failure Index (Riegel et al., 2000).

*Self-Efficacy and Health*

Research psychologists have been active in searching for the explanation of people’s engagement in unsafe and unhealthy behaviors. Beliefs about efficacy and personal control are major features of theories of health-behavior change. Self-efficacy may influence health in two areas. The first area is the adoption of healthy behaviors, quitting unhealthy behaviors, and maintaining newer healthier habits. The second area is the positive effect higher self-efficacy may have on the body’s physiological response to stress, especially the immune system (Maddux, 1995). Bandura (1998) used results from animal and human physiologic stress and coping research to support his assertion that high efficacy activates health-promoting biological functions while low efficacy produces a health-hindering autonomic system response.

Three major types of health behaviors explored by researchers are prevention, promotion, and detection. Self-efficacy has been found to be important in each of the three types of behaviors and all are applicable to chronic disease self-care management. Research has demonstrated that self-efficacy has an impact on health practices as well as adaptation to illness and treatment. In his overview of the literature, Maddux (1995) cited numerous studies that found a positive correlation between self-efficacy and specific self-care behaviors (Maddux, 1995).
Six COPD studies used self-efficacy as a major variable. Only one was a randomized controlled trial. One study included self-efficacy as a variable and followed both COPD and HF patients. Six HF studies used self-efficacy as a major variable. Four of the studies were nonrandomized with the objective to explore the relationship of self-efficacy to other variables of interest.

**Relationship of Self-Efficacy to Other Variables**

Kohler, Fish, and Greene (2002) evaluated a social cognitive model of QOL with COPD by analyzing relationships among measures of biomedical status, QOL, and self-efficacy among subjects \( N = 208 \) enrolled in a longitudinal medication-adherence study. This aspect of the study examined the relationship among the variables from measures obtained at baseline. Path analysis results indicated that the association of pulmonary function with level of functional impairment was mediated by self-efficacy for functional activities. In other words, patients with low self-efficacy may have been more limited in function than those with equivalent symptoms but who had higher self-efficacy in carrying out functional activities.

R. Arnold, Ranchor, DeJongste, et al. (2005) conducted a cross-sectional study to determine if self-reported physical functioning of COPD and HF patients could be explained by illness-specific differences related to the diagnosis, or if other generic factors contributed. Patients were recruited from outpatient clinics of a university hospital and a general hospital. A total of 65 patients with HF and 56 patients with COPD agreed
to participate in the study. Results found that COPD patients scored significantly lower than HF patients in self-reported physical function and psychological function. Both groups scored much lower than healthy people of the same age in the area of physical functioning and social functioning. There were no significant differences in social functioning or overall QOL. COPD patients perceived lower health competence compared to HF. There were no differences between the groups in measures of mastery, self-efficacy to control symptoms, or self-efficacy to maintain function. Regression analysis demonstrated that the diagnosis and disease severity contributed to self-reported physical functioning, but that self-efficacy contributed significantly to the explanation of self-reported physical functioning.

Oka, Gortner, Stotts, and Haskell (1996) conducted a cross-sectional trial ($N = 43$) to identify predictors of physical activity in HF patients. The predictive model included fitness variables, knowledge, attitudes, beliefs including self-efficacy for general activity, self-rating of daily exertion levels, and social factors. Self-efficacy was the stronger predictor of physical activity.

Tsay and Chao (2002) used an exploratory correlational design to study the relationship of self-efficacy to depression. Perceived self-efficacy had a strong direct negative effect on depression, with functional status as a mediating factor between the two variables. A positive relationship was shown between self-efficacy and functional status and a negative relationship between functional status and depression.

Salamah, Wahl, and Abriam-Yago (2003) used the Cardiac Self-Efficacy Questionnaire to measured confidence level in a convenience sample of 20 individuals with HF in order to identify factors that influenced self-management behaviors. The
lowest levels of confidence related to managing symptoms by adhering to prescribed therapeutic regimens. The researchers felt that the study supported self-efficacy as a prognostic factor.

Joekes (2007) conducted a nonrandomized repeated measures design to explore the relationship of self-efficacy and overprotection to psychological well-being, HRQOL and self-management. Data originated from two parallel studies of HF and myocardial infarction. Forty-one HF participants were surveyed at Time one and again 3 months later. Regression analysis indicated that higher levels of self-efficacy correlated with less psychological distress, better self-management and better HRQOL, and that a greater sense of self-efficacy predicted better self-management.

Impact of Intervention on Self-Efficacy

Scherer, Schmieder, and Source (1996) examined the changes in self-efficacy measures after attendance in a pulmonary rehabilitation program for COPD patients. Twenty-nine subjects were enrolled in the outpatient program consisting of 36 one-hour classes conducted three times weekly by a clinical nurse specialist. Content focused on COPD and its management, training and workout sessions, and relaxation training. Results showed a significant increase in self-efficacy for managing and controlling dyspnea during activity. Results were maintained 6 months after completion of the program.

Scherer and Schmieder (1997) used the same self-efficacy measure in a later study that examined changes in self-efficacy measures, perception of dyspnea, and exercise endurance. In this study, 60 COPD patients participated in pre- and posttesting in which
the intervention consisted of an educational and exercise training program using methods to increase self-efficacy. Results showed a significant difference in pre- and posttest scores on the dyspnea measure. A negative correlation was demonstrated between self-efficacy and dyspnea measures, and a positive correlation between self-efficacy and 12-minute walking distance test. Results indicated that higher self-efficacy correlated with lower perception of dyspnea and greater distances walked.

Lox and Freehill (1999) examined the impact of 12-week pulmonary rehabilitation on physiological, psychological, and behavioral performance variables. Forty subjects participated and provided measures of a 6-minute walking test, efficacy measure for the 6-minute walk, QOL, dyspnea, fatigue, and emotional function. Results showed significant improvement in all of the measures, regardless of disease severity. Improvements in exercise tolerance correlated significantly with increases in self-efficacy, which in turn correlated significantly with improved QOL.

Wong, Wong, and Chan (2005) conducted a randomized controlled study in which 60 COPD patients were recruited from an acute care hospital. The intervention consisted of nursing telephone follow-up designed to improve self-efficacy of patients for managing dyspnea and corresponding decrease use of health care services. A COPD self-efficacy dyspnea measure was obtained, in addition to data on resource utilization. Results showed a significant improvement in self-efficacy scores in the intervention group compared to controls. Telephone follow-up, participating in a pulmonary rehabilitation program, not smoking, and less health care use were significant predictors of self-efficacy. Although there was no statistical difference in health care utilization, there was a trend toward less use in the intervention group.
Davis, Carrierei-Kohlman, Janson, Gold, and Stulbarg (2006) studied the effects of intervention on self-efficacy, and if a relationship exists between domain-specific self-efficacy, walking performance, and symptom anxiety. Data for this study were collected as part of a larger randomized controlled study examining self-management for dyspnea in COPD. One hundred and fifteen subjects were randomized into three treatment groups. Data were collected at baseline and again at 8 weeks, after completion of the intervention. There were no significant differences between treatment groups. All groups demonstrated significant improvements in self-efficacy. Self-efficacy for walking was positively related to walking performance. Self-efficacy for managing dyspnea was positively related to severity of symptoms. The major finding was that a program that combined education with a home walking program significantly improved patient’s self-efficacy for walking and for managing shortness of breath. Improved self-efficacy for walking was related to improvement on the 6-minute walking test.

Barnason et al. (2003) used a subsample of ischemic HF Coronary Artery Bypass Graft (CABG) postsurgical patients to study the impact of an in-home communication device (telemonitoring) on self-efficacy, risk factor modification, and functioning. Patients (N = 35) were randomized into usual care or the intervention group. Baseline scores were used as covariates in the analysis. At 3 months the intervention group showed significantly higher scores on mean-adjusted self-efficacy scores and on adjusted mean levels of functioning. The intervention group also had significantly higher exercise adherence, and lower reported stress as compared to the usual care group. Study results seem to indicate that self-efficacy will increase over time as patients increase their confidence level through successful changes and incorporation of recommended lifestyle
changes into their daily routines. This study also supported Bandura’s assertion that mastery and habits are developed through repetition of the skill, and as mastery is gained, scores in self-efficacy will increase.

A smaller study (Oka, DeMarco, & Haskell, 2005) randomized 24 HF patients into usual care or a home-based walking and resistance exercise program. Patients were assessed at baseline before and after treadmill testing and again at 3 months. There was no difference at baseline between groups on studied variables and no difference in self-efficacy for general activity in either group by 3 months. Self-efficacy for walking was significantly improved in the intervention group by month 3, but not in the usual care group. These results support Bandura’s assertion that mastery of a skill is a contributor to increased self-efficacy for that skill.

In summary, self-efficacy has been studied in both COPD and HF populations, as a contributing factor to relationships among variables of interest, and as an outcome variable. Studies have shown a relationship between self-efficacy and symptom and disease severity, functional level, quality of life, skill performance, and depression. Self-efficacy was a predictor of activity level, and improved after intervention. The studies support Bandura’s assertions that self-efficacy relates to mood, influences activity level, and increases with opportunity for mastery experiences. The negative relationship of SE to depression and to disease/symptom severity lends support to Bandura’s theory that low self-efficacy produces a health-hindering autonomic system response. Results of these studies indicate that Bandura’s Self-Efficacy is an applicable theoretical “fit” with this population, an important prognostic factor, and an indicator of positive changes after
intervention. Study results suggest that positive changes in self-efficacy are associated with improved self-management behaviors, quality of life, and emotional well-being.

Telemonitoring

During the time period reviewed, 1995–2008, healthcare providers have increased the use of telecommunication technology to provide assessment, treatment and monitoring of patients from a distance. *Telehealth, telemedicine, and e-health* are some of the terms used to describe the use of distance technology in healthcare. A motivating factor behind home-based telemedicine is the need for high-quality, cost-effective home-based service in the era of managed care. Patient-centered care can be enhanced by the addition of telemedicine so the patient is assessed, progress monitored, and support provided directly in the home (Burgiss & Dimmick, 2003). Interest in telemonitoring has increased due to the rising cost of healthcare, advances in communication technology, and availability of lower cost telemonitoring devices (Louis et al., 2003).

Louis et al. (2003) reported results of a literature review on telemonitoring and HF for the time period between 1966 and 2002. The reviewers identified 18 observational studies and 6 randomized trials. Seven of the studies evaluated patient compliance and acceptance of telemonitoring and all showed high (80–90%) acceptance. Results of the observational studies showed reduction of hospital days. However, many of the studies used small number of patients and telemonitoring in combination with other components, such as outpatient clinic visits and automatic medication reminders, so it was difficult to attribute the effects to telemonitoring alone. Similar results occurred with mortality rates. The reviewers concluded that telemonitoring might reduce hospitalization and improve
mortality and morbidity but that larger long-term studies need to occur before efficacy could be adequately demonstrated (Louis et al., 2003). A systematic review on COPD and telemedicine was not found.

Meystre (2005) performed an extensive review of the literature on telemonitoring published prior to 2002, with the purpose to develop a global view of telemonitoring. In the research studies reviewed, medical conditions frequently monitored were asthma, chronic obstructive pulmonary disease and chronic heart failure. Telemonitoring allowed patients to remain in their homes and provided better follow-up, which reduced the effects of chronic disease. Her analysis of the literature indicated that patients’ homes were viewed as the most common, and perhaps the most promising, location for telemonitoring. Meystre concluded that although still in the early stages of development, telemonitoring has the potential to appreciably improve healthcare.

Overview of Telemonitoring Studies

A similar literature review was performed for this study to identify relevant COPD and HF studies published after the reviews performed by Louis et al. (2003) and Meystre (2005). CINAHL and Medline databases were searched for telemonitoring studies published between 2003–2007. Articles that provided program evaluation results were not included. Articles that did not provide a clear description of measurement tools were not included. A total of eight randomized and five observational studies were selected for review.

Because a comparable COPD review was not found, the investigator searched for articles published between 1995–2008 on the topic COPD and telemedicine/
telemonitoring. There were fewer published articles compared to the HF population. A total of two randomized and two nonrandomized were included. In addition, three other studies (two randomized) were used with other populations, in addition to COPD. Summary of the review is divided into the impact of telemonitoring on mortality, resource utilization, quality of life, and other variables such as self-efficacy and depression.

*Impact of TM on Mortality*

Only one of the COPD studies measured mortality as an outcome. de Toledo et al. (2006) carried out a randomized study in which 157 COPD subjects were followed. Patients in the intervention group were followed at home via an integrated telemedicine/electronic health records system. As this was a pilot, the telemedicine component was not fully implemented and patients interacted with the interdisciplinary team via phone calls to the call center. The initial experiment lasted one year. Both control and intervention received home-based education services but the intervention group received an additional education session and telephone access to the call center. Mortality was not significantly different in the intervention group, although the trend was for less mortality, with 20.3% mortality in intervention and 16.9% in control (de Toledo et al., 2006).

Two of the HF studies measured mortality as an outcome. Both found a strong relationship between telemonitoring and mortality. One of those was a large multisite randomized trial \(N = 280\) in the U.S. that included mortality as an outcome variable. This study compared standard care to standard care with the addition of a monitoring
device over a 6-month period. Both groups contained patients who were in advanced stages of heart failure and under aggressive treatment by cardiologists. Optimal medical management was provided to both groups, but the telemonitoring group demonstrated a 56.2% reduction in mortality ($P < .003$) (Goldberg et al., 2003).

A large multisite randomized trial (Cleland et al., 2005) in the U.K. compared patients ($N = 426$) randomized into one of three groups: usual care, nurse telephone contact, and telemonitoring. Patients were followed for 240 days. A significant difference was found in mortality in the usual care group compared to the other groups. One-year mortality was highest in the usual care group (45%), compared to patients in the nurse telephone group (27%) and the telemonitoring group (29%).

Finkelstein, Speedie, and Potthoff (2006) conducted a randomized clinical trial with patients assigned to one of three levels of homecare. Patients had a diagnosis of COPD, HF, or chronic wound care. Levels of intervention were standard homecare, standard homecare plus video visits/Internet access, or standard care plus video visits/Internet access and physiologic monitoring. Patients were followed for 6-months after discharge. There were no differences found in mortality between the three levels of care.

*Impact of TM on Resource Utilization*

Two of the COPD studies measured clinical outcomes of hospitalization and emergency room use. De Toledo et al. (2006) (study description in preceding section) found a significant reduction in the number of readmissions in one year. No significant differences were found in use of emergency room services. Paré, Sicotte, St-Jules, and
Gauthier (2006) conducted a quasi-experimental study and compared effects and cost of care a group of 19 patients under home health to a control of 10 patients receiving homecare without telemonitoring. The cost-minimization analysis demonstrated a reduced cost of $355 per patient, for an overall program savings of $6,750, a net gain of 15% over the traditional program. The main cost savings was through lower hospital readmissions. Finkelstein et al. (2006) found that discharge to higher level of care (hospital or nursing home) was highest in the control group (standard homecare) at 42%, 21% in the standard care plus video visits, and 15% in the standard care plus video visits plus physiologic monitoring.

Eight of the HF studies, four of which were randomized, measured the impact of telemonitoring on hospital admissions and/or costs. One of the randomized studies ($N = 37$) compared three models of post-discharge nursing care over a 180-day period. Results showed 80% lower costs in the telenursing groups compared to the usual care group. Both groups had significantly fewer emergency room visits as compared to usual care (Jerant et al., 2003). The other randomized study (Benatar et al., 2003) compared usual homecare to homecare with telemonitoring ($N = 216$) over a 12-month period and also found a significant difference in readmissions, length-of-stay, and total charges between the monitoring and the usual care group. Goldberg et al. (2003) found no difference in hospital utilization rates between the control and the intervention groups. Woodend et al. (2008) ($N = 121$) also found no differences in emergency department visits or hospital admissions between intervention and control.

The four nonrandomized HF studies reported results similar to that of the randomized studies. One of the larger studies (Berg, Wadhwa, & Johnson, 2004), a
concurrent matched cohort study \((N = 533)\) found overall lower hospitalizations, inpatient days, emergency room visits, and lower nursing home days. The nursing intervention provided telemonitoring, education, and counseling. A Minnesota project \((N = 60)\) reported statistically decreased hospital utilization and related costs compared to pre-study values (Bondmass et al., 1999). Another study (Heidenreich, Ruggerio, & Massie, 1999) \((N = 154)\) matched a convenience sample to a control group from the previous year by medical records. In this model the control group had received usual care managed by primary care physicians. The intervention group received a multidisciplinary program of daily self-monitoring, patient education, and physician notification of abnormal symptoms. This program also reported significantly lower hospital utilization and costs in the intervention group compared to the control. The last study (Cordisco et al., 1999) compared 30 patients with telemonitoring to 51 without. Both groups received specialized CHF care. By the end of 6-months the telemonitoring group had significantly lower rates in hospitalization and use of the emergency room.

**Impact of TM on Quality of Life Measures**

Results on measurements of quality of life are not as definitive as mortality and utilization. There is little agreement across studies on the impact of telemonitoring on QOL. Artinian et al. (2003) found that QOL as measured by the Minnesota Living with Heart Failure Questionnaire (MHFQ) improved significantly by 3 months over baseline compared to the control group. Improvement occurred in the physical, not emotional, subscale of the tool. Bondmass et al. (1999) had also used the MHFQ in their
observational study. They collected measures on a monthly basis through the 12-month follow-up and found that QOL improved significantly over baseline ($P < 0.002$).

Goldberg et al. (2003) used the MHFQ, the Medical Outcomes Study Short Form-12 (SF-12) and the Health Stress questionnaires. No difference between control and intervention were noted at baseline. Results showed that both groups improved in all measures over baseline and there was no statistical difference at 6-months follow-up. Another randomized study (LaFramboise et al., 2003) utilized the Medical Outcomes Study Short Form-36 (SF-36) to measure QOL. Results of this study of 90 HF patients demonstrated improvement over baseline in both the intervention and control, with no significant differences by the two-month follow-up. Whitten and Mickus (2007) used the SF 36 as an outcome measure to follow COPD and HF patients assigned to traditional homecare, or homecare with the addition of video visits. SF 36 scores were available for 37 patients in the experimental and 30 in the control who completed the study. The authors found that the addition of telehealth to standard homecare was not a significant predictor of health or well-being. Woodend et al. (2008) also used the SF36 and assessed QOL at baseline, and 1, 3, and 12 months. They found significant improvements over time in both groups, with the intervention group having higher QOL on five of the eight subscales by 3 months, but in only one of the subscales by 12 months.

**Impact of TM on Other Variables**

Other variables examined in studies were patient satisfaction, patient function, self-efficacy, depression, changes in physiologic measures and adherence to self-care behaviors. Bondmass et al. (1999) measured mean arterial pressure (MAP) in HF patients
who required blood pressure reduction. Patients who required blood pressure reduction had significantly reduced MAP by the end of 12-months. Lusignan et al. (2000) studied the feasibility of a wireless monitoring device in the homes of patients with COPD, HF, and atrial fibrulation. They found that the system was satisfactory for patients and the equipment functioned well in the home setting.

Demiris, Speedie, Finkelstein, and Harris (2003) described a qualitative study which examined the content of video phone visits provided to 10 home health patients with diagnoses of either HF, COPD, or who required diabetes wound care. One hundred and twenty-two visits were reviewed for technical quality and received an average overall rating of 95%, with 78 visits conducted without any type of technical problems. Content analysis revealed 13 themes, with the most prevalent relating to patient assessment, promotion of compliance, psychosocial issues and education.

Artinian et al. (2003) found that HF patients in the intervention groups demonstrated a higher rate of compliance to the self-management behaviors of daily weights and blood-pressure checks. LaFramboise et al. (2003) found no difference in functional status or depression between HF groups but did find that the telephonic and monitoring groups had higher confidence than the usual care.

Finkelstein et al. (2004) conducted a study designed to examine the usefulness of telehomecare using connectivity via the plain old telephone system (POTS) in providing high-quality, clinically useful and patient satisfactory interactions. Patients with COPD, HF, or chronic wounds were randomized to receive standard care, standard care plus videoconferencing/Internet access, or standard care with videoconferencing/Internet access plus physiological monitoring. Fifty-three patients completed the study. Results
showed high level of satisfaction across all three groups, but with higher satisfaction among the telehealth groups, with the highest in the group receiving videoconferencing/Internet access plus telemonitoring. The technical ratings of video visits were 94.7%. Patients rated them as useful as face to face visits in 90.7% of the cases.

*Quality of Telemonitoring Evidence*

The results of the above studies present a positive outlook regarding the feasibility and efficacy of telemonitoring. Studies that measured impact on hospital utilization found a positive effect, with the exception of the randomized trial performed by Goldberg et al. (2003). One explanation for the difference is that the subjects were undergoing aggressive treatment apart from the telemonitoring and received care that met or exceeded published guidelines. None of the other studies enrolled patients treated exclusively by cardiologists who specialized in heart failure. The U.K. study found similar results, despite differences in the credentials of the primary care provider.

Cleland et al. (2005) purposely enrolled subjects from hospitals that did not provide specialty care for HF patients. They had a stronger comparison design by including a nurse telephone group as well as the usual care and telemonitoring group. The researchers were not measuring mortality as a primary outcome, and were surprised when results showed a significant reduction in mortality in the telephone and monitoring groups. Telephone groups and monitoring groups actually increased number of hospital and physician services but used fewer days and had a higher survival rate than the usual care group. There were no significant differences in mortality or utilization between the
telephone group and the monitoring group. Like Goldberg’s group, these researchers hypothesized that improved mortality was a direct result of improved disease management by the physician and nurses in response to frequent monitoring of the patients (Cleland et al., 2005). Of interest to note is that the telephone group experienced similar benefits to the more costly and technologically-complex telemonitoring intervention.

The majority of studies reviewed showed a positive impact of telemonitoring, although the degree of effect varied across studies and variables. All studies provided intervention that enabled close monitoring of patient status, education of the patient, and a mechanism to communicate relevant information to the primary care physician. Those studies that compared telephone interventions to telemonitoring found a positive effect from both. Only five of the studies reported controlling for confounding variables (Bondmass et al., 1999; Cleland et al., 2005; Goldberg et al., 2003; Heidenreich et al., 1999; Jerant et al., 2003). However, the fact that those studies’ results were similar to results of the others gives added credibility to the overall results from all of the studies reviewed. Compilation of results supports that there is a clinical benefit to patients who receive regular in-home monitoring of their health status by qualified healthcare professionals. Quality of life, depression, self-efficacy, and self-management need further study to determine if telemonitoring has a positive impact on these variables and to determine what aspects of monitoring produces the greatest effect.
Purpose of Current Study

The results of the literature review suggest that there is an urgent need for programs that can improve HF and COPD disease management, reduce hospitalization, and increase survival. Multidisciplinary programs that address critical biopsychosocial factors may be the most efficacious. Telemonitoring may be a valuable tool for helping patients improve their confidence in their self-care management skills and simultaneously may improve their emotional well-being. This study will examine the impact of a home health telemonitoring program on self-efficacy, emotional well-being, and the clinical outcomes of mortality, hospitalization, and use of emergency department services. It will also explore the relationships among those variables at baseline and at 3 months.
CHAPTER III

METHODS

The primary purpose of this study was to examine the impact of telemonitoring on self-efficacy, emotional well-being, and clinical outcomes of mortality, emergency room use, and hospitalization in patients with HF or COPD. The secondary purpose was to determine if there is a relationship among the variables of telemonitoring, diagnosis, self-efficacy, emotional well-being, and clinical outcomes.

Research Questions and Hypotheses

Primary Research Question

Do patients who receive telemonitoring (TM), in addition to standard homecare, show differential improvement when compared with those who receive standard care only (SC) in the following outcome variables: (a) self-efficacy for disease management, (b) sense of emotional well-being, and (c) clinical outcomes of mortality, emergency room use, and hospitalization?

Secondary Research Question

Is there a significant relationship among the variables of self-efficacy, emotional well-being, and clinical outcomes at 3-months post index hospital discharge?
Experimental Hypotheses

The following hypotheses were examined within this study:

\( H_1 \): Patients with HF or COPD who are randomly assigned to receive standard care plus telemonitoring, compared with patients with HF or COPD who receive standard care only, will demonstrate greater improvement in the following variables:

a. Self-efficacy as measured by Section C (SCI-C) from the Self-Care of Heart Failure/COPD Index at 3-months post hospital discharge compared to baseline.

b. Emotional well-being as measured by the SF 36 Version One Mental Health Component Score (MCS) at 3-months post hospital discharge compared to baseline.

c. Clinical outcomes of mortality, emergency room use, and hospital admissions at 3-months post hospital discharge, with the TM group experiencing less mortality, emergency room use, and hospitalization.

\( H_2 \): Three-month scores in self-efficacy and emotional well-being will correlate positively with each other, and negatively with 3-month clinical outcomes of emergency room use and hospitalization; the relationships will be of greater magnitude in the TM versus SC groups.

A model of the theoretical relationships for the study was displayed by Figure 1 in Chapter I. The following Figure 6 represents the full study framework and displays the main variables and hypothesized relationships.
Research Design

This study was a randomized controlled trial designed to investigate the difference between standard care (SC) and standard care plus telemonitoring (TM) treatments in terms of patient perception of self-efficacy (SE) and emotional well-being (EWB), and clinical outcomes. Data to conduct this study were gathered as part of a larger project (Western Michigan University HSIRB approved protocol number 05-02-22) in which home health patients recruited from a Midwestern home health agency had been randomly assigned to either the control or experimental group and were followed over a 12-month period. The goal for the larger study was to recruit 100 subjects each to...
participate in the HF and COPD arms of the main study. It is those subjects whose baseline and 3-month data were analyzed in this study.

Population and Study Sample

The targeted sample for the dissertation study was 200 adult patients, with 100 randomized into the SC control condition, and 100 randomized into the experimental condition of SC+TM. Criteria for the selection of patients for the primary study are described in the following list. If eligible, patients were provided the opportunity to consent to participate in the primary study. To be included in the dissertation research, they must have provided additional consent, which was included as a checkbox on the informed consent form from the parent study. Approval from the Human Subjects Review Board of Western Michigan University and Borgess Health were obtained before this study was implemented. Copies of those approval letters are provided in Appendices A and B.

Inclusion Criteria

1. Patient meets admission criteria for home care per agency policy.
2. Patient has a documented diagnosis of HF or COPD.
3. Patient has a recent hospital admission for HF or COPD.
4. Patient’s treatment plan includes optimum medical management.
5. Patient is able to read and speak English.
Exclusion Criteria

1. Patient is physically unable to participate.
2. Patient does not have functioning land-line phone service.
3. Patient is physically unable to use equipment safely.
4. Patient has end-stage HF or COPD, or the focus of care is symptom management and quality of life.

Demographic data, with the exception of education, were obtained from the Outcome and Assessment Information Set (OASIS), which is a comprehensive clinical assessment and interview typically completed on patient admission into homecare and which generally coincided with enrollment into the parent study. Demographic variables used for this study were gender, age, educational level, severity of disease, and level of caregiver support.

Patient Enrollment

This study analyzed a portion of the baseline and 3-month data obtained from patients with HF or COPD who consented to participate in the parent study and who also consented to have their data utilized in this dissertation research. Those patients who met inclusion criteria in the main study, and who signed the informed consent to participate, were randomized into the control or experimental group. The control group received the usual SC and the experimental group received SC+TM. Patients in both groups completed study questionnaires at admission and again at 3 months post hospital discharge (index hospitalization).
SC consisted of assessment, establishment of treatment goals in collaboration with patient and family, education of the patient and family on disease management, and coordination of care with the primary physician. Care was directed toward the key patient outcomes of adherence to prescribed medication and treatment, demonstration of self-management behaviors, and advice seeking from health care provider as needed. At minimum, patients received intervention from a registered nurse. Other professionals that may have been involved in the standard care of subjects were social workers, physical therapists, occupational therapists, and dieticians.

The experimental group hence referred to as TM, received SC+TM. Patients in the experimental group independently, or with the assistance of a caregiver, took daily physiologic measures using the medical peripherals attached to the Health Buddy® monitoring device. The telemonitoring device (TD) included a computer-aided education program that provided daily sessions so that patients were able to test their knowledge of their disease, and receive recommendations for proper steps in management, reinforcement for correct responses, and corrective feedback for incorrect responses.

In this study, patients used either the COPD or HF disease program designed by the Health Hero Network, the developer and marketer of the Health Buddy®. Some of the educational content was modified to reflect regional practices in the treatment of HF and COPD. These data (physiological measures and responses to questions) were transmitted automatically on a daily basis through the phone lines to a secure website. Home health nurses received additional information from the telemonitoring device after analysis by system software that allowed them to individualize the disease management program.
The COPD disease management program available through the HB provided medication reminders and educational content on medications and the importance of taking those medications. The curriculum also provided instruction on different medication delivery systems (such as inhalers), the importance of nutrition, prevention of complications, lifestyle modification, safe use of oxygen, the importance of physical activity, and psychosocial factors that may affect the patient and the caregiver. The HB curriculum also provided content on signs and symptoms to report, the disease process, and risk factors.

The HF disease management program available through the HB contained medication reminders, and educational content about medication and the importance of taking medications, dietary guidelines, and information on the importance of physical activity and psychosocial factors that may affect both patient and caregiver. The HB curriculum also provided information on signs and symptoms to report, emergency procedures, ways to manage HF, the disease process, and risk factors.

Patients received the telemonitoring device within 2 days of enrollment into the study. Installation and training (with the patient and sometimes the caregiver) took approximately 3 hours. Patients were then encouraged to use the device on a daily basis. The device was removed from the home when the patient was discharged from home health care. Because the length of home health treatment varied among study participants, so did the length of time patients had access to the Health Buddy® device and the educational content.
Key Variables and Measurement

Variables that were examined in this study are self-efficacy and emotional well-being, as well as clinical outcomes of mortality, emergency room use, and hospitalization.

*Self-Efficacy*

Self-efficacy for HF management was measured by the Confidence Component score (section C) from the Self-Care of Heart Failure Index (SCHFI) (Riegel et al., 2000) version R4 updated 9/15/03. Reigel described self-care management as a cognitive decision-making process consisting of four stages: (a) recognizing that a change in symptoms is related to the illness, (b) evaluating the change, (c) implementing a selected treatment strategy, and (d) evaluating the effectiveness of the treatment strategy. The four stages are often sequential but may occur simultaneously. This construct of self-management was utilized to develop the Self-Care of Heart Failure Index (SCHFI). Each of these four stages was queried specifically by one of the four questions in the SCI-C, which were designed collectively to assess patient confidence in the four stages of self-care management.

The SCHFI can be completed by self or by an interviewer and takes approximately 5 minutes to complete. The complete survey form contains 15 items divided into subscales of self-care maintenance, self-care management, and self-care confidence. Riegel et al. (2000) included a measure of self-care self-confidence in the tool due to recognition that self-efficacy impacts behavior, and because research by others showed self-efficacy to be predictive of performance.
Riegel et al. (2004) reported findings of psychometric testing of the SCHFI. Construct validity was analyzed by confirmatory factor analysis, exploratory factor analysis, known-groups technique, and assessment of subscale-to-subscale correlations. Internal consistency of the SCHFI and subscales were estimated with coefficient alpha. The mean SCHFI score was $192.0 \pm 17.2$ (range 80 to 268 of 300) in a sample of 98. Internal consistency was calculated and coefficient alpha of the full scale was .76. Riegel and colleagues concluded that reliability and construct validity were sufficiently supported for use of the tool for research.

For purposes of the parent study, the SCHFI was modified to create a parallel version, the Self Care of COPD Index (SCCOPDI), that could be administered to the COPD subjects enrolled in the study, and allow comparisons between the diagnoses using the SCHFI and SCCOPDI. After obtaining consent from the creator of the SCHFI (B. Riegel, personal communication, January 31, 2005), the new tool was constructed to replicate the SCHFI as closely as possible but to address symptoms and healthcare regimen applicable to COPD. The initial version was developed by a clinical nurse specialist from the home health agency. This version was then reviewed for content validity by a pulmonary nurse specialist. The next version was reviewed by the creator of the SCHFI, who evaluated it to be consistent with the original tool in terms of organization of content, appearance, format, and scoring. The final version of the tool was not pilot-tested prior to implementation in this study and the parent study.

The questions, format, and scoring on subscale Section C of the SCHFI and SCCOPDI are identical. Subjects responded to four questions and rated their level of confidence on a 4-point Likert scale with the anchors, 1 = Not Confident and 4 =
Extremely Confident. Questions are listed here, numbered according to how they appear in Section C.

1. How confident are you that you can evaluate the importance of your symptoms?

2. Generally, how confident are you that you can recognize changes in your health if they occur?

3. Generally, how confident are you that you can do something that will relieve your symptoms?

4. How confident are you that you can evaluate the effectiveness of whatever you do to relieve your symptoms?

Items were scored as follows: 1 = 6.25; 2 = 12.5; 3 = 18.75; 4 = 25. The range for possible scores on Section C is from 25 (4 × 6.25) – 100 (4 × 25).

*Emotional Well-Being*

In this study, emotional well-being was measured by the SF-36 V1 Mental Component scores using Version 2 norms. The SF 36 is a multipurpose, short-form health survey. The 36-question tool produces an eight-scale profile of functional health and well-being scores and a psychometrically-based physical and mental health summary. The tool allows comparison of the burden of disease and treatment benefits. The SF-36 has been widely evaluated and found to exceed minimum psychometric standards for in-group comparisons (McHorney, Ware, & Raczek, 1993; Ware et al., 1995; Ware & Sherbourne, 1992). Deficiencies in the original version were corrected in the 1996 SF-36 Version 2. Norms were also updated at that time. Validity studies have demonstrated that
both versions of the SF-36 have content, concurrent, criterion, construct, and predictive validity. Reliability studies on the SF-36 have consistently exceeded the recommended minimum standard of .70.

The SF-36 may be administered by self, computerized version or by in-person or by phone interviewer. This tool can be administered in 5–10 minutes (Ware, 2005). The SF36 Version II was intended for the parent study. Due to an administrative error, however, Version I was used instead. Therefore, for consistency, Version I was used for the remainder of the study. The SF36 Version I was administered in person at enrollment, and by phone at subsequent time intervals.

Four subscale measures of the SF36 contribute to the Mental Component Score: Vitality, Social Functioning, Role Emotional, and Mental Health. The Mental Health subscale has been found the most valid measure of the Mental Component Score. The Vitality subscale measures subjects’ perception of level of energy from the lowest possible of feeling tired and worn out all of the time, to the highest possible of feeling full of pep and energy all of the time. The Social Functioning subscale measures subjects’ perception of ability to carry out social activities free from physical and emotional interference. The Role Emotional subscale measures subjects’ perception of ability to carry out work or other daily activities without interference from emotional problems. The Mental Health subscale measures subjects’ perception of mental health from the lowest possible of feeling nervous and depressed all of the time, to the highest possible of feeling peaceful, happy, and calm all of the time (Ware, 2005). Refer to Appendix C for questions and response choices for each of the subscales.
The SF36 Mental Component Score has been evaluated for its utility in screening for depression. Additionally, the Mental Health subscale, by itself, has been found to be a valid screening tool for mental health status, including as a screening tool for anxiety and major depression (Berwick et al., 1991; Friedman, Heisel, & Delavan, 2005; Hoeymans, Garssen, Westert, & Verhaak, 2004; Kelly, Dunstan, Lloyd, & Fone, 2008; Means-Christensen, Arnau, Tonidandel, Bramson, & Meagher, 2005; Rumpf, Meyer, Hapke, & John, 2001; Yamazaki, Fukuhara, & Green, 2005).

MCS score ranges (shown in Table 1) were derived based on the percentage of adults that screened positive for depression, using the receiver operating curve (ROC) analysis. ROC is a graphical method (N. Anderson, 2001) to evaluate a diagnostic test in terms of its ability to discriminate between a healthy person and a diseased person. The analysis helps to provide a “cut point” in the score above which the test is considered to be normal. The best all-around cut-off for the MCS in regards to depression is at the score of 42 or below, which achieves an area under the ROC curve of 0.77 and is considered to be “fair” in the ability to discriminate depressed from nondepressed individuals. These guidelines may be used to interpret differences in scores throughout the score ranged for clinical relevance and are provided in Table 1 (Ware, 2005).

Scoring of the SF36 is accomplished in three steps. First, the subscale scores are standardized using means and SD from the 1998 general U.S. population. They are then aggregated using weights from the 1990 general U.S. population. Last, the aggregate Physical Component and Mental Component scores are standardized using a linear T-score transformation so as to have a mean of 50 and a standard deviation of 10, in the 1998 general U.S. population. All scores above and below 50 are above and below the
Table 1  

*MCS Levels as Indicators of Possible Depression*  

<table>
<thead>
<tr>
<th>Levels</th>
<th>Score Range</th>
<th>n (Percentage) Screened for Depression</th>
<th>Levels</th>
<th>Score Range</th>
<th>n (Percentage) Screened for Depression</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>65–74</td>
<td>28 (10.7)</td>
<td>6</td>
<td>40–44</td>
<td>190 (58.9)</td>
</tr>
<tr>
<td>2</td>
<td>60–64</td>
<td>269 (12.3)</td>
<td>7</td>
<td>35–39</td>
<td>153 (73.9)</td>
</tr>
<tr>
<td>3</td>
<td>55–59</td>
<td>729 (18.4)</td>
<td>8</td>
<td>30–34</td>
<td>102 (89.2)</td>
</tr>
<tr>
<td>4</td>
<td>50–54</td>
<td>512 (29.1)</td>
<td>9</td>
<td>9–29</td>
<td>123 (93.5)</td>
</tr>
<tr>
<td>5</td>
<td>45–49</td>
<td>287 (45.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

average respectively. A 1-point difference in score is 1/10th of a standard deviation (Ware, 2005). Scoring for the parent study was calculated using the QualityMetric Health Outcomes™ Scoring Software Version 2.0.

A sample size of 140 is needed to detect a 2-point difference in PCS or in MCS scores over time within one group. A sample size of 23 is needed to detect a 5-point difference in either score over time within one group. A sample size of 201 is needed to detect a 2-point difference between two experimental groups on post-intervention scores using pre-intervention scores as covariates. A sample size of 33 is required to detect a 5-point difference in scores in the same situation. The previous sample size estimates assume alpha = 0.05, two-tailed test (Ware, 2005).
Clinical Outcomes

Mortality data were retrieved from medical records and family report at the time of scheduled phone interview (if not previously known from medical record).

Data for hospital and emergency services were derived from information retrieved from electronic medical records and from patient interview using the Stanford Patient Education Research Center Survey Health Care Utilization (PERCHCU) during the follow-up phone visits. Data gathered included incidence of emergency room visits and hospital admissions.

The Health Care Utilization Survey asks questions regarding physician office visits, emergency room use, and hospitalization. For this study, all but the question regarding physician office visits were utilized. The PERCHCU questions are as follows:

1. In the past 3 months, how many times did you go to a hospital emergency room?

2. How many different times did you stay in a hospital overnight or longer in the last 3 months?

3. How many total nights did you stay overnight in the last 3 months?

The PERCHCU items are scored individually. The original tool was evaluated on 1,130 chronic disease subjects with 51 involved in test-retest for reliability. Reliability measures for the questions used in this study are as follows: ER visits = .94; hospitalization = .89; nights in hospital = .97((Lorig et al., 1996).

Due to differences between patient reported healthcare utilization, and information retrieved from the regional healthcare system electronic medical records, data
were treated separately. Differences may have been due to subject confusion regarding timelines, how days are calculated for inpatient stays, or, in the case of regional health records, possible use of another healthcare system.

**Statistical Methods**

Descriptive and inferential statistical tests were completed to determine if there was a significant difference at baseline on demographic and key variables between the control and experimental groups. Analyses were also completed on baseline and 3-month measures to check for normality and other assumptions related to the statistical methods utilized. As is typical with small sample sizes, normality of data was not achieved on the majority of the measures. In research, parametric assumptions are met in a less than perfect fashion and yet researchers opt to use parametrics, or a combination of parametrics and nonparametrics to analyze the data. For purposes of this study, both were utilized and comparisons of statistical differences were made across the two methods.

Three-month data were analyzed using survivor data only. The majority of analyses were completed within the diagnostic categories (HF and COPD). Survivors were those subjects “active” (alive and participating) at the 3-month timeline. Paired $t$ tests and Wilcoxon Signed Rank tests were utilized to determine if there was a significant change in scores from baseline to 3 months within each group. Independent $t$ test and the Mann–Whitney $U$ were used to compare differences in change scores on main variables between the groups. Chi-square was used to determine if was a difference in the frequency of mortality, emergency room use, and hospitalization between the groups by 3
months. The Pearson correlation and Kendall’s tau were utilized to assess for the degree of relationship between variables at baseline and again at 3 months.
CHAPTER IV

RESULTS

This study was conducted with patients with COPD and patients with HF who consented to participate in this dissertation research study in addition to a larger parent study. Patients in the parent study were randomized into standard (usual) care (SC) or standard care with the addition of telemonitoring (TM) groups and were followed for 12 months. This study used secondary data to compare 3-month outcomes between TM patients and SC patients on several measures collected in the parent study. Dependent variables for this study were self-efficacy for disease management (SE) based on responses to SCI-C (Riegel et al., 2000), emotional well-being (EWB) based on SF36 MCS (Ware et al., 1995), and clinical outcomes based on mortality, hospitalization, and emergency room use. Data used in the analysis included demographics collected at baseline, baseline measures in SE and EWB, 3-months measures in SE and EWB, and clinical outcomes obtained from the hospital system database and from patient or family report.

The chapter is divided into three main sections. The first section provides descriptive data for demographic characteristics of patients enrolled in the study and data for treatment received during the time period that they were enrolled in home health. The second section presents results for comparison of groups at baseline in order to determine if the randomization had produced equivalent groups. The third presents results of
statistical analyses used to answer the research questions. These results are presented in order of the primary and secondary research questions with their corresponding hypotheses. Results are shown separately by diagnostic group, comparing the COPD-TM and COPD-SC (experimental and control) groups first, and repeating the pattern for the HF-TM and HF-SC groups in response to each question.

Descriptive Statistics for Sample Participants

Participant Demographics

The sample for this study consisted of 46 home health patients enrolled in the parent study, with two diagnostic subgroups consisting of 26 patients with COPD and 20 patients with HF. Problems in the parent study with the screening process resulted in groups of unequal size. Randomization of patients in the COPD group resulted in 11 patients in the COPD-TM group and 15 in COPD-SC. The HF group consisted of 8 patients in the HF-TM group and 12 in HF-SC. By 3 months, 38 patients remained active in the study. Five patients had died, and 3 had withdrawn. Analyses of all pre-post dependent variables, with the exception of mortality, are examined for the 3-month survivors, with subgroup numbers as follows: 9 COPD-TM, 13 COPD-SC, 6 HF-TM, and 10 HF-SC.

Table 2 summarizes patient demographics and data on education, living situation, and disease severity. Only limited information was available on disease severity; thus, it was not feasible to compare the groups for equivalency on this variable. The diagnostic group of 26 COPD patients (mean age = 72.96, SD = 9.42, range = 51–90) included 18
Table 2

**Patient Demographics**

<table>
<thead>
<tr>
<th>Characteristics of Enrolled Patients</th>
<th>COPD</th>
<th>HF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TM</td>
<td>SC</td>
</tr>
<tr>
<td>N</td>
<td>11</td>
<td>15</td>
</tr>
<tr>
<td>Age: Mean and (SD)</td>
<td>74.8 (9.46)</td>
<td>71.6 (9.48)</td>
</tr>
<tr>
<td>Gender (% male)</td>
<td>18.2%</td>
<td>40%</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>College Grad</td>
<td>9.1%</td>
<td>6.7%</td>
</tr>
<tr>
<td>High School Grad</td>
<td>54.4%</td>
<td>20%</td>
</tr>
<tr>
<td>&lt; High School</td>
<td>36.4%</td>
<td>46.7%</td>
</tr>
<tr>
<td>Unknown</td>
<td>26.7%</td>
<td>37.5%</td>
</tr>
<tr>
<td>Living Situation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alone</td>
<td>36.4%</td>
<td>20%</td>
</tr>
<tr>
<td>Spouse</td>
<td>27.3%</td>
<td>33.3%</td>
</tr>
<tr>
<td>Family/friends</td>
<td>27.3%</td>
<td>46.7%</td>
</tr>
<tr>
<td>Unknown</td>
<td>9.1%</td>
<td></td>
</tr>
<tr>
<td>Heart Failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NYHA class</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COPD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuous oxygen</td>
<td>36.36%</td>
<td>40%</td>
</tr>
</tbody>
</table>

*Statistically significant difference between telemonitoring and standard care groups.*
women (mean age = 71.85, \( SD = 10.19 \), range = 51–84) and 8 men (mean age = 75.45, 
\( SD = 7.36 \), range = 65–90. The diagnostic group of 20 HF patients (mean age = 72.48, \( SD 
= 10.56 \), range = 44–88) included 12 women (mean age = 69.34, \( SD = 10.42 \), range = 44–85) and 8 men (mean age = 77.20, \( SD = 9.49 \), range = 61–88).

*Self-Efficacy at Baseline*

Baseline self-efficacy scores for the total group of COPD patients (mean = 66.10, 
\( SD = 15.12 \), range = 37.5–100) were similar to those for the total group of HF patients 
(mean = 69.3, \( SD = 17.19 \), range = 37.5–100). Similar proportions of patients with each 
diagnosis (54% for COPD and 60% for HF) reported feeling very confident or extremely 
confident in their ability to evaluate the importance of their symptoms. A lower 
proportion of patients with COPD than with HF (65% for COPD and 80% for HF) 
reported feeling either very confident or extremely confident in their ability to recognize 
changes in health status. Patients in the two groups reported similar levels of confidence 
in their ability to do something to relieve their symptoms (46% for COPD and 50% for 
HF). Confidence in ability to evaluate the effectiveness of strategies they used to relieve 
symptoms was slightly higher for patients with COPD (58% for COPD and 45% for HF) 
than for those with HF. Table 3 displays the baseline group SE scores on the composite 
measure (SCI-C), as well as the scores on the individual questions, which are added 
together to calculate the composite SE score. Table 4 displays the frequencies of 
responses to the individual questions across the four groups.
### Table 3

**Self-Efficacy at Baseline**

<table>
<thead>
<tr>
<th></th>
<th>Chronic Obstructive Pulmonary Disease</th>
<th>Heart Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCI-C</td>
<td>63.8 (14.9)</td>
<td>71.8 (20.0)</td>
</tr>
<tr>
<td>Question 12</td>
<td>15.9 (6.3)</td>
<td>17.7 (7.3)</td>
</tr>
<tr>
<td>Question 13</td>
<td>16.6 (6.2)</td>
<td>21.8 (5.2)</td>
</tr>
<tr>
<td>Question 14</td>
<td>15.9 (3.3)</td>
<td>14.5 (6.4)</td>
</tr>
<tr>
<td>Question 15</td>
<td>15.3 (3.3)</td>
<td>17.7 (6.1)</td>
</tr>
</tbody>
</table>

Note. SCI-C score range: 25–100. Question score range: 6.25–25

### Emotional Well-Being at Baseline

Baseline emotional well-being (EWB) baseline scores on the SF36 MCS were similar for patients with COPD (mean = 46.97, SD = 14.96, range = 23.85–68.13) and with HF (mean = 45.39, SD = 12.5, range = 19.92–62.67). These are norm-based, standardized scores. At the most basic level of interpretation, the “mental component score” (MCS) indicates above-average overall mental health when compared to the U.S. population when the SF36-MCS > 50; whereas scores < 50 indicate below-average mental health compared to the U.S. population. As scores drop below 50, the likelihood of the existence of depression rises proportionately. Table 5 displays baseline scores across groups in the overall measure of EWB (SF36 MCS), as well as scores on the
Table 4

Responses to Self-Efficacy Questions

<table>
<thead>
<tr>
<th>Number Responding</th>
<th>COPD-TM</th>
<th>COPD-SC</th>
<th>HF-TM</th>
<th>HF-SC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q. 12. How confident are you that you can evaluate the importance of your symptoms?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not confident</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Somewhat confident</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Very confident</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Extremely confident</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Q. 13. Generally, how confident are you that you can recognize changes in your health if they occur?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not confident</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Somewhat confident</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Very confident</td>
<td>3</td>
<td>7</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Extremely confident</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Q. 14. Generally, how confident are you that you can do something that will relieve your symptoms?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not confident</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Somewhat confident</td>
<td>4</td>
<td>5</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Very confident</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Extremely confident</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Q. 15. How confident are you that you can evaluate the effectiveness of whatever you do to relieve your symptoms?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not confident</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Somewhat confident</td>
<td>5</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Very confident</td>
<td>4</td>
<td>9</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Extremely confident</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>
Table 5

Baseline Emotional Well-Being of Patients With COPD and With HF

<table>
<thead>
<tr>
<th></th>
<th>Patients with COPD</th>
<th></th>
<th>Patients with HF</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TM</td>
<td>SC</td>
<td>TM</td>
<td>SC</td>
</tr>
<tr>
<td>n</td>
<td>9</td>
<td>13</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>51.3 (2.4)</td>
<td>45.9 (16.6)</td>
<td>50.7 (9.1)</td>
<td>43.2 (12.8)</td>
</tr>
<tr>
<td>SF36-MCS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitality</td>
<td>41.4 (4.4)</td>
<td>39.7 (9.6)</td>
<td>32.1 (10.1)</td>
<td>32.7 (8.8)</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>39.6 (10.1)</td>
<td>37.2 (13.9)</td>
<td>30.9 (9.9)</td>
<td>30.5 (13.1)</td>
</tr>
<tr>
<td>Role Emotional</td>
<td>45.9 (12.2)</td>
<td>41.2 (15.1)</td>
<td>50.1 (12.9)</td>
<td>46.9 (12.9)</td>
</tr>
<tr>
<td>Mental Health</td>
<td>47.4 (13.8)</td>
<td>42.1 (17.6)</td>
<td>53.1 (7.1)</td>
<td>39.1 (11.9)</td>
</tr>
</tbody>
</table>

subscales that contribute to the overall measure. Forty-two percent of the group with COPD and 50% of the group with HF at baseline had scores < 50. Thirty-eight percent of patients with COPD scored in the lower three levels, which indicated an even higher risk for depression. Thirty percent of patients with HF also scored in the lower three levels.

Table 6 displays the frequencies of scores in the MCS categories. Refer to Appendix C to view questions and response items used to calculate each of the subscales.

**Group Equivalence**

**Equivalence on Demographic Variables and Baseline Measures**

Groups were compared on demographic variables and baseline measures of SE and EWB. With the exception of disease severity (for which there were insufficient data)
Table 6

Baseline Emotional Well-Being by SF36 MCS Levels

Baseline SF36 Mental Component Score Frequencies
by MCS Levels for 3-Month Survivors

<table>
<thead>
<tr>
<th>Frequency of Responses</th>
<th>Patients with COPD</th>
<th>Patients with HF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TM ( n = 9 )</td>
<td>SC ( n = 13 )</td>
</tr>
<tr>
<td>MCS Levels</td>
<td>SF36-MCS Range</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>65–74</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>60–64</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>55–59</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>50–54</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>45–49</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>40–44</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>35–39</td>
<td>1</td>
</tr>
<tr>
<td>8</td>
<td>30–34</td>
<td>0</td>
</tr>
<tr>
<td>9</td>
<td>9–29</td>
<td>1</td>
</tr>
</tbody>
</table>

Comparisons were made for each of the variables between the diagnoses of COPD and HF using \( t \) tests, chi-square, and Pearson's \( r \). When comparing the COPD-TM and COPD-SC participants at baseline, several of the measures were not normally distributed. Therefore, Mann–Whitney \( U \) was utilized to confirm the results of the \( t \) tests and Kendall’s tau to confirm the results of the Pearson's \( r \).

There were no significant differences between the diagnostic groups on any of the baseline variables with the exception of the relationship between baseline SE and baseline
EWB. Patients with COPD did not demonstrate a relationship but patients with HF demonstrated a positive relationship between baseline SE and baseline EWB \((r = .416; p \text{ (one-tailed)} = .056; \tau = .244; p \text{ (one-tailed)} = .101)\).

Experimental (TM) and control (SC) groups were also compared within both diagnostic groups on the demographic variables and baseline measures of SE and EWB. There were no significant differences between the COPD TM and SC groups on any of the variables when using either parametric or nonparametric statistical tests. Variables were also compared between HF-TM and HF-SC groups using \(t\) tests and chi-square, and confirming the \(t\) tests with the Mann–Whitney \(U\). Two significant differences were found between the HF-TM and HF-SC groups. First, a significant difference was found for age \((t = 2.88; p = .010), \ z = .452; p = .007)\), with participants in the HF-TM (mean age 79.57; \(SD\ 4.95)\) older than those in the HF-SC group (mean age 67.76; \(SD\ 10.79)). Second, a significant difference was found in the relationship between baseline SE and baseline EWB. HF-TM did not demonstrate a relationship between the variables but HF-SC did demonstrate a positive relationship between baseline SE and baseline EWB \((r = .530; p \text{ (one-tailed)} = .057; \tau = .349; p \text{ (one-tailed)} = .086)\).

The above analyses showed that patients in the HF-TM group were significantly older than those in the HF-SC group and a positive relationship was found between SE and EWB for the HF group, which further analysis showed to be confined to the HF-SC group only. Otherwise, randomization was effective in creating equivalent groups within diagnostic categories between SC and TM. Although demographic and baseline scores were similar between the two diagnostic groups, analyses addressing the experimental
questions were conducted separately so as not to obscure differences in how patients with the two conditions might respond to treatment as their diseases progressed.

*Equivalence of Treatment Data*

Length of intervention for this study was directly related to the number of days each subject was enrolled in home health care. Length of intervention varied among individual patients due to factors such as how quickly they reached care plan goals, medical stability, and functional status, which then removed them from homebound status and allowed discharge from home care. When patients were discharged from home health, the TM device was removed from their home. For this study, treatment is quantified for describing treatment groups according to the number of days the patients received home health services, number of skilled nursing visits provided, and number of TM sessions in the TM groups.

The purpose of describing the frequency of treatment was to provide data that could indicate whether level of treatment was similar across the groups. Days were tracked to indicate span of time patients received the SC components of direct care and disease management education by nursing and rehabilitation specialists. Some patients did not receive rehabilitation services, but all patients received visits from RNs, making it a variable that could be compared across all groups. Telemonitoring sessions were tracked separately because placing the device in the home did not guarantee that patients used the device on the recommended daily basis. Session adherence was calculated to indicate the degree of adherence among those patients who received TM. Figure 7
displays the number of TM sessions in the TM groups. Table 7 presents data for all treatment variables across the four groups.

**Comparison of Groups by Number of Telemonitoring Sessions**

![Comparison of Groups by Number of Telemonitoring Sessions](image)

*Figure 7. Number of telemonitoring sessions.*

The *t* test and Mann–Whitney *U* were used to test for differences. There were no significant differences between HF and COPD diagnostic groups, or between the TM and SC subgroups within the diagnostic categories on any of the treatment measures.

**Primary Research Question and Results**

Do patients who receive telemonitoring (TM), in addition to standard homecare, show differential improvement when compared with those who receive standard care only (SC) in the following outcome variables: (a) self-efficacy for disease management,
### Table 7

**Frequency of Treatment Sessions**

<table>
<thead>
<tr>
<th></th>
<th>COPD</th>
<th>HF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TM Mean (SD)</td>
<td>SC Mean (SD)</td>
</tr>
<tr>
<td><strong>Home Health Days</strong></td>
<td>34.7 (15.5) (range: 11-58)</td>
<td>34.7 (10.5) (range: 14-58)</td>
</tr>
<tr>
<td><strong>Skilled Nursing Visits</strong></td>
<td>5.8 (1.8)</td>
<td>5.2 (1.9)</td>
</tr>
<tr>
<td><strong>Telemonitoring Sessions</strong></td>
<td>21.2 (12.6)</td>
<td>NA</td>
</tr>
<tr>
<td><strong>TM Adherence</strong></td>
<td>81.3%a (range: 7-47 days)</td>
<td>NA</td>
</tr>
</tbody>
</table>

*a One patient treated as outlier and not used in calculation due to patient request to have TM removed from home 3 days after installation.

(b) sense of emotional well-being, and (c) clinical outcomes of mortality, emergency room use, and hospitalization?

**$H_1$:** Patients with HF or COPD who are randomly assigned to receive standard care plus telemonitoring, compared with patients with HF or COPD who receive standard care only, will demonstrate greater improvement in the following variables:

a. Self-efficacy as measured by Section C from the Self-Care of Heart Failure/COPD Index at 3-months post hospital discharge compared to baseline.
b. Emotional well-being as measured by the SF 36 Version One Mental Health Component Score at 3-months post hospital discharge compared to baseline.

c. Clinical outcomes of mortality, emergency room use, and hospital admissions at 3-months post hospital discharge, with the TM group experiencing less mortality, emergency room use, and hospitalization.

_Self-Efficacy Results at Three Months_

Paired *t* tests were used to analyze changes in SE scores from baseline to 3 months within each group. Because data for some of the measures did not meet assumptions of normality, the Wilcoxon Signed Ranks test was used to confirm the results of the paired *t* tests. Independent *t* tests were used to compare change scores at 3 months between the two groups within each diagnostic category. Because distributions for some of the scores did not meet assumptions of normality, the Mann–Whitney *U* was used to confirm the results of the *t* test.

_Self-Efficacy at Three Months for Patients With COPD_

Members of the COPD-TM group demonstrated significant improvement in SE on the SCI-C composite measure of their confidence for self-management of their disease from baseline to 3 months. However, change scores were not significantly different between COPD groups by 3 months.

Members of the COPD-TM group demonstrated a significant improvement in confidence in their ability to evaluate the effectiveness of strategies they used for
symptom management (Q.15) from baseline to 3 months and the extent of improvement compared to members of the COPD-SC group was significant. Refer to Table 8 to view changes in SE from baseline to 3 months.

Although COPD-TM improved in the composite scores on SE compared to baseline, there was only a marginally significant difference between the groups on that measure. There were no significant differences between SE measures on three of the four individual questions of those who had received TM, and those who had not. The null hypotheses could not be rejected for the composite SE (SCI-C) measure, or for questions 12 through 14. The null was rejected for Q.15. The extent of change in the COPD-TM patients' SE for evaluating the effectiveness of strategies used for symptom management was significantly greater than patients in the COPD-SC group. Refer to Table 9 to view comparisons on SE between TM and SC.

*Self-Efficacy at Three Months for Patients With HF*

Members of the HF groups did not demonstrate significant improvement in SE for self-management of their disease from baseline on either the composite measure (SCI-C) or on any of the individual questions. There were no significant differences in SE change scores between the TM and SC groups and so the null hypothesis regarding a significant treatment effect could not be rejected. Table 10 displays changes in SE measures by 3 months. Table 11 displays the comparison between the HF groups change scores.
### Table 8

*Changes in SE in Patients with COPD by 3 Months*

<table>
<thead>
<tr>
<th>Change Score</th>
<th>Within Group</th>
<th>Telemonitoring</th>
<th>Standard Care</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Dependent $t$</td>
<td>Wilcoxon</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Signed Rank</td>
<td></td>
</tr>
<tr>
<td>$M (SD)$</td>
<td>$t$ test $p$</td>
<td>$Z_{p}$</td>
<td>$M (SD)$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$t$ test $p$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$Z_{p}$</td>
</tr>
<tr>
<td>SCI-C</td>
<td>11.1 (18.16)</td>
<td>.052</td>
<td>.052</td>
</tr>
<tr>
<td>Q.12</td>
<td>2.77 (7.06)</td>
<td>.13</td>
<td>.12</td>
</tr>
<tr>
<td>Q.13</td>
<td>1.38 (6.83)</td>
<td>.27</td>
<td>.31</td>
</tr>
<tr>
<td>Q.14</td>
<td>2.08 (6.98)</td>
<td>.19</td>
<td>.17</td>
</tr>
<tr>
<td>Q.15</td>
<td>4.86 (2.75)</td>
<td>.000</td>
<td>.004</td>
</tr>
<tr>
<td>SCI-C</td>
<td>-2.08 (27.35)</td>
<td>.60</td>
<td>.47</td>
</tr>
<tr>
<td>Q.12</td>
<td>-1.56 (11.34)</td>
<td>.67</td>
<td>.31</td>
</tr>
<tr>
<td>Q.13</td>
<td>-1.56 (7.59)</td>
<td>.75</td>
<td>.25</td>
</tr>
<tr>
<td>Q.14</td>
<td>1.56 (6.03)</td>
<td>.19</td>
<td>.20</td>
</tr>
<tr>
<td>Q.15</td>
<td>-.52 (7.75)</td>
<td>.59</td>
<td>.45</td>
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</tbody>
</table>

### Table 9

*Comparison of SE Between Patients With COPD by 3 Months*

<table>
<thead>
<tr>
<th>Change Score</th>
<th>Change Score</th>
<th>$t$ test</th>
<th>Mann–Whitney $U$</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCI-C</td>
<td>11.1 (18.16)</td>
<td>.11</td>
<td>.13</td>
</tr>
<tr>
<td>Q.12</td>
<td>2.77 (7.06)</td>
<td>.16</td>
<td>.21</td>
</tr>
<tr>
<td>Q.13</td>
<td>1.38 (6.83)</td>
<td>.18</td>
<td>.15</td>
</tr>
<tr>
<td>Q.14</td>
<td>2.08 (6.98)</td>
<td>.42</td>
<td>.43</td>
</tr>
<tr>
<td>Q.15</td>
<td>4.86 (2.75)</td>
<td>.03</td>
<td>.024</td>
</tr>
</tbody>
</table>
Table 10

*Changes in SE in Patients With HF by 3 Months*

<table>
<thead>
<tr>
<th>SE Change Scores by 3-Months Patients with HF</th>
<th>Telemonitoring</th>
<th></th>
<th></th>
<th>Standard Care</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Change Score</td>
<td>Within Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dependent t</td>
<td>Wilcoxon Signed Rank</td>
<td></td>
<td>Dependent t</td>
<td>Wilcoxon Signed Rank</td>
</tr>
<tr>
<td></td>
<td>M (SD)</td>
<td>t test p</td>
<td>Z p</td>
<td></td>
<td>M (SD)</td>
<td>t test p</td>
</tr>
<tr>
<td>SCI-C</td>
<td>-5.2 (23.52)</td>
<td>.69</td>
<td>.25</td>
<td></td>
<td>-.62 (18.26)</td>
<td>.54</td>
</tr>
<tr>
<td>Q.12</td>
<td>.000 (7.9)</td>
<td>1.0</td>
<td>1.0</td>
<td></td>
<td>-.62 (9.52)</td>
<td>.58</td>
</tr>
<tr>
<td>Q.13</td>
<td>-3.12 (6.55)</td>
<td>.85</td>
<td>.12</td>
<td></td>
<td>-1.2 (5.74)</td>
<td>.74</td>
</tr>
<tr>
<td>Q.14</td>
<td>.000 (6.84)</td>
<td>1.0</td>
<td>1.0</td>
<td></td>
<td>1.25 (4.93)</td>
<td>.22</td>
</tr>
<tr>
<td>Q.15</td>
<td>-2.08 (9.40)</td>
<td>.69</td>
<td>.25</td>
<td></td>
<td>.000 (5.89)</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Table 11

*Comparison of SE Between Patients With HF by 3 Months*

<table>
<thead>
<tr>
<th>Comparison of 3-Month SE in Patients With HF</th>
<th>TM Change Score</th>
<th>SC Change Score</th>
<th>t test</th>
<th>Mann–Whitney U</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M (SD)</td>
<td>M (SD)</td>
<td>p</td>
<td>p</td>
</tr>
<tr>
<td>SCI-C</td>
<td>-5.2 (23.52)</td>
<td>-.62 (18.26)</td>
<td>.67</td>
<td>.31</td>
</tr>
<tr>
<td>Q.12</td>
<td>.000 (7.9)</td>
<td>-.62 (9.52)</td>
<td>.44</td>
<td>.43</td>
</tr>
<tr>
<td>Q.13</td>
<td>-3.12 (6.55)</td>
<td>-1.2 (5.74)</td>
<td>.27</td>
<td>.28</td>
</tr>
<tr>
<td>Q.14</td>
<td>.000 (6.84)</td>
<td>1.25 (4.93)</td>
<td>.33</td>
<td>.43</td>
</tr>
<tr>
<td>Q.15</td>
<td>-2.08 (9.40)</td>
<td>.000 (5.89)</td>
<td>.32</td>
<td>.39</td>
</tr>
</tbody>
</table>
Summary of Results for SE in COPD and HF Groups

The COPD-TM group made significant improvements in the composite SE measure over baseline but the results were not significant when compared to COPD-SC on the composite SE measure and three out of four of the individual questions. The COPD-TM made significant improvement in the confidence in their ability to evaluate the effectiveness of what they did to manage their symptoms (Q. 15) and the change was significantly greater than patients in the COPD-SC group.

The HF groups did not make any significant improvements on the SE main measure or any of the questions. Patients in COPD-TM demonstrated greater improvement in SE over baseline compared to patients with HF.

Emotional Well-Being Results at Three Months

Paired t tests were used to calculate change in EWB (SF36 MCS) scores from baseline to 3 months within each group. Because distributions for some of the measures did not meet assumptions of normality, the Wilcoxon Signed Ranks test was also calculated to confirm the results of the paired t tests. Because some of the scores did not meet normality criteria, the Mann–Whitney U was used to confirm the results of the independent t tests comparing the effect of treatment between the two groups.
Emotional Well-Being at Three Months for Patients With COPD

Members of the COPD-TM group demonstrated significant improvement in overall emotional well-being (SF36 MCS) from baseline to 3 months. The extent of change for the COPD-TM compared to the COPD-SC group was not significant.

When additional analyses were conducted for the subscale measures, members of the COPD-TM group demonstrated significant improvement in scores on Social Functioning (impact of physical and/or emotional problems on social activities) from baseline to 3 months. The extent of change for the COPD-TM compared to the COPD-SC group was not statistically significant. Members of COPD-TM group also demonstrated significant improvement in scores on Role Emotional (impact of anxiety or depression on ability to perform daily activities) from baseline to 3 months. The extent of change for the COPD-TM compared to COPD-SC group was not significant.

Although COPD-TM demonstrated significant improvement in overall EWB (SF36 MCS), and on subscales Social Functioning and Role Emotional from baseline to 3 months, there were no significant differences between EWB measures of those who had received TM and those who had not. Therefore, the null hypotheses could not be rejected.

Table 12 displays change scores at 3 months. Table 13 displays the comparison of change scores between groups.

Emotional Well-Being at Three Months for Patients With HF

Members of the HF-TM group did not make significant improvement in overall emotional well-being (SF36 MCS) from baseline to 3 months. Members of the HF-SC
**Table 12**

*EWB at 3 Months in Patients With COPD*

<table>
<thead>
<tr>
<th></th>
<th>Telemonitoring</th>
<th></th>
<th>Standard Care</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Change Score</td>
<td>Within Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dependents</td>
<td>Wilcoxon</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>M (SD)</td>
<td>t test p</td>
<td>Z p</td>
<td>M (SD)</td>
</tr>
<tr>
<td>SF36 MCS</td>
<td>5.4 (7.8)</td>
<td>.034</td>
<td>.033</td>
<td>2.3 (19.0)</td>
</tr>
<tr>
<td>Vitality</td>
<td>1.8 (6.3)</td>
<td>.20</td>
<td>.20</td>
<td>1.2 (8.5)</td>
</tr>
<tr>
<td>Social Function</td>
<td>10.2 (8.3)</td>
<td>.003</td>
<td>.005</td>
<td>5.8 (17.2)</td>
</tr>
<tr>
<td>Role Emotional</td>
<td>5.8 (9.3)</td>
<td>.047</td>
<td>.051</td>
<td>1.7 (18.9)</td>
</tr>
<tr>
<td>Mental Health</td>
<td>3.8 (10.2)</td>
<td>.14</td>
<td>.20</td>
<td>4.2 (16.8)</td>
</tr>
</tbody>
</table>

**Table 13**

*Comparison of 3-Month EWB Between Patients With COPD*

<table>
<thead>
<tr>
<th></th>
<th>TM Change Score</th>
<th>SC Change Score</th>
<th>t test</th>
<th>Mann–Whitney U</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M (SD)</td>
<td>M (SD)</td>
<td>p</td>
<td>p</td>
</tr>
<tr>
<td>SF36 MCS</td>
<td>5.4 (7.8)</td>
<td>2.3 (19.0)</td>
<td>.32</td>
<td>.27</td>
</tr>
<tr>
<td>Vitality</td>
<td>1.8 (6.3)</td>
<td>1.2 (8.5)</td>
<td>.42</td>
<td>.45</td>
</tr>
<tr>
<td>Social Function</td>
<td>10.2 (8.3)</td>
<td>5.8 (17.2)</td>
<td>.24</td>
<td>.40</td>
</tr>
<tr>
<td>Role Emotional</td>
<td>5.8 (9.3)</td>
<td>1.7 (18.9)</td>
<td>.28</td>
<td>.25</td>
</tr>
<tr>
<td>Mental Health</td>
<td>3.8 (10.2)</td>
<td>4.2 (16.8)</td>
<td>.53</td>
<td>.45</td>
</tr>
</tbody>
</table>
group did demonstrate significant improvement in overall emotional well-being (SF36 MCS) from baseline to 3 months. Change scores on SF36 MCS were significantly greater in the HF-SC group when compared to the HF-TM group.

When additional analyses were conducted for the subscale measures, members of the HF-SC group demonstrated significant improvement on subscale Mental Health (happy/calm vs. nervous/downhearted) from baseline to 3 months. The extent of change compared to the HF-TM group was significant. Members of the both groups demonstrated significant improvement in subscales Vitality (energetic/pep vs. tired/worn-out) and Social Functioning compared to baseline but there were no significant differences in change scores between the groups.

Members of the HF-SC group demonstrated significant improvement in Role Emotional subscale scores. The extent of change compared to the HF-TM group was not significant.

Although both HF groups improved in EWB compared to baseline, there were significant differences between the groups but in an unexpected direction. HF-SC patients had significantly greater change scores in EWB (SF36 MCS and subscale Mental Health) as compared to HF-TM patients. The null hypothesis was rejected but the experimental hypothesis was not supported because the change was in favor of the SC patients. Table 14 displays the 3-month EWB change scores for patients with HF. Table 15 displays the comparison in change scores between the groups.
### Table 14

*Change in EWB by 3 Months in Patients With HF*

<table>
<thead>
<tr>
<th>EWB Change Scores by 3-Months Patients with HF</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Telemonitoring</strong></td>
</tr>
<tr>
<td><strong>Change Score</strong></td>
</tr>
<tr>
<td><strong>M (SD)</strong></td>
</tr>
<tr>
<td>SF36 MCS</td>
</tr>
<tr>
<td>Vitality</td>
</tr>
<tr>
<td>Social Function</td>
</tr>
<tr>
<td>Role Emotional</td>
</tr>
<tr>
<td>Mental Health</td>
</tr>
</tbody>
</table>

### Table 15

*Comparison of 3-Month EWB Between Patients With HF*

<table>
<thead>
<tr>
<th>Comparison of 3-Month EWB in Patients With HF</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TM Change Score</strong></td>
</tr>
<tr>
<td><strong>M (SD)</strong></td>
</tr>
<tr>
<td>SF36 MCS</td>
</tr>
<tr>
<td>Vitality</td>
</tr>
<tr>
<td>Social Function</td>
</tr>
<tr>
<td>Role Emotional</td>
</tr>
<tr>
<td>Mental Health</td>
</tr>
</tbody>
</table>
Summary of Results for EWB in COPD and HF Groups

The COPD-TM group made significant improvements in EWB over baseline but the results were not statistically significant when compared to COPD-SC on the SF36 MCS measure or on any of the subscales and so the null was not rejected Both of the HF groups made improvements in EWB over baseline and the difference was significant, but in an unexpected direction. Patients in the HF-SC group made greater gains in EWB (SF36 MCS and subscale Mental Health) as compared to patients in the TM group. The null was rejected but the experimental hypotheses could not be supported. Table 16 illustrates the difference between HF and COPD by displaying baseline and 3-month EWB frequency scores per MCS levels.

Clinical Outcomes at Three Months

Chi-square tests were used to evaluate associations between group membership (TM vs. SC) and the clinical outcomes of mortality, emergency room use, and hospitalization. A comparison of hospitalization and emergency department services was made using hospital database information for the first comparison and patient-reported data for the second comparison.

Clinical Outcomes at Three Months for Patients With COPD

One patient in the COPD-SC group had died by 3 months. There were no deaths in the COPD-TM group. The chi-square test was used to analyze association between group membership and mortality. A significant relationship between group membership
and mortality ($\chi^2 (1) = .115, (.735)$) was not found. Because chi-square assumptions were not met for cell size, the Likelihood Ratio was also calculated ($L \chi^2 (1) = .113, (.736)$), which confirmed results of the chi-square test showing no difference between the COPD-TM and COPD-SC groups on mortality by 3 months.

Table 16

*MCS Scores by MCS Levels*

<table>
<thead>
<tr>
<th>Levels</th>
<th>Range</th>
<th>T1</th>
<th>T2</th>
<th>T1</th>
<th>T2</th>
<th>T1</th>
<th>T2</th>
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<tr>
<td>1</td>
<td>65–74</td>
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<td>2</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>60–64</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>55–59</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
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<td>4</td>
<td>50–54</td>
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<td>2</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>45–49</td>
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<td>0</td>
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<td>7</td>
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<td>30–34</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>9</td>
<td>9–29</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

| MCS <50 | 33% | 11% | 46% | 38% | 33% | 16% | 50% | 10% |

*a* Data missing on one patient.
By 3 months, two COPD-TM patients and three COPD-SC had experienced at least one database-retrieved hospitalization event. Data were missing for one patient. The chi-square test was used to analyze association between group membership and hospitalization events. A significant association between group and hospitalization \( \chi^2 (1) = .010, (.920) \) was not found. Because chi-square assumptions were not met for cell size, the Likelihood Ratio was also calculated \( L \chi^2 (1) = .010, (.920) \), which confirmed results of the chi-square test showing no difference between the COPD-TM and COPD-SC groups on this measure.

Database-retrieved hospitalization information matched patient-reported hospitalization information. Data were missing for two subjects. By 3 months, two COPD-TM patients and three COPD-SC had experienced at least one hospitalization event. A significant association between group and hospitalization \( \chi^2 (1) = .000, (1.00) \), \( L \chi^2 (1) = .000, (1.00) \) was not found.

There were differences between database-retrieved emergency room events (ER) and patient-reported ER, so they are reported separately. According to database-retrieved data by 3 months, three COPD-TM patients and three COPD-SC patients had experienced at least one ER event. Data were missing for one patient. A significant association between group and emergency room events \( \chi^2 (1) = .505, (.477) \), \( L \chi^2 (1) = .497, (.481) \) was not found.

Data were missing for two subjects for patient-reported ER events. By 3 months, two COPD-TM patients and four COPD-SC patients reported that they had experienced at least one ER event. Chi-square was used to test for an association between group
membership and hospitalization events. A significant association between group and ER visits ($\chi^2 (1) = .159, (.690)$, $\chi^2 (1) = .161, (.688)$) was not found.

To summarize, there were no differences in any of the clinical outcome measures between COPD-TM and COPD-SC, and so the null hypotheses could not be rejected.

**Clinical Outcomes at Three Months for Patients With HF**

A total of 4 patients with HF had died by 3 months, 2 in each group. The chi-square test was used to analyze association between group membership and mortality. A significant relationship between group membership and mortality ($\chi^2 (1) = .208, (.648)$) was not found. Because chi-square assumptions were not met for cell size, the Likelihood Ratio was also calculated ($L \chi^2 (1) = .205, (.651)$), which confirmed results of the chi-square test showing no difference between the HF-TM and HF-SC groups on mortality by 3 months.

There were differences between database-retrieved hospitalization and patient-reported hospitalization events, and so data are reported separately. By 3 months, 2 HF-TM patients and 2 HF-SC had experienced at least one database-retrieved hospitalization event. Data were missing for 1 patient. The chi-square test was used to test for an association between group membership and hospitalization events. A significant association between group and hospitalization ($\chi^2 (1) = .227, (.634)$) was not found. Because chi-square assumptions were not met for cell size, the Likelihood Ratio was also calculated ($L \chi^2 (1) = .225, (.636)$), which confirmed results of the chi-square test.

Data were available from all patients for patient-reported hospitalization events. By 3 months, 4 HF SC-TM patients and 1 HF-SC reported at least one hospitalization. A
significant association between group and hospitalization ($X^2 (1) = 5.60, (.018)$, $L X^2 (1) = .573, (.017)$) was found, with HF-TM patients reporting more hospitalization.

There were differences between database-retrieved emergency room and patient-reported emergency room events, and so data are reported separately. By 3 months, 1 HF-TM patient and 3 HF-SC patients had experienced at least one database-retrieved emergency room event. Data were missing for 1 patient. A significant association between types of treatment and emergency room events ($X^2 (1) = .511, (.475)$, $L X^2 (1) = .533, (.465)$) was not found.

By 3 months, 4 HF-TM patients and 3 HF-SC patients reported that they had experienced at least one ER event. A significant association between group and ER events ($X^2 (1) = 2.049, (.152)$, $L X^2 (1) = 2.075, (.150)$) was not found. To summarize, a significant difference was found in patient-reported hospitalizations, with more patients in the HF-TM group reporting hospitalization. All other clinical outcomes were nonsignificant when compared between the two groups. The null was retained on the outcome measures of mortality, database-retrieved hospitalization, and emergency-room use. The null was rejected for patient-reported hospitalizations. TM patients reported hospitalization more frequently compared to SC. Although the null was rejected, the experimental hypothesis was not supported because SC patients reported hospitalization with lower frequency than TM patients.

**Summary of Clinical Outcome Results for COPD and HF Groups**

Deaths occurred in both diagnostic categories, with four of the five occurring in the HF groups. All groups experienced a similar level of hospitalization and emergency
room events. The only significant difference was reported in the HF groups with HF-TM patients reporting significantly more hospitalizations as compared to HF-SC patients. Table 17 displays the frequencies of the clinical outcome events and Figure 7 displays cumulative survival for each of the treatment groups. The small cell sizes evident in Table 17 are considered in Chapter V.

Table 17

**Clinical Outcomes Among 3-Month Survivors**

<table>
<thead>
<tr>
<th>Clinical Outcomes Among 3-Month Survivors</th>
<th>Frequency of Incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPD HF</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0 1</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>2 3</td>
</tr>
<tr>
<td>Patient-reported Hospitalization</td>
<td>2 3</td>
</tr>
<tr>
<td>Emergency Room</td>
<td>3 3</td>
</tr>
<tr>
<td>Patient-reported Emergency Room</td>
<td>2 4</td>
</tr>
<tr>
<td>HF</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>2 2</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>2 2</td>
</tr>
<tr>
<td>Patient-reported Hospitalization</td>
<td>4 1</td>
</tr>
<tr>
<td>Emergency Room</td>
<td>1 3</td>
</tr>
<tr>
<td>Patient-reported Emergency Room</td>
<td>4 3</td>
</tr>
</tbody>
</table>

**Secondary Research Question and Results**

**Secondary Question: Relationships Among Variables**

Is there a significant relationship among the variables of self-efficacy, emotional well-being, and clinical outcomes at 3-months post index hospital discharge?

\( H_2: \) Three-month scores in self-efficacy and emotional well-being will correlate positively with each other, and negatively with 3-month clinical outcomes of
emergency room use and hospitalization; the relationships will be of greater magnitude in the TM versus SC groups.

Analyses were conducted separately for each diagnostic group. Pearson’s product–moment correlation and Kendall’s tau were utilized to compare the variables of EWB and SE. Primary measures were tested first, and then the subscales and individual questions. Pearson’s product–moment correlation and Kendall’s tau also were utilized to examine the relationship between EWB and clinical outcomes, and the relationship between SE and clinical outcomes. Clinical outcomes were coded as dichotomous variables with 1 = the event had occurred, and 0 = the event had not occurred. The hypothesis is directional and tests for significance are one-tailed.

**Relationships Between SE and EWB**

**Relationships Between SE and EWB for Patients With COPD**

At baseline, there was no statistically significant relationship between primary scores of SE and EWB in either group. By 3 months there was a significant positive relationship in the COPD-TM group \( r = .566; p = .056 \), \( \tau = .487; p = .040 \). Scores on composite SE (SCI-C) accounted for 32% of the variability found in overall EWB (SF36 MCS). The COPD-SC group did not show a significant relationship \( r = -.007; p = .491 \), \( \tau = -.016; p = .472 \).

To further explore the relationship between the two constructs, examination at the submeasure level was completed to determine if significant relationships existed among subscale measures of EWB and individual SE questions. By 3 months, the COPD-TM
group demonstrated a significant negative relationship between Vitality and Question 12 and significant positive relationships between Social Function and Questions 12 and 13, and Mental Health and Questions 13, 14, and 15. The COPD-SC group demonstrated a significant negative relationship between Social Function and Question 15, indicating that as Social Function scores increased, Q. 15 scores decreased. Results of correlations between the individual questions of SE and the subscales of EWB are provided in Table 18.

Table 18

<table>
<thead>
<tr>
<th>COPD</th>
<th>Relationship Between SE and EWB at 3 Months</th>
<th>Individual SE Question and EWB Subscales</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Telemonitoring</td>
<td>Standard Care</td>
</tr>
<tr>
<td></td>
<td>Q.12 Q.13 Q.14 Q.15</td>
<td>Q.12 Q.13 Q.14 Q.15</td>
</tr>
<tr>
<td>Vitality</td>
<td>-.49* .32 .16 .15</td>
<td>-.18 -.02 -.15 -.39</td>
</tr>
<tr>
<td></td>
<td>-.44* .15 .00 .00</td>
<td>-.15 .00 -.12 -.30</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>.43 .56* .06 .27</td>
<td>-.26 -.26 -.04 -.42*</td>
</tr>
<tr>
<td></td>
<td>.48* .49* .07 .19</td>
<td>-.17 -.10 -.15 -.36*</td>
</tr>
<tr>
<td>Role</td>
<td>.00 .19 .37 .26</td>
<td>.34 .13 -.05 -.01</td>
</tr>
<tr>
<td>Emotional</td>
<td>.00 .28 .30 .27</td>
<td>.35 .26 .00 .11</td>
</tr>
<tr>
<td>Mental Health</td>
<td>.05 .14 .56* .37</td>
<td>.14 .01 -.01 -.09</td>
</tr>
<tr>
<td>Health</td>
<td>.18 .47* .66** .61**</td>
<td>.05 .10 .04 -.02</td>
</tr>
</tbody>
</table>

Note. The top row in each cell is the Pearson r. The second row is the Kendall’s tau. All tests are one-tailed. *p < .10. **p < .05. ***p < .01.

The null was rejected in the TM group. There was a significant positive relationship between the composite measures of SE (SCI-C) and overall EWB (SF36
MCS). Additionally, several of the MCS subscales had significant relationships to individual SE questions. The null could not be rejected in the SC group with the exception of the negative relationship between Social Functioning and SE for evaluating the effectiveness of methods used to relieve symptoms (Q. 15). More subscale measures in SC were negative, while all but Vitality in TM were in the expected positive direction.

The null for equivalency of the magnitude of relationship between SE and EWB in COPD-TM as compared to COPD-SC could be rejected. The COPD-TM group had a positive relationship between composite SE and overall EWB and the magnitude of the effect was greater than COPD-SC. The fact that significant relationships among the variables existed in the TM group, but were nonsignificant for most of the relationships in the SC group, does suggest that there may be an influence by another variable, such as treatment, to account for the differences between the groups.

**Relationships Between SE and EWB for Patients With HF**

At baseline, there was no significant relationship between composite SE (SCI-C) and overall EWB (SF36 MCS) in the HF-TM group. There was a significant relationship in the HF-SC group ($r = .530; p = .057$), ($\tau = .349; p = .086$). By 3 months there was no significant relationship between composite SE and overall EWB measures in HF-TM, but there was a significant relationship in the HF-SC group ($r = .328; p = .178$), ($\tau = .497; p = .031$).

To further explore the relationship between the two constructs, examination at the submeasure level was completed to determine if significant relationships existed between subscale measures of EWB and individual SE questions. By 3 months, HF-TM group
showed a significant negative relationship between Vitality and Question 15 and a significant negative relationship between Role Emotion and Question 14. HF-SC showed a significant positive relationship between Vitality and Question 12 and a significant positive relationship between Mental Health and Questions 12, 14, and 15. Results of correlations between the individual questions and subscales are provided in Table 19.

Table 19

| 3-Month Relationships Among EWB Subscales and Individual SE Questions in Patients With HF |
|-----------------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|---------------------------------|
|                                       | HF                              | Telemonitoring                   |                                    | Standard Care                    |                                    |                                  |                                 |
|                                       |                                 | Q.12 | Q.13 | Q.14 | Q.15 | Q.12 | Q.13 | Q.14 | Q.15 |
| Vitality                              |                                 | -.34 | .11  | .06  | -.90*** | .54* | .04  | -.01 | .34  |
|                                       |                                 | -.23 | .18  | .19  | -.80**  | .53** | .08  | .00  | .27  |
| Social Functioning                    |                                 | -.42 | .00  | -.05 | -.53    | .38  | -.24 | -.24 | .21  |
|                                       |                                 | -.38 | .00  | .00  | -.48    | .28  | -.31 | -.31 | .24  |
| Role                                  |                                 | -.20 | .00  | -.63* | -.44    | .33  | -.17 | -.17 | .25  |
| Emotional                              |                                 | -.20 | .00  | -.63* | -.45    | .33  | -.17 | -.17 | .32  |
| Mental                                |                                 | .1   | .28  | .00  | -.40    | .46* | .10  | .29  | .57**|
| Health                                |                                 | .12  | .18  | -.09 | -.26    | .37  | .16  | .46* | .45* |

*Note. The top row in each cell is the Pearson r. The second row is the Kendall’s tau. All tests are one-tailed.

*p < .10, **p < .05, ***p < .01.

Correlations between the primary measures of EWB and SE were nonsignificant in the HF-TM group and so the null could not be rejected. The relationship was significant in HF-SC and so the null could be rejected. The null were also rejected in the SC group for several submeasure relationships. There was a positive relationship between
Vitality and SE in ability to evaluate the importance of symptoms (Q. 12). There was also
a positive relationship between Mental Health and SE in ability to evaluate importance of
symptoms (Q. 12), do something to relieve symptoms (Q. 14), and evaluate the
effectiveness of methods used to relieve symptoms (Q. 15). In the HF-TM group the null
was rejected but the experimental hypotheses were not supported. Although significant
relationships were present for two submeasure relationships, they were negative versus
positive. Vitality was negatively related to SE to evaluate the effectiveness of what was
done to relieve symptoms (Q. 15). As Vitality scores decreased, SE Q. 15 scores
increased. Role Emotional was also negatively related to SE for doing something to
relieve symptoms (Q. 14).

Summary of Relationships Between SE and EWB

There was a significant positive relationship in the COPD-TM group between the
primary SE and EWB measures and several of the submeasures across the two scales.
There was the suggestion of a positive trend between primary measures in the HF-SC
group and significant positive trends between several of the submeasures. In contrast, the
HF-TM group had significant negative relationships between several submeasures.
Overall, there appeared to be trends toward the hypothesized positive relationship
between EWB and SE in the COPD-TM and HF-SC patients, with the subscale Mental
Health having the strongest correlation across the individual questions in those two
groups. When scores increased on the Mental Health subscale for patients in COPD-TM
and HF-SC, scores also increased on SE for doing something to relieve symptoms (Q.14),
and on SE for evaluating the effectiveness of those symptoms (Q.15).
Relationships Between SE and Clinical Outcomes

Relationships Between SE and Clinical Outcomes for Patients With COPD

There were no significant relationships between SE (SCI-C) and database-retrieved hospitalization, or SE and patient-reported hospitalization in either of the COPD groups. There were no significant relationships between SE and database-retrieved emergency room events, or SE and patient-reported emergency room events in either of the COPD groups. The null hypotheses could not be rejected for patients with COPD in either group.

Relationships Between SE and Clinical Outcomes for Patients With HF

There was no significant relationship between SE (SCI-C) and database-retrieved hospitalization in either HF groups. There was a trend toward a positive relationship between SE and patient-reported hospitalizations in both the HF-TM group ($r_{pb} = .600; p = .104$), ($\tau = .490; p = .117$) and the HF-SC group ($r_{pb} = .327; p = .178$), ($\tau = .389; p = .103$).

There was no significant relationship between SE and emergency room events in the HF-TM group but there was a significant negative relationship in the HF-SC group ($r_{pb} = -.552; p = .062$), ($\tau = -.438; p = .09$). There was no significant relationship between SE and patient-reported emergency room events in either group.

The null hypotheses were retained with the exception of the negative relationship between SE and ER events in the HF-SC group. Although the null was rejected, the
experimental hypothesis was not supported because the relationship was in the HF-SC (control) group.

Relationships Between EWB and Clinical Outcomes

Relationships Between EWB and Clinical Outcome Measures for COPD

There was no significant relationship between overall EWB (SF36 MCS) and hospitalization in the COPD-TM group ($r_{pb} = -.380; p = .177$), ($\tau = -.327; p = .159$) although there was a trend toward a negative relationship. There was a significant positive relationship in the COPD-SC group ($r_{pb} = .479; p = .057$), ($\tau = .403; p = .058$). As EWB scores increased, so did hospitalization events. There was a significant negative relationship between EWB and patient-reported hospitalizations in the COPD-TM group ($r_{pb} = -.834; p = .005$), ($\tau = -.655; p = .023$). As EWB scores increased, patient-reported hospitalization events decreased. There was no significant relationship in the COPD-SC group.

There was no significant relationship between EWB and ER events in the COPD-TM group ($r_{pb} = .373; p = .182$), ($\tau = .146; p = .327$) although there was a trend toward a positive relationship. There was no significant relationship in the COPD-SC group. There was no significant relationship in either group between EWB and patient-reported emergency room events.

The null was rejected for COPD-TM patients who had a negative relationship with EWB and patient-reported hospitalization events (expected direction). The null could be rejected for the SC group with a significant positive relationship between EWB
and hospitalization events (unexpected direction) but the experimental hypothesis was not supported. Null hypotheses for the remainder of the tested relationships could not be rejected.

*Relationships Between EWB and Clinical Outcome Measures for HF*

There was no significant relationship between overall EWB and hospitalization in the HF-TM group but there was a significant negative relationship in the HF-SC group ($r_{pb} = -0.568; p = .055$), ($r = 0.178; p = .279$). There was no significant relationship between EWB and patient-reported hospitalization in either HF group.

There was no significant relationship between EWB and emergency room visits in the HF-TM group. There was a significant negative relationship in the HF-SC group ($r_{pb} = -0.644; p = .030$), ($r = -0.707; p = .010$). The trend continued with patient-reported emergency room events. There was no significant relationship in the HF-TM group. There was a significant negative relationship in the HF-SC group ($r_{pb} = -0.537; p = .055$), ($r = -0.358; p = .105$).

No significant relationship was found between EWB and the clinical outcomes of hospitalization and emergency room in the TM group and so the null was retained. Several significant relationships were found in the SC group and in the expected direction: as EWB increased, database-retrieved hospitalization decreased, as did both database and patient-reported emergency room events. The null was retained for patient-reported hospitalization in the HF-SC group, but rejected for the other clinical variables. The experimental hypothesis was not supported because HF-SC demonstrated stronger negative relationships among the tested variables as compared to HF-TM.
Summary of Relationships Between SE, EWB, and Clinical Outcome Measures

There were no significant relationships between measures of SE (SCI-C) and any of the clinical outcomes in patients with COPD. Measures of overall SE at 3 months did not seem to have any relationship with hospitalization or ER events. COPD-TM did display a negative (expected direction) relationship between patient-reported hospitalization and EWB (SF36 MCS). COPD-SC patients displayed a positive relationship (unexpected direction) between hospitalization and EWB (SF36 MCS).

There were no significant relationships between 3-month measures of SE or EWB and clinical outcomes in the HF-TM patients. Several significant relationships, and in the expected direction, were found in the HF-SC group. As SE scores increased, ER events decreased. As EWB scores increased, hospitalization, ER events, and patient-reported ER events also decreased.

In both COPD and HF patients, there seemed to be a greater relationship between EWB and clinical outcomes than between SE and clinical outcomes.

Summary

The Primary Research Question addressed differences between TM and SC groups on the dependent variables of SE, EWB, and clinical outcomes by 3 months. COPD-TM patients had greater changes in their SE for evaluating the effectiveness of what they did to manage symptoms (Q. 15) as compared to COPD-SC. The null hypothesis was rejected for the individual question 15, but retained for composite SE, the remainder of the individual questions, for EWB, and for clinical outcomes. HF-SC
patients had greater changes in overall EWB, subscale Mental Health, and had fewer patient-reported hospitalization events as compared to patients in HF-TM. The null was rejected for these measures, but the experimental hypotheses were retained because the greater changes occurred in HF-SC (control group). The null were retained for the remainder of the measures in the HF groups.

Secondary Research Question One addressed the relationships among dependent variables at 3 months. COPD-TM had significant positive relationships among the primary measures of SE and EWB as well as several of the submeasures. The magnitude of the relationships was greater than COPD-SC and so the null was rejected. COPD-TM and COPD-SC had significant positive relationships between EWB and hospitalization; TM with patient-reported events and SC with database-retrieved events. The null was rejected for both but the experimental hypotheses were not supported because the relationships were in an unexpected direction. Neither group demonstrated significant relationships between SE and ER events.

HF-SC had significant positive relationships among the primary measures of SE and EWB as well as several of the sub-measures. The magnitude of the relationship was greater than HF-TM. The null was rejected but the experimental hypotheses were not supported because the HF-SC (control) group displayed the strongest relationships among the tested variables. HF-SC displayed significant negative relationships between EWB and ER events, and SE and database-reported ER events. The magnitude of the relationships was greater than in the HF-TM group. The null was rejected for these measures but the experimental hypotheses were not supported because the HF-SC (control) group displayed the strongest relationships among the tested variables.
This chapter presented results from the analysis of the dependent variables of EWB and SE in order to examine the effect of TM on patients with COPD and patients with HF enrolled in a home health program after hospital discharge. The next chapter provides an overview of the most salient findings from this study and a comparison to previous research, identifies study limitations, discusses applicability of findings to patient self-care management programs, and makes recommendations for further research in this topic area.
CHAPTER V

DISCUSSION

This chapter is divided into four sections. The first summarizes results of the study. The second compares results from this study to results from published studies of a similar nature. The third contains conclusions and practical implications, followed by the study limitations. The final section presents recommendations for future studies in this topic area.

Sample Characteristics, Procedural Issues, and Treatment Results

Comparison of Sample Characteristics

This study was designed to study self efficacy (SE) and emotional well-being (EWB) among patients with COPD and HF who, after an episode requiring hospitalization, were receiving home health care, either using the standard care (SC) model of home health visits, or standard care plus telemonitoring (TM). The sample for this study consisted of 46 home health patients with 26 having a diagnosis of COPD and 20 having the diagnosis of HF. The average length of patient enrollment for the home health agency involved in this study was 45 days. Mean days for home health treatment for patients in this study was 42 days (11–111 days), which was comparable to the agency average.
Patients in the parent study were randomly assigned to the SC or TM group. Thus, a preliminary question asked whether the two COPD groups (COPD-TM and COPD-SC) and two HF groups (HF-TM and HF-SC) were equivalent at baseline on demographics and measures of self-efficacy and EWB. Baseline demographic variables were equivalent between both COPD groups and with HF groups with two important exceptions. First, patients in HF-TM were significantly older than patients in HF-SC. Second, patients in HF-SC showed a positive relationship between SE and EWB at baseline, whereas none of the other patient groups showed any relationship between the two variables.

In this study, the tool used to measure SE was Reigel’s (2000) Self-Care of Heart Failure Index Section C. The same four SCI-C questions were used to measure SE for both the COPD and HF patients. The findings of the study showed that levels of SE were similar within the experimental and control groups for the two diagnoses, and also between the diagnoses of COPD and HF. That is, no significant differences were found in SE for patients with COPD or HF at the beginning of this study. This result was similar to findings by R. Arnold, Ranchor, DeJongste, et al. (2005), who also compared SE between COPD and HF patients using a different SE scale with subscales control symptoms and maintain function. In their study investigating whether self-reported physical functioning was explained by illness-specific or generic factors, Arnold et al. found no difference when they compared SE measures between COPD ($n = 56$) and HF ($n = 65$) patients on specific SE measures of SE control symptoms and SE maintain. Although only one study was available for comparison, similar results between the studies indicate it may be feasible to compare SE between COPD and HF using a generic measure of the construct of self-efficacy for recognizing and managing symptoms of chronic disease.
A theoretically related but distinct variable of interest in this study was EWB. EWB was measured with the SF36, which is a tool that has been studied extensively. The SF36 Mental Component Score (MCS) has been strongly correlated to standardized depression screening tools and thus has some utility with identifying patients at risk for depression. An analysis of data on 30,801 adults from the 1999 National Health Interview Survey determined that the 12-months prevalence (age/sex adjusted) odds of major depression for HF was 7.9% and 15.4% for COPD, almost twice the rate of HF (Egede, 2007). In this study, 33% of patients with COPD and 12.5% with HF had scores that placed them into MCS level 7 or 8, which are scores indicating high risk for depression. The patients in this study, therefore, seem to reflect the prevalence for depressive symptoms in the larger U.S. population of individuals with COPD and HF, and the trend toward higher incidence of depressive symptoms in COPD compared to HF. Both diagnoses in this study had SF36 MCS means below that of the general U.S. population but comparable to published MCS norms for both CHF and chronic lung disease.

Although baseline analysis of EWB scores showed no difference between the experimental and control groups for the two diagnoses, or between the diagnoses of COPD and HF, the proportion of patients at risk for depression were comparable to the proportion found in the analysis of national data on HF and COPD.

Procedural Issues

This study was conducted as secondary analysis of data collected from a larger randomized clinical trial (referred to in this document as the “parent study”), which was conducted with patients with HF and patients with COPD recruited through a home
health agency in southwest Michigan. All patients received SC, which included visits by registered nurses. Visits varied from once weekly to as often as three times weekly, with frequency based upon patient need. As part of routine care, nursing staff evaluated the patient’s physical status and physiological measures such as pulse and blood pressure. Nurses also provided patients in both experimental and control conditions with education on the disease process and self-care management. Patients who received only SC were instructed to contact the home health agency with any concerns regarding health status in between scheduled nursing visits.

Patients in the experimental group received the same SC as those in the control group and analysis showed no significant differences in the frequency of nursing visits between TM and SC patients in each diagnostic group or between the diagnoses. In addition to SC, patients in the TM groups engaged in daily telemonitoring activities using the Health Buddy (HB) device. Thus, the TM group received two additional treatment components—patient control of physiological monitoring on a daily basis and immediate access to disease management education via technology. TM patients were responsible for measuring their own blood pressure, weight, and oxygen levels in the blood (pulse oximeter), which were then transmitted to a secure website via the telemonitoring device (TD). In addition, TM patients responded to HB curriculum questions about their understanding of their disease and symptoms, and appropriate actions to take in response to symptoms. Built into the HB program were reminders and reinforcers for appropriate disease management behaviors. Responses to questions were recorded via the telemonitoring device, and were transmitted to the secure website. Daily physiological data and question responses were available to nursing staff for review. If responses
exceeded pre-set parameters, an “alarm” was created to bring the attention of the reviewer to the situation.

The Health Buddy was chosen by the home health agency in this study for the fact that it included a disease-specific educational curriculum in addition to physiological monitoring. An issue that complicates the comparison of TM across studies is that the TD is not always identified by manufacturer name, although all provide a general description. Educational curriculum, if provided, may differ between devices. In fact, the HB curriculum may be modified to the specifications of the purchaser. Several studies identified in the literature review utilized the Health Buddy device (Barnason et al., 2003; LaFramboise et al., 2003), while others identified TM without an educational component (Cleland et al., 2005; Goldberg et al., 2003; Woodend et al., 2008) or devices with both components but not Health Buddy (Cordisco et al., 1999). An issue that further complicates comparison across studies is the difference in length of time that patients used the TD. In studies that controlled intervention, length of treatment varied from 6 weeks to 8 months.

In this study patients received TM during the time that they were under the care of the home health agency and the TD was removed upon patient discharge from home care. Only two other home health care studies were found using TM with COPD or HF (Finkelstein et al., 2006; Whitten & Mickus, 2007) with the duration of TM dependent upon the length of time the patient was enrolled in home health. Providing TM in a controlled manner does allow objective comparison of an intervention effect between groups. However, in actual clinical practice, a TD provided by and monitored by the home health agency would be removed at discharge. Thus, this study elucidates the
challenge involved with evaluating the effectiveness of an intervention provided within the current parameters of skilled home health services in the U.S.

Summary of Results

Data were analyzed to answer the primary question about whether TM, in addition to SC, would have an effect on perception of self-efficacy (confidence) for managing disease, overall emotional well-being, and clinical outcomes by patients with COPD or HF. Independent variables were diagnosis (COPD or HF) and treatment group (TM or SC). Dependent variables for this pilot study were measures of self-efficacy (SCI-C from the Self-Care of Heart Failure Index (SCHFI)) and emotional well-being (MCS from SF36 V.1). Data were also collected on mortality, emergency room use, and hospitalization. These data were analyzed to describe relationships among 3-month posttest scores and outcome variables.

By 3 months, patients in the COPD-TM group showed greater improvement in their perceptions of SE for evaluating the effectiveness of strategies to relieve symptoms than patients in the COPD-SC group. A significant positive relationship was also found between EWB and SE for the COPD-TM patients when compared to the COPD-SC patients at 3 months. There were no differences between the experimental and control groups for patients with COPD on EWB, mortality, emergency room use, or hospitalization.

Contrary to the experimental hypothesis that TM would be beneficial, results for the HF patients in the area of EWB went the other way. That is, patients in the HF-SC group showed greater improvement on EWB than those in the HF-TM group. They also
showed a significant positive relationship between EWB and SE, and a significant negative relationship between EWB and hospitalization, and EWB and emergency room use, when compared to the HF-TM patients. There were no differences between the experimental and control groups for patients with HF on SE, mortality, emergency room use, and hospitalization, with the exception of patient-reported hospitalizations. Patients who had received TM reported hospitalization more frequently than patients who received SC only.

Discussion of Results

Self-Efficacy

Reigel (2000) described self-care management as a cognitive decision-making process consisting of four stages: (a) recognizing that a change in symptoms is related to the illness, (b) evaluating the change, (c) implementing a selected treatment strategy, and (d) evaluating the effectiveness of the treatment strategy. This construct of self-management was utilized to develop the Self-Care of Heart Failure Index (SCHFI). Each of these four stages was queried specifically by one of the four questions in the SCI-C, which were designed collectively to assess self-efficacy in the four stages of self-care management (Riegel et al., 2000). A modified version of the tool was constructed for use with COPD for the parent study (Self-Care of Chronic Obstructive Pulmonary Disease Index [SCCOPDI]). The SCI-C (SE) for both COPD and HF tools is identical.
Discussion of COPD Results

In this study, the COPD-TM group made significantly greater changes in SE when compared to COPD-SC as measured by a single question (Q.15) on the SCI-C. This was the question that was aligned with the fourth stage, in that it asked patients how confident they were of their ability to evaluate the effectiveness of what they did to relieve their symptoms. Pre-post test comparisons showed that patients with COPD who received TM also made significant positive change from baseline on the composite SE score on the SCI-C. The fact that the extent of change was not significantly greater than change made by the COPD-SC group means that no treatment effect on overall SE can be attributed to adding TM to a SC protocol. Although construct validity has been established for the SCI-C for use with patients with HF (Riegel et al., 2004) analysis at the discrete question level has not been reported in the literature, and so analyses at the single question level should be interpreted with caution.

Despite a thorough review of the literature, previous research that examined the impact of TM on SE of patients with COPD was not found. However, several studies of patients with COPD have demonstrated a positive impact of other interventions (e.g., pulmonary rehabilitation) upon SE for this diagnostic group. All of these programs included an educational component (Davis et al., 2006; Lox & Freehill, 1999; Scherer et al., 1996; Wong et al., 2005). In the current study, transmission of physiological data through TM was accompanied by computer-supported education. The HB curriculum provided educational content on the COPD disease process and symptoms, and information for applying appropriate strategies to relieve symptoms. The HB also
provided experiential training and feedback for monitoring health status and symptoms. Results indicated that TM, in combination with SC, was more effective in improving patient’s SE for evaluating strategies used to relieve symptoms compared to SC alone. It may be that the educational component, in combination with the experience of obtaining physiological measures and self-monitoring symptoms on a daily basis, is helpful in improving perceived SE for specific disease management behaviors.

Discussion of HF Results

Analysis of pre-post test changes showed patients in neither the HF-TM nor HF-SC group to demonstrate significant improvement in SE from baseline to 3 months, nor were there significant differences in the extent of change when gain scores for the two groups were compared at 3 months for the composite score and for each of the four questions analyzed separately.

Previous researchers have examined the impact of TM on SE in HF patients and have found different results. Two studies found significant improvements in HF patients who received TM in addition to usual care (Barnason et al., 2003; LaFramboise et al., 2003). Those prior studies also used the Health Buddy TM system, which provided similar disease-specific educational curriculum along with physiological monitoring for patients with other forms of heart disease. In Barnason’s (2003) randomized study ($n = 35$), 18 postsurgical HF patients received daily TM for 6 weeks, with a curriculum designed for postcoronary bypass patients. Patients in the control group received the typical patient education and counseling provided before discharge from the hospital. In the LaFambroise (2003) randomized study ($n = 90$), 46 HF patients received daily TM for
8 weeks using a curriculum designed for patients with HF and based upon the literature and the Agency for Healthcare Policy and Research Guidelines. Patients who received phone contacts only showed decreased SE while those who received home visits, HB visits only, or both home visits plus HB significantly improved SE for self-care management. There were no differences between the groups where patients had improved SE measures (LaFramboise et al., 2003).

A number of explanations might account for the fact that, in the current study, neither patients in the HF-TM nor HF-SC made improvements in SE for self-care management of their disease. Differences in sample size and variation in length of intervention may help to explain the lack of change in the HF-TM patients enrolled in this study. However, it is difficult to determine the contributing factors to the lack of change in both the TM and the SC groups in SE for disease management.

Another possible reason for the different findings is that HF patients in this study were at a later stage of the disease process. Patients in this study were predominantly NYHA class III. Van der Wal, Jaarsma, Moser, et al. (2006) found that patients with a NYHA classification of III or IV experienced more barriers to effective symptom recognition and adherence. Patients with depressive symptoms also perceived barriers to medication and diet regimens. Van der Wal et al. also found that patients with a low level of knowledge perceived more barriers to medication and diet regimen as well as symptom recognition, results also reported in other studies. In this study, all but one patient enrolled in the HF groups (exception of missing data) was classified as NYHA class III. Fifty percent of HF patients scored < 50 on the baseline MCS, and 30% scored in the lower three levels, indicating significant risk for depression. Previous studies have
shown that depression has a negative impact on SE. Although knowledge level was not a
variable examined in this study, it is possible that knowledge barriers existed in the HF
patients which could have had a negative impact on SE for disease management, in
addition to the other factors identified by van der Wal et al. (2006).

*Emotional Well-Being*

EWB describes patient perception of satisfaction with quality of life, including
happiness and pleasant emotions, and the perceived ability to meet personal goals and
fulfill important life roles. In this study, EWB was measured with the SF 36 Mental
Component Summary Scale (MCS) (Ware, 2005). Patients responded to all questions of
the SF36, which includes eight subscales The SF36 MCS score reflects responses to all
eight subscales, but greater weight is given to scores on the subscales of Vitality, Social
Functioning, Role Emotional, and Mental Health in computing the MCS. Both the MCS
and the four subscales that were used in this study yield standardized scores with a mean
of 50 and a standard deviation of 10. Measures from the four subscales—Vitality, Social
Functioning, Role Emotional, and Mental Health—were analyzed in this study to obtain
additional information on patients’ EWB.

*Discussion of COPD Results*

Pre-post changes for patients in the COPD-TM group reflected improved EWB
(as measured with the SF36 MCS) by 3 months. The COPD-TM group made significant
changes from baseline on overall EWB (MCS) and on the subscales Social Functioning
and Role Emotional. Because EWB gain scores were not significantly greater for the
patients who received TM in addition to SC, no additional benefit was found when TM was added to SC. As a group, COPD patients improved EWB from baseline (Mean = 46) to 3 months (Mean = 51), a change equivalent to .5 of one standard deviation and suggesting that standard care alone was sufficient in improving EWB.

Previous research has found multidisciplinary self-management intervention to have a positive impact on QOL and emotional factors in COPD (Blackstock & Webster, 2007) but very little prior research is available on the impact of TM on these factors in patients with COPD. Whitten and Mickus (2007) studied a group of patients with COPD and HF. They compared usual home care to home care plus telemonitoring. Theirs was one of the few studies similar to this one in that TM was not provided in a standardized manner (i.e., not all patients received exactly the same number of sessions). Rather, TM equipment was removed from patients' homes after discharge from home health, which varied based on individual patient factors. A difference in that study was that intervention was provided once weekly, versus once daily, as in the current study. Neither the experimental nor control group demonstrated significant improvement in SF36 physical or mental composite scores over baseline (controlling for variables) in the Whitten and Mickus study. The researchers concluded that the addition of TM did not predict physical health and well-being.

In the current study, patients in the COPD-TM group did improve significantly on the composite MCS measure and on the Social Functioning and Role Emotional subscales for EWB. However, the difference in gain scores between the groups was not significant and so it must be concluded that TM did not improve EWB in patients with COPD. Thus, the results from this study are consistent with those from the Whitten and
Mickus (2007) study in indicating that for COPD patients, TM did not show an effect on EWB. The results of these two studies differ from other studies of TM that controlled for the length of intervention. Traditional home health care with the addition of TM, may not have the same impact on physical and emotional well-being as home care that provides TM consistently over longer periods of time.

Discussion of HF Results

Contrary to the hypothesis, the HF-SC group made significant changes in overall EWB and on all of the subscales. Furthermore, the extent of change, when compared to HF-TM, was significantly greater on overall EWB and on the subscale Mental Health. Although patients in HF-TM did not show significant improvement on overall EWB, they did improve on the subscales Vitality and Social Functioning. As a group, HF patients improved EWB from baseline (Mean = 45) to 3 months (Mean = 55), suggesting that standard care alone was advantageous for them. Patients in the HF-TM group did not make significant improvements in overall EWB; whereas patients in the HF-SC group did improve in the overall EWB and on all of the subscales and to a greater degree than HF-SC. The conclusion from this study is that TM did not contribute significantly toward improving EWB in patients with HF.

Unlike COPD in which few studies of TM have been published, numerous randomized studies have examined the impact of TM on QOL and emotional measures in patients with HF. A review of the relevant literature showed mixed results. Two studies found significant improvements (Bondmass et al., 1999; Woodend et al., 2008) associated with TM, whereas another found no difference (LaFramboise et al., 2003) between
groups although pre and post measures did improve within groups. The result from this study has more similarities to the latter study.

Clinical Outcomes

Utilization rates for hospital and emergency services were derived from data retrieved from medical records and from structured patient interview. Mortality was determined by review of hospital records and other valid sources, such as family report.

Discussion of COPD Results

There were no significant differences in the clinical outcomes of mortality, ER events, or hospitalization events between COPD-TM and COPD-SC. Other studies that have used a randomized design have reported the impact of TM on clinical outcomes of patients with COPD. Finkelstein et al. (2006) found no differences in mortality between groups by 6 months. De Toledo et al. (2006) found that by the end of 12 months, there was no significant difference in mortality, although a trend toward lower mortality was reported for the intervention group. De Toledo et al. also found a significant reduction in hospitalization, but not in emergency room services, in patients who had received TM.

When interpreting the results of the current study, it may be that the 3-month time was insufficient to detect any effects of TM on clinical outcomes. It is possible that an effect from TM may appear when data are analyzed at 6 and 12 months in the parent study.
Discussion of HF Results

The results of the current study revealed a significant difference in patient-reported hospitalization between experimental and control groups. In this case, patients who received TM reported more hospitalization more often compared to patients who received SC only. Differences in the other clinical measures were nonsignificant.

Other randomized HF studies that provided TM for at least 6 months and over multiple sites have found evidence that TM reduces mortality (Cleland et al., 2005; Goldberg et al., 2003) but not hospitalization (Goldberg et al., 2003). Other studies (Benatar et al., 2003; Bondmass et al., 1999; Cordisco et al., 1999; Jerant et al., 2003) have found that TM was associated with lower hospitalization and use of emergency room services. On the other hand, Woodend et al. (2008) found no difference in hospitalization between usual care and TM.

In general, clinical trials that have provided TM over an extended period of time (> 2 months) have found an association between TM and improved clinical outcomes. Thus, it appears that the length of intervention may be a crucial factor in determining the impact of TM over time. In this study, TM was not associated with lower patient-reported hospitalization events, database-retrieved hospitalization, ER events, or mortality. It is possible that an effect from TM may appear when data are analyzed at 6 and 12 months in the parent study.
Relationship Between EWB and SE

Discussion of COPD Results

In the current study, a significant positive relationship was found for the COPD-TM group between overall EWB and composite SE at 3 months that was not present at baseline. In addition, several significant relationships were found between EWB subscale measures and SE individual questions. There was an unexpected negative relationship between the subscale, Vitality, and SE Q. 15, which asked patients to evaluate the effectiveness of strategies to relieve symptoms. Social Functioning was positively related to both the SE question that asked patients to rate their ability to evaluate the importance of symptoms and the SE question that asked about their ability to recognize changes in health if they occur. Mental Health was positively related to the SE question that asked patients to rate their ability to recognize changes in health if they occur and the SE question that asked about their ability to relieve symptoms. Although there was no significant relationship between overall EWB and composite SE in the COPD-SC group, a significant negative relationship was found between Social Functioning and SE for evaluating the effectiveness of strategies to relieve symptoms.

Caution should be exercised when interpreting results of multiple statistical tests regarding relationships between subscales and single questions from the SCI. Due to the pilot nature of this investigation and the small sample size, the Bonferroni correction was not applied. Any time there are multiple comparisons on the same data set, the likelihood increases that spurious results may be found purely by chance. It is also the case that the SCI-C from the Self-Care of Heart Failure Index (SCHFI) has been subjected to less
rigorous research than the SF36, and it is not entirely clear that the four questions analyzed separately in the current study are really measuring different things.

These results are consistent with previous research that has found a relationship between SE and emotional factors in COPD. Specifically, R. Arnold et al. (2006) found that patients \( n = 39 \) with COPD improved in both SE for symptom management and QOL during rehabilitation and that the changes in SE contributed significantly to changes in social functioning and psychological function subscales of the SF36. Arnold et al. suggested that results indicated that perceptions of personal control and SE play an important role in the adjustment to COPD and that positive changes in SE and well being can occur during intervention, even with patients in advanced stages of the disease.

According to Bandura’s (1998) theory on SE, positive mood enhances SE, and social support strengthens SE. In the current study higher Mental Health was associated with higher SE on three of the four SE questions and higher Social Function was associated with higher SE on two of the questions. These findings lend support to Bandura’s theory. An unexpected result, however, was that Vitality was negatively associated with SE for evaluating the effectiveness of strategies used to relieve symptoms. It may be that despite limitations in Vitality, COPD patients are able to accommodate and still demonstrate improvements in SE for disease management.

Discussion of HF Results

A positive relationship was found between overall EWB and composite SE at baseline and at 3 months in patients who received SC only. In addition, a positive relationship at 3 months was found in SC between subscale Vitality and SE for evaluating
the importance of symptoms. There also were positive relationships between the subscale Mental Health and three SE questions for evaluating importance of symptoms, doing something to relieve symptoms, and evaluating effectiveness of strategies used. Results indicate that in the HF-SC patients a more positive mood state was associated with higher SE in symptom management. There were no significant relationships between measures of SE and EWB in the HF-TM group at baseline or by 3 months. The HF-SC patients showed a positive relationship between EWB and SE at baseline and again by 3 months.

Other studies have found an association between EWB and SE. Tsay and Chao (2002) studied the relationship of depression to SE in patients with HF (n = 100) and found a negative relationship between SE and depression, with functional status as a mediating factor. A positive relationship existed between SE and functional status, and a negative relationship between functional status and depression. They interpreted their results as suggesting that SE helps to maintain physical and emotional function in HF patients and that patients with higher SE have higher function, which decreases the likelihood of depressive symptoms. Joekes (2007) found that higher levels of SE in HF patients (n = 41) were associated with lower levels of psychological distress, better self-management, and better HRQOL. His research was consistent with previous research and supported the idea that patients with higher SE and well-being were “protected” from negative emotions after an exacerbation event.

In this study, TM was not associated with a positive relationship between EWB and SE for HF patients. Although a positive relationship was identified in the HF-SC group, it was present at baseline, indicating that SC treatment may not have been a factor. Although EWB in the HF-SC group significantly improved from baseline, this change
was not accompanied by a corresponding increase in SE, nor was a strengthening found for the association between the two variables.

**Relationship Between EWB and SE to Clinical Outcomes**

In the current study, there was a significant positive relationship between patient-reported hospitalizations and EWB in the COPD-TM group, which was unexpected. However, this was based upon only two events and should be interpreted with caution. There was a significant positive relationship between database-retrieved hospitalization and EWB in the COPD-SC group which was also unexpected. These results also were based upon only a few patients who required rehospitalization, and therefore should be interpreted with caution.

HF-SC demonstrated significant negative relationships between EWB and both database-retrieved ER events (three patients) and patient-reported hospitalizations (one event). They also had a significant negative relationship between SE and database-retrieved ER events (two events). No significant relationships were identified in the HF-TM group. Due to the low numbers, these results should be interpreted with caution.

Bandura (1998) asserted that personal efficacy influences health and that people’s belief in their ability to cope with stressors activate biological systems that can actually improve health. After SE is strengthened, people manage the same stressors without experiencing as much distress, and the negative physiological consequences such as suppression of the immune system (Bandura, 1998) may also be reduced. Patients in the COPD-TM group improved SE and EWB from baseline to 3 months and demonstrated a positive relationship between the two variables. It may be that hospitalization did not
negatively impact EWB due to adequate coping strategies present in those particular patients.

Research has demonstrated the interrelationship of depression and worsening HF symptoms (Joynt et al., 2004). Research also has demonstrated that in HF patients lower EWB (or higher rates of depression in some studies) has a negative impact on health, which could result in the need for urgent care or hospitalization (Bennett et al., 1997; Murberg, Bru, Svebak, Tverérás, & Aarsland, 1999). Patients in the HF-SC group in the current study had significantly improved EWB from baseline at 3 months, and also had demonstrated a positive relationship between SE and EWB. The relationship between EWB and clinical outcomes was in the expected direction for these patients and may have been associated with the fewer patient reports hospitalization compared to patients in HF-TM group.

Conclusions

Differences were found on several measures between COPD-TM and COPD-SC in favor of the TM patients, which supported the hypothesis that TM may improve SE, as well as strengthening the relationship between SE and EWB in COPD patients. Significant differences occurred on several measures between HF-TM and HF-SC but the differences were in favor of the SC group. No evidence was found that TM made a difference in 3-month clinical outcomes of mortality, emergency room use, or hospitalization for COPD or for HF patients.

A significant improvement was found in both EWB in COPD-TM and HF-SC. TM was associated with improved SE and a positive association between SE and EWB in
the COPD patients but not with the HF patients. This may indicate differences in the way in which patients with different medical conditions respond to TM in the home health setting, although the small sample size and failure of randomization to yield equivalent groups within and between the diagnoses at baseline reduces the confidence that these differences represent a true difference between the diagnostic groups.

Practical Application

Implications for practice are limited due to the fact that this was a pilot study with a relatively small sample size. At the very least, descriptive information and the trends in the data can be compared to findings from previous research. In this study, patients with either COPD or HF had lower EWB compared to the general population. Many were at risk for depression, which is underdiagnosed, undertreated, and yet has been found to have a significant impact on SE, adherence to self-care management, and to clinical outcomes (De Jong et al., 2005; T. Rutledge et al., 2006; Yohannes, Roomi, Baldwin, & Connolly, 1998). Although EWB had improved by 3 months, none of the patients with HF and the patients in the COPD-SC group improved in their perception of SE for self-care management. This was the case even though all had received education from home health nurses, and many had additional education from rehabilitation professionals. Patients in the COPD-TM group did seem to benefit from the addition of daily telemonitoring and reporting of health status and symptoms, as well as participating in additional education content provided in a novel manner through the TM system. Information gained in this study suggests that it would be valuable to include EWB and SE measures as part of the ongoing assessment process so that members of the
multidisciplinary team (nurse, social worker, rehabilitation professionals) are able to provide targeted intervention that improves emotional health and empowers patients to improve self-care management. It may also be helpful to assess learning needs of patients and belief in their ability to make positive changes in their health status, taking into consideration factors such as education level and emotional status, so as to provide self-management intervention tailored to the needs of the individual. TM and other information technology may be a useful adjunct to SC if the content and methods are designed in such a way as to enhance SE for self-management, which in turn may improve adherence and clinical outcomes.

Study Limitations

This was a pilot study and the sample size was small, so results should be interpreted with caution. Due to problems in the parent study randomization did not produce numerically equivalent groups. By 3 months, 5 patients had died and 3 had withdrawn or were lost to follow-up. This substudy also analyzed just a small portion of the total data from the parent study. It was intended that results from this analysis could be used to guide the direction of the analysis for the parent study. The larger dataset for the longitudinal study will utilize rigorous analysis methods with alpha <.05. The small sample size significantly reduced the power of this pilot, which made it difficult to establish significant differences in the studied variables. Analyses were completed as one-tailed based upon directional hypotheses specific to the 3-month time point. Alpha was set at $p < .10$ so as to identify pertinent trends. Another limitation was that corrections
were not made for multiple statistical tests on the same data set. Although this was done so that trends were not obscured; it increased the risk for Type I error.

Several other limitations also should be noted. The TM intervention was not uniform in length, and so the content dosage (experiential training and education) was not distributed evenly across patients who received the intervention. This was because the treatment length was controlled by home health agency procedures rather than by the investigators. Many of the patients were not enrolled long enough to complete the educational curriculum provided in the HB TM system. Another weakness is that the tool selected for measuring SE, from which the SCI-C was extracted, had been tested previously for use with patients with HF, but not with COPD patients, as included in this study. Although SE questions were not changed from the original version, there is the chance that there may be unanticipated differences when using the questions with patients with COPD. Finally, clinical outcome information was gathered from hospital database and patient report. There is a chance that patient information was not accurate or that the hospital database might not have included events that occurred in another health care system. Mortality information was not available for patients who were lost to follow-up.

Recommendations for Future Studies

It is apparent that there is a need for methods to improve self-management skills in patients with chronic disease such as COPD and HF. Evaluation research is needed to follow patients longitudinally to study the impact of multidisciplinary self-management programs and to also evaluate the cost-benefit of adjunctive intervention and follow-up activities. The development of assessment tools that formally evaluate self-management
would provide objective measures of program outcomes. Previous research shows SE is a valuable construct to measure and many disease-specific tools have been developed. A standardized generic SE tool for patients with chronic disease would also be valuable to compare the impact of self-management programs across diseases, programs, and disciplines. Such a tool was not found in the review of the literature.

Information technology, such as the TM device used in this study, may be a valuable adjunct to standard self-management programs provided through the multidisciplinary health care team. Other studies have shown equivalent benefit between telephone follow-up and the more costly TM devices. This study was not designed to provide qualitative data about the nature of differences. In the case of the patients with COPD, it may be that it is the follow-up process, beyond the traditional face-to-face limited interaction reimbursed through the current healthcare system that is of value. Methods for achieving these aims may vary depending upon patient access to technology, user preferences, and third-party reimbursement available to fund those services.

Larger randomized trials are indicated with adequate power to detect differences between groups and identification of meaningful predictors that will allow health care providers to tailor programs to the needs of patients identified to be at low, medium, and high risk for “failure” with self-care management. A mixed methods approach would capture both quantitative and qualitative information and allow researchers to answer specific questions related to user issues such as preference for different types of technology, and impact on learning self-care for disease management. Qualitative information may help explain trends identified in this and other studies, for example, increase in hospitalization in HF patients who receive TM.
It is also suggested that research focus on an array of methods to deliver enhanced self-management care via information technology. Studies that compare low cost methods such as regular phone contact, email, video visits on home computer systems, are examples of lower cost services that would require minimal adjustment to the patient's home situation. Ultimately, reimbursement for enhanced services needs to be addressed to cover the cost of the time for the health care professionals as they engage in non face-to-face follow-up activities.

Low-cost information technology (IT), such as the telephone, is fairly ubiquitous in the U.S. More sophisticated information technology, such as cell phones and computers with Internet access, has become more commonplace. Patients are more receptive, skilled, and expectant of enhancing health care management through the use of IT. The cost of health care, the shortage of health care professionals, and the growing aging population should be an impetus toward aggressively examining alternative methods for health care delivery and evaluating the cost-benefit of programs that empower individuals with chronic disease to effectively manage their health.
REFERENCES


stay, and higher hospitalization costs in older adults with heart failure. *Journal of the American Geriatrics Society*, 55(10), 1585-1591.


Appendix A

Human Subjects Institutional Review Board Approval
From Western Michigan University
Date: November 2, 2006

To: Nickola Nelson, Principal Investigator
    Jaclyn West-Frasier, Student Investigator for dissertation

From: Amy Nangle, Ph.D., Chair

Re: HSIRB Project Number: 06-10-30

This letter will serve as confirmation that your research project entitled “Relationships Among Self-efficacy, Emotional Well-being, Clinical Outcomes, Telemonitoring and Diagnosis in Patients with Heart Failure or Chronic Obstructive Pulmonary Disease” has been approved under the exempt category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may only conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition, if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: November 2, 2007
Appendix B

Institutional Review Board Approval
From Borgess Health
December 20, 2006

Jaclyn West-Frasier
Department of Occupational Therapy
Western Michigan University
1249 Earl Wilbur Building
Kalamazoo, MI 49008

Protocol: Relationships Among Self-efficacy, Emotional Well-being, Clinical Outcomes, Telemonitoring and Diagnosis in Patients with Heart Failure or Chronic Obstructive Pulmonary Disease

Dear Ms. West-Frasier,

As the Chairman of the Institutional Review Board (IRB) of Borgess Medical Center, I have received and reviewed the above-named protocol. According to Borgess Medical Center IRB Guidelines, Section 6.21, this protocol meets the qualifications for Expedited Review. The protocol meets our standards of research and I have approved the study for use in this institution.

As you conduct your research, you are responsible for complying with all policies and procedures of the FDA, OHRP, HIPAA, Borgess Medical Center, and the Borgess Institutional Review Board.

The approval is granted with the understanding that any changes in the protocol are promptly reported to the Committee; that changes in the approved protocol cannot be initiated without Committee review and approval unless there are immediate hazards to human subjects; and that all unanticipated or serious problems involving risks to human subjects are also promptly reported to the Committee.

Approval for this protocol is granted for a period of one year and will expire on December 14, 2006. The FDA and this Committee, require you submit in writing a Continuation Review Application by Friday, November 2, 2007. The protocol cannot continue after December 14, 2007 until re-approved by the Borgess IRB even if closed to patient enrollment. You must complete a Close Out Report if your protocol has been completed, terminated or if you are not renewing the protocol. We will determine if the research was carried out as planned, and that patient benefit outweighed the risk.

If you have any questions in this regard, please feel free to contact me.

Sincerely,

Richard Lammers, MD
Chair
Institutional Review Board
Appendix C

SF36 Version One Subscale Questions for Mental Health Summary Score
SF36 Version I
Question Items for Subscale Scoring

Note: Questions are not in the order of appearance in the SF36 Health Survey
(4-week recall)

Vitality
How much of the time during the past four weeks did you feel full of pep?
How much of the time during the past four weeks did you have a lot of energy?
How much of the time during the past four weeks did you feel worn out?
How much of the time during the past four weeks did you feel tired?

Responses to above
• All of the time
• Most of the time
• A good bit of the time
• Some of the time
• A little of the time
• None of the time

Social Functioning
During the past four weeks, to what extent has your physical health or emotional health problems interfered with your normal social activities with family, friends, neighbors or groups? Has it interfered....
Response to above:
• Not at all
• Slightly
• Moderately
• Quite a bit
• Or Extremely?
During the past four weeks, how much of the time has your physical health or emotional problems interfered with your social activities like visiting with friends or relatives? Has it interfered…

Response to above:

- All of the time
- Most of the time
- Some of the time
- A little of the time
- Or None of the time?

**Role Emotional**

During the past four weeks, have you had to cut down the amount of time you spent on work or regular daily activities as a result of any emotional problems, such as feeling depressed or anxious?

During the past four weeks, have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious?

During the past four weeks, did you do work or other regular daily activities less carefully than usual as a result of any emotional problems, such as feeling depressed or anxious?

Responses: Yes or No

**Mental Health**

How much of the time during the past four weeks have you been very nervous?

How much of the time during the past four weeks have you felt so down in the dumps that nothing could cheer you up?

How much of the time during the past four weeks have you felt calm or peaceful?

How much of the time during the past four weeks have you felt downhearted and blue?

How much of the time during the past four weeks have you been happy?
Responses:

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time