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Healthcare Providers Monitoring Of Serum Potassium Levels In The Treatment Of Heart Failure

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HEALTHCARE PROVIDERS' MONITORING OF SERUM POTASSIUM LEVELS IN THE TREATMENT OF HEART FAILURE

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Graduate Committee Approval

The Graduate Committee of Lori Duke and Cindy Patrick hereby approves their research project as meeting partial fulfillment of the requirements for the Degree of Master of Science in Nursing

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DEDICATION

I, Lori Duke, wish to dedicate this research project to my family. To my husband, Leslie, thank you for your love and encouragement. I am grateful to my parents, Shirley and Waymon Samples. Your support is greatly appreciated. Most of all, I would like to thank my beautiful daughter, Kaylee, for being so encouraging and supportive of me. I know this has been hard on you. Your smiling face and hugs have helped me continue on this journey. I love you, sweetie pie.

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Abstract

Heart failure is a chronic disease responsible for over 11 million outpatient clinic visits each year. According to the Healthcare Cost and Utilization Project (2009), heart failure is one of the most frequent principal diagnoses utilized. Hypokalemia and hyperkalemia, which can be caused by some of the medications used to treat heart failure, are often associated with cardiac arrhythmias and sudden cardiac death. The researchers investigated healthcare provider compliance with the recommended 2009 American College of Cardiology Foundation/American Heart Association guidelines for monitoring routine serum potassium levels in heart failure patients. Sister Callista Roy's Adaptation Model was used as the conceptual framework to guide this study's assessment of healthcare providers' monitoring levels of serum potassium, our main intracellular electrolyte. Using a retrospective chart review, 200 charts from two rural primary care clinics in north and east central Mississippi were examined regarding the follow-up monitoring of potassium levels in heart failure patients. Participants were 18 years of age and older.

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CHAPTER I

Dimensions of the Problem

Background

Heart failure is a condition resulting in the loss or dysfunction of heart muscle. It is characterized by venous congestion, inadequate peripheral oxygen delivery, and ventricular dilation/hypertrophy which lead to circulatory abnormalities. This disease can occur as the result of impaired pumping of blood out of the heart, called *systolic heart failure*, or impaired relaxation of heart muscle, called *diastolic heart failure*. In some patients, abnormalities of both systolic and diastolic heart dysfunction can co-exist.

Certain medications used in the treatment of heart failure, such as diuretics, angiotensin-converting enzyme inhibitors (ACE-I), angiotensin II receptor blockers (ARB), beta-blockers, and aldosterone antagonists, can have adverse effects on the body's potassium level. Fluid and electrolyte disorders accounted for 17% of the secondary diagnoses for heart failure in 2009, which was an increase from 11% in 1997 (Wier et al., 2011). An appropriate potassium level is needed to maintain the body's fluid balance, conduct nerve impulses and muscle contraction, and help prevent cardiac arrhythmias. Patients with heart failure should maintain a potassium level in the 4.0-5.0 mEq/L range (Jessup et al., 2009). An alteration of the potassium level, either hyperkalemia or hypokalemia, can affect a patient's cardiac conduction and excitability which can lead to sudden cardiac injury or death (Hunt et al., 2005). Hypokalemia, which is common in heart failure, can enhance cell membrane excitability and delay ventricular repolarization. Hyperkalemia, another common complication of

heart failure, can affect the repolarization phase of the heart and depress the contraction of the sinoatrial node. Both of these conditions predispose patients to cardiac arrhythmias, therefore increasing their mortality rate (Bowling et al., 2009).

Heart failure affects males and females, all age groups from children to the elderly, and all races. At 40 years of age, the lifetime risk for developing heart failure for both men and women is 1 in 5. At 80 years of age, the remaining lifetime risk for developing a new diagnosis of heart failure remains at 20%, despite the fact that the patient has a much shorter life expectancy (Roger et al., 2011). The incidence of heart failure increases with age. Statistical data demonstrates a fourfold increase in new diagnosis for Caucasian men greater than 85 years (Roger et al., 2011).

An estimated 6 million people in the U.S. have been diagnosed with heart failure, with over 670,000 new cases being diagnosed each year (Centers for Disease Control and Prevention [CDC], 2012). Nearly 1.4 million people 60 years of age and under have been diagnosed with heart failure, and African-Americans are 1.5 times more likely to develop this disease than Caucasians (Emory Healthcare Heart and Vascular, 2012). According to the Healthcare Cost and Utilization Project of 2009 (Wier et al., 2011), heart failure was listed among the top 10 most frequent principal diagnoses utilized. Heart failure can be contributed to approximately 287,000 deaths per year (Emory Healthcare Heart and Vascular, 2012). The Heart Failure Society of America (n.d.) reported that < 50% of patients will survive 5 years after the initial diagnosis of heart failure, with < 25% of patients surviving after 10 years of initial diagnosis. Sudden death is common in patients with heart failure, occurring at a rate of 6 to 9 times greater than the general population (Emory Healthcare Heart and Vascular, 2012). The diagnosis of heart failure is mentioned on 1 out of 9 death certificates in the U.S. (Roger et al., 2011). The poor

prognosis can be linked to a limited understanding of the disease process, prevalence of comorbid conditions, and socioeconomic status.

Heart failure is responsible for 11 million outpatient clinic visits each year, and for more hospitalizations than all forms of cancer combined (Emory Healthcare Heart and Vascular, 2012). Heart failure accounts for nearly 875,000 hospitalizations and is the most common diagnosis documented in hospitalized patients 65 years of age and older (Emory Healthcare Heart and Vascular, 2012). The Prevention Quality Indicator for Heart Failure hospital readmission rates for 2009 indicated the highest rate is for 75 years of age and older, with approximately 2,500 per 100,000 people (U.S. Department of Health and Human Services Agency for Healthcare Research and Quality [AHRQ], 2012). Groups of patients 65 to 74 years of age had a rate of approximately 840 out of 100,000 people, 40 to 64 years of age had a rate of approximately 200 out of 100,000 people, and 18 to 39 years of age had a rate of approximately 19 out of 100,000 people (AHRQ, 2012).

The economic burden of managing heart failure in the U.S. can be overwhelming. Heart failure is a serious public health concern with a cost of approximately $40 billion from health services and medications, as well as the loss of productivity (CDC, 2012). An estimated $2.6 trillion was spent on health care in 2009, which represented more than 17.6% of the gross domestic product for the U.S.; moreover heart failure expended more Medicare dollars than any other diagnosis (Dunlay et al., 2010). The increased prevalence of heart failure can be illustrated by frequent hospitalizations, a growing mortality rate, a complex treatment regimen, and a rising financial and societal burden.

Compliance with the 2009 American College of Cardiology Foundation/American Heart Association (ACCF/AHA) guidelines (see Appendix A) for monitoring routine

potassium levels with the management of heart failure could potentially decrease adverse cardiac outcomes (Jessup et al., 2009). The Institutes for Clinical Systems Improvement (ICSI) Guidelines for Heart Failure in Adults (2011) (see Appendix B) further recommend that stable patients in the clinic setting should have electrolyte levels monitored at least every 4 months for the duration of the heart failure medication therapy. If an electrolyte imbalance is discovered, increased lab monitoring would be justified until levels return to normal. According to the AHRQ, patients may require hospitalization if their condition is not effectively monitored in the outpatient setting (2012).

Problem Statement

Despite many medical advances, the incidence of heart failure continues to rise. Heart failure adds to the economic burden in our country and greatly increases a patient's mortality rate. Certain medications used in the treatment of heart failure can have adverse effects on serum potassium levels. Because the lack of testing serum potassium levels can lead to life-threatening cardiac complications, it is important to ensure that the healthcare provider is monitoring serum potassium levels routinely in patients with a diagnosis of heart failure.

Statement of Purpose

The purpose of this study was to evaluate healthcare providers' compliance with the recommended 2009 ACCF/AHA guidelines for monitoring routine serum potassium levels in heart failure patients. The researchers of this study focused on the importance of monitoring routine serum potassium levels in heart failure patients at least every 4 months. The results of this study could help healthcare providers effectively manage heart failure patients and possibly help prevent the development of life-threatening

complications. According to the guidelines and latest evidence-based practice, the healthcare provider should routinely monitor serum potassium levels. Devastating outcomes such as cardiac arrest can be the result of severe hypokalemia.

Significance of the Study

Heart failure is widely recognized as an increasingly common health problem associated with a high mortality rate. It can result from any condition that interferes with blood volume being sufficiently pumped from the heart. Potassium, the main intracellular electrolyte, plays a critical role in the heart's electrical conduction. Serum potassium levels affect cardiac automaticity and membrane excitability as well as repolarization (Bowling et al., 2009).

Many of the medications used in the treatment of heart failure can alter the body's potassium level. Other factors such as renal function can also affect potassium levels. Patients with heart failure should maintain a potassium level in the 4.0-5.0 mEq/L range (Jessup et al., 2009).

Efforts should be made by healthcare providers to routinely monitor for changes in serum potassium levels in order to help prevent potentially life-threatening cardiac arrhythmias. Data from the current research can be applied to show the importance of following the recommended 2009 ACCF/AHA guidelines for monitoring serum potassium levels in the treatment of heart failure. Following evidence-based guidelines has been considered to have substantial medical advantages. The healthcare provider will utilize these heart failure guidelines in the detection, prevention, and management of this condition. Critical evidence indicates that both hypokalemia and hyperkalemia may cause fatal arrhythmias.

The study by the current researchers provides data regarding compliance with the 2009 ACCF/AHA guidelines, differences in treatment as evidenced by payer source, as well as age, sex, and ethnicity of participants. There is limited current information in this area of study.

Theoretical Foundation

Sister Callista Roy's Adaptation Model (RAM) will be used to guide this research study. This theory provides the framework that will assist in evaluating the role of the healthcare provider related to caring for a patient's physical, medical, social, and environmental issues associated with adapting to a chronic illness, such as heart failure. By utilizing this theory, the healthcare provider/patient relationship can be used to achieve a comprehensive approach to efficient and effective healthcare management.

The RAM nursing theory views the individual as a holistic adaptive system as related to the concepts of person, health, environment, and nursing (George, 2011). It is aimed at understanding human behavior in order to maintain and enhance coping mechanisms to promote optimal health. The individual must have the ability to adapt to biological and psychological changes.

Adaptation includes two control processes, the regulator and the cognator subsystem coping mechanisms (George, 2011). The regulator subsystem includes automatic reflexes through endocrine, neural, and chemical channels. The cognator subsystem processes are associated with perception and information processing, learning, judgment and emotion. The effects of the regulator and cognator processes interrelate and are measured by behavioral outcomes. Adaptation occurs when these subsystems are stimulated, causing a change in behavior measured in physiologic and psychosocial modes.

Adaptation can be grouped into four modes: physiological-physical, self-concept/group identity, role function, and interdependence (George, 2011). The physiological mode represents the physical body and environmental interactions. It includes basic human needs such as oxygenation, nutrition and fluid balance, elimination patterns, activity and rest, and protection. The self-concept mode represents the maintenance of the psyche and spirit. It represents an individual's perceptions or beliefs, which are central to behavior responses. The role function mode represents social integrity. It represents an individual or group's adaptation to role changes. The interdependence mode also represents social integrity. It includes the personal relationships and the need for love, respect, and security.

The individual is also continuously influenced by different types of internal and external stimuli (George, 2011). Focal stimulus is the most demanding situation and is perceived as an immediate concern. Contextual stimulus is an internal or external factor that will produce a positive or negative response. Residual stimulus is a factor, such as an attitude or habit, which can produce an uncertain effect. Observation of an individual's behavior can identify the effectiveness of his or her coping abilities. Coping mechanisms are viewed as either adaptive or ineffective. A provider should work with the patient in order to develop intervention goals needed to meet positive adaptive coping strategies. Monitoring serum potassium levels at least every 4 months and adjusting the medication regimen if the serum potassium level is not in the recommended range help the patient adapt to the effects of heart failure. Adaptive mechanisms are appropriate responses for strengthening positive actions. Ineffective mechanisms will prevent the individual's ability for effective change and promotion of health.

Research Questions

Research questions were constructed to guide this investigation and assist in obtaining data. The study's objectives were to analyze the healthcare providers' documentation of routine monitoring of potassium levels in heart failure patients. The following questions were addressed:

1. Was the serum potassium level in patients being treated for heart failure monitored and documented at least every 4 months as recommended by the ICSI Guidelines for Heart Failure in Adults?
2. Was the potassium level in the recommended range of 4.0-5.0 mEq/L according to the 2009 ACCF/AHA recommended guideline when monitored?
3. If the potassium level was not in the recommended range, was there a medication adjustment?

Definition of Terms

For the purposes of this study, the following terms were defined:

Serum potassium

Theoretical: A chemical element that serves as both the principal cation in intracellular fluid and an important electrolyte in extracellular fluid. It has many functions, including metabolism, cell membrane homeostasis, nerve conduction, and muscle contraction (Venes, 2001).

Operational: Serum potassium lab values of heart failure patients obtained through retrospective chart reviews.

Patient

Theoretical: One who is sick with, or being treated for, an illness or injury; an individual receiving medical care (Venes, 2001).

Operational: Person who has sought medical care at the primary care clinic on prior occasions before the retrospective review of their chart.

Heart Failure

Theoretical: The heart's inability to circulate blood effectively enough to meet the body's metabolic needs. Heart failure may affect the left ventricle, right ventricle, or both. It can result from the impaired ejection of blood from the heart during systole or from impaired relaxation of the heart during diastole (Venes, 2001).

Operational: a condition that results in the loss of heart muscle leading to circulatory abnormalities. Patients with ICD-9 diagnosis code 428.

ICSI Guidelines for Heart Failure

Theoretical: Evidence-based healthcare guidelines developed by an independent, nonprofit healthcare improvement organization that unites clinicians, health plans, employers, policymakers, and consumers to improve health, optimize the patient experience, and make health care more affordable (Institute for Clinical Systems Improvement, 2011).

Operational: Evidence-based guideline for heart failure in adults used by the current researchers as the recommended timeframe that serum potassium should be monitored.

Recommended range

Theoretical: The difference between the highest and lowest in a set of variables or in a series of values or observations (Venes, 2001).

Operational: The difference between the lowest mEq/L of potassium (4.0 mEq/L) and the highest mEq/L of potassium (5.0 mEq/L) a person with heart failure should have as stated by the ACCF/AHA (Jessup et al., 2009).

ACCF/AHA guidelines

Theoretical: Evidence-based health care guidelines developed by a group of medical professionals that have jointly engaged in critically evaluating the use of diagnostic procedures and therapies as they are introduced to effectively manage or prevent cardiovascular disease since 1980 (Jessup et al., 2009).

Operational: Evidence-based guidelines for the diagnosis and management of heart failure in adults, used by the current researchers as a guide for the recommended range of potassium as well as a medication regimen for patients diagnosed with heart failure, ICD-9 diagnosis code 428.

Medication adjustment

Theoretical: A medication change made to improve function or condition (Venes, 2001).

Operational: An increase or decrease of dosage or amount made in a patient's medication regimen, i.e. ace inhibitor, angiotensin receptor blocker, diuretic, or aldosterone antagonist that would be made due to a serum potassium level out of the recommended range.

Hypokalemia

Theoretical: An abnormally low concentration of potassium in the blood (Venes, 2001).

Operational: A serum potassium lab value of heart failure patients < 4.0 mEq/L.

Hyperkalemia

Theoretical: An excessive amount of potassium in the blood (Venes, 2001).

Operational: A serum potassium lab value of heart failure patients > 5.0 mEq/L.

Assumptions

Clinical practice guidelines exist to help healthcare providers effectively manage heart failure. For the purpose of this study, the following assumptions were made:

1. Healthcare providers are knowledgeable regarding the 2009 ACCF/AHA guidelines for monitoring serum potassium levels in the treatment of heart failure.
2. Information concerning the serum potassium level, medications, age, gender, ethnicity and payer source is documented on the patient's charts.
3. Documentation regarding heart failure diagnosis and treatments are sufficient for data collection.

Limitations

The limitations noted for this research study were as follows.

1. The sample was limited to charts of adult patients, 18 years of age and older, being treated with a diagnosis of heart failure.
2. Participants were selected from two rural primary care clinics in north and east central Mississippi, which limited the generalizability to a smaller geographic area.
3. The provider's adherence to the guidelines relied on their documentation in the medical records from these two rural primary care clinics.

Summary

Despite advances in pharmacological treatment, the prevalence of heart failure is on the rise. Inpatient and outpatient management of this condition exhausts more Medicare monies than any other diagnosis (Dunlay et al., 2010). An alteration in potassium levels, either hyperkalemia or hypokalemia, can greatly impact a heart failure patient's morbidity and mortality. The increased incidence of heart failure, in addition to complications caused by an alteration of potassium, supported the need for careful evaluation of these patients. The purpose of this study was to determine if healthcare providers are monitoring serum potassium levels in heart failure patients according to the 2009 ACCF/AHA guidelines. Proper assessment, diagnosis, and treatment are needed to provide quality care to the heart failure patient.

CHAPTER II

Review of Literature

Each year in the United States, more than 670,000 people are diagnosed with heart failure. A plethora of existing comorbidities, such as diabetes, hypertension, and hyperlipidemia, contribute to heart failure. Socioeconomic status, race, and culture of the population can be linked with progression of this deadly disease. The following review of literature supports the significance of appropriate treatment of heart failure.

In a quantitative, non-randomized propensity-matched study conducted by Alper et al. (2009) data were collected from participants in a randomized trial in the early 1990s. The researchers sought to determine the long-term effects of low serum potassium on mortality and hospitalization of older adults age 65 years and over diagnosed with chronic systolic and diastolic heart failure. The elderly are often excluded from clinical trials; therefore, existing data are limited in the > 65-year-old age group.

The large randomized clinical trial was conducted during 1991-1993 in 186 U.S. and 116 Canadian locations. From the sample of 7,788 participants in the Digoxin Investigative Group (DIG) trial, 4,036 were 65 years of age or older. A total of 3,598 out of 4,036 had data on baseline serum potassium levels (Alper et al., 2009). After exclusion of participants with serum potassium > 5.0mEq/L, a subset of 3,274 individuals were identified. A total of 590 of the 3,274 participants had low potassium defined as serum potassium < 4.0 mEq/L, and 2,684 participants had normal potassium defined as 4.0-4.9 mEq/L. Propensity score matching was used to balance the covariates between patients with low versus normal potassium. The researchers used a non-parsimonious multivariable logistic regression model to estimate propensity scores (Alper et al., 2009).

Propensity scoring for hypokalemia was defined as the conditional probability of that participant developing hypokalemia given his or her baseline covariates (Alper et al., 2009). After matching, 1,670 participants had normal serum potassium levels of 4.0-4.9 mEq/L, and 561 or 95% of the initial 590 had low serum potassium documented < 4.0 mEq/L.

For matching purposes with this model, the dependent variable was low-serum potassium. Baseline characteristics consisted of co-morbidities, medications, signs and symptoms, vital signs, diagnostic data, and information on gender and race. After matching, participants were studied to determine a relationship between hypokalemia in the elderly population and mortality or hospitalization. Alper et al. (2009) suggested that there are limited studies with this age group. Ten percent of the articles in the review of literature were published in the last 5 years, with approximately 45% in the last 10 years. Of the 31 articles in their literature review, 61% were published in journals of cardiology or heart-related journals. Surprisingly, only 6% were published in journals related to gerontology with other related journals accounting for the remaining 32%. The researchers identified that hypokalemia may be an indicator of disease progression. In addition to diastolic and endothelial dysfunction, an increased rate of thrombosis and platelet aggregation was associated with low potassium (Alper et al., 2009).

Bias was avoided by estimating pre- and post-match absolute standardized differences of covariates between the two groups. "An absolute standardized difference of 0% indicated no residual bias, and an absolute standardized difference below 10% suggested inconsequential residual bias" (Alper et al., 2009, p. 2). In addition to having absolute standardized differences, McNemar and paired sample t tests compared the baseline characteristics of matched patients (Alper et al., 2009). "Kaplan-Meier plots and

matched Cox regression analysis were used to estimate associations of low potassium with various outcomes" (Alper et al., 2009, p. 2). According to Alper et al. (2009), researchers used three different approaches to test for bias: unadjusted, adjusted for raw propensity scores, and adjusted for all covariates used in the propensity score model. In addition, they reviewed outcomes for the full pre-match cohort in an effort to show that decreasing the sample size of the larger study did not skew their data (Alper et al., 2009). Findings from this propensity-matched study of ambulatory adults over 65 years of age diagnosed with heart failure and hypokalemia did have an increase in mortality but not hospitalization (Alper et al., 2009). According to Alper et al. (2009), the dissociation between mortality and hospitalization may have been caused by preventable fatal ventricular dysrhythmias that precluded the hospital admission.

This study's findings indicate that maintaining a normal serum potassium level of 4.0-4.9 mEq/L in patients with chronic heart failure may improve their survival. They further stated that spironolactone or eplerenone may be preferable to a potassium supplement to correct hypokalemia in chronic heart failure patients. A strength identified in this study was the degree to which the researchers went to match and analyze the data to avoid any bias or misrepresentations. Weaknesses identified included the lack of data on dosages of diuretics, magnesium levels, or sudden cardiac deaths (Alper et al., 2009).

This study is significant to the current researchers; interest shows the importance of monitoring the serum potassium levels and regulating within the desired range of 4.0-4.9 mEq/L for patients diagnosed with heart failure. Many labs consider 3.5-5.0 mEq/L normal for most healthy individuals. This study reveals a tighter control of 4.0-4.9 mEq/L is needed to prevent fatal dysrhythmias for patients diagnosed with heart failure. This study supported the importance of maintaining electrolyte levels within an

acceptable range in order to prevent hyperkalemia, which could cause detrimental effects if not controlled.

In a study conducted by Desai et al. (2007), hyperkalemia was indicated as a serious adverse event in patients diagnosed with heart failure. It can cause many complications ranging from medical intervention to lethal cardiac arrhythmias. Adequate renal perfusion is needed to help maintain normal potassium levels through sodium reabsorption, maintaining normal aldosterone concentrations and normal potassium channels in the collecting duct system (Desai et al., 2007). A decreased renal function, associated with age and comorbid conditions, can lower the body's ability to excrete potassium. Certain medications can also increase the probability of developing hyperkalemia. Angiotensin-converting enzyme (ACE) inhibitors, angiotensin-receptor blockers (ARB), and mineralocorticoid receptor antagonists can reduce morbidity and mortality with heart failure patients but can increase serum potassium levels (Desai et al., 2007).

Quantitative data obtained in the Candesartan in Heart Failure-Assessment of Reduction in Mortality and Morbidity (CHARM) Program was utilized to perform a retrospective analysis of the incidence and predictors of hyperkalemia with a median follow-up of 3.2 years. The CHARM Program defined clinically important hyperkalemia as hyperkalemia requiring medical intervention, such as medication dose reduction, study drug discontinuation, hospitalization, or death (Desai et al., 2007). The researchers utilized the Mantel-Haenszel method to determine the incidence of hyperkalemia, compare treatments, and calculate variable duration. The Cox proportional hazards model was used to analyze the timing for development of hyperkalemia requiring medical

intervention. The Cox model was also used to analyze multivariate predictors, such as age, gender, medication, and diabetes.

The CHARM Program was compromised of 7,599 participants who were treated according to standard heart failure guidelines in addition to randomized treatment with a titrated dose of the ARB candesartan, or placebo. The CHARM Program researched the benefit and risks of using candesartan, alone and in combination with an ACE inhibitor (Desai et al., 2007). The choice of the ACE inhibitor was determined according to the preference of the investigator with the dosage based on proven clinical trial effectiveness in addition to patient tolerance. The researchers identified a CHARM Program North American cohort subset of 2,675 eligible male and female patients, age 18 years and older, who were diagnosed for at least 4 weeks with symptomatic class II to IV heart failure according to New York Heart Association Classification guidelines (Desai et al., 2007).

Patients were evaluated at 2, 4, and 6 weeks; 6 months; and then every 4 months until the conclusion of the study. The investigators performed serial monitoring of lab values including potassium and creatinine levels in addition to close observation for serious complications, such as hyperkalemia. According to Desai et al. (2007), lab values were assessed prior to the initiation of the medication, again within 2 weeks after the medication dose was stabilized, then yearly. The investigators also had the option of performing additional lab monitoring according to their discretion.

The investigators determined that heart failure patients at risk for developing hyperkalemia, 12.6 per 1,000 patient-years, were males of advanced age with a history of diabetes, as well as those using an ACE inhibitor or spironolactone. It was also noted these patients had a baseline potassium level of 5.0 or greater and creatinine of 2.0 or

greater. The patients at greater risk were those with baseline renal insufficiency, accounting for more serious hyperkalemia events including hospitalization or death (Desai et al., 2007). The investigators also concluded patients with creatinine levels of 2.0 or above receiving the placebo were twice as likely to develop hyperkalemia as those patients with creatinine levels < 2.0 who were receiving the ARB candesartan (Desai et al., 2007). The investigators concluded serious hyperkalemia episodes occurred in 2.7 per 1,000 patient-years, although the rate could have been elevated to 11.9 per 1,000 patient-years if effective monitoring protocols had not been followed (Desai et al., 2007).

Desai et al. (2007) reported inhibitors of the renin-angiotensin aldosterone system (RAAS) can decrease potassium excretion, especially in patients with compromised renal function. Drugs that can hinder the production or action of renin and angiotensin include non-steroidal anti-inflammatory drugs, beta-blockers, ACE inhibitors, and ARBs. When used in effective doses, RAAS inhibitors have been noted to reduce morbidity and mortality outcomes; however, potassium levels can be increased < 1 mEq/l (Desai et al., 2007). Spironolactone, an aldosterone receptor antagonist, has also been associated with hyperkalemia, including associated hospitalizations.

Several limitations were identified by the researchers. Potassium monitoring guidelines were furnished to the CHARM investigators; however, the decision to manage the hyperkalemia and report it as an adverse event was left to the judgment of the investigator. The definition of clinically important hyperkalemia was not assigned actual serum potassium values; therefore, the researchers considered the possibility that some physicians may have managed a tolerable increase in the potassium level or that some increases in potassium level could have gone undetected. Another limitation identified was that although dose reduction or discontinuation of candesartan due to hyperkalemia

was reported for the trial, hospitalization and death were only identified by investigator-reported adverse event review (Desai et al., 2007).

Further studies in larger cohorts are needed for more precise hyperkalemia occurrence rates; however, a strength identified by the researchers was the data provided by the CHARM Program provided important information regarding hyperkalemia risk in the management of patients with heart failure. Desai et al. (2007) concluded the periodic laboratory testing of serum potassium level and creatinine level is important to reducing adverse events related to hyperkalemia (Desai et al., 2007).

The research study conducted by Desai et al. (2007) was significant to the current study of monitoring potassium levels in the treatment of heart failure since it studied the incidence and predicting factors that are associated with hyperkalemia events associated with heart failure treatments. Their findings found that hyperkalemia occurred in a large group of heart failure patients, whether or not they were taking the ARB medication candesartan (Desai et al., 2007). Certain populations were identified as having a higher occurrence risk for developing clinically important hyperkalemia. Male patients aged 75 years and older, with a decline in renal function and comorbid medical conditions, have an increased risk of developing hyperkalemia. Patients with a low left ventricular ejection fraction were found to be more likely to develop hyperkalemia as opposed to patients with a left ventricular ejection fraction of 40% or greater (Desai et al., 2007). The practitioner must understand the affecting risk factors in order to be able to carefully weigh the benefits of treatment options as it relates to morbidity and mortality rates for heart failure. Careful monitoring of labs should be performed to help prevent the development of hyperkalemia in patients treated with heart failure medications.

Bowling et al. (2009) performed a quantitative, propensity matched study that investigated the effects of hypokalemia on patients suffering from chronic heart failure with the comorbidity of chronic kidney disease (CKD). Sampling data used in the current study came from the Digitalis Investigative Group (DIG), a randomized clinical trial, conducted in the early 1990s. The DIG study consisted of 7,788 patients diagnosed with chronic heart failure and chronic kidney disease (CKD). Prior research had shown that hypokalemia and CKD were associated with poor outcomes in heart failure patients. The researchers evaluated the effect hypokalemia has on patients suffering from both heart failure and chronic kidney disease.

Of the 7,788 ambulatory patients with chronic systolic and diastolic heart failure in normal sinus rhythm enrolled in the DIG trial, 6,800 had a left ventricular ejection fraction < 45% (Bowling et al., 2009). More than 90% of DIG participants were receiving angiotensin-converting enzyme inhibitors, and close to 80% were receiving non-potassium sparing diuretics. Patients with a serum creatinine > 2.5 and serum potassium > 5 were excluded from the study. After exclusion of the creatinine and potassium in those ranges, a cohort of 6,278 patients was available for analyses (Bowling et al., 2009). The researchers further broke down this cohort into those who had chronic kidney disease. Of the 6,278 patients, 2,793 had a glomerular filtration rate (GFR) < 60 mL/min per 1.73 m2 body surface area (Bowling et al., 2009). Of the 2,793 with CKD, 527 had hypokalemia (serum potassium < 4 mEq/L), and 2,266 had normokalemia (4.0-4.9 mEq/L) (Bowling et al., 2009). Of particular interest to the current study, using a 1-to-1 greedy matching protocol, the current researchers matched 522 heart failure patients with hypokalemia to 522 heart failure patients with normokalemia who had similar propensity scores (Bowling et al., 2009). This study also reviewed patients that were

considered severely hypokalemic with a serum potassium < 3.5 and advanced stages of CKD with a GFR < 45 mL/min per 1.73 m2 (Bowling et al., 2009). In addition to the aforementioned, three additional cohorts were assembled within the current research. The dependent variable in the study was the presence of hypokalemia. There were 32 measured baseline characteristics and 2 covariates, creatinine by diuretic use and creatinine by angiotensin-converting enzyme inhibitor use (Bowling et al., 2009). In addition to information on age, race, and gender, the baseline characteristics consisted of diagnostic and radiology results, signs and symptoms, and other objective data. The researchers were interested in hypokalemia versus normokalemia in the heart failure patients with CKD as it pertained to all-cause mortality, cardiovascular mortality, and hospitalizations. The study found that all-cause mortality occurred in 48% and 36%, respectively, of all 522 patients with hypokalemia versus normokalemia in chronic heart failure and CKD (Bowling et al., 2009). Cardiovascular mortality for patients with hypokalemia was 39% as compared to 28% of those with normokalemia. Mortality related to progressive worsening heart failure was 21% in the hypokalemic patient as compared to 14% in the normokalemic patient (Bowling et al., 2009). All-cause hospitalization for heart failure patients with hypokalemia was 72% as compared to 69% with normokalemia. Cardiovascular hospitalization for hypokalemia and normokalemia was 59% and 53%, respectively. Hospitalization related to worsening heart failure was 39% in the hypokalemic patient versus 34% in the normokalemic patient. The researchers further showed that even mild hypokalemia as defined by serum potassium of 3.5-3.9 in this study and considered normal by many textbooks can be significant to the patient diagnosed with heart failure. All-cause mortality for the patient with mild hypokalemia was 47% as compared to 38% of the patients with normokalemia, defined as

serum potassium 4.0-4.9. All-cause cardiovascular mortality was 39% for the mildly hypokalemic patient versus 30% with normokalemia. Thirty percent of the patients with mild hypokalemia expired from worsening progressive heart failure versus 13% of those with normokalemia. Sixty-five of the 522 patients in this study had more severe hypokalemia as defined by serum potassium levels below the 3.5 mEq/L range. Thirty-one percent of patients with severe hypokalemia died from events related to worsening heart failure in comparison to 14% of those with normokalemia. The theoretical framework used in the study was not evident; however, Roy's Adaptation Model (RAM) by nurse theorist Sister Callista Roy could be considered here. This theory can be applied because of the physiological-physical mode, one of four adaptive modes identified by Roy. This mode consists of the need for fluid and electrolyte balance along with the process of maintaining homeostasis of the body's internal environment.

The statistical analysis was performed using SPSS version 15 for Windows, a computerized statistical package. For descriptive analyses, the researchers used Pearson X^2 and Wilcoxon rank sum tests for the pre-match data and the McNemar test and paired sample t test for post-match comparisons. Kaplan-Meier plots and matched Cox regression were used in estimation of hypokalemia with other outcomes. To determine the homogeneity of hypokalemia with all-cause mortality among patients with heart failure and CKD, the researchers examined the association in various subgroups of matched patients (Bowling et al., 2009).

Due to this study being conducted through a retrospective chart review, the researchers did not interact with participants from the DIG trial. Therefore, no data were outlined in the study as to how the participant's rights were affected. A particular weakness identified was the exclusion of data on the dosages of diuretics. The inclusion

of dosing regimens would have been an added strength (Bowling et al., 2009). Many believe that the signs and symptoms of heart failure are strongly associated with the dosage of the diuretic. Another limitation to this study was that no data were provided on the B-type natriuretic peptide levels (BNP) which could have provided further information on the severity of heart failure (Bowling et al., 2009). In addition to absence of data regarding the BNP, no data existed on the use of beta-blockers due to the fact that they were not approved at the time of the original research from which this dataset was extracted. Strengths of the study were to bring attention to the public and healthcare professionals about the imperative monitoring of serum potassium levels in heart failure patients with CKD. "In ambulatory patients with chronic heart failure and CKD, hypokalemia is associated with increased mortality and hospitalization. Research shows that even mild hypokalemia defined as 3.5-3.9 for heart failure patients with CKD are associated with poor outcomes" (Bowling et al., 2009, p. 259).

This article statistically shows the percentage of mortality and hospitalizations related to both mild and severe hypokalemia. "Hypokalemia is known to enhance membrane excitability, increase cardiac automaticity, delay ventricular repolarization and predispose patients to reentrant arrhythmias" (Bowling et al., 2009, p. 258). For this reason, it is imperative that practitioners follow the guidelines to maintain the potassium levels of heart failure patients between 4.0-5.0 mEq/Liter. Serum potassium should be monitored and maintained in this range to avoid even mild hypokalemia in patients with heart failure that also have chronic kidney disease. The importance of following current heart failure guidelines combined with a thorough physical exam protocol for the general medical profession is imperative in order for continuity of care and preventative treatment outside the hospital setting.

In a study by Aranda, Johnson, and Conti (2009), heart failure was shown to affect approximately 5 million adults in the United States. In 2008 heart failure costs were an estimated $34 billion. The researchers concluded that 12 to 15 million office visits and 6.5 million yearly hospital days can be attributed to heart failure, despite improvements in treatment with medications, such as angiotensin-converting enzyme inhibitors, B-blockers, and aldosterone antagonists. Patients hospitalized with a diagnosis of heart failure are at a higher risk for readmission within 6 months—as high as 50% (Aranda et al., 2009).

The investigators utilized a retrospective, observational study to estimate current rates of readmission for Medicare patients with heart failure, identify the reasons for these readmissions, and identify associated factors related to increased risk of readmissions. The information was gathered from 2002-2004 Medicare data obtained from the Centers for Medicare and Medicaid Services. Although previous studies on readmission rates have been useful, those results have often been limited to single-center experiences which are not representative to the general population current practices. According to Aranda et al. (2009), a 5% sample was created by selecting records with a health insurance claim number ending in 05, 20, 45, 70, or 95. This type of sampling technique provided consistency, allowing the researchers the ability to identify records associated with the same beneficiary across several years. All patient information, recorded by a calendar-year quarter, included hospital discharge during 2003 with an ICD-9 discharge code of 428.0 through 428.9 (heart failure) or 398.91 (rheumatic heart failure).

Aranda et al. (2009) limited baseline patient characteristics to age, gender, race, comorbidities, and geographical location. Other baseline characteristics considered were

previous hospitalizations, length of stay for the initial heart failure hospitalization, implantation of a pacemaker or cardioverter-defibrillator during the initial heart failure hospitalization (Aranda et al., 2009). A multivariate logistic regression method was utilized to examine the associations between the baseline characteristics and rates of readmission. Readmission rates within each of the characteristics were compared after calculating odds ratios.

The researchers' investigation identified 28,919 patients which totaled 38,849 heart failure hospitalizations in the 2003 Medicare sample. The identified patient data revealed 51% with one or more hospitalizations for any cause in the 6 to 9 months prior to the first heart failure hospitalization. Patients with a previous heart failure hospitalization in the preceding calendar year totaled 18%, while 6% of patients had two or more previous heart failure hospitalizations. Utilizing this information, the researchers were able to predict an estimated 776,980 hospitalizations involving 578,380 patients (Aranda et al., 2009).

According to Aranda et al. (2009), heart failure accounted for the most frequent reason of all hospital readmissions, totaling 28% during the review period. The patients in the 65 years and older age group comprised 89% of the sample selection. The data also revealed that 83% were Caucasian, 56% were female, and 37% had a comorbidity of diabetes. Patients who resided in the southern region of the United States totaled 41%, which was the highest of any demographic rate.

The researchers used a multivariate logistic regression model to identify factors associated with readmission for any cause within 6 to 9 months of the initial heart failure hospitalization. Aranda et al (2009) determined that 60% of the patients had at least one readmission, with an average of 2.2 readmissions noted per patient. The data revealed

patients younger than 65 years of age had a decreased probability of readmissions within 6 to 9 months as compared with patients 65 to 85 years of age. Caucasian patients had a higher risk for readmission as compared to minority patients. Patients diagnosed with heart failure had a higher occurrence of comorbidities, which will also influence readmission rates. However, findings of the study indicated that patients diagnosed with hypertension, or those who received an implanted cardiac device at the time of the initial heart failure hospitalization, had a lower risk of readmission (Aranda et al., 2009). The population included in this study had a mean length of stay of 5.4 to 5.5 hospital days. The researchers also determined the patients in the sample population had a 4.4% in-hospital mortality rate, and approximately 8% of the patients that were not readmitted died within the first 6 to 9 months after the initial heart failure hospitalization (Aranda et al., 2009).

One of the study's limitations identified by the researchers was that there was a lack of extensive clinical information which prevented detailed evaluations, such as identifying New York Heart Association (NYHA) classification or disease severity. Another limitation identified was that the information from the sampling of Medicare claims in the Medicare Standard Analytical File Limited Data Set did not provide an exact date of each hospitalization, making it difficult to identify discharges in 2003. Although this is done to help protect patient privacy, it can lead to certain challenges when a patient had other hospitalizations during the same calendar-year quarter (Aranda et al., 2009).

The strength of this study was the use of a large public health database to identify current trends in healthcare, such as readmission rates for heart failure patients. This

resource can help identify associated factors that lead to poor outcomes after the initial heart failure hospitalization (Aranda et al., 2009).

The research study conducted by Aranda et al. (2009) was important to the current study of monitoring potassium levels in the treatment of heart failure. The study confirms that despite improved medication options and evidence-based treatment guidelines, heart failure patients continue to experience an increased chance for disease exacerbation. Aranda et al. (2009) concluded that individuals with heart failure have a 60% hospital readmission rate, as well as significant mortality rate. It is important for the healthcare provider to identify this high-risk population in order to decrease the possibilities of comorbidity events, such as monitoring alterations in potassium levels which could cause life-threatening arrhythmias. Therefore, increased awareness and education are needed for the appropriate treatment of heart failure patients, while at the same time helping decrease the economic burden associated with this disease.

In a study conducted by Dunlay et al. (2010), heart failure is an ever-increasing economic burden on the United States healthcare system. Medical care costs have risen over the years and are projected to continue to rise partly due to an aging population, a rise in the diagnosis of heart failure, and additional co-morbid conditions. Heart failure treatment constituted an estimated $37 million in 2009 and consumed more U.S. Medicare dollars than any other diagnosis (Dunlay et al., 2010). Despite what is known about hospitalization care costs, much less is known about the cost of outpatient medical care.

Dunlay et al. (2010) investigated the estimated lifetime costs from heart failure diagnosis until death. The study was conducted in Olmsted County, Minnesota, from 1987 to 2006. Medical records from 97% of the population involving all care sources

were indexed and linked in a centralized system known as the Rochester Epidemiology Project database. This database contained medical record information and billing information for hospitalization, surgery, and outpatient visits.

This cohort longitudinal study identified residents with a diagnosis of heart failure using the ICD-9 code 428. Patients were excluded from the study if heart failure was diagnosed prior to the study period or diagnosed before moving to the county. Records were reviewed by abstractors to ensure that all criteria and diagnosis documentation were present. A total of 1,054 heart failure patients were randomly sampled. The baseline characteristics of the population were 46.1% male with a mean age of 76.8 years. The mean follow-up was conducted at 4.6 years and found that 765 patients had died (Dunlay et al., 2010).

After cases were identified and grouped into the appropriate heart failure category, the lifetime costs data were estimated using the 2-part Tian and Huang method. The first part of the model estimated the probability of having positive costs. The second part of the model uses generalized linear methods to pattern the lifetime costs in the event of positive cost. A similar 2-part model was used to determine the independent predictors of lifetime costs by predicting inpatient, outpatient, and total costs (Dunlay et al., 2010).

The investigators' data revealed 77% of the costs were due to hospitalization with an average of $73,762 per person, while outpatient costs averaged $22,032 per person with the highest proportion stemming from evaluation, management, and procedures in the provider's office. Certain co-morbid conditions, such as (a) hypertension, (b) renal disease, (c) COPD, (d) anemia, (e) diabetes mellitus, and (f) cerebrovascular disease, which could lead to or exacerbate heart failure, were found to increase the costs. The

researchers determined that the distribution of costs were high at the time of initial diagnosis and decreased and remained relatively low until the end stage of the heart failure disease process when costs increased again. The investigators further analyzed the cost effect by comparing healthcare costs in the year prior to the diagnosis of heart failure with the year beginning with the diagnosis. A mean total cost of $8,000 per person was noted prior to the diagnosis, with a marked increase of a mean total cost of $34,000 per person in the year after diagnosis (Dunlay et al., 2010).

One limitation to the study was the fact that the researchers identified only direct medical care in interpreting the data. The investigators did not include indirect costs of care or outpatient medications in research. Another limitation identified was that some costs may have been underestimated if a patient received medical care outside the community due to travel or other extenuating circumstances. Although the researchers did not compare lifetime costs of care with a control group of patients without heart failure, there is evidence of a marked increase in the costs of care post-diagnosis of heart failure in the same patients as compared to before the diagnosis. The researchers also acknowledged that the results related to a single geographical area; however, the ability to examine lifetime costs of medical care in a stable population provides valuable information. Despite the limitations identified, the researchers acknowledged this study's importance in determining the distribution of resources and cost and various patient characteristics that can predict high or low costs. The strengths included the use of a validated population of heart failure patients followed longitudinally and the inclusion of both inpatient and outpatient costs of healthcare costs (Dunlay et al., 2010).

The research study conducted by Dunlay et al. (2010) further supported the significance of conducting the current study of monitoring potassium levels in the

treatment of heart failure by identifying factors associated with higher medical costs. This can be helpful in targeting patients in order to carefully prevent or treat certain co-morbid conditions, improve quality of care, and avoid inpatient admissions to help reduce healthcare costs. This study suggested these are key areas for the practitioner to focus appropriate medical intervention in the treatment and management of heart failure.

Fonarow et al. (2012) performed a mixed study with a nested matched case-control design using data retrieved through retrospective chart review. The current study obtained data from the longitudinal, cohort study, Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting, known as (IMPROVE HF). IMPROVE HF is one of the largest heart failure studies. There has been limited research exploring the application of guideline-recommended therapy with clinical outcomes in patients with heart failure (Fonarow et al., 2012). The researchers in this study sought to discover the individual and incremental gains associated with each of seven current guideline-recommended therapies for heart failure and reduced left ventricular ejection fraction (LVEF) (Fonarow et al., 2012). The seven guideline-recommended therapies consisted of the following: (a) angiotensin converting enzyme inhibitor or angiotensin receptor blocker (ACEI/ARB), (b) beta-blocker, (c) aldosterone antagonist, (d) anticoagulation for atrial fibrillation/flutter, (e) cardiac resynchronization therapy (CRT) with a pacemaker or defibrillator, (f) implantable cardioverter-defibrillator (ICD or CRT with defibrillator), and (g) patient education about heart failure (Fonarow et al., 2012).

The researchers sought to define the significance or value of each individual therapy as recommended by the guidelines. "The primary analysis was designed to evaluate the association of baseline use of the seven guideline-recommended heart failure

therapies and mortality within 24 months and follow-up" (Fonarow et al., 2012, p. 18). In addition, the researchers measured the probability of death in patients eligible for therapy versus those not receiving any treatment. Investigators sought to determine the association between the total number of guideline-recommended therapies received by all patients at baseline and death within 24 months (Fonarow et al., 2012). The sequential contribution of ACEI/ARB, beta blockers, cardiac resynchronization therapy (CRT), and ICD were analyzed. A defined theory was not explicit.

The population of patients from which the current study derived was 15,177 of the original participants enrolled in IMPROVE HF. Eligibility criteria to participate in the study included a clinical diagnosis of heart failure or prior myocardial infarction, with a LVEF $\leq 35\%$. Initially, a random sample beginning with approximately 90 participants from 167 clinics across the United States was available prior to propensity matching. The sample of participants for this current study was 4,128 after the propensity score matching process. This sample was then divided into two groups: (a) those that had expired from any cause before 24 months and (b) those alive at 24 months. The participant group which expired was defined as cases, and the group alive at 24 months was referred to as controls. The sample of 4,128, after division into cases and controls, were 1,376 and 2,752, respectively. Propensity score matching on the case and control groups was completed using a 1:2 greedy-matching. Between the two groups, the participants were well-matched with race being the only statistically significant difference (Fonarow et al., 2012). The majority of the outpatient practices was not affiliated with a university or teaching facility and was well-matched with the number of individuals on staff (Fonarow et al., 2012). The probability of death was the propensity score in this analysis. A logistic regression model was used to generate the probability of

death. The outcome consisted of deceased versus those alive. Covariates consisted of 22 baseline patient characteristics and 4 practice characteristics. "Patients who met the guideline eligibility criteria for each individual therapy, with no contraindications, intolerance, or other documented reasons for not receiving it, were eligible for inclusion in the analyses for that measure" (Fonarow et al., 2012, p. 18). To qualify for an aldosterone antagonist, CRT, or ICD therapy, documentation of the New York Heart Association functional class must exist in the medical record (Fonarow et al., 2012). Chart reviewers received training from members of the IMPROVE HF committee to ensure abstraction of data was accurate (Fonarow et al., 2012). A report on data was generated on a monthly basis during data collection over the 24-month period. In addition, an audit was completed on 20% of all participant data. Thorough matching and education of chart reviewers helped to avoid bias. However, socioeconomic factors or patient adherence to therapeutic regimens could not be adjusted (Fonarow et al., 2012). The two-sample *t* test and chi-square test were used for analysis of the continuous variables and categorical variables, respectively. Baseline treatment rate was calculated for the case and control groups. Differences between the two were compared using the chi-square test (Fonarow, et al. 2012). Initially, "an unadjusted odds ratio (OR) of death was determined using a logistic regression model with the therapy the predictor variable and no covariate adjustment" (Fonarow et al., 2012, p. 18). Further analysis to identify potential covariates was completed with the use of a univariate logistic regression model (Fonarow et al., 2012). Characteristics with a value $\leq .10$ in the univariate regression were fit into a multivariate regression model with treatment as the main effect. Therapies were listed in order of how commonly prescribed in clinical practice from greatest to

guidelines recommend serum potassium monitoring with the use of these medications. Without monitoring of potassium by healthcare providers in patients prescribed these medications, a patient may die as a result of serious electrolyte abnormalities. Fonarow et al. (2012) stated that independently valuing heart failure therapies would enable a provider to make the best decision on which medicine to continue or discontinue if a choice must be made for reasons of cost, tolerance, or adherence. In addition, many hospitals and clinics provide performance improvement programs to ensure that guideline-recommended therapies are utilized.

Conceptual Framework

Several studies have focused on the use of Sister Callista Roy's Adaptation model. The innovative work of Sister Callista Roy, RN, PhD. presented the nursing theory that views the individual as a holistic adaptive system as related to the concepts of person, health, environment, and nursing. Roy's Adaptation Model (RAM) is aimed at understanding human behavior in order to maintain and enhance coping mechanisms to promote optimal health. RAM can be applied not only to the individual, but it can be easily adapted to group situations. The current research group reviewed one original article by Sister Callista Roy and three additional research articles using the Roy Adaptation Model as the theoretical framework. The current researchers demonstrated how these researchers utilized Roy's Adaptation Model to guide their studies as well as discuss how the Roy Adaptation Model was used as the foundation of the current research study.

As a graduate student in 1964, Sister Callista Roy saw the person as an entity, which not only persisted on the individual self, but included the environment as a whole contributing to the health and well-being of the person holistically. She believed that the

portal to human health was not only for nurses to care for the person physically but to incorporate environment, beliefs, roles, economics, and population-based care into the equation. Nursing exists as an academic discipline and a practice profession, and both rely on timely knowledge development. People of today's society have evolving needs that increase the complexity of care, such as a) chronic illnesses due to increasing longevity, (b) rising ethnic and racial populations, and (c) global economic status. Nurses must work for the common good and dignity of people within their realm of existence. In order to accomplish this task, Roy reevaluated the RAM to bring nursing care into the 21st century and beyond. "The social mandate of nursing is to contribute to the good of society by knowledge-based practice related to contemporary and emerging health needs" (Roy, 2011, p. 1). Roy devised Epochs to extrapolate past thought to modern times in order to describe the needs and thoughts relevant to each Epoch period. Roy integrated Laszlo's view of the human brain when he described it as a quasi-neural energy-information-processing network into a view of nursing around the globe that interacts with each other, to nature, and reality. This allows existing and future nurses to view the increasing role of knowledge expansion and care expectations placed on the nursing society as a whole. In addition, it allows nurse practitioners to build upon the solid foundation of knowledge that has been established in previous years for use in today's 21st century.

Thomas (2007) reviewed a study on how self-concept has negative impacts on treatment modalities in patients with heart failure. Although there have been many surgical and medical advances in heart failure, poor adherence to recommended diet, exercise, and medication regimens continue to negatively impact outcomes (Thomas, 2007). The RAM was used to guide this study in which Roy emphasized that self-

concept or the perceptions that one holds of oneself directs behavior. Roy identified five different aspects on self-concept which include body image, body sensation, self-ideal, self-consistency, and moral-ethical-spiritual self (Thomas, 2007). A descriptive correlational design was used to assess if there was a correlation between self-concept and treatment modality compliance. Two heart failure clinics were included in the study. One clinic was located in a rural/suburban area, and the other was located in a large urban inner city (Thomas, 2007). Patients who met criteria for the study were asked questions as they visited the clinics. Descriptive and predictive correlational analysis, using the Pearson product moment correlation and the stepwise multiple regression were used to analyze the answers. The overall threat to self-concept was 12% ($p < .01$), threat to body image was 14% ($p < .01$), challenge to self-concept was 13% ($p < .01$), and challenge to moral-ethical-spiritual self and body image was 14.5% ($p < .01$) with the challenge to moral-ethical-spiritual self and body image being the strongest predictor of adherence to health regimens (Thomas, 2007). Using a theory-based nursing study helps us understand how self-concepts influence treatment modalities for HF patients. In addition, it identifies the imperative need for positive reinforcement, praise, and education.

Abbas, Schahanz, and Saeed (2011) embarked on a study in Iran using RAM in attempts to describe the adherence to therapeutic regimens in patients with heart failure. As described in a previous study using the RAM, noncompliance to heart failure treatment has become global. A descriptive correlational study was conducted in two medical centers in Iran with questionnaires filled out by participating patients who met the qualifying criteria. Results showed the following analysis: 33% were female with average age 62 years, 80.6% were married, 56.9% used medications, 54.9% did not use medications, and 39.0% exercised. The findings of this study showed that a viewed

threat to the components of self-concept (including body sensation, body image, self-consistency, self-ideal, and moral-ethical-spiritual self) has a negative relationship with regimen adherence, whereas a viewed challenge to self-concept and its components is positively related to the adherence (Abbas et al., 2011). Nurses around the world should assess the outcomes of this study and others as well in order to involve patients in their treatment regimens. Sister Callista Roy has modernized the RAM to incorporate a more consistent global response between all members of the medical profession in order to form a smoother transition from a noncompliant society due to decreased knowledge of the disease process and treatments to a better educated and involved compliant society.

Bakan and Akyol (2007) did an interesting study that examined the effectiveness of a RAM as a useful guide for nursing practice when caring for heart failure patients. The researchers utilized data from a secondary analysis of a randomized-controlled trial to determine how programs such as education, exercise, and social support impacted adaptation in patients with heart failure (Bakan & Akyol, 2007). The information was obtained by utilizing the Minnesota Living with Heart Failure Questionnaire. The study was directed by the RAM, which focused on environmental stimuli and the associated response modes to those stimuli (Bakan & Akyol, 2007). The four biopsychosocial modes used to measure the level of adaption are physiological mode, self-concept mode, role function mode, and interdependence mode. The authors established that patients with physical, emotional, social, and economic difficulties can have impaired coping mechanisms. Intervention groups for the four modes of adaptation were established to monitor and improve coping mechanisms. RAM is an important theory concept guide in the care of patients who have been diagnosed with heart failure. This article corroborates the need to incorporate RAM into patient education programs to enhance the patient's

knowledge and skills necessary to evoke behavior changes for appropriate coping of this long-term health problem. Using the Roy Adaptation Model, patients who had participated in the intervention group had improved emotional status and quality of life, increased functional abilities, and enhanced social support (Bakan & Akyol, 2007).

Adaptation involves coping mechanisms to control internal and learned environment. The mechanisms for coping can be learned or inherited (George, 2011). Roy developed the concept of control mechanisms. Through her model, she classifies these mechanisms of coping as subsystems of the person's adaptive function (George, 2011). Of significance to the current research project are the *regulator* and *cognator* subsystems and the physiological-physical mode, one of four developed by Roy's model. Rogers and Keller (2009) stated the effects of coping at the subsystem level cannot be measured. "The *cognator* subsystem involves four cognitive channels: perceptual and information processing, learning, judgment and emotion" (Rogers & Keller, 2009, para. 8). Noncompliance with medication adherence and follow-up for serum potassium monitoring could be a result of cognitive impairment. Three components of the *regulator subsystem* include input, internal process, and output. It contains transmitters that can be characterized as chemical, neural, or endocrine. Work of breathing and regulatory feedback mechanisms of respiration and heart rate, the regulator subsystem, can be evident in patients with heart failure. Fluid and electrolyte balance, oxygenation, activity/rest and nutrition are complex processes of the physiological-physical mode. Rogers and Keller (2009) stated that, "stimulation to the *regulator* and *cognator* subsystems result in behavior changes measured in the physiologic and psychosocial modes" (para. 8). Through monitoring of the potassium level in patients with heart failure and bringing an increased awareness to the national guidelines, the current

researchers will identify how providers can stabilize the internal environment. In addition, patients must be able to cognitively process information discussed with them on heart failure education. Neurologically, their memory must be intact with an appropriate attention span. They must be able to adhere to follow-up visits for the monitoring of their potassium level, our main intracellular electrolyte. Through the current study, these researchers will be more aware of our future patients' need for regulation of potassium levels and the need to positively reinforce follow-up.

Summary

The need to monitor serum potassium level is shown to be clinically significant in the outpatient setting. The review of literature clearly demonstrates that without providers monitoring the body's main intracellular electrolyte, death could occur. Evidence shows that ventricular arrhythmias could cause sudden death or increased mortality related to either hypokalemia or hyperkalemia. The 2009 ACCF/AHA guidelines should be followed by all providers in the outpatient setting with routine monitoring of all heart failure patients.

CHAPTER III

Design and Methodology

The focus of this study was to evaluate healthcare providers' compliance with the recommended 2009 ACCF/AHA guidelines for monitoring routine serum potassium levels in heart failure patients. An alteration in potassium levels, either hyperkalemia or hypokalemia, can cause severe cardiac arrhythmias. The results from this study could help healthcare providers effectively manage heart failure according to the guidelines and prevent life-threatening complications that can affect heart failure patients.

The occurrence of primary care providers' monitoring potassium levels in the treatment of heart failure was determined by using a nonexperimental, quantitative design. Data were retrospectively obtained from a population sample of 200 charts of adult patients, 18 years of age and older, with the diagnosis of heart failure, ICD-9 diagnosis code 428. The data were collected from the patient's electronic medical record. A standardized data collection worksheet was implemented to obtain all information. Specific data concerning the serum potassium level, frequency of collection, medication utilized, medication adjustment done if the serum potassium was out of range, age, gender, ethnicity, and payer source were obtained. In order to maintain the facility's records and ensure that each patient's right to privacy and confidentiality were preserved, all data collection will be conducted in a designated area of the facility.

Population, Sample, and Setting

The population in this study was any adult patient with the diagnosis of heart failure identified with ICD-9 diagnosis code 428. Only adult patients, 18 years of age and older, with a diagnosis of heart failure were selected for the evaluation of potassium monitoring. The researchers manually obtained a convenience sample of 200 charts from

two rural primary care clinics in north and east central Mississippi with an ICD-9 diagnosis code 428.

Implementation of the Project

Protection of human rights. Prior to the collection of data, the researchers received written approval by the Mississippi University for Women's Institutional Review Board (IRB) (see Appendix C). Consent was obtained from the two primary care clinics in north and east central Mississippi where the data was collected for this study. The researchers obtained informed consent from each facility's director via a consent letter (see Appendix D) identifying the purpose and nature of the study. This research was retrospective chart review only and involved no disclosure related to human participants. Patient confidentiality was maintained at all times. Access to medical record numbers, names, date of birth, diagnosis, and other personal information was limited to the researchers. The research data collection worksheet (see Appendix E) contained no personal information, such as name, date of birth, or social security number. Data obtained from the data collection worksheet were stored on two password-protected media drives that were purchased explicitly for this purpose.

Data collection procedure. Utilizing the medical records, the researchers performed a query and collected a list of patients with an ICD-9 diagnosis code 428. Only charts with ICD- 9 diagnosis code 428 for heart failure were selected for review in this study. The data were obtained from charts of documented medical care provided to patients with heart failure. After the list was collected, the researchers manually reviewed a convenience sample of the first 200 medical records meeting the sample criteria for this study.

Once the sample was selected, a chart audit was performed using the standardized data collection worksheet to obtain data for sample inclusion. The researchers completed the chart reviews in a secluded area of the clinic. This area allowed privacy and did not impede patient flow. The data collection worksheets were stored on two password-protected media drives purchased explicitly for this purpose. Each researcher remained in possession of her respective media drive and kept it in a locked box for safekeeping. The password was only known to the researcher. After the data had been compiled and the completed data collection worksheets were no longer needed, the media devices and worksheets were destroyed.

Instrumentation. The researchers developed a standardized data collection worksheet. This worksheet allowed the following information to be collected in a systematic method: (a) diagnosis of heart failure; (b) the serum potassium level; (c) frequency of collection; (d) medications to include ARBs, ACE-I, aldosterone antagonist, diuretics (potassium-sparing, loop, or thiazide), and beta-blockers; (e) was a medication adjustment made if the potassium level was out of the recommended range; (f) age; (g) gender; (h) ethnicity; and (i) payer source. The data collection worksheet was used to evaluate each patient's chart for eligibility of inclusion in the sample. This data collection worksheet was utilized solely for the purpose of this research study.

Data Analysis

After compilation, data pertaining to the research questions were analyzed using descriptive statistics. The researchers utilized assistance of a professional statistician to further correlate categorized percentiles and frequencies to answer the research questions.

Summary

The importance of monitoring routine potassium levels in the treatment of heart failure needs to be emphasized. Once consent from the two rural primary care clinics in north and east central Mississippi was obtained to conduct the study, the researchers performed a nonexperimental, descriptive retrospective chart review on 200 medical charts. The sample was chosen by use of a convenience sample. Confidentiality and protection of human rights were maintained at all times. The researchers utilized a data collection worksheet to gather information needed for descriptive statistics and correlation analysis to answer the research questions. Data were gathered from the patient records and analyzed descriptively to answer each of the research questions. The nominal data were accumulated and presented to a statistician or entered into a computer database for analysis.

CHAPTER IV

Research Findings

The purpose of this study was to evaluate healthcare providers' compliance with the recommended 2009 ACCF/AHA guidelines for monitoring routine serum potassium levels in heart failure patients. In addition, the researchers evaluated if the routine serum potassium level was documented at least every 4 months as recommended by the ICSI Guidelines for Heart Failure in Adults. In this chapter, the sample will be described and the research questions will be answered utilizing the findings from the study.

Profile of Study Participants

A convenience sample of 200 charts ($N = 200$) with an ICD-9 diagnosis code 428 was obtained from two rural primary care clinics in north and east central Mississippi. The data were manually extracted and recorded on a data collection worksheet designed by the researchers. Charts were not selected earlier than 2009 due to ACCF/AHA updated guidelines. Subsequent analyses of the data were performed using Minitab statistical software, version 16. The population sample was eligible for inclusion in the study when data collection instrument criteria were met.

The sample population included both male and female individuals 18 years of age and older. The mean for the ages collected was 75 years, with ages ranging from 35-98 years. The median age of the data set was 78 years.

Participant Characteristics

The first question on the researchers' data collection worksheet was in regard to gender. The sample consisted of 51.5% females ($n = 103$) and 48.5% males ($n = 97$). Figure 1 illustrates the percentage of the gender in the sample population.

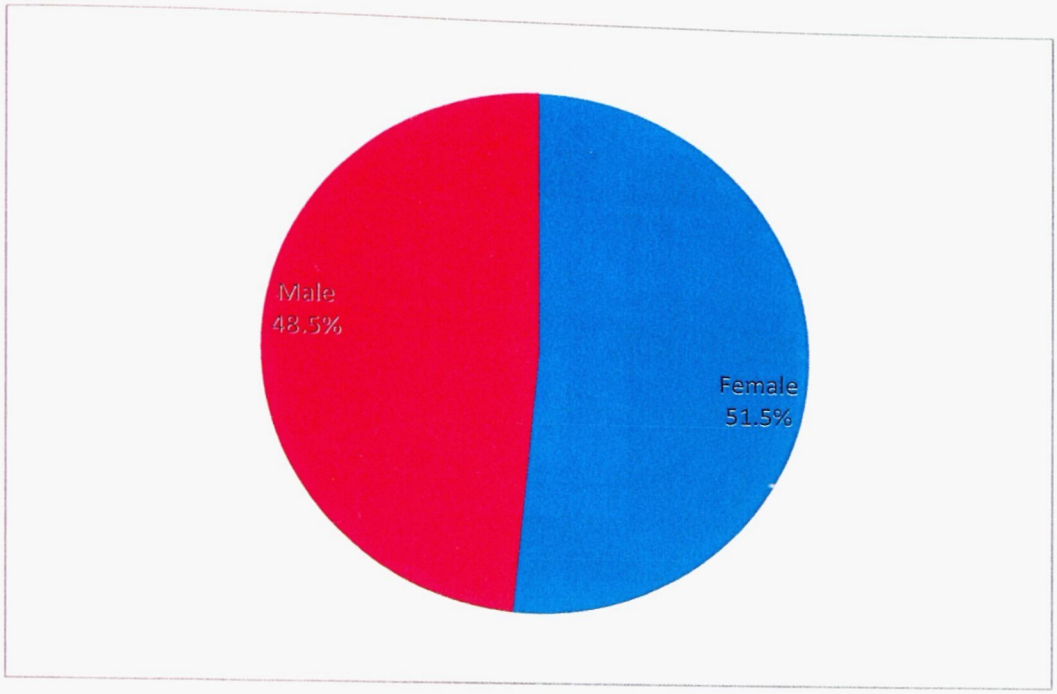

Figure 1. Gender of sample population ($N = 200$).

The second question on the researchers' data collection worksheet was in regard to age. The sample consisted of patients between the ages of 35 and 98 years. The mean age was 75 years. No patients with an ICD-9 diagnosis code 428 in the age range of 18-30 years were identified. Ages 31-50 years consisted of 4.5% ($n = 9$), ages 51-70 years consisted of 26% ($n = 52$), and ages 71 and greater consisted of 69.5% ($n = 139$) of the sample. Figure 2 demonstrates the age range of the sample population.

The third question on the researcher's data collection worksheet was in regard to ethnicity. Of the sample collected, 79.5% ($n = 159$) were Caucasian, 20% ($n = 40$) were African American, and 0.5% ($n = 1$) were other. No Hispanic patients with the ICD-9 diagnosis code 428 were identified. Figure 3 depicts the ethnicity of the sample population.

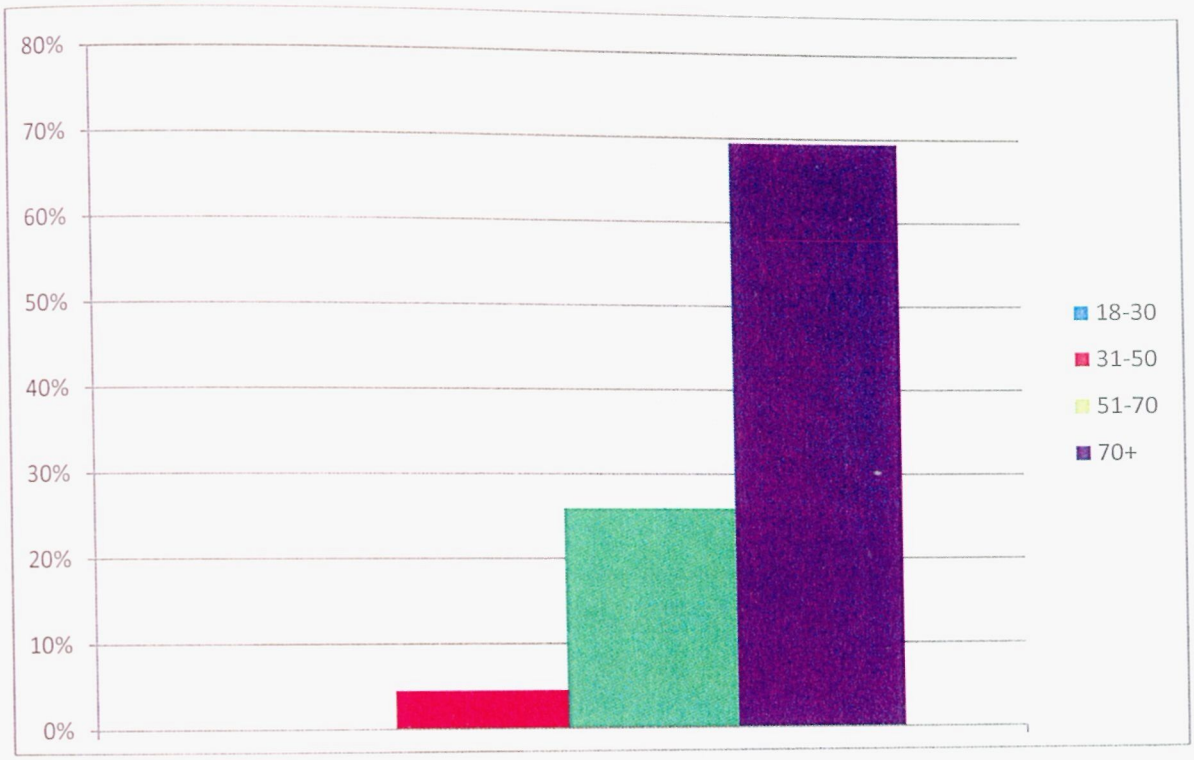

Figure 2. Age of sample population.

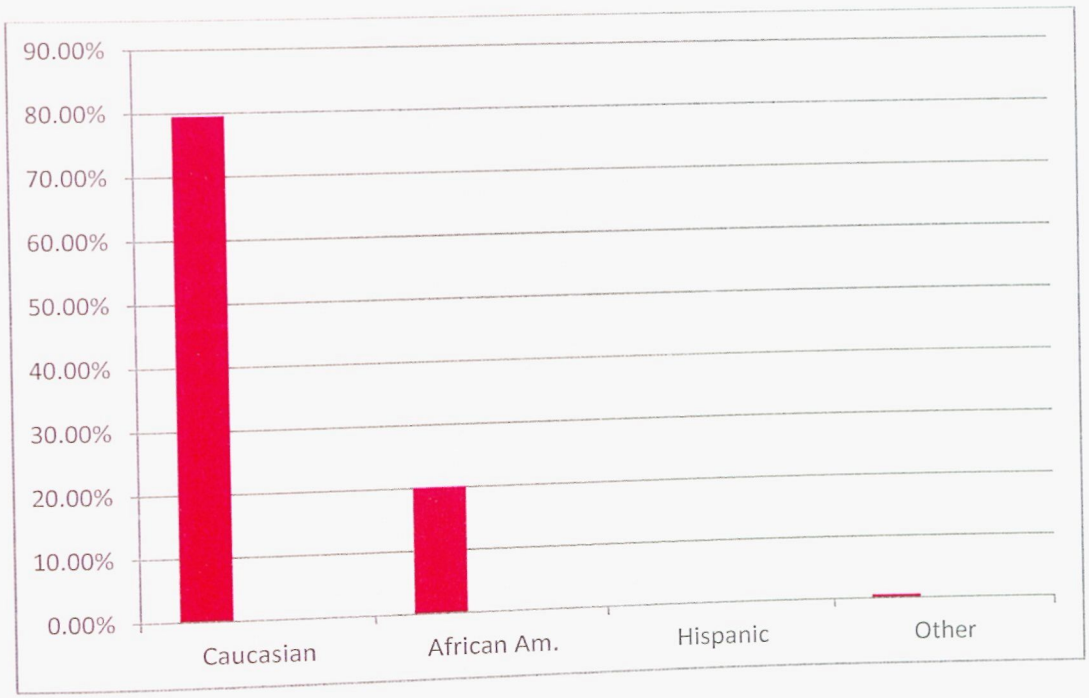

Figure 3. Ethnicity of sample population.

The researchers also assessed the sample population's payer source on the data collection worksheet. Of the sample collected, 92% (n = 184) had Medicare, 0.015% (n = 3) had Medicaid, 0.06% (n = 12) had commercial insurance, and 0.005% (n = 1) was self-pay. Table 1 is used to illustrate these findings.

Table 1

Payer Source of Sample Population

Payer source	%
Medicare	92.000
Medicaid	.015
Commercial insurance	.060
Self-pay	.005

Results of Data Analysis

According to the 2009 ACCF/AHA guidelines, patients with heart failure, ICD-9 diagnosis code 428, should have routine monitoring of serum potassium levels. The recommendations state the serum potassium level should be maintained between 4.0-5.0 mEq/L.

The ICSI Guidelines for Heart Failure in Adults were utilized to define routine monitoring as at least every 4 months. If the serum potassium level was not in the recommended range of 4.0-5.0 mEq/L, the researchers assessed if there was a medication adjustment. The following figures will illustrate the statistical findings of the research questions.

Research question 1. Was the serum potassium level in patients being treated for heart failure monitored and documented at least every 4 months as recommended by the Institutes for Clinical Systems Improvement Guidelines for Heart Failure in Adults? Of the 200 charts reviewed, 187 had documentation of a serum potassium level checked in the past four months. This corresponds to a 93.5% compliance rate with the recommendation by the ICSI Guidelines for Heart Failure in Adults. Figure 4 is used to illustrate these findings.

Figure 4. Frequency of serum potassium documentation.

Research question 2. Was the serum potassium level in the recommended range of 4.0-5.0 mEq/L according to the 2009 ACCF/AHA recommended guideline when monitored? Of the 187 charts reviewed in which a serum potassium level was checked within the past 4 months, 142 charts had a documented serum potassium level between 4.0-5.0 mEq/L. This represents 75.9% compliance with the recommended range, and

24.1% (n = 45) outside the recommended range. Figure 5 is used to illustrate the findings.

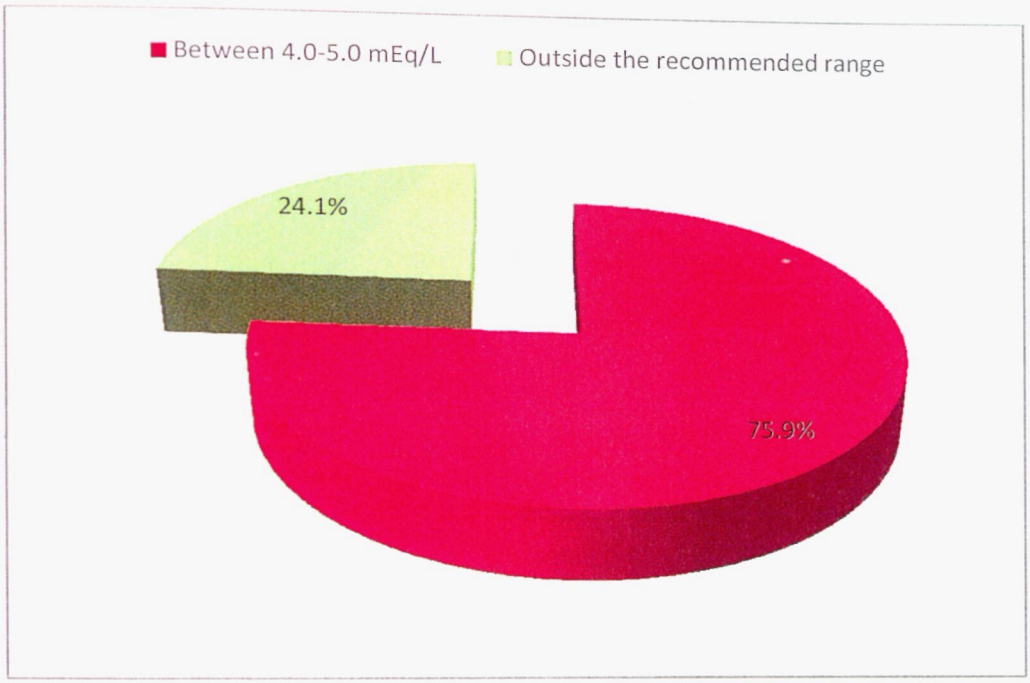

Figure 5. Percentage of patients' serum potassium level within the recommended range.

Research question 3. If the serum potassium level was not in the recommended range, was there a medication adjustment? Of the 45 charts reviewed in which the serum potassium level was outside the recommended range, 55.6% (n = 25) of the patients did receive a medication adjustment. The remaining 44.4% (n = 20) of the patients did not receive a medication adjustment. Figure 6 is used to illustrate the findings.

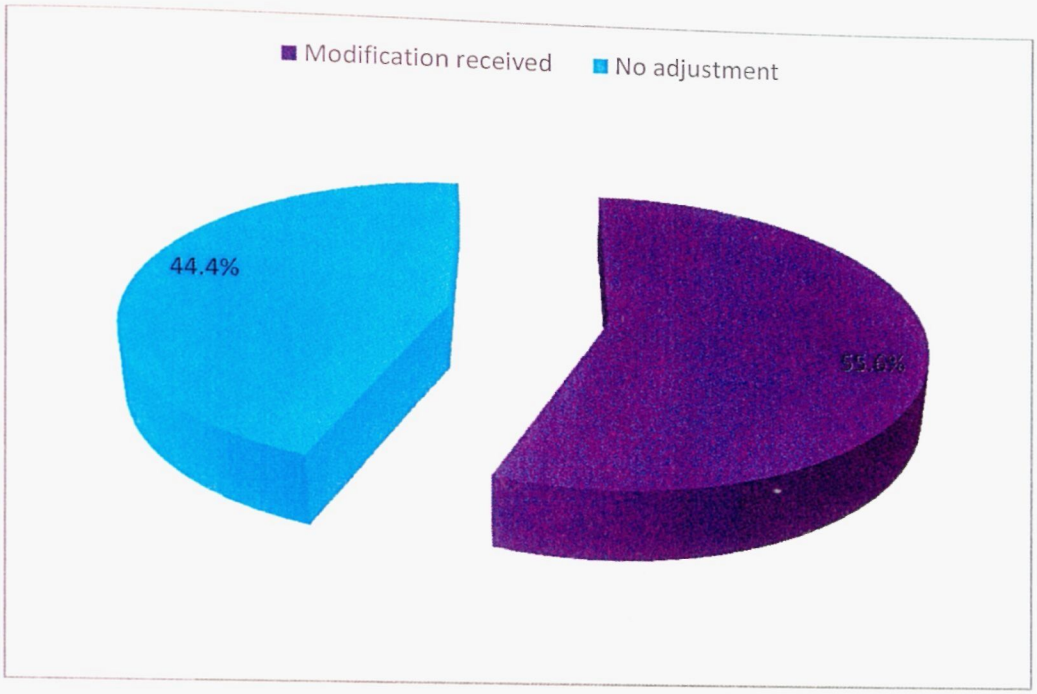

Figure 6. Percentage of patients outside the recommended range receiving a medication adjustment.

Conclusion of Findings

The data collected in the retrospective chart review was analyzed using descriptive statistics. This study utilized both tables and figures to present and describe the findings. Of the 200 charts reviewed, 93.5% ($n = 187$) of the sample population had documentation of a serum potassium level within the last 4 months. Of the 187 patients with documentation of a serum potassium level, 24.1% ($n = 45$) had a serum potassium level outside the recommended range of 4.0-5.0 mEq/L. However, out of the 45 patients who were not within the recommended range, only 55.6% ($n = 25$) received a medication adjustment to help correct the electrolyte imbalance. In conclusion, the primary care providers had a 93.5% compliance with serum potassium monitoring and medication adjustment if needed according to the 2009 ACCF/AHA guidelines in regard to the total sample population ($N = 200$). However, this study revealed there is an opportunity

among healthcare providers for improvement in the routine monitoring of serum potassium level.

CHAPTER V

The Outcomes

Implications

Heart failure is a common complication of heart disease as a result of damage to the heart muscle. It is a chronic, progressive condition in which the heart muscle becomes too weak to efficiently pump an adequate amount of blood to meet the body's need for blood and oxygen. Increasing prevalence, hospitalizations, and death rate have made CHF a major chronic condition affecting all ages and races. A review of literature was completed and demonstrated that heart failure is an overwhelming disease in the United States affecting millions. Also, it revealed that suboptimal treatment relates to increased hospitalization and office visits. According to the Healthcare Cost and Utilization Project of 2009, heart failure was listed among the top 10 most frequent principal diagnoses utilized (Wier et al., 2011). Many medications used in the treatment of heart failure can alter the body's serum potassium level. Potassium plays a critical role in the heart's electrical conduction, affecting cardiac automaticity and membrane excitability, as well as repolarization (Bowling et al., 2009). Heart failure patients should maintain a serum potassium level in the 4.0-5.0 mEq/L range to help prevent potentially life-threatening cardiac arrhythmias (Jessup et al., 2009).

The purpose of this study was to evaluate healthcare provider's compliance with the recommended 2009 ACCF/AHA guidelines for monitoring routine serum potassium levels in heart failure patients. In addition, the researchers evaluated if the routine serum potassium level was documented at least every 4 months as recommended by the ICSI Guidelines for Heart Failure in Adults. Sister Callista Roy's Adaptation Model was utilized as the theoretical framework for this study. This chapter will discuss the

importance of the findings, limitations of the study, implications for nursing, and recommendations for further research and practice.

Interpretation of the Findings

The sample (N = 200) included patients >18 years of age who received care at one of the two rural primary care clinics in north and east central Mississippi and had a diagnosis of heart failure with an ICD-9 diagnosis code of 428. The sample was primarily compromised of Caucasians (n = 159 or 79.5%), with almost equal male (n = 97 or 48.5 %) and female (n = 103 or 51.5%) participants. The mean age was 75 years with ages ranging from 35 to 98 years. The primary payer source was Medicare (n = 184 or 92%).

The research project was guided by the following questions:

1. Was the serum potassium level in patients being treated for heart failure monitored and documented at least every 4 months as recommended by the Institutes for Clinical Systems Improvement Guidelines for Heart Failure in Adults?
2. Was the potassium level in the recommended range of 4.0-5.0 mEq/L according to the 2009 ACCF/AHA recommended guideline when monitored?
3. If the potassium level was not in the recommended range, was there a medication adjustment?

According to these findings, healthcare providers have a 93.5% compliance rate with monitoring and documenting the serum potassium level as recommended by the 2009 ACCF/AHA Guidelines for the management of heart failure and the ICSI Guidelines for Heart Failure in Adults. However, these findings reveal there is a need among healthcare professionals for continued improvement in this critical area in the

treatment. Patients with heart failure should be carefully monitored for changes in serum potassium level. Every effort should be made to prevent the occurrence of either hypokalemia or hyperkalemia, both of which may adversely affect cardiac excitability and conduction leading to cardiac arrhythmias and sudden death.

The review of literature indicated the importance of routine monitoring of serum potassium levels and regulating within the desired range of 4.0-5.0 mEq/L for patients diagnosed with heart failure. If the acceptable range is not maintained, an alteration of serum potassium could cause detrimental effects. Age, gender, and ethnicity can be linked with progression of this deadly disease.

Alper et al. (2009) sought to determine the effects of an alteration of serum potassium on older adults age 65 years and over diagnosed with heart failure. The investigators suggested that there were limited studies with this high-risk age group although the incidence of heart failure increased with age. The data revealed from the sample of 7,788 participants, 4,036 were 65 years of age or older. Ambulatory adults 65 years of age and older diagnosed with heart failure and hypokalemia had increased adverse effects and mortality rate. The current research study revealed that 139 of the 200 charts (69.5%) reviewed were 71 years and older. The current study correlates with the importance of healthcare providers identifying certain high-risk populations, especially the elderly, in order to decrease the possibilities of an alteration in the serum potassium level.

Fonarow et al. (2012) identified the significance for following guideline-recommended therapies in the treatment of heart failure. Without monitoring of serum potassium levels by healthcare providers in patients prescribed certain medications used in the treatment of heart failure, serious electrolyte abnormalities can develop. These

abnormalities can lead to cardiac arrhythmias and death. The current study correlates the need for increased awareness and education in the appropriate treatment of heart failure patients. Although the data revealed a 93.5% compliance rate following the current guidelines in regard to monitoring serum potassium levels, it was also shown that improvement in this area is still needed to improve quality of patient care, reduce mortality rate, and lessen the economic burden caused by this disease.

Limitations of the Study

Limitations were identified in this study including the fact that data were only collected from two primary care clinics within the state of Mississippi which may not adequately represent diversity of the population. Another limitation is the serum potassium level may have been performed at a specialty office with no results forwarded to the primary healthcare provider leaving the charts with missing or inaccurate data. In addition, this study did not identify the reason why a medication adjustment was not done when the serum potassium level was not within the recommended range of 4.0-5.0 mEq/L. Finally, the various class of medications used to treat heart failure was not evaluated for their potential effects on serum potassium level.

Implications for Nursing

This study is significant to the nurse practitioner role because there are established guidelines for managing heart failure which represent evidence-based practices that healthcare providers are expected to utilize. Sister Callista Roy's Adaptation Model was used to guide this research study by influencing the relationship between the healthcare provider and patient. This enhanced relationship encouraged the patient to develop positive adaptive coping mechanisms leading to a comprehensive, holistic approach to care.

Heart failure has an increasing prevalence and high mortality rate which has led to a growing economic burden to the U.S. at an estimated $40 billion. By performing routine monitoring of serum potassium level at least every 4 months, an alteration outside the recommended 4.0-5.0 mEq/L range can be detected and interventions, such as a medication adjustment, can be implemented to help prevent the development of possible cardiac complications. Through this study, nurse practitioners were made aware of the importance of adhering to the 2009 ACCF/AHA guidelines for monitoring routine serum potassium levels in heart failure patients.

Recommendations for Research and Education

Further research can be conducted by replicating this study with an increased number of clinical sites and a larger sample size to more adequately represent the population. This would reveal if more healthcare providers are following the 2009 ACCF/AHA guidelines for monitoring routine serum potassium levels in heart failure patients. A special computer alert for the electronic health record could help ensure that heart failure patients had a timely evaluation of potassium levels.

The authors believe that provider education is the best way to improve compliance in monitoring serum potassium levels in heart failure patients. An educational in-service, presented to healthcare providers, may increase knowledge and compliance with the 2009 ACCF/AHA heart failure guidelines. In hopes that healthcare providers will realize the importance of following recommended guidelines, the authors plan to present the outcomes of this study to the two rural primary care clinics in which the data were collected.

Summary of Implications

Certain medications used in the treatment of heart failure can alter the body's serum potassium level. A serum potassium level outside the recommended range of 4.0-5.0 mEq/L in heart failure patients can increase adverse cardiac outcomes which can lead to potentially life-threatening arrhythmias. The purpose of this study was to determine if healthcare providers were adhering to the 2009 ACCF/AHA guidelines for monitoring serum potassium levels in heart failure patients. The study revealed that of the 200 charts reviewed for the first research question 187 patients had documentation of a serum potassium level within the past 4 months. For the second research question, the authors determined that 45 out of those 187 patients or 24.1% had a serum potassium level outside the recommended range of 4.0-5.0 mEq/L. The research findings further concluded that 25 of the 45 patients who were not within the recommended range or 55.6% received a medication adjustment to help correct the electrolyte imbalance. In conclusion, healthcare providers were 93.5% compliant with the 2009 ACCF/AHA guidelines. If recommendations from this study are applied to practice, heart failure patients would receive optimal healthcare decreasing the potential of life-threatening complications and decreasing outpatient clinic visits and hospitalizations. This could help improve the quality of life for heart failure patients and reduce the economic burden of managing heart failure in the U.S.

REFERENCES

Abbas, H., Schahanz, A., & Saeed, V. (2011). The relationship between self-concept and adherence to therapeutic regimens in patients with heart failure. *Journal of Cardiovascular Nursing*, *26*(6), 475-480. doi.org/10.1097/JCN.0b013e318215bb78

Alper, A. B., Campbell, R. C., Anker, S. D., Bakris, G., Wahle, C., Love, T. E., Hamm, L. L., ... Ahmed, A. (2009). A propensity-matched study of low serum potassium and mortality in older adults with chronic heart failure. *International Journal of Cardiology*, *137*, 1-8. doi.org/10.1016/j.ijcard.2008.05.047

Aranda, J., Johnson, J., & Conti, J. (2009). Current trends in heart failure readmission rates: Analysis of Medicare data. *Clinical Cardiology*, *32*(1), 47-52. doi: 10.1002/clc.20453

Bakan, G., & Akyol, A. (2007). Theory-guided interventions for adaptation to heart failure. *Journal of Advanced Nursing*, *61*(6), 596-608. doi.org/10.1111/j.1365-2648.2007.04489.x

Bowling, C.B., Pitt, B., Ahmed, M. I., Aban, I. B., Sanders, P. W., Mujib, M., Campbell, R. C., Love, T., ... Ahmed, A. (2009). Hypokalemia and outcomes in patients with chronic heart failure and chronic kidney disease: Findings from propensity-matched studies. *Circulation of Heart Failure*, *3*, 253-260.

Centers for Disease Control and Prevention. (2012). *Heart failure fact sheet*. Retrieved from http://www.cdc.gov/DHDSP/data_statistics/fact_sheets/fs_heart_failure.htm

Desai, A., Swedberg, K., McMurray, J., Granger, C., Yusuf, S., Young, J., ... Pfeffer, M. (2007). Incidence and predictors of hyperkalemia in patients with heart failure:

An analysis of the CHARM program. *Journal of the American College of Cardiology*, *50*(20), 1959-1966. doi.org/10.1016/j.jacn2007.07.067

Dunlay, S. M., Shah, N. D., Shi, Q., Morlan, B., VanHouten, H., Long, K. L., & Roger, V. L. (2010, December). Lifetime costs of medical care after heart failure diagnosis. *Circulation: Cardiovascular Quality and Outcomes, 4*, 68-75. doi: 10.1161/ CIRCOUTCOMES.110.957225

Emory Healthcare Heart and Vascular. (2012). *Heart failure statistics*. Retrieved from www.emory.org/heart-failure/learn-about-heart-failure/statistics.html

Fonarow, G. C., Albert, N. M., Curtis, A. B., Gheorghiade, M., Liu, Y., Mehra, M. R., & Yancy, C. W. (2012). Incremental reduction in risk of death associated with use of guideline-recommended therapies in patients with heart failure: A nested case-control analysis of IMPROVE HF. *Journal of the American Heart Association*, *1*(1), 16-26. doi.org/doi:10.1161/JAHA.111.000018

George, J. B. (2011). Roy Adaptation Model. In M. Connor (Ed.), *Nursing theories: The base for professional nursing practice* (6th ed., pp. 291-337). Upper Saddle River, NJ: Pearson Education.

Heart Failure Society of America. (n.d.). *Quick heart failure facts*. Retrieved from http://www.hfsa.org/heart_failure_facts.asp

Hunt, S. A., Abraham, W. T., Chin, M. H., Feldman, A. M., Francis, G. S., Ganiats, T. G., ... Riegel, B. (2005). ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines: Developed in collaboration with the International Society for Heart

and Lung Transplantation. *Circulation*. doi: 10.1161/CIRCULATIONAHA.105.167586

Institute for Clinical Systems Improvement. (2011). *Health care guidelines: Heart failure in adults*. Retrieved from http://www.icsi.org/heart_failure_2/heart_failure_in_adults_.html

Jessup, M., Abraham, W. T., Casey, D. E., Feldman, A. M., Francis, G. S., Ganiats, T. G., ... Mancini, D. M. (2009). 2009 Focused update: ACCF/AHA guidelines for the diagnosis and management of heart failure in adults: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: Developed in collaboration with the International Society for Heart and Lung Transplantation. *Circulation*. doi:10.1161/CIRCULATION AHA.109.192064

Roger, V. L., Go, A. S., Lloyd-Jones, D. M., Adams, R. J., Berry, J. D., Brown, T. M., ... Wong, N. D. (2011). Heart disease and stroke statistics 2011 update: A report from the American Heart. *Circulation, 123*(e114-e119). doi: 10.1161/CIR.0b013e3182009701

Rogers, C., & Keller, C. (2009). Roy's Adaptation Model to promote physical activity among sedentery older adults. *Geriatric Nursing*, *30*(2), 21-26. doi.org/10.1016/j.gerinurse.2009.02.002

Roy, C. (2011). Extending the Roy Adaptation Model to meet changing global needs. *Nursing Science Quarterly*, *24*(345). doi.org/10.1177/0894318411419210

Thomas, C. (2007). The influence of self-concept on adherence to recommended health regimens in adults with heart failure. *Journal of Cardiovascular Nursing*, *22*(5). doi.org/10.1111/j.1365-2648.2007.04489.x

U.S. Department of Health and Human Services Agency for Healthcare Research and Quality. (2012). Retrieved from http://qualityindicators.ahrq.gov

Venes, D. (Ed.). (2001). *Taber's cyclopedic medical dictionary* (19th Ed.). Philadelphia, PA: F.A. Davis.

Wier, L., Maeda, J., Ryan, K., Pfuntner, A., Stranges, E., Jagadish, P., ... Elixhauser, A. (2011). *Agency for Healthcare Research and Quality*. Retrieved from http://www.hcup-us.ahrq.gov/reports

APPENDIX A

2009 Focused Update: ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults (pp. 1985-1987)

to exclude the presence of primary valve disease. Secondary changes in valve function, particularly the severity of mitral and tricuspid valve insufficiency, should be determined.

Noninvasive hemodynamic data acquired at the time of echocardiography are an important additional correlate for patients with preserved or reduced EF. Combined quantification of the mitral valve inflow pattern, pulmonary venous inflow pattern, and mitral annular velocity provides data about characteristics of LV filling and left atrial pressure. Evaluation of the tricuspid valve regurgitant gradient coupled with measurement of inferior vena caval dimension and its response during respiration provides an estimate of systolic pulmonary artery pressure and central venous pressure. Stroke volume may be determined with combined dimension measurement and pulsed Doppler in the LV outflow tract.[24] However, abnormalities can be present in any of these parameters in the absence of HF. No single parameter necessarily correlates specifically with HF; however, a totally normal filling pattern argues against clinical HF.

A comprehensive echocardiographic evaluation is important, because it is common for patients to have more than 1 cardiac abnormality that contributes to the development of HF. Furthermore, the study may serve as a baseline for comparison, because measurement of EF and the severity of structural remodeling can provide useful information in patients who have had a change in clinical status or who have experienced or recovered from a clinical event or received treatment that might have had a significant effect on cardiac function.

Other tests may be used to provide information regarding the nature and severity of the cardiac abnormality. Radionuclide ventriculography can provide highly accurate measurements of LV function and right ventricular EF, but it is unable to directly assess valvular abnormalities or cardiac hypertrophy. Magnetic resonance imaging or computed tomography may be useful in evaluating chamber size and ventricular mass, detecting right ventricular dysplasia, or recognizing the presence of pericardial disease, as well as in assessing cardiac function and wall motion.[25]

Magnetic resonance imaging may also be used to identify myocardial viability and scar tissue.[26] Chest radiography can be used to estimate the degree of cardiac enlargement and pulmonary congestion or to detect the presence of pulmonary disease. A 12-lead electrocardiogram may demonstrate evidence of prior MI, LV hypertrophy, cardiac conduction abnormality (e.g., left bundle-branch block), or a cardiac arrhythmia. However, because of their low sensitivity and specificity, neither the chest x-ray nor the electrocardiogram should form the primary basis for determining the specific cardiac abnormality responsible for the development of HF.

3.1.3.2. Laboratory Testing

Laboratory testing may reveal the presence of disorders or conditions that can lead to or exacerbate HF. The initial evaluation of patients with HF should include a complete blood count, urinalysis, serum electrolytes (including calcium and magnesium), glycohemoglobin, and blood lipids, as well as tests of both renal and hepatic function, a chest radiograph, and a 12-lead electrocardiogram. Thyroid function tests (especially thyroid-stimulating hormone) should be measured, because both hyperthyroidism and hypothyroidism can be a primary or contributory cause of HF. A fasting transferrin saturation is useful to screen for hemochromatosis; several mutated alleles for this disorder are common in individuals of Northern European descent, and affected patients may show improvement in LV function after treatment with phlebotomy and chelating agents. Magnetic resonance imaging of the heart or liver may be needed to confirm the presence of iron overload. Screening for human immunodeficiency virus (HIV) is reasonable and should be considered for all high-risk patients. However, other clinical signs of HIV infection typically precede any HF symptoms in those patients who develop HIV cardiomyopathy. Serum titers of antibodies developed in response to infectious organisms are occasionally measured in patients with a recent onset of HF (especially in those with a recent viral syndrome), but the yield of such testing is low, and the therapeutic implications of a positive result are uncertain (see a recent review of the role of endomyocardial biopsy,[13] and Section 3.1.3.4, Evaluation of the Possibility of Myocardial Disease, in the full-text guideline. Assays for connective tissue diseases and for pheochromocytoma should be performed if these diagnoses are suspected, and serum titers of Chagas disease antibodies should be checked in patients with nonischemic cardiomyopathy who have traveled in or emigrated from an endemic region.

Several recent assays have been developed for natriuretic peptides (BNP and NT-proBNP). Several of the natriuretic peptides are synthesized by and released from the heart. Elevated plasma BNP levels have been associated with reduced LVEF,[27] LV hypertrophy, elevated LV filling pressures, and acute MI and ischemia, although they can occur in other settings, such as pulmonary embolism and chronic obstructive pulmonary disease.

Natriuretic peptides are sensitive to other biological factors, such as age, sex, weight, and renal function.[28] Elevated levels lend support to a diagnosis of abnormal ventricular function or hemodynamics causing symptomatic HF.[29] Trials with these diagnostic markers suggest use in the urgent-care setting, where they have been used in combination with clinical evaluation to differentiate dyspnea due to HF from dyspnea of other causes,[4] and suggest that its use may reduce both the time to hospital discharge and the cost of treatment.[30] BNP levels tend to be less elevated in HF with preserved EF than in HF with low EF and are lower in obese patients.[31,32] Levels of natriuretic peptides may be elevated meaningfully in women and in people over 60 years of age who do not have HF, and thus these levels should be interpreted cautiously in such individuals when distinguishing between cardiac and noncardiac causes of dyspnea. Elevated natriuretic peptide levels may lend weight to a suspected diagnosis of HF or trigger consideration of HF when the diagnosis is unknown but should not be used in isolation to confirm or exclude the presence of HF.[30,33]

3.2.3. Laboratory Assessment

Serum electrolytes and renal function should be monitored routinely in patients with HF. Of particular importance is the

serial measurement of serum potassium concentration, because hypokalemia is a common adverse effect of treatment with diuretics and may cause fatal arrhythmias and increase the risk of digitalis toxicity, whereas hyperkalemia may complicate therapy with angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), and aldosterone antagonists. Worsening renal function may require adjustment of the doses of diuretics, renin-angiotensin-aldosterone system antagonists, digoxin, and noncardiac medications. Development of hyponatremia or anemia may be a sign of disease progression and is associated with impaired survival.

Serum BNP levels have been shown to parallel the clinical severity of HF as assessed by NYHA class in broad populations. Levels are higher in hospitalized patients and tend to decrease during aggressive therapy for decompensation (see Section 3.1.3.2. in the full-text guideline, Laboratory Testing).[29] Indeed, there is an increasing body of evidence demonstrating the power of the addition of BNP (or NT-proBNP) levels in the assessment of prognosis in a variety of cardiovascular disorders. However, it cannot be assumed that BNP levels can be used effectively as targets for adjustment of therapy in individual patients. Many patients taking optimal doses of medications continue to show markedly elevated levels of BNP, and some patients demonstrate BNP levels within the normal range despite advanced HF. The use of BNP measurements to guide the titration of drug doses has not been shown conclusively to improve outcomes more effectively than achievement of the target doses of drugs shown in clinical trials to prolong life.[34] Ongoing trials will help to determine the role of serial BNP (or other natriuretic peptides) measurements in both diagnosis and management of HF.

Serial chest radiographs are not recommended in the management of chronic HF. Although the cardiothoracic ratio is commonly believed to reflect the cardiac dilatation that is characteristic of HF, enlargement of the cardiac silhouette primarily reflects changes in right ventricular volume rather than LV function, because the right ventricle forms most of the border of dilated hearts on radiographs. Similarly, changes in the radiographic assessment of pulmonary vascular congestion are too insensitive to detect any but the most extreme changes in fluid status.[35]

Repeat assessment of EF may be most useful when the patient has demonstrated a major change in clinical status. Both improvement and deterioration may have important implications for future care, although the recommended medical regimen should be continued in most cases. Improvement may reflect recovery from a previous condition, such as viral myocarditis or hypothyroidism, or may occur after titration of recommended therapies for chronic HF. Thus, it is appropriate to obtain a repeat EF after some period of optimal medical therapy, typically 4 to 6 months, to decide about the implantation of an implantable cardioverter-defibrillator (ICD). Deterioration may reflect gradual disease progression or a new event, such as recurrent MI. Routine assessment of EF at frequent, regular, or arbitrary intervals is not recommended.

There has been no established role for periodic invasive or noninvasive hemodynamic measurements in the management of HF. Most drugs used for the treatment of HF are prescribed on the basis of their ability to improve symptoms or survival rather than their effect on hemodynamic variables. Moreover, the initial and target doses of these drugs are selected on the basis of experience in controlled trials and are not based on the changes they may produce in cardiac output or pulmonary wedge pressure. Nevertheless, invasive hemodynamic measurements may assist in the determination of volume status and in distinguishing HF from other disorders that may cause circulatory instability, such as pulmonary diseases and sepsis. Measurements of cardiac output and pulmonary wedge pressure through a pulmonary artery catheter have also been used in patients with refractory HF to assess pulmonary vascular resistance, a determinant of eligibility for heart transplantation. Cardiac output can also be measured by noninvasive methods.

3.2.4. Assessment of Prognosis

Although both healthcare providers and patients may be interested in defining the prognosis of an individual patient with HF, the likelihood of survival can be determined reliably only in populations and not in individuals. However, some attempt at prognostication in HF may provide better information for patients and their families to help them appropriately plan for their futures. It also identifies patients in whom cardiac transplantation or mechanical device therapy should be considered.

Multivariate analysis of clinical variables has helped to identify the most significant predictors of survival, and prognostic models have been developed and validated.[36] Decreasing LVEF, worsening NYHA functional status, degree of hyponatremia, decreasing peak exercise oxygen uptake, decreasing hematocrit, widened QRS on 12-lead electrocardiogram, chronic hypotension, resting tachycardia, renal insufficiency, intolerance to conventional therapy, and refractory volume overload are all generally recognized key prognostic parameters, although the actual prognostic models incorporating them are not widely used in clinical practice.[36,37] Although elevated circulating levels of neurohormonal factors have also been associated with high mortality rates, the routine assessment of neurohormones such as norepinephrine or endothelin is neither feasible nor helpful in clinical management. Likewise, elevated BNP (or NT-proBNP) levels predict higher risk of HF and other events after MI, whereas marked elevation in BNP levels during hospitalization for HF may predict rehospitalization and death. Nonetheless, the BNP measurement has not been clearly shown to supplement careful clinical assessment for management.

Because treatment of HF has improved over the past 10 years, the older prognostic models need to be revalidated,[38] and newer prognostic models may have to be developed. Outcomes have been improved for most high-risk patients, which has resulted in a shift in the selection process for patients referred for heart transplantation.[38] Routine use of ambulatory electrocardiographic monitoring, T-wave alternans analysis, heart rate variability measurement, and signal-averaged electrocardiography have not been shown to provide incremental value in assessing overall prognosis, although ambulatory electrocardiographic

monitoring can be useful in decision making regarding placement of ICDs.[39]

4. Therapy

4.3.1. Patients With Reduced Left Ventricular Ejection Fraction

Changes in this section focused on 3 areas: recommendations about electrical device therapy (e.g., cardiac resynchronization therapy [CRT] and ICDs), the use of a fixed dose combination of hydralazine and isosorbide dinitrate in self-identified African Americans, and the management of atrial fibrillation in patients with HF. The previous version of the guidelines had a number of possibly confusing recommendations about selection of patients for ICD implantation. The writing group has tried to simplify the recommendations, and keep them concordant with the most recent guidelines covering the same issue.[39,40] Updated trial information has led to the change in the recommendations about the use of hydralazine/isosorbide dinitrate and about the management of atrial fibrillation (Table 3).

4.3.1.1. General Measures

Measures listed as Class I recommendations for patients in stage A or B are also appropriate for patients with current or prior symptoms of HF (also see Section 5, Treatment of Special Populations). In addition, moderate sodium restriction, along with daily measurement of weight, is indicated to permit effective use of lower and safer doses of diuretic drugs, even if overt sodium retention can be controlled by the use of diuretics. Immunization with influenza and pneumococcal vaccines may reduce the risk of a respiratory infection. Although most patients should not participate in heavy labor or exhaustive sports, physical activity should be encouraged (except during periods of acute exacerbation of the signs and symptoms of HF, or in patients with suspected myocarditis), because restriction of activity promotes physical deconditioning, which may adversely affect clinical status and contribute to the exercise intolerance of patients with HF.[142–145]

Three classes of drugs can exacerbate the syndrome of HF and should be avoided in most patients:

1. Antiarrhythmic agents[146] can exert important cardiodepressant and proarrhythmic effects. Of available agents, only amiodarone and dofetilide[147] have been shown not to adversely affect survival.
2. Calcium channel blockers can lead to worsening HF and have been associated with an increased risk of cardiovascular events.[148] Of available calcium channel blockers, only the vasoselective ones have been shown not to adversely affect survival.[139,149]
3. Nonsteroidal anti-inflammatory drugs can cause sodium retention and peripheral vasoconstriction and can attenuate the efficacy and enhance the toxicity of diuretics and ACE inhibitors.[84–87] A discussion of the use of aspirin as a unique agent is found later in this section (see Section 4.3.1.2.2.1., Angiotensin Converting Enzyme Inhibitors in the Management of Heart Failure, in the full-text guideline).

Patients with HF should be monitored carefully for changes in serum potassium, and every effort should be made to prevent the occurrence of either hypokalemia or hyperkalemia, both of which may adversely affect cardiac excitability and conduction and may lead to sudden death.[150] Activation of both the sympathetic nervous system and renin-angiotensin system can lead to hypokalemia,[151,152] and most drugs used for the treatment of HF can alter serum potassium.[153] Even modest decreases in serum potassium can increase the risks of using digitalis and antiarrhythmic drugs,[150,154] and even modest increases in serum potassium may prevent the use of treatments known to prolong life.[155] Hence, many experts believe that serum potassium concentrations should be targeted in the 4.0 to 5.0 mmol per liter range. In some patients, correction of potassium deficits may require supplementation of magnesium and potassium.[156] In others (particularly those taking ACE inhibitors alone or in combination with aldosterone antagonists), the routine prescription of potassium salts may be unnecessary and potentially deleterious.

Of the general measures that should be used in patients with HF, possibly the most effective yet least used is close observation and follow-up. Nonadherence with diet and medications can rapidly and profoundly affect the clinical status of patients, and increases in body weight and minor changes in symptoms commonly precede by several days the occurrence of major clinical episodes that require emergency care or hospitalization. Patient education and close supervision, which includes surveillance by the patient and his or her family, can reduce the likelihood of nonadherence and lead to the detection of changes in body weight or clinical status early enough to allow the patient or a healthcare provider an opportunity to institute treatments that can prevent clinical deterioration. Supervision need not be performed by a physician and may ideally be accomplished by a nurse or physician's assistant with special training in the care of patients with HF. Such an approach has been reported to have significant clinical benefits.[157–160]

Recommendations Concerning Aldosterone Antagonists. The addition of low-dose aldosterone antagonists is recommended in carefully selected patients with moderately severe or severe HF symptoms and recent decompensation or with LV dysfunction early after MI. These recommendations are based on the strong data demonstrating reduced death and rehospitalization in 2 clinical trial populations.[155,161] The entry criteria for these trials describe a broader population than was actually enrolled, such that the favorable efficacy/ toxicity ratio may not be as applicable to patients at the margins of trial eligibility. For both of these major trials, patients were excluded for a serum creatinine level in excess of 2.5 mg per dL, but few patients were actually enrolled with serum creatinine levels over 1.5 mg per dL. In the trial of patients after MI, there was a significant interaction between serum creatinine and benefit of eplerenone. The average serum creatinine of enrolled patients was 1.1 mg per dL, above which there was no demonstrable benefit for survival.

To minimize the risk of life-threatening hyperkalemia in patients with low LVEF and symptoms of HF, patients should have initial serum creatinine less than 2.0 to 2.5 mg per dL without recent worsening and serum potassium less than 5.0

APPENDIX B

Institute for Clinical Systems Improvement: Health Care Guidelines for Heart Failure in Adults 2011 (p. 15)

using either continuous infusion or bolus intravenous injections *[Meta-Analysis]*. In acute decompensated heart failure, there also has been shown to be no difference in the use of low dose (equivalent to the patient's previous oral dose) or high dose (2.5 times the previous oral dose) in terms of the patient's global assessment of symptoms or in the change in renal function. Therefore, no benefit is seen to either low versus high dose or infusion versus bolus injection as long as adequate natriuresis is maintained.

- **Sodium, Potassium, Chloride/Bicarbonate, BUN/Scr (basic chemistry panel)**
  - Before diuretic initiation
  - During the diuretic initiation phase, the first lab after starting therapy is dependent on the degree of diuresis:
    - Outpatients on oral diuretic therapy should have their labs repeated once approximately five to seven days after diuretic initiation. If lab abnormalities are present, labs should be repeated weekly until they have stabilized.
    - Inpatients on large intravenous (IV) doses of diuretics (including drips) or who require frequent dose changes should have labs repeated daily at a minimum.
  - Following the initiation phase, stable outpatient diuretic patients should have a basic chemistry panel drawn every four months for the duration of therapy. If any of the following occurs, lab monitoring will need to be more frequent until the patient stabilizes:
    - Changes in diuretic dose, route, or frequency
    - The patient's condition worsens
    - The patient develops signs/symptoms of electrolyte abnormalities
  - If lab abnormalities are found at any time, increased lab surveillance is warranted until levels have normalized.
- **Magnesium, Calcium**
  - Before diuretic initiation, then every four months for the duration of therapy
- **Glucose Checks (diabetic patients)**
  - Before diuretic initiation

APPENDIX C

Approval of Mississippi University for Women's

Institutional Review Board

Mississippi University
for Women
A Tradition of Excellence for Women and Men

Provost and Vice President for Academic Affairs
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May 31, 2013

Sueanne Davidson, DNP
Mississippi University for Women
College of Nursing and Speech-Language Pathology
MUW - 910
Columbus, Mississippi 39701-5800

Dear Dr. Davidson:

I am pleased to inform you that the members of the Institutional Review Board (IRB) have reviewed the following ***revised*** proposed research and have approved it as submitted:

Name of Study:	Health Care Provider's Monitoring of Potassium Levels in the Treatment of Heart Failure
Investigator(s):	Lori Duke and Cindy Patrick
Research Faculty/Advisor:	Sueanne Davidson

I wish you much success in your research.

Sincerely,

Dan Heimmermann, Ph.D.
Provost and Vice President for Academic Affairs

DH/jh

pc: Tammie McCoy, Institutional Review Board Chairman

APPENDIX D

Letter of Consent for Participation in a Research Study

January 28, 2013

Dear Healthcare Provider,

We are graduate students in the Family Nurse Practitioner Program at Mississippi University for Women in Columbus, MS. As a program requirement for graduation, we are conducting a quality assurance research study to assess compliance of recommendations for monitoring potassium from the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) and the Institute for Clinical Systems Improvement guidelines for heart failure in adults. Potassium is one of our body's main intracellular electrolytes, which could cause an adverse cardiac event if the level is not monitored and kept in the acceptable range for this diagnosis. The results of this study will improve the healthcare provider's adherence to the 2009 ACCFAHA guidelines in the care of heart failure patients, enhancing patient outcomes and decreasing the potential of life-threatening complications.

We would like to use your facility's charts for compiling data for this study. Your participation will involve granting us the privilege of reviewing 100 medical records of your patients 18 years of age and older with ICD-9 diagnosis code 428 for heart failure. We agree to refrain from discussing or disclosing any information regarding your clients. All information acquired from this retrospective chart review would be completely confidential. Neither names of patients nor the facility name will be used in the study. Each researcher will receive HIPAA and Corporate Compliance training through the facility before beginning the research. The chart reviews will be recorded on a data collection worksheet. The information will be entered into a computer data sheet for preparation of statistical analysis and saved to a password-protected media drive. The media drive and worksheets will be destroyed at the end of the study. The facility may withdraw at any time and participation is voluntary. Results of this research study will be shared with each facility and provider. Specific providers will not be named, and data will be resulted as a group.

If you would like any further information, please feel free to contact Lori Duke at (662) 882-0798 or lduke2009@yahoo.com, Cindy Patrick (601) 513-2337 or Cpatrickmuw2012 @gmail.com, or contact the chair of our research committee, Dr. Sueanne Davidson, at (662) 329-7322 or Sdavidson@nsgslp.muw.edu. Thank you for your willingness to consider this request.

Sincerely,

Lori Duke, RN, BSN

Cindy Patrick, RN, BSN, CCRN

APPENDIX E

Data Collection Worksheet

Date of chart review _____

1. Patient's gender: Male_____ (1) Female _____ (2)

2. Patient's age _____ years

3. Ethnicity:

   Caucasian_____ (1) African-American_____ (2) Hispanic_____ (3)

   Other_____ (4)

4. Was a serum potassium level checked in the last four months?

   Yes_____ (1) No_____ (2)

5. Was the last serum potassium level between 4.0-5.0 mEq/L?

   Yes _____ (1) No _____ (2)

6. Was a medication adjustment made if the serum potassium level was not in the 4.0-5.0 mEq/L range?

   Yes _____ (1) No _____ (2)

7. Is this patient on any of the following medications?

   ARB_____ (1) ACE-I_____ (2) Aldosterone Antagonist_____ (3)

   Beta-blockers_____ (4) Diuretic (loop, thiazide, or potassium-sparing)_____ (5)

8. What was the payer source?

   Medicare _____ (1) Medicaid _____ (2) commercial _____ (3)

   Self-pay_____ (4)