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Predictors of Early Rehospitalization Among Elderly African American and Caucasian Women  
Hospitalized with Heart Failure

A DISSERTATION

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By

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Predictors of Early Rehospitalization Among Elderly African American and Caucasian Women  
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ABSTRACT

**Background.** Heart Failure remains a complex clinical syndrome that affects all races and backgrounds. Periodically individuals with a heart failure diagnosis will require hospitalization during the course of the disease progression. Consequently, early and repeated rehospitalizations for acute exacerbations presents additional social and economic difficulties. Prior research demonstrated that elderly African-American and Caucasian women account for a large proportion of the population at risk for future heart failure hospitalizations along with readmissions within 60 days of discharge. Unfortunately, the literature remains unpredictable or largely non-existent regarding the unique associations between risk predictors for heart failure and early (31 to 60-day) heart failure rehospitalization in these two groups of women. Improved understanding of the predictors that influence avoidable early heart failure rehospitalization may engender strategies to reduce readmissions in these at-risk populations.

**Purpose.** Using a risk factor model for heart failure rehospitalization as a conceptual framework, this research determined if certain social, hemodynamic and comorbid risk factors associated with elderly African-American and Caucasian women HF patients influenced hospital readmission within 31 to 60-day of discharge.

**Methods.** The study utilized a descriptive, correlational, non-equivalent case-control, and quantitative study design that incorporated a retrospective review of the medical records of elderly African-American and Caucasian women discharged or readmitted with a primary diagnosis of heart failure from October 2012 to October 2015. Predictor variables included pulmonary hypertension, hypertension, diabetes mellitus, body mass index, social factors, heart failure with preserved or reduced ejection fraction, and race. The outcome variable measured was 31 to 60-day heart failure rehospitalization following index heart failure hospitalization. Relationships among model variables were explored using multiple logistic regression analysis and cross-tabulation techniques.

**Results.** The full model containing all predictors was not supported,  $X^2(21, N = 188) = 35.77, p = 0.120$ ; indicating that the full model was not able to distinguish between predictors that contribute to rehospitalization after an index HF hospitalization. However, findings indicated that individual predictor variables including body mass index, age (75-80), and lipid-lowering agent made significant contributions to the prediction of HF rehospitalization within 31-60-day after an index HF hospitalization. Neither HFpEF nor HFrEF, or race, predicted the likelihood of HF rehospitalization after an index HF hospitalization, but the data showed that subjects with HFrEF were 1.6 times more likely to experience rehospitalization. Significant relationships were found between subtypes of heart failure (HFpEF or HFrEF) and obesity, diabetes mellitus, and causes contributing to heart failure.

**Implications.** The findings of this study bear importance to nurse scientists and nurse practitioners who are directly involved in the care of patients with acute or chronic heart failure and want to influence heart failure rehospitalization. Implications for policy, future research, and limitations are presented.

This dissertation by Carolyn Sue-Ling fulfills the dissertation requirement for the doctoral degree in Nursing approved by Nalini N. Jairath, RN, PhD, as director, and by Nancy Steffan, RN, PhD, CCRN, CRNP, and Arthur Bleakley Chandler, Jr., M.D., F.A.C. C.

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# Chapter 1: Introduction

## Introduction of Problem

Individuals with a diagnosis of heart failure (HF) periodically require hospitalization during the course of the disease and its inevitable progression (Akintoye et al., 2017). Early and repeated rehospitalizations for acute exacerbations present both social and economic difficulties for patients, families, care providers and insurance companies in the United States and worldwide (Giamouzis et al., 2011, Xu et al., 2018). Approximately 5.7 million Americans over the age of 20 suffer from HF. At the same time, the Centers for Medicare and Medicaid Services predict the emergence of 670, 000 new cases annually (Go et al., 2014; Mozaffarian et al., 2016). Recent projections indicate that eight million Americans will develop HF by year 2030 (Heidenreich et al., 2013). Two millions of these patients are the aging baby boomer population who will reach to be 80 years or more, with the cost of their care expected to exceed \$50 billion annually (Heidenreich et al., 2013; Office of the Actuary, 2016). In 2013, one out of nine death certificates in the United States listed HF as a coexisting health (Mozaffarian et al., 2016).

Furthermore, the mortality rate within five years after the initial HF diagnosis is approximately 50%, with HF hospitalizations significantly contributing to all-cause rehospitalizations including illnesses such as acute myocardial infarction or pneumonia (Krumholz et al., 2009; Yancy et al., 2013). Research that evaluates hospital prediction models for HF as well as customary patient characteristics such as (age, race, and comorbidities) often fails to consistently predict rehospitalization. This suggests an urgent need to explore other emerging predictive factors (Xu et al., 2018). Understanding emerging predictor variables for HF and predicting specific at-risk subpopulations as well as HF subtypes and their associated comorbidities remains essential to reducing HF rehospitalizations (Giamouzis et al., 2011).

In general, the lifetime risks for HF vary by age, sex, and specific population sub-group (Pandey et al., 2018). Pandey and colleagues (2018) pooled data abstracted from two large prospective cohort studies, the Cardiovascular Health Study (CHS) and the Multiethnic Study of Atherosclerosis (MESA) to evaluate sex and race differences in HF. Data revealed that when HF affects individuals at the index age of 45 years, the lifetime risk for any HF through age 90 remains higher in men than women (27.4% vs. 23.8%) (Pandey et al., 2018). Similarly, statistics from the ARIC (Atherosclerosis Risk in Communities) study showed that the incidence rate per 1,000 person-years is highest among African-American (AA) men and lowest among Caucasian women (Yancy et al., 2013).

Projected statistics suggest that one in five Americans will be over the age of 65 by year 2050 (Yancy et al., 2013). Because HF's incidence and prevalence remain highest in this group, the number of elderly female Americans with HF will continue to significantly increase (Stamp et al., 2018; Yancy et al., 2013). Research also continues to document disparities in the epidemiology of HF, with AA showing the highest risk for HF. In the Medicare-eligible population, the prevalence of HF in non-Hispanic AA females remains at 3.8%, versus 1.8% in non-Hispanic Caucasian females (Yancy et al., 2013). Elderly Caucasian and AA women represent the dominant groups of women hospitalized with HF and included in research studies (Cheng et al., 2014; Zhang & Baik, 2014). Furthermore, AA female HF patients with lower financial status often experience four to six times a higher risk of cardiac hospitalizations compared to Caucasian female HF patients (Wu, Lennie, & Moser, 2017). The above data and statistics strongly underscore a need to understand the factors contributing to HF hospitalizations or rehospitalizations among elderly AA and Caucasian women. While clinicians, nurses, and nurse practitioners understand that social factors and comorbid risk factors that affect HF

rehospitalization, existing research fails to examine the influence of specific comorbid risk factors on early (31 to 60-day) HF rehospitalization, particularly among the high risk elderly AA female HF patient group. Therefore, this study explored the relationship of selected clinical, hemodynamic, and social factors with early HF rehospitalization amongst elderly AA and Caucasian females in order to contribute to the development of targeted strategies aimed at reducing HF rehospitalizations.

### **Race, Ethnicity, and Economic Burden of Heart Failure Rehospitalization**

Previous research studies evaluating HF in the elderly population continue to address race/ethnicity as equivalent terms for analytical purposes (Cheng et al., 2014; Zhang & Baik, 2014), even though they are two separate and distinct concepts (Orlandi, 1998). Race refers to persons with similar genetic features or characteristics, whereas ethnicity refers to a category of people with common cultural, national and social experience (Orlandi, 1998). Individuals with multiracial or multiethnic backgrounds create complications for researchers who categorize participants into separate groups. However, at the time of a HF admission, patients often self-identify themselves as black or AA, white or Caucasian, Asian, American-Indian, Hispanic, or other (Silverman et al., 2016).

Hospital admissions and/or rehospitalizations create continual social, economic, and mortality burdens in all racial and ethnic groups (Ho et al., 2016). Available data illustrate that approximately, one in five patients develops the lifetime risk of HF by age 40 regardless of gender. This translates into a higher incidence, prevalence, and burden of HF in the older population (Husaini et al., 2016). According to Husaini and colleagues, data from the Center for Medicare and Medicaid Services (CMS) disclose that 14 % of Medicare patients struggle with the challenges of living with HF and utilizes 43% of annual Medicare spending in doing so.

A higher burden of HF exists among AA and Hispanics (Husaini et al., 2016; Mozaffarian et al., 2016). Increased HF rehospitalizations among minority groups seem to imply more severe disease, but research data suggest other causes such as inadequate access to follow-up care, poor self-care decision-making, and a lack of outpatient management of symptoms and medications (Vivo et al., 2014, Xu et al., 2018). Complexity of comorbidities, number of admissions and length-of-stay invariably reflect hospital costs (Husaini et al., 2015). These findings appear to be regional and hospital-type specific. Husaini (2015) determined that the average HF cost per patient reaches almost \$36,200 annually, with similar statistics showing annual hospital costs approximating 69% higher for a patient with HF compared with a non-HF patient (\$82,509 vs \$40,301,  $p < 0.001$ ). Other data illustrate that AA and Hispanics share a greater burden and severity of HF (Ambrosy et al., 2014). According to Ambrosy and colleagues (2014), virtually no data on race, ethnicity, and HF exists outside the United States. In the United States, the authors illustrate that African-Americans comprise approximately 20% of hospitalized HF patients, which mean a greater economic burden for this vulnerable population.

### **Socioeconomic Status and Heart Failure Rehospitalization**

Social factors and socioeconomic status (SES) play important roles in HF rehospitalization, and present challenges to vulnerable patients during the post-discharge transition period (Calvillo–King et al., 2013; Damiani et al., 2015). Calvillo-King et al. (2013) conducted a systematic review of articles addressing a broad range of social factors and their impact on HF rehospitalization following an index HF admission. The investigators divided social factors into three levels of socioeconomic status, socio-demographic, and socio-environment. Data illustrated that a broad range of social factors influenced early HF rehospitalization. In a similar review, Damiani et al. (2015) evaluated a range of socioeconomic



factors on HF admission and concluded that race/ethnicity and marital status affected the risk of rehospitalization in elderly people with HF. Kangovi et al. (2013) conducted a qualitative study with the primary objective of exploring challenges faced by patients with low SES following a HF admission. The authors interviewed 65 patients who were uninsured, on Medicaid, were residents of five low-income zip codes, and identified six themes that low-SES patients shared in their narratives of hospitalization. Among the themes, socioeconomic factors, loss of self-efficacy, and socioeconomic constraints remained extremely relevant to risk of rehospitalization.

### **Mortality Burden**

HF hospitalizations and rehospitalizations eventually lead to an increase in mortality. Vivo et al. (2014) conducted a retrospective correlation study analyzing data from 47,149 Medicare patients who received hospital care for HF between 2005 and 2011. During this period, 39,213 Caucasians (83.2%) and 4,926 (10.5%) African-Americans received inpatient HF care. Data demonstrated that cardiovascular readmissions remained higher at 30 days and one-year among AA patients compared to Caucasians, while short-and long-term mortality among AA patients remained modestly lower, regardless of SES. Fee-for-service Medicare beneficiaries comprised the study population, and as such the results of the study may not be reflective of other HF populations located in different regions of the United States (Vivo et al., 2014). Nevertheless, these data remain relevant to the proposed research study which addressed the impact of social factors on hospital readmission within 60 days of discharge among elderly AA and Caucasian HF patients.

### **Burden of Hospital Readmissions Reduction Program**

Recent data suggest that after the implementation of a national provider-administered Hospital Readmissions Reduction Program (HRRP) the 30-day risk-adjusted post-discharge

mortality in hospitalized Medicare HF beneficiaries increased from 7.9% in 2008 to 9.2% in 2014 (Dharmarajan et al., 2017). In addition, the increase in mortality rates appear to extend beyond 30 days, which reflects a potential adverse effect of HRRP, as the program relates to the development of new hospital policies designed to comply with program requirements and reduce hospital financial burdens (Fonarow, Konstam & Yancy, 2017). The Centers for Medicare & Medicaid Services (CMS) designed the HRRP to reduce payments to hospitals with excess readmissions, putting forward an effort toward improving quality and lowering costs for Medicare patients. However, hospitals incurred penalties because of excessive rehospitalization rates related to inappropriate care strategies such as delaying readmissions beyond discharge day 30, increasing observational stays, and shunting patients to outpatient clinics, despite their presenting condition warranting readmission (Fonarow, Konstam & Yancy, 2017). Previous statistics illustrate that 30-day risk adjusted mortality rates decreased by 16.4% during the decade prior to HRRP. This suggests increased mortality after the implementation of HRRP reflects inappropriate or untimely discharges (Fonarow, Konstam & Yancy, 2017).

Research suggests that an improved and informed understanding of racial/ethnic differences in HF rehospitalization and mortality guides critical initiatives aimed at reducing health disparities and financial burdens of HF rehospitalizations, thus improving outcomes (Vivo et al., 2014). Therefore, understanding the incidence, prevalence, and associated comorbidities of the different subtypes of HF allows the researcher to gain insight into HF rehospitalization among two racial/ethnic groups.

### **Influence of Nursing Role on Heart Failure Rehospitalization**

Many nursing professions focus solely on the specialty of HF and provide continuous care to patients and families, contributing to community education regarding development and

management of the disease (Prasun et al., 2012; Prasun et al., 2017). According to Prasun et al. (2017), nursing interventions are most effective in optimizing outcomes by facilitating application of guideline-directed medical therapy that focuses on reducing health disparities. For instance, nurses inform and educate patients regarding treatment options and self-care, thus facilitating an improved understanding of comorbid risk factors. Since HF consists of a combination of multi-morbidity issues, disease management inevitably presents dynamic and complex challenges that nurses must deal with in care planning and delivery (Stewart, Riegel & Thompson, 2015). The American Association of Heart Failure Nurses (AAHFN) recently recognized the unique contributions that nurse scientists make around wellness, disease management, and prevention of HF in older adults (Stamp et al., 2018). Additionally, nurses are well positioned to lead, serve as role models, and provide comprehensive patient education to elderly HF patients during hospital admissions and at the time of discharge (Prasun et al., 2017).

Two recent studies addressed the role of nurses and their impact on early HF rehospitalization (Lee et al., 2016; Smith et al., 2015). Lee et al. (2016), along with expert cardiac nurses evaluated 11,985 adults with HF within seven days of their discharge. They revealed that nursing interventions alone lowered 30-day HF rehospitalizations (adjusted odds ratio [OR] 0.81, 95%CI: 0.70 - 0.94). In a similar research, Smith et al. (2015) utilized a nurse-led multidisciplinary approach which evaluated the effects of group clinic appointments on rehospitalizations. Here, the research focused on established criteria linked to HF subtypes that relate to the pumping ability or ejection fraction of the left ventricle (Pandey et al., 2018; Smith et al., 2015). Findings demonstrated that nursing interventions improved HF self-care regardless of subtype, which in turn reduced subsequent HF related hospitalizations.

## **Background**

### **Heart Failure Subtypes**

Patients hospitalized with HF fit into two distinct HF subtypes: those with HF with preserved ejection fraction (HFpEF; LVEF>50%) and those with HF with reduced ejection fraction (HFrEF; LVEF<50%) (Borlaug & Redfield, 2011; Mentz et al., 2014; Yancy et al., 2013). Women in particular ethnic groups represent over 50 % of patients with HF, and a substantial portion of female patients suffer from HFpEF, wherein their ejection fraction is preserved (Lam et al., 2012; Hsieh et al., 2012). Even though patients with HFpEF account for 40 to 50% of all HF related admissions, there remain many uncertainties surrounding this subtype of HF (Ferrari et al., 2015; Stamp et al., 2018). According to Ferrari and colleagues, HFrEF and HFpEF subtypes differ in terms of etiology, pathophysiology, co-morbidities, clinical, and demographic characteristics, time to overt disease, biochemical parameters, and responses to therapy. Patients with HFpEF appear more likely to be females with higher body mass indexes, older, hypertensive, with less coronary heart disease, and suffer from all or several components of the metabolic syndrome (MetS) (Ferrari et al., 2015). Furthermore, researchers and clinicians often associate HFpEF and HFrEF with different cardiac and non-cardiac comorbidities such as hypertension, diabetes, anemia, obesity, elderly, and previous hospitalizations (Chamberlain et al., 2015; Davis et al., 2016; Gupta et al., 2013). Therefore, understanding relationships between comorbidities and HF subtypes open possibilities to guided therapies.

### **Comorbidities and Heart Failure Subtypes**

A cluster of comorbid risk factors determine risk for new onset HFpEF versus HFrEF (Ho et al., 2013) as well as early rehospitalization among elderly HF patients (<30 or 31 to 60-

day) (Muzzarelli et al., 2010). Therefore, the distinction between etiologies of HF remains important because HFpEF or HFrEF related hospitalizations and early readmissions reflect different prognostic implications and selection of effective therapies (McMurray et al., 2012). HFpEF and HFrEF also affect the physical, social, and psychological well-being (state of health and happiness) of an individual from different racial or ethnic backgrounds (Wu, Lennie, Frazier & Moser, 2016). Selected physical, social, and psychological components include functional status, education level, SES, depression, and anxiety.

### **Emerging Comorbid Risk Factors**

Despite decades of knowledge and awareness of traditional comorbid risk factors and their association with HF patients, population-based studies on HF risk prediction often lack external validation and none have included HF subtypes (Echouffo-Tcheugui et al., 2015; Ho et al., 2016). In addition, there remains a persistent difference in incidence and prevalence of HFpEF and HFrEF among racial/ethnic populations (Eaton et al., 2016). Perhaps other emerging comorbid risk factors, such as the MetS or its individual components, and pulmonary hypertension (PH), play important roles. MetS and PH coexist with either HFpEF or HFrEF amongst the elderly (Aune et al., 2016; Bonomini, Rodella, & Rezzani, 2015; Cheng et al., 2016; Choudhary, Jankowich & Wu, 2014; Han & Lean, 2016). Studies further show that PH remains a risk factor for adverse outcomes in HFpEF (Shah et al., 2013). Delineating individuals at risk for specific HF subtypes and their associated comorbid risk factors assists with identifying future preventive strategies. Therefore, underscoring the importance of preventative strategies emphasizes the concomitant significance of appreciating clinical characteristics, emerging risk factors, and social determinants when associated with HFpEF and HFrEF as well as the timing of their appearance (Gheorghiade, Vaduganathan, Fonarow & Bonow, 2013). The timing of the

appearance of these clinical characteristics becomes extremely important especially for racial or ethnic minorities, especially disproportionately-affected elderly African-Americans (Gheorghide et al., 2013).

## **Problem Statement**

*Elderly AA and Caucasian female HF patients who comprise a substantial proportion of the overall HF population often experience higher than normal HF rehospitalizations* (Del Gobbo et al., 2015; Dreyer, Dharmarajan, Hsieh, Welsh, Qin & Krumholz, 2017). Previous data reveal that discharge from a hospital with a primary diagnosis of HF carries a 50% chance of rehospitalization within 6 months (Butler & Kalogeropoulos, 2008). Investigators conducting recent analyses involving Medicare fee-for-service readmissions to hospitals concluded that HF remains the primary cause of rehospitalizations (Jencks, Williams & Coleman, 2009; Ong et al., 2016; Vivo et al., 2014). Many studies to date address 30-day (0 to 30-day) rehospitalization rates because of legislative efforts to reduce healthcare costs, high rehospitalization rates, and variations between hospital readmission rates (Bradley et al., 2013; Hansen, Young, Hinami, Leung & Williams, 2011; Joynt & Jha, 2011). Other studies have sought to determine predictors (Au et al., 2012; Muzzarelli et al., 2010), timing (Dharmarajan et al., 2013), differences in HFpEF and HFrEF (Loop et al., 2016; Nichols et al., 2015; Quiroz et al., 2014), age (Whellan et al., 2016), and 30-day rehospitalization. Very few studies addressed 60-day (31 to 60-day) HF rehospitalization, even though readmissions beyond 30 days remain high in the elderly population (Gheorghide et al., 2012; Muzzarelli et al., 2010; Nichols et al., 2015). In addition, the prevalence of HF remains unusually high among elderly women (Razzolini & Dal Lin, 2015). Projected statistics reveal a higher prevalence of HF in men over the age of 40, but this ratio declines after the age of 80 (Heidenreich et al., 2013). Similar data also reveal a 24 %

increase in the prevalence of HF among elderly Caucasian women from 2012 to 2030. These findings are troublesome because further predictions reveal a 29% increase in the prevalence of HF amongst elderly AA women during the same period (Heidenreich et al., 2013). This trend in prevalence amongst elderly AA and Caucasian women translates into higher mortality and HF-related hospitalizations and rehospitalizations. Therefore, understanding determinants for 31 to 60-day rehospitalization amongst elderly AA or Caucasian female HF patients may eventually contribute to lower readmission rates and a decreased economic burden.

### **Statement of Purpose**

*This research study determined if certain social and comorbid risk factors associated with elderly AA and Caucasian female HF patients influence hospital readmission between 31 to 60 days following discharge.* The researcher utilized a descriptive, correlational, non-equivalent case-control, and quantitative study design that incorporates a retrospective review of the medical records of elderly AA and Caucasian women discharged or readmitted with a primary diagnosis of HF. Cases consisted of subjects who were readmitted, while controls were those subjects who were not readmitted. Assignment of subjects as cases and controls was not randomized, resulting in non-equivalent case-control groups. Elderly AA and Caucasian women comprised the predominant subjects with different ethnic backgrounds admitted with index HF during the study period, and the researcher chose to utilize these two groups of elderly women as study subjects. However, the researcher did not match elderly AA and Caucasian women.

For this proposed study, the researcher abstracted data from databases at a large, 650-bed private, not-for-profit, tertiary hospital located in Augusta, Georgia. The researcher analyzed the data after modifying an existing conceptual framework in order to examine the relationships of clinical, hemodynamic, and social factors to early HF rehospitalizations.

If this newly designed conceptual framework adequately explains a portion of the variability in HF rehospitalizations, it may substantially contribute to the current understanding of the social and economic burdens of HF. Heightened awareness by caregivers about predictors of HF rehospitalizations may also lead to reduced healthcare expenditures for avoidable HF rehospitalizations which became a major focus of hospitals due to value based purchasing program of the Affordable Care Act (ACA) (Fonarow, Konstam & Yancy, 2017). Moreover, clinical researchers may use results from this study to develop interventions that address HF initial hospitalizations and rehospitalizations. For this reason, the researcher selected a correlational design to examine relationships between variables of interest and HF rehospitalization rates among elderly AA and Caucasian women. A correlational design functions as an appropriate design when a clinical researcher desires to evaluate whether a relationship exists between dichotomous or continuous variables, and to find the magnitude of the correlation (Creswell, 2014). In this new area of research, researchers use non-experimental quantitative research to analyze secondary data sources in order to identify existing relationships. This methodology often leads to further advanced forms of non-experimental or experimental quantitative research (Christensen, Johnson & Turner, 2015). Consequently, interviews and surveys represent inappropriate research methods for data collection in the proposed research study.

The specific aims of this study are:

1. To examine the effects and relative contributions of PH, hypertension, diabetes mellitus, body mass index (BMI), race, HFpEF or HFrEF, and social factors on 31 to 60-day HF rehospitalization amongst elderly AA or Caucasian women.



2. To compare the prevalence of PH, HF (HFpEF or HFrEF), hypertension, diabetes mellitus, and BMI amongst elderly AA and Caucasian women hospitalized with index HF.

### **Research Questions and Hypotheses**

The researcher guided this study based on the following two research questions:

1. Do PH, hypertension, diabetes mellitus, BMI, race, HFpEF or HFrEF, and social factors predict the likelihood of 31to 60- day HF rehospitalization among elderly AA and Caucasian women?
2. What is the relationship between PH, hypertension, diabetes mellitus, BMI, HFpEF or HFrEF, and with race amongst elderly AA and Caucasian women hospitalized with index HF?

Further, the researcher used logistic regression and cross tabulation techniques to test the following hypotheses:

H 1: PH, hypertension, diabetes mellitus, BMI, HFpEF or HFrEF, race, and social factors predict the likelihood of 31to 60-day HF rehospitalization amongst elderly AA and Caucasian women.

H 2: Direct relationship exists between PH and race amongst elderly AA and Caucasian women hospitalized with index HF.

H 3: Direct relationship exists between hypertension and race amongst elderly AA and Caucasian women hospitalized with index HF.

H 4: Direct relationship exists between diabetes mellitus and race amongst elderly AA and Caucasian women hospitalized with index HF.

H5: Direct relationship exists between BMI and race amongst elderly AA and Caucasian women hospitalized with index HF.

H 6: Direct relationship exists between HFpEF or HFrEF and race amongst elderly AA and Caucasian women hospitalized with index HF.

### **Conceptual Model**

The newly designed conceptual framework for the current study is based upon a conceptual model developed by Calvillo-King et al. (2013). Calvillo-King et al. (2013) initially constructed this conceptual model (Figure 1) in 2013 to determine the impact of social and other factors on risk of readmission or mortality in pneumonia and HF patients. The original model reflects the reality of patients burdened with HF who remained at risk for early (<30 days) rehospitalization and addresses their ethnicity, economic disparity, and socio-demographic factors. The authors identified these factors and relations based on the existing literature. This conceptual model was modified for the current study to organize and evaluate factors reported in previous literature as influencing early HF rehospitalization in individuals hospitalized with index HF. This newly designed “Conceptual Framework of HF Rehospitalization” identifies relationships between clinical, hemodynamic, and social factors (predictor variables) to the outcome variable (31 to 60-day HF rehospitalization). This dissertation’s literature review revealed no testing of the model on a larger scale.

Figure 1. Original Conceptual Model illustrating how Different Factors Influence Readmission and Mortality

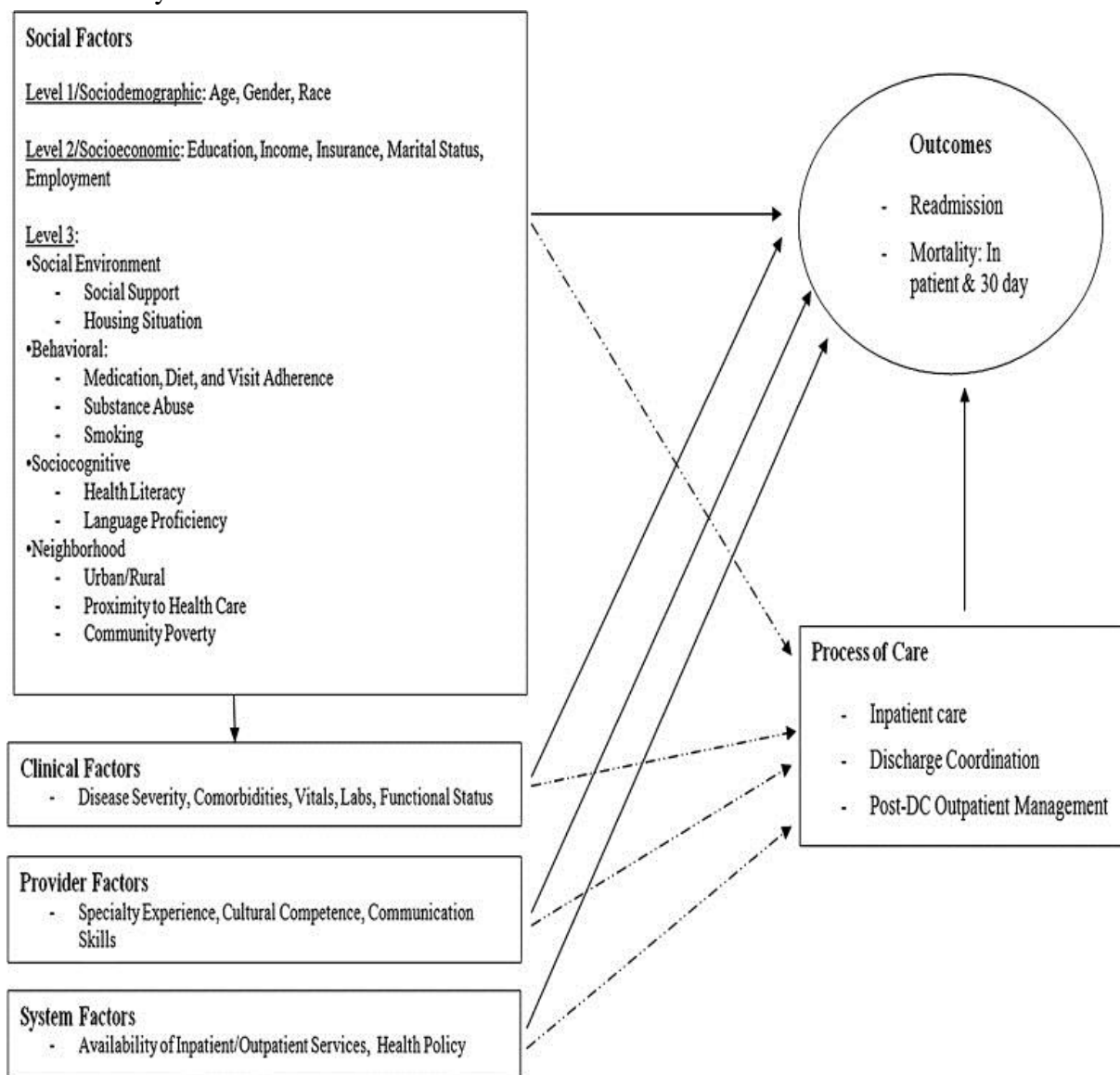


Figure 1. Conceptual Model illustrating how Social Factors, Clinical Factors, Provider Factors, and System Factors Influence Readmissions and Mortality. An adaptation from “Impact of social factors on risk of readmission or mortality in pneumonia and heart failure: systematic review,” by L. Calvillo–King and D. Arnold K. J. Eubank, M. Lo, P. Yunyongying, H. Stieglitz, and E. A. Halm, 2013, *Journal of General Internal Medicine*, 28, p. 269. Reprinted with permission.

## Model Components

Calvillo-King et al. (2013) constructed the basic model to outline a diverse range of domains that influenced post-discharge outcomes reflecting mortality or rehospitalization within 30 days of an index hospitalization for pneumonia or HF. The clinical perspective involved

individual characteristics as well as encounters at the individual or group level and multiple encounters at the organizational level (Vest, Gamm, Oxford, Gonzalez, & Slawson, 2010). Specific factors represented in the model included social factors, clinical factors, provider factors, and system factors. The authors further subdivided social factors into three sub-levels based on the mechanistic potential to directly influence post-discharge outcomes (Calvillo–King et al., 2013). Level I included simple socio-demographic characteristics such as age, gender, and race. Level 2 factors reflected socioeconomic variables such as marital status, income, and education. The authors subdivided third level factors into social environment, behavioral, socio-cognitive, and neighborhood factors. All factors included in the model correlated directly with outcomes (mortality or rehospitalization).

### **Conceptual Framework of Heart Failure Rehospitalization**

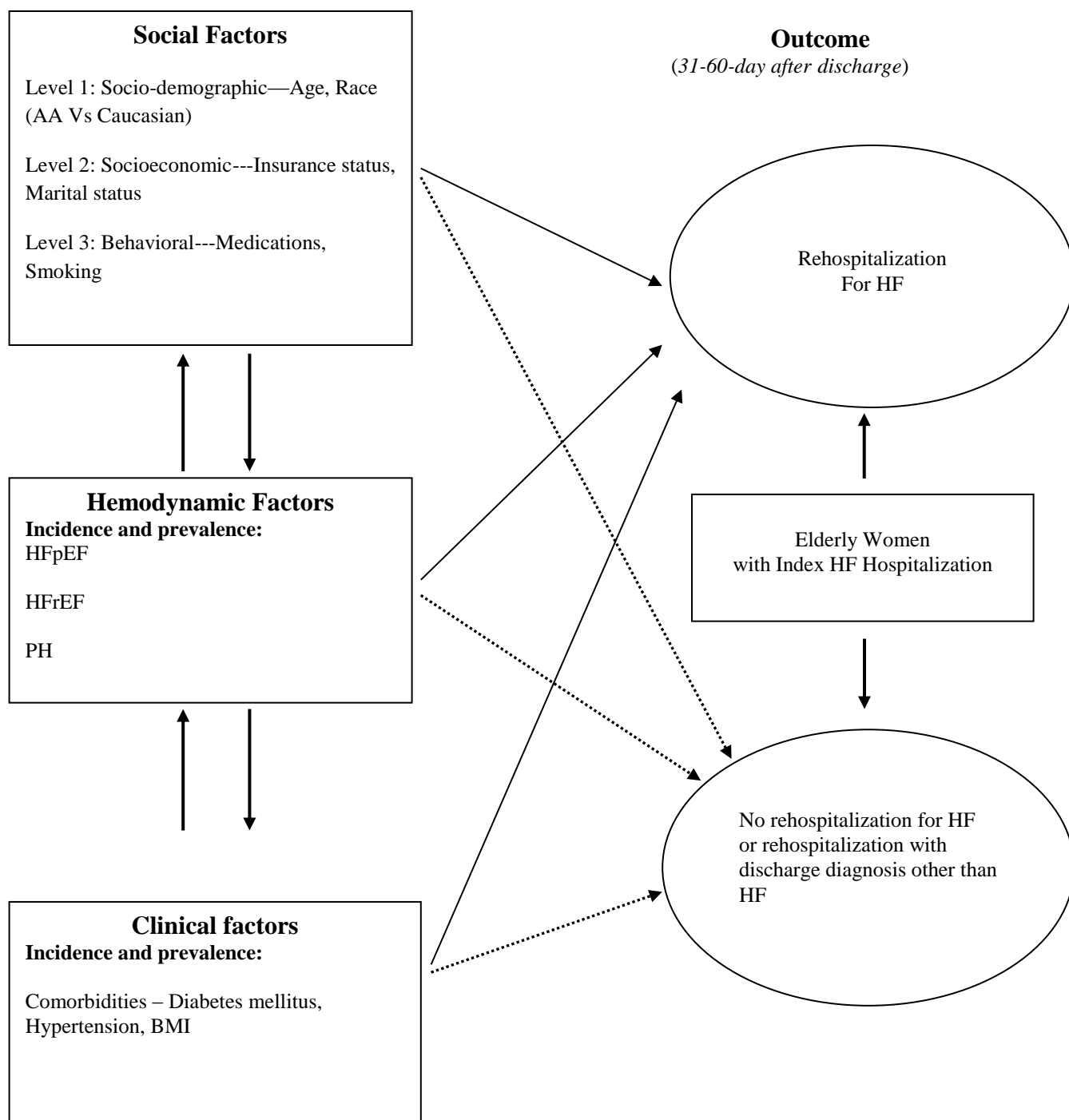
The conceptual framework for this study, the “Conceptual Framework of HF Rehospitalization” represented a modification of the original model (Calvillo–King et al., 2013). This newly designed conceptual framework specifically addressed HF rehospitalization in elderly AA and Caucasian women in a particular geographic location (Figure 2). This framework retained similar concepts/factors to the original model. However, the researcher adjusted model factors and selected new model variables based on disparate meanings, measurements, and variables compared to the original conceptual model. This effort created the “Conceptual Framework of HF Rehospitalization” model that fits with the purpose of the research study. The system factors were removed because of the difficulty of retrieving system factors from the hospital database. The researcher also excluded “process of care” because the items represented under this heading are irrelevant to the current research study. Hemodynamic factors were added because they represent predictors known to influence early HF rehospitalization in the extant

literature. Thus, the “Conceptual Framework of HF Rehospitalization” represents a modified and simplified version of the original model in order to reflect the focus of this research study and the limitations of the data which are being tracked institutionally. This conceptual framework identified relationships between selected clinical, hemodynamic, certain social factors, and early HF rehospitalization, which are congruent with data fields nationally associated with HF patients. In addition, the framework allowed the researcher to examine relationships between these factors in elderly AA and Caucasian women hospitalized with index HF (Bakal et al., 2014; Ruigómez, Michel, Martín-Pérez & Rodríguez, 2016; Zaya, Phan & Schwarz, 2012).

The researcher divided social factors (age, race, insurance status, marital status, medications, and smoking) into three levels to separate simple characteristics (socio-demographic factors) from other social factors that usually require a more thorough and detailed data abstraction (Calvillo–King et al., 2013). The factors that relate to social environment remained external to the individual or provider and strongly influence HF rehospitalizations (Amarasingham et al., 2010; Calvillo–King et al., 2013; Fleming et al., 2014). The final step in the proposed research study included an analysis plan designed to understand and identify relationships between hemodynamic, clinical factors, social factors, and early HF rehospitalization. The researcher addressed three hemodynamic factors which include PH and HF with preserved (HFpEF) or reduced (HFrfEF) ejection fraction. Similarly, the study identified the incidence and prevalence of clinical factors such as higher BMI, vitals and selected laboratory tests, as well as specific components of the MetS. Specific aims of this proposed research study, therefore involved understanding the associations between selected clinical and hemodynamic factors, and certain social factors, as well as their relationship to early (31 to 60-day) HF rehospitalization amongst elderly AA and Caucasian women.

The relationship of contextual factors in HF to risk factors for HF would show additional reasons why early HF rehospitalization after an index HF hospitalization remains problematic amongst elderly AA and Caucasian women, and perhaps is a reason for the development of therapeutic and preventive strategies for this chronic illness.

Figure 2. Conceptual Framework of Heart Failure Rehospitalization



## Definition of Terms

For the purpose of this study, the researcher provided the following conceptual and operational definitions in Table 1.

Table 1. Conceptual and Operational definitions

<b>Concept</b>	<b>Conceptual Definition</b>	<b>Operational definition</b>
Elderly Women	Women whose physical appearance reflects an older person.	Women identified as 65 years or older based on standard documents
Caucasian Women	A term used to describe females who are citizens of the United States with European ancestry	Self-identification as white on the hospital admissions questionnaire
African-American Women	AA women is a term used to describe females who are citizens of the United States with African ancestry	Self-identification as black on the hospital admission questionnaire
Heart Failure	HF is a “syndrome caused by cardiac dysfunction, generally resulting from myocardial muscle dysfunction or loss and characterized by LV dilation or hypertrophy” (HFSA, 2006, Lindenfeld et al., 2010)	A set of signs and symptoms supported by laboratory data in persons admitted or discharged from the participating hospital with a diagnosis of HF. ICD 9. of HF Physician identified Diagnostic Related Group (DRG) = 291, 292, 293,428;
Sixty-day Rehospitalization	Readmission between 1 to 60 days.	Readmission to the participating hospital between 31to 60-day
Index Hospitalization	Defined as the first time a person is admitted to an in-patient hospital facility for a specified condition and remains admitted for over 24 hours (Horwitz et al. 2011).	Person admitted to the participating hospital for their first hospitalization because of HF
Rehospitalization	Any hospitalization to an acute care hospital that occurs within a specific time period following discharge from an acute care hospital	Person readmitted to the participating hospital for HF between 31to 60-day after an index/first hospitalization for HF for a period greater than 24 hours

Comorbid Risk Factors	An additional disease or disorder risk that exists in the presence of any other disease or disorder.	Specific diseases (Diabetes Mellitus and Hypertension) associated with elderly female HF patients as reported in the literature
Social Factors	Social factors are specific social determinants that may influence one's state of health apart from medical care (Braveman, 2014)	Social factors into three levels using the criteria identified by Calvillo–King et al. (2013) : socio-demographic (Level 1); socioeconomic (Level 2); Behavioral (Level 3) Appendix C coding form)
Clinical Factors	Individual risk factors that influence the health of a person	Risk factors that include comorbidities, disease severity, functional status (Calvillo–King et al., 2013)
Pulmonary Hypertension (PH)	An abnormal increase of the blood pressure in the pulmonary artery, pulmonary vein, or pulmonary capillary, together known as the lung vasculature (Choudhary et al., 2013)	Elevation of the pulmonary artery systolic pressure (PASP)( $>33$ mm Hg), as calculated by addition of 5 mm Hg right atrial pressure to the transtricuspid gradient measured by transthoracic echocardiogram (Choudhary et al., 2014). ICD 9. DRG = 416.8
Heart Failure with preserved ejection (HFpEF)	A clinical syndrome diagnosed by HF signs and symptoms, but with preserved LVEF; associated with a non-dilated LV chamber and may result from valvular heart disease or other causes. (HFSA, 2006).	Quantifiable left ventricular ejection fraction (LVEF) by standard echocardiography with ejection fraction $>50\%$ (Gupta et al., 2013).
Heart Failure with reduced ejection fraction (HFrEF)	A clinical syndrome diagnosed by HF signs and symptoms, but with reduced LVEF; associated with a LV chamber dilatation (HFSA, 2006).	Quantifiable LVEF by standard echocardiography with ejection fraction $<50\%$ (Gupta et al., 2013).



## **Assumptions**

The study comprised of seven assumptions, which include:

1. The data compiled in the database at one large urban non-for-profit tertiary hospital located in the southeastern United States represent accurate and comprehensive data for the Southeastern region.
2. The collected data accurately reflected the demographic characteristics, socioeconomic status, and comorbid risk factors of each patient.
3. Patients admitted to the local hospitals self-report their race/ethnicity as contained in the database. This self-report did not reflect social response/desirability bias.
4. Race/ethnicity in the research study affected social factors and not physiologic factors.
5. Self-identified AA or black women based on race who are citizens of the United States constituted a distinct cohesive group in terms of HF risk.
6. Self-identified Caucasian women based on race who are citizens of the United States constituted a distinct cohesive group in terms of HF risk.
7. Clinical, hemodynamic, and social factors influenced post-discharge rehospitalization in elderly AA and Caucasian women after an index HF hospitalization.

## **Limitations of the Study**

Limitations of the study include:

1. A multitude of interacting factors, which the study could not control, may affect early rehospitalization. These included self-care, medication adherence, home care situations, and social care services affected early rehospitalization.
2. A retrospective study design using secondary data posed challenges in capturing a complete data set for all key variables, which the researcher could not control.

3. Inability to generalize the data to other groups in other areas of the country.
4. Inability to differentiate self-identified AA and Caucasian women who may or may not be biracial or have a complex ancestry.
5. Inability to track enrolled subject cases who were rehospitalized at another hospital between 31 to 60-days following the index HF hospitalization.
6. Inability to generalize data to current time frame because of the advanced changes in the treatment of HF.
7. The researcher conducted the proposed study over a certain interval of time, which reflected the conditions and characteristics of selected enrolled cases during that time interval.
8. The researcher could not make causal conclusions because the research design was observational.

### **Delimitations of the Study**

Delimitations of the study include:

1. Location of study: A large not-for-profit tertiary hospital located in the southeastern United States.
2. Sample population: AA and Caucasian women aged 65 or older. These two racial groups represented the predominant women admitted to the not-for-profit tertiary hospital during the selected study period.
3. Time frame: Selected timeframe of the study ranged between October 2012 and October 2015.

4. Readmission time frame: The rehospitalization time period chosen for the proposed research study which occurred within 31 to 60-days following index HF hospitalization.
5. Readmission criteria: The study included all subjects from enrolled cases who experienced HF rehospitalization within the 31 to 60-days following index HF hospitalization.
6. Controls: subjects from enrolled cases with an index HF hospitalization and with a discharge diagnosis of HF who were not rehospitalized as well as subjects readmitted with a diagnosis other than HF during the 31 to 60-day period.
7. Selected criteria: The selected variables fit the purpose of the study and directly impact rehospitalization.

This research study only included the subset of patients who have not received surgical interventions such as left ventricular assist devices (LVAD) and automated implantable cardioverter defibrillator (AICD). Previous cardiac transplant patients or those designated as candidates for cardiac transplantation were excluded. The researcher also excluded any patient with subject mortality within 60 days after their index HF hospitalization, or patients discharged to a hospice setting with a life expectancy of less than 90 days.

### **Significance of Study**

Nursing personnel assume a significant role when implementing risk-reduction strategies to reduce HF patient rehospitalization, particularly readmission during the early 31 to 60-day period following hospital discharge. Murtaugh et al. (2017) demonstrated the effectiveness of early and intensive nursing involvement and early physician follow-up in reducing the probability of readmission by roughly 8 points ( $p < .001$ ; CI = -12.3, -4.1). Early and effective

nursing involvement combined with the identification of comorbid risk factors that associate with elderly female HF (HFpEF or HFrEF) patients may strengthen the potential for further reductions in HF readmission.

In addition, incorporating comorbidities management and evidence-based therapy improves the odds of decreasing readmission after adjusting for patient characteristics, care planning (OR 1.03, 95%CI 1.00 to 1.03), teaching (OR 1.02, 95% CI 1.00 to 1.04), care coordination (OR 1.03, 95%CI 1.00 to 1.06), and treatment (OR 1.08, 95%CI 1.02 to 1.14) (Carthon, Lasater, Sloane & Kutney-Lee, 2015). These preventive strategies remain particularly important to elderly AA HF patients and those with lower financial status as suggested by Wu, Lennie, & Moser (2017). Wu et al. (2017) established that AA race/ethnicity and poor financial status resulted in poor outcomes such as experiencing a cardiac event and higher mortality as well as more HF readmissions ( $p < 0.005$ ) when controlling for covariates. AA female HF patients with lower financial status experienced a four to six times higher risk of experiencing cardiac hospitalizations compared to Caucasian female HF patients (Wu et al., 2017). This proposed research study contributed similar unique knowledge about social and comorbid risk factors in elderly female HF patients and their propensity for early HF hospital readmission.

The clinical syndrome of HF associates itself with complex features that reveal different characteristics depending on race/ethnicity, age, gender, left ventricular ejection fraction (LVEF), and HF etiology (Bui, Horwich & Fonarow, 2011). Understanding the incidence and prevalence of HFpEF and HFrEF among elderly AA and Caucasian women remains difficult as evidenced by the apparent inability to make any significant inroads toward reducing the national burden of this chronic illness (Giamouzis et al., 2011). Recent studies involving chronic HF and HF related hospitalizations and rehospitalizations have centered on comorbid risk factors and

geriatric factors (Chaudhry et al., 2013), health disparities (Wu, Lennie, Frazier & Moser, 2016; Wu, Lennie & Moser, 2016), HF-self-care management (Dickson et al., 2013), knowledge of HF, and socioeconomic factors. These studies added important dialogue to some of the causes associated with hospitalizations and early rehospitalizations. However, a significant gap exists due to lack of sex-specific data (Taylor, 2015) along with the underrepresentation of elderly AA women in terms of age and geographic location (Gupta et al., 2013; Lekavich & Barksdale, 2016). This lack of data require further studies to highlight the incidence and prevalence of HFpEF, and HFrEF in elderly AA and Caucasian women and explain associations between PH, hypertension, diabetes mellitus, BMI, HFpEF, HFrEF, and their contributions to HF hospitalization and rehospitalization. Expert clinical nurses may find themselves better positioned to provide clinical care for this elderly population of women when armed with additional knowledge regarding specific factors that contribute to HF rehospitalizations within this racial/ethnic group. Nursing may then significantly advance the science and improve the short and long-term outlook for this patient cohort in both preventing and/or controlling for HF.

### **Conclusion**

Chapter I outlined the background, purpose, and significance of this study as well as a conceptual framework that outlines predictors reported in previous literature as influencing early rehospitalizations in elderly AA and Caucasian women hospitalized with index HF. The current framework is based on the original conceptual model which addressed the impact of social as well as other factors on risk of readmission or mortality in pneumonia and HF (Calvillo–King et al., 2013). The original model reflected the contemporary reality of patients associated with chronic HF who remained at risk for early (<30-day) rehospitalization, and addressed their ethnicity, economic disparity and sociodemographic factors. The model lent itself as a guide for

the development of the “Conceptual Framework of HF Rehospitalization”, which conceptualizes early HF rehospitalization. This new conceptual framework organized and incorporated specific contextual factors along with certain hemodynamic factors to examine their relationship with each other as well as their influence on early HF rehospitalization.

A review of studies discussing HF rehospitalization reveal that clinical researchers attempted to address early (<30-day) readmissions after CMS began publicly reporting 30-day risk-standardized readmission rates (Dharmarajan et al., 2017). However, very few studies exist that addressed early (31 to 60-day) rehospitalization, even though HF-readmissions extend beyond 30 days (Gheorghide et al., 2012; Muzzarelli et al., 2010; Nichols et al., 2015). For that reason, this study offered substantial benefits to primary care providers, specialists, healthcare facilities, and third-party payers, attempting in their efforts to reduce the cost of preventable hospitalizations through effective care coordination. Findings of this study would also provide valuable information to hospitals that are currently penalized related to excessive rehospitalization rates, and reducing inappropriate care strategies such as delaying readmissions beyond discharge day 30 or increasing a patient’s observational stay (Fonarow, Konstam & Yancy, 2017).

Increasing mortality and generating poorer long-term outcomes expose the end results of such inappropriate strategies, particularly in high risk patients with multiple comorbidities. Therefore, identifying predictor variables associated with risk of developing HF in elderly AA and Caucasian women would assist in the design of risk-reduction strategies which deter or delay HF rehospitalization in these racial/ethnic groups (Sherer, Crane, Abel & Efird, 2016). Clinicians and the nursing profession recognize that risk-reduction strategies involving social and comorbid risk factors affect HF rehospitalization. Nevertheless, the existing data or nursing research failed

to examine the influence of specific comorbid risk factors (higher BMI, PH, social factors, and components of MetS) on early HF rehospitalization among elderly AA and Caucasian female HF patients.

A gap in knowledge therefore exists regarding the identification of specific comorbid/contextual or hemodynamic risk factors either separately or in combination, which determines the greatest impact on early HF rehospitalization in elderly AA and Caucasian women. This study attempted to address this gap in the existing literature regarding the unique associations between clinical, hemodynamic, and social risk factors, and early (31 to 60- day) HF rehospitalization, which remains critical to elderly AA and Caucasian women predisposed to HF rehospitalization.

## **Chapter II: Review of Literature**

### **Introduction**

This chapter contains a review of relevant literature related to the causes of early rehospitalization among elderly African American (AA) and Caucasian women after an initial heart failure (HF) hospitalization. The search criteria prioritized focus on titles, abstracts, and full text articles enabling access to publications relevant to the proposed research. A plethora of literature specific to HF and rehospitalization exists and continues to grow because of providers' interest and the increasing number of elderly patients developing the disease (O'Connor et al., 2016). In addition, the rapid expansion and use of the electronic medical record throughout the world has led to a proliferation of easily retrievable articles, chapters, and books on these topics. As such, the search strategy will continue until the researcher completes the proposed study.

### **Search Query**

Search strategies specific to each data subset utilized both computerized and manual searching. These strategies included:

Boolean Operators words such as AND, OR, or NOT, which the researcher used to expand, join, or exclude all key terms relevant to the study.

MeSH terms – The researcher developed Medical Subject Headings (MeSH) terms to facilitate the retrieving of information using different terminology for the same keyword.

Truncation – The researcher developed variations of keywords by adding a truncation symbol (\*, "?,! ) to the root of the word. In a similar manner, the researcher identified truncation symbols that varied with different databases using online help such as “advanced search” and “search tips”.



## **Ancestry Searches**

These studies include earlier studies cited in a reference list of primary or secondary sources. The researcher chose several studies that met criteria.

## **Search Strategy**

Search strategy incorporated searches of six computerized databases located at The Catholic University of America. These include Cumulative Index of Nursing and Allied Health Literature (CINAHL), MEDLINE (accessed through PubMed), Web of Science: CMS website, PubMed, and Google Scholar. Titles, abstracts, and full texts were reviewed to assess whether they fit inclusion criteria.

The research title, hypotheses, and conceptual framework provided the terms used for the literature search. Key terms included heart failure, elderly, women, African-American, metabolic syndrome, pulmonary hypertension, heart failure with preserved ejection fraction, heart failure with reduced ejection fraction, socioeconomic status and social factors, genetic factors, provider factors, comorbidities, hospitalization, and rehospitalization. The researcher used each word separately and in combination. Search strategies attempted were limited to English language studies published in the last decade (2006 - 2016) in an attempt to keep the literature as current as possible. However, the researcher reviewed and included studies conducted before 2006 and after 2016 that could potentially hold relevance. The reviewed studies included articles published in international journals, since HF research now remains a global phenomenon. The researcher included published results from articles whose authors have published their research in peer reviewed journals.

Table 2. Search Results from Different Electronic Databases

Database	Keywords	Results
MEDLINE	(1) heart failure, elderly; (2) women; (3) metabolic syndrome; (4) pulmonary hypertension; (5) heart failure with preserved ejection fraction; (6) heart failure with reduced ejection fraction; (7) socioeconomic status and social factors; (8) genetic factors; (9) provider factors; (10) comorbidities; (11) African-American; (12)1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 10 or 11; (13) hospitalization or rehospitalization; (14) 12 and 13.	73,109
CINAHL	(1) heart failure, elderly; (2) women; (3) metabolic syndrome; (4) pulmonary hypertension; (5) heart failure with preserved ejection fraction; (6) heart failure with reduced ejection fraction; (7) socioeconomic status and social factors; (8) genetic factors; (9) provider factors; (10) comorbidities; (11) African-American; (12)1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 10 or 11; (13) hospitalization or rehospitalization; (14) 12 and 13.	7,973
CMS Website	(1) heart failure, elderly; (2) women; (3) metabolic syndrome; (4) pulmonary hypertension; (5) heart failure with preserved ejection fraction; (6) heart failure with reduced ejection fraction; (7) socioeconomic status and social factors; (8) genetic factors; (9) provider factors; (10) comorbidities; (11) African-American; (12)1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 10 or 11; (13) hospitalization or rehospitalization; (14) 12 and 13.	100
PubMed	(1) heart failure, elderly; (2) women; (3) metabolic syndrome; (4) pulmonary hypertension; (5) heart failure with preserved ejection fraction; (6) heart failure with reduced ejection fraction; (7) socioeconomic status and social factors; (8) genetic factors; (9) provider factors; (10) comorbidities; (11) African-American; (12)1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 10 or 11; (13) hospitalization or rehospitalization; (14) 12 and 13.	3912
Google Scholar	(1) heart failure, elderly; (2) women; (3) metabolic syndrome; (4) pulmonary hypertension; (5) heart failure with preserved ejection fraction; (6) heart failure with reduced ejection fraction; (7) socioeconomic status and social factors; (8) genetic factors; (9) provider factors; (10) comorbidities; (11) African-American; (12)1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 10 or 11; (13) hospitalization or rehospitalization; (14) 12 and 13.	5,040
Web of Science	(1) heart failure, elderly; (2) women; (3) metabolic syndrome; (4) pulmonary hypertension; (5) heart failure with preserved ejection fraction; (6) heart failure with reduced ejection fraction; (7) socioeconomic status and social factors; (8) genetic factors; (9) provider factors; (10) comorbidities; (11) African-American; (12)1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 10 or 11; (13) hospitalization or rehospitalization; (14) 12 and 13.	2,129
Total number of citations retrieved		92,253

CINAHL = Cumulative Index to Nursing and Allied Health Literature; CMS = Centers for Medicare & Medicaid Services

## Search Outline

Table 2 provides details on specific search terms, combinations of key words, and databases. The researcher entered “HF” into the Medline database with only one filter (2006-2016). This initial search yielded 80,084 articles. The researcher also included an addition of “English language” and “peer review,” resulting in 73,109 articles. When the researcher added “elderly,” and “women,” the search yielded 49 articles. With the addition of elderly AA women, the search yielded no articles.

The researcher used the CINAHL database for a second search regarding elderly women and HF. An initial search with only “HF” yielded 7,973 articles. The identification of seven articles resulted from adding “elderly”, “women” and “peer review” filters. With the addition of the AA restriction, the search yielded no articles. When the researcher entered “HF,” and “elderly,” and “Caucasian,” and “women” into the database, the search netted 538 articles. The researcher set aside these articles for review and inclusion.

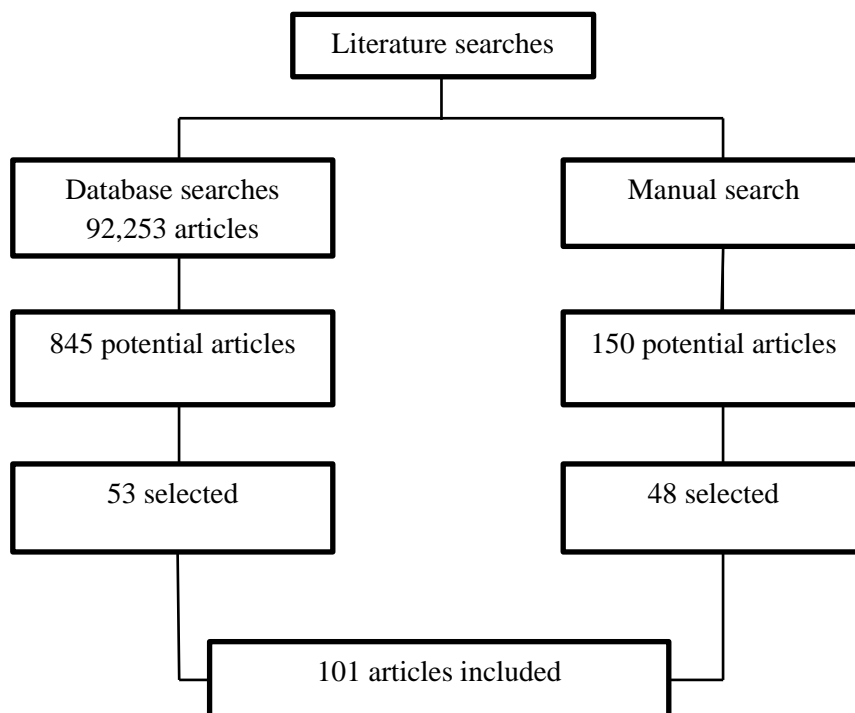
The Web of Science provided a third database to study the association between HF and MetS. An initial search yielded 2,129 articles. With the addition of “women” and “peer review,” the researcher retrieved 288 articles. Adding “elderly” into the database, the search yielded 32 articles. The researcher set aside these articles for review and inclusion.

PubMed database provided a fourth site to study the association between HF and elderly women. An initial search with only HF and women yielded 4,666 articles. With the addition of “elderly”, the researcher retrieved 3,524 articles. Upon entering “AA” into the database, the search yielded 110 articles which the researcher set aside for review.

Manual searches of bibliographies using an ancestry approach as well as a hand search of previous identified papers from key authors yielded 150 potential articles. The researcher

selected 43 articles for inclusion into the current research study. Thus, the researcher incorporated a final total of 96 articles in this section of the research study. Figure 3 details the search.

Figure 3. Flow Diagram of the Literature Search



### Thematic Approach

The researcher divided the literature review into three sections. The first section focused on women and HF and includes statistics related to the incidence and prevalence of HF in women, particularly AA women. A discussion of comorbidities, race, genetics, and risk factors for HF concludes this section.

The second section focuses on the conceptual framework proposed to organize and evaluate factors reported in previous literature as influencing admissions and early rehospitalizations in elderly AA and Caucasian women who were hospitalized with index HF.

Discussions in this section include the incidence, prevalence and associations of HFpEF, HFrEF, PH, MetS, socioeconomic factors of HF hospitalization and rehospitalization.

The literature review concludes with a third section that discussed the dependent variable: rehospitalization. In this section, a review of subheadings such as provider factors, risk factors, and predictors will follow. The researcher also examines the thematic section's study design, length of stay, sample size, cost and outcomes under this section.

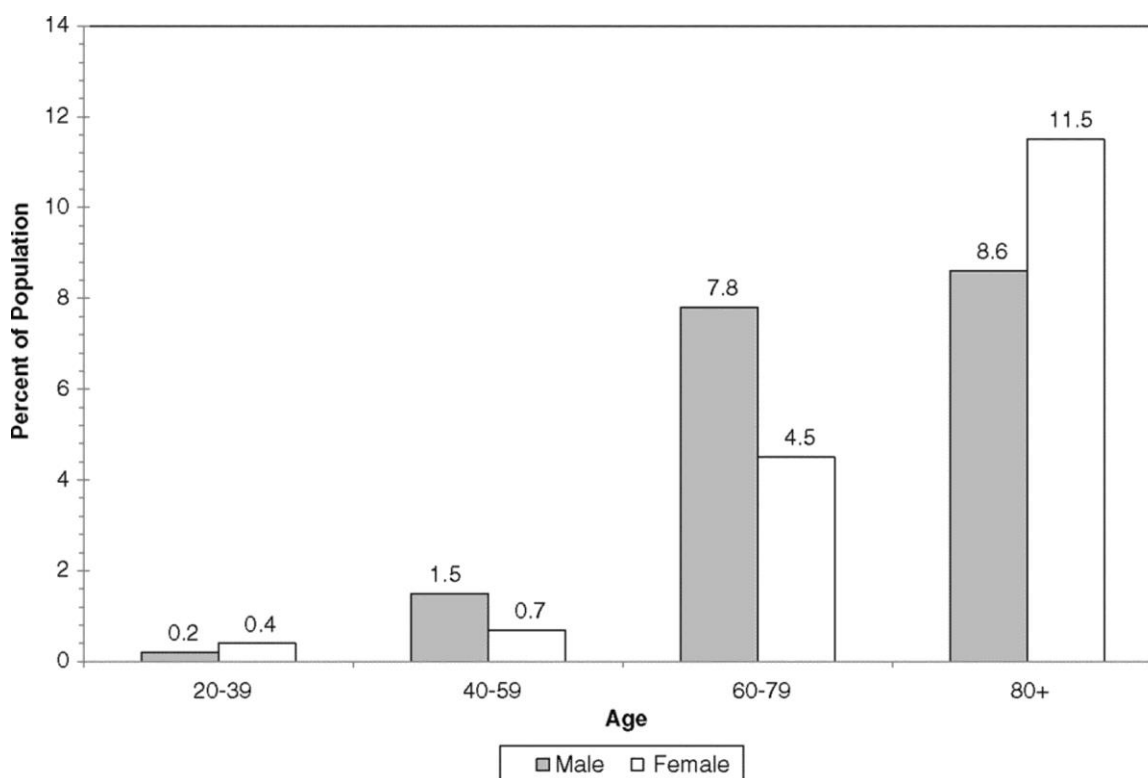
## **Women and Heart Failure**

### **Incidence and Prevalence**

HF remains a complex clinical syndrome that affects all races, and clinicians characterize this syndrome as a structural or functional impairment of an ejection of blood from the left ventricle (Yancy et al., 2013). Current literature reports approximately 23 to 25 million persons suffer from HF worldwide, and its prevalence in the United States exceeds 5.8 million adults (Bui, Horwich & Fonarow, 2011; Yancy et al., 2013). Statistics based on sex and age show that the incidence of HF will rise from approximately 20 per 1000 individuals in the 65 to 69-year-old age group to over 80 per 1000 in the over 85-year-old age groups (Figure 4) (Go et al., 2013; Yancy et al., 2013). The incidence of HF increases with age and among women, especially AA women (Bahrami et al., 2008; Yancy et al., 2013). In a recent position statement developed by the American Association of Heart Failure Nurses (AAHFN), the authors noted that the prevalence of HF continues to rise despite declining incidences of HF. They attribute this trend to an increase in the aging population with HF patients living longer (Stamp et al., 2018). The authors also noted that previous data showed a 3.2% HF prevalence amongst AA women greater than 20 years of age, compared to a 2.2% HF prevalence in Caucasian women or men in similar age groups. These data clearly forecast higher HF prevalence in elderly women and underscores

the need to understand which risk factors predict HF hospitalizations or rehospitalizations. This information addresses prevalence of HF but not predictors of HF rehospitalizations.

Figure 4. Prevalence of Heart Failure by Sex and Age



National Health and Nutrition Examination Survey: 2007–2010. Source: National Center for Health Statistics and National Heart, Lung, and Blood Institute. ©2013 American Heart Association, Inc. All rights reserved. Go AS et al. Published online in *Circulation* Dec. 18, 2013

HF affects men and women equally, but the characteristics of HF remains different depending on the individual's age, sex, race, or ethnicity (Bui, Horwich & Fonarow, 2011). The prevalence of HF trends higher in AA women, and they tend to present at a younger age than Caucasian women (Bui et al., 2011). Significant differences in etiology, expression, outcomes, and response to therapy also exist among different genders or races with HF. Taylor (2015) reported that women afflicted with hypertension tend to suffer more from HF especially the HFpEF subtype. However, data illustrate that survival in women exceeds men, and women

remain less susceptible to sudden cardiac death (Taylor, 2015). Data also demonstrate that the inclusion of women in randomized clinical trials (RTC) remains at about 20% despite the high prevalence of female HF patients. Clinical researchers often fail to incorporate women as a pre-specified subgroup for statistical analysis, which leads to HF treatment for women that is not supported by sex-specific data (Taylor, 2015). Clinicians direct their analyses and therapies of elderly AA women with HF based on data from younger participants in clinical trials, which reflects the inconsistent literature regarding factors that predict early HF rehospitalizations.

### **Heart Failure and Elderly**

Elderly women, especially AA women, suffer with HF described by clinicians as the heart's inability to circulate blood efficiently to vital organs of the body (Hunt et al., 2009). In addition, elderly persons, particularly women, suffer from the cumulative effects of comorbid conditions and cardiac risk factors such as frailty, chronic kidney disease, hypertension, diabetes, anemia, obesity, atrial fibrillation, and lower socioeconomic status (Bahrami, et al., 2008; Murad & Kitzman, 2012; Mureddu et al., 2012; Ruiz-Laiglesia et al, 2014). Bahrami et al. (2008) conducted a cohort study, the Multi-Ethnic Study of Atherosclerosis (MESA), which involved men and women from four ethnic groups. Fifty-three percent of participants were elderly women. The researchers designed the study to examine the relationship between incident HF and ethnicity. Over a four year period, 79 participants developed HF, which was the highest incidence and prevalence rates in AAs compared to Caucasians (4.6 vs 2.4 in 1000 person-years respectively; HR, 1.81; 95% CI, 1.07 - 3.07;  $p = 0.03$ ). Hypertension, diabetes, and lower socioeconomic status remained highly prevalent in AA women and appeared to influence the development of incident HF. In contrast, interim myocardial infarction least influenced the development of HF among AA participants. The strengths of the study included its longitudinal

timeframe, prospective design, and being conducted in an ethnically diverse population.

Limitations of the study included a shorter time span (four years) for the development of HF and the inability to form temporal associations among baseline risk factors. The ability of this study to demonstrate key differences between AA and Caucasian participants during a relatively short follow-up period reflected the importance of these associations (Bahrami et al., 2008).

Ruiz-Laiglesia et al (2014) conducted a similar study which sought to identify the comorbidities associated with elderly HF patients and their effect on rehospitalization. The most frequent comorbidities identified by the researchers included diabetes mellitus (44.3%), chronic renal impairment (30.8%) and chronic obstructive pulmonary disease (COPD) (27.4%). This study offered limited generalizability because the authors conducted the study using a Spanish cohort and failed to include elderly AA women. Murad & Kitzman (2012) emphasized the negative impact on the management of elderly HF patients among elderly frail women with multiple comorbidities, and their lack of inclusion in clinical trials. According to Murad & Kitzman (2012), frailty and multiple comorbidities adversely impact the management of HF in the elderly on many levels, including recruitment and representation in clinical trials, early and accurate diagnosis of HF, treatment of HF and its associated comorbid conditions, and providing accurate prognosis to guide clinical care. The authors hypothesized that clinical researchers exclude elderly females from RCT's because of their frailty and comorbidities. These two studies point to the lack of inclusion of elderly women in clinical trials, which makes the management of elderly female HF patients challenging because of the lack of sex-specific data regarding comorbidities.

Age-related changes in ventricular function also contribute to the prevalence of HF associated with preserved ejection (HFpEF) in elderly women (Hunt et al., 2009; Lazzarini,



Mentz, Fiuzat, Metra & O'Connor, 2013). As a result, this subset of elderly women tends to develop classic symptoms and signs of HF such as edema, shortness of breath, fatigue, paroxysmal nocturnal dyspnea, and nocturnal cough (Maestre et al., 2009) (Table 3). Elderly women with HF often present to their healthcare providers with classic symptoms of HF (Table 3) at a wide spectrum of American College of Cardiology (ACC) stages or New York Heart Association (NYHA) functional classes (Table 4). Table 4 elucidates the stages of HF and complement NYHA functional classes that elderly HF female patients suffer with when they present to the emergency room or clinics for acute or chronic evaluation. It is notable that non-invasive cardiac imaging commonly fails to reveal poor systolic function because HFpEF coexists frequently in this subset of elderly women. Patients and their healthcare providers often attribute their symptoms to aging or interaction with non-prescribed medications (e.g., non-steroidal anti-inflammatory drugs), which often leads to inadequate diagnosis and treatment. Understanding the association of HF subtypes with a selected racial/ethnic group remains important because of different approaches to specific therapies. Furthermore, the data underscores the need to properly diagnose and treat elderly HF patients which may lead to a reduction in early HF rehospitalization.

Table 3. Framingham Criteria for Heart Failure

Major Criteria	Minor Criteria
Acute pulmonary edema Cardiomegaly Hepatojugular reflex Paroxysmal nocturnal Dyspnea or Orthopnea Pulmonary rales Third heart sound (S <sub>3</sub> Gallup Rhythm)	Ankle edema Dyspnea on exertion Hepatomegaly Nocturnal cough Pleural effusion Tachycardia (heart rate >120 beats per min)

Interpretation: Heart failure diagnosis requires 1 major and 2 minor criteria (Maestre et al., 2009)

Five studies (Lam et al., 2012; Mureddu et al., 2012; Shah et al., 2013; Sheppard et al., 2005; Zsilinszka et al., 2015) have investigated gender differences, clinical characteristics, and outcomes in elderly patients with HF and preserved left ventricular function. A longitudinal prospective trial, the I-PRESERVE Trial, included 60% females and revealed that elderly women with HFpEF tended to be more obese compared to men and suffered from chronic kidney disease more often, but were less likely to develop HF related to an ischemic etiology (Lam et al., 2012). Women often presented with systolic blood pressure >140 mm Hg (62.5% vs 56.4%;  $P = .0001$ ) and higher EF. The data revealed no sex differences in 30 and 180-day rehospitalizations. After adjustment, women stayed longer LOS (0.40 days, 95% confidence interval [CI] 0.10–0.70;  $P = .008$ ). In this study, the authors recognized that the data revealed by the study failed to confirm the outcomes that appeared to be sex-related, and suggested caution when interpreting or referencing the data. In a study conducted in Italy, elderly men and women underwent preclinical HF assessments using physical examinations, echocardiography, and biochemistry/ N-terminal pro-brain natriuretic peptide (NT-proBNP) levels (Mureddu et al., 2012). Low participation rates remained one of the study's limitations. However, the authors carefully concluded that the prevalence of preclinical HF in the elderly is high, primarily related to HFpEF. Furthermore, data revealed that a good proportion of participants in stage B of HF (Table 4) did not achieve acceptable risk factor control. Collectively, these studies present data involving elderly women, but the data remain inconsistent, and suggest the need for further studies to determine what risk factors contribute commonly to HF rehospitalization.

Table 4. Categorizing Heart Failure

<b>ACC/AHA stages of heart failure: Stage of heart failure based on structure and damage to heart muscle</b>	<b>NYHA functional classification: Severity based on symptoms and physical activity</b>
<b>Stage A</b> At high risk for developing heart failure. No identified structural or functional abnormality; no signs or symptoms.	<b>Class I</b> No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea.
<b>Stage B</b> Developed structural heart disease is strongly associated with the development of heart failure, but without signs or symptoms.	<b>Class II</b> Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.
<b>Stage C</b> Symptomatic heart failure associated with underlying structural heart disease.	<b>Class III</b> Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity results in fatigue, palpitation, or dyspnea.
<b>Stage D</b> Advanced structural heart disease and marked symptoms of heart failure at rest despite maximal medical therapy.	<b>Class IV</b> Unable to carry on with physical activities without discomfort. Symptoms at rest. If any physical activity is undertaken, discomfort is increased.

ACC = American College of Cardiology; AHA = American Heart Association;  
 NYHA = New York Heart Association. Yancy C W. et al. *JACC*, 2013; Dickstein K. et al.  
*European Journal of Heart Failure*, 2008.

Shah et al. (2013) also illuminated in a similar population of subjects the lack of evidence-based strategies in HFpEF. The predominant findings in their study included low activity level and significantly decreased quality of life amongst the elderly. In an earlier study conducted in Quebec, Canada, Sheppard et al. (2005) evaluated the effect of gender on treatment and outcomes in elderly men and women with HF. Women with HF generally were older, suffered more from hypertension (41% vs. 28%,  $p < 0.001$ ) and hyperlipidemia (18% vs. 14%,  $p < 0.001$ ), but less frequently from myocardial infarction (19% vs. 25%,  $p < 0.001$ ). Remarkably, women remained less likely to have assessment of left ventricular function (61% vs. 65%,  $p <$

0.001), and less likely to be prescribed an angiotensin-converting enzyme inhibitor (60% vs. 66%). Zsilinszka et al (2015) utilized a retrospective analysis on secondary data to compare baseline characteristics, emergency department (ED) therapies, hospital length of stay (LOS), in-hospital mortality, and post-discharge outcomes among HFpEF patients. The data revealed that women represented 67% of the study population appeared older and hypertensive, but were less likely to be diabetic or have a smoking habit (all  $P < .01$ ). The study concluded that more women than men suffered with HFpEF and presented to the ED with a systolic blood pressure  $>140$  mmHg (62.5% vs 56.4%,  $p = 0.0001$ ), but overall ED management strategies remained similar to those in men. These past and recent HF studies clearly underscore the importance of following clinical guidelines when managing health for elderly women with HFpEF. The three studies complement each other, revealing characteristics and risk factors common to elderly women with HFpEF. However, the data failed to discuss the predictive values of these risk factors regarding HF readmissions among elderly women, which the proposed research study sought to understand.

### **Clinical Guidelines in Heart Failure**

Landmark HF trials as well as recent HF trials upon which clinicians ultimately base current guidelines often exclude elderly patients (Cherubini et al., 2011; Lazzarini, Mentz, Fiuzat, Metra & O'Connor, 2013; McMurray et al., 2012). According to Cherubini et al (2011), clinicians often base research relevance to elderly patients on younger patients rather than those who most often suffer from the disease in question. These authors extracted data from the World Health Organization Clinical Trials Platform on December 1, 2008 to determine why clinical research excludes the elderly. The authors classified exclusion criteria into two categories of justified and poorly justified. Results showed that in 251 trials investigating treatment for HF,

25% excluded patients using an arbitrary upper age limit. The authors concluded that this type of selection process remains widespread. As a result, therapies recommended in current guidelines (Table 5) remain based largely on a younger population who differ physiologically from the elderly and who exhibits a different clinical profile (Lazzarini, Mentz, Fiuzat, Metra & O'Connor, 2013). Nevertheless, clinicians must follow current guidelines to improve prognosis in the elderly and reduce the burden of this complex disease, adhering to the standard of medical practice for the population served. Table 5 outlines current and updated guidelines for the four stages of HF. Nursing personnel and clinicians often utilize these clinical HF parameters and guidelines to determine modes of therapy (Table 5), length of stay, prognosis, rehospitalization probability, and placement at the time of hospital discharge. Moreover, these guidelines remain helpful when assessing elderly women who suffer with both HFpEF and HFrEF. However, since clinicians conducted previous HF trials in younger, more frequently male patients with minimal comorbidity, who took fewer medications, their restrictive eligibility criteria may compromise their external validity (Cherubini et al., 2011). As such, clinicians remain unsure how to apply guidelines to the typical older HF patient, including patients in the proposed research study.

Table 5. Stages in the Development of Heart Failure and Recommended Therapy

<b>At Risk for Heart Failure</b>		<b>Heart Failure</b>	
<b>Stage A</b>	<b>Stage B</b>	<b>Stage C</b>	<b>Stage D</b>
No structural heart disease or symptoms of HF	Structural heart disease but no symptoms of HF	Structural heart disease with current symptoms of HF	Refractory HF requiring specialized interventions or medical therapy
Patients with hypertension Atherosclerotic disease Diabetes	Patients with Previous MI LV remodeling Preserved ejection fraction	Patients with known structural heart disease and shortness of breath fatigue	Patients with marked symptoms despite maximal medical therapy

Obesity Metabolic syndrome	Low ejection fraction	edema poor exercise tolerance	
<b>Therapy</b>	<b>Therapy</b>	<b>Therapy</b>	<b>Therapy</b>
Exercise Smoking cessation Treat hypertension Weight loss <b>Drugs</b> ACEI or ARB in appropriate patients	All measures under Stage A <b>Drugs</b> ACEI or ARB Beta blocker	All measures under Stage A and B <b>Drugs in Selected Patients</b> Aldosterone antagonist ARBs Digitalis Hydralazine /nitrates in select patients ARNI therapy	All measures under Stage A,B, and C <b>Options</b> Heart transplant Chronic inotropes Mechanical support Experimental drugs ARNI therapy

ACEI= angiotensin- converting enzyme inhibitor; ARB= angiotensin II receptor blocker; HF= heart failure; LV= left ventricle; ARNI= angiotensin receptor-neprilysin inhibitor; Hunt et al., 2009; Lindenfield et al., 2010; McMurray et al., 2012; Yancy et al., 2016

### Genetic Factors and Heart Failure

HF characteristically affects AAs at an earlier age compared to Caucasians, leading one to speculate that racial differences in HF possibly reflect a genetic component (Hunt et al., 2009; Ishizawa & Yancy, 2010). Increased awareness of HF in special populations remains warranted as the demographics of the United States have continually changed over the last two decades (Hunt et al., 2009). Researchers conducted two studies in the last decade addressing genetic factors and their influence on the risk of developing heart failure in the AA population (Liggett et al., 2008; Small, Wagoner, Levin, Kardia & Liggett, 2002). Liggett et al. (2008) prospectively followed 375 AA HF patients (ages 18 to 80 years) for 6 years to determine whether G-protein coupled receptor kinases (GRKs) can desensitize the beta-adrenergic receptor and lead to better survival. The study revealed that GRKs in AA patients imparted genetic beta blockage and improved survival in AA with NYHA class II-IV HF ((single allele: RR=0.28, 95% CI = 0.12 - 0.66; two alleles: RR=0.08, 95% CI = 0.04 - 0.19; P = 0.004). Small et al. (2002) theorized that a

combination of two receptor variants, the alpha 2C and beta 1 adrenergic receptors may act synergistically to predispose persons to HF. The study enrolled 159 participants, 78 AA patients (mean age 49 +/- 12 years), and 81 Caucasian patients (mean age, 53 +/- 16 years). All of the patients met the study criteria of NYHA class II-IV and a diagnosis of either idiopathic dilated or ischemic cardiomyopathy. The study revealed a synergy between the alpha 2C and beta 1 receptors which resulted in an increased synaptic norepinephrine release and greater risk of HF among AA, compared to the reference group (unadjusted odds ratio, 12.67; 95 percent confidence interval, 2.70 to 59.42; P=0.001). The participants in this study self-reported their racial class, which introduced a perceived limitation as stated in the proposed research study. In addition, the investigators excluded HF caused by primary valvular disease, myocarditis or obstructive or hypertrophic cardiomyopathies, which reflected different exclusion criteria. Even though the outcomes in both studies differ, they complement each other by studying AA patients with similar ages and NYHA classifications.

The African-American Heart Failure Trial (A-HeFT) provides further evidence that a genetic component remains responsible for the increased incidence of HF in the AA population. In this trial, researchers randomly assigned 1050 self-identified AA patients with NYHA class III-IV HF to receive a fixed dose of isosorbide dinitrate (BiDil™) or placebo along with standard HF therapy (Taylor et al., 2004). The study characteristics included younger patients (56 +/- 12 years) and women (45%). The results of A-HeFT showed that BiDil™ provided significant mortality benefits for AA with HF compared to placebo (Taylor et al., 2004). Cappola et al (2010) identified inherent variations in genes among Caucasian women (30%) with advanced HF which could possibly contribute to HF risk. The authors identified regions containing HSPB7 and FRMD4B as novel susceptibility loci for advanced heart failure (Cappola

et al., 2010). Although neither of these studies addressed risk factors related to HF rehospitalization, they both suggest that a genetic element contributes to recurrent HF. Both studies contributed to the proposed research due to their evaluation of HF risk amongst AA and Caucasian women.

### **Comorbid Risk Factors and Heart Failure**

Cardiac and non-cardiac comorbid risk factors coexist with acute or chronic HF in elderly men and women (Ruiz-Laiglesia et al., 2014; Sato et al., 2010). Sato and colleagues compared the clinical characteristics of patients hospitalized with acute HF in four epidemiological studies presented in Table 6, and illustrated in Figure 5 (Sato et al., 2010). Most patient ages fell into the over-sixty-five range (>65 years) and demonstrated a higher incidence of hypertension and diabetes. Data also revealed that women remained under-represented in the Acute Decompensated Heart Failure Syndromes (ATTEND) and Euro Heart Failure Survey II (EHFS II) studies (Nieminen et al., 2006; Sato et al., 2010). Atrial fibrillation remains moderately prevalent in all studies and suggests a close link between the two major disorders (Deedwania & Lardizabal, 2010). The coexistence between HF and atrial fibrillation reflects a concomitant association with an adverse prognosis and underscores the complex electrophysiological and neurohormonal processes they share (Deedwania & Lardizabal, 2010). In addition, these studies collectively underscore a need to further explore HF research in elderly women.

Two recent international studies also examined comorbid risk factors in elderly patients with HF (Ruiz-Laiglesia et al., 2014; van Deursen et al., 2014). Both studies addressed mortality and rehospitalization. van deursen et al (2014) studied 3226 European outpatients with chronic HF for approximately one year. The researchers examined multiple cardiac and non-cardiac comorbidities to determine incidence, prevalence, and prognosis. The study showed that chronic



kidney disease (41%), anemia (29%), and diabetes (29%) remained the most prevalent non-cardiac comorbidities. The authors concluded that the three comorbidities independently related to HF hospitalization. Ruiz-Laiglesia et al (2014) also found similar comorbidities in the Spanish RICA registry. In their sample of population, data showed the left ventricular ejection fraction (LVEF) exceeded 50 % in 59.1% of the cohort. Both studies contribute to knowledge about comorbid risk factors and HF rehospitalization, but conducting the research using European participants limit their generalization to the AA population. However, the studies offer an opportunity to compare similar cardiac and non-cardiac comorbidities (HFpEF, diabetes) which the current research proposes to study.

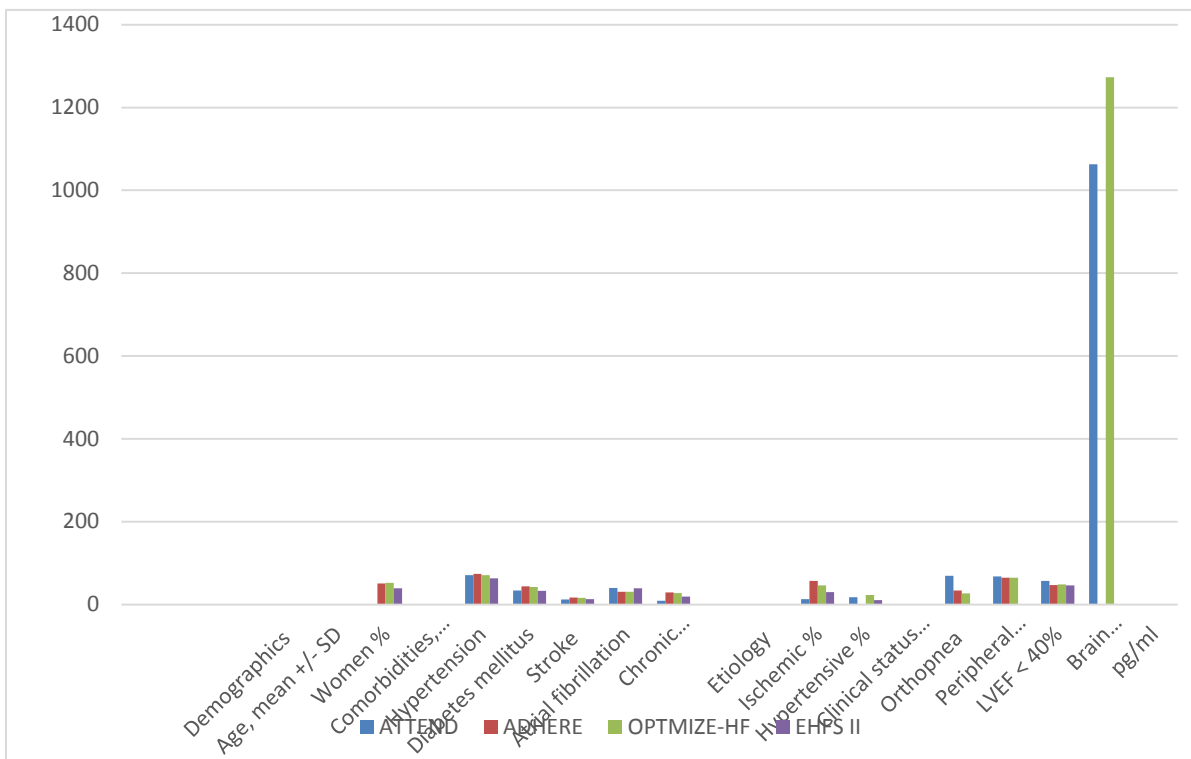
Table 6. Clinical Characteristics of Patients Hospitalized with Acute Heart Failure Syndromes: A Comparison of 4 Epidemiological Studies-- Sato et al., 2010

	<b>Sato et al., 2010</b> n = 1110	<b>Fonarow et al.,2007</b> n = 187,565	<b>Gheorghiade et al., 2006</b> n = 48, 612	<b>Nieminen et al., 2006</b> n = 3580
<b>Demographics</b>				
Age, mean +/- SD	73 +/- 14	72 +/- 14	73 +/- 14	70 +/- 13
Women %	41	51	52	39
<b>Comorbidities, %</b>				
Hypertension	71	74	71	63
Diabetes mellitus	34	44	42	33
Stroke	12	17	16	13
Atrial fibrillation	40	31	31	39
Chronic obstructive pulmonary disease	9	29	28	19
<b>Etiology</b>				
Ischemic %	13	57	46	30
Hypertensive %	18	N/A	23	11
<b>Clinical status on admission %</b>				
Orthopnea	69	34	27	N/A
Peripheral edema	68	65	65	N/A
LVEF < 40%	57	47	48.8	46
<b>Brain natriuretic</b>	1063	Median 843	1273	N/A

<b>peptide level (BNP)</b>				
pg/ml				

ATTEND=Acute Decompensated Heart Failure Syndromes; ADHERE=Acute Decompensated Heart Failure National Registry; OPTIMIZE-HF=Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure; EHFS-II=Euro Heart Failure Survey II; LVEF=left ventricular ejection fraction;

Figure 5. Bar Graph Showing Clinical Characteristics of Patients Hospitalized with Acute Heart Failure Syndromes: A Comparison of 4 Epidemiological Studies-- Sato et al., 2010



**Summary of Section Topic/Women and Heart Failure**

This section summarizes the incidence and prevalence of HF among elderly AA and Caucasian women including the expected trend over the next ten years. Data from studies reviewed in this section addressed prevalence of HF but did not address predictors of HF rehospitalizations. The literature remains inconsistent regarding factors which predict early HF rehospitalizations because clinicians directed their analyses and therapies of elderly AA women with HF based on data from younger participants in clinical trials. In addition, studies point to

the lack of inclusion of elderly women in clinical trials, which makes management of elderly female HF patients challenging due to lack of sex-specific data regarding comorbidities. Most data failed to discuss the predictive values of these risk factors regarding HF readmissions among elderly women, which the proposed research study sought to understand. Other studies contributed to the proposed research because they evaluated HF risk among AA and Caucasian women. Some studies conducted research using European participants limiting their generalization to the AA population. However, the studies offer an opportunity to compare similar cardiac and non-cardiac comorbidities (HFpEF and diabetes) which the current research proposes to study. Collectively, these studies present data involving elderly women, but the data remain inconsistent, which advocated the need for further studies to determine what risk factors commonly contribute to HF rehospitalization.

### **Heart Failure with Preserved or Reduced Ejection Fraction**

#### **Demographic and Clinical Characteristics**

Patients with HF exhibit a high prevalence of comorbid risk factors and those with HFpEF show, on average more comorbidity than those with HFrEF (Berry et al., 2005; Chamberlain et al., 2015). Yancy et al. (2006) described the demographics and clinical characteristics of patients with preserved or reduced systolic function using data from the Acute Decompensated Heart Failure National Registry (ADHERE) database. The comparison showed that patients with HFpEF appeared more likely to be women, older, hypertensive, and less likely to have a history of coronary artery disease (CAD) (Table 7). In-hospital mortality trended lower in patients with HFpEF compared to patients with HFrEF (2.8% vs. 3.9%; adjusted odds ratio: 0.86;  $p = 0.005$ ). Three recent HF studies (Quiroz et al., 2014; Gupta et al., 2013; Mentz et al., 2014) confirmed the characteristics of patients with preserved or reduced ejection fractions

published from the ADHERE database. According to Quiroz et al (2014), limited data existed regarding the prevalence, characteristics, and short-term outcomes of patients hospitalized with HFpEF. The investigators evaluated hospitalized HFpEF patients using the Get with the Guidelines registry retrospectively from December 1, 2006 to September 30, 2008. Data showed that patients with HFpEF remained predominantly older, and overweight women, with hypertension and dyslipidemia. The investigators also observed the relationships between HFpEF or HFrEF and 30-day rehospitalization. Results showed an initial lower 30-day readmission rate for patients with HFpEF, which failed to correspond with improved long-term outcomes. Gupta et al. (2013) evaluated an entire middle-aged AA cohort (n = 2,445) from the Jackson, Mississippi Atherosclerosis Risk in Communities (ARIC) study. The study period included 13.7 years of follow-up. In this cohort of AA patients, HFpEF persisted as the most common form of HF, and carried a better prognosis than HFrEF. Mentz et al (2014) reviewed the role of non-cardiac comorbidities in patients with HFpEF versus HFrEF, emphasizing prevalence, and found pulmonary disease, diabetes mellitus, anemia, and obesity more prevalent in HFpEF patients. The results of these previous demographic studies (Table 7) remain important comparisons, since the current proposed research study involved the evaluation of similar comorbidities in elderly females with HFpEF or HFrEF.

Despite the results of the ARIC study, controversy continues to surround the description of patient populations most commonly affected by incident HFpEF. According to the recent American College of Cardiology Foundation/American Heart Association (ACCF/AHA) practice guidelines, women, persons >65 years of age, and persons with hypertension remain most commonly affected by HFpEF (Yancy et al., 2013). However, previous studies showed a higher prevalence of HFpEF in AA women <65 years of age (Gupta et al., 2013; Wong et al., 2013).

Since hypertension remains very common in elderly AA women, nursing personnel and clinical researchers need to further explore race and age in future HFpEF studies.

Table 7. Demographic and Clinical Characteristics from the ADHERE Database

<b>Characteristic</b>	<b>Systolic Function</b>	
	<b>Preserved (n = 26,322)</b>	<b>Reduced (n = 25,865)</b>
<b>Demographic</b>		
Age (years, mean +/- SD)	73.9 +/- 13.2	69.8 +/- 14.4
Women (%)	62	40
African American (%)	17	22
<b>Clinical</b>		
Hypertension (%)	77	69
CAD (%)	50	59
Diabetes Mellitus (%)	45	40
Chronic Kidney Disease (%)	26	26
History of Heart Failure (%)	63	72
COPD (%)	31	27
Prior Myocardial Infarction (%)	24	36

Comparison between preserved and reduced ejection fraction groups (Yancy et al., 2006); CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease

### **Guidelines for HFpEF and HFrEF**

Experts in the field of Cardiology published several sets of criteria for the diagnosis of HFpEF and HFrEF, including the ACCF/AHA guidelines for the management of HF (Yancy et al., 2013); European Society of Cardiology (ESC) guidelines (McMurray et al., 2012), Paulus et al., 2007 and the European Study Group on Diastolic Heart Failure (Paulus, 1998). All the HFpEF guidelines require the presence of four conditions: 1. Symptoms typical of HF; 2. Signs

typical of HF; 3. Normal or mildly reduced ejection fraction, usually  $>50\%$ ; 4. Relevant structural heart disease such as left ventricular hypertrophy, left atrial enlargement, or diastolic dysfunction. All of the above guidelines remain unvalidated (Borlaug & Paulus, 2011). The diagnosis of HFrEF requires three conditions to be satisfied: 1. Symptoms typical of HF, 2. Signs typical of HF, and 3. Reduced left ventricular systolic function, with an ejection fraction normally less than 50% (McMurray et al., 2012).

### **Predictors for New Onset Heart Failure: HFpEF versus HFrEF**

HFpEF remains prevalent in approximately 50% of patients suffering with acute or chronic HF (Ho et al., 2013). Moreover, HFpEF and HFrEF usually exhibit identical signs and symptoms, which make identification of either subtype challenging in patients presenting with HF. Clinicians based at referral centers often use demographic and objective measures of the left ventricular function to determine the difference between the two subtypes of HF (Borlaug & Paulus, 2011; McMurray et al., 2012). However, healthcare providers practicing in the outpatient setting rely heavily on differences in risk factors of the two subtypes of HF for clinical determinations. Ho and colleagues (2013) studied new-onset HF cases between 1981 and 2008, using data from the Framingham Heart Study participants (Kannel, Feinleib, McNamara, Garrison & Castelli, 1979). The average age of participants was 60 +/- 12 years. During the follow-up period, 512 participants developed incident HF. The study identified 14 predictors of overall HF. Elderliness, a history of valvular disease, and diabetes mellitus predicted both types of HF ( $p < 0.0025$ ). Elevated body mass index (BMI), smoking, and atrial fibrillation were the only predictors of HFpEF. In contrast, higher heart rate, male sex, smoking, left ventricular hypertrophy, hypertension, higher cholesterol level, and left bundle branch block (LBBB) predicted definite risk for HFrEF. In this study, the investigators studied predominantly

Caucasian subjects, thereby limiting generalizability of the study to other ethnic backgrounds. Furthermore, the investigators based the diagnosis of HF on HF hospitalization as the primary outcome, which potentially underestimated the prevalence of HF and HFpEF. Since the prevalence of HF persists among elderly populations, investigation into the differences in risk factors associated with the two subtypes of HF among other ethnic populations remains warranted.

### **Section Review/Heart Failure Preserved or Reduced Ejection Fraction**

In this section, the researcher discussed demographics and clinical characteristics of patients suffering with HFpEF or HFrEF. Results of selected previous demographic studies remain important comparisons since the current proposed research study involves the evaluation of similar comorbidities in elderly females with HFpEF or HFrEF. This section illuminated the controversies surrounding what comorbidities associate with what subtype of HF. In one study, other ethnic populations remained underrepresented, thereby limiting generalizability of the study to other ethnic backgrounds. Since the prevalence of HF persists among elderly populations, the section concludes that investigation into the differences in risk factors associated with the two subtypes of HF among other ethnic elderly populations remains warranted.

### **Metabolic Syndrome and Heart Failure**

The MetS contributes to incident HF, morbidity and mortality in young adults and the elderly (Aguilar et al., 2015; Butler et al., 2006; Han & Lean, 2016; Mcneill et al., 2006; Suzuki et al., 2008; Voulgari et al 2010). A clustering of risk factors comprises the syndrome. Patients, furthermore, need to possess three of five criteria to exhibit the MetS: abdominal obesity (waist circumference >102 cm in men and >88 cm in women; triglycerides >150 mg/dl; blood pressure >140/90; fasting glucose >100 mg/dl; and HDL-C <40 mg/dl in men and <50 mg/dl in women

(Voulgari et al., 2010). MetS increases with age and in women. More than 50% of women 60 years of age or older suffered with the metabolic syndrome (Aguilar et al., 2015). Two studies conducted in the last decade addressed HF and the MetS. Suzuki et al. (2008) studied 4017 elderly men and women who participated in the Cardiovascular Health Study for 12 years. This observational study addressed incident HF and inflammation. The authors found that MetS and elevated inflammation markers indicated independent associations with HF risk (hazard ratios, 95% CI: 1.32, 1.16 to 1.51 for MetS). In a prospective cohort study involving 3,585 elderly subjects in the Cardiovascular Health Study conducted for 11 years, 554 participants developed HF (hazard ratio, 1.3, 95% CI: 1.07) (McNeill et al., 2006). Both studies linked the presence of the MetS with the development of cardiovascular disease and underscored the importance of treating individual components of MetS.

Obesity as an isolated risk factor or associated with the MetS also remains a major independent risk factor for incident HF (Haass et al., 2011). Haass and colleagues evaluated 4,109 elderly patients for five years as part of the Irbesartan in HF Preserved Ejection Fraction (I-PRESERVE) trial. Most patients (71%) exhibited a BMI greater than 26.5. Women constituted 60% of the subjects, and the authors reported a mean left ventricular ejection fraction (LVEF) of 59%. The average LVEF tended to increase with BMI, whereas age remained inversely related to BMI. The study showed that obesity and HFpEF formed a definite association, and the combination of clinical factors exhibited multiple differences in clinical characteristics. Findings from the Third National Health and Nutrition Examination Survey (NHANES III) showed a link between MetS, insulin resistance, and self-reported HF (Li, Ford, McGuire & Mokdad, 2007). Li and colleagues concluded that MetS may act as a surrogate indicator for the association between insulin resistance and HF. The previous studies clearly demonstrate an association between MetS



or its components and the elderly. Specific studies addressing associations between MetS and elderly AA females remain sparse and none address HF rehospitalization. Furthermore, earlier studies (Suzuki et al., 2008) lacked echocardiographic data on systolic function, thereby failing to differentiate between the two subtypes of HF or their association with MetS. However, the studies address MetS, its components, the elderly, and their association with the index for HF, thereby providing the researcher of the current study valuable data for comparison.

Further studies also revealed that MetS contributes to subclinical vascular disease in Caucasians, which often lead to cardiovascular disease and incident HF (Xanthakis et al., 2015). This association remains poorly studied in the AA population and the relationship between subclinical vascular disease measures and AA remains unclear. Xanthakis et al. (2015) addressed this issue by evaluating 4,416 participants attending the first examination of the Jackson Heart Study (mean age 54 years; 64 % women). Components of subclinical disease included peripheral artery disease (PAD), high coronary artery calcium (CAC) score, left ventricular hypertrophy, microalbuminuria, and low ejection fraction. The study found that participants with diabetes mellitus or the MetS suffered with higher odds of subclinical disease compared to subjects without these two clinical entities. The presence of higher subclinical vascular disease often translates to a greater risk for cardiovascular related HF. Bahrami et al. (2008) found microalbuminuria and other inflammatory markers to exist as independent predictors of incident HF when the Multi-Ethnic Study of Atherosclerosis (MESA) study evaluated four ethnicities: Caucasians, AAs, Hispanics, and Chinese Americans (Bahrami et al., 2008). The participants' ages fell between 45 and 84 years, with 3,601 women, and the medium follow-up period of four years. During this period, 79 participants developed HF. 65 % of the cases exhibited HFpEF with a baseline ejection fraction greater than 40%. Microalbuminuria and other inflammatory markers

remained predictors of HF independent of obesity or other established risk factors (Bahrami et al., 2008). Subclinical markers of inflammation, possibly in conjunction with the MetS, appear to play vital roles in the development of incident HF. The two studies provide indirect evidence linking MetS to incident HF although the association remains poorly studied in the AA population and provides no sex or age-specific data. However, the data demonstrated consistency and contributed to the association with index HF.

Individual components of the MetS syndrome often predict the development of incident HF. Wang et al. (2010) demonstrated that hypertension remained the most predictive component of the MetS during a 20 year study among elderly Finns. Karadag & Akbulut (2009) explored the prevalence of the MetS and individual MetS components among stable HF patients. The purpose of the study took place to determine the most common MetS component according to gender and the significance of MetS with both genders. One hundred and nine patients including 37 women (mean age, 67 +/- 12 years) participated in the study. The authors of the study recorded MetS and individual components according to the Adult Treatment Panel III (ATP II) of the National Cholesterol Education Program (NCEP). Low HDL (69%) and hypertension (69%) remained the most prevalent components of MetS. Hypertension, hypertriglyceridemia, and increased waist circumference remained significantly more common in women ( $p < 0.05$ ). The prevalence of MetS decreased with age, but the difference showed no statistical significance. Based on the results of this study, the authors concluded that directing therapeutic measures towards individual components of MetS may prevent or improve HF among women. This study provides important data about the components of MetS and their relation to gender. However, women in the study remain underrepresented, and generalizability remains limited since the authors conducted the study using elderly Finns. The study contributed to the association between

age/race and the prevalence of MetS, to be an important association addressed by one hypothesis in the proposed research study.

MetS also predicts structural changes of the left or right ventricles, which often lead to increased cardiovascular events and incident HF. Three studies (Almeida et al., 2014; de Simone et al., 2009; Kumar, Rajasekhar, Vanajakshamma & Latheef, 2014) evaluated the prevalence of MetS on the left ventricular function and with respect to structural changes. Kumar et al. (2014) used a Philips IE33 echocardiography machine to determine the left ventricular myocardial performance index (LVMPI) in 50 consecutive patients attending an outpatient cardiology clinic. The sample population was aged 60 years or less. The results of study showed that the LVMPI value in patients with MetS was 0.64 +/- 0.09 compared to 0.49 +/- 0.06 in healthy controls. The authors concluded that MetS remains a strong predictor of the sub-clinical myocardial dysfunction even in patients without apparent heart disease. Similarly, Almeida et al., (2014) found impaired myocardial function and markers of cardiovascular disease in asymptomatic individuals with MetS. In their study, women represented 63% of the sample population and the mean age fell between 65 +/- 9 years (Almeida et al., 2014). deSimone et al. (2009) failed to evaluate the association between the prevalence of MetS and the left ventricular function, but rather studied the association between MetS and the left ventricular hypertrophy (LVH). Participants in the study, women which accounted for 63% of those involved remained part of the second Strong Heart Study and demonstrated no evidence of coronary artery disease or HF. The study showed a strong correlation between MetS and LVH after controlling for other cardiac risk factors. This finding suggests that the cardiovascular risk associated with MetS may be related to the presence of LVH (deSimone et al 2009). The data from these three studies suggests

that MetS may influence the index of HF through subclinical changes in the left ventricle. This information would contribute to the relationship between MetS and early HF rehospitalization.

Karakurt, Oztekin, Yazihan & Akdemir (2011) conducted a compelling study which focused on the function of the right ventricle in patients with MetS and HFpEF. Healthcare providers find the results of this study important for one glaring reason. Dysfunction of the right ventricle often leads to right heart failure which then manifests clinically with severe edema in the lower extremities and hepatic congestion (Melenovsky, Hwang, Lin, Redfield & Borlaug, 2014). The study included 192 consecutive patients (77% women with a mean age of 54 +/- 8.5 years) with a diagnosis of MetS. The number of MetS components varied between 3 and 5 in the study subjects. The number of MetS components and right ventricular parameters determined by echocardiography demonstrated no clear association. However, the study showed both systolic and diastolic functions of the right ventricle deteriorated in patient with MetS, which may represent novel therapeutic targets (Karakurt et al., 2011; Melenovsky et al., 2014). Association between the right ventricular parameters and MetS remains important because of the relationship between the right ventricular dysfunction and symptoms of HF. Signs and symptoms of HF related to right ventricular dysfunction often compels clinicians and nursing personnel to recommend hospitalization for acute therapy. This data further added to the understanding of the relationship between MetS and early HF rehospitalization.

### **Section Review/ Metabolic Syndrome**

This section offers an insight into the association between the MetS or its individual components and their contribution to the clinical syndrome of HF and HF rehospitalization. Specific studies addressing associations between MetS and elderly AA females remain sparse, and none address HF rehospitalization. Data illustrate that at least one earlier study lacked

echocardiographic information on systolic function, thereby failing to differentiate between the two subtypes of HF or their association with MetS. However, other studies address MetS, its components, the elderly, and their association with index HF, providing the researcher of the proposed study with rich data for comparison. MetS predicts structural changes of the left or right ventricles, which often lead to increased cardiovascular events and index HF. Signs and symptoms of HF related to the right ventricular dysfunction often compels clinicians and nursing personnel to recommend hospitalization for acute therapy. Data regarding HF related to the right ventricular dysfunction further added to the understanding of the relationship between MetS and early HF rehospitalization. Finally, two studies provided indirect evidence linking MetS to index HF, in possible conjunction with subclinical markers of inflammation. However, the association remains poorly studied in the AA population and provides no sex or age-specific data.

### **Pulmonary Hypertension and Heart Failure**

#### **Pulmonary Hypertension and HFpEF or HFrEF**

Patients with both HFpEF and HFrEF frequently suffer with PH, which contributes to exercise intolerance, symptoms of right-sided HF, and poor long-term outcomes (Guglin & Khan, 2010; Lam et al., 2009). Although contributing factors to PH remain poorly understood, previous studies demonstrate a close association between left-sided HF and PH (Lam et al., 2009). Lam et al. (2009) conducted a community-based study of 244 patients with HFpEF (women = 55%; age 76 +/- 13 years) to determine the prevalence and severity of PH in this population. The authors derived pulmonary artery systolic pressure (PASP) from the tricuspid regurgitation velocity, and defined PH as PASP >35 mm Hg. The study showed that PH remained highly prevalent (83%) in patients with HFpEF and often severe. The authors suggested that pulmonary arterial hypertension (PAH) may be a contributing factor in cases of

severe PH. In contrast to assessing PH in patients with HFpEF, Miller, Grill & Borlaug (2013) evaluated clinical, functional, and hemodynamic characteristics of passive and mixed PH in patients with HFrEF. The researchers evaluated all patients (n = 463) retrospectively and divided the study into passive PH (n = 151) and mixed PH (n = 186). The presence of any PH or mixed PH coexisted with older age, atrial fibrillation, and diuretic usage. Miller and colleagues concluded that PH remains associated with markers of greater disease severity and mortality risk among patients with HFrEF. These studies offered data which suggest that the presence of HFpEF predisposes patients to developing PH, which confers poor prognosis (Potus, Ranchoux, Tremblay, Provencher & Bonnet, 2016). This data provided critical information to better understand the relationship between PH and early HF rehospitalization.

### **Pulmonary Hypertension and African-American**

Data from the National Vital Statistics System showed a steady increase of age-standardized related PH death rates from 1980 to 2002 (4.5% to 7.3%) in AAs compared to approximately no change (5 to 5.5%) among Caucasians (Choudhary, Jankowich & Wu, 2013; Hyduk et al., 2005). These statistics confirmed that PH in AAs remained associated with a higher age-adjusted death rate than any other racial group, with no known specific determinants identified (Hyduk et al., 2005). Choudhary, Jankowich & Wu (2013) conducted a cross-sectional study to address the prevalence of PH and associated clinical characteristics in AAs using the Jackson Heart Study cohorts (n = 3,282; women = 67.5%; mean age 56.1 +/- 12.6 years). Prevalence data showed that PH increases with age (Prevalence Ratio: 10.0, 95 % CI 4.0 - 25.1, >65 versus <45). The authors confirmed an increasing prevalence of obesity, diabetes mellitus, obstructive or restrictive spirometry patterns, severe left heart valvular disease, left atrial size and left ventricular function in patients with PH. The association between the prevalence of PH and

age constitutes important information because researchers often find PH associated with other factors such as MetS and HFpEF. The identified cardiopulmonary and metabolic risk factors also offered important data to assist in further understanding the relationship of PH in elderly AA women who often suffer with HFpEF.

### **Pulmonary Hypertension and Hospitalization**

Previous studies show close associations between HFpEF, left-sided HF, obstructive and restrictive lung disease, and metabolic risk factors. The predictive ability of PH for HF admissions, especially amongst AAs, remains unknown (Choudhary, Jankowich & Wu, 2014). Choudhary et al. (2014) conducted a longitudinal analysis using the Jackson Heart Study cohort to determine the association between PH and future HF admissions. The study lasted for 3.4 years and included 3,125 subjects (68 % of which were women). Each subject in the cohort provided base-line PASP data. During the follow-up period, 3.4 % of the cohorts were admitted for HF. Data from the study showed an association between higher baseline PASP and HF admissions irrespective of HFpEF or HFrEF. The Heart and Soul Study remains another prospective study which examined the association between PH and hospitalization for HF (Ristow, Ali, Ren, Whooley & Schiller, 2007). Recorded data registered 63 HF hospitalizations during the follow-up period of 3 years. The echocardiographic findings of tricuspid regurgitation >30 mm Hg predicted HF hospitalization (or 3.4, 95% CI: 1.9 to 6.2,  $p < 0.0001$ ). These two studies offer alternative factors which contribute to HF hospitalizations. It remains important, therefore, to determine whether PH contributes to HF rehospitalizations especially amongst elderly AA women.

## **Section Review/Pulmonary Hypertension and Heart Failure**

This section reviews the association between PH and either HFpEF or HFrEF as well as the demographics, prevalence, and comorbidities that coexist with this abnormal pulmonary condition. Prevalence data show that PH increases with age. The association between the prevalence of PH and age constitutes valuable information because researchers often find PH associated with other factors such as MetS and HFpEF, the presence of HFrEF, predisposes patients to developing PH. Identified cardiopulmonary and metabolic risk factors offered important data to assist in further understanding the relationship of PH in elderly AA women who often suffer with HFpEF. The predictive ability of PH for HF admissions, especially amongst AAs remains unknown.

### **Socioeconomic Status or Social Factors and Heart Failure**

#### **Socioeconomic Status and Heart Failure**

According to several studies that evaluated the impact of social economic status (SES) on incident HF among men and women, SES is a powerful predictor of HF development and adverse outcomes (Benderly, Haim, Boyko & Goldbourt, 2013; Foraker et al., 2011; Hawkins, Jhund, McMurray & Capewell, 2012; Hu, Gonsahn & Nerenz, 2014). Benderly, Haim, Boyko & Goldbourt (2013) studied 2,951 CHD patients free of HF at baseline over an eight-year period, during which 511 patients developed HF. The characteristics of these patients included older age, a higher frequency of metabolic risk factors, and advanced heart disease. When the authors adjusted for sex, obesity, diabetes, metabolic syndrome, and hypertension, the HF hazard ratios [HRs] showed values of 0.85 (95% confidence interval [CI] 0.70–1.03) and 0.76 (95% CI 0.58–0.99) for high school and academic education versus elementary education. The authors concluded that SES indicators result in HF incidence only marginally explained by cofounders



such as hypertension. Foraker et al. (2011) used generalized linear Poisson mixed models to estimate rehospitalization rates after an incident HF hospitalization. The authors controlled for variables such as race, body mass index, hypertension, education level, and risk behaviors. High comorbidity influenced rehospitalization. Foraker et al. (2011) noted that all-cause rehospitalizations remained more prevalent in Medicaid recipients with a low level of comorbidity. (HR, 1.19;95% CI: 1.05-1.36). Hawkins, Jhund, McMurray & Capewell (2012) reviewed literature from multiple electronic databases, evaluating measures such as education, occupation, employment relations, social class, and income. The adjusted risk of developing HF has increased by ~30–50% in most reports reviewed by the authors. Hu, Gonsahn & Nerenz (2014) conducted a retrospective cohort study to evaluate SES on 30-day rehospitalization incidences using secondary data from Henry Ford Hospital, a teaching hospital in Detroit with 802 beds. The authors used multivariate logistic regressions to examine the associations and found that patients living in neighborhoods with high poverty rates remained at risk of being readmitted. However, the results of the study remain biased because of unavailable or missing data and a substitution of patients' marital status as a proxy for social support. Social support and SES represent important social factors which the researcher intends to study in the proposed study. The use of the electronic medical record (EMR) data ensures the capturing of information relevant to HF patients who exhibited higher risk for early rehospitalization. Amarasingham et al. (2010) developed an automated predictive model for 30-day rehospitalization based on clinical and non-clinical risk factors in 1,372 HF hospitalizations to a major urban hospital. The authors abstracted clinical and social factors within hours of hospital presentation from the EMR database and used this information to predict early HF rehospitalization. Complex social factors increased the model's accuracy and suggested potential usage to determine rehospitalization

rates. This study contributed important data about the relationship between social factors and HF rehospitalization and may help in understanding why elderly AA or Caucasian women remain vulnerable to early HF rehospitalizations.

### **Social Factors and Heart Failure**

Racial and ethnic disparities in healthcare persist for decades and contribute to poor health among minorities (Williams, Mohammed, Leavell & Collins, 2010). According to Williams et al. (2010), AAs characteristically suffer from lower education, higher levels of depression, environmental and racial stressors, and usually lack health insurance and adequate access to healthcare providers. This combination of social factors often leads to an earlier onset of illness with greater severity and poorer survival rate. Clarke, Davis & Nailon (2007) compared outcomes in patients with HF hospitalized at Pennsylvania and Virginia hospitals which served both AA and non-AA patients. The investigators reported no difference in HF treatment between the two groups. However, they noted that the mortality rate remained higher in both AA and non-AA patients with HF treated predominantly at hospitals serving mainly the AA population. In a retrospective review study of 72 articles evaluating the impact of social factors on HF and rehospitalization, Calvillo-King et al. (2013) found a direct relationship between social factors and rehospitalization or mortality. Older age remained specifically associated with worse outcomes in HF patients. Lower income, home instability, lack of social support, unmarried status, risk behaviors (smoking, medication non-adherence), and lower SES all contributed to more HF rehospitalizations (Calvillo-King et al, 2013). Chaudhry et al. (2011) sought to determine whether racial differences in health literacy or access to outpatient medical care contributed to more frequent hospitalizations in AA patients with HF. The study looked at 1,464 patients with HF (644 AA and 820 Caucasians). The study found that AA groups across the

States were associated with poorer health literacy levels and access to healthcare. The strongest associations existed between race, health literacy (OR 2.13, 95% CI: 1.46 - 3.10), absence of a medical home (OR 1.76, CI: 1.19 - 2.61), and cost of health care (OR 1.55, CI: 1.07 - 2.23). The researchers noted that the differences in racial and social support persisted even after adjustments for other social factors. Social cultural factors also influence self-care and adherence to medication prescribed. Dickson et al. (2013) conducted a small study (30 AA subjects) evaluating self-care and the influence of social cultural factors. The authors concluded that poor self-care and a lack of social support eventually leads to HF hospitalizations. These studies clearly link social factors or factors related to cultural heritage to HF hospitalization or rehospitalization. The persistence of social factors in vulnerable populations often creates issues such as poor self-care and adherence to medication prescribed, which leads to recurrence of HF and/or rehospitalization. This information remained relevant to the proposed study which sought to understand the relationship between social factors and early HF rehospitalization.

### **Section Review/ Socioeconomic Status or Social Factors and Heart Failure**

This section discusses the predictive value that SES or social factors offer in their contribution to HF admission or rehospitalization. Data show that social factors such as lower income, home instability, lack of social support, unmarried status, risk behaviors (e.g. smoking, medication non-adherence), and lower SES all contributed to a higher incidence of HF rehospitalizations. Studies link social factors or factors related to cultural heritage to HF hospitalization or rehospitalization. The persistence of social factors in vulnerable populations often creates issues such as poor self-care and medication adherence, which lead to the recurrence of HF and/or rehospitalization. Social support and SES represent important social factors targeted for study in the proposed research.

## **Heart Failure and Rehospitalization**

### **National and Regional Trends of Rehospitalization in Heart Failure Patients**

HF rehospitalization after an index HF hospitalization remains problematic and a burden to society (Gheorghiade et al. 2013). According to Gheorghiade et al., 27% of Medicare beneficiaries experience rehospitalization within 30 days after an index HF hospitalization either for HF rehospitalization (37%) or for a hospitalization unrelated to HF. Data show that rates of rehospitalization beyond 30 days (60 to 90 days) are approximate 30% after discharge in the Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure (OPTIMIZE-HF) trial (Fonarow et al., 2007). Bergethon et al. (2016) analyzed data from the American Heart Association's Get With The Guidelines-Heart Failure Registry to determine trends and relative reduction rates of 30-day all cause rehospitalization amongst HF patients. The study included 21,264 HF patients from 70 sites for 4 years. Data showed that all-cause admissions decreased slightly from 20% to 19%. Only 1 in 70 hospitals achieved the 20% relative reduction in 30-day risk adjusted readmission rates. Early HF rehospitalizations remained problematic for the public after an index HF hospitalization. This contributes to an increase in economic burdens for society with an annual cost exceeding \$30 billion (Mozaffarian et al., 2016). Further research remained warranted to better understand what specific predictors/risk factors contribute to HF rehospitalizations, especially in elderly women who share a disproportionate burden.

## **Predictors of Rehospitalization in Heart Failure Patients**

Prediction of HF or all-cause HF rehospitalization after an index HF hospitalization remains elusive despite access to enormous hospital databases and predictive models. Several studies looked at early (<30-day) rehospitalization after index HF hospitalizations in order to identify possible causes (Amarasingham et al., 2010; Au et al., 2012; Dharmarajan et al., 2013; Joynt, Orav & Jha, 2011; McLaren et al., 2016; Muzzarelli et al., 2010). Amarasingham et al (2010) incorporated clinical and social factors from health records into a real-time electronic predictive model at the time of admission to predict 30-day rehospitalization. The authors found that the model performed as well as the CMS models or ADHERE model particularly after the incorporation of social instability and lower SES, which is an area of interest in proposed research (C statistic 0.72 vs. 0.61,  $P < 0.05$ ). Au et al. (2012) evaluated unplanned readmissions among 59,652 adults (with a mean age of 76: women accounting for 50% of participants) after a HF hospitalization over 10 years using four databases in Alberta, Canada. This study involved elderly people and women, but only looked at unplanned readmission within 30 days of a participant being discharged. Joynt et al. (2011) evaluated disparities and site of care among elderly AA patients with HF. The National Medicare Data Bank provided data for research. AA patients from minority serving hospitals showed the highest readmission rates (26.4%; OR, 1.35; 95% CI: 1.28 - 1.42). Three conditions of HF, pneumonia, and acute myocardial infarction, predicted rehospitalization among this elderly population (Joynt, Orav & Jha, 2011). Dharmarajan et al. (2013) conducted their research to improve strategies aimed at reducing 30-day readmission rates for HF patients. Specifically, the authors evaluated readmission timing and associated this information to patient age, sex, and race, which represent similar factors of interest. The authors concluded that HF rehospitalizations remained frequent throughout the

month after index HF hospitalization regardless of age, sex, race, or time after discharge.

McLaren et al. (2016) evaluated the role of prior hospitalizations to predict 30-day readmission for HF patients with index HF hospitalizations using retrospective analysis of secondary data over a four-year period. Data showed that one prior admission carried a 50% higher risk (confidence interval [CI] 1.10–2.05,  $p = 0.011$ ) for readmission, while  $\geq 2$  prior admissions carried a 3-fold increase in readmission (CI 2.27–4.09,  $p < 0.001$ ). This study provides relevant data, since the authors utilized patients with index HF hospitalizations and secondary data.

Similarly, Muzzarelli et al. (2010) conducted their research to identify predictors of early hospital readmission in elderly patients with HF. The researchers demonstrated that predictors of HF rehospitalization at 30 days included angina, lower systolic blood pressure, anemia, more extensive edema, higher creatinine levels, and dry cough. At 90 days, the results included coronary artery disease, prior pacemaker implantation, high jugular venous pressure, pulmonary rales, prior abdominal surgery, older age, and depressive symptoms. The study failed to evaluate the rehospitalization of participants at 60 days (31 to 60-day), but provides valuable information related to elderly patients. These studies also confirm that the understanding of risk factors related to HF rehospitalizations remains elusive and justifies the need for studies that evaluate 60 days (31- 60-day) HF rehospitalization, as in the proposed research.

Hamner & Ellison (2005) conducted a descriptive, correlational study designed to understand the characteristics of a HF patient population who clinicians admitted to a large southeastern, acute-care hospital. A secondary purpose of the study was to determine the risks of rehospitalization within 6 months. Variables from the hospital data bank provided rich data used to identify patients at risk for rehospitalization (Table 8). The researchers developed four models composed of subsets of variables and tested them using logistic regression. Hamner & Ellison

(2005) concluded that the model composed of discharge variables stood out as the only model that predicted rehospitalization at a significant level. Anderson (2014) also evaluated discharge clinical characteristics in patients rehospitalized for HF within 60 days after an incident HF admission. The investigator completed a descriptive, correlational, quantitative study using retrospective analysis of 134 HF patients. Anderson (2014) derived a predictive model from the study results that accurately predicted 77.4% of the cohort, 78.2% of those with subsequent rehospitalization along with 76.7% of subjects with no rehospitalization. Other studies evaluated other causes of rehospitalization including timing and non-cardiac comorbid risk factors (Vader et al., 2016) as well as initial HF hospitalization (Ruigómez, Michel, Martín-Pérez & Rodríguez, 2016). Both index HF hospitalization and non-cardiac comorbid risk factors predicted rehospitalization. Although researchers identified clinical markers (BNP level) and other risk factors mentioned previously as parameters that predict early rehospitalization, social factors may be the more predictive in special populations. Howie-Esquivel & Dracup (2007) conducted a study to determine whether demographic, clinical, or psychological variables conferred increased risk of rehospitalization among a multiethnic hospitalized HF population. The study found that women had a two and half times greater chance of rehospitalization than men. Socio-demographic factors emerged as more powerful predictors of rehospitalization than clinical markers. These studies collectively illustrate that discharge parameters as well as other risk factors contribute to HF rehospitalization and appear to be population specific. The above data as well as the data recorded by Hamner & Ellison (2005) (Table 8) remain extremely valuable since this data discussed factors potentially affecting HF rehospitalization similar to the underpinning of the proposed secondary research study.

Table 8. Predictors of Rehospitalization in Heart Failure Patients

<b>Description of variables</b>
Race – Caucasian, AA, Hispanic, Asian
Age – recorded in years
Gender – male or female
CHF class – NYHA I to IV
Ejection fraction – recorded this admission as percentage
Comorbidities – current history reported in the chart and include diabetes, hypertension, renal disease, COPD, alcohol abuse, pulmonary hypertension, atrial fibrillation
Cardiology consult this admission – primary MD is a cardiologist
Case managed status – IS CASE MANAGED- yes or no
Living status at time of admission – alone, family, care facility
Payor – Medicaid, Medicare, private insurance, self-pay
Point of entry into the hospital this admission – ED, admission office, transfer from another facility
Length of hospital stay—recorded in days
Discharge disposition – home with home health, acute care hospital, other type of institution, expired
Medical assistance referrals – indigent drug program, given drug samples
Discharge referrals – hospice, assisted living facility, home health, skilled nursing facility,
Medications prescribed during admission – ACE inhibitors, angiotensin receptor blockers, inotropic infusions, anticoagulants, beta blockers, antiarrhythmics, digoxin, insulin

CHF= congestive heart failure; COPD= chronic obstructive lung disease; ED=emergency room department; ACE=angiotensin converting enzyme; MD= medical doctor; NYHA= New York Heart Association; Hamner et al (2005)

### **Rehospitalization and HFpEF or HFrEF**

Both HFpEF and HFrEF continue to associate with index HF hospitalizations. However, the relationships between HFpEF or HFrEF and rehospitalizations remain unclear. Nichols, Reynolds, Kimes, Rosales & Chan (2015) used an observational cohort design to study 6,513 patients hospitalized with HF to determine the influence of HFpEF or HFrEF on rehospitalization after HF hospitalization within one year. The study recorded HFpEF in 65% of female participants and HFrEF in 64% of male participants. Notably, data from the study



revealed minimal relationship between HFpEF or HFrEF and rehospitalization or inpatient resource utilization in the year after an HF hospitalization. A similar study compared length of stay and 30-day readmission rates in Medicare patients with HFpEF and HFrEF (Loop et al., 2016). The authors used a cohort of 19,477 Medicare beneficiaries discharged with a primary diagnosis of HF between 2007 and 2011. The study revealed that rehospitalization rates between patients with either subtype of HF remained similar. The data appear to suggest that both HFpEF and HFrEF may equally contribute to HF rehospitalization. However, the data failed to reflect 60-day HF rehospitalization or discuss rehospitalizations related to sex-specific populations, but discussed the relationship of the two subtypes of HF to HF rehospitalization, which the proposed research plans to address.

### **Rehospitalization and Provider Factors**

Management of HF patients admitted to an acute care hospital usually requires care provided by primary care physicians or care provided in conjunction with physicians specializing in cardiovascular diseases. These physicians or providers possess certain factors such as cultural competence, or understanding the needs of diverse patients particularly minority groups (Garham, 2015) and specialty experience that influence HF rehospitalizations. Therefore, specialty care provided by cardiologists usually involves diagnostic tests such as echocardiography to determine left and right ventricular function. Ansari, Alexander, Tutar, Bello & Massie (2003) conducted a landmark study which examined the outcomes of new onset HF outpatients managed by cardiologist or primary care (PC) physicians. This retrospective cohort study involved 403 men and women with a primary endpoint of either death or cardiovascular rehospitalization at 24 months. The patients who received care by a cardiologist also received more ejection fraction assessments as well as treatment with angiotensin converting

enzyme inhibitors (83% vs. 68%,  $p < 0.001$ ) and beta blockers (38% vs. 22%,  $p < 0.001$ ).

Cardiology care improved guideline adherence and reduced risk of cardiovascular rehospitalization. Desai & Stevenson (2012) stated that comprehensive discharge planning and caregiver education may reduce earlier rehospitalization HF rates by as much as 25%. The authors also noted that outpatient care involving a cardiologist and primary care physician determines the best health outcomes. Calvin et al (2012) recently conducted a study observing physician adherence to evidence-based guidelines. The study showed that only 63% of physicians prescribed evidence-based medications that clinical practice guidelines recommended. Interestingly, management of patients with acute decompensated HF varies by specialty (Uthamalingam et al., 2015). In a recent study, Uthamalingam et al. examined rehospitalization for HF and an adherence to Joint Commission HF performance core measures (2015). The study revealed that cardiologists received the highest marks in all four HF core measures compared with hospitalists and non-hospitalists. Adherence to practice guidelines by cardiologists translated into lower rehospitalization rates (16.2%) compared with hospitalist (40.1%) and non-hospitalist (34.9%,  $p < 0.001$ ). Provider factors appear to play a role in HF rehospitalization, possibly related to adherence of evidence-based therapy and awareness of the ejection fraction of HF patients. These studies provide valuable data regarding provider factors and their relationship with HF rehospitalization.

### **Section Review/Heart Failure and Rehospitalization**

This last section evaluated the predictive powers of comorbidities, subtypes of HF, and provider factors on HF rehospitalization mainly at 30-day or less. Data show that three conditions of HF, pneumonia, and acute myocardial infarction, predicted HF rehospitalization among the elderly population. HF rehospitalizations remained frequent throughout the month

after hospitalization regardless of age, sex, race, or time after discharge. Researchers demonstrated that predictors of HF rehospitalization at 30 days included angina, lower systolic blood pressure, anemia, more extensive edema, higher creatinine levels, and dry cough, while at 90 days predictors included coronary artery disease, prior pacemaker implantation, high jugular venous pressure, pulmonary rales, prior abdominal surgery, older age, and depressive symptoms. Studies failed to evaluate rehospitalization at 60 days (31 to 60-day). Moreover, research confirms that the understanding of risk factors related to HF rehospitalizations remains elusive. Provider factors appear to play a role in HF rehospitalization, possibly related to adherence of evidence-based therapy and awareness of the ejection fraction of HF patients.

### **Conclusion**

Chapter two contains a historical review of relevant literature that evaluated the determinants of early rehospitalizations and their relationship to elderly women. The review illustrated and discussed current and past literature that addresses HF rehospitalization with many studies focusing on early (<30-day) readmissions. The review also demonstrated that factors such as patient's characteristics, physiological factors, HFpEF or HFrEF, MetS and its individual components, and PH all influenced HF rehospitalization rates. In most of the reviewed research, the underrepresentation of women remained a common finding in the literature (Melloni et al., 2010). In the studies wherein they were included, elderly AA women remained significantly underrepresented even though they comprise a substantial portion of those with HF (Lekavich & Barksdale, 2016). In addition, research regarding any relationships among early HF rehospitalization, elderly women, and various HF determinants are inconsistent at best and probably related to varying factors such as setting, sample characteristics, and sample size.

Alternatively, different combinations of factors may have contributed to the inconsistency in reported results.

Given the current literature, it is unclear which factors or combination of factors predict early rehospitalization in elderly AA and Caucasian women. In addition, previous research studies illustrated that HF rehospitalizations after an index HF hospitalization not only occurred in less than 30 days, but also extend beyond 30 days. Yet a review of the literature revealed that studies addressing 60-day (31 to 60-day) HF rehospitalization remain nonexistent. The inconsistent literature regarding factors that predict early HF rehospitalizations, underrepresentation of elderly AA women, and the paucity of studies evaluating 60-day (31 to 60-day) rehospitalizations created a significant gap in existing research. This proposed study intended to bridge this gap, as health care providers must recognize patients at higher risk for early unplanned HF rehospitalizations, pinpoint the factors that lead to higher percentages of rehospitalizations, and develop tailored interventions to reduce early HF unplanned rehospitalizations. Recognizing the precise factors associated with early HF rehospitalization among elderly AA women and designing a research study utilizing secondary data to understand the influence of these factors on early HF rehospitalization in this vulnerable population justified the importance of this proposed research study.

## **Chapter III: Research Methodology**

### **Introduction**

This chapter presents the research design and methods to explore the effects and relative contributions of predictor variables to the risk of early rehospitalization amongst elderly AA and Caucasian women admitted with decompensated HF. The predictor variables proposed for this study include PH, hypertension, diabetes mellitus, BMI, race, HFpEF or HFrEF, and social factors. The study also examined relationships between race and PH, hypertension, diabetes mellitus, BMI, and HFpEF or HFrEF.

This chapter includes an overview of the design, followed by a description of the sample, setting, recruitment, data collection methods, and ethical considerations specific to the proposed work. A description of the instrumentation method and variable type precedes a detailed description of anticipated data management, analysis and related procedures developed for the proposed research. The chapter concludes with the limitations and delimitations of the study alone with a chapter summary.

### **Research Design**

The study used a descriptive, correlational, non-equivalent case-control, quantitative study design with a retrospective review of medical records. The research design is correlational in that it examines relationships between two or more variables, test predictions, and determines whether exploratory findings between variables in the topic of interest require more vigorous research (Rockinson-Szapkiw, 2017). Cases consisted of subjects who were readmitted (31 to 60-day rehospitalization) while controls were those subjects who were not readmitted. Assignment of subjects as cases and controls were not randomized, resulting in non-equivalent case control groups. The researcher chose this case-control design because it allows the comparison of

rehospitalized and non-rehospitalized subjects in relationship to certain contributory factors (predictor variables) including race/ethnicity. This design is also congruent with use of retrospective data and will facilitate modelling the predictors of rehospitalization. The predictors being studied cannot be assigned (randomly or non-randomly) to subjects making experimentation non-feasible. The absence of experimentation prohibits the ability to show a causal relationship between the predictors and the outcome variable (31 to 60-day rehospitalization).

Although a retrospective chart review of existing data in this study population failed to capture all practice changes, it allowed the researcher to conduct the research study in a timely manner. Considering the limitation of the data source, matching cases with controls resulted in an adequate sample size to power the study. In addition, the existing database provided available high-quality data, eliminated several steps in research which saves time and money, and provided data that show some evidence for acceptable reliability and validity (Tappen, 2011, p. 254). The current design of the proposed study minimized threats to external validity such as selection bias. The researcher compensated or minimized these threats by choosing a setting (a large tertiary hospital database) which compares satisfactorily to other real-world settings. The researcher also carefully analyzed characteristics of the selected subjects from enrolled cases and compared them with other larger databases (Heidenreich et al., 2012; Jalnapurkar et al., 2018; Ogah et al., 2014; Pandey et al., 2016). Comparing findings with similar previous studies completed at earlier dates offers some ability to generalize the results of the proposed study to other HF populations. Most of data extracted from the database at the large not-for-profit tertiary local community hospital represent recorded demographic information and laboratory tests such as lipid levels and blood glucose levels. These data remain accurate and reliable.

## **Setting**

The setting is a large not-for-profit tertiary local community hospital which provided data for retrospective medical records review of a large existing database. At this hospital setting, recorded data showed admissions of 40 to 60 patients with the diagnosis of HF per month. The tertiary care setting made potential subjects with acute decompensated HF in enrolled cases available for data abstraction during the research study period, as well as those subjects in enrolled cases rehospitalized during a 31 to 60-day period following the index HF stay. The researcher selected this setting because it is a major provider of care in its catchment area as well as a major provider of care to AA patients.

## **Sampling of Subjects**

### **Subjects**

The sample consisted of elderly AA and Caucasian women admitted to the large not-for-profit tertiary local community hospital with a diagnosis of decompensated HF (index HF) during the selected time frame of the research study. Cases consisted of subjects who were readmitted, while controls were those subjects who were not readmitted, or subjects who experienced rehospitalization within the 31-60-day readmission period with a primary discharge diagnosis other than HF. A convenience sampling approach was used in which available subject cases were retrieved sequentially (Kandola, Banner, O'Keefe-McCarthy, & Jassal, 2014). This type of approach involves a selection of enrolled cases in a non-random manner from accessible databases located in a hospital system in the South Eastern region of the United States.

### **Sample Size Estimation**

Several factors (Soper, 2017) determined the sample size for the research study (Appendix B). These factors included effect size, desired statistical power level, number of

predictors/variables, and level of significance (alpha). The researcher determined the effect size by evaluating previous research involving gender, age, and ethnicity on rehospitalization in patients with HF (Howie-Esquivel & Dracup, 2007). For race, one of the variables in the proposed study, the effect size measured small (HR: 2.15; 95% CI: 1.03 - 4.50;  $p = 0.04$ ). For this study, the researcher selected a small to moderate effect size (2.5 odds ratio). Two studies provided data regarding an appropriate number of variables because of limited research on 31 to 60-day HF rehospitalizations. A retrospective study of hospitalized patients with decompensated HF evaluated 15 multivariate predictors of HF rehospitalization at 30 days, and three variables emerged as significant predictors of readmission (Hernandez et al., 2013). The variables included negative fluid balance, discharge serum sodium level, and N-terminal BNP reduction (Hernandez et al., 2013). A second international study evaluated 282 patients who the researchers discharged after their first HF hospitalization (Kaneko et al., 2015). Kaneko et al. (2015) followed this cohort for one to three years post discharge. Older age, diabetes, increased heart rate and loop diuretics use emerged as independent risk factors for HF rehospitalization. Based on these two studies, the number of variables for the proposed study remains set at six. The level of significance (alpha) was set at 0.05, with a power of 0.80. A power level of 0.80 allowed for a 20% tolerance of a Type II error (Gray, Grove & Sutherland, 2017). The estimated range of readmission probability was .20 to .50. The above data produced a sample size range of 164 to 192 when entered into the G-power software (Bell, Teixeira-Pinto, McKenzie, & Olivier, 2014; Faul, Erdfelder, Buchner, & Lang, 2009). The researcher determined that the research study needs this estimated sample size to detect if a significant relationship exists between the proposed variables for this study and 31 to 60-day rehospitalization. The researcher determined a total sample size of 226 in order to consider individuals meeting potential exclusion criteria.



## **Subject Case Recruitment**

The researcher screened enrolled cases of subjects which indicated a discharge with a clinical diagnosis of HF following an index HF hospitalization during a pre-defined period between October 2012 and October 2015 for inclusion in the study sample. Medical providers who delivered care at the large not-for-profit tertiary hospital identified all subjects included in the study sample based on a clinical diagnosis of HF. The researcher continued the screening process for enrolled cases of subjects who meet the inclusion criteria, until the researcher achieved the proposed sample size. For purposes of this study, the researcher defined an initial HF hospitalization as the first hospitalization lasting over 24 hours and with an admitting or discharge diagnosis of HF defined as Diagnostic Related Group (DRG) 428.0. The researcher coded or compiled data such that individual research participants in the enrolled cases cannot be identified and confidentiality maintained.

### **Sample Selection Criteria**

The researcher based the sample selection criteria on specific delimitations of the study alone with prior studies as well (Saheb Sharif-Askari et al., 2014; Ziaeeian et al., 2017) conducting HF research (Appendix A). These criteria assisted in controlling for known confounding factors that may influence the results of the study (Anderson, 2014).

### **Inclusion Criteria**

1. Index hospitalization with admitting and discharge diagnosis of HF
2. Diagnostic Related Group (DRG) 291, 292, 293, 428.
3. Elderly AA and Caucasian women
4. Admitted for greater than 24 hours
5. Age greater than or equal to 65 years

6. Rehospitalization time period is within 31 to 60-day following discharge after an index HF hospitalization
7. Admitted during 3-year period between October 2012 and October 2015 to obtain robust data

### **Exclusion Criteria**

1. Patients with left ventricular assist devices (LVAD) and automated implantable cardioverter defibrillator (AICD)
2. Patients who have received a previous cardiac transplant or are candidates for cardiac transplantation
3. Admitted for less than 24 hours
4. Patient mortality who died less than 60 days after index hospitalization
5. Patients discharged to a hospice setting with life expectancy of less than 90 days
6. Patients who left against medical advice
7. Patients whose discharge disposition or regional socioeconomic status are unknown

### **Protection of Human Subjects and Data Handling**

#### **Protection of Human Subjects/ Benefits and Risks of Participation**

There remained no anticipated risks or adverse events associated with subjects in this study since all data have been collected and data were de-identified (steps presented in detail under Institutional Review Board (IRB) section) prior to incorporation into the research study. As such, the collaborating institution during preliminary consultation indicated that the requirements for informed consent would be waived. Therefore, no informed consent was obtained from subjects of enrolled cases included in the proposed research. The research

reflected no anticipated benefits to registered subjects and the research involves no monetary costs to them or the institution. Possible societal benefits include a greater understanding of the relationships between clinical and hemodynamic factors and early HF rehospitalization in a vulnerable population, which may result in lower readmission rates and a decreased economic burden to society.

### **Confidentiality of Data Protection**

The researcher submitted research study documentation to The Catholic University of America (CUA) School of Nursing and facility IRB for approval prior to the initiation of the study. In compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), a facility data collector de-identified the data prior to permitting the researcher to access the data from the database. The facility data collector removed all direct identifiers in the limited data set including name, social security numbers, age, account numbers, and health plan beneficiary numbers. The researcher respected specifications for confidentiality by assigning a unique code number to each participant's health record retrieved from the secondary database. Also, as discussed in detail previously, the researcher placed a code number on the data collection forms which was not linked to any identifiable patient information.

### **Data Handling**

The researcher kept all de-identified sources of information in a password protected computer or locked files in the researcher's office for the duration of the research study. In addition, the researcher also requested a confidentiality statement from a contracted statistician who provided guidance with sampling size estimations and the adequacy of the researcher's analytical approach. Following the completion of this study, the researcher will comply with regulations requiring data retention for five years, after which all data will be destroyed. After

five years, the researcher will shred and recycle all paper records, and erase all records stored on a computer hard drive or other storage devices through the use of commercial software applications designed to remove data from storage devices. The researcher will keep accounts indefinitely delineating a record of the disposition of the data.

### **Instrumentation**

This section includes a description of the forms that the researcher used to record data as well as measured the study variables. The researcher created health record data collection forms to abstract pertinent health record data from enrolled cases of subjects who met inclusion criteria, and included demographic data, patient history, physical examination, diagnostic testing, and billing records. The researcher compiled demographic data and medical history from the medical record databases and entered the data onto the Demographic Form (Appendix C) and the Data Collection Form (Appendix D). The researcher compiled data related to index HF hospitalizations for both groups (Cases and Controls) on the Demographic Form (Appendix C) and the Data Collection Form (Appendix D). Furthermore, the researcher abstracted data for subjects who met inclusion criteria for HF rehospitalization using another standardized form (Appendix E).

The researcher captured variables from both the index HF hospitalizations and rehospitalization records when appropriate. Predictor variables were captured and recorded from the entire sample of subjects with index HF hospitalizations, whereas predictor and outcome variables were recorded from HF rehospitalization data.

**Predictor variables**

Predictor variables proposed for this study included PH, hypertension, diabetes mellitus, BMI, social factors, race, HFpEF or HFrEF. PH, BMI, HFpEF, and HFrEF are categorical variables which the researcher captured from the hospital database. Hypertension and diabetes mellitus represent dichotomous variables which the researcher determined from the following five metabolic components of the MetS: visceral obesity, arterial blood pressure, HDL cholesterol level, fasting plasma glucose, and triglyceride concentration. Social factors and race remain discrete categorical variables.

**Outcome variable**

The primary outcome variable for the study remained a dichotomous variable which determined whether or not a subject was readmitted for HF (HFpEF or HFrEF) within a 31 to 60-day of discharge following an index HF hospitalization. The researcher accomplished determination of readmission status by reviewing of both electronic and paper-based data since the tertiary not-for-profit hospital used a hybrid health record system during the study period.

**Procedures for Data Collection**

This section describes procedures for data collection from the large, 650-bed, private, not-for-profit, tertiary hospital used in this study. The researcher included proposed planned agreements to conduct research on human subjects in this section. This section also includes the recruitment and procedure protocol used for data collection, how data were accessed, and the data management of subjects who met the inclusion criteria. Finally, this section addresses the analysis of proposed variables for the research study.

### **Institutional Review Board**

The researcher signed an agreement with the director of research and obtained approval from the IRB at the research site prior to the initiation of the research project. The agreement granted the researcher access to the electronic medical records for different data points, including the type of data, different data collection procedures, protection of human subjects, compliance with HIPAA, and data security procedures. In addition, the researcher obtained an IRB approval from The CUA School of Nursing and The Catholic University Committee for the Protection of Human Subjects (Appendix F) following all the policies and guidelines proposed by the research sites in the process of data collection. The researcher protected data through several steps for data security and to prevent deductive de-identification. These steps include: 1. Limit data only to items necessary to the research purpose; 2. De-identify all data retrieved from the databases using specific codes; 3. Password protect all electronic data; 4. Maintain codes and passwords in a separate location from the locked and secured records; 5. Identify protocols for access to stored data to prevent loss, destruction, modification, or disclosure; 6. Maintain records only for the required period of time specified by The Catholic University Committee for the Protection of Human Subjects.

### **Recruitment and Procedure**

The researcher began the data collection protocol (Appendix G) with an evaluation of enrolled cases of subjects' charts for individuals admitted with index HF at the large, 650-bed, private, not-for-profit, tertiary hospital used in this study from October 2012 through October 2015. The researcher utilized a facility data collector to review medical records of potential subject cases to determine if the subjects met inclusion or exclusion criteria for the proposed research study. In addition, the researcher selected enrolled cases of subjects for the

rehospitalization group (Cases) and created a representative group of control subjects (Controls) who met inclusion criteria but were not rehospitalized for HF within 31 to 60-day from index HF hospitalization. Extracted data for both cases and controls were recorded on standardized forms (Appendix D and E) and coded in Excel and Statistical Package for the Social Sciences (SPSS), version 25.0.

### **Original Data**

Many departments use the original clinical database at the large not-for-profit tertiary hospital repository for tracking quality, cost, billing purposes, and decision support. The admissions department represents the first data entry point. Admissions clerical responsibilities include collecting from the patient (or a family member) a correct name, address with zip code, race/ethnicity, marital status, age, gender, health insurance provider, employment status, primary care physician, and advance directive if available. The major objective of the admissions department is to collect consistent and accurate data. Health Information Services or the medical records department enters data for coding. The patient's discharge abstract, i.e., the Diagnosis and Procedure Form, served as the DRG verification for Medicare and Medicaid patients. A hospital compliance officer oversaw the entire process to ensure that entered data remain accurate. Nurses and/or physicians collected and recorded clinical data of all hospitalized patients which remain stored in databases. Similarly, qualified technicians obtained and recorded laboratory data from specimens such as blood and urine. Professional and certified sonographers or magnetic resonance imaging (MRI) technicians obtained data on cardiac parameters.

## **Accessing Data**

The researcher utilized a facility data collector familiar with data collection procedures, information technology (IT), and privacy issues to download patient files with DRG 291, 292, 293, and 428, which reflected index HF admissions or discharges for the study period (October 2012- October 2015). Data collection began by reviewing the notes of the professional nursing staff or physician assessment findings captured in the database. Following these reviews, the researcher followed a data collection protocol (Appendix G) which began with the selection of elderly AA and Caucasian women from the database who met inclusion criteria. The researcher worked closely with the facility data collector in validation of data transfer accuracy as well as accuracy of the collected data. Following enrollment of ten subject cases into the study, data analysis procedures were undertaken. These were followed by a preliminary data review by the dissertation committee faculty for their guidance and approval. The researcher continued data analysis at regular intervals when 25 to 50 cases are identified and data extracted until data of all enrolled subjects met the determined sample size (226). After data collection and before data analysis, the researcher cleaned and coded all data before downloading the information into the study database repository. Missing or non-interpretable data were addressed using imputation techniques (Data Analysis), if indicated. Missing data which were not found were not included in the database. The researcher maintained data integrity and privacy following the steps outlined under the IRB section.

## **Data Tracking System**

Once the researcher enrolled the first subject case in the study, a customized tracking system allowed for calculating and tracking the number of enrolled case subjects for the study that met the inclusion criteria until achievement of the pre-determined sample size. Additionally,



the researcher recorded the characteristics of each subject in the enrolled cases, the date of case subject enrollment, the subject's code number, study completion date, year of study, outliers, and missing data.

### **Data Safety Monitoring**

The researcher served as the Data Safety Monitor for this study and assumed primary responsibility for all aspects of the study including maintaining case subjects' recruitment, confidentiality, data collection and entry, and data analysis. After collection, the researcher exclusively handled all data collectively. When data were not in use, the data resided in a locked drawer in the researcher's locked private office where they will remain until destroyed five years after completion of the study. Using password protection, the researcher secured data files, and created and stored backup copies of all electronic datasets in a separate secure location. The researcher used all information solely for statistical and descriptive purposes and kept the data strictly confidential.

### **Data Filing System**

First, the researcher created a well-organized filing system to handle the data collected from subject's data-bases. Second, the researcher logically separated this filing system into pieces of data including original data, progress notes, consent forms (if needed), and data collection forms.

### **Codes and Codebook**

Prior to setting up the database and data collection, the researcher created names for the proposed variables and determine coding decisions and developed a codebook to provide detailed information needed to transfer information from the hospital database into the researcher

study's database. The codebook ensured consistency of the data during data entry, increasing data accuracy and study finding validity.

### **Creating the Database**

The researcher created a database on the Statistical Package for Social Science (SPSS) software, version 25.0, using variables such as age, gender, race, and code number instead of symbols. Definitions for each variable relate to its numeric value, text, date, or identification and label variables or other data entries to explain the abbreviations. The designation of missing data and outliers occurred by numbering such as 88 or 99. Under the measure column, the researcher specified variables as ordinal, nominal, or categorical.

### **Data Analysis**

The first step in data analysis includes cleaning and checking the quality of the data by evaluating descriptive statistics of all study variables. The researcher checked each variable by evaluating frequency distributions, measures of central tendency, variability, skewness, and kurtosis. Once the researcher completed descriptive statistics and univariate analysis, the results included means  $\pm$  standard deviation (SD) for normally distributed, interval level variables such as, age, length of stay, body mass index, height, EF, differences between weight on discharge from weight on admission, and a number of laboratory values. In addition, the researcher described frequencies and percentages for variables such as race, marital status, social factors, and screen data for the presence of outliers and missing data. In the case of missing data less than 10% and when data was missing at random, listwise deletion was used. When more than 10% of the data were missing and the missingness occurred on multiple variables (depleting the sample size), imputation technique was employed. The researcher considered a p-value  $\leq 0.05$  statistically significant. Logistic regression was used to determine the effect of PH, hypertension,

diabetes mellitus, body mass index, HFpEF or HFrEF, social factors, and race on 31 to 60-day HF rehospitalization among elderly AA and Caucasian women. This analysis is appropriate because the outcome variable and rehospitalization is binary (dichotomous). Figure 6 represents the model that the researcher used to analyze the data:

Figure 6. Statistical Model Represents Equation that was Analyzed:

$$\ln\left(\frac{y}{1-y}\right) = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 + \beta_5 X_5 + \beta_6 X_6 + \beta_7 X_7 + \text{error}$$

Where:  $y$  = the probability of rehospitalization

$\beta_0$  = intercept

$\beta_1 - \beta_7$  = coefficients of predictors

$X_1$  = pulmonary hypertension (PH)

$X_2$  = hypertension

$X_3$  = diabetes mellitus

$X_4$  = body mass index (BMI)

$X_5$  = HFpEF or HFrEF

$X_6$  = social factors

$X_7$  = race

PH was defined as PASP > 33 mm HG. Hypertension was defined as blood pressure >140/90; presence of diabetes was determined based on a fasting glucose > 100 mg/dl. BMI is a calculated value based on weight and height of an individual and is an indicator of health status (Bener et al., 2013; Pursey, Burrows, Stanwell, & Collins, 2014). Social factors selected for the research study include age, race, insurance status, marital status, medications, and smoking. The primary outcome variable for the study remains a dichotomous variable where 1= HF rehospitalization 31to 60-day of discharge following an index HF hospitalization, and 0 = no HF

rehospitalization during same period. Correlations and the chi square test of independence were used to explore the relationships between PH, hypertension, diabetes mellitus, BMI, HFpEF or HFrEF, and with race amongst elderly AA and Caucasian women hospitalized with index HF. Continuous associations were assessed using Pearson correlation and nominal associations were assessed using the Chi square test of independence.

### **Limitations of the Study**

Limitations of the study include:

1. A multitude of interacting factors such as self-care, medication adherence, home care situations, and social care services affected early rehospitalization, which the study could not control.
2. A retrospective study design of secondary data which posed challenges in capturing a complete data set for all key variables, which the researcher could not control.
3. Inability to generalize the data to other groups in other areas of the country.
4. Inability to differentiate self-identified AA and Caucasian women who may or may not be biracial or have a complex ancestry.
5. Inability to track enrolled subject cases who were rehospitalized at another hospital between 31 to 60-day following the index HF hospitalization.
6. Inability to generalize data to current time frame because of the advanced changes in the treatment of HF.
7. The researcher conducted the proposed study over a certain interval of time which reflected the conditions and characteristics of selected enrolled cases during that time interval.

8. The researcher was not able to make causal conclusion because the research design is observational.

### **Delimitations of the Study**

Delimitations of the study include:

1. Location of study: A large not-for-profit tertiary hospital located in southeastern United States.
2. Sample population: AA and Caucasian women aged 65 or older. These two racial groups represented the predominant women admitted to the not-for-profit tertiary hospital during the selected study period.
3. Time frame: Selected time frame of the study ranged between October 2012 and October 2015.
4. Readmission time frame: The rehospitalization time period chosen for the proposed research study which occurred within 31 to 60-day following index HF hospitalization.
5. Readmission criteria: The study included all subjects from enrolled cases who experienced HF rehospitalization within the 31 to 60-day following index HF hospitalization.
6. Controls: Subjects from enrolled cases with an index HF hospitalization and with a discharge diagnosis of HF who were not rehospitalized as well as subjects readmitted with a diagnosis other than HF during the 31 to 60-day period.
7. Selected criteria: The selected variables were appropriate for the purpose of the study and directly impacted rehospitalization.

## Chapter Summary

This descriptive, correlational, non-equivalent case-control, quantitative, retrospective study evaluated the influence of predictor factors such as clinical factors, patients' characteristics (hemodynamic factors), and social factors on 31 to 60-day unplanned rehospitalization in HF patients. This chapter described the research design and methods proposed for use in this study to explore the relationships between the predictor variables included in the conceptual model. The researcher presented a description of and rationale for the design and provided descriptions of the sample, setting, recruitment, data collection methods, ethical considerations, and instrumentation. The chapter concluded with procedures related to data analytics.

Health record data for secondary research pose challenges largely due to the potential for missing data when there remains inconsistent clinical care and documentation. Nonetheless, this retrospective use of secondary data remained advantageous because the researcher examined the health records of large numbers of enrolled cases which enhanced the statistical power and generalizability of the findings. Secondary data analysis results in an authentic representation of real-life or usual clinical care, not necessarily possible in prospective study designs (Anderson, 2014).

## **Chapter IV: Results**

### **Introduction**

This chapter reports the results of the statistical analysis which were performed to explore the effects and relative contributions of predictor variables to the risk of early (31 to 60-day) rehospitalization amongst elderly AA and Caucasian women admitted with decompensated HF and their relationship to race. The study utilized a descriptive, correlational, non-equivalent case-control, quantitative study design with a retrospective review of medical records located in an existing database at a large not-for-profit tertiary local community hospital. This section addresses findings pertaining to the research questions, related hypotheses, statistical analyses, as well as two specific aims of the research study. The aims of study included 1. Examine the effects and relative contributions of PH, hypertension, diabetes mellitus, body mass index (BMI), race, HFpEF or HFrEF, and social factors on 31-60-day HF rehospitalization amongst elderly AA or Caucasian women; and 2. Compare the prevalence of PH, HF (HFpEF or HFrEF), hypertension, diabetes mellitus, and BMI amongst elderly AA and Caucasian women hospitalized with index HF.

### **Sample Characteristics**

The sample consisted of elderly AA and Caucasian women hospitalized with a diagnosis of decompensated HF (index HF) during the selected time frame of the research study (Cases and Controls). Cases consisted of subjects who experienced rehospitalization within the 31 to 60-day readmission period, while controls were not rehospitalized or were rehospitalized with a diagnosis other than heart failure. A total of 143 subjects met the criteria for index HF hospitalization and rehospitalization. Thirty-two subjects were disqualified because inclusion criteria were not met (AICD implantation; mortality within 60 days of discharge; discharged to

hospice setting). In contrast, 1,172 subjects met the criteria for controls. A sample of 115 subjects was randomly selected using simple random sampling. As such, a total of 226 subjects were included in the final cohort of the research study, 111 cases (49.1%) and 115 controls (50.9%). Baseline sample characteristics are presented separately for each group (Cases & Controls) (Table 9 &10).

Caucasian was the primary racial group in either cases (53.6%) or controls (57.9%) (Table 9 &10). In either group, the predominant age group was 80 and above and the majority of subjects were widowed, cases (57.5%) versus controls (56.6%). Most of the subjects were admitted on an emergency basis from the emergency room, and the majority was discharged routinely to home, cases (75%) versus controls (85%). BMI were divided into four levels (<25 to >40) in order to address obesity and its contribution to rehospitalization. In addition, the BMI at admission was compared to the BMI at discharge. Analysis of data for the cases group showed a reduction in BMI at all levels, while in the control group there was an increase in BMI level 1 (>25 and <30), and no change at the reference BMI (<25). All subjects in the cohort suffered with frequent comorbidities. The predominant comorbidities included hypertension, CAD, anemia, treated diabetes mellitus, and dyslipidemia (Table 9 &10). Data regarding the association of left ventricular ejection fraction (reduced vs preserved) with either group (Cases vs Controls) were compelling. Statistics illustrated that either HFpEF or HFrEF were equally common in the subjects rehospitalized after index HF hospitalization (cases), (HFpEF (43.1 %) versus HFrEF (45.9%), whereas HFpEF was more prevalent in the control group, HFpEF (55.7%) versus HFrEF (42.6%) (Table 9 &10).



Table 9. Baseline Sample Characteristics of Cases, n = 111

<b>Variable</b>	<b><i>f</i></b>	<b>%</b>
Age groups (years)		
65-70	19	17.9
70-75	20	18.9
75-80	16	15.1
80 and above	51	48.1
Race		
White/Caucasian	59	53.6
Black/African-American	51	46.4
Marital status		
Married	18	17.0
Single	14	13.2
Widowed	61	57.5
Divorced	13	12.3
Primary payer		
Medicare	108	100
Medicaid	00	
Social status		
Live alone	43	39.8
Live with family member	47	43.5
Nursing home resident	16	14.8
Personal care facility	1	0.9
Other	1	0.9
Types of admission		
Emergency	104	93.7
Urgent	7	6.3
Index source of admission		
Emergency room	102	91.9
Physician office	2	1.8
Transfer from a hospital	5	4.5
Transfer from nursing home	1	0.9
Other	1	0.9
Index discharge status		
Routine/discharge to home	83	75.5
Discharge to short-term facility	6	5.5
Discharge to long-term facility	21	19.1
Smoking history		
Current smoker	5	4.5
Never	59	53.2
Past history	47	42.3
Cardiac rhythm at admission		
Normal sinus	50	45.5
Sinus tachycardia	13	11.9
Atrial fibrillation	33	30.0
Sinus bradycardia	1	0.9
Other rhythm disorder	12	11.0

Table 9 (continued)

Variable	<i>f</i>	%
Body mass index (BMI) kg/m <sup>2</sup> on admission		
< 25	22	20.0
>25 and < 30	39	35.5
>30 and <40	34	30.9
>40	15	13.6
Body mass index (BMI)kg/m <sup>2</sup> on discharge		
< 25	21	22.6
>25 and < 30	36	38.7
>30 and <40	26	28.0
>40	10	10.8
Comorbidities		
Hypertension (BP>140/90)	102	91.9
Coronary artery disease	58	52.7
Atrial fibrillation	46	41.4
Obesity (BMI>30)	32	29.4
Chronic lung disease	36	32.4
Anemia (Hgb<11.5 g/dl)	55	50.0
Treated diabetes mellitus (pills or shots)	61	55.5
Previous stroke	18	16.2
Dyslipidemia	61	56.0
Peripheral vascular disease	11	10.0
Valvular heart disease	22	20.2
Type of heart failure		
Ischemic	42	38.5
Non-ischemic	26	23.6
Hypertensive	43	39.4
Tachycardia-induced	18	16.7
Other	3	3.0
Discharge medications		
Angiotensin converting enzyme inhibitor (ACE-I)	43	38.7
Angiotensin II receptor blocker (ARB)	22	19.8
Aldosterone antagonist	7	6.4
Antiplatelet therapy	74	66.7
Vasodilator	48	43.2
Beta blocker	83	74.8
Anti-coagulant therapy	33	29.7
Diuretic	87	78.4
Statin	81	73.6
Diabetic medication (shot or pills)	51	45.9
Other medications	108	97.3
Left ventricular ejection fraction		
Reduced (<50%)	50	45.9
Preserved (>50%)	47	43.1

Table 10. Baseline Sample Characteristics of Controls, n = 115

<b>Variable</b>	<b><i>f</i></b>	<b>%</b>
Age groups (years)		
65-70	23	20.2
70-75	16	14.0
75-80	26	22.8
80 and above	49	43.0
Race		
Caucasian	66	57.9
Black/African-American	48	42.1
Marital status		
Married	26	23.0
Single	9	8.0
Widowed	64	56.6
Divorced	14	12.4
Primary payer		
Medicare	113	99.1
Medicaid	1	0.9
Social status		
Live alone	63	55.3
Live with family member	50	43.9
Nursing home resident	1	0.9
Types of admission		
Emergency	113	98.3
Urgent	2	1.7
Index source of admission		
Emergency room	105	91.3
Physician office	5	4.3
Transfer from a hospital	5	4.3
Index discharge status		
Routine/discharge to home	97	85.1
Discharge to short-term facility	6	5.3
Discharge to long-term facility	11	9.6
Smoking history		
Current smoker	6	5.3
Never	66	57.9
Past history	42	36.8
Cardiac rhythm at admission		
Normal sinus	69	60.9
Sinus tachycardia	7	6.1
Atrial fibrillation	23	20.0
Sinus bradycardia	1	0.9
Other rhythm disorder	15	13.0

Table 10 (continued)

<b>Variable</b>	<b><i>f</i></b>	<b>%</b>
Body mass index (BMI) on admission		
< 25	36	31.3
>25 and < 30	30	26.1
>30 and <40	31	27.0
>40	18	15.7

Body mass index (BMI) kg/m <sup>2</sup> on discharge		
< 25	36	33.0
>25 and < 30	35	32.1
>30 and <40	23	21.1
>40	15	13.8
Comorbidities		
Hypertension (BP>140/90)	110	95.7
Coronary artery disease	59	51.3
Atrial fibrillation	39	34.2
Obesity (BMI>30)	33	28.9
Chronic lung disease	37	32.7
Anemia (Hgb<11.5 g/dl)	75	65.2
Treated diabetes mellitus (pills or shots)	54	47.0
Previous stroke	18	15.7
Dyslipidemia	65	56.5
Peripheral vascular disease	15	13.2
Valvular heart disease	34	29.6
Type of heart failure		
Ischemic	57	49.6
Non-ischemic	15	13.0
Hypertensive	41	35.7
Tachycardia-induced	14	14.0
Other	3	3.0
Discharge medications		
Angiotensin converting enzyme inhibitor (ACE-I)	47	40.9
Angiotensin II receptor blocker (ARB)	22	19.1
Aldosterone antagonist	15	13.0
Antiplatelet therapy	79	68.7
Vasodilator	55	47.8
Beta blocker	86	74.8
Anti-coagulant therapy	31	27.0
Diuretic	99	86.1
Statin	65	56.5
Diabetic medication (shot or pills)	52	45.2
Other medications	114	99.1
Left ventricular ejection fraction		
Reduced (<50%)	49	42.6
Preserved (>50%)	64	55.7

### Descriptive Statistics for Sample Characteristics

Descriptive statistics showing minimums, maximums, mean, and standard SD) were conducted for three groups: 1. Cases with index HF hospitalization; 2. Controls with index HF hospitalization; and 3. Rehospitalization data of cases (31to 60-day) after index HF admission (Tables 11-13). In the cases group, length of stay varied between one and twenty-seven days, with a mean of 6.69 days (SD 4.85) (Table 11). Some subjects were severely obese (177.1 kg)

and hypertensive (systolic BP =233 mm HG) (Table 11). The mean BNP level increased from 14,130 (SD 21,026.48) at admission to 19,832 (SD 41,341.26) at discharge (Table 11).

Table 11. Descriptive Statistics of Cases, n = 111

<b>Variable</b>	<b>n</b>	<b>Minimum</b>	<b>Maximum</b>	<b>Mean</b>	<b>SD</b>
Index length of stay (days)	111	1	27	6.69	4.850
Index labs & vitals at admission: Heart Rate (bpm)	111	51	147	87.19	21.029
Index labs and vitals at admission: Systolic Blood Pressure (mm HG)	111	92	233	144.54	30.889
Index labs and vitals at admission: Diastolic Blood Pressure (mm HG)	111	46	140	79.75	19.381
Index labs and vitals at admission: Height (inches)	111	51.0	70.0	62.857	3.6468
Index labs and vitals at admission: Weight (kg)	111	43.5	177.1	82.386	23.9098
Index labs and vitals at admission: BUN	110	8.0	104.0	31.296	19.6026
Index labs and vitals at admission: Creatinine	110	0.1	13.6	1.690	1.6461
Index labs and vitals at admission: NT-pro BNP	92	6.488	171,507.00	14,130.896	21,026.468
Index labs and vitals at admission: Total Cholesterol	54	83	250	149.65	41.159
Index labs and vitals at admission: Hgb	106	6	15	11.08	2.042
Index labs and vitals at admission: Hct	106	20	48	33.91	6.506
Index labs and vitals at discharge: Heart Rate	110	56	111	75.77	11.994
Index labs and vitals at discharge: Systolic Blood Pressure (mm HG)	110	94	194	129.35	19.011
Index labs and vitals at discharge: Diastolic Blood Pressure (mm HG)	110	41	160	68.58	15.241
Index labs and vitals at discharge: Height (inches)	111	51.0	69.0	63.109	5.1662
Index labs and vitals at a discharge: Weight (Kg)	96	39.1	178.6	78.978	23.2663
Index change in weight: Admission – Discharge (Kg)	96	-(31.20)	13.90	3.4354	13.81082
Index labs and vitals at discharge: BUN	105	7.0	119.0	34.733	21.9673
Index labs and vitals at discharge: Creatinine	105	0.3	13.3	1.848	1.8654
Index labs and vitals at discharge: NT-proBNP	18	381	175,000	19,832.72	41,341.269
Index labs and vitals at discharge: Total Cholesterol	2	83	119	101.00	25.456
Index labs and vitals at discharge: Hgb	76	5.7	15	10.61	2.169
Index labs and vitals at discharge: HCT	76	23	46	33.64	8.119
Index pulmonary hypertension: Trans-Tricuspid Gradient Recorded	93	7	73	35.86	12.799

Index pulmonary hypertension: Pulmonary Artery Systolic Pressure (PASP) Recorded	93	14	83	49.58	14.932
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BUN, blood urea nitrogen; Hgb, hemoglobin; HCT, hematocrit; NT-proBNP, N-terminal-proB-type naturetic peptide; SD, standard deviation

In the control group, length of stay varied from one to thirty-five days, and the NT-proBNP level varied from a minimum of 84.0 to a maximum of 174,154.0 at admission (Table 12). A negative minimum weight reduction (-20 kg) was recorded. The mean BNP level decreased from 12,751 (SD 24,133.29) at admission to 8,676 (SD 1003.04) at discharge.

Table 12. Descriptive Statistics of Controls, n = 115

Variable	n	Minimum	Maximum	Mean	SD
Index length of stay (days)	115	1	35	6.76	5.890
Index labs & vitals at admission: Heart Rate (bpm)	115	52	149	84.18	18.343
Index labs and vitals at admission: Systolic Blood Pressure (mm HG)	115	86	231	148.73	30.257
Index labs and vitals at admission: Diastolic Blood Pressure (mm HG)	115	42	133	80.65	19.788
Index labs and vitals at admission: Height (inches)	115	56.0	69.0	63.678	2.9336
Index labs and vitals at admission: Weight (kg)	115	40.8	136.1	78.032	21.8937
Index labs and vitals at admission: BUN	114	7.0	100.0	30.105	19.4474
Index labs and vitals at admission: Creatinine	114	0.2	9.8	1.505	1.3325
Index labs and vitals at admission: NT-pro BNP	102	84.0	174,154.0	12751.735	24133.296
Index labs and vitals at admission: Total Cholesterol	64	74	277	144.06	40.909
Index labs and vitals at admission: Hgb	114	6	16	10.96	1.803
Index labs and vitals at admission: Hct	114	17	54	33.82	5.731
Index labs and vitals at discharge: Heart Rate	114	54	106	75.90	12.275
Index labs and vitals at discharge: Systolic Blood Pressure (mm HG)	114	2	183	127.46	21.606
Index labs and vitals at discharge: Diastolic Blood Pressure (mm HG)	114	40	99	66.96	13.771
Index labs and vitals at discharge: Height (inches)	114	43.0	70.0	63.225	3.3293
Index labs and vitals at a discharge: Weight (Kg)	110	35.8	136.6	75.185	20.6300
Index change in weight: Admission – Discharge (Kg)	110	-(20.0)	30.50	2.6864	6.31418
Index labs and vitals at discharge: BUN	112	8.0	106.0	33.579	20.2949

Index labs and vitals at discharge: Creatinine	112	0.2	6.5	1.575	1.0916
Index labs and vitals at discharge: NT-proBNP	28	155	41,435.00	8,676.43	1,003.044
Index labs and vitals at discharge: Total Cholesterol	5	124	195	165.60	33.005
Index labs and vitals at discharge: Hgb	104	7	18	10.78	1.761
Index labs and vitals at discharge: HCT	104	22	58	33.07	5.659
Index pulmonary hypertension: Trans-Tricuspid Gradient Recorded	104	7	71	36.26	12.901
Index pulmonary hypertension: Pulmonary Artery Systolic Pressure (PASP) Recorded	103	17	90	50.75	14.517

BUN, blood urea nitrogen; Hgb, hemoglobin; HCT, hematocrit; NT-proBNP, N-terminal-proB-type naturetic peptide; SD, standard deviation

The mean BNP on readmission (31to 60-day) after index admission was 15,063 (SD 16,290.17) associated with a mean weight of 80.00 kg (SD 26.178). This is lower than the mean weight for the case group at index HF admission, but higher than the subject control group at index HF admission (Tables 11-13).

Table 13. Descriptive Statistics of Rehospitalization Data (31-60-day), n = 110

<b>Variable</b>	<b>n</b>	<b>Minimum</b>	<b>Maximum</b>	<b>Mean</b>	<b>SD</b>
Readmit length of stay (days)	110	1	32	6.64	5.694
Readmit labs & vitals at readmission: Heart Rate (bpm)	110	49	150	83.48	20.485
Readmit labs and vitals at admission: Systolic Blood Pressure (mm HG)	110	92	233	137.15	29.253
Readmit labs and vitals at admission: Diastolic Blood Pressure (mm HG)	110	36	140	73.53	18.104
Readmit labs and vitals at admission: Height (inches)	110	16	70	62.44	5.788
Readmit labs and vitals at admission: Weight (kg)	108	63	184.0	80.004	26.1784
Readmit labs and vitals at admission: BUN	110	7	147	35.76	23.051
Readmit labs and vitals at admission: Creatinine	110	0.1	12.9	1.862	1.6899
Readmit labs and vitals at admission: NT-pro BNP	69	365	74,898.00	15,063.96	16,290.17
Readmit labs and vitals at admission: Total Cholesterol	27	60	345	152.44	55.594
Readmit labs and vitals at admission: Hgb	107	5	16	11.02	2.040
Readmit labs and vitals at admission: Hct	107	17	49	34.06	6.098
Readmit pulmonary hypertension: Trans-Tricuspid Gradient Recorded	40	11	67	39.15	14.395
Readmit pulmonary hypertension: Pulmonary					

Artery Systolic Pressure (PASP) Recorded	39	21	81	53.90	15.014
Valid N (listwise)	9				

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BUN, blood urea nitrogen; Hgb, hemoglobin; HCT, hematocrit; NT-proBNP, N-terminal-proB-type natriuretic peptide; SD standard deviation

### Research Question One

Do PH, hypertension, diabetes mellitus, BMI, race, HFpEF or HFrEF, and social factors predict the likelihood of 31to 60- day HF rehospitalization among elderly AA and Caucasian women?

A logistic regression was conducted to predict the likelihood that pulmonary hypertension, hypertension, diabetes mellitus, BMI, race, HFpEF or HFrEF, age, marital status, smoking history, angiotensin converting enzyme inhibitor, Angiotensin II receptor blocker, aldosterone antagonist, antiplatelet therapy, vasodilators, beta-blocker, anticoagulation therapy, diuretic, lipid-lowering agent, diabetic medications, and other medication would contribute to rehospitalization after an index HF hospitalization amongst elderly AA and Caucasian women. The extracted data from the hospital database were initially downloaded onto an excel spreadsheet and then transferred to SPSS version 25 software for analysis.

### Outliers

The data were evaluated for outliers or cases that were not well explained by the model through the use of the explore data statistics command in SPSS version 25. The residuals were inspected. There were no significant outliers noted.

### Missing Data

The database was also analyzed for missing data. There was no pattern to the missing data. The database had 16 percent of missing data. All missing data were subjected to listwise deletion, resulting in the complete removal of all missing data. All of the variables were



categorical and there is no standard imputation technique for handling categorical data within a logistic regression model.

### Results

The full model containing all predictors was not statistically significant,  $X^2(21, N = 188) = 35.77, p = 0.120$ ; indicating that the model was not able to distinguish between predictors that contribute to rehospitalization after an index HF hospitalization. In other words, the model “goodness of fit” was not statistically significant. The model as a whole explained between 17.3% (Cox and Snell R square) and 23.1% (Nagelkerke R squared) of the variance in HF readmission after an index of HF hospitalization, and correctly classified 69.7% of subjects as cases or controls. Table 14 shows the regression coefficient, Wald Statistics, odds ratio, and the 95% confidence intervals odds ratios for each variable. The Wald Statistics demonstrated that the BMI level 1 ( $p = 0.003$ ), BMI level 2 ( $p = 0.018$ ), age level 3 ( $p = 0.043$ ), and lipid-lowering agent ( $p = 0.004$ ) made a significant contribution to the prediction of HF rehospitalization within 31-60-day after an index HF hospitalization (Table 14). One of the stronger predictor variables was subjects use of a lipid-lowering agent; the B value for this predictor was negative, such that individuals treated with this medication were therefore .317 times more likely to be rehospitalized for HF (OR = 0.317; 95% CI: 0.144 – 0.697). The aggregate BMI was significant in predicting the likelihood of HF rehospitalization ( $p=0.016$ ). Subjects who had a level 1 BMI (< 25 to >30) were 4.22 times more likely to experience rehospitalization with HF (OR = 4.220; 95% CI: 1.639 – 10.865), compared to the reference level. Also, subjects with a level 2 BMI (>30 to <40) were 3.26 times more likely to experience rehospitalization with HF (OR = 3.265; 95% CI: 1.220 – 8.738), compared to the reference level. Finally, B value for subjects who fell into the age group 3 (75-80) were negative, and were therefore 0.335 times more likely to be

rehospitalized for HF (OR = 0.335; CI: 0.116 – 0.965). Neither HFpEF nor HFrEF predicted the likelihood of HF rehospitalization after an index HF admission, but the data showed that subjects with HFrEF were 1.6 times more likely to experience rehospitalization.

Table 14. Logistic Regression Model Predicting Likelihood of HF Rehospitalization

Variable	B	SE	Wald	df	Sig.	Exp(B)	Upper	Lower
Index pulmonary hypertension	-0.429	0.550	0.608	1	0.435	0.651	0.222	1.914
Index comorbidities: History of hypertension (BP >140/90)	-0.842	0.721	1.364	1	0.243	0.431	0.105	1.770
Index comorbidities: Treated diabetes mellitus	0.744	0.469	2.511	1	0.113	2.104	0.839	5.278
Index labs and vitals at admission: BMI			10.260	3	0.016			
Index labs and vitals at admission: BMI-1	1.440	0.482	8.908	1	0.003	4.220	1.639	10.865
Index labs and vitals at admission: BMI-2	1.183	0.502	5.549	1	0.018	3.265	1.220	8.738
Index labs and vitals at admission: BMI-3	0.447	0.641	0.486	1	0.486	1.564	0.445	5.495
Race	-0.098	0.371	0.070	1	0.791	0.906	0.438	1.876
Index ejection fraction	0.479	0.367	1.700	1	0.192	1.614	0.786	3.31
Age at index heart failure admission			5.054	3	0.168			
Age at index heart failure admission-1	-0.744	0.528	1.988	1	0.159	0.475	0.169	1.337
Age at index heart failure admission-2	-0.255	0.552	0.213	1	0.644	0.775	0.263	2.287
Age at index heart failure admission-3	-1.093	0.540	4.101	1	0.043	0.335	0.116	0.965
Marriage status			2.045	3	0.563			
Marriage status-1	-0.475	0.692	0.470	1	0.493	0.622	0.160	2.416
Marriage status-2	0.405	0.773	0.274	1	0.601	1.499	0.329	6.821
Marriage status-3	-0.360	0.646	0.310	1	0.578	0.698	0.197	2.476
Index smoking history			0.486	2	0.784			
Index smoking history-1	-0.445	0.863	0.266	1	0.606	0.641	0.118	3.479
Index smoking history-2	-0.221	0.384	0.331	1	0.565	0.802	0.378	1.702
<b>Index discharge medications</b>								
Angiotensin converting enzyme inhibitor	0.292	0.390	0.561	1	0.454	1.340	0.624	2.878
Angiotensin II receptor blocker	0.398	0.478	0.692	1	0.406	1.488	0.583	3.800
Aldosterone antagonist	1.107	0.644	2953	1	0.086	3.025	0.856	10.689
Antiplatelet	0.216	0.406	0.283	1	0.595	1.241	0.560	2.748
Vasodilators	0.264	0.373	0.501	1	0.479	1.302	0.627	2.705
Beta blocker	0.133	0.421	0.101	1	0.751	1.143	0.501	2.606
Anticoagulant therapy	-0.313	0.399	0.618	1	0.432	0.731	0.335	1.597
Diuretic	0.392	0.456	0.738	1	0.390	1.480	0.605	3.617
Lipid lowering agent	-1.150	0.403	8.163	1	0.004	0.317	0.144	0.697
Diabetic medications	2.018	1.579	1.634	1	0.201	7.526	0.394	2.316
Other medications	-1.047	1.537	0.464	1	0.496	0.351	0.341	166.172

Figure 7. Final Statistical Model;

$$\ln \left( \frac{y}{1-y} \right) = -1.047 + -0.429 X_1 + -0.842 X_2 + 0.744 X_3 + 1.44 X_4 + 0.479 X_5 + -0.475 X_6 + -0.098 X_7 + \text{error}$$

Where:  $y$  = the probability of rehospitalization

$\beta_0$  = intercept

$\beta_1 - \beta_7$  = coefficients of predictors

$X_1$  = pulmonary hypertension (PH)

$X_2$  = hypertension

$X_3$  = diabetes mellitus

$X_4$  = body mass index (BMI)

$X_5$  = HFpEF or HFrEF

$X_6$  = social factors

$X_7$  = race

### Research Question Two and Related Hypotheses

What is the relationship between PH, hypertension, diabetes mellitus, BMI, HFpEF or HFrEF, and with race amongst elderly AA and Caucasian women hospitalized with index HF?

Cross-tabulation analysis using Chi-Square test of independence as well as the corresponding Cramer's V examined associations between major study predictor variables and race (Table 15) as well as in cases or controls (Table 16) amongst elderly AA and Caucasian women hospitalized with index HF. Results of the analysis illustrate that treated diabetes mellitus (pills or shot) against race was statistical significant ( $p=0.001$ ). Data illustrate that the percent within index comorbidities for diabetes mellitus was Caucasian (44.6%) versus AA (55.4%). Within race for this variable, the percentages were more compelling, Caucasians (43.2%) versus AA (67.7%) ( $p=0.001$ ). BMI (4 levels) against race on index HF hospitalization was not statistically significant ( $p=0.234$ ). However, at discharge, BMI (4 levels) against race clearly

showed statistical significance at each level ( $p=0.033$ ) (Table 15). With regard to subtypes of ejection fraction (HFpEF vs HFrEF), data show that there was no statistical significant relationship between race and HFpEF or HFrEF.

Table 15: Relationship between Predictor Variables and Race

<b>Variables</b>	<b>1= Caucasian</b>	<b>2 = African American (AA)</b>	<b>Total</b>	<b>Pearson Chi-square</b>	<b>Cramer's V</b>
Index Pulmonary Hypertension Count % within Index Pulmonary hypertension % within race % of total	93 54.7% 84.5% 47.7%	77 45.3% 90.6 % 39.5%	170 100 87.2% 87.2%	1.567	0.090
Index Comorbidities: History of Hypertension (B/P >140/90mmHg) Count % within Index comorbidities History of Hypertension % within race % of total	117 55.7% 93.6% 52.2%	93 44.3% 93.9% 41.5%	210 100% 93.8% 93.8%	0.011	0.007
Index Comorbidities: Treated Diabetes Mellitus (pills or shots) Count % within Index Comorbidities History of Diabetes Mellitus % within race % of total	54 44.6% 43.2% 24.1%	67 55.4% 67.7% 29.9%	121 100.0% 54.0% 54.0%	13.344*	0.0244*
Index Labs & Vitals at Admission: BMI Reference Level = < 25 Count % within Index Lab & Vitals at Admission: BMI % within race % of total	38 65.5% 30.4% 17.0%	20 34.5% 20.2% 8.9%	58 100% 25.9% 25.9%	4.265	0.138
Index Labs & Vitals at Admission: BMI Level 1 = > 25 - < 30 Count % within Index Lab & Vitals at Admission: BMI % within race % of total	39 57.4% 31.2% 17.4%	29 42.6% 29.3% 12.9%	68 100.0% 30.4% 30.4%	4.265	0.138
Index Labs & Vitals at Admission: BMI Level 2 = 30 - < 40 Count % within Index Lab & Vitals at Admission: BMI % within race % of total	31 47.7% 24.8% 13.8%	34 52.3% 34.3% 15.2%	65 100.0% 29.0% 29.0%	4.265	0.138
Index Labs & Vitals at Admission: BMI Level 3 = > 40 Count	17	16	33	4.265	0.138

% within Index Lab & Vitals at Admission: BMI	51.5%	48.5%	100.0%		
% within race	13.6%	16.2%	14.7%		
% of total	7.6%	7.1%	14.7%		
Index Labs & Vitals at Discharge: BMI Reference Level =< 25					
Count	41	16	57	8.728*	0.208*
% within Index Lab & Vitals at Discharge: BMI	71.9%	28.1%	100.0%		
% within race	36.6%	18.0%	28.4%		
% of total	20.4%	8.0%	28.4%		
Index Labs & Vitals at Discharge: BMI Level 1 = < 25 - < 30					
Count	36	34	70	8.728*	0.208*
% within Index Lab & Vitals at Discharge: BMI	51.4%	48.6%	100.0%		
% within race	32.1%	38.2%	34.8%		
% of total	17.9%	16.9%	34.8%		
Index Labs & Vitals at Discharge: BMI Level 2 = 30 - < 40					
Count	23	26	49	8.728*	0.208*
% within Index Lab & Vitals at Discharge: BMI	46.9%	53.1%	100.0%		
% within race	20.5%	29.2%	44.4%		
% of total	11.4%	12.9%	44.4%		
Index Labs & Vitals at Discharge: BMI Level 3 = > 40					
Count	12	13	25	8.728*	0.208*
% within Index Lab & Vitals at Discharge: BMI	48.0%	52.0%	100.0%		
% within race	14.6%	12.4%	12.4%		
% of total	6.0%	6.5%	12.4%		
Index Ejection Fraction Reduced					
Count	56	43	99	1.067	0.069
% within Index Ejection Fraction	56.6%	43.4%	100.0%		
% within race	44.8%	43.9%	44.4%		
% of total	25.1%	19.3%	44.4%		
Index Ejection Fraction Preserved					
Count	63	47	110	1.067	0.069
% within Index Ejection Fraction	57.3%	42.7%	100.0%		
% within race	50.4%	48.0%	49.3%		
% of total	28.3%	21.1%	49.3%		

BMI, body mass index; Asterisk (\*)=values are significant at level p= 0.05

Cross-tabulation analyses were also conducted to understand the relationships between predictor variables and cases or controls. Data showed that a statistical significant relationship exists between the two subtypes of HF and subjects (Cases) and subjects (Controls) (Table 16). Data failed to show any further statistical relationships.

Table 16. Subtypes of Heart Failure in Relation to Cases or Controls

<b>Variables</b>	<b>Case</b>	<b>Control</b>	<b>Total</b>	<b>Pearson Chi-Square</b>	<b>Cramer's V</b>
Index Ejection Fraction Reduced Count	50	49	99		
% within Index Ejection Fraction	50.5%	49.5%	100.0%	9.603*	0.207*
% within Group	45.9%	42.6%	44.2%		
Index Ejection Fraction Preserved Count	47	64	111		
% within Ejection Fraction	42.3%	57.7%	100.0%	9.603*	0.207*
% within Group	43.1%	55.7%	49.6%		

Asterisk (\*)=values are significant at level  $p=0.05$

Cross-tabulation analyses were also conducted to further understand the relationships between predictor variables and the two subtypes of HF. The analyzed data showed statistical significant relationships between the two subtypes of HF and obesity (Table 17), and Diabetes Mellitus (Table 18).

Table 17. Subtypes of Heart Failure in Relation to Obesity

<b>Variables</b>	<b>1 = yes</b>	<b>2 = no</b>	<b>Total</b>	<b>Pearson Chi-Square</b>	<b>Cramer's V</b>
Index Ejection Fraction Index: Reduced Count	23	76	99		
% within Index Ejection Fraction	23.2%	76.8%	100.0%	7.517*	0.184*
% within Index Comorbidities: Obesity (BMI > 30)	34.3%	49.0%	44.6%		
% of Total	10.4%	34.2%	44.6%		
Index Ejection Fraction Index: Preserved Count	36	73	109		
% within Ejection Fraction	33.0%	67.0%	100.0%	7.517*	0.184*
% within Index Comorbidities: Obesity (BMI > 30)	53.7%	47.1%	49.1%		
% of Total	16.2%	32.9%	49.1%		

Asterisk (\*)=values are significant at level  $p=0.05$

Table 18. Subtypes of Heart Failure in Relation to Diabetes Mellitus

<b>Variables</b>	<b>1 = yes</b>	<b>2 = no</b>	<b>Total</b>	<b>Pearson Chi-Square</b>	<b>Cramer's V</b>
Index Ejection Fraction: Reduced Count	46	53	99		
% within Index Ejection Fraction	46.5%	53.5%	100.0%	6.585*	0.171*
% within Index Comorbidities: Diabetes Mellitus	37.7%	52.0%	44.2%		
% of Total	20.5%	23.7%	44.2%		
Index Ejection Fraction :Preserved Count	65	46	111		
% within Ejection Fraction	58.6%	41.4%	100.0%		

% within Index Comorbidities: Diabetes Mellitus	53.3%	45.1%	49.6%	6.585*	0.171*
% of Total	29.0%	20.5%	49.6%		

Asterisk (\*)=values are significant at level  $p= 0.05$

Cross-tabulation analyses further evaluated the relationship between subtypes of HF and comorbid condition (Type of Heart Failure) that contributed to the index HF hospitalization according to the data recorded in the medical records. The analyzed data showed statistical significant relationships between the two subtypes of HF and non-ischemic heart disease (Table 19), and hypertension (Table 20).

Table 19. Subtypes of Heart Failure in Relation to Type of Heart Failure (Non-ischemic)

Variables	1 = yes	2 = no	Total	Pearson Chi-Square	Cramer's V
Index Ejection Fraction: Reduced Count					
% within Index Ejection Fraction	35	64	111		
% within Index Type of Heart Failure: Non-Ischemic	35.4%	64.6%	100.0%	40.289*	0.424*
% of Total	87.5%	34.8%	44.2%		
	15.6%	28.6%	44.2%		
Index Ejection Fraction : Preserved Count	2	109	111		
% within Ejection Fraction	1.8%	98.2%	100.0%		
% within Index Type of Heart Failure: Non-Ischemic	5.0%	59.2%	49.6%	40.289*	.424*
% of Total	0.9%	48.7%	49.6%		

Asterisk (\*)=values are significant at level  $p= 0.05$

Table 20. Subtypes of Heart Failure in Relation to Type of Heart Failure (Hypertensive)

Variables	1 = yes	2 = no	Total	Pearson Chi-Square	Cramer's V
Index Ejection Fraction Index: Reduced Count					
% within Index Ejection Fraction	22	77	99		
% within Index Type of Heart Failure: Hypertensive	22.2%	77.8%	100.0%	20.072*	0.299*
% of Total	25.9%	55.4%	44.2%		
	9.8%	34.4%	44.2%		
Index Ejection Fraction Index: Preserved Count	58	53	111		
% within Ejection Fraction	52.3%	47.7%	100.0%		
% within Index Type of Heart Failure: Hypertensive	68.2%	38.1%	49.6%	20.072*	0.299*
% of Total	25.9%	23.7%	49.6%		

Asterisk (\*)=values are significant at level  $p= 0.05$

## Hypotheses

H 1: PH, hypertension, diabetes mellitus, BMI, HFpEF or HFrEF, race, and social factors predict the likelihood of 31-60-day HF rehospitalization among elderly AA and Caucasian women.

Cumulative BMI ( $p=0.016$ ), level 1 BMI ( $p=0.003$ ), level 2 BMI ( $p=0.018$ ), age (level 3) ( $p=0.043$ ) at index HF hospitalization, and index discharge lipid lowering agent ( $p=0.004$ ) were statistically significant in predicting likelihood of 31 to 60-day HF rehospitalization.

H 2: Direct relationship exists between PH and race amongst elderly AA and Caucasian women hospitalized with index HF.

No statistical significance existed between PH and race. Thus, the Null Hypothesis is not rejected.

H 3: Direct relationship exists between hypertension and race amongst elderly AA and Caucasian women hospitalized with index HF.

No statistical significance existed between hypertension and race. Thus, the Null Hypothesis is not rejected.

H 4: Direct relationship exists between diabetes mellitus and race amongst elderly AA and Caucasian women hospitalized with index HF.

There is a statistical significance between diabetes and race ( $p= 0.001$ ). Thus, the Null Hypothesis is rejected.

H5: Direct relationship exists between BMI and race amongst elderly AA and Caucasian women hospitalized with index HF.

There is a statistical significance between diabetes and race ( $p= 0.033$ ). Thus, the Null Hypothesis is rejected.



H 6: Direct relationship exists between HFpEF or HFrEF and race amongst elderly AA and Caucasian women hospitalized with index HF.

No statistical significance existed between HFpEF or HFrEF and race. Thus, the Null Hypothesis is not rejected.

### **Chapter Summary**

The purpose of this descriptive, correlational, non-equivalent case-control, quantitative study was to determine if certain social and comorbid risk factors associated with elderly AA and Caucasian female HF patients influence hospital readmission between 31 to 60-day following discharge. Baseline sample characteristics of the cohort (n=226) indicated that the primary racial group were Caucasians, mostly widowed, and fell into the 80 and above age group.

Comorbidities such as hypertension, CAD, anemia, treated diabetes mellitus, and dyslipidemia were commonly associated with both groups (cases & controls) and with both subtypes of HF. HFpEF or HFrEF were equally common in the subjects rehospitalized after index HF hospitalization (cases), whereas HFpEF was more prevalent in the control group.

Descriptive statistics provided important minimum, maximum, and means of a number of study variables in all three groups, cases, controls, and subjects rehospitalized within 31 to 60-day period after index HF admission. The results of the descriptive statistics indicated important differences of the study variables among the three groups.

To address research question one, a logistic regression analysis was conducted to determine whether twenty-one individual study variables, derived from the seven predictor variables, contributed to HF rehospitalization. The full model containing all variables was not statistically significant. However, three independent variables BMI (individual or aggregate), age group 3, and lipid lowering agents made significant contributions to the model.

To address research question two and its related hypotheses, cross-tabulation analyses using Chi-Square test of independence as well as the corresponding Cramer's V examined associations between major study predictor variables and race. Treated diabetes (pills or shots) and BMI at discharge after an index HF hospitalization showed statistical significance when examined against race. The Null Hypothesis for three hypotheses (H2, H3, and H6) was not rejected. On the other hand, it was rejected for two hypotheses (H4 and H5).

The following chapter presents a discussion of the research study results, study limitations, implications for nursing practice and further nursing research, areas for policy implementation, and conclusion of the study.

## **Chapter Five: Discussion**

### **Introduction**

The primary purpose of this study was to determine why elderly AA and Caucasian female HF patients who comprise a substantial proportion of the overall HF population often experience higher than normal HF rehospitalizations (Del Gobbo et al., 2015; Dreyer, Dharmarajan, Hsieh, Welsh, Qin & Krumholz, 2017). In this chapter, a summary of the findings and a discussion of the results are presented as well as relevance of the findings to nursing practice, policy, and research, limitations of the study, implications, and recommendations for future research.

### **Research Questions and Hypotheses**

Two research questions guided the study: 1. Do PH, hypertension, diabetes mellitus, BMI, race, HFpEF or HFrEF, and social factors predict the likelihood of 31-60- day HF rehospitalization among elderly AA and Caucasian women; 2. What is the relationship between PH, hypertension, diabetes mellitus, BMI, HFpEF or HFrEF, and with race amongst elderly AA and Caucasian women hospitalized with index HF. Six hypotheses were also proposed to test hypothesized relationships among variables in a “Conceptual Framework of HF Rehospitalization” model, which identified relationships between clinical, hemodynamic, and social factors (predictor variables) to the outcome variable (31 to 60-day HF rehospitalization):

H 1: PH, hypertension, diabetes mellitus, BMI, HFpEF or HFrEF, race, and social factors predict the likelihood of 31 to 60-day HF rehospitalization among elderly AA and Caucasian women.

H 2: Direct relationship exists between PH and race amongst elderly AA and Caucasian women hospitalized with index HF.

H 3: Direct relationship exists between hypertension and race amongst elderly AA and Caucasian women hospitalized with index HF.

H 4: Direct relationship exists between diabetes mellitus and race amongst elderly AA and Caucasian women hospitalized with index HF.

H5: Direct relationship exists between BMI and race amongst elderly AA and Caucasian women hospitalized with index HF.

H 6: Direct relationship exists between HFpEF or HFrEF and race amongst elderly AA and Caucasian women hospitalized with index HF.

## **Presentation and Discussion of Major Findings**

### **Sample characteristics**

The sample in this study was divided into cases (111) or those subjects with index HF hospitalization who met the criteria for HF rehospitalization and controls (115) or subjects who did not meet the criteria for HF rehospitalization or were readmitted for with a diagnosis other than HF during the selected time frame. In both subgroups, the majority of subjects were octogenarians and Caucasians, but data showed no significant difference between the two subgroups. Current study findings are in contrast to previous studies which demonstrate that AA women have a significantly higher risk of developing acute or chronic HF than other ethnic groups (Graham, 2015; Yancy et al., 2013). However, current study findings support previous studies which also recognized the association between advanced age and HF hospitalization, with statistics showing a prevalence of 80 per 1000 in the over 85-year-old age groups (Go et al., 2013; Yancy et al., 2013). Previous research demonstrated that AA women often suffer with multiple comorbidities such as hypertension and diabetes and have a higher rate of obesity (Graham, 2015). Current data show no statistically significance in BMI at any level at index HF

admission for either race even though 50% of AA women were either obese or morbidly obese. Severe obesity appears to play a significant role in acute HF hospitalization (Joyce et al., 2016). The results of three previous trials addressing obesity and acute HF revealed that women with severe obesity were often younger, hypertensive, diabetic, and were more likely to have a lower NT-proBNP level (Joyce et al., 2016). In the current data, 14.7 % of women were severely obese at index HF admission, and 12.4% at discharge, which resulted in a statistically significant finding for this predictor variable against race.

Hypertension and diabetes mellitus are comorbidities normally associated with early HF rehospitalization related to either HFpEF or HFrEF (Ho et al., 2013) even though only a small amount of studies addressed 31 to 60-day HF rehospitalization and none with a similar cohort as in the present study. Current data show that 93.8 % of subjects in both subgroups suffered with hypertension, while 54% of total subjects suffered with treated diabetes mellitus. AA women represented a statistically significant group of subjects (68%) treated for diabetes mellitus (pills or shots). Unfortunately, these negative health indicators appear to be the predominant finding in this sample of elderly women. Two recent international studies do not support these findings (Ruiz-Laiglesia et al., 2014; van Deursen et al., 2014). The studies showed that chronic kidney disease (41%) represented the most prevalent non-cardiac comorbidity, while diabetes was more uncommon (29%). Both studies were performed internationally and the results may not be generalizable to this cohort.

Elderly women with multiple comorbidities normally require therapy with multiple medications. Current study shows that both subgroups required therapy with multiple medications including diuretics, beta blockers, vasodilators, and ACE-I or ARB. Aldosterone therapy did not appear to be commonly prescribed for either subgroup. Data showed no

statistical significance for use of Aldosterone drug therapy in either cases or controls, even though recent studies show that this therapy appears beneficial in patients with HFrEF and possible beneficial in patients with HFpEF (Merrill, Sweitzer, Lindenfeld & Kao, 2019; Haselhuhn, Brotman, & Wittstein, 2019). Zhang & Baik (2014) addressed medication adherence among Medicare beneficiaries with HF to determine whether race/ethnicity contributed to low adherence of HF drugs. The authors defined adherence as having prescriptions in possession for > 75% of days. Results of the study showed that adherence was best for Caucasians (63%) and worse for AA (52%). Despite these important findings regarding medication adherence and race, current data failed to show a significant difference between race and HF rehospitalization.

The mean length of stay (LOS) at index HF admission were 6.69 days (cases) and 6.76 days (controls) revealing no statistical significance for either subgroup in relation to HF rehospitalization. The literature does not support these findings. These findings contradict the data from the EVEREST trial which concluded that longer LOS resulted in a higher risk for all-cause non-CV readmissions, but a lower risk for HF rehospitalizations (Khan et al., 2015). However, in this trial, AA subjects (6.6%) were underrepresented, the mean age group was lower than in the current study, and the authors only evaluated readmission within 30 days of discharge. No significant relationship was found between BMI (4 levels) and race at index HF admission. In contrast, a significant relationship was noted between BMI (4 levels) and race at discharge. The analyzed data showed a mean reduction in weight (admission to discharge) of 3.43 (Kg) for subjects (cases) and a mean reduction in weight (admission to discharge) of 2.68 (Kg) for controls. While these findings appear subtle, previous literature addressing findings from the ASCEND-HF trial concluded that a substantial number of patients experienced minimal weight loss, while other patients experienced weight gain (Ambrosy et al., 2016). Interestingly,

patients who experienced weight gain were independently associated with a worse post-discharge prognosis in relation to HF rehospitalization (Ambrosy et al., 2016).

### **Research Question One**

Based on the analysis presented in Table 14, only total aggregate of BMI as well as BMI level 1 and BMI level 2 made a positive contribution to the prediction of HF rehospitalization within 31 to 60-day after an index HF hospitalization. None of the other predictor variables showed positive statistical significant relationships to HF rehospitalization within the selected time frame.

Prediction of all-cause HF rehospitalization (31 to 60-day) after an index HF admission remains elusive despite access to an enormous hospital database and evaluation of multiple predictor variables. There are no prior studies evaluating HF rehospitalization within the selected time frame amongst elderly AA and Caucasian women. Previous studies evaluated early (<30-day) HF rehospitalization after index HF hospitalizations in order to identify possible causes (Amarasingham et al., 2010; Au et al., 2012; Dharmarajan et al., 2013; Joynt, Orav & Jha, 2011; McLaren et al., 2016; Muzzarelli et al., 2010). Amarasingham et al (2010) incorporated clinical and social factors from health records into a real-time electronic predictive model at the time of admission to predict 30-day rehospitalization. The authors found that the model performed as well as the CMS models or ADHERE model, particularly after the incorporation of social instability and lower SES. The current research study also incorporated social factors such as marital status and smoking, but could not capture data regarding socioeconomic status because of the retrospective analysis of existing data. Joynt et al. (2011) evaluated disparities and site of care among elderly AA patients with HF. The National Medicare Data Bank provided data for research. AA patients from minority serving hospitals showed the highest readmission rates.

Three conditions of HF, pneumonia, and acute myocardial infarction predicted rehospitalization among this elderly population (Joynt, Orav & Jha, 2011). The current data again failed to capture these comorbid conditions and statistical analysis showed no significant relationship between race and early HF rehospitalization. Hamner & Ellison (2005) conducted a descriptive, correlational study designed to understand the characteristics of a HF patient population who clinicians admitted to a large southeastern, acute-care hospital. A secondary purpose of the study included the determination of risks for rehospitalization within 6 months. Variables from the hospital data bank provided rich data used to identify patients at risk for rehospitalization (Table 8). Hamner & Ellison (2005) concluded that the model composed of discharge variables stood out as the only model that predicted rehospitalization at a significant level. Characteristics of the predictor variables such as age, comorbidities, and types of medications, which are baseline sample characteristics of this study are similar to those presented in the model. Despite these similarities, predictor variables other than BMI in the current study failed to show a positive relationship with early HF readmission. In the current study, both HFpEF and HFrEF showed an association with early HF rehospitalization, but the relationships were not statistically significant. A closer evaluation of the data showed that subjects with HFrEF were 1.6 times more likely to be rehospitalized with HF following an index HF hospitalization.



Table 21. Predictors of Rehospitalization in Heart Failure Patients

<b>Description of variables</b>
Race – Caucasian, AA, Hispanic, Asian
Age – recorded in years
Gender – male or female
CHF class – NYHA I to IV
Ejection fraction – recorded this admission as percentage
Comorbidities – current history reported in the chart and include diabetes, hypertension, renal disease, COPD, alcohol abuse, pulmonary hypertension, atrial fibrillation
Cardiology consult this admission – primary MD is a cardiologist
Case managed status – IS CASE MANAGED- yes or no
Living status at time of admission – alone, family, care facility
Payor – Medicaid, Medicare, private insurance, self-pay
Point of entry into the hospital this admission – ED, admission office, transfer from another facility
Length of hospital stay—recorded in days
Discharge disposition – home with home health, acute care hospital, other type of institution, expired
Medical assistance referrals – indigent drug program, given drug samples
Discharge referrals – hospice, assisted living facility, home health, skilled nursing facility,
Medications prescribed during admission – ACE inhibitors, angiotensin receptor blockers, inotropic infusions, anticoagulants, beta blockers, antiarrhythmics, digoxin, insulin

CHF= congestive heart failure; COPD= chronic obstructive lung disease; ED=emergency room department; ACE=angiotensin converting enzyme; MD= medical doctor; NYHA= New York Heart Association; Hamner et al (2005)

## **Research Question Two and Related Hypotheses**

### **Subtypes of Heart Failure and Obesity**

Based on the analysis presented in tables 17, both HFpEF and HFrfEF showed statistical significant relationships with obesity. Previous literature supports the association between obesity and HFpEF or HFrfEF. Obesity as an isolated risk factor or associated with the MetS remains a major independent risk factor for incident HF (Haass et al., 2011). Haass and colleagues evaluated 4,109 elderly patients for five years as part of the Irbesartan in HF Preserved Ejection Fraction (I-PRESERVE) trial. Most patients (71%) exhibited a BMI greater than 26.5. Women constituted sixty percent of the subjects, and the authors reported a mean left

ventricular ejection fraction (LVEF) of 59%. The average LVEF tended to increase with BMI and the study showed that obesity and HFpEF formed a definite association.

### **Subtypes of Heart Failure and Diabetes Mellitus**

Based on the analysis of Table 18, both HFpEF and HFrEF showed statistical significant relationships with diabetes mellitus. Previous literature supports the association between diabetes and HFpEF or HFrEF (Cavender et al., 2015; dei Cas et al., 2015; Kenchaiah & Vasan, 2015). Kenchaiah and Vasan (2015) evaluated data from the Framingham study and concluded that diabetes mellitus created a 5-fold relative risk for HF in women. Furthermore, in subjects with new-onset HF, women have a 2.8-fold higher odd of HFpEF. Current data showed that AA women often suffer with diabetes mellitus (68%) as well as with HFpEF (48%). Subjects in the control group also exhibited a higher prevalence for HFpEF compared to HFrEF (Table 16), suggesting that this subtype of HF (HFpEF) may contribute less to early HF rehospitalization.

### **Subtypes of Heart Failure in relation to Types of Heart Failure**

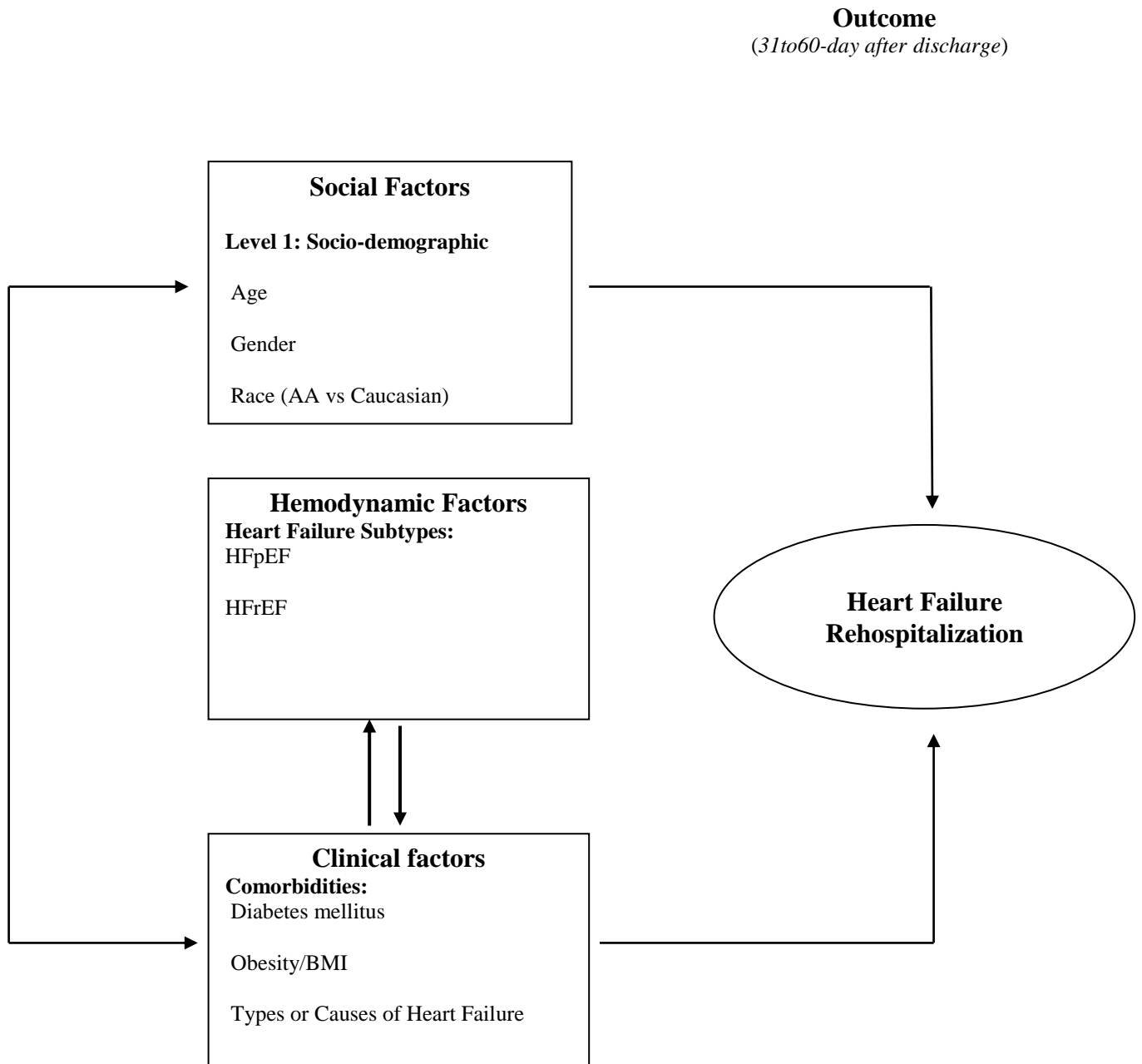
Based on the analyses of Tables 19 and 20, either HFpEF or HFrEF showed statistical relationships with non-ischemic heart disease (cardiomyopathy) and hypertension. Current data showed that non-ischemic heart disease was more prevalent in subjects with HFrEF compared to HFpEF (Table 19). In contrast, hypertension was more prevalent in subjects with HFpEF (Table 20). The literature supports these observations (Messerli, Rimoldi & Bangalore, 2017; Ruiz-Laiglesia et al., 2014; Sato et al., 2010; Shore et al., 2015). Literature shows that cardiac and non-cardiac comorbid risk factors coexist with acute or chronic HF in elderly women (Ruiz-Laiglesia et al., 2014; Sato et al., 2010). Sato and colleagues compared the clinical characteristics of patients hospitalized with acute HF in four epidemiological studies. Most patient ages fell into the over-sixty-five range (>65 years) and demonstrated a higher incidence of hypertension.

Messerli and colleagues (2017) evaluated the pathophysiology of hypertension and proposed that hypertension was more common in patients with HFpEF and longstanding hypertension eventually causes cardiovascular changes that lead to chronic HF. The analyzed data show that hypertension was the most common predictor variable amongst this cohort. Shore et al. (2015) analyzed HF patients from 2005 to 2013 to determine whether the characteristics and outcomes of these patients differ by cardiomyopathy etiology. The authors found that 40.8% suffered with a non-ischemic cardiomyopathy (no history of CAD) with the ejection fraction less than 50%. Hypertension was also a common prevalent predictor variable (48.5%), as noted in the current study. However, this predictor variable failed to show statistical significance with either race or early HF rehospitalization in the current study.

### **Novel Conceptual Framework**

The developed conceptual framework for this study, the “Conceptual Framework of HF Rehospitalization”, was proposed to specifically address HF rehospitalization in elderly AA and Caucasian women in a particular geographic location (Figure 2). This conceptual framework was modified to organize and evaluate factors reported in previous literature as influencing early HF rehospitalization in individuals hospitalized with index HF. The “Conceptual Framework of HF Rehospitalization” identified relationships between clinical, hemodynamic, and social factors (predictor variables), to the outcome variable (31 to 60-day HF rehospitalization). A novel conceptualization is offered which represents the significant findings of the current study (Figure 8). The results propose that a relationship exists between subtypes of HF and clinical factors, as well as between certain social or clinical factors and HF rehospitalization.

Figure 8. Novel Conceptualization Framework of Heart Failure Rehospitalization



## Study Limitations

The design and methodology of this research study created intrinsic limitations that surfaced during and after the data collection period and during the analytical process of the data. This section discusses some potential limitations inherent to secondary analysis of existing data (Cheng & Phillips, 2014; Johnston, 2017). The researcher analyzed the extracted data based on a research question-driven approach and relied on the integrity and accuracy of the dataset, its comprehensiveness, and the facility data collector. As such, it was not possible to review all the codebooks, guidebooks, assessment tools, and quality control measures intrinsic to the dataset, or determine whether the available data may address the research questions and hypotheses (Cheng & Phillips, 2014). Furthermore, the retrospective design posed challenges in capturing a complete set of data for all key variables, which resulted in missing data.

Another potential limitation includes the design of the study. A descriptive, correlational, quantitative design was suitable to address the specific aims of this study, but resulted in the inability to make causal interpretations based on the results (Curtis, Comiskey, & Dempsey, 2016). As such, questions regarding internal and external validity of the results remain unanswered. A longitudinal approach with randomization of research subjects is warranted to address these issues.

The use of self-reporting was another limitation for the study. Subjects self-reported their racial identities, smoking history, and place of residence. In general, self-reporting data are not reliable and may lead to the inability to differentiate self-identified AA and Caucasian women who may be biracial or have a complex ancestry. This perception also encompassed imaging modalities and the reporting of ejection fraction (EF), which may vary within typical error ranges depending on the operator (Cheng et al., 2014). Fortunately, the majority of data were directly

observed measures such as laboratory tests and demographic data which were recorded directly from the hospital database, resulting in accurate and dependable data.

A fourth potential limitation relates to the interval time frame during which the study was conducted. The selected time frame reflected the conditions and characteristics of enrolled subjects during that time interval, their medication profile, and the state of art of the imaging modalities available during that time period. Since that time frame, researchers and pharmacologists have proposed and adopted more advanced therapies for the treatment of HF, and the state of art for imaging modalities have been innovative and modernized.

A final limitation of the study centers on the inability to generalize the results of this study to other groups in other areas of the country. The sample size and sample characteristics reflected elderly AA and Caucasian women residing in a certain geographic location. In addition, data were collected from one site, a large tertiary not-for profit, local community hospital. Therefore, generalizing the results of this study to other HF populations residing in different geographic locations or who are receiving care at tertiary for profit hospitals remains problematic. Future research involving random sampling methods and a longitudinal approach recruiting from a larger and more diverse population of elderly women would be necessary to better inform the public regarding early HF rehospitalization.

### **Implications for Nursing**

The results of this study will provide important data to nurses and nursing managers in nursing practice located in the hospital and outpatient settings. Nurses influence patients' outcomes by serving as advocates as well as educating staff and family when desired changes need to occur regarding specific disease processes such as chronic HF (Kennedy, Murphy &

Roberts, 2013). This study was designed in response to the identified absence of research studies addressing 31 to 60-day HF rehospitalization among elderly AA and Caucasian women.

The study primarily focused on demographic characteristics of research subjects as well as comorbid risk factors of subjects known to be associated with either HFpEF or HFrEF, thereby adding to the growing body of knowledge in the field of risk management (Kenchiah & Vasan, 2015).

This study revealed a number of desired areas where active participation by nurses and nursing leaders may result in subtle changes to health status, thus leading to a reduction in HF hospitalization or rehospitalization. Specifically, analysis of the study data revealed that treated diabetes mellitus (pills or shots), BMI, and hypertension form a statistically significant relationship with HFpEF or HFrEF. Nurses or nurse practitioners may accomplish significant changes in these modifiable risk factors by stressing behaviorally based modifications such as regularly exercising and lowering fat intake.

Given the current study's findings, every attempt should be made to screen elderly AA and Caucasian women hospitalized with HF to determine the subtype of HF which contributed to admission as well as associated co-morbid risk factors. Individuals who fall into the category for increased rehospitalization within 31 to 60-days after index HF hospitalization should undergo a thorough education by nurse educators and nurse leaders regarding their medications and lifestyle changes prior to discharge. In addition, these individuals will benefit from social service interventions and referral to established healthcare sources such as a HF clinic, general practitioners or other health care professionals.

### **Implications for Policy**

The results of this research identified important associations between modifiable and non-modifiable risk factors and subtypes of HF (HFpEF & HFrEF), as well as early (31 to 60-day) HF rehospitalization, among a unique cohort. Nurse practitioners and other healthcare providers have described the association of comorbidities with the two subtypes of HF, as well as with HF hospitalizations and rehospitalizations (Prasun et al., 2012; Prasun et al., 2017). However, policies addressing the data identified by this research are nonexistent since this research is unique, involving 31 to 60-day HF rehospitalization amongst elderly AA and Caucasian women. Therefore, nurses and nurse leaders should adopt policies designed to address elderly AA and Caucasian women and identified risk factors.

Healthy People 2020 centers on a continuous governmental strategy which identifies goals and objectives to improve the health status of all Americans and increase public and professional awareness of prevention ([www.healthypeople.gov](http://www.healthypeople.gov)). Healthy people 2020 describe 28 focus areas, one of which emphasizes heart disease and stroke. The overarching goal of this governmental initiative is to “improve CV health through prevention, detection, and treatment of risk factors” ([www.healthypeople.gov](http://www.healthypeople.gov)).

Research clearly demonstrates that modifiable and non-modifiable risk factors are often linked to chronic diseases such as HF, which results in a tremendous financial burden to society, since costs include treatment of both the comorbidities and HF (Voigt et al., 2014). Effective interventional policies that nurses may find beneficial for this cohort should also address modifiable risk factors. These policies may include: 1. Promote health-related programs through social marketing and seminars as well as home telemonitoring interventions (Kitsiou, Paré & Jaana, 2015). 2. Target audiences at churches, government groups, clinics, rehabilitation centers,



and outpatient cardiovascular (CV) centers. 3. Promote social awareness through holistic, coordinated, and person-centered care, which may address frailty, a condition common to this cohort (Prince et al., 2015). 4. Finally, adopt a universal language through the use of a seamless computer system to raise the level of awareness of risk factors amongst elderly women.

### **Implications for Future Nursing Research**

The recently concluded study expanded the understanding of how certain predictor variables contribute to early HF rehospitalization after an index HF hospitalization and the association of these variables with race and HFpEF or HFrEF. The following recommendations for future research are proposed, based on the limitations of the research study and on guidelines that were beyond the scope of the current analysis.

The first recommendation is to reexamine the design and methodological approach of the current study. This study utilized a descriptive, correlational, cross-sectional, quantitative study design with a retrospective review of medical records to address HF rehospitalization based on a conceptual framework, the “Conceptual Framework of HF Rehospitalization.” While this study addressed important phenomena in the area of HF amongst elderly AA and Caucasian women, many questions remain unanswered regarding external validity. A single research site provided the database for the research study rather than from quality registries. Future studies utilizing a similar conceptual model should investigate the same predictor variables, but in a prospective manner using a longitudinal approach and incorporating more diverse samples of gender, race, and research sites, because of the increasing complexity of cardiac care and gender specific cardiac diastolic dysfunction (Jaarsma et al., 2014; Maslov et al., 2019).

Further exploration involving the contribution of predictor variables to early HF rehospitalization should include a nursing intervention. Recent developments in healthcare

through the application of more advanced imaging techniques, improved therapeutic and medical therapy such as sacubitril/valsartan (Entresto), and incorporation of advanced cardiac devices such as the left ventricular assist device (LVAD) and automated implantable cardioverter defibrillator (AICD) (excluded from this study), invites a new creative approach to HF management (Jaarsma et al., 2014, Stamp et al., 2018; Yandrapalli et al., 2018). Nurse scientists and advanced practice nurses will influence “precision medicine” by integrating novel modalities into HF research to the right population at the right time (Stamp et al., 2018).

A final recommendation regarding future nursing research relating to HF rehospitalization involves a broader approach for endpoints that address time frame, health outcomes, dissatisfaction, and perhaps the economic consequences of healthcare (Fonarow, Konstam & Yancy, 2017; Mozaffarian et al., 2016). Nurse scientists could develop an innovative conceptual model that provides a stronger explanatory power to capture the phenomena of predictor variables and their association with early HF rehospitalization and HFpEF or HPrEF. This will aid in identifying the most effective frameworks that nursing scientists can incorporate in their endeavors to translate theory into practice.

### **Chapter Conclusion**

This chapter discussed the most important findings of the current dissertation study; the limitations of the study, nursing implications, and recommendations for future research in the context of HF rehospitalization. The specific aims of the study were achieved and cross tabulation analyses added clinically relevant information. The results of the study generated evidence regarding which predictor variables contributed to early HF rehospitalization, as well as specific associations amongst study variables. This study provided a basis for future research by nurse scientists and nurse practitioners in the areas of investigation in HF research. Future nurse

leaders must be aware that retrospective review of existing data creates opportunities to advance nursing science as well as study limitations.

## APPENDIX A

### Inclusion and Exclusion Study Criteria

#### *Inclusion Criteria*

- \_\_\_\_\_ Index hospitalization with admitting or discharge diagnosis of HF
- \_\_\_\_\_ Diagnostic Related Group (DRG) 291, 292, 293, 428.0
- \_\_\_\_\_ Greater than 24 hours admission.
- \_\_\_\_\_ Elderly AA and Caucasian women
- \_\_\_\_\_ Age greater than or equal to 65 years
- \_\_\_\_\_ Rehospitalization within 31-60-day following discharge after an index hospitalization for HF
- \_\_\_\_\_ Admitted between October 2012 and October 2015

#### *Exclusion Criteria*

- \_\_\_\_\_ Left ventricular assist devices (LVAD) and automated implantable cardioverter defibrillator (AICD).
- \_\_\_\_\_ Previous cardiac transplant or are candidates for cardiac transplantation
- \_\_\_\_\_ Less than 24 hours admission
- \_\_\_\_\_ Subject mortality within 60 days after index hospitalization
- \_\_\_\_\_ Patients discharged to a hospice setting with life expectancy of less than 90 days
- \_\_\_\_\_ Left against medical advice
- \_\_\_\_\_ Discharge disposition or regional socioeconomic status unknown

## APPENDIX B

### Sample Size Determination Formula

Effect size 2.5 = Small to Moderate Effect Size for odds ratio

Derived for Ethnicity variance in Howie-Esquivel & Dracup (2007)

Alpha = 0.05

Probability of readmission range 20% to 50%

Power = 0.8

Sample Size = 164 - 192

15% to account for exclusions = 25 - 29

Final Sample Size = 221

APPENDIX C

Demographic Form

Abstractor initials _____	Date Completed _____
Index Admission Date ___/___/___	Index Discharge Date ___/___/___
Code Number _____	
HF rehospitalization within 31-60-day of index	
HF admission	1= yes; 2= no
Admission Year _____	
Race	1 = White/Caucasian 2 = Black/ African American 3 = Not stated 4 = Other
Marital Status	1 = Married 2 = Single 3 = Widowed 4 = Divorced 5 = Separated 99 = Not stated
Age at Index HF Admission	1 = 65-70 2 = 70-75 3 = 75-80 4 = > 80
Primary Payer	1 = Medicare 2 = Medicaid 3 = Private including HMO 4 = Self pay 5 = No charge 6 = Other
Social Status	1 = Living alone 2 = Living with family 3 = Nursing home resident 4 = Personnel care facility 5 = Other

APPENDIX D

Data Collection Form

Code Number \_\_\_\_\_

Admission Year \_\_\_\_\_

Type of Admission  
1 = Emergency  
2 = Urgent  
3 = Elective  
99 = Not available

Length of Stay \_\_\_\_\_days

Source of Admission  
1 = Emergency room  
2 = Physician office  
3 = Transfer from a hospital  
4 = Admitted from a clinic  
5 = Admitted from urgent care facility  
6 = Transfer from nursing home  
7 = Other  
99 = Not available

Discharge Status  
1 = Routine/discharge home  
2 = Discharged to short term facility  
3 = Discharged to long term facility  
4 = Left AMA  
5 = Transferred to another hospital  
99 = Not stated

Smoking History  
1 = Current smoker  
2 = Never  
3 = Past history  
99 = Missing

Heart Rhythm on Admission

Normal sinus rhythm	1 = yes, 2 = no, 3 = missing
Sinus tachycardia	1 = yes, 2 = no, 3 = missing
Supraventricular tachycardia	1 = yes, 2 = no, 3 = missing
Atrial fibrillation	1 = yes, 2 = no, 3 = missing
Sinus bradycardia	1 = yes, 2 = no, 3 = missing
Other rhythm disorder	1 = yes, 2 = no, 3 = missing

Laboratory Data and Vitals at Admission and Discharge

Admission Data

Heart rate \_\_\_\_\_ bpm  
Blood pressure \_\_\_\_\_ mmHG  
Height \_\_\_\_\_ inches  
Weight \_\_\_\_\_ Kg  
BMI 1 = <25, 2 = 25-<30, 3 = 30-<40, 4 = >40

BUN Result \_\_\_\_\_  
Creatinine Result \_\_\_\_\_  
NT-proBNP or BNP Result \_\_\_\_\_  
Total cholesterol Result \_\_\_\_\_  
Hgb/HCT Result \_\_\_\_\_

Discharge Data

Heart rate \_\_\_\_\_ bpm  
Blood pressure \_\_\_\_\_ mmHG  
Height \_\_\_\_\_ inches  
Weight \_\_\_\_\_ Kg  
BMI 1 = <25, 2 = 25-<30, 3 = 30-<40, 4 = >40

BUN Result \_\_\_\_\_  
Creatinine Result \_\_\_\_\_  
NT-proBNP or BNP Result \_\_\_\_\_  
Total cholesterol Result \_\_\_\_\_  
Hgb/HCT Result \_\_\_\_\_

Comorbidities

History of hypertension (BP>140/90) 1 = yes, 2 = no, 3 = missing  
History of CAD 1 = yes, 2 = no, 3 = missing  
Atrial Fibrillation 1 = yes, 2 = no, 3 = missing  
Obesity (BMI>30) 1 = yes, 2 = no, 3 = missing  
Chronic lung disease 1 = yes, 2 = no, 3 = missing  
Anemia (Hgb < 11g/dl) 1 = yes, 2 = no, 3 = missing  
Treated Diabetes Mellitus (pills or shots) 1 = yes, 2 = no, 3 = missing  
Previous Stroke 1 = yes, 2 = no, 3 = missing  
Peripheral vascular Disease 1 = yes, 2 = no, 3 = missing  
Dyslipidemia (chol>200) 1 = yes, 2 = no, 3 = missing  
Valvular heart disease 1 = yes, 2 = no, 3 = missing



Type of Heart Failure at Index Hospitalization

Ischemic (hx of CAD or MI)	1 = yes, 2 = no, 3 = missing
Non-Ischemic (no hx of CAD or MI)	1 = yes, 2 = no, 3 = missing
Hypertensive	1 = yes, 2 = no, 3 = missing
Valvular	1 = yes, 2 = no, 3 = missing
Tachycardia induced	1 = yes, 2 = no, 3 = missing
Endocrine/Toxic causes (Thyroid, drug induced)	1 = yes, 2 = no, 3 = missing
Defined cardiomyopathy (e.g. hypertrophic)	1 = yes, 2 = no, 3 = missing
Unknown	1 = yes, 2 = no, 3 = missing
Other	1 = yes, 2 = no, 3 = missing

Discharge Medications after Index Hospitalization

*Obtained from the Medication Reconciliation Form*

Angiotensin converting enzyme Inhibitor	1 = yes, 2 = no, 3 = missing
Angiotensin II receptor blocker	1 = yes, 2 = no, 3 = missing
Aldosterone antagonist	1 = yes, 2 = no, 3 = missing
Antiplatelet therapy	1 = yes, 2 = no, 3 = missing
Vasodilators	1 = yes, 2 = no, 3 = missing
Beta-blocker	1 = yes, 2 = no, 3 = missing
Anticoagulation therapy	1 = yes, 2 = no, 3 = missing
Diuretic	1 = yes, 2 = no, 3 = missing
Lipid-lowering agent (any)	1 = yes, 2 = no, 3 = missing
Diabetic medications (any)	1 = yes, 2 = no, 3 = missing
Other Medications (any)	1 = yes, 2 = no, 3 = missing

Left ventricular (LV) Function

LV evaluation (transthoracic echo or MRI) done this admission      1 = yes, 2 = no

Ejection fraction (EF) % documented      1 = yes, 2 = no

EF value

Reduced or < 40%      Result\_\_\_\_\_

Borderline or 41-50%      Result\_\_\_\_\_

Preserved or >50%      Result\_\_\_\_\_

EF based on clinical description

Normal LV function	1 = yes, 2 = no
Mild LV dysfunction or mild hypokinesis	1 = yes, 2 = no
Moderate to severe LV dysfunction	1 = yes, 2 = no
Unable to determine	1 = yes, 2 = no
No echo	1 = yes, 2 = no

#### Pulmonary Hypertension

Right atrial pressure recorded	1 = yes, 2 = no
Result_____	
Transticuspid gradient recorded	1 = yes, 2 = no
Result_____	
Pulmonary artery systolic pressure (PASP) recorded	1 = yes, 2 = no
Result_____	

APPENDIX E

Rehospitalization Data Collection Form

Code Number \_\_\_\_\_

Admission Year \_\_\_\_\_

Readmission Admit Date \_\_\_/\_\_\_/\_\_\_

Type of Admission  
1 = Emergency  
2 = Urgent  
3 = Elective  
99 = Not available

Length of Stay \_\_\_\_\_ days

Readmission Discharge date \_\_\_/\_\_\_/\_\_\_

Source of Admission  
1 = Emergency room  
2 = Physician office  
3 = Transfer from a hospital  
4 = Admitted from a clinic  
5 = Admitted from urgent care facility  
6 = Transfer from nursing home  
7 = Other  
99 = Not available

Smoking History  
1 = Current smoker  
2 = Never  
3 = Past history  
99 = Missing

Heart Rhythm on Admission  
Normal sinus rhythm 1 = yes, 2 = no, 3 = missing  
Sinus tachycardia 1 = yes, 2 = no, 3 = missing  
Supraventricular tachycardia 1 = yes, 2 = no, 3 = missing  
Atrial fibrillation 1 = yes, 2 = no, 3 = missing  
Sinus bradycardia 1 = yes, 2 = no, 3 = missing  
Other rhythm disorder 1 = yes, 2 = no, 3 = missing

Laboratory Data and Vitals at Admission

Admission Data

Heart rate \_\_\_\_\_ bpm

Blood pressure \_\_\_\_\_ mmHG

Height \_\_\_\_\_ inches  
 Weight \_\_\_\_\_ Kg  
 BMI 1 = <25, 2 = 25-<30, 3 = 30-<40, 4 = >40

BUN Result \_\_\_\_\_  
 Creatinine Result \_\_\_\_\_  
 NT-proBNP or BNP Result \_\_\_\_\_  
 Total cholesterol Result \_\_\_\_\_  
 Hgb/HCT Result \_\_\_\_\_

Comorbidities

History of hypertension (BP>140/90) 1 = yes, 2 = no, 3 = missing  
 History of CAD 1 = yes, 2 = no, 3 = missing  
 Atrial Fibrillation 1 = yes, 2 = no, 3 = missing  
 Obesity (BMI>30) 1 = yes, 2 = no, 3 = missing  
 Chronic lung disease 1 = yes, 2 = no, 3 = missing  
 Anemia (Hgb < 11g/dl) 1 = yes, 2 = no, 3 = missing  
 Treated Diabetes Mellitus (oral or injection) 1 = yes, 2 = no, 3 = missing  
 Previous Stroke 1 = yes, 2 = no, 3 = missing  
 Peripheral vascular Disease 1 = yes, 2 = no, 3 = missing  
 Dyslipidemia (chol>200) 1 = yes, 2 = no, 3 = missing  
 Valvular heart disease 1 = yes, 2 = no, 3 = missing

Type of Heart Failure at Readmission

Ischemic (hx of CAD or MI) 1 = yes, 2 = no, 3 = missing  
 Non-Ischemic (no hx of CAD or MI) 1 = yes, 2 = no, 3 = missing  
 Hypertensive 1 = yes, 2 = no, 3 = missing  
 Valvular 1 = yes, 2 = no, 3 = missing  
 Tachycardia induced 1 = yes, 2 = no, 3 = missing  
 Endocrine/Toxic causes (Thyroid, drug induced) 1 = yes, 2 = no, 3 = missing  
 Defined cardiomyopathy (e.g. hypertrophic) 1 = yes, 2 = no, 3 = missing  
 Unknown 1 = yes, 2 = no, 3 = missing  
 Other 1 = yes, 2 = no, 3 = missing

Medications at time of Readmission after Index Hospitalization

*Obtained from the Medication Reconciliation Form*

Angiotensin converting enzyme Inhibitor 1 = yes, 2 = no, 3 = missing  
 Angiotensin II receptor blocker 1 = yes, 2 = no, 3 = missing  
 Aldosterone antagonist 1 = yes, 2 = no, 3 = missing  
 Antiplatelet therapy 1 = yes, 2 = no, 3 = missing  
 Vasodilators 1 = yes, 2 = no, 3 = missing  
 Beta-blocker 1 = yes, 2 = no, 3 = missing  
 Anticoagulation therapy 1 = yes, 2 = no, 3 = missing

Diuretics	1 = yes, 2 = no, 3 = missing
Lipid-lowering agent (any)	1 = yes, 2 = no, 3 = missing
Diabetic medications (any)	1 = yes, 2 = no, 3 = missing
Other medications (any)	1 = yes, 2 = no, 3 = missing

### Left ventricular (LV) Function

LV evaluation (transthoracic echo or MRI) done this admission 1 = yes, 2 = no

Ejection fraction (EF) % documented 1 = yes, 2 = no

EF value

Reduced or < 40% Result\_\_\_\_\_

Borderline or 41-50% Result\_\_\_\_\_

Preserved or >50% Result\_\_\_\_\_

EF based on clinical description

Normal LV function 1 = yes, 2 = no

Mild LV dysfunction or mild hypokinesis 1 = yes, 2 = no

Moderate to severe LV dysfunction 1 = yes, 2 = no

Unable to determine 1 = yes, 2 = no

No echo 1 = yes, 2 = no

### Pulmonary Hypertension

Right atrial pressure recorded 1 = yes, 2 = no

Result\_\_\_\_\_

Transticuspid gradient recorded 1 = yes, 2 = no

Result\_\_\_\_\_

Pulmonary artery systolic pressure (PASP) recorded 1 = yes, 2 = no

Result\_\_\_\_\_

## APPENDIX F

### IRB Protocol Form of CUA

The protocol form must have information spelling out the following:

1. Name and department(s) of the investigator(s)
2. Title
3. Signature of responsible faculty members
4. Whether or not external funding is proposed
5. Purpose of the study
6. Description of the subject or control cases
7. Description of the methodology
8. Potential scientific benefits of the research
9. Qualifications of the investigator(s)
10. Description of any deception
11. Procedures for protecting the anonymity of the subjects
12. Methods for ensuring informed consent, including a copy of the proposed informed consent statement (if needed).

## APPENDIX G

### Data Collection Protocol

1. Evaluate enrolled cases of elderly AA and Caucasian women admitted with index HF during inclusive research period
2. Determine if enrolled cases of subjects meet inclusion or exclusion criteria
3. Select subjects who did not experience HF rehospitalization (no HF readmission within 31-60-day after index HF hospitalization)
4. Select controls who meet inclusion criteria
5. Match institution, admission month and admission year
6. Review medical records for data collection purposes
7. Obtain demographic data
8. Obtain patient history data
9. Obtain physical examination data
10. Obtain diagnostic testing data
11. Extract data relevant to left ventricular ejection fraction (EF)
12. Extract data relevant to pulmonary artery systolic hypertension (PASP)
13. Evaluate abstracted data with guidance of dissertation committee faculty after registering 10 enrolled cases into the study and continue at regular intervals until completion of research study
14. Evaluate for data security and HIPAA compliance

## APPENDIX H

### Conceptual Model of Social Factors

---

**Calvillo-King, Linda** <Linda.Calvillo-King@med.usc.edu>  
To: Carolyn Sue-Ling <74sueling@cua.edu>

Thu, Feb 15, 2018 at 5:38 PM

Dear Carolyn Sue-Ling,

Glad to hear of your interest in this field. You have my permission to use my conceptual model of social factors.

Best Regards,  
Linda Calvillo-King, MD  
[Quoted text hidden]



## APPENDIX I

### COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

#### COMPLETION REPORT – PART 1 OF 2

##### COURSEWORK REQUIREMENTS\*

\* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details.

See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Carolyn Sue-Ling (ID: 6069462)
- **Institution Affiliation:** The Catholic University of America (ID: 2060)
- **Institution Email:** 74sueling@cua.edu
- **Institution Unit:** Nursing
- **Curriculum Group:** Social & Behavioral Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 2 - Stage 2
- **Description:** Social & Behavioral Research
- **Record ID:** 26044439
- **Completion Date:** 01-Feb-2018
- **Expiration Date:** 01-Feb-2019
- **Minimum Passing:** 80
- **Reported Score\*:** 100

##### REQUIRED AND ELECTIVE MODULES ONLY DATE COMPLETED SCORE

- SBE Refresher 1 – Instructions (ID: 943) 01-Feb-2018 No Quiz
- SBE Refresher 1 – History and Ethical Principles (ID: 936) 01-Feb-2018 2/2 (100%)
- SBE Refresher 1 – Federal Regulations for Protecting Research Subjects (ID: 937) 01-Feb-2018 2/2 (100%)
- SBE Refresher 1 – Informed Consent (ID: 938) 01-Feb-2018 2/2 (100%)
- SBE Refresher 1 – Research with Prisoners (ID: 939) 01-Feb-2018 2/2 (100%)
- SBE Refresher 1 – Research in Educational Settings (ID: 940) 01-Feb-2018 2/2 (100%)
- The Catholic University of America Courses (ID: 14411) 01-Feb-2018 No Quiz

**For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution**

**identified above or have been a paid Independent Learner.**

**Verify at:** [www.citiprogram.org/verify/?k9a684161-90ec-4de1-b879-6274b84fb371-26044439](http://www.citiprogram.org/verify/?k9a684161-90ec-4de1-b879-6274b84fb371-26044439)

**Collaborative Institutional Training Initiative (CITI Program)**

Email: [support@citiprogram.org](mailto:support@citiprogram.org)

Phone: 888-529-5929

Web: <https://www.citiprogram.org>

### COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

#### COMPLETION REPORT – PART 2 OF 2

##### COURSEWORK TRANSCRIPT\*\*

\*\* NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Carolyn Sue-Ling (ID: 6069462)
- **Institution Affiliation:** The Catholic University of America (ID: 2060)
- **Institution Email:** 74sueling@cua.edu
- **Institution Unit:** Nursing
- **Curriculum Group:** Social & Behavioral Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 2 - Stage 2
- **Description:** Social & Behavioral Research
- **Record ID:** 26044439
- **Report Date:** 31-Mar-2018
- **Current Score\*\*:** 100

##### REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES MOST RECENT SCORE

- SBE Refresher 1 – History and Ethical Principles (ID: 936) 01-Feb-2018 2/2 (100%)
- The Catholic University of America Courses (ID: 14411) 31-Mar-2018 No Quiz
- SBE Refresher 1 – Federal Regulations for Protecting Research Subjects (ID: 937) 01-Feb-2018 2/2 (100%)
- SBE Refresher 1 – Informed Consent (ID: 938) 01-Feb-2018 2/2 (100%)
- SBE Refresher 1 – Research with Prisoners (ID: 939) 01-Feb-2018 2/2 (100%)
- SBE Refresher 1 – Research in Educational Settings (ID: 940) 01-Feb-2018 2/2 (100%)
- SBE Refresher 1 – Instructions (ID: 943) 01-Feb-2018 No Quiz
- SBE Refresher 1 – International Research (ID: 15028) 01-Feb-2018 2/2 (100%)
- SBE Refresher 1 – Defining Research with Human Subjects (ID: 15029) 01-Feb-2018 2/2 (100%)
- SBE Refresher 1 – Assessing Risk (ID: 15034) 01-Feb-2018 2/2 (100%)

SBE Refresher 1 – Privacy and Confidentiality (ID: 15035) 01-Feb-2018 2/2 (100%)

SBE Refresher 1 – Research with Children (ID: 15036) 01-Feb-2018 2/2 (100%)

**For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution**

**identified above or have been a paid Independent Learner.**

**Verify at:** [www.citiprogram.org/verify/?k9a684161-90ec-4de1-b879-6274b84fb371-26044439](http://www.citiprogram.org/verify/?k9a684161-90ec-4de1-b879-6274b84fb371-26044439)

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Web: <https://www.citiprogram.org>

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