A QUANTITATIVE, RETROSPECTIVE, QUASI-EXPERIMENTAL STUDY

COMPARING IN-HOME MONITORING INTENSITY OF CONGESTIVE HEART

FAILURE

by

Vera Cigan

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of the Requirements for the Degree

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Approved:

James O. Connelly, Ed.D., Committee Chair

Rita Hartman, Ph.D., Committee Member

Barbara Shambaugh, Ph.D., Committee Member

Accepted and Signed: _____ 5/12/2011

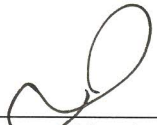James O. Connelly   Date

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Rita Hartman   Date

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Barbara Shambaugh   Date

_____ 5/26/2011

Jeremy Moreland, Ph.D.   Date
Dean, School of Advanced Studies
University of Phoenix

ABSTRACT

The retrospective approach was used to examine in-home monitoring records of CHF Telecare patients in a southeastern MI health care system. A total of 134 electronic medical records were examined over 0-30 days, 31-60 days and 61-90 days time frame. The independent variable is the level of intensity of in-home monitoring. The intervention group ($n = 92$) consisted of scripted, daily, in-home monitoring. The control group ($n = 42$) consisted of less than daily, audio-visual in-home monitoring. The dependent variables consisted of emergency department episodes, rehospitalizations and total hospital days lengths of stay. The study was approved by the Hospital Internal Board of Review and the University Of Phoenix Institutional Review Board. Data were collected from the electronic medical records and input into SPSS statistical software analysis. Non-parametric Mann Whitney tests were performed. No statistical significance was found between the scripted, daily monitored group and the less than daily audio-visual monitored group. The results suggest that there is no difference in health outcomes between daily, scripted in-home monitoring and less than daily, audio-visual in-home monitoring for CHF patients.

DEDICATION

To my mother, Edna Lovoll RN, for whose inspiration and support of becoming a registered nurse this journey would never have been possible. For my father, Dr. Kaare Lovoll MD, who has supported me in my journey throughout my life.

I thank my family, my children Kaare and Terashawn for their constant support and understanding. I also thank my son-in law, Carl Kinzel, for his encouragement and spirited conversations. My heart goes to my husband, Randy, for your constant encouragement, love and support on this doctoral journey. Like you said "when do we graduate with our doctorate"?

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1: INTRODUCTION

The National Center for Chronic Disease and Prevention (NCCDPHP; 2006) described

congestive heart failure (CHF) as the most serious and common cause of hospitalization for

individuals age 65 and over. An estimated 5 million people suffer from CHF, with an estimated

700,000 new diagnoses each year (American Heart Association [AHA], 2008). CHF is the

principal cause of death for approximately 42,000 people in the United States each year, and this

number increases to 250,000 persons annually as a factor contributing to death (AHA). Frequent

emergency department episodes, rehospitalizations, increased lengths of hospital stay, and

increased health care costs signal the need to address this problem.

Although controversial, one possible key to improving health outcomes might be the use

of an intensive, daily, in-home Telecare technology to remotely monitor CHF patients (Dang,

Dimmick, & Kelkar, 2009). The purpose of this quantitative, retrospective, quasi-experimental

study was to determine through statistical comparison whether any significant differences in

health outcomes occurred as the result of the intensity of in-home monitoring for CHF patients.

This study is not about CHF; rather, this study is a comparison of two different in-home

monitoring intensities used to monitor the medical condition of CHF. The topic CHF was chosen

because patients with CHF commonly experience episodic exacerbations requiring frequent and

costly rehospitalizations. Chapter 1 introduces the problem of CHF, the purpose statement, the

significance, the nature of the study, the research questions, the hypotheses, and the theoretical

framework. Also included are definitions, assumptions, and limitations of the research study.

Background of the Problem

CHF is defined as a pumping failure of the heart resulting in a failure of circulated blood

volume (Grossman & Brown, 2006). Episodic exacerbation of severe CHF presents with

symptoms such as difficulty of breathing, shortness of breath, or systemic edema (Grossman &

Brown). Hypertension (HTN) has been cited as the primary cause and antecedent of CHF, due to

the increased workload this condition places on the heart muscle (Haider, Larson, Franklin, &

Levy, 2003). The National Heart, Lung, and Blood Institute (NHLBI, 2010) estimated that 70%

of heart failure patients are diagnosed with HTN. The end result of CHF is pulmonary edema, in

which fluid seeps out of the cells and into the lungs.

CHF affects the patient's ability to perform functional activities of daily living, therefore

resulting in great economic and social costs in terms of hospital admission, mortality, and quality

of life (Candelieri, Conforti, Sciacqua, & Perticone, 2009). How to better monitor these patients

is critical to developing health policy and new research. More intensive monitoring may help

clinicians to evaluate patients' changing conditions, therefore enabling earlier detection,

intervention, and treatment before the patient requires emergency care (Candelieri et al., 2009).

In an effort to provide a standard for earlier detection and treatment, the CHF patient's condition

is classified into functional levels.

Classification of CHF

The New York Heart Association (NYHA), classified congestive heart failure into four

functional levels according to patient presentations (Dumitru, 2011). Class I indicates patients

who are asymptomatic with no physical limitations. These patients do not experience any fatigue

or difficulty breathing with normal activity. Class II indicates patients who are symptomatic with

fatigue or dyspnea. These patients may feel fine at rest, but may experience some fatigue or

difficulty breathing with increased activity. Class III indicates patients who are symptomatic, and

performing activities required of daily living with great effort and difficulty. These patients

experience fatigue and difficulty breathing with any activity. Class IV indicates patients who are symptomatic at rest without any activity.

On the other hand, heart failure may be present before patients experience fatigue and or difficulty breathing (Dumitru, 2011). The American College of Cardiology stages heart failure according to the following stages: (A) No diagnosis, but high risk due to comorbidities such as high blood pressure, diabetes, obesity or coronary artery disease, (B) Heart injury other than heart failure and asymptomatic, (C) Heart damage and symptomatic and (D) Severe heart failure requiring medical treatment (Heart Failure Matters). The loss of functional ability and increasing cost in terms of quality of life and increasing health care costs makes this problem of critical importance.

Hospitalization and CHF

CHF is the most frequently described hospital admission diagnosis, and is a common cause of re-hospitalizations affecting more than 5,000,000 people in America each year (AHA, 2008). The AHA (2008) cited CHF as the primary cause of morbidity, with associated costs for treatment exceeding $33 billion in 2008. Additionally, CHF may cost the health care industry as much as $37 billion dollars, as estimated for the year 2009 (Centers for Medicare & Medicaid Services, 2005).

Experts have agreed that current trends in cardiovascular illness have indicated increasing numbers of re-hospitalizations and health care costs due to the progressive nature of heart failure (Centers for Disease Control and Prevention [CDCP], 2006; NHLBI, 2010; Thom et al., 2006). More than one million patients were hospitalized with CHF in 2007 (AHA, 2008). More than 1,100,000 hospital discharges were reported with CHF in 2006 (AHA, 2009). The incidence of CHF is 10 out of 1,000 people who are older than 65 years of age (Thom et al.).

Despite current best medical practices and treatment, mortality, morbidity, and costs will likely increase with an increasingly aging population (CDCP, 2006).

Historically, healthcare reform touted disease management as an approach to provide cost control measures, thereby improving organizational effectiveness (Krouse, 2005). Typically, managed care developed measures attempting to control and manage costs while also improving quality of care. Disease management programs attempted to decrease exacerbations of heart failure to reduce the frequency of costly re-hospitalizations and the associated healthcare costs (Krouse).

There has been general agreement regarding the benefits of disease management programs (Krouse, 2005; The Institute of Medicine Report, 2001). Few studies, however, have linked economic effectiveness with chronic disease management programs (Krouse). The difficulty has been in linking the economic effectiveness of disease management to statistical significance (Fetterolf, 2006). Disease management programs vary regarding interventions, which may account for variances in program effectiveness with managing CHF (Wagner, 2004). Criterion intervention, which is of specific interest, is the intensity or frequency of patient contact (Wagner). Although people find traditional face-to-face episodes, for which the evidence portrayed in a more positive viewpoint, both positive and negative, studies are of importance for determining effective disease management (Wagner). Telecare monitoring using daily, scripted, intensive in-home monitoring may provide added value in improving health outcomes in coordination with a CHF disease management program. Researchers at the Indiana University School of Medicine examined the impact of disease management on CHF and found positive outcomes, but admitted that their study was lacking in statistical significance (Indiana University, 2008).

Current trends in CHF outcomes have experts agreeing that the increasing numbers of re-hospitalizations and resulting health care are costly due to the progressive nature of this chronic illness (CDCP, 2006; NHLBI, 2010; Thom et al., 2006). Heart failure, specifically CHF, has been approaching epidemic proportions, resulting in more than 1 million discharged heart failure patients in 2006 (AHA, 2009). Despite current best medical practices and treatment, mortality, morbidity, and costs will likely increase with an increasingly aging population (National Center for Chronic Disease Prevention, 2006). Knowing how to better monitor the CHF patient is of critical social and theoretical concern in an effort to reduce the rising health care costs and to improve the quality of everyday living.

Statement of the Problem

The general problem is that despite current monitoring practices, people with CHF experience acute, episodic, and exacerbation of illness, which results in the need for emergency intervention requiring emergency department episodes, re-hospitalization episodes, and extended lengths of hospital stay (AHA, 2008). The specific problem is that the evidence does not show which level of intensity of in-home monitoring would reduce the frequency of re-hospitalization episodes, emergency department episodes, and hospital inpatient days (Artinian, 2007). Although research (Artinian, 2007; Del Sindaco et al., 2007) has shown the benefits of in-home monitoring, there has been a dearth of research to establish what method of in-home monitoring is needed to improve health outcomes for patients living with CHF. Appropriate in-home monitoring technology may help to improve the outcomes of patients with heart failure. A quantitative, retrospective, quasi-experimental approach was used to compare two levels of monitoring intensity: (a) daily, scripted, protocol (group A), and (b) less often audio-visual protocol (group B) that may help establish the optimum level of in-home monitoring.

Purpose of the Study

The purpose of this quantitative, retrospective, quasi-experimental study was to determine through statistical comparison whether any significant differences in health outcomes exist as the result of two different intensities of in-home monitoring for patients with the medical condition of CHF. The quasi-experimental design was used designating the daily, scripted monitored group as the intervention group, and the less than daily monitored group as the control group (Cooper & Schindler, 2006). The retrospective method was preferred because the cause and effect observed between groups has already occurred (Salkind, 2003).

Health outcomes are reported by hospitals in terms of total emergency department episodes, rehospitalization episodes, and total inpatient days. Data was collected by accessing electronic medical records of a demographically similar population of CHF patients that had participated in the Home Care Telecare CHF program. Statistical analysis using hypothesis testing was used to compare variables to determine if there were any differences between the daily, scripted monitored group, and the less often, audio-visual monitored group. The quantitative method is appropriate to measure observable data regarding variables (Creswell, 2005). The retrospective design is also appropriate because the research involved examining medical records of CHF patients who participated in the Home Care Telecare CHF monitoring program.

The independent variable or treatment is monitoring intensity. The three dependent variables are rehospitalization episodes, total inpatient days, and total emergency department episodes. The experimental group (group A) consisted of the medical records of CHF patients who received intensive, daily, scripted monitoring protocol using an in-home monitoring appliance. The comparison group (group B) consisted of records from CHF patients who

received less often, audio-visual, in-home monitoring. The quantitative, retrospective, quasi-experimental design was used to examine the independent variables and dependent variables to compare CHF health outcomes over a 0-30, 31-60, and 61-90-day time period.

Significance of the Study

This research study potentially adds new insight regarding the benefit of daily, intensive in-home monitoring using a scripted in-home monitoring protocol appliance. Despite best monitoring practices, CHF re-hospitalizations have been increasing (Neubauer, 2007). The increasing CHF population may be partially due to improved mortality, using optimal surgical interventions such as cardiac stenting, and improved combinations of diuretic and vasodilator medication to prevent further myocardial injury (Neubauer). Any insight regarding decreasing rehospitalization episodes, emergency department episodes, or hospital inpatient days may add to the knowledge base of CHF research.

Significance to Leadership

Should a scripted monitoring protocol reduce rehospitalization episodes, total inpatient days, or total emergency department episodes, this study could be significant to people living with CHF and healthcare leaders. In 2009, President Barack Obama proposed health care policy reform targeting reducing rehospitalization episodes (Connolly, 2009). New policy would introduce payment incentives to hospitals in an effort to lower rehospitalization episodes. CHF has been the most frequent diagnosis submitted for Medicare reimbursement (AHA, 2008. Current literature describes CHF management as a combined effort of clinical management, supportive emergent care, and inpatient health care (Neubauer, 2007). The literature does not describe what level of in-home monitoring intensity would reduce emergency department episodes, rehospitalization episodes, or inpatient days. Should more intensive methods of patient

monitoring reduce total emergency department episodes, rehospitalization episodes, and total inpatient days, health care leadership would likely realize the importance of implementing such systems. Consequently, the findings of this study could have a measurable impact for leadership, including administration, nurses and policymakers, on improving health outcomes.

<div align="center">Nature of the Study</div>

Research Method

The research study used a quantitative, retrospective, quasi-experimental methodology to examine retrospectively the effect of intensive, daily, scripted in-home monitoring on CHF health outcomes. Four different quantitative research methods commonly used in healthcare are (a) descriptive, (b) correlational, (c) quasi-experimental, and (d) experimental methodologies (Burns & Grove, 2009). Descriptive or correlational methodologies are used in healthcare to describe or examine the relationship between variables (Burns & Grove). According to Cooper and Schindler (2006), "the purpose of a descriptive study is to answer the question of who, what, where, when or how much" (p. 141). A causal study or correlational studies are used to examine the relationship between variables (Cooper & Schindler).

A quasi-experimental design was used because the purpose is to examine the effect between specific dependent and independent variables (Cooper & Schindler, 2006). The retrospective method is preferred because the effect observed between groups has already occurred (Salkind, 2003). In this case, group assignment has already taken place as described by the monitoring method. The quantitative, retrospective, quasi-experimental method is appropriate because the intent is to examine the effect of monitoring intensity using an intervention group and a control group. A retrospective review of the electronic medical records was conducted to collect data from both groups. These data were both measurable and observable. The data

consisted of the frequency of rehospitalization episodes, total inpatient days, and total emergency department episodes for patients who receive in-home monitoring consisting of the daily, scripted, protocol, or less often audio-visual protocol.

Research Design

Cooper and Schindler (2006) referred to the research design as a necessary framework for finding answers to research questions. The design serves as an integral component in the collection, measurement, and examining of research results (Cooper & Schindler). Quasi-experimental designs are commonly used in healthcare to examine the relationship between specific variables (Burns & Grove, 2009). A retrospective, quasi-experimental design was used to examine the data from CHF medical electronic records. The audited electronic records represent 134 CHF patients from Healthcare System in southeastern Michigan. The sample consisted of health outcomes scores from 134 patients diagnosed with CHF: 92 charts from patients having previously received the daily scripted in-home monitoring protocol were compared to 42 patients having previously received the less often, audio-visual in-home monitoring. The groups were selected from a database of CHF patients. Selected records consisted of CHF patients having previous in-home monitoring as provided by Oakwood Home Care Services in southeastern Michigan. Home Care provided all monitoring services. Both groups consisted of previous in-home monitoring service records. The difference between the two groups was in the level of monitoring intensity. Analyses compared CHF health outcomes in terms of rehospitalization episodes, total inpatient days, and total emergency department episodes over a 0-30, 31-60, and 61-90-day time period.

How the Research Design Will Accomplish the Goals

The quantitative design is preferred over qualitative because the purpose is to measure variables and to examine the relationship. In a qualitative design, the purpose is to explore or understand a phenomenon (Cooper & Schindler, 2006). The quantitative, retrospective, quasi-experimental design is the most appropriate design to meet the research objectives. In this research, the intent was to examine the relationship between the intervention-intensive, daily, scripted, in-home monitoring protocol on rehospitalization episodes, total inpatient days, and total emergency department episodes for CHF patients. The first objective of an experiment is to obtain statistical evidence that one variable is linked to another (Cooper & Schindler). The advantage is the ability to control the independent variable and being able to control the measurement of variables over time (Cooper & Schindler). In descriptive or correlational studies, an intervention or treatment is not used; therefore this type of design would not be appropriate for this study (Burns & Grove, 2009).

The true experimental design would have been an ideal design. Cooper and Schindler (2006) described the experimental design as the most powerful evidence as proof of hypothesis causation. A true experimental design was not possible due to lack of funding and resources. Statistical analysis was used to allow for hypotheses testing. In this case, the two groups have not been randomly assigned because the independent variable has already taken place (Salkind, 2003). Although the treatment intervention has already taken place, the method for measuring the variables can be controlled to produce quantifiable data for both levels of monitoring intensity. Statistical analyses were performed on these data regarding the existence of any possible link between intensity of in-home monitoring and CHF outcomes.

Research Questions

CHF is characterized by illness exacerbations resulting in frequent emergency room episodes or hospital readmissions. The question is whether these exacerbations can be reduced through more intensive monitoring. A quantitative approach was used to retrospectively examine, measure, and compare the resulting CHF outcomes in terms of rehospitalization episodes, total emergency department episodes, and total inpatient days. Statistical analysis through Windows-based SPSS statistical software was used to compare the effect of intensive, daily, scripted in-home monitoring protocol, and the less often audio-visual in-home monitoring protocol on health outcomes. The following question was asked in this research study: To what extent does intensive, daily, scripted monitoring protocol influence congestive heart failure patients' total emergency department episodes, rehospitalization episodes, and total inpatient days?

Hypotheses

Scripted, daily, monitoring protocol (group A) will be compared to less often audio-visual monitoring protocol (group B) by reviewing previous in-home monitoring records. Three directional hypotheses were tested. According to Weiers (2005), the directional hypotheses assert results in either direction, and the null hypothesis is presumed true unless supportive evidence is observed. The data was used to address the research questions through testing of the following three directional hypotheses:

$H1_0$: There is no statistically significant difference between the two monitoring protocols for total emergency department episodes during, 0-30, 31-60, and 61-90-day time periods for patients with congestive heart failure.

H1$_A$: There is a statistically significant difference between the two monitoring protocols for total emergency department episodes during, 0-30, 31-60, and 61-90-day time periods for patients with congestive heart failure.

H2$_0$: There is no statistically significant difference between the two monitoring protocols for rehospitalization episodes during, 0-30, 31-60, and 61-90-day time periods for patients with congestive heart failure.

H2$_A$: There is a statistically significant difference between the two monitoring protocols for rehospitalization episodes during, 0-30, 31-60, and 61-90-day time periods for patients with congestive heart failure.

H3$_0$: There is no statistically significant difference between the two monitoring protocols for total inpatient days during, 0-30, 31-60, and 61-90-day time periods for patients with congestive heart failure.

H3$_A$: There is a statistically significant difference between the two monitoring protocols for total inpatient days during, 0-30, 31-60, and 61-90-day time periods for patients with congestive heart failure.

Theoretical Framework

Telehealth services typically target access to services, cost, and quality of care. However, this study focuses on the intensity of monitoring provided using scripted versus audio-visual telehealth technology. The theoretical structure of this study is based on a combination of social, technical, and *structuration* (Hoffman, Norman & Wagners, 2009) framework and subcomponents of chronic illness and disease management models. These concepts form the framework upon which the research questions and the purpose of the research study are founded.