EXAMINATION OF FACTORS THAT IMPACT MEDICATION ADHERENCE AMONG HEART FAILURE PATIENTS IN SOUTHERN RURAL COUNTIES

A DISSERTATION

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

IN THE GRADUATE SCHOOL OF THE

TEXAS WOMAN'S UNIVERSITY

DEPARTMENT OF HEALTH STUDIES

COLLEGE OF HEALTH SCIENCES

BY

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DENTON, TEXAS

MAY 2014

DEDICATION

For my loving husband, Raymond Washington Jr., and my children, Antwanette Britton, Sterlon Washington, and Delvin Washington. Raymond Jr. you have inspired me in ways that I could never imagine, for that and much more, I thank you with my whole heart. Antwanette Britton, we have been on this journey for many years. Momma appreciates your patience and love throughout this time.

Sterlon Washington, I thank you for your never-ending search of understanding the concepts of life, it kept the innovation going strong during this time. Last but not least Delvin Washington, I thank you for your unconditional inspiration during this time.

To Ellenda Marie Kyles, my loving friend that fight the challenges of heart failure on a daily basis, you are my hero.

In addition to my immediate family, this dedication is for the three angels that motivated me from heaven above. My loving grandmother, Essie B. Talton, who died from congestive heart failure April 29, 2006 and my wonderful mother-in-law, Dorothy G. Washington, who died from heart failure April 9, 2005 and my loving friend/brother Mark A. Johnson who died from cardiovascular disease leading to a massive heart attack August 22, 2013.

ACKNOWLEDGMENTS

First and foremost, I would like to thank my Lord and Savior, Jesus Christ. My spiritual foundation has leveraged me to this point in my life. To my husband and children, you have been extremely supportive. Words cannot express how thankful I am to have you in my life. To the best parents imaginable, Kenneth Gipson and Ruthie Hall: I cannot thank you enough for the sacrifices you have made for me. I would not have made my accomplishments in life without your unwavering support. To Virginia Keener, Leon Talton, Louetta Talton, Angelia Washington, and Fredrecio Washington: your spiritual advice, late night calls, drive by lunches, and family support will never be forgotten. To my remaining family and friends, each of you at some point extended words of support, comfort, and motivation; I am eternally grateful for sharing this journey with you by my side.

Mr. Dennis Patrick Evans, I would not be the woman I am today without your educational and spiritual guidance. You have supported me for over twelve years to reach my educational goals. Words cannot express the “respect” I have for you and your family. To the staff of UAMS AHEC FMC and TCC your patience in my educational endeavors will never be forgotten. UAMS will always be an alma mater I’m proud to claim.

Ms. Stephanie Holden, your supported is immeasurable. You have supported me from day one of my doctoral journey. I will forever be indebted to you. I pray I have the time and strength to pay it forward.

I acknowledge all of the faculty and staff at TWU who have contributed to this dissertation through their guidance. I would like to express special appreciation for Dr. Kimberly Parker, my committee chair. Her knowledge, experience, and patience were the basis of completing this mission. I am forever indebted to you for your guidance through this journey. To Dr. Douglas Coyle, Dr. Roger Shipley, Dr. Katie Crosslin, and Dr. Gay James thank you for your helpful comments and thoughtful inquiries that prepared me for the proposal and dissertation defense.

ABSTRACT

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EXAMINATION OF FACTORS THAT IMPACT MEDICATION ADHERENCE AMONG HEART FAILURE PATIENTS IN SOUTHERN RURAL COUNTIES

MAY 2014

Approximately 5.7 million people in the United States have been diagnosed with heart failure as of 2012, with an estimated annual cost of $34.4 billion (Centers for Disease Control and Prevention [CDC], 2012a). Expenditures associated with heart failure include healthcare services, medications, and lost work productivity (CDC, 2012a). Treatment for those who suffer from heart failure relies heavily upon adherence to specific medications and other treatment regimens. The appropriate use of medication is essential to self-management of most chronic diseases such as heart failure; however, it is estimated that over 50% of prescribed medication is not taken as directed by patients with cardiovascular disease, including heart failure (Horne & Weinman, 1999).

The purpose of this study was to examine the relationships among perceived severity, beliefs about medication, necessity-concern of medication and medication adherence among Medicare eligible patients with HF receiving

treatment from the University of Arkansas for Medical Sciences-Area Health Education Centers (UAMS-AHEC). The majority of the 81 heart failure patients sampled from the two clinic locations in the Texarkana, Arkansas area indicated prescribed medications were essential for maintaining their health. Participants with negative beliefs about prescribed medications were more likely to have lower medication adherence and those with positive beliefs about medication revealed higher medication adherence. Participants with higher perceived severity of heart failure reported lower medication adherence, while those with lower perceived severity of heart failure reported higher medication adherence. This research study provided a one-time event snapshot of patients' self-reported behaviors relative to medication usage and possible relationships among other modifying factors that may facilitate or mediate adherence. In clinical practice, the discovery of patients' beliefs about medication during the early stage of diagnosis could aid in establishing better communication and education to promote sustainable medication adherence.

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CHAPTER I

INTRODUCTION

Heart disease is the leading cause of death in the United States, contributing to approximately 25% (600,000) of total deaths reported annually (Centers for Disease Control and Prevention [CDC], 2012a). The term heart disease collectively describes several different heart conditions, including heart failure (HF), myocardial infarction, congenital heart disease, and coronary artery disease (CDC, 2009). Heart disease is often characterized by risk factors that contribute to the illness. Risk factors associated with heart disease include heredity, pre-existing health conditions, and lifestyle behaviors (CDC, 2009). Although heredity is an uncontrollable risk factor, close and effective management of the disease and its symptoms is still warranted. The growing prevalence of pre-existing health conditions such as elevated blood cholesterol levels, hypertension, diabetes, and poor lifestyle behaviors are potential modifiable factors contributing to heart disease (CDC, 2009). Practicing healthy lifestyle behaviors can reduce the risk of health conditions that contribute to heart disease. For patients diagnosed with heart disease, healthier lifestyle behaviors and regiment of medication are typically prescribed to treat and control the disease (CDC, 2009). Increased emphasis has been placed on medication

adherence in an effort to decrease mortality, morbidity, emergency room visits, and inpatient admissions associated with heart disease. However, an estimated 83.6 million Americans suffers from debilitating symptoms and impairments associated with heart disease (American Heart Association [AHA], 2012).

HF and Congestive Heart Failure (CHF) are terms used to describe the heart's inability to pump blood in sufficient volume to meet the body's needs, leading to shortness of breath, enlargement of the liver, swollen ankles, and other symptoms (Bryg, 2009). HF causes the stretching, stiffening, or thickening of the muscles located in the heart's chambers (CDC, 2012a). Also, HF can be caused by other heart diseases such as coronary artery disease, myocardial infarction, and cardiomyopathy, which also increase the workload of the heart. Bryg (2009) noted HF affects approximately 5 million people in the United States and is the leading cause of hospitalizations in adults older than 65 years of age.

HF is primarily a disease of the elderly with prevalence estimates in the United States that exceeds 10% in adults 65 years and older (Toh, Jackson, Gascard, Manning, & Tuck, 2010). HF requires long-term usage of medications in order to reduce morbidity and mortality. Despite the utilization of evidence based practice in prescribing medications, treatment regimens are beneficial only if adherence is consistent (Albert, 2008). Estimates of medication adherence among HF patients are obscure, ranging from 10% to 94% depending on how adherence is measured and the population group being studied (Dunlay, Eveleth,

Shah, Mcnallan, & Roger, 2011). Gatti, Jacobson, Gazmararian, Schmotzer and Kripalani (2009) stated 20% of medication adherence issues are correlated with patients' beliefs that medication have unsafe effects. Additionally, minimum health literacy is critical for understanding treatment information and following recommended treatment plan (Robinson et al., 2011). Rural geographical studies related to patients' beliefs about medication and medication adherence in Medicare eligible HF patients are lacking and require further investigation. To address these gaps in knowledge, this study aimed to evaluate medication adherence among HF patients receiving care at rural based clinics. Survey tools that had established validity and reliability were used to examine beliefs about medications and medication adherence among Medicare eligible patients with HF and to identify factors potentially associated with medication adherence.

Statement of Purpose

Disease management is based on several factors, including healthcare provider-patient communications, patient's health condition, patient's health behaviors, and the utilization of health services (Lorig et al., 1999). Medication adherence is essential to successful disease management; it reduces the likelihood of comorbidities, hospitalizations, and mortality associated with chronic diseases. French, James, Horne, and Weinman (2010) study noted heart disease patients as having a perceived association between taking medications and the presence or absence of symptoms; indicating such patients were likely to

alter the prescribed medication regimen according to their symptoms. Albert (2008) examined medication adherence among HF patients with previous hospitalizations and concluded that patients' perceived benefits from taking medication are higher if they receive appropriate discharge instructions about medication adherence. Nonadherence to HF medications among Medicare eligible population can be a major challenge due to complex health conditions with complex medication regimens (Toh et al., 2010).

The catchment area of Texarkana, Arkansas can be considered rural, socially and economically disadvantaged, with limited research related to patients' beliefs about medication and medication adherence relative to this area and population groups. Such lack of research, evidence-based practices, or benchmarks could lead to ineffective methods of implementing medication regiments and practices. The purpose of this study was to examine the relationships among perceived severity, beliefs about medication, necessity-concern of medication and medication adherence among Medicare eligible patients with HF receiving treatment from the University of Arkansas for Medical Sciences-Area Health Education Centers (UAMS-AHEC).

Theoretical Framework

A person's beliefs about the benefits of medication are vital to the prevention and proper management of HF. The Health Belief Model (HBM) is a conceptual framework that is widely used in health behavior research. According

to Glanz, Rimer, and Viswanath (2008), embedded in the HBM are five levels of influence that impact health related behaviors: intrapersonal (only involve the individual's thoughts and beliefs), interpersonal (involve other individuals and society), institutional/organizational, community factors, and public-policy factors (external factors involving administrative and policy regulations). The HBM was first used to explain the lack of participation in programs addressing the prevention and detection of diseases. The HBM states the intrapersonal level of influence is formatted to predict the causal factors related to patient's health behaviors (Glanz et al., 2008). The foundation of this study was narrowed to target intrapersonal levels of influence as outlined in the HBM.

The intrapersonal level of influence in the HBM focuses on sociodemographic information, such as: age, gender, ethnicity, culture; as well as knowledge, and personality, otherwise known as modifying factors (Glanz et al., 2008). Modifying factors impact behavioral change and the perceived constructs of the HBM. The perceived constructs are intrapersonal levels of influence which include: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and self-efficacy (Glanz et al., 2008). A combination of the perceived susceptibility, a person's belief about the chances of contracting a disease, and perceived severity constitute a person's perceived threat. The HBM posits, prior to implementing a health behavior, an individual assesses the perceived barriers and threats associated with the health outcome. As a result,

the perceived benefit shapes the actions necessary for the positive health outcome. Additionally, self-efficacy gauges the confidence in one's ability to comply with the outcome, such as taking medication as prescribed. The final construct of the HBM is the "cues to action" that instigate readiness to take action (Glanz et al., 2008). Based upon the HBM, the product of the constructs purports to lead to the action or outcome behavior.

Research Questions

The purpose of this study was to examine the relationships among perceived severity, beliefs about medication, necessity-concern of medication and medication adherence among Medicare eligible patients with HF receiving treatment from the UAMS-AHEC. This study addressed the following research questions:

1. Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, what factors (perceived severity, belief about medication and necessity-concern) mediate or serve as barriers to medication adherence
2. Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, which factor(s) of perceived severity, belief about medication and necessity-concern differential predict medication adherence?

Hypotheses

The associated hypotheses are:

1. H_o: Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, there is no statistically significant difference in medication adherence among the different HF severity classification groups.
2. H_o: Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, there is no statistically significant difference in medication adherence among the different beliefs about medication groups.
3. H_o: Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, there is no statistically significant difference in medication adherence between the necessity and concerns groups.

Delimitations

This study was limited to Medicare eligible patients 18 years or older and receiving care at UAMS-AHEC facilities, the Family Medical Center (FMC), or the Texarkana Community Clinic (TCC), located in Texarkana, Arkansas. Participants had prior diagnosis of HF at least two months prior to the study and prescribed at least one medication to address HF at least two months prior to the study. Additionally, participants were required to have taken the medication for at

least 30 days before the study. Finally, participants had to be eligible for Medicare insurance to assist with the financial cost associated with treatment and medications.

Limitations

Participation in the study was voluntary and participants were selected based on their previous diagnosis of HF. This method of nonprobability sampling does not allow outcome generalization to population groups beyond the region. Both the FMC and TCC only treat patients within the northeast Texas and southwestern Arkansas regions; therefore, comparison to other population groups is limited to the geographical locations. Participant recruitment was not limited to a particular race or ethnicity. Consequently, all individuals within the inclusion criteria requirements had an equal chance to participate in the study.

Assumptions

It was assumed that all participants were able to read and understand the English language and that they completed the questionnaire accurately and truthfully. It was also assumed that all participants received the correct HF International Classification of Disease (ICD-9; 9th Edition) diagnosis code for identification.

Definition of Terms

Medication adherence – the extent to which a patient takes medications as prescribed.

Cardiovascular disease – any condition that involves the narrowing or blocking of blood vessels, which can lead to a heart attack, chest pain (angina), or stroke.

Heart disease – an ailment affecting the daily functions of the heart. For this study, heart disease is collectively comprised of the following ailments: heart valve disease, myocardial infarction, congestive heart failure, coronary artery disease, conduction disorders, cardiac dysrhythmias, and cardiomegaly.

Heart Failure – a serious condition defined as the inability of the heart to supply sufficient blood flow to meet the body's need for efficient blood supply to the organs and tissues. It is also called congestive heart failure or chronic heart failure.

Necessity-Concern Differential - an indication of a cost-benefit analysis captured by the Belief about Medications Questionnaire (BMQ).

Importance of Study

Medication adherence is essential for the self-management of many chronic conditions. There are many modifying factors that could impact medication adherence; ranging from access to medical care to financial support for medication. This study focused on the intrapersonal influences on medication

adherence among those diagnosed with HF. The perceived factors in the HBM theoretical framework addressed the intrapersonal factors that could prevent patients from taking medications as prescribed. Although there exists a vast body of knowledge and research outcomes noting the complexities of medication adherence with respect to external factors, yet the concepts of perceived barriers, perceived benefits, and self-efficacy examined as intrapersonal influencers is minimum. This study examined such intrapersonal influences associated with medication adherence and belief about medications.

The results of this research study can be used to address how healthcare providers communicate and engage their HF patients based upon the patients' beliefs about medications, which can be instituted at the clinic level of care. Efforts to create customized patient education, communication, or literature based upon patient's beliefs about medications are plausible and straightforward solutions to achieving sustainable medication adherence in this population group. Such efforts could result in decrease morbidity, co-morbidities, emergency care and hospitalizations; and ultimately improve health status and quality of life among HF patients.

CHAPTER II

LITERATURE REVIEW

The literature review provided an integrative overview of the current research regarding the relationship between HF patients' beliefs about medication and medication adherence. The review of literature began with an assessment of HF, and then it defined and described the variables, the outcomes and behaviors associated with medication adherence. Prior research documented multifactorial causes that impacted the intrapersonal levels of influence, in which most were identified as having causal relationships with medication adherence. The research outcomes heightened the importance of medication adherence among HF patients as outlined in previous research. The perceived constructs, self-efficacy, and potential social determinants of medication adherence were reviewed within the context of the HBM theoretical framework.

The literature search was conducted using CINAHL database limited to peer-reviewed articles. Search terms used, but not limited to: included heart disease; cardiovascular disease; heart failure; medication adherence; health literacy; health belief model; perceived severity; and beliefs about medications. The initial search resulted in 242 usable articles. The resultant articles yielded rich secondary references cited throughout the articles. Although the search

provided a substantial amount of prior research, there was a limited amount of research utilizing theoretical frameworks related to medication adherence among HF population groups. The search was expanded to include all relevant articles that would add to the research study.

Heart Failure

HF has been defined as the heart's inability to pump blood at a rate to meet the body's needs, resulting in symptoms to include shortness of breath, leg swelling, and limitations to physical activities (Bryg, 2009). HF has been characterized by the stretching, stiffness, or thickening of the muscles of the heart's chambers. Overtime, the heart lacks in the functionality to maintain the demands of daily activities required for sustain living; and, adaption to the symptoms places stress on other body systems. The complexity of HF led to the classification of four types of HF. The first and most common type of HF known as left ventricular failure (LVF). LVF has been defined as the inability of the left ventricle to contract forcefully enough to maintain a normal cardiac output (blood flow to organs and tissues) and peripheral perfusion (blood flow to blood vessels). As a result of LVF, pulmonary congestion and edema developed from back pressure of accumulated blood in the left ventricle (Mosby, 2012). The second class of HF known as right ventricular failure (RVF), which typically occurred secondary to LVF, lung disease, hardened heart valves, or other heart defects. The most common cause of RVF has been LVF, due to the pressure

built up from the left ventricle's inability to pump blood forward efficiently, leading to increased blood volume and increased pressure in the lung and right ventricle. As a result, RVF has been manifested by distention of the neck veins, enlargement of the liver and edema (Mosby, 2012). The third class, known as systolic HF, occurred when the heart muscle does not contract with enough force, resulting in less oxygen-enriched blood that has been pumped throughout the body (Byrg, 2009). The fourth class, known as diastolic HF, occurred when the heart contracts normally, but the ventricles failed to relax properly, reducing the amount of blood that may have entered the heart and raised the blood pressure in lungs (Maddox, 2012).

HF has been routinely diagnosed through several physical assessments and diagnostic examinations. Upon completion of medical and family histories, the physical assessments were undertaken. Physical assessments included (a) auscultation of the lungs and heart, (b) examining the veins in the neck, and (c) examining the abdomen and legs for fluid buildup (Mayo Clinic, 2011). The primary diagnostic test has been the echocardiogram, which documents the ejection fraction. The ejection fraction has been a measurement of how well the heart was pumping blood throughout the body (Heart Failure Society of America, 2011). A healthy heart typically has an ejection fraction of fifty percent or greater, while individuals with HF usually have an ejection fraction of forty percent or less (Heart Failure Society of America, 2011). A B-type Natriuretic Peptide (BNP)

blood test has been used to provide additional evidence of a positive HF diagnosis. BNP has been a hormone that rises during HF; elevated rates may have indicated the presence or worsening condition of HF (National Heart Lung and Blood Institute [NHLBI], 2012). Other tests used to assess HF included chest x-ray, electrocardiogram, stress test, cardiac computerized tomography (CT) or magnetic resonance imaging (MRI), and coronary catheterization (angiogram).

HF has been further classified according to the severity of symptoms. The New York Heart Association (NYHA) Functional Classification has been the most commonly used system to classify HF patients (AHA, 2011). The NYHA Functional Classification rank HF in one of four categories based on physical limitations. These rankings range from Class I (mild), indicating that a patient has no limitations of physical activity and does not experience any discomfort, to Class IV (severe), in which a patient has been unable to engage in physical activity due to high levels of discomfort even at rest. The NYHA Functional Classification measures the functional capacity utilizing the following classifications: (1) I Mild classification included patients with cardiac disease but have no limitation of physical activity. Ordinary physical activity did not cause undue fatigue, palpitation, dyspnea, or anginal pain; (2) II Mild classification included patients diagnosed with cardiac disease that experienced slight limitation with physical activity. They were comfortable at rest. Ordinary physical activity resulted in fatigue, palpitation, dyspnea, or anginal pain; (3) III Moderate

classification included patients diagnosed with cardiac disease that experienced a marked limitation of physical activity. They were comfortable at rest. Less than ordinary activity caused fatigue, palpitation, dyspnea, or anginal pain; (4) IV Severe classification included patients diagnosed with cardiac disease that experienced an inability to carry on any physical activity without discomfort. Symptoms of HF were present even at rest. If any physical activity was undertaken, discomfort increased.

Medication Adherence

Treatment for chronic diseases routinely requires long-term usage of pharmacotherapy (medications). Even when there were established pharmacotherapy treatment plans with evidence of positive outcomes, there were still increases in morbidity, co-morbidities and mortality. To demonstrate the true effects of a particular medication, the patient must take the medication at the recommended dosage and times, a practice commonly referred to as medication adherence (Brown & Bussell, 2011). Ho, Bryson, and Rumsfeld (2009) defined medication adherence "as the active, voluntary, and collaborative involvement of the patient in a mutually acceptable course of behavior to produce a therapeutic result" (p. 3028). This definition implied that the patient has a choice and that both parties (patient and provider) mutually established treatment goals and the medical regiment. In this research, medication adherence assumes both adherence and persistence; whereas adherence refers to the intensity of

medication use during the duration of therapy, while persistence refers to the overall duration of medication therapy (Ho et al., 2009).

The problem of medication adherence has been documented for more than three decades, yet efforts to address it and improve health outcomes have only recently been brought to the forefront (Epstein, 2011). As the United States population continues to age and patients take more medications to treat chronic conditions, medication nonadherence has been estimated to increase (Ho et al., 2009). Medication nonadherence transcends the borders of the United States. The National Council on Patient Information and Education (NCPIE) (2007) highlighted several figures documenting medication nonadherence has been a global concern. In developed countries similar to the United States and Great Britain, only 50% of patients with chronic diseases adhere to their medication regimen (NCPIE, 2007). NCPIE (2007) also reported that even though hypertension increases the risk of heart disease three to fourfold, and increases overall cardiovascular risk by two to threefold, only 51% of patients take prescribed medications to manage their condition. In contrast, Corda, Burke, and Horowitz (2000) self-reported adherence to medication averaged 79% among patients who were healthcare professionals.

The lack of medication adherence may have led to unnecessary disease progression, disease complications, reduced functional abilities, decrease quality of life, and premature death (NCPIE, 2007). Clinical measures of medication

adherence were not routine in clinical practices, but the issue of medication adherence has been deemed the “next frontier in quality improvement” due to the outstanding consequences related to medication adherence (Ho et al., 2009, p. 3028). Medication adherence has been a growing concern of healthcare systems and other stakeholders such as insurance payers (Ho et al., 2009). The prevalence of nonadherence in conjunction with adverse health outcomes and associated cost of care leads to far-reaching financial consequences. Thus, a continual spotlight on medication adherence has its place in improving both health outcomes and the financial burdens associated with the United States’ healthcare system.

Several population groups were reported to be at risk from the adverse effects of medication nonadherence. The most salient population group affected by medication nonadherence were individuals 65 years and over. The risk of medication nonadherence may have intensified in this group if there were complex and competing health issues, such as diabetes, HTN, and heart disease (NCPIE, 2007). According to Marinker and Shaw (2003), individuals 75 years and older took an average of eight medications per day. Meadows (2003) reported complicating factors, such as multiple health issues, multiple providers, and physical and cognitive challenges, contributed to medication nonadherence among the elderly patients. Specific medications were a necessity in the treatment of HF among the elderly population. Monane et al. (1997) found that

only 10% of elderly HF patients complied with digitalis therapy during a one-year period in the New Jersey Medicaid program. Digitalis therapy helps an injured or weakened heart function more efficiently by strengthening the force of contractions, balancing the heart rhythm, and improving blood circulation (Karriem-Norwood, 2012).

Patients with lower socioeconomic status who lack health insurance, access to quality healthcare, and lower health literacy were at higher risk of the consequences associated with medication nonadherence (NCPIE, 2007). Health disparities and low health literacy were neither secluded social problems nor independent attributes of disadvantaged groups of people; however, both bring the focus of health related issues to underserved populations with chronic diseases (Ferguson, 2008). Health disparities were defined as the differences that subsist among specific population groups in the United States (Ferguson, 2008). Health literacy has been defined as “the ability of an individual to access, understand and use health related information and services to make appropriate health decisions” (NCPIE, 2007, p. 14). Bennett, Chen, Soroui, and White (2009) found health literacy mediates some health disparities in preventative healthcare utilization among older adults. Nearly 40% of the general public or an estimated 60 million Americans have been affected by limited health literacy (Andrulis & Branch, 2007).

Brown and Bussell (2011) noted health literacy as a contributing factor to behaviors related to medication adherence among individuals with lower socioeconomic status. Health literacy has played a significant role in the ability to communicate with providers, understand, and act upon the instructions for taking medications (NCPIE, 2007). Gottlieb (2000) reported 10 to 80 minutes after receiving medication instructions by their provider, at least 60% of patients could not correctly repeat the instructions. According to Nielsen-Bohlman, Panzer, and Kindig (2004) 45% of the adult population have literacy skills at or below the eighth grade reading level. Thus, nearly half of the adult population may have difficulty with reading and understanding basic health and medication instructions. This population group may have encountered barriers ranging from access to health services to communication, whereas they may not fully comprehend the treatment plan (Brown & Bussell, 2011).

To manage the crisis associated with medication nonadherence, appropriate measuring and trending have been undertaken (Brown and Bussell, 2011). Measuring medication adherence and determining the causes have been a difficult challenge as it could result from complex determinants or an individual behavior. Brown and Bussell (2011) defined three methods of measuring medication adherence. The first method was a subjective and indirect measurement, and included surveying the patient, family member or guardian about the patients' medication usage. The next method was to collect objective

(indirect) data including counting pills taken during a specific timeframe or obtaining pharmacological data detailing the frequency of refills from the pharmacy. The final method for measuring medication adherence was an objective (direct) method that utilized laboratory data. By adding a nontoxic marker to the medication, a lab test may have detected the medication presence in blood, urine, or serum drug levels. Researchers and healthcare providers typically used a combination of these measures to assess medication adherence and behavior (Brown & Bussell, 2011).

Both indirect and direct methods of measuring medication adherence had associated advantages and disadvantages. The use of each method has been dependent on clinical scenario and availability of pharmacological data. Direct methods may have been costly and difficult to complete; therefore, indirect methods were more commonly used to measure medication adherence (Ho et al., 2009). Patient questionnaires were one of the most common indirect methods of measuring medication adherence. According to Ho et al., the Morisky's scale has been "a commonly used, validated, 4-item self-reported adherence measure that has been shown to be predictive of adherence to cardiovascular medications and blood pressure control" (p. 3029). Gehi, Ali, Na, and Whooley (2007) found that there was a strong association with self-reported nonadherence and adverse cardiac events.

Pill counting has been commonly used to indirectly assess medication adherence. Medication adherence under this method has been defined as the number of pills absent in a given time period divided by the number of pills prescribed by the healthcare provider in that same given time period (Brown and Bussell, 2011). Brown and Bussell considered patients with adherence scores of 80% or greater as adherent. Although considered an effective method for calculating medication adherence, the assumption has been the patient actually took all the missing pills as directed. Even the direct method of laboratory data has not been 100% reliable, as there may be variations in the drug metabolism that could potentially affect serum levels of certain medications. To combat the measurement issues associated with adherence, many researchers were utilizing electronic pharmacy data. Obtaining refills and the frequency of refills may detect different aspects of patients' medication adherence behaviors (Ho et al., 2009).

Medication Adherence in Heart Failure Patients

Physicians prescribed medications for HF patient based on the type of diagnoses, severity of HF, and the patient's response to different medications (NHLBI, 2012). With the appropriate treatment, signs, and symptoms of HF may significantly improve and the heart became stronger, leading to improved quality of life (Mayo Clinic, 2011). All HF patients who were prescribed medications take at least one of the medications (see Table 1, appendices H) (Mayo Clinic, 2011).

Medication nonadherence among patients suffering from HF has been a major concern in the treatment of this population group. Between one-third and two-thirds of all medication-related hospitalizations in the United States were resultants of poor medication adherence (Brown & Bussell, 2011). HF disease management involves multiple medications to reduce morbidity, mortality, and the signs and symptoms (Albert, 2008). Despite advancements in HF treatment regimens, research continually document implications of medication nonadherence. The 44-year follow up of the Framingham Heart Study of the National Heart, Lung, and Blood Institute revealed approximately 80% mortality at eight years post- diagnosis of HF (Albert, 2008). The objective of the Framingham Heart Study was to identify common factors that contribute to various CVD. The study followed a large group of participants over several decades. The original cohort included 5209 men and women between the ages of 30 and 62 from Framingham, Massachusetts. The participants had yet to develop overt symptoms of CVD and not suffered a heart attack or stroke at the time of enrollment in the study (Arruda, 2012). The participants completed extensive physical examinations and lifestyle interviews every two years. The results were analyzed for common patterns related to CVD development.

The Candesartan in Heart Failure: Assessment of Reduction in Mortality and Morbidity (CHARM) study in 2003 revealed an association between medication adherence and mortality in HF patients. The purpose was to assess

the cost-effectiveness of candesartan cilexetil, an angiotensin II receptor blocker. In this double-blinded, randomized, controlled clinical trial, candesartan was compared with a placebo for a median of 38 months in approximately 7600 HF patients. Good adherence, defined as taking more than 80% of study medication during the allotted time period, lead to lower all-cause mortality in the treated group of HF patients (Albert, 2008). After adjustments for predictive factors, the results revealed that good medication adherence was associated with lower all-cause mortality in patients at $p < 0.001$. The CHARM HF patients with poor medication adherence demonstrated an increased number of cardiovascular-related emergency department visits (Ho et al., 2009). In general, patients who practice good medication adherence with the angiotensin receptor blocker were more likely to practice other positive health behaviors that lead to positive health outcomes (Albert, 2008).

In a study of low-income patients with HF, Murray et al. (2007) examined whether a more active role of the pharmacist improved medication adherence and health outcomes as compared with the traditional pharmacist role in care. This randomized control study was conducted at a university affiliated, inner city, ambulatory care clinic in Indianapolis and included 314 low-income HF patients with confirmed HF diagnosis. Patients were followed for 12 months. A multidisciplinary team of investigators constructed the intervention to support medication management by patients who have low health literacy and limited

resources. The treatment group (n=122) received a pharmacist-led, 9-month, multi-tier intervention, with a 3-month post-study phase.

The primary study variable was medication adherence. Using the Medication Event Monitoring System (MEMS), an electronic measuring system, medication adherence was measured in three phases: taking adherence, scheduling adherence, and refilling adherence (Murray et al., 2007). Taking adherence was defined as the percentage of prescribed medication taken and measured the deviation from the time of the physician's prescription. Scheduling adherence sought to describe the reliability or consistency of dosing over time. Refill adherence was measured by the medication received relative to medication prescribed, or the possession ratio. Three other areas examined secondary outcomes: health related quality of life, patient satisfaction with pharmacy services and total direct costs. The health related quality of life was measured using the Chronic Heart Failure Questionnaire. Patient satisfaction of pharmacy services was measured utilizing an internally developed and validated survey. Direct healthcare cost was measured using fixed and variable intervention cost. The fixed costs included pharmacist training, development of materials, equipment and programming. The variable costs included time spent by the staff administering the intervention, physician's interaction with the pharmacist about patients in the intervention group, and time spent by pharmacists performing direct observations.

Using a 95% confidence interval, medication adherence at all phases was statistically significantly greater in the intervention group (Murray et al., 2007). Study results also demonstrated an approximately 19% decrease in emergency department visits or hospital admissions for HF exacerbations when participants adhered to taking, scheduling, and refilling medications. “Disease-specific quality of life improved from baseline to six months and twelve months by 0.28 and 0.39 respectively for the intervention group compared with 0.21 and 0.24 for the usual care group” (Murray et al., 2007, p. 719). Murray et al. (2007, p. 719) reported the following cost savings in their study:

> The overall actual mean fixed cost of developing the intervention and the variable costs of implementing it were $205 per patient. Outpatient healthcare was $886 lower for patients in the intervention group (CI, -$2289 to $660) and was lower across all cost categories except drugs. Moreover, the cost of inpatient healthcare was $2277 less in the intervention group (CI, -$6329 to $1225). The mean difference in the overall cost of healthcare was $3165 lower in the intervention group (CI, -$7800 to $1138). Considering cost of development and implementation, the intervention saved $2960 per patient (CI, -$7603 to $1338). However, no cost comparisons between groups were statistically significant because of the large variability in cost of over-all inpatient healthcare. (p. 719)

Overall, the study results found that pharmacy based intervention for outpatients with HF improved adherence to prescribed medications and decreased healthcare utilization (Murray et al., 2007). However, the benefits of intervention quickly diminished once the intervention was completed. Therefore, efforts to continue components of the intervention embedded within the daily management of HF were warranted for sustainable medication adherence.

Though medication adherence has been the key to decreasing mortality and healthcare costs in HF patients, so has been the judicious use of certain types of medications used to treat HF. To address this issue, Skrepnek et al. (2005) examined the incremental difference of concurrent and persistent use of ACEI, β-blockers, loop diuretics and digoxin in a one-year study at a managed care facility. All of the medications had shown to increase the risk of hospitalizations and total healthcare cost associated with treatment of HF patients. This retrospective study analyzed 350,000 patient records. Patient level data included demographics, eligibility information, diagnostic codes, health services utilization, inpatient and emergency visits, pharmacy services and ambulatory utilization. The inclusion criteria were (a) patients aged 35 years or older, (b) diagnosed with HF using ICD-9 clinical modification code 428.x, (c) one or more medication claims for HF during the study period, (d) continuous eligible claims for 6 months prior to the index date (the day of the first claim for either HF diagnosis or ACEI utilization) and 12 months post index date.

In this research study, the dependent variables were all-cause hospitalizations and total direct medical cost. The independent variables were (a) demographics; (b) Chronic Disease Score (CDS) (a validated index used to control for differences in case mix based on prescription drug utilization); (c) resource utilization involving outpatient department, emergency department, or inpatient setting coded with appropriate ICD-9; (d) costs to the managed care organization related to pharmacy cost; (5) outpatient cost, hospital inpatient cost; (e) emergency department cost (defined as all direct medical costs involved in the treatment of the patient); (f) comorbid diseases; and (g) prescription drug utilization of HF patients (Skrepnek et al., 2005). Medication usage was considered long-term when therapy was used for 6 months or more for treatment during the study period.

Of the 350,000 patients identified in the Skrepnek et al (2005) study, 1903 patients met the inclusion criteria; with average age of 69.4 years. Approximately 49% of the patients were male, and over half the population had other comorbid diseases (diabetes, atrial fibrillation, myocardial infarction, renal disease, depression, and/or pneumonia). The final analyses found a low proportion of HF patients were adherent to their medication regimen. Approximately 32.3% of the patients with HF were not receiving treatment, which contributed to a 2.5 times higher risk of hospitalizations and 43.6% higher costs relative to other HF patients receiving treatment. Patients receiving three or more medications for at

least 6 months were associated with a decrease in all-cause hospitalization (including comorbid diseases) of 80% and total cost of 70% relative to patients receiving no treatment for HF. This study demonstrated the need for managed care organizations to view factors leading to increase healthcare utilization due to the potential lack of medication adherence with patients with high-cost diseases, such as HF.

Medication cost may have been a modifying factor associated with medication adherence. Clearly, the consequences of medication nonadherence contribute to increased healthcare costs, but medication adherence may have fluctuate in many patients due to the cost of medications. Dunlay et al (2011) examined the relationship between medication adherence and medication cost among HF patients living in Olmsted County, Minnesota. In this research, patients were prospectively recruited and required to complete questionnaires, undergo an echocardiographic study and venipuncture to measure blood levels. Nurses administered the questionnaires during a face-to-face outpatient interview. The questionnaires obtained information related to medication adherence and the cost of medications. The Mayo Clinic Echocardiographic Laboratory performed the echocardiography and venipuncture for the physical portion of the study. During the study, pharmacy records were obtained for the 6 months following enrollment and medication adherence was measured by

proportion of days covered (PDC). A PDC of less than 80% was classified as poor adherence.

Two hundred nine HF patients participated in the research: 59% male and average age 73.7 years. About 11 medications were filled during the 6-month study period, with 55% of the patients taking the medications three to four times a day. Most patients were prescribed the conventional HF medication therapy; whereas 70% prescribed β-blockers, 75% prescribed angiotensin-converting enzyme inhibitors (ACEI) or angiotensin II receptor blockers and 62% prescribed statins. The findings revealed that those with poor medication adherence experienced more cost-related medication issues, concluding cost as a barrier to medication adherence. Being eligible for Medicare Part D did not solve medication cost related issues completely. In this community cohort study, medication nonadherence was more likely to be due to cost-related medication issues instead of other factors, such as education level, marital status or medication frequency. Results revealed increasing ACEI drug copayments by $10 resulted in a 2.6% decrease in medication adherence, which contributed to 6.1% increase in hospitalizations for HF patients. The researchers noted other prescription medications for HF patients have demonstrated similar financial findings.

Aside from medication cost, there exist other barriers to medication adherence. In an observational study that followed HF patients in the home

health capacity, Toh et al. (2010) examined other possible barriers in efforts to identify solutions to medication nonadherence. In this study, pharmacists for chronic HF patients received referrals from multidisciplinary chronic HF services if issues with medication adherence were identified. The pharmacist attended home visits of 66 HF patients over two years. The demographical data revealed a mean age of 68.4 years with 70% male.

During the home visit, the pharmacist collected data, including demographic data; non-pharmacological issues related to HF management; barriers to medication adherence; and previous solutions used during home visits by the nursing staff. The pharmacist provided education and training, consisting of simplified medication lists, information on the purpose of medications, adverse effects and dosing information related to the prescribed medications taken by every HF patient. Approximately 15% of HF patients required multiple home visits, motivational interviewing and telephone coaching. The pharmacist examined the 3-month post intervention data utilizing electronic records and manual case notes reviews. The pharmacist reduced dosing frequency at 64% visits and initiated dose administration aids at 32% of visits.

The researchers analyzed data three months after the first home visit, to include hospital readmissions, emergency department readmissions, mortality and cause of death from cardiac and non-cardiac events. Hospital readmissions occurred with 4.5% of the HF participants with an average 6.3 days length of

stay. Overall, three patients had six episodes of admissions to emergency departments and inpatient hospitalizations. The admission rate was 4.5% with an average length of stay of 6.3 ± 1.3 days. Deaths due to chronic HF 3-months post-home visit intervention occurred with 3% of the HF participants.

The barriers to medication adherence for this cohort of 66 HF patients were poor and/or complex medication instruction (71%), not having medications (33%), and adverse medication reactions (20%). The results from this foundational study could be leveraged as comparison for further research related to pharmacist involvement with medication adherence. The research concluded the need for further research into multiple strategies to overcome barriers to medication adherence in HF patients (Toh et al., 2010).

Cholowski and Cantwell (2007) examined relationships between demographics, psychosocial and pathophysiological measures, and medication adherence in HF patients. In this research, self-efficacy, defined "as a higher order subjective judgment of one's own capacity to overcome a particularly challenging task," was hypothesized as a predictor of both medication adherence and health recovery (Cholowski & Cantwell, 2007, p. 251). Regulating continued medical and lifestyle changes has been central to ongoing rehabilitation in HF patients. Cholowski and Cantwell discussed coping strategies as a way to productively manage negative lifestyle behaviors during rehabilitation. Moreover, self-efficacy theory not only allowed prediction of current behaviors, but also

allowed for the existence of a feedback loop in which the individual's self-judgments as to the efficacy of previous behaviors enabled predictions of future behaviors. To quantify the link between medication adherence and coping mechanisms, Cholowski and Cantwell used an exploratory correlation design study involving 54 elderly HF patients recruited from a convenience sample at a cardiac rehabilitation clinic. Data was collected using the following survey tools: Outpatient Cardiac Rehabilitation Assessment Form; Beck Depression Inventory-II; Beliefs about Medication and Diet Questionnaire; Reactions to Daily Events Questionnaire; Self-Regulation Scale; and Compliance Behavior Assessment. After the exclusions were applied, 51 patients were enrolled in the study. Descriptive statistics and independent *t*-tests were used to evaluate gender effects. Pairwise correlations were used to examine the relationships between existing circumstances, psychosocial characteristics, beliefs about medication adherence, and self-reported medication adherence behaviors.

The researchers found that positive coping strategies and self-regulation provide a positive foundation for medication adherence and successful long-term rehabilitation for HF patients. Males were significantly more prone to adopt proactive coping and self-regulatory strategies than females. The proactive coping and self-regulatory strategies demonstrated a positive correlation to medication adherence; meaning, beliefs about medication adherence were linked to increased medication adherence. The research outcomes suggested an

educative opportunity in the care plan of HF patients. Healthcare providers encountering adherence issues should monitor behaviors by addressing both the quality of affect in patients' reactions to HF (self-concept, self-esteem, and self-efficacy) as well as the quality of health-related metacognitive knowledge underlying the self-regulatory decisions, such as general understanding of "wellness" and the strategic knowledge of supporting its accomplishment and maintenance of therapies.

In summary, medication adherence in HF patients has been broad and complex in scope. HF has been a progressive illness that marks the end-stage of heart diseases and has been known as a disease of the elderly. HF has been associated with high morbidity, co-morbidities, mortality and significant cost burdens. Numerous factors at the patient, physician and policy level contribute to the complexity of medication adherence in HF patients. Research has consistently highlighted underlying factors that negatively influence medication adherence, such as low health literacy, miscommunication, and socioeconomic status. These underlying factors were further amplified in HF patients taking complex medication regimens and other co-morbidities.

Multifactorial Causes of Intrapersonal Influence

Although it has been common for patients and providers to agree upon a recommended treatment and medication plan, nonadherence to medication continued to exist regardless of the disease, disease severity, and accessibility to

health resources (Brown & Bussell, 2011). In most circumstances, medication adherence issues were observed when self-administration was required. According to the WHO (2003), the existing evidence clearly supported that poor medication adherence increases mortality and severely contributes to co-morbidities. Many behaviors influenced by social, economics, health status and policy-related factors contribute to the crisis of medication nonadherence and each should be consideration to effectively address medication adherence (NCPIE, 2007). According to Brown and Bussell (2011), the causes of medication nonadherence were placed into three broad categories: patient-related factors, physician-related factors and health system or team building-related factors. NCPIE (2007) added three additional categories: medication-related, pharmacy-related, and policy-related factors. To effectively address nonadherence, the causal factors should be isolated and identified. These causal factors encompassed the HBM intrapersonal constructs, which were the independent variables of this research study, and how they influenced or impacted medication adherence, the dependent variable.

Patient-related factors that facilitate medication nonadherence included lack of understanding the disease process, lack of involvement in treatment decisions, low health literacy, patients' attitudes and beliefs related to the treatment, and environmental or socioeconomic barriers (Brown & Bussell, 2011). It was important for the patient to understand the etiology of the disease

or illness, and low health literacy may have increased the likelihood for miscommunications and eventually poorer clinical outcomes. Additionally, prior knowledge and experiences related to treatment and disease prognosis potentially shaped attitudes and beliefs about medication adherence. Lastly, barriers to receipt of medication were often found among patients with lower socioeconomic status (Brown & Bussell, 2011). These barriers posed a silent and collateral impact on medication adherence, and include such barriers as lack of health insurance, lack of transportation, availability and distance to nearest pharmacy, wait times at the pharmacy and cost burden, all of which the patient may or may not communicate to the healthcare provider.

In addition to the aforementioned patient-related factors, there has been growing concern among providers and public health officials about patients with chronic diseases who make a conscious choice not to take their medications as prescribed, not to refill prescriptions, or to simply discontinue medications. NCPIE (2007) outlined several attitudes and beliefs that may contribute to this growing concern: (a) perceptions about the nature and severity of disease, (b) diagnosis denial and the need to take medications, (c) assumptions that once symptoms improve, medications may have been discontinued, (d) beliefs about the effectiveness of the medication regiment, (e) acceptance of taking medications for preventative purposes, (f) the social stigma associated with

taking the medications, (g) media influence, and (h) lack of positive motivations or incentives to make a positive behavior change.

Medication adherence may have been hindered by physicians who prescribe complex medication regimens and do not fully consider patients culture, literacy level or financial implications (Brown & Bussell, 2011). Brown and Bussell (2011) noted medication nonadherence has been associated with ineffective communication. Ineffective communications may have occurred between the patient and physician as well as the nurse, pharmacist or other support staff. Ineffective or miscommunications may have occurred among the different caregivers, leading to overall suboptimal coordination of care. The lack of coordination of care increased the risk of assumptions and communication errors to the extent it may result in decreases in medication adherence, as well as increases in medication errors and potentially avoidable morbidities.

NCPIE (2007) noted the physician related factor of assumption of adherence and compliance may have been pervasive during patient visits. NCPIE reported physicians tend to overestimate the adherence to an agreed upon medication regimen due to assumptions, such as patients understand the recommended medication treatment and have the necessary resources to obtain the medication. In a study conducted by Dunbar et al. (2000) within a 10-physician practice group, physicians significantly underestimated medication adherence among their patients who were receiving continuous care at their

practice for more than five years. Only one of the ten physicians accurately estimated medication adherence. In concert with physician's lack of medication adherence awareness, the World Health Organization (WHO, 2003) reported inadequate medication counseling also contributes to medication nonadherence. Physicians or providers often argue that time constraints and lack of reimbursement for education and counseling contribute to the availability of medication counseling (NCPIE, 2007). Lastly, lack of culturally competent care and patient mistrust of physicians or providers may have influenced medication nonadherence (NCPIE, 2007).

The complexities of the healthcare delivery system and models of care delivery may have resulted in built-in factors that negatively influence medication adherence. This may result from breakdowns in the overall health system and the larger team of healthcare providers. Fragmented storage of patients' health records was shown to compromise care coordination, which in turn created hidden or underlying barriers associated with medication adherence (Brown and Bussell, 2011). Health information technology (HIT), which typically provides the infrastructure for storage of health records, may not be readily available to all physicians and healthcare providers; leading to ineffective care coordination between the team of healthcare providers. The lack of HIT infrastructure may have been added to communication errors discussed earlier. In addition to HIT, the increased demand of achieving mandated quality measures accompanied by

an increase in patient volume have led to decreases in the amount of time providers have to monitor, assess, and educate patients with chronic diseases about treatment regimens and medication adherence. As such, inclusion of educational protocols or productive conversations related to medication adherence seems to be a low priority and often excluded in the process of care.

The more complex a medication regimen, the lower the likelihood that the patient would adhere to medication schedules (Brown & Bussel, 2011; NCPIE, 2007). When diagnosed with chronic health conditions such as HF, complex medication regimens were commonplace in treatment protocols. According to a 2001 survey conducted by the American Society of Health-System Pharmacists, 82% of patients with chronic diseases over the age of 65 take at least one prescription medication, approximately 54% take three or four prescription medications, and 33% take eight or more prescription medications daily. Multiple medications prescribed by different physicians or providers were added to an already complex treatment regimen. If the primary physician does not adequately coordinates care with other specialty physicians, the patient must rely on their own ability to manage medication regimen. Brown and Bussell (2011) reported the likelihood of the average patient comprehending and remembering medication regimen instructions has been low.

Pharmacists were an underutilized resource that could assist with the communication gap between physicians and patients. While pharmacists may

have direct contact with patients, physicians and providers, most do not have a well-defined role in the direct care plan; thereby indirectly contributing to medication nonadherence (NCPIE, 2007). The Impact of Managed Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers' (IMPROVE) study was undertaken to assess the impact of ambulatory care clinical pharmacists on patient outcomes at selected Veterans Affairs medical centers (Carter et al., 1998). This was the first study conducted that examined how the ambulatory care pharmacists' role affected patients' outcomes. The study concluded clinical pharmacists were responsible for adjusting patients' drug regimens, as well as identifying and preventing medication related problems with their patients (Carter et al., 1998). Although improved use of HIT has decreased the number of medication errors at the pharmacist level, including the pharmacist in the care delivery process could further aid medication adherence.

While patients and physicians were the key decision-makers guiding the treatment and medication regimens, health systems and policy related factors also play a role in medication adherence. A health policy that may have served as a barrier or impediment to medication adherence has been the federal anti-kickback statute which contains rules that govern businesses reimbursed by Medicare, Medicaid, or other federally funded healthcare programs (NCPIE, 2007). The statutes were broad in context and many healthcare practices

designed to increase medication adherence may theoretically be subject to criminal prosecution under the statues. The Office of the Inspector General (OIG) issued guidelines granting protection to certain types of healthcare practices and business agreements under the federal anti-kickback statute. However, the guidelines failed to outline patient education, prescription refill reminder programs and pharmacy-based adherence messaging programs; therefore, many businesses opt on the side of caution to exclude patients who participate in any federal healthcare program. Another policy-related barrier results from the Privacy Rule and the Health Insurance Portability and Accountability Act (HIPAA) of 1996. HIPAA law prevents additional healthcare personnel from viewing patient's medical record, thereby limiting the ability to monitor medication adherence. For example, computer technology utilizing messaging software programs triggered by automated pharmacy dispensing records may have assisted in monitoring medication adherence using data from a microchip embedded in the packaging that monitors the dates and times the package was opened. This may have allowed pharmacies to scan information and trend medication patterns. However, due to computer network security concerns and without patients' permission to access medical record, the pharmacist capacity to monitor medication adherence has been limited. The HIPAA laws designed to protect patient privacy may also prevent potential solutions to aid medication adherence. The multifactorial causes related to medication nonadherence in HF

patient warrant continued research to identify and execute effective and efficient strategies to minimize the morbidity, mortality, and cost burdens associated with medication adherence in HF patients.

Health Belief Model and Medication Adherence

According to Horne and Weinman (1999), social cognition models, such as the HBM, have been used in various research exploring acute illnesses; however, there has been limited research using HBM to explore medication adherence in chronic diseases. Horne and Weinman conducted a cross-sectional study with 324 patients from four chronic disease groups: asthma, renal, cardiac and oncology diseases to examine personal beliefs about the necessity of prescribed medication and their concerns about taking the medication. They also examined the relationship between beliefs about medications and self-reported medication adherence. The researches stated utilizing the HBM would assist with explaining how patients' beliefs might influence their decisions about taking prescribed medication as recommended. It was hypothesized that although beliefs about medications generally influence the patients' initial behaviors associated with medication adherence, it has been strongly related to personal views about the specific prescribed medication.

To measure the patients' beliefs about medication, the Beliefs about Medicines Questionnaire (BMQ) was administered as the survey tool. The internal consistency reliability of the necessity scale was moderate (Cronbach α

0.80 and 0.74 at 3 and 12 respectively), whereas the internal consistency reliability of the concern scale was lower; however, it met the acceptability (Cronbach α 0.68 and 0.65 at 3 and 12 respectively (Lakepointe, 2010). Medication adherence was assessed using Morisky's Self-Reported Medicine Scale (MSRMS); internal consistency reliability was noted as Cronbach α 0.83. The research revealed significant variations in reported medication adherence and beliefs about medication within and between disease groups. A substantial proportion of the variance in reported medication adherence was explained by three causal factors: patients' beliefs about medication, the specific chronic disease, and age. A key finding was that patients' beliefs about medication were stronger predictors of reported medication adherence than clinical and sociodemographic factors. If the patient felt there was benefit in taking the medication as prescribed, he/she was more likely to have a positive behavioral outcome.

Patients who were active decision-makers in their medication regimens were more likely to be motivated to take medications as prescribed. George and Shalansky (2006) surveyed 350 HF patients at an outpatient clinic with an aim to identify the health beliefs and patient individualities associated with medication nonadherence. The research study encompassed HBM, demographics, clinical characteristics, BMQ and the Multidimensional Health Locus of Control. The variables associated with the HBM were perceived susceptibility, perceived

severity, perceived benefits, perceived barriers and perceived quality of medical care. Of the 350 patients, refill nonadherence was found in 22%, and 38% self-reported medication nonadherence. The research revealed several factors associated with nonadherence in HF patients, which included the perceived need to make major change in daily routines to accommodate the recommended medication schedule, the need to change smoking behaviors and the desire for fewer administration times. Perceived barriers were a significant predictor of both refill nonadherence and self-report medication nonadherence among low-income patients. Perceived barriers include cost and access to medications. This research highlighted the need for continued research related to the perceived barriers to both refill and medication nonadherence.

Though the HBM may be useful when examining medication adherence, the HBM constructs may vary in effectiveness as predictors of behavior due to the limited number of studies evaluating its usefulness. In a meta-analysis, Carpenter (2010) reviewed susceptibility, severity, benefits and barriers as variables of the HBM. In the research, five of the 18 studies were related to medication adherence. In this subset, the studies related to medication adherence had a larger effect size than studies examining other behavioral outcomes. The effect size estimates the variance within an experiment that has been explained by the experiment's model. In addition, these studies were the only subset such that susceptibility was positively related to the behavioral

outcome of medication adherence. Carpenter noted the reasons contributing to this relationship were unclear. Due to the limited number of research studies utilized for this cross-sectional study, it was suggested to view the results related to the HBM theoretical framework with caution.

Conclusion

Prior research studies highlighted the proliferated efforts to sustain quality of life for patients diagnosed with HF. Oftentimes, HF led to other comorbidities, requiring long-term and complex medication regiments. Research outcomes resulting in evidence-based practices for medication adherent have been proven successful in sustaining a higher quality of life for HF patients. These medication regiments were individualized to complement the type and severity of HF diagnosis, medication receptivity and existing comorbidities. Factors associated with medication nonadherence may have been attributed to the patient, physician, pharmacy, health system, or health policy.

In addition to demographic and environmental determinants, the intrapersonal influences associated with medication adherence such as perceived severity, perceived barriers, and perceived benefits have been directly linked to medication nonadherence in HF patients. Instituting health education or intervention programs to address such issues as health literacy and better physician or provider-patient communication may have abated nonadherence during the initial or early stage of HF diagnosis.

CHAPTER III

METHODOLOGY

The key objectives of this questionnaire-based research were to collect and analyze primary data on medication adherence among Medicare eligible HF patients receiving care at FMC and TCC in Texarkana, Arkansas and compare medication adherence with selected intrapersonal levels of influences delineated by the HBM. A quantitative research design was used to examine how patients' perceived severity, beliefs about medications, and necessity-concern differential influenced medication adherence in patients identified using ICD-9 codes listed in Table 2 in appendices H.

Population and Sampling

The study was conducted at two clinics located in Texarkana, Arkansas. The rural clinics serve patients from Bowie (Texas) and Miller (Arkansas) counties. Geographically, the counties were directly adjacent, but located in different states. According to the United States Census Bureau (2012), in 2011 the estimated population of Bowie County was 92,793, and the estimated population of Miller County was 43,759. Approximately 16.8% of the Bowie County population lived below the poverty level during 2006 to 2010. Comparatively, an estimated 18.1% of the Miller county residents lived below the poverty level during 2006 to 2010. According to Texas Department of State

Health Services (2009) and Arkansas Department of Health (2008) both Miller and Bowie have been deemed rural counties with health disparities that exaggerate efforts of sustaining and achieving optimal health. Health disparities in these counties included lack or minimum access to healthcare services and lower socioeconomic conditions of the general population.

The CDC defines health disparities as the “preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health that were experienced by socially disadvantaged populations” (2012b, para. 1). Historically, research has shown health disparities were a result of complex interactions between such factors as culture, environment, biology and health behaviors that were difficult to address due to barriers to include discrimination, income inequalities, limited education and access to healthcare (National Institutes of Health [NIH], 2011). According to the NIH, there has been growing evidence that medically underserved population groups experience poorer health compared to the overall population of the country, leading to shorter life expectancy and increased risk for chronic illnesses.

In 2010, Congress made a commitment to health impartiality by elevating the National Center on Minority Health and Health Disparities (NCMHD) to the National Institute on Minority Health and Health Disparities (NIMHD). NIH’s strategic plan and budget set the following priorities (a) research focused on health disparities experienced by racial and ethnic minorities, rural and urban

poor, and other medically underserved populations; (b) population-specific community based participatory research; (c) enhancing capacity to conduct health disparities research; (d) recruiting and retaining racial and ethnic minorities and other underrepresented groups into scientific research workforce; (e) establishing health education programs for special populations; and (f) promoting the inclusion of women, minorities, and other medically underserved groups in clinical trials. This research study aligned with the NIH's strategic plan and reinforced the supposition that medication adherence has been a complex phenomenon influenced by many modifying factors, but also suggested that health disparities may play a key role.

Health disparities in both Bowie and Miller included lack of access to healthcare and disadvantages in socioeconomic status of the general population. Health disparities are a result of complex confounding factors caused by various perceived barriers. Therefore, in an effort to decrease the variability of complex health interactions, this research study was limited to Medicare eligible patients receiving care at UAMS-AHEC FMC and TCC in Texarkana, Arkansas, with cost as the only perceived barrier examined. Research addressing intrapersonal levels of influence on medication adherence has been nearly nonexistent for this population group. Inclusion criteria included a documented HF diagnosis at least two months preceding the questionnaire completion. Additionally, participants had to be prescribed at least one medication to treat HF at least two months

preceding the questionnaire completion. Lastly, participants were required to take the medication for at least 30 days beyond the questionnaire completion. According to Bryg (2009), a majority of the HF population were of non-childbearing age; therefore, participants meeting the inclusion criteria but were pregnant were excluded from the study. A convenience sample was taken from the total population of 519 participants identified by the HF ICD-9 code and meeting all study criteria.

Protection of Human Subjects

Upon receipt of signed approval letters from the participating clinic locations, an application for expedited review of the research study was submitted to Texas Woman's University Institutional Review Board (IRB). IRB approval was subsequently granted. The initial data collection method proved to be ineffective. Due to time constraints associated with patient flow at the clinic locations, patients were unable to ask questions or complete the questionnaire per protocol. After approximately two months, an addendum to the IRB was submitted and subsequently approved for an additional data collection method. The additional data collection method allowed for distributing questionnaires by mail.

The research study incorporated steps to minimize risks to confidentiality and anonymity of the participants by keeping de-identified completed questionnaires in a locked and password protected file and permanently deleting

email communications from all involved computer hard-drives. All electronic data and communications were completed on the PI's personal computer. Questionnaires will be destroyed approximately three years upon completion of the study. An introduction letter (APPENDIX B), recruitment flyer (APPENDIX C), recruitment script (APPENDIX D), consent to participate in research and questionnaire instrument (APPENDIX E) were drafted and accompanied the IRB application and addendum.

Data Collection Procedures

One week prior to the recruitment event, a recruitment flyer was posted in the clinic's lobbies and treatment rooms. The location, date and time were noted on the recruitment flyer. During the recruitment event, the PI was situated in a secured location in the lobby. Once a potential participant approached the PI and inquired about the study, the PI read the recruitment script. Potential participants were not able to contact the PI prior to the scheduled recruitment event. Participants were allowed to ask all questions related to the research study and obtained answers prior to agreeing to participate and moving forward to the consent.

Each patient agreeing to participate was provided a consent form, but no signature was required. Completion of the questionnaire indicated consent to participate. Review of the consent was done in private. The PI reviewed the consent and further explained the purpose of the study and the survey

instrument. Participants were also told results would be collected anonymously and participating in the survey would not have any bearing on current or future medical treatment.

The questionnaire could be completed immediately in the treatment room and placed directly in a secure-box by the particpant, completed at home and mailed, or hand delivered to the PI at the clinic. A self-addressed stamped envelope was provided to participants wishing to complete the questionnaire at home. Completed questionnaires were mailed by the participant to a designated United States Post Office Box obtained only for purposes of the research study. Only the PI had access to the Post Office Box.

Participants wishing to complete the quesionnare immediately had access to a private office or treatment room. The office and treatment room provided space for participants to ask questions and complete questionniaires privately. The PI remained at the site until all completed questionnaires were collected and questions answered. After the in-person meeting, participants completing the questionnaire at home were able to ask the PI questions via phone or email. No phone numbers or email addresses were stored. The PI only logged the questionnaire responsed into a password-protected data file.

To prevent duplication, participants were asked not to return the questionnaire by mail if it was completed and returned to the clinic location. According to Shih and Fan (2009), a meta-analysis comparing survey response

rates revealed a 15% unweighted response rate for mailed surveys. The study also affirmed response rates were affected by respondents characteristics and survey design. The Simple Measure of Gobbledygook (SMOG) Readabiltiy Index estimated nine years of education was required to fully comprehend the questionnaire; therefore, for the present study, the goal of 15% response rate was reasoned as acceptable for the population.

To control for privacy and insure minimal risk, no identifiable information was stored to include name, addresses or other health related information. Since the PI did not receive any identifiable information, there was no need for a Waiver of Authorization. The clinic staff prepared and mailed the research packets directly to the participants. The research packet included the introduction letter, consent, questionnaire and self addressed/pre-paid postage envelope. The returned questionnaire was mailed to the designated Post Office Box listed above.

There was an additional attempt to increase the response rate. An announcement for recruitment purposes was placed in the Texarkana Gazette. The Texarkana Gazette newspaper had an extensive service area, serving a four-state area surrounding the catchment area. The advertisement utlized the same in-person recruitment script and extended the questionnaire return date to allow additional time to complete and return the questionnaires. There was a third attempt to increase the questionniare response rate. Prior to the intial due

date, another article was placed in the Texarkana Gazette and extended the return due date. Only 3 participants (3%) returned surveys utilizing the face to face data collection approach. Sixty-seven participants (83%) responded to the initial mail data collection approach, and an additional eleven participants (13%) responding to the newspaper announcement.

Instruments

The independent variables of perceived severity, beliefs about medications, and necessity-concern differential, and the dependent variable of medication adherence were measured using an established instrument with various sections and items. The combined SMOG Readability Index (APPENDIX F) was nine for all survey items, indicating that the participants needed as least nine years of education to understand the questionnaire. Section 1 of the instrument captured basic demographic information of the participant.

Section 2 of the instrument assessed participant's usage of medication or medication adherence. This was assessed using Morisky's Self Reported Medicine Scale (MSRMS), an eight-item self-report scale that has been utilized more than a decade in research. Questions 1 to 7 consisted of yes/no responses, with a value of 1 assigned to all yes responses except question 5, in which the no response was assigned a value of 1. Question 8 consisted of 5 possible options, with never/rarely assigned a value of 0 and all other assigned a value of 1. The summative score could range from zero to eight. Low medication adherence (LA)

was designated if the summative score was greater than two; moderate medication adherence (MA) if the summative score was one or two; and high medication adherence (HA) if the score was zero. Morisky, Ang, Krousel-Wood, and Ward (2008) documented the success of the psychometric properties of the survey items as well as concurrent and predictive validity measures. In a study of patients with hypertension, Morisky et al. noted internal consistency reliability of Cronbach $\alpha = 0.83$ for the medication adherence scale. The result of the internal consistency of reliability of the MSRMS was reported as acceptable for future research (Morisky et al., 2008).

The perceived severity of the disease was measured utilizing the NYHA classification scale based on patients' reported symptoms. Section 3 assessed this categorical response to participant's perceived severity of HF. Selection of the A response indicated Class I or Mild I perceived severity, B indicated Class II or Mild II perceived severity, C indicated Class III or Moderate perceived severity and D indicated Class IV or Severe perceived severity.

The NYHA functional classification system was developed to assist physicians in clinical practice evaluate the effect of cardiac symptoms on a patient's daily activities (Holland, Rechel, Stepien, Harvey, & Brooksby, 2010). The role of the NYHA classification system has expanded, and has been frequently used in clinical research (Holland et al., 2010). Holland et al. (2010) conducted an observational study and revealed patients' self-assigned NYHA

class was a good predictor of hospitalization, quality of life and mortality among patients with HF. Servero et al. (2011) measured the internal consistency reliability in a study of 1136 patients with cardiac disease. Using the NYHA classification, internal consistency reliability was noted as Cronbach α = 0.57 in participants with Class I (n=263), Cronbach α = 0.33 in participants with Class II (n=232), Cronbach α = 0.66 in participants with Class III (n=258) and Cronbach α = 0.67 in participants with Class IV (n=257). Even with low to moderate internal consistency reliability measures, exploring the strengths and limitations of the NYHA revealed the ability to predict a functional status of HF, a concept that diverges from functional capacity and functional performance (Servero et al., 2011).

Section 4 assessed measures related to both beliefs about medication and necessity-concern differential. The participants' beliefs about medication were measured using the BMQ. The BMQ embodies two sections: a 10-item BMQ-Specific section, which assesses belief about prescribed medications, and 7-item BMQ-General section, which assesses beliefs about medications in general. Using a Likert scale of measurement with1 assigned to Strongly Disagree continuing to 5 for Strongly Agree, summative scoring ranged from 17 to 85. According to the Center for Technology and Aging (2011) positive belief about medications was indicated if the summative score was < 47; neutral belief

if the summative score = 47; and negative belief if the summative score was > 47.

The BMQ has been shown to be valid and reliability for use in studies of various chronic diseases (Horne & Weinman, 1999). Allen-Lakepointe et al. (2010) reported internal consistency and test-retest reliability measures, and criterion-related and discriminant validity measures. In a study of patients with heart disease, the internal consistency reliability of the necessity scale revealed Cronbach $\alpha = 0.80$ and 0.74 at 3 and 12 months, respectively, whereas the internal consistency reliability of the concern scale was lower at Cronbach $\alpha = 0.68$ and 0.65 at 3 and 12 months, respectively. The Horne and Weinman (1999) noted the internal consistency of reliability measures were acceptable for future research.

As noted, the BMQ was also used to measure the necessity-concern differential variable. The necessity-concern differential measured attitude about the necessity of prescribed medication for controlling disease and concerns about the potential adverse constraints of taking the medication (Horne & Weinman, 1999). The necessity-concern differential was an indication of cost-benefit analysis by the patient, such that the patient's perception of benefit or necessity was weighed against the perception of cost or concerns. The necessity-concern differential was assessed using the 10-item BMQ-Specific section of the BMQ. Questions 1, 3, 5, 7 and 10 assessed the necessity of

medications, while questions 2, 4, 6, 8 and 9 assessed the concerns of medications. The difference between the summative necessity and concern score was used to establish differential. This differential measure determined if or which, necessity or concern of medication, was the primary influencer for the behavior of medication adherence. Positive scores indicated the necessity of medication was the primary influence of medication adherence, while negative scores indicated the concern of medication was the primary influence of medication adherence or non-adherence. Scores of zero indicated neutral reaction to necessity and concern.

Data Analysis

The statistical package SPSS v19 for Windows was used to analyze the data and address the research questions and hypotheses. Descriptive statistics using percentages and frequency distribution were used to capture the demographic profile of the sample, and mean values of each variable. Because ordinal data points were captured for each variable, non-parametric testing was selected as well as Spearman's rho correlation coefficient matrix. Relationships between the dependent variable of medication adherence and each independent variable were explored using Kruskal-Wallis test as an alternative to the parametric one-way analysis of variances (ANOVA). Regression analysis was used to address the predictability that perceived severity, belief about

medication, and necessity-concern had on the dependent variable of medication adherence.

Each hypothesis used a significance level of $p < 0.05$. Data analyses addressed the research questions and hypotheses below:

1. Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, what factors (perceived severity, belief about medication and necessity-concern) mediate or serve as barriers to medication adherence.
2. Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, which factor(s) of perceived severity, belief about medication and necessity-concern differential predict medication adherence?

The hypotheses were:

1. H_o: Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, there is no statistically significant difference in medication adherence among the different HF severity classification groups.
2. H_o: Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, there is no statistically significant difference in medication adherence among the different beliefs about medication groups.

3. H_o: Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, there is no statistically significant difference in medication adherence between the necessity and concerns groups.

Summary

The research methodology consisted of primary data collection using convenience sampling at two clinic locations in Texarkana, Arkansas. A consent form was created and the NYHA Self-Assessment Scale, MSRMS and BMQ survey instruments were used. The survey was anonymous and required no personal identifiable information. Upon IRB approval, recruitment flyers were posted at the clinic locations at predetermined dates. Participants were given options of completing the questionnaires during an office visit and then returning the questionnaire to a secured lock box, or complete the survey at home and mail to a secured Post Office Box. The research recruitment packet included an introduction letter, consent form, questionnaire and a self-addressed envelope. During both recruitment options, the participants received detailed information about the purpose of the study and study procedures. To prevent duplication, participants were asked not to return the questionnaire by mail if they plan to complete it at either clinic location. Participants were also informed their individual results would be anonymous and participating in the study would not have any bearing on current or future medical treatment.

Basic demographic information was collected to further define variable relationships. The demographic information included age, gender, racial background, diagnosis, duration of medication treatment (prescribed greater than two months), quantity of prescribed medications, and treatment location within the clinic. Both descriptive and inferential statistical tests were conducted to address research questions.

CHAPTER IV

ANALYSIS OF DATA

The purpose of this study was to examine the relationships among perceived severity, beliefs about medication, necessity-concern of medication and medication adherence among Medicare eligible patients with HF receiving treatment from the UAMS-AHEC. While the target population was fairly homogeneous in socioeconomic status, demographic data were collected to examine potential associations between or among select variables and medication adherence. From the final sample, survey data was analyzed using descriptive statistics and inferential statistical tests.

Sample

The clinic official assigned as the primary contact for the research study identified the total patient population (N= 519) with the corresponding ICD-9 codes indicating a positive HF diagnosis. Two data collection methods were approved for the research study; however, only the mailing option proved successful in obtaining completed questionnaires. Twenty research packets were returned due to incorrect mailing addresses. This could have been indicative of the patients no longer residing in the geographical area, or no longer receiving care at the clinics. These were removed from the total population, resulting in a

final patient population of N = 499, in which questionnaire deliveries were assumed successful. Eighty-one questionnaires were subsequently returned to the Post Office box designated for the research study. While the final sample was small, it exceeded the minimum response rate goal of 15%.

Descriptive Statistics

Descriptive statistics using frequencies and percentages provided a demographic profile of the final sample. The final sample (n=81) had a mean age of 61.43 years, but seven participants did not provide their age, thus the age variable consisted of n=74 participants (see Table 3 in appendices H). The minimum age was 24 years and maximum was 90 years. Approximately 70% (n=57) participants were female with mean age of 60.2 years and 29.6% males (n=24) with mean age of 64 years. The largest racial group was African Americans at nearly 47% of the sample and second largest was white/Caucasian at 43%.

All participants indicated they were taking medication; however, the majority (n=64) did not report their specific medications. The average number of different medication prescribed or taken was 4.2. Participants' scoring from the MSRMS identified which medication adherence category or group they were placed, resulting in a 3-level grouping for the dependent variable of medication adherence. Approximately twenty-two percent of the sample (n=18) placed in the high adherence (HA) category, 33.3% (n=27) fell in the moderate adherence

(MA) category, and 44.4% (n=36) were in the low adherence (LA) category (see Table 4 in appendices H). Male participants had a fairly even distribution between medication adherence groups, 33.3% HA category, 29.2% MA category, and 37.5% LA category. Female participants were as follows: 15.8% HA category, 35.1% MA category, and 49.1% LA category. Note the low medication adherence category was the largest in both genders (see Table 5 in appendices H).

Recall belief about medication was measured using the BMQ measurement scale. Participants were placed in three categories or groups based upon a summative score. The positive belief about medication group was identified if the summative score was < 47; neutral belief group if the summative score = 47; and negative belief group if the summative score was > 47. Fifty-eight % of the participants (n=47) had negative beliefs about medications, 34.6% (n=28) had positive beliefs about medications, and the remaining 7.4% (n=6) had neutral beliefs about medications (see Table 4 in appendices H). Approximately fifty-eight % of male (n=24) and female (n=57) participants reported negative beliefs about medications (see Table 6 in appendices H). Again, the negative belief about medication group was the largest.

Recall the BMQ measurement scale was also used to capture the necessity-concern differential variable. The necessity-concern differential measured attitudes about the necessity of medication and concerns about the

potential adverse constraints or cost of taking the medication. This variable was considered a cost-benefit measurement. The difference between the summative necessity and concern score was used to calculate the differential variable. This variable categorized the participants based upon whether the necessity or benefit of medication outweighed their concerns or cost of the medication, or vice versa. Nearly 83% of the sample (n=67) indicated the necessity or benefit of their medications outweighed their concerns or the cost of medication. Approximately 14% (n=11) indicated that concern or cost about their medication outweighed the necessity or benefit of their medications. The remaining 3.7% (n=3) were neutral in their attitude regarding necessity and concern.

The frequency of the BMQ individualized questions supported higher scores for the measurements of necessity over concern in the specific items (Section 4) of the research instrument (see Table 7 in appendices H). Seventy-two % to 85.2% of the participants reported agree to strongly agree on each question related to necessity of medications. Twenty-two % to 44.4% of the participants reported agree to strongly agree on each question related to concerns of medications.

Inferential Statistics

Statistical testing was conducted to explore relationships between the dependent and independent variables in order to answer the research questions and address the null hypotheses. Using SPSS v19, non-parametric tests were

performed because of the ordinal level data collected. An initial Spearman's rho correlation matrix was calculated to explore the relationship(s) among all variables. As an alternative to the parametric analysis of variance (ANOVA), the nonparametric Kruskal-Wallis analysis of variance method was used to examine any statistically significant differences between medication adherence and each independent variable. Lastly, multinomial regression analysis was used to examine the predictability of perceived severity, belief about medication and necessity-concern on medication adherence.

At p = .05, Spearman's rho correlation coefficients indicated no significant difference between medication adherence and perceived severity, but the correlation between medication adherence and belief about medication was found to be significant at r = .346 (see Table 8 in appendices H). Also, the correlation between medication adherence and necessity-concern was significant (r = -.298), yet negative. Since necessity was coded as "1" and concern coded as "2", this was suggestive that medication adherence increased when necessity or benefit outweighed concern.

To further explore these relationships or confirm statistical significant differences at the group-levels, analyses of variance were calculated using the Kruskal-Wallis analysis of variance method at significant level p = .05. There was no statistically significant difference found in medication adherence and perceived severity across the four groups of Mild I, Mild II, Moderate and Severe

($H=X^2 = 2.359$, p=.501) (see Table 9 in appendices H). The highest mean rank ($\mu_r = 48.20$) was in the Mild I severity group. The highest mean rank indicated which group corresponded to the highest group of the dependent variable of medication adherence, being the HA group (Pallant, 2010). With only n=5 in the Mild I group, the perceived severity groups were collapsed to three groups of Mild, Moderate and Severe. Another Kruskal-Wallis analysis of variance was calculated, and again no statistically significant difference was found ($H=X^2 = 2.193$, p=.334) (see Table 10 in appendices H). Even though there was no statistically significant difference, the results confirmed the Mild severity group had the highest mean rank ($\mu_r = 44.57$), which indicated participants perceiving their HF diagnosis as mild had the highest medication adherence.

Statistically significant difference was found in medication adherence and belief about medication across the three groups of neutral, negative and positive belief ($H=X^2 = 10.675$, p=.005) (see Table 11 in appendices H). The positive belief group had the highest mean rank ($\mu_r = 50.96$), which indicated participants with positive belief had higher medication adherence. Due to the small sample size (n=6) in the neutral belief group, this group was removed and another test was run. Statistically significant difference was again found between the negative and positive belief groups ($H=X^2 = 10.243$, p=.001) and the positive belief group still had the highest mean rank ($\mu_r = 47.68$) (see Table 12 in

appendices H). Follow-up post-hoc testing was not needed because the number of groups was collapsed to only the two groups.

Statistically significant difference was also found in medication adherence and necessity-concern across the groups of neutral, necessity and concern ($H=X^2 = 7.089$, $p=.029$), with the neutral group having the highest mean rank at $\mu_r = 57.50$ (see Table 13 in appendices H). However, since the neutral group was small (n=3), this group was omitted and the test recalculated. Statistically significant difference was again found in medication adherence and the two groups of necessity and concern ($H=X^2 = 5.330$, $p=.021$) (see Table 14 in appendices H). The necessity group had the highest mean rank ($\mu_r = 41.72$), which indicated participants who believed the necessity or benefit of their medications outweighed their concerns or cost of medication had higher medication adherence. Again, follow-up post-hoc testing was not needed because the number of groups was collapsed to only two groups due to the small sample representing the neutral group.

Regression Analysis

In addition to the analyses of variance testing, a multinomial logistic regression model was calculated in an attempt to identify the predictability of perceived severity, belief about medication, and necessity-concern across the medication adherence groups. In regression analysis, it was recommended to combine or omit sub-groups with small sample sizes (Pallant, 2010). The

perceived severity variable groups of Mild I (n=5) and Mild II (n=24) were combined to form one Mild group (n=29). The belief about medication neutral group (n=6) was omitted, reducing this variable to negative belief (n=47) and positive belief (n=28) groups. The necessity-concern neutral group (n=3) was omitted, reducing this variable to necessity (n=67) and concern (n=11) groups. This resulted in a total of 9 missing values (see Table 15 in appendices H). Using only the response-combination with no missing value, the final sample for regression analysis was n = 72. The final combination of responses was displayed in Table 16 in appendices H. Note there were no medication adherence responses associated with Mild severity-positive belief-concern for medication. Also there were no medication adherence responses associated with Severe severity-positive belief-concern for medication.

Due to the small sample sizes in the individual cells, caution was noted in the interpretation of the regression output. At $p \leq .05$ with LA medication as the reference group, the belief about medication was the only significant predictor ($b = -2.39$, Wald $X^2(1) = 10.11$, $p < .05$) of medication adherence (see Table 17 in appendices H). The odds ratio (OR) inferred that as belief about medication changed from negative to positive, the change in odds of being HA compared LA was 0.092. In other words, the odds of a positive belief participant being classified as high medication adherence was (1/.092) 10.87 times more likely than a negative belief participant being high adherence. Thus, participants with

negative beliefs about medication were less likely to report HA medication. Note from Table 16 in appendices H, this has been confirmed, because no participant in the negative belief about medication group reported high medication adherence. Even though perceived severity and necessity-concern were not significant predictors of medication adherence (all p-values ≥ .05), the necessity-concern ORs for the MA and HA groups were nearly 7 and 5.5, respectively, as compared to the reference LA group.

Qualitative Data

The research yielded minimal qualitative responses from the participants. Therefore, caution was noted in the interpretation of results. The responses revealed by the Medicare eligible men and women participating in the research study identified underlying conflicts that deserved careful consideration in the data analysis. Seven participants with positive beliefs about medications provided qualitative responses; only 4 were related to the research variables (see Table 18 in appendices H). There were 2 participants with positive beliefs about medications that reported concerns with access to care. Fifteen participants with negative beliefs about medications provided qualitative responses; only twelve were related to the research variables. Table 19 in appendices H, outlined the qualitative responses of participants with negative beliefs about medications. One of the notable findings that emerged from the qualitative responses was

participants with negative beliefs about medication also believed medications were necessary for HF management.

Summary

Primary data collection using an anonymous questionnaire provided rich data points for the targeted population. While a small sample (n=81), both the demographic data points and research specific data points were sufficient in examining the relationships between the dependent variable of medication adherence and independent variables of perceived severity, beliefs about medications, and the necessity -concern about medication. The rural patient population was fairly homogenous in terms of socioeconomic status. Descriptive statistics revealed a sample with a broad age range with varying perceptions of HF severity levels The majority had negative beliefs about medication yet an overwhelming majority believed the necessity or benefits of medication outweighed their concerns or the cost of medication. Medication adherence was found to be statistically significant different between the belief about medication and necessity-concern groups. Also, the belief about medication variable was found to be the best predictor of medication adherence.

Qualitatively, the reported concerns and attitudes expressed by the sample population were generally consistent across both participants with positive beliefs about medications and participants with negative beliefs about medications. A few exceptions emerged in participants with negative beliefs

about medications. Participants with negative beliefs about medication were concerned with physician collaboration, side effects of medications, and fear of addiction to medications. For example, one participant wrote, “Doctors prescribe heart medication one time and could not get in to see the doctor to get a refill. I’m always switched to a different doctor. The hospital doctors and clinic doctors do not seem to be on the same page difficult to get refills and miss a few days of meds because pharmacists are waiting on calls from doctors.” An additional comment included, “Fluid pill increase my urination, when I go to Wal-Mart it wipes me out. A final comment included, “I know my limits-on worse days don't do physical activities; retired nurse afraid of becoming addicted to anything.”

CHAPTER V

CONCLUSIONS AND RECOMMENDATIONS

HF is the leading cause of hospitalizations in adults older than 65 years of age (Bryg, 2009). Approximately 5.7 million people in the United States have been diagnosed with HF, costing the United States $34.4 billion each year (CDC, 2012a). Treatment for those who suffer from HF relies heavily upon medication adherence and following other treatment regimens. Nonadherence to medications is a universal concern for patients with cardiovascular diseases, including HF (Ho et al., 2009). Medication adherence is a growing concern to healthcare providers, healthcare systems, and other stakeholders because of mounting evidence that nonadherence is prevalent and linked with adverse health outcomes and higher costs of care.

Patients' beliefs and attitudes can have a positive or a negative influence on medication adherence (Gatti et al., 2009). This research study has a quantitative assessment using the HBM theoretical framework, with an aim to examine medication adherence in Medicare eligible patients with a documented ICD-9 classification indicative of HF. A convenience sample of 81 participants was recruited from UAMS-AHEC clinic locations, FMC and TCC. Data analyses using similar methods described by Horne and Weinman (1999) provided a systematic methodology for conducting the research study. A summary and

discussion of the findings were provided below. Interpretations of findings were drawn and recommendations for clinical practice and future or follow-up studies were proposed.

Summary of Research Design

Designed as a quantitative research study, the key purpose of the research was to examine independent variables that influence medications and medication adherence among HF patients receiving care at UAMS-AHEC in Texarkana, Arkansas. An anonymous questionnaire was distributed to participants at the clinic locations or by mail to capture demographical data (gender, age, insurance, and clinic) and other data points adopted from existing survey instruments to include MSRMS, NYHA and BMQ. The key dependent variable was medication adherence and the independent variables of perceived severity level, beliefs about medications, and necessity-concern of medication.

Discussion of Findings

Even the best medications can be rendered ineffective if not taken as prescribed. Medication nonadherence is a major issue in the United States, yielding negative health outcomes for people with chronic diseases (Bardi, 2013). Although the origins and remedies of medication nonadherence have been debated for at least three decades, the problems have been disregarded as a severe public health concern. As a result, the constructs associated with medication nonadherence have received diminutive direct, systematic, or

sustained interventions to surmount this challenge (NCPIE, 2007). The overall findings of this study show this rural sample to be consistent with the research study of Horne and Weinman (1999). The majority of the sample (*n* = 63, 78%) demonstrate moderate to low medication adherence, meaning those patients are not taking their medication as prescribed. Several factors are identified as concerns with HF patients in this rural area. First, approximately 58% of the participants state they had negative beliefs about medications. Negative beliefs about medications are associated with low medication adherence. On the contrary, 83% of the sample report the necessity or benefits of their medications outweigh the concern or cost of their medications.

The frequencies of the gender class highlight several interesting concepts. First, 58 % of males have negative beliefs about medications. The male participants represent a fairly homogeneous distribution between each medication adherence category. Approximately 71% of males with negative beliefs about medication feel necessity of medications outweigh the concern of medications. In addition, 58% of females have negative beliefs about medications. However, female participants are 3.1 times likely to represent LA than HA. Approximately, 79% of females with negative beliefs about medication feel the necessity of medications outweigh the concern of medications.

The frequencies of the BMQ individual questions further support the overarching necessity of medications. Approximately, 82% reports agree to

strongly agree to the question “Without my medications I would be very sick”. In addition, 80% reports agree to strongly agree to the question “My current health depends on my medication”. In comparison, 44% reports agree to strongly agree to the question, “I sometimes worry about the long term effects of my medications”. There is an even distribution of data related to the question, “If doctors had more time with patients, they would prescribe fewer medication”. Thirty % of participants’ reports agree to strongly agree, 32% reports neutral, while the remaining 35% reports disagree to strongly disagree.

The frequency of the BMQ individualized questions and qualitative responses further support the participants view treatment for HF requires medications. The most prominent theme among participants with negative beliefs about medication relates to the necessity of medications to treat HF. The following theme relates to the quantity of medications and the frequency of taking medications. Finally, the themes related to side effects of medication and physician collaboration with other healthcare providers are repetitive in this sample. Necessity to treat HF and access to care are prominent themes of participants with positive beliefs about medication reports.

Research Questions

Various statistical tests are conducted to explore relationships between the dependent and independent variables to address the research questions and null hypotheses. The first research question state: Among Medicare eligible HF

patients residing in two rural counties located in Texas and Arkansas, what factors (perceived severity, belief about medication and necessity-concern) mediate or serve as barriers to medication adherence? The initial Spearman's rho correlation matrix indicates belief about medication had the strongest association with medication adherence. Analysis of variance testing confirms a statistically significant difference in medication adherence between participants with positive beliefs and patients with negative beliefs about medication. Also statistically significant difference in medication adherence is found between the necessity-concern groups. With participants indicating the necessity of medication outweigh their concern having greater adherence. As such, belief about medication and the necessity of medication have positive impacts or mediate medication adherence.

Research question two states: Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, which factor(s) of perceived severity, belief about medication and necessity-concern differential predict medication adherence? A multinomial logistic regression model is calculated in an attempt to identify the predictability of perceived severity, belief about medication, and necessity-concern across the medication adherence groups. Due to the small sample sizes distributed across the individual responses, caution is noted in the interpretation of the regression output. The results indicate belief about medication is the only significant predictor of

medication adherence. The odds of a positive belief participant being classified as high medication adherence is 10.87 times more likely than a negative belief participant being high adherence. Thus belief about medication is the best predictor of medication adherence.

Null Hypotheses

The first hypothesis states: H_o: Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, there is no statistically significant difference in medication adherence among the different HF severity classification groups. Kruskal-Wallis analysis of variance method at significant level p = .05, with the Mild groups combined, indicates no statistically significant difference was found in medication adherence across the different severity levels. Therefore, the results fail to reject the null hypothesis.

The second hypothesis states: H_o: Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, there is no statistically significant difference in medication adherence among the different beliefs about medication groups. Kruskal-Wallis analysis of variance method at significant level p = .05 finds statistically significant difference between the negative and positive belief groups. Therefore, the results reject the null hypothesis.

The final hypothesis states: H_o: Among Medicare eligible HF patients residing in two rural counties located in Texas and Arkansas, there is no

statistically significant difference in medication adherence between the necessity and concerns groups. Kruskal-Wallis analysis of variance method at significant level p = .05 finds statistically significant difference in medication adherence and the two groups of necessity and concern. Therefore, the results reject the null hypothesis.

Limitations

Participation in the study was voluntary and participants were selected based on their previous diagnosis of HF. This method of nonprobability sampling does not allow outcome generalizations to population groups beyond the region. Both the FMC and TCC only treat patients within the northeast Texas and southwestern Arkansas regions; therefore, comparison to other population groups is limited to the geographical locations. Participant recruitment was not limited to a particular race or ethnicity. Consequently, all individuals within the inclusion criteria requirements had an equal chance to participate in the study. It was estimated that participants required nine years of education to fully comprehend the questionnaire; therefore, participants may have erred in their responses. Due to cognitive decline among elderly participants, the format of the research instrument can be limitation to the research study. Participants in this study may have been hesitant to convey some of their attitudes and beliefs about the behaviors associated with medication adherence. The participants may have failed to recall earlier behaviors associated with medication adherence, and thus

provided inaccurate data. The study did not evaluate the degree of comorbidity in the sample and cannot rule out the possibility that participants were receiving medication for comorbidity conditions in addition to the medication prescribed for their HF diagnosis.

Conclusions and Implications

The conclusions of this study are as follows: (a) nonadherence to medications was common among this sample group of HF patients; (b) study findings confirm the concept that medication adherence is a multifaceted phenomenon influenced by many modifying factors, with patients' beliefs about medication as a key function; (c) nonadherence to medications is not exclusively related to patient's beliefs and (d) study findings supported the supposition that patients make decisions about behaviors associated with medication adherence based on an inherent cost-benefit analyses. Study findings highlight the need to elicit information related to patients' beliefs about medications at the clinic level of care to assess their predicted medication adherence. Patients, being active decision-makers, will be more motivated to use their medication as instructed if their belief in its necessity outweigh their concerns about taking the medication as prescribed.

Advances in medicine and technology provide the potential for longer and healthier lives. However, unrelenting and well documented health disparities continue to outweigh the efforts of healthcare providers. Governmental efforts,

such as Healthy People 2020 and Patient Protection and Affordable Care Act (PPACA), seek to decrease health disparities and reduce overall healthcare cost while improving patients quality of life. Healthy People 2020 outline health literacy as a component associated with inferior health outcomes and higher costs (U.S. Department of Health and Human Services [DHHS], 2010). Limited health literacy affects people of all socioeconomic levels, but the impact of limited health literacy disproportionately affects the lower socioeconomic and minority groups (DHHS, 2001). Improving health literacy is critical to achieving the objectives of Healthy People 2020. Decreasing the chasm of knowledge between healthcare professionals and patients can improve the basic fundamentals of healthcare delivery, resulting in improved outcomes related to medication adherence of lower socioeconomic and minority groups.

The Congressional Budget Office (CBO) released a report, projecting large savings in healthcare as a result of the PPACA; Medicare patients have saved $5 billion in prescription drug cost since 2010 (Johnson, 2012). This law improves the prescription coverage of Medicare recipients by closing the gap in out of pocket cost. The DHHS projects Medicare recipients will save more than $18,000 between 2012 and 2022, while sustaining their medication regimen. It is postulated that helping Medicare recipients afford their medication will result in increased medication adherence leading to lower mortality and healthcare cost.

Ambulatory care personnel often observe modifying factors that contribute to healthcare disparities associated with medication nonadherence, but hesitate to address the factors. The implications of this research study may support and link the significant role of health education in addressing health disparities, such as health literacy, within the targeted population. Implications related to the study include: (a) data to advocate for regulatory changes to remove health disparities associated with medication adherence, (b) design an avenue to share information about best practices in medication adherence education and management, (c) implement professional training and increase professional education to clinicians dealing with patients and medication adherence, (d) implement a team approach to educate patients at point of care and (e) assess the health literacy of patients prior to administering education. These strategies will assist patients with learning capabilities, enhancing their ability to manage their HF and increase medication adherence. Outcomes from this research study can provide clinicians knowledge and insight into factors that influence medication adherence among Medicare eligible HF patients in the geographic locale.

Recommendations for Further Study

Substantial evidence and research studies document that many patients with chronic diseases have difficulty adhering to their suggested medication regimen. The multifactorial constructs allied with poor medication adherence

implies only constant, coordinated efforts will ensure optimal medication adherence and realization of full benefit of treatment regimens (Brown & Bussell, 2011). Obtaining a better understanding of beliefs and attitudes associated with medication adherence is imperative in decreasing health disparities and healthcare expenditures associated with HF. The study results reveal a difference in access to care associated with the FMC and TCC clinics. The TCC clinic was a grant-funded clinic providing care to uninsured patients. This was not the focal area of the present study; therefore, the follow-up research questions are recommended for further evaluation at the geographical locations.

1. Is there a difference in medication adherence scores between patients receiving care from FMC and TCC?
2. Is there a difference in necessity-concern differential scores between patients receiving care from FMC and TCC?

Additional research recommendations include: (a) further research to assess the degree of comorbidity and rule out the possibility that patients receiving medication for comorbidity conditions in addition to medications prescribed for HF contribute to medication adherence, (b) a randomized control trial to evaluate the effectiveness of education provided in clinical settings, (c) examination of the effects of health literacy on enhancing education, knowledge, and medication adherence with chronic disease management, and (d) examine

the efficiency of patient hand-off with physicians completing residency at the FMC.

Future research methodologies should include a mixed method of data collection for this population. Sinclair, O'Toole, Malawaraarachchi, and Leder (2012) reports mail survey as the most cost effective community based survey approach; however, telephonic survey approach yields a higher response rate. Kaldenbert, Koeing, and Becker (1994) reports there are inefficiencies with obtaining face to face information from the elderly due to the decrease comfort level of face to face interviews with healthcare providers. Therefore, it is recommended to use a mixed method with the telephonic and mail approach to increase the survey return rate. In addition to the mixed method approach, incentives have the potential to increase survey return rate.

Patients with HF are prescribed an assortment of evidence-based medications to optimize outcomes, as well as medications for commonly related comorbidity conditions, such as hypertension and diabetes (Dunlay et al., 2011). Socioeconomic factors such as subordinate education attainment and low health literacy have been correlated with medication nonadherence due to the patients' inability to comprehend the complexity of the regimen and the perceived or experienced side effects (Ho et al., 2009). Therefore, an important goal of healthcare systems and all stakeholders must be to shift the effectiveness

archetype of medication adherence closer to what is achievable in efficacy settings (Epstein, 2011).

Summary

The conclusions from this research study provided a better understanding of how perceived severity of HF, beliefs about medication and necessity or concern of medication influence medication adherence in Medicare eligible HF patients. Understanding the patients' beliefs and other modifying factors with medication adherence is fundamental to eliminating health disparities. The conclusions and implications from this study may encourage healthcare professionals to provide effective patient education about medication adherence and other possible health outcomes at the clinic level of care. As the Patient Affordability and Accountable Care Act move forward, the emphasis on preventative medicine, such as medication adherence, will increase dramatically.

The conclusions from this study support the behavioral aspects of medication adherence. Intrapersonal levels of influence play a key role in participants' health outcome. The cost-benefit analysis (necessity-concern differential) noted participants view necessity to medication over cost of medication, yet majority of the sample exhibit low medication adherence. Participants with negative beliefs about medications report themes indicative of decreased knowledge of medications and lack of collaborative treatment efforts

among providers. Both have the potential to decrease health outcomes among the study population.

The implications of this research study support and link the role of health education in addressing health disparities, such as health literacy, within the targeted population. This study only assesses cost as a barrier to medication adherence, but aforementioned research references other perceived barriers to health outcomes. The qualitative data outlined side effects and addictive behavior as a potential intrapersonal level of influence that may hinder medication adherence. Enhancing health education at the clinic level with credentialed health educators to identify and address health disparities at the clinic level will decrease the knowledge gap associated with medication adherence and health outcomes of the targeted population. This study contributes to the behavioral science of health determinants by reinforcing the importance of evidence-based interventions and further research regarding health disparities and chronic disease management.

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APPENDIX A

SMOG Readability Index

Examining the Relationships between Patient's Beliefs about Medication and Medication Adherence among Patient with Heart Failure

1. What is your gender?
2. What is your age?
3. Do you have Medicare Insurance Coverage?
4. Have you been diagnosed with Heart Failure?
5. If no, provide the best response to the following statement:
   "I am likely to get heart failure in the future"
6. Which clinic do you attend?
7. What best describes your race?
8. Are you currently prescribed a daily medication to treat heart failure?
9. Please list daily medication(s) and prescribed dosage, list one medication per box
10. Do you sometime forget to take your medications?

    Total: 7

1. When you feel like your symptoms are under control, do you sometimes stop taking your medications?
2. Taking medications everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?
3. How often do you have difficulty remembering to take all your medications?
4. There are no restrictions of physical activity.
5. I generally don't become overly tired or experience shortness of breath.
6. I'm in control the disease.
7. I exercise regularly, limiting alcohol consumption, and eat healthy (with moderate sodium intake)
8. I will feel slight restrictions with everyday physical actions like bending over or walking.
9. I will experience getting tired and shortness of breath.
10. Non-invasive surgical procedures like ACE-Inhibitors or Beta Blockers (medications) may be considered.

    Total: 19

1. My medications disrupt my life
2. I sometimes worry about becoming too dependent on my medications
3. My medications protect me from becoming worse
4. Doctors prescribed too many medications
5. People who take medications should stop their treatment for a while every now and then
6. Most medications are addictive
7. Medications do more harm than good
8. All medications are poisons
9. Doctors place too much trust on medications
10. If doctors had more time with patients, they would prescribe fewer medications

    Total: 12

    7+19+12=38

    Square root 38=6.1

    6.1+3=9

    READABILTIY INDEX 1.5 =/- 9th grade reading level

APPENDIX B

Introduction Letter

Dear Sir or Ms.
You are being invited to participate in a research study being conducted by UAMS Family Medical Center and Rosalind Washington (Primary Investigator), doctoral candidate at Texas Woman's University. The objective of this research project is to attempt to understand medication adherence among patients with heart failure in our organization. You are receiving this letter as a potential participant. Under the Privacy Act and HIPPA guidelines, no identifiable information related to you or your health has been shared with the PI or Texas Woman's University.

Participation is strictly voluntary; you may choose to participate or not participate as you wish without penalty. Enclosed with this letter is a brief questionnaire that asks a variety of questions related to demographics and medication adherence. We are asking you to look over the questionnaire and, if you choose to do so, to complete the questionnaire and to send it back to us in the ***pre-paid postage envelope*** provided by January 15, 2013. **Do not write your name on the questionnaire**. We do not need to know who you are.

The results of this project will be summarized and appropriate people with the UAMS Family Medical Center will be given a summary report. We hope you will take a few minutes to complete this questionnaire and to return it in the enclosed self-addressed and envelope. There is no postage required.

We emphasize that this is a research project. We guarantee that your choice to participate and your responses if you do participate will not be identified with you personally. Nothing you do or say will in any way reflect your past or even future treatment with the clinic. Without the help of people like yourself, research with patients would not be conducted. Regardless of whether you choose to participate or not, a summary of our findings will be available to you at the clinic.

Understanding why people comply or not comply with their medication is important to our clinic as well as our community. Through your participation, we hope to understand how to best satisfy the needs of our patients. We ask your participation, and thank you for reading this letter.

Cordially,

_____
Pat Evans, Clinical Director

_____
Rosalind Washington, TWU Doctoral Candidate

This project has been reviewed by Texas Woman's University Committee for the Protection of Human Subjects (phone: 940-898-3375).

APPENDIX C

Recruitment Flyer

Texas Woman's University

Doctoral Candidate is conducting a study:

Examining the Relationships between Patient's Beliefs about Medication and Medication Adherence among Patient with Heart Failure

Are You:

Medicare Eligible

Diagnosed with Heart Failure for at least 2 months

Prescribed at least one medication to address Heart Failure at least two months prior to date, and must be required to take the medication for at least another 30 days

If **YES**:

You are invited to participate in a research study

Purpose of Study: To explore the relationship between health beliefs about medication and medication adherence among patients with heart failure (HF), a profound heart disease. The study is being conducted as part of a graduate dissertation.

- The study is strictly ***voluntarily*** and ***anonymous***
- Results of the study will be available to the clinics within six months of successful completion of the research and dissertation

If you have any questions about the study, please contact:

Primary Investigator: Rosalind Washington 903-244-9827 or RWashington2@twu.edu Faculty Advisor: Dr. Kimberly Parker 940-898-2899 or KParker6@twu.edu

There is potential risk of loss of confidentiality in all email, downloading, and internet transactions

APPENDIX D

Recruitment Script

Examining the Relationship between Patient's Beliefs about Medications and Medication Adherence among Patients with Heart Failure

My name is Rosalind Washington, a graduate student from the Department of Health Studies at Texas Woman's University. I would like to invite you to participate in my research study to explore the relationship between health beliefs about medication and medication adherence among patients with heart failure (HF), a profound heart disease. You may participate if you meet the following criteria:

- Females: Not pregnant
- Receiving care at the University of Arkansas for Medical Science (UAMS) Family Medical Center and Texarkana Community Clinic in Texarkana, Arkansas.
- Diagnosed with HF at least two months prior to completing the questionnaire
- Participants must be prescribed at least one medication to address HF at least two months prior to completing the questionnaire as well, and must be required to take the medication for at least 30 days beyond the time the participant completes the questionnaire.
- Patients must have Medicare insurance to cover financial cost associated with treatment and medications

There are no known physical risks if you decide to participate in this research study. Minimal risks include loss of confidentiality of questionnaire information, loss of confidentiality of communications via email, and loss of anonymity. There are no costs to you for participating in the study. The questionnaire will take about 15-20 minutes to complete. The information collected may not benefit you directly, but the information learned in this study should provide more general benefits.

If you would like to participate in this research study each potential participant will be provided a consent form, but no signature will be required. Review of the consent will be done in private. The PI will review the consent, explain the purpose of the study and the questionnaire instrument. Participants will be allowed to ask questions throughout the entire process.

The questionniare will be distributed to individuals agreeing to participate. Completion of the questionnaire will indicate consent to participate. Completion of the questionnaire may be done immediately in the treatment room and placed directly in a secure-box by the particpant, completed at home and mailed, or hand delivered to the PI only at the clinic. A self-addressed stamped envelope will be provided to individuals wishing to complete Questionnaire at home.

You are allowed to stop participation in the study at any time.

Within six months of successful completion of the research and dissertation, copies of the study results will be provided to each location to be disseminated or made available to participants. The study results will include an aggregate total of the responses with no identifiable information. Dissemination will be made via hand-outs at the clinic locations waiting rooms and treatment rooms. The participants will be told this information during the recruitment phase.

Do you have any questions now? If you have questions later, please contact me or my advisor at: Primary Investigator: Rosalind Washington 903-244-9827 or RWashington2@twu.edu Faculty Advisor: Dr. Kimberly Parker 940-898-2899 or KParker6@twu.edu

There is potential risk of loss of confidentiality in all email, downloading, and internet transactions

APPENDIX E

Questionnaire Instrument & Consent to Participate in Research

The return of your completed questionnaire constitutes your informed consent to act as a participant in this research

Section 1: Demographics (*Please indicate the option that best describes you)*

What is your gender?	☐ Male ☐ Female	Which clinic do you attend?	☐ Family Medical Clinic ☐ Texarkana Family Clinic
What is your age?		What best describes your race?	☐ African American ☐ American Indian ☐ Asian/Pacific Islander ☐ Mexican Latino ☐ White/Caucasian ☐ Other:_____
Do you have Medicare Insurance Coverage?	☐ Yes ☐ No		

Have you been diagnosed with Heart Failure?	☐ Yes ☐ No If yes, provide the estimated date of diagnosis: _____	If no, provide the best response to the following statement: **"I am likely to get heart failure in the future"** ☐ Strongly Disagree ☐ Disagree ☐ Uncertain ☐ Agree ☐ Strongly Agree

Section 2: Medication Adherence *(We would like to ask about your current medication regimen. There is no right or wrong answer)*

Are you currently prescribed a daily medication to treat heart failure?	☐ Yes ☐ No If yes, provide the estimate date prescribed:		
Please list daily medication(s) and prescribed dosage List one medication per box			
	Use back of consent sheet if you need additional space		

Section 2a: Medication Adherence

We would like to ask about your personal views related to adherence with your medications. Please check your response. There is no right or wrong answer.

Do you sometime forget to take your medications?	☐ Yes ☐ No	Did you take all your medications yesterday?	☐ Yes ☐ No
Thinking over the past 2 weeks, were there any days when you did not take your medications?	☐ Yes ☐ No	When you feel like your symptoms are under control, do you sometimes stop taking your medications?	☐ Yes ☐ No
Have you ever cut back or stopped taking your medications without telling your doctor because you felt worse when you took it?	☐ Yes ☐ No	Taking medications everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	☐ Yes ☐ No

When you travel or leave home, do you sometimes forget to bring along our medications?	□ Yes □ No	How often do you have difficulty remembering to take all your medications?	□ Never/rarely □ Once in a while □ Sometimes □ Usually □ All the time

Section 3: Classification of Heart Failure

We would like to ask about your personal views about your physical symptoms associated with heart failure in general. Please circle only one letter that best describes your daily symptoms and treatment regimen. There is no right or wrong answer.

A.	There are no restrictions of physical activity. I generally don't become overly tired or experience shortness of breath. I'm in control the disease. I exercise regularly, limiting alcohol consumption, and eat healthy (with moderate sodium intake)
B.	I will feel slight restrictions with everyday physical actions like bending over or walking. I will experience getting tired and shortness of breath. Non-invasive surgical procedures like ACE-Inhibitors or Beta Blockers (medications) may be considered.
C.	I experience definite limitations during physical activity. I remain comfortable at rest, but most all physical activity will cause undue fatigue. I'm under physician care, my diet and exercise is monitored. I'm on diuretics, to combat water retention.
D.	I'm virtually unable to do any physical activity without discomfort. There may be significant signs of cardiac problems even while resting. Surgical options will be explored.

Section 4: Belief about Medication

We would like to ask about your personal views about your medicine and medicine in general. Please circle your response. There is no right or wrong answer.

Specific Items		General Items	
My current heath depends on my medications	□ Strongly Disagree □ Disagree □ Uncertain □ Agree □ Strongly Agree	Doctors prescribed too many medications	□ Strongly Disagree □ Disagree □ Uncertain □ Agree □ Strongly Agree
Having to take medications worries me	□ Strongly Disagree □ Disagree □ Uncertain □ Agree □ Strongly Agree	People who take medications should stop their treatment for a while every now and then	□ Strongly Disagree □ Disagree □ Uncertain □ Agree □ Strongly Agree
My life would be impossible without my medications	□ Strongly Disagree □ Disagree □ Uncertain □ Agree □ Strongly Agree	Most medications are addictive	□ Strongly Disagree □ Disagree □ Uncertain □ Agree □ Strongly Agree
I sometimes worry about the long term effects of my medications	□ Strongly Disagree □ Disagree □ Uncertain □ Agree □ Strongly Agree	Medications do more harm than good	□ Strongly Disagree □ Disagree □ Uncertain □ Agree □ Strongly Agree □

Without my medications I would be very sick	☐ Strongly Disagree ☐ Disagree ☐ Uncertain ☐ Agree ☐ Strongly Agree	All medications are poisons	☐ Strongly Disagree ☐ Disagree ☐ Uncertain ☐ Agree ☐ Strongly Agree
My medications are a mystery to me	☐ Strongly Disagree ☐ Disagree ☐ Uncertain ☐ Agree ☐ Strongly Agree	Doctors place too much trust on medications	☐ Strongly Disagree ☐ Disagree ☐ Uncertain ☐ Agree ☐ Strongly Agree
My health in the future will depend on my medications	☐ Strongly Disagree ☐ Disagree ☐ Uncertain ☐ Agree ☐ Strongly Agree	If doctors had more time with patients, they would prescribe fewer medications	☐ Strongly Disagree ☐ Disagree ☐ Uncertain ☐ Agree ☐ Strongly Agree
My medications disrupt my life	☐ Strongly Disagree ☐ Disagree ☐ Uncertain ☐ Agree ☐ Strongly Agree	**(Optional)** Please provide any additional details related to taking your medications **(Do not write your name or any other identifiable information)** _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	
I sometimes worry about becoming too dependent on my medications	☐ Strongly Disagree ☐ Disagree ☐ Uncertain ☐ Agree ☐ Strongly Agree		
My medications protect me from becoming worse	☐ Strongly Disagree ☐ Disagree ☐ Uncertain ☐ Agree ☐ Strongly Agree		

Examining the Relationship between Patient's Beliefs about Medications and Medication Adherence among Patients with Heart Failure

You are being invited to participate in a research study to explore the relationship between health beliefs about medication and medication adherence among patients with Heart Failure. This study is being conducted by Rosalind Washington, Doctorial Candidate from the Department of Health Studies at Texas Woman's University. The study is being conducted as part of a graduate dissertation.

There are no known physical risks if you decide to participate in this research study. Minimal risks include loss of confidentiality of questionnaire information, loss of confidentiality of communications via email, and loss of anonymity. There are no costs to you for participating in the study. The information you provide will assist in understanding the correlation between health beliefs and medication adherence. The questionnaire will take about 15-20 minutes to complete. The information collected may not benefit you directly, but the information learned in this study should provide more general benefits.

This questionnaire is anonymous. Do not write your name on the questionnaire. No one will be able to identify you or your answers, and no one will know whether or not you participated in the study. Should the data be published, no individual information will be disclosed.

Your participation in this study is voluntary. By completing and returning the questionnaire in secured box located at the nursing station or mailing to the address on the self addressed envelope, you are voluntarily agreeing to participate. You are free to decline to answer any particular question you do not wish to answer for any reason. You are allowed to stop participation in the study at any time.

The Texas Woman's University Institutional Review Board and University of Arkansas for Medical Science Institutional Review Board has reviewed my request to conduct this project. If you have any concerns about your rights in this study, please contact:

If you have any questions about the study, please contact (Primary Investigator) Rosalind Washington, 3211 Cutler Place, Carrollton, TX 75007, (903) 244-9827, and RWashington2@twu.edu or (Faculty Advisor) Dr. Kimberly Parker, PO Box 425499, Denton, TX 76204-5619, 940-898-2899, and KParker6@twu.edu

If you have any concerns about your rights in this study, please contact:

TWU's Office of Research & Sponsored Programs
Institutional Review Board
PO Box 425619
Denton, TX 76204-5619
irb@twu.edu

APPENDIX F

Institutional Review Board Approval (Initial)

TWU

DENTON DALLAS
HOUSTON

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940-898-3378 FAX 940-898-4416
e-mail: IRB@twu.edu

July 24, 2012

Ms. Rosalind Washington
3211 Cutler Place Carrollton,
TX 75007

Dear Ms. Washington:

Re: Examining the Relationship Between Patient's Beliefs About Medication and Medication Adherence Among Patients with Heart Failure (Protocol #: 17067)

The above referenced study has been reviewed by the TWU Institutional Review Board (IRB) and appears to meet our requirements for the protection of individuals' rights.

If applicable, agency approval letters must be submitted to the IRB upon receipt PRIOR to any data collection at that agency. A copy of the annual/final report is enclosed. A final report must be filed with the Institutional Review Board at the completion of the study. Because you do not utilize a signed consent form for your study, the filing of signatures of subjects with the IRB is not required.

This approval is valid one year from July 24, 2012. Any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any unanticipated incidents. If you have any questions, please contact the TWU IRB.

Sincerely,

Rhonda R B

Dr. Rhonda Buckley, Co-Chair /
Institutional Review Board - Denton

enc.

cc. Dr. Gay James, Department of Health Studies
Dr. Kimberly Parker, Department of Health Studies
Graduate School

APPENDIX G

Institutional Review Board Approval (Addendum)

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RESEARCH & SPONSORED PROGRAMS

TWU INSTITUTIONAL REVIEW BOARD (IRB)
MODIFICATION REQUEST FORM

Complete this form when you would like to request a change on an approved study. This change could be a change in the research team, data collection sites, protocol (e.g., compensation, study procedures, etc.), and/or the informed consent. Submit this signed form along with copies of any new or modified materials you describe below to the IRB. NOTE: You may not implement any changes to an IRB-approved study until your Modification Request has been approved.

PRINCIPAL INVESTIGATOR: Rosalind Washington

DATE APPROVED BY IRB (most recent): July 25, 2012

TITLE OF STUDY: Examining the Relationship between Patient's Beliefs about Medication and Medication Adherence Among Patients with Heart Failure

Provide a detailed description of the modification(s) requested:

In addition to the clinic recruitment procedures outline in the initial request. The PI would like to add an additional data collection method with minimal to no risk associated. The PI would like a complete Waiver of Authorization. Additional Minimal Risk include mailings delivered to the wrong address* To control for this minimal risk, none of the documents are addressed to a specific patient or list any diagnosis or other health related information. The additional data collection is to mail the previously approved questionnaire to all Medicare eligible participants with a HF diagnosis. The PI would not receive any identifiable information of the patients. This includes names, address, or diagnosis information. The staff at UAMS AHEC Family Medical Center and Texarkana Community Clinic will mail the research packet to the patients, without providing the PI any identifiable information. The research packet will include the Introduction Letter (see attachments), Consent/Questionnaire, Self addressed/prepaid postage envelope. The returned questionnaires will be mailed to a designated P.O. Box with the United States Postal Services obtained for purposes of this research study only. Only the PI will have access to the P.O. Box located in Carrollton, Texas. Please note the Introduction Letter contains a generic salutation (not to obtain patient information)

Provide a list of any new or modified documents materials and attach these items to this form:

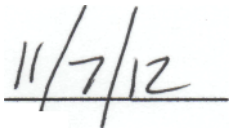
Introduction letter for patients at the UAMS AHEC SW Family Medical Center Introduction letter for patients a the Texarkana Community Clinic

Principal Investigator Assurance: I certify that the revised information provided for this project is correct and that no other procedures or forms will be used. I confirm that no changes will be implemented until I receive written approval for the changes from the TWU IRB.

Signature of Principal Investigator

APPROVED:

Signature of IRB Chair/Co-Chair /
Date



APPENDIX H

Data Set Appendices

Table 1

Medications Used to Treat Heart Failure

Type of Medication	Treatment Benefit
Angiotensin-converting enzyme (ACE) inhibitors Examples: Enalapril, Lisinopril, and Captopril	A drug that widens blood vessels to lower blood pressure, improve blood flow, and decrease workload on the heart
Angiotensin II receptor blockers Examples: Losartan and Valsartan	The same benefits as ACE inhibitors. It is used in patients that are unable to take ACE inhibitors
Digoxin Example: Lanoxin	Also referred to as digitalis. It increases the strength of the patients' heart muscle contractions. It tends to decrease the heartbeat.
Beta Blockers Examples: Carvedilol, Metoprolol, and Bisoprolol	It slows the heart rate, reduces blood pressure, and limits or reverses some damage to the heart. This medication reduces the risk of abnormal heart rhythms and lessens chances of sudden death.
Diuretics Examples: Bumetanide and Furosemide	Often referred to as water pills. It causes frequent urination to prevent fluid from collecting in the patients' body, especially the lungs. Diuretics are usually complemented with supplements to replace the loss of potassium and magnesium, due to frequent urination.
Aldosterone Antagonists Examples: Spironolactone and Eplerenone	They are potassium-sparing diuretics. They also have additional properties that may reverse heart scarring.

Table 2

International Diagnostic Codes – 9th Edition

International Diagnosis Code	**Diagnosis Description**
428	Congestive Heart Failure
428.1	Left Heart Failure
428.20, 428.21, 428.22, 428.23	Systolic Heart Failure
428.30, 428.31, 428.32, 428.33	Diastolic Heart Failure
428.40, 428.41, 428.42, 428.43	Combined Systolic and Diastolic Heart Failure

Table 3

Demographics Characteristics

Variable	n	%
Clinic		
FMC	46	56.8
TCC	35	43.2
Gender		
Male	24	29.6
Female	57	70.4
Age* (yrs)		
≤ 45	2	2.5
46 – 60	36	44.4
61 – 75	30	37.03
75 +	6	7.4
Race		
African American	38	46.9
American Indian	3	4.9
Asian/Pacific Islander	0	-
Mexican Latino	0	-
White/Caucasian	35	43.2
Other	4	4.9

Note: *(n=81).* *Six females and one male participant did not provide age

Table 4

Variable Groups and Frequencies

	n	%
Medication Adherence		
Low Adherence (LA)	36	44.4
Moderate Adherence (MA)	27	33.3
High Adherence (HA)	18	22.2
Perceived Severity		
Mild I	5	6.2
Mild II	24	29.6
Moderate	40	49.4
Severe	12	14.8
Belief About Medications		
Negative	47	58.0
Positive	28	34.6
Neutral	6	7.4
Necessity-Concern Differential		
Necessity (benefit outweigh concern/cost)	67	82.7
Concern (cost/concern outweigh benefit)	11	13.6
Neutral	3	3.7

Table 5

Gender- Beliefs about Medications

	Positive		Neutral		Negative	
	n	%	n	%	n	%
Male (n=24)	7	29.2%	3	12.5%	14	58.3%
Female (n=57)	21	36.8%	3	5.3%	33	57.9%

Table 6

Gender –Medication Adherence

	High Adherence		Moderate Adherence		Low Adherence	
	n	%	n	%	n	%
Male (n=24)	8	33.3%	7	29.2%	9	37.5%
Female (n=57)	9	15.8%	20	35.1%	28	49.1%

Table 7

BMQ- Individual Question Response

	Disagree-Strong Disagree		Neutral		Agree- Strong Agree	
Specific Items	n	%	n	%	n	%
My current heath depends on my medications (Necessity)	4	4.9%	12	14.8%	65	80.2%
Having to take medications worries me (Concern)	44	54.3%	11	13.6%	26	32.1%
My life would be impossible without my medications (Necessity)	8	9.9%	9	11.1%	64	79.0%
I sometimes worry about the long term effects of my medications (Concern)	32	39.5%	13	16.0%	36	44.4%
Without my medications I would be very sick (Necessity)	5	6.2%	10	12.3%	66	81.5%
My medications are a mystery to me (Concern)	50	61.7%	14	17.3%	17	21.0%
My health in the future will depend on my medications (Necessity)	5	6.2%	17	21.0%	59	72.8%
My medications disrupt my life (Concern)	53	65.4%	10	12.3%	18	22.2%
I sometimes worry about becoming too dependent on my medications (Concern)	46	56.8%	9	11.1%	26	32.1%
My medications protect me from becoming worse (Necessity)	6	7.4%	6	7.4%	69	85.2%
General Items						
Doctors prescribed too many medications	46	56.8%	16	19.8%	19	23.5%
People who take medications should stop their treatment for a while every now and then	68	84.0%	9	11.1%	4	4.9%
Most medications are addictive	48	59.3%	17	21.0%	16	19.8%
Medications do more harm than good	59	72.8%	16	19.8%	6	7.4%
All medications are poisons	67	82.7%	10	12.3%	4	4.9%
Doctors place too much trust on medications	39	48.1%	25	30.9%	17	21.0%
If doctors had more time with patients, they would prescribe fewer medications	31	38.3%	26	32.1%	24	29.6%

Table 8

Correlation among Dependent and Independent Variables

Spearman's rho		Med Adhere	Perceived Severity	Belief	Necessity Concern
Med Adhere	Correlation Coefficient	1.000	-.163	**.346****	**-.298****
	Sig. (2-tailed)	.	.147	.002	.007
	n	81	81	81	81
Perceived Severity	Correlation Coefficient	-.163	1.000	.037	.215
	Sig. (2-tailed)	.147	.	.743	.054
	n	81	81	81	81
Belief	Correlation Coefficient	**.346****	.037	1.000	-.044
	Sig. (2-tailed)	.002	.743	.	.696
	n	81	81	81	81
Necessity-Concern	Correlation Coefficient	**-.298****	.215	-.044	1.000
	Sig. (2-tailed)	.007	.054	.696	.
	n	81	81	81	81

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

Table 9

Kruskal-Wallis Analysis of Variance for Medication Adherence and Perceived Severity (4-groups)

	Perceived Severity	n	Mean Rank (μ_r)
Med Adhere	Mild I	5	48.20
	Mild II	24	43.81
	Moderate	40	40.66
	Severe	12	33.50
	Total	81	

Test Statistics	Med Adhere
Chi-square	2.359
df	3
Asymp. Sig.	**.501**

Table 10

Kruskal-Wallis Analysis of Variance for Medication Adherence and Perceived Severity (3-groups)

	Severity Level	n	Mean Rank (μ_r)
Med Adhere	Mild	29	44.57
	Moderate	40	40.66
	Severe	12	33.50
	Total	81	

Test Statistics	Med Adhere
Chi-square	2.193
df	2
Asymp. Sig.	**.334**

Table 11

Kruskal-Wallis Analysis of Variance for Medication Adherence and Belief About Medication (3-groups)

	Belief	n	Mean Rank (μ_r)
Med Adhere	Neg Belief	47	34.30
	Pos Belief	28	50.96
	Neutral Belief	6	47.00
	Total	81	

Test Statistics	Med Adhere
Chi-square	10.675
df	2
Asymp. Sig.	**.005**

Table 12

Kruskal-Wallis Analysis of Variance for Medication Adherence and Belief About Medication (2-groups)

	Belief	n	Mean Rank (μ_r)
Med Adhere			
	Negative	47	32.23
	Positive	28	47.68
	Total	75	

Test Statistics	Med Adhere
Chi-square	10.243
df	1
Asymp. Sig.	**.001**

Table 13

Kruskal-Wallis Analysis of Variance for Medication Adherence and Necessity-Concern About Medication (3-groups)

	NecConcern	n	Mean Rank (μ_r)
Med Adhere	Neutral	3	57.50
	Necessity	67	42.68
	Concern	11	26.27
	Total	81	

Test Statistics	Med Adhere
Chi-square	7.089
df	2
Asymp. Sig.	**.029**

Table 14

Kruskal-Wallis Analysis of Variance for Medication Adherence and Necessity-Concern About Medication (2-groups)

	NecConcern	n	Mean Rank (μ_r)
Med Adhere			
	Necessity	67	41.72
	Concern	11	25.95
	Total	78	

Test Statistics	Med Adhere
Chi-square	5.330
df	1
Asymp. Sig.	**.021**

Table 15

Revised Sample Frequencies

Variable groups		n	Percentage
Med Adherence	LA	34	47.2
	MA	23	31.9
	HA	15	20.8
Severity Level	Mild	26	36.1
	Moderate	34	47.2
	Severe	12	16.7
Belief	Negative	44	61.1
	Positive	28	38.9
NecesConcern	Concern(Cost)	11	15.3
	Necessity(Benefit)	61	84.7
Valid		72	100.0
Missing		9	
Total		81	

Table 16

Final Regression Sample Response Frequencies

Severity Level	Belief	Necessity-Concern	Med Adherence		
			LA	MA	HA
Mild	Negative	Concern-Cost	1	0	0
		Necessity-Benefit	8	6	1
	Positive	Necessity-Benefit	1	4	5
Moderate	Negative	Concern-Cost	5	0	0
		Necessity-Benefit	8	5	2
	Positive	Concern-Cost	1	1	1
		Necessity-Benefit	3	3	5
Severe	Negative	Concern-Cost	2	0	0
		Necessity-Benefit	3	2	1
	Positive	Necessity-Benefit	2	2	0

Table 17

Multinomial Regression Model Parameter Estimates

Med Adhere(a)		B	Std. Error	Wald	df	Sig.(p)	Exp(B) OR	95% Confidence Interval Exp(B)	
								Low Bound	Up Bound
MA	**Intercept**	-1.538	1.316	1.367	1	.242			
	Mild Severity=1	.457	.822	.309	1	.578	1.579	.315	7.906
	Mod Severity=2	.085	.811	.011	1	.917	1.088	.222	5.334
	Severe Severity=3	0(b)	.	.	0	.	.	.	.
	Neg Belief=1	-1.101	.627	3.081	1	.079	.332	.097	1.137
	Pos Belief=2	0(b)	.	.	0	.	.	.	.
	Necessity=1	1.946	1.131	2.960	1	.085	6.999	.763	64.225
	Concern=2	0(b)	.	.	0	.	.	.	.
HA	**Intercept**	-2.230	1.670	1.784	1	.182			
	Mild Severity=1	1.433	1.285	1.244	1	.265	4.190	.338	51.946
	Mod Severity=2	1.377	1.259	1.197	1	.274	3.964	.336	46.762
	Severe Severity=3	0(b)	.	.	0	.	.	.	.
	Neg Belief=1	-2.387	.751	10.109	1	**.001**	**.092**	.021	.400
	Pos Belief=2	0(b)	.	.	0	.	.	.	.
	Necessity=1	1.714	1.245	1.893	1	.169	5.548	.483	63.703
	Concern=2	0(b)	.	.	0	.	.	.	.

a. The reference category is: LA.

b. This parameter is set to zero because it is redundant.

Table 18

Qualitative Data – Positive Beliefs about Medications

Repeated Themes - Medication Adherence Responses	**Frequency**	**% Total Responses**
There is a necessity of medication to treat HF	2	28.6%
The access to care is a related concern	2	28.6%

Table 19

Qualitative Data – Negative Beliefs about Medications

Themes - Medication Adherence Responses	**Frequency**	**% Total Responses**
There is a necessity for medications to treat HF	4	26.7%
The increase number of medications and/or frequency of medication is a concern	3	20.0%
The side effects or fear of addiction is a concern of taking medications	2	13.3%
The lack of physician collaboration with other physicians and pharmacist is a concern with taking medications	2	13.3%
The cost of medication is a related concern	1	6.7%