

Fall 12-12-2010

The Relationship of Personal Characteristics, Behavioral Capability, Environmental Factors, and Hypertension Medication Adherence in African American Adults with Metabolic Syndrome

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This dissertation, THE RELATIONSHIP OF PERSONAL CHARACTERISTICS, BEHAVIORAL CAPABILITY, ENVIRONMENTAL FACTORS, AND HYPERTENSION MEDICATION ADHERENCE IN AFRICAN AMERICAN ADULTS WITH METABOLIC SYNDROME by Karen Andrea Armstrong was prepared under the direction of the candidate's dissertation committee. It is accepted by the committee members in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing in the Byrdine F. Lewis School of Nursing in the College of Health and Human Sciences, Georgia State University.

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ABSTRACT

THE RELATIONSHIP OF PERSONAL CHARACTERISTICS, BEHAVIORAL CAPABILITY, ENVIRONMENTAL FACTORS, AND HYPERTENSION MEDICATION ADHERENCE IN AFRICAN AMERICAN ADULTS WITH METABOLIC SYNDROME

by

KAREN ANDREA ARMSTRONG

Disparities in medication adherence (MA) associated with African American (AA) adults may be related to a dynamic interplay between personal factors, behavioral capability, and environmental factors. The purpose of the study was to examine this relationship in AA adults with metabolic syndrome (MetS).

A cross-sectional, correlational analysis was conducted from baseline data from a larger intervention study. Constructs from the Social Cognitive Theory were used to predict MA. The sample of 91 AA adults with MetS was primarily middle-aged (age range 45-70 years old; M 53, SD 6.3), female (79%), relatively well-educated, and married.

Despite being on antihypertensive medications, 53% of the participants presented with uncontrolled high blood pressure ($\geq 130/90$ mmHg). Although the vast majority (95%) of the sample displayed adequate health literacy (HL), 30% of the sample was non-adherent to their medication regimen.

A positive significant relationship was found between age and MA [χ^2 (1, n = 90) = 6.71, p = .01]. Stress [χ^2 (1, n = 90) = 6.28, p = .012] and social support (SS) [χ^2 (1, n = 90) = 4.10, p = .04] were the only significant relationships among environmental

factors, barriers and hypertension MA. Highly stressed AA adults were significantly more likely to be non-adherent or had a 15% reduction in the odds of hypertension MA. Similarly, adults with a low income were 5.8 times more likely to be non-adherent (OR 5.828, 95% CI, 1.014-33.493, $p = .0482$), while those with low SS had a 9% reduction in the odds of MA; SS trended toward significance (OR.914. 95% CI .823-1.016, $p = .09$). With increasing age, AA adults were more likely to be non-adherent (OR 1.12, 95% CI 1.028-1.220, $p = .0096$).

Most of the participants reported a high degree of autonomy, satisfaction with their health care climate, and the availability of SS. Although increasing age, adequate SS, high stress, and adequate HL appeared to influence MA in AA adults with MetS, the research questions were only partially answered. Further investigation of the relationships and potential mediating pathways between personal characteristics, environmental factors, behavioral capability and hypertension MA in AA adults with MetS is needed.

INDEX WORDS: Medication Adherence, Health Literacy, Stress, Depression, Social Support, Health Care Climate, and Medication Non-adherence

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KAREN ANDREA ARMSTRONG

A DISSERTATION

Presented in Partial Fulfillment of Requirements for the
Degree of Doctor of Philosophy in Nursing in the Byrdine F. Lewis
School of Nursing in the College of Health and Human Sciences
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2010

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ACKNOWLEDGEMENTS

First, I thank God for His faithfulness and guidance as He brought me to the completion of this dissertation. I thank God for His loving care and gentle reminders that all things work together for my good.

I thank Dr. Pat Clark for getting me started on this incredible journey, and for offering me guidance and support throughout the program.

To my committee chair, Dr. Cece Grindel, I owe you a debt of gratitude. You took me under your wing and nurtured me. I will always be grateful for your patience, dedication, support, concern, and most of all, for sharing your wealth of knowledge and experience with me. Thank you for generously giving of your time and attention in refining this product. Thank you for your investment in my success.

I also thank Drs. Laura Kimble and Dorothy Coverson for their support, invaluable advice, and encouragement.

To my other committee members----Drs. Dee Baldwin and Frances McCarty, thank you for your guidance and incredible support. You have made an indelible impression on my personal and professional development and I am very grateful to you both. Special thanks to Dr. Carol Grantham, Liping Zhao and Dawn Aycock for going above and beyond the call of duty to help me.

I would like to express my sincere appreciation and heartfelt thanks to the Principal Investigators of the Meta health study, Dr. Sandi Dunbar, Dr. Pat Clark, Dr. Priscilla Pemu and Dr. Arshed Quyyumi, for affording me the privilege of using the META-health data for my dissertation research. I owe you a huge debt of gratitude.

Thank you to my parents, siblings, and friends for your incredible love and support. Last, but certainly not least, I thank my husband, Winston, and my children, Shenelle and Shane for their unwavering love and support. Thank you for always being there for me and for taking such great care of me as I worked on this dissertation. Thank you for your patience, understanding, care, and many acts of love. I appreciate your prayers, encouragement, and commitment to my success. I could not have achieved this milestone without your unconditional love and support. Your dedication is truly unmatched.

To God be the glory, great things He has done!

“This work was partially supported by funding from National Heart, Lung, and Blood Institute, NIH (1 U01 HL079156) (Dr. Quyyumi, PI) and PHS Grant M01-RR00039 from the Emory General Clinical Research Center, NIH, National Center for Health Resources.”

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LIST OF ABBREVIATIONS

AA	African Americans
AACE	American Association of Clinical Endocrinologists
ACE	Angiotensin Converting Enzyme
ACS	Acute Coronary Syndrome
ADA	American Diabetes Association
AHA	American Heart Association
ALLHAT	Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial
ARB	Angiotensin Receptor Blockers
ATP III	Adult Treatment Panel, Third Meeting
BDI	Beck Depression Inventory
BMI	Body Mass Index
BP	Blood Pressure
CDC	Centers for Disease Control and Prevention
CAD	Coronary Artery Disease
CHD	Coronary Heart Disease
CKD	Chronic Kidney Disease
CPN	Community Practitioner Network
CRP	C-Reactive Protein
CVD	Cardiovascular Disease
ESRD	End Stage Renal Disease
ESSI	<i>Enrichd</i> Social Support Scale

FG	Fasting Glucose
GED	General Education Diploma
HC	Hip Circumference
HCC	Health Care Climate
HDL	High Density Lipoprotein
HL	Health Literacy
HHS	Health and Human Services
HPA	Hypothalamus Pituitary Adrenal Axis
HTN	Hypertension
IDF	International Diabetes Foundation
IFG	Impaired Fasting Glucose
IOM	Institute of Medicine
IR	Insulin Resistance
IRB	Institutional review Board
JNC7	Seventh Meeting of the Joint National Committee for the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
LDL	Low Density Lipoprotein
MA	Medication Adherence
Meta-health	Morehouse and Emory Team Up to Eliminate Cardiovascular Health Disparities
MetS	Metabolic Syndrome
MMSE	Mini Mental Status Exam
NAFLD	Non-Alcoholic Fatty Liver Disease

NCEP	National Cholesterol Education Program
NHANES	National Health and Nutrition Examination Survey
NHLBI	National Heart, Lung, and Blood Institute
NIH	National Institutes of Health
OGTT	Oral Glucose Tolerance Test
OR	Odds Ratio
OSA	Obstructive Sleep Apnea
REALM	Rapid Estimate of Adult Literacy in Medicine
PAI	Plasminogen Activator Inhibitor
PCI	Percutaneous Coronary Intervention
PSS	Perceived Stress Scale
SAS	Statistical Analysis Software
SCT	Social Cognitive theory
SE	Self Efficacy
SNS	Sympathetic Nervous System
SS	Social Support
TG	Triglycerides
TOFHLA	Test of Functional Health Literacy in Adults
U.S.	United States
VIF	Variance Inflation Factor
WC	Waist Circumference
WHO	World Health Organization

Chapter I

Introduction

Medication adherence (MA) is important because many of the medications prescribed are for chronic illnesses, such as metabolic syndrome (MetS). MetS is a cluster of metabolic abnormalities that increases one's susceptibility to risks of cardiovascular disease (CVD) (Grundy, 2005) and like other chronic illnesses, if left uncontrolled can lead to more serious outcomes. MetS is categorized by multiple risk factors which confer greater risks for adverse clinical outcomes compared to a single factor (Chen et al., 2004; Blank & Brunton, 2008). Given that multiple medications are prescribed for adults with chronic illnesses (Murray et al., 2004a), medication adherence may be especially challenging in this cohort of African American (AA) adults with MetS and its attendant multiple risk factors.

Empiric evidence shows that African Americans frequently report multiple co-morbidities, for which prescription medications are the primary therapeutic interventions (Hilgers & Mann, 2008; Murray et al., 2004b). The finding is significant because AA adults with chronic conditions frequently self-administer multiple prescription medications without adequate supervision (Murray et al., 2004a). Sudano and Baker (2001) found that a greater percent (73%) of AA adults report not following their medication regimens compared to their White counterparts (64%). Therefore, medication self-management in AA adults is an important health care issue because AA adults frequently display low medication adherence (Sudano & Baker, 2001).

Low medication adherence appears to be a patient-centered term; it illuminates the extent to which an individual's behavior deviates from medical or health advice (Arozullah, Kim & Lee, 2006). It is well-documented that low medication adherence contributes to additional health care costs due to frequent hospital re-admissions and emergency department visits and a reduction in therapeutic value, and increases in the risk for complications from chronic illnesses as a result of inappropriate dosing (Baker et al., 2007; Frishman, 2007; Gazmararian, Baker, Parker, & Blazer, 2006; Osterberg & Blaschke, 2005; Sudano & Baker, 2001).

Moreover, of considerable concern to nursing practice is that, although medication adherence research spans over 30 years, very little of the existing research addresses the topic from an African American perspective (Vlasnick, Aliotta, & DeLor, 2005). More research is needed since minorities, especially AA adults, continue to experience significant health disparities (Anuurad, Chiem, Pearson, & Berglund, 2007; Smedley, Stith, & Nelson, 2003) in cardiovascular disease and diabetes mellitus.

Although African American(s) (AA) have an increased risk for cardiovascular disease (CVD) and diabetes, several studies have found that most AAs are unaware of their increased risk for developing metabolic syndrome (MetS) (Grundy, Brewer, Cleeman, Smith, & Lenfant, 2005). In fact, African Americans are at greatest risk (39%) for hypertension when compared to Whites (29%), and Hispanics (28%) (Angell et al., 2008). The increasing risk for hypertension in African Americans confers added risks for cardiovascular disease (Anuurad, Chiem, Pearson, & Berglund, 2007; Poon, Lal, Ford, & Braun, 2009). Given the greater prevalence of hypertension-related morbidity and mortality in African Americans, low hypertension medication adherence may be an even

greater problem in this population because empiric evidence shows that low medication adherence is a barrier to achieving proper blood pressure control (Bosworth et al., 2006; Grundy, Brewer, Cleeman, Smith, & Lenfant, 2005). Low hypertension medication adherence often results in uncontrolled high blood pressure, a critical component of MetS which frequently leads to severe complications associated with CVD (Grundy, Brewer, Cleeman, Smith, & Lenfant, 2008; Martins, Tareen, Ogedegbe, Pan, & Norris, 2008).

Purpose Statement

The purpose of this study was to examine medication adherence in AA adults with MetS by determining the relationships among personal characteristics, behavioral capability, and environmental factors. Personal characteristics included age, gender, income, depression, and education, behavioral capability was conceptualized as health literacy, while environmental factors included stress, social support, complexity of the medication regimen, and quality of the therapeutic relationship between patient and healthcare provider. The research suggests that a significant relationship exists among medication adherence and key study variables in a variety of clinical populations, albeit the exact nature of the relationship remains unclear. Therefore, more research was warranted to describe more clearly suspected relationships in a cohort of AA adults with MetS. It was expected that an investigation of key study variables would yield similar findings to those unearthed in other study populations. In study populations such as cancer, high blood pressure, renal populations, and diabetic populations, research has provided evidence that key study variables influenced hypertension medication adherence (Bosworth et al., 2006; Schillinger, Barton, Karter, Wang, & Adler, 2006).

Empiric evidence suggests that medication non-adherence contributes to disparately high rates of morbidity and mortality in African American adults (Angell et al., 2008; Wright et al., 2008). The proposed study examined factors that may influence hypertension medication-taking health behavior. Investigating factors that may influence hypertension medication adherence in this population may lead to a greater understanding of the way African American adults engage in self-management behavior, which in turn may help explain the differences between African American and White adults in morbidity and mortality.

The Social Cognitive Theory (SCT), a learning theoretical framework, provided the justification for examining key study variables in a cohort of AA adults with MetS. Study findings may help to develop interventions to promote positive outcomes in this vulnerable population.

A secondary analysis was conducted, using baseline data that were collected as part of a larger study, the Morehouse and Emory Team Up to Eliminate Cardiovascular Health Disparities in AA (META Health) study (U.S. Department of Health and Human Services [HHS], National Institutes of Health [NIH], National Heart, Lung, and Blood Institute, [NHLBI] 2004-2010). A secondary analysis was used to illuminate the nature of the relationship between medication adherence and personal characteristics, behavioral capability, and environmental factors in a cohort of AA with MetS. Specifically, the project illuminated several relationships by utilizing various analyses of existing data to examine key study variables. The study produced a subtler picture of the state of the science that is not present in the current existing literature. Based on the literature review describing links among personal characteristics and environmental factors, the following

research questions were posed:

Question 1: What is the relationship of personal factors (age, gender, income, depression, co-morbidities, and education), behavioral capability (health literacy), and medication adherence in AA adults with MetS?

Question 2: What is the relationship between environmental factors (stress and social support), barriers (complexity of the medication regimen and non-therapeutic health care climate), and medication adherence in AA adults with MetS?

Question 3: Will age, gender, income, education, health literacy, complexity of the medication regimen, and quality of the therapeutic relationship explain a greater variance in medication adherence over and above social support, stress, and depression in AA adults with MetS?

Question 4: Will AA adults with adequate behavioral capability (health literacy) report greater medication adherence than those with inadequate behavioral capability (health literacy)?

Statement of the Problem

Framingham risk investigators analyzed their extensive database and found several associations between MetS and CVD (Mosca et al., 2006). It is therefore very problematic that although AA adults experience greater disease burden from CVD compared to Whites and other minorities, several studies have found that most AA are unaware of their increased risk for developing CVD (Chobanian et al., 2003; Grundy et al., 2005). Moreover, no studies were found which addressed the awareness of risk factors for MetS in AA adults who experience disparately negative health outcomes from this syndrome. The finding is concerning because MetS is categorized by multiple risk

factors which confer greater risks for adverse clinical outcomes compared to a single factor (Blank & Brunton, 2008) and is a cluster of metabolic abnormalities that increases one's susceptibility to risks of CVD (Grundy, 2005).

Similarly, although the magnitude of the problem of low medication adherence is well-documented (Gazmararian et al, 2006; Schillinger, Barton, Karter, Wang, & Adler, 2002), no studies were found that examined the potential factors which contribute to low medication adherence in AA adults with MetS. Indeed, it is well-documented that AA adults suffer a higher disease burden from CVD morbidity and mortality which is often linked to low medication adherence. Moreover, very little of the current medication adherence research explored the specificity of African American adults' social contexts or experiences that might explain their disparately low self-management behavior. Low health behavior including low hypertension medication adherence has been shown to exacerbate chronic conditions (Bosworth et al, 2006).

A large body of evidence reveals that AA adults have high rates of obesity, and in overweight persons, MetS increases significantly to rates of over 50% (Grundy et al., 2008). The evidence suggests that the disproportionate levels of obesity in AA translate into a disproportionate burden of CVD morbidity and mortality (Lechleitner, 2008; Rocha, 2008, Ryan, Farin, Abbasi, & Reaven, 2008). According to the Third National Health and Nutrition Examination Survey (NHANES III) data, AA women have the highest rate of abdominal obesity when compared to other ethnic groups (Brown, Vaidya, Rogers et al., 2008; Park et al., 2003; Williams, Flack, Gavin, Schneider, & Hennekens, 2007). Notwithstanding, although extensive research has been conducted to examine the relationships among personal characteristics and environmental factors, no study

examined the mechanisms through which environmental factors, such as social support and stress, interact with or mediate health literacy to predict hypertension medication adherence in a cohort of AA adults with MetS. It is believed that increasing access to care could improve healthcare outcomes for AA with MetS by early identification of persons at risk for MetS and by targeting modifiable risk factors for medication non-adherence such as quality of social support, level of stress and depression, and health literacy.

Background

Health Disparities

Nelson (2003) defined health disparities as racial or ethnic differences in the quality of healthcare. Research suggests that much of the health disparity in diagnosis and treatment has been linked to personal and environmental factors but findings are inconclusive (Brietzke, 2007; Gazmararian et al., 2006). Similarly, Smedley (2003) and colleagues found that health disparities are not necessarily due to access-related factors, clinical needs, preferences, or appropriateness of intervention (Smedley, Stith, & Nelson, 2003). According to the National Center for Health Statistics (2002), life expectancy at birth is 71.1 years for AA, and 77.1 years for Whites. AAs have the lowest self-rated health status relative to Whites and Hispanics (Wright et al., 2008; Hilgers & Mann, 2008; Schoenthaler, Ogedegbe, & Allegrante, 2007). Also, African American adults have the highest death rates of any of America's racial and ethnic groups related to CVD events (Centers for Disease Control and Prevention [CDC], National Vital Statistics Report, 2006). In addition, several epidemiologic studies provide evidence that vascular

disease and its cardiovascular complications increase morbidity and mortality in AA versus their White counterparts (American Heart Association [AHA], 2007).

Health Disparities Related to MetS

MetS afflicts 50 million Americans or 25% of the adult population (Chen et al., 2004; Grundy et al., 2008). Empiric evidence supports the existence of ethnicity-specific differences in metabolic complications associated with obesity (Grundy et al., 2005). In fact, among minority populations, the escalating incidence of obesity significantly increases the risk for MetS by over 50% (Ford, 2006). In addition, the prevalence of MetS increases with advancing age; 44% of adults over 50 years old have MetS (Ford, 2006; Grundy, 2005).

The age-adjusted prevalence of MetS is 32% of Mexican Americans, 24% of Whites, and 22% of AA (Park et al., 2003). Although AA women seem to have a higher (21%) than AA men (14%), this incidence is somewhat lower than that of White women (23%) and Mexican American women (27%). Brown et al., 2008; Ford, 2006).

Paradoxically, although AA adults have lower rates of MetS than Whites or Mexican Americans, their history of CVD puts them at greater risk for mortality from coronary heart disease (CHD) and stroke (Chobanian et al., 2003; Grundy et al., 2008).

Personal and environmental factors that impact medication adherence and subsequent use of the healthcare delivery system may be rooted in sociological underpinnings such as cumulative disadvantage and multiple-jeopardy. These sociological underpinnings will be briefly addressed.

Cumulative Disadvantage

Dannefer (2003) defines cumulative disadvantage as a compounding of negative circumstances where inadequate social capital confers major disadvantage for older African American adults. African American adults have experienced a lifetime of cumulative disadvantage from opportunity structures of education, social services, and healthcare delivery (Smedley, Stith, & Nelson, 2003). A lifetime of discrimination and poverty translates to an accumulation of disadvantages and poor health in later life (Dannefer, 2003; Lee & Carrington, 2007; Stoller & Gibson, 2005). This cumulative disadvantage results from a complex and dynamic interplay of macro-social and micro-social forces and is often reflected in disparities in the healthcare delivery system (Kripalani et al., 2006; Toren, Kerzman, Koren, & Baron-Epel, 2005; Williams, 1998). For example, negative emotions such as stress and anger may be caused by racial discriminations and institutionalized racism in health care or in the workplace (Williams, 1998). Empiric evidence showed that stress was linked to depression which frequently resulted in poor health care outcomes (Berkman et al., 2003; Cohen, Kamarck, & Mermelstein, 1983).

Multiple-jeopardy

Research suggests that AA adults experience *multiple-jeopardy* because they fall in more than one marginalized category (Dannefer, 2003). This multiple jeopardy compounds the issue of vulnerability for AA adults. It is well-established that African American adults have been disenfranchised and denied access to care because of limited financial resources or inadequate social capital (Canto et al., 2000; Chisholm, 2004;

Daumit, Hermann, Coresh, & Powe, 1999). One can readily appreciate the gravity of this situation because African American middle-aged adults experience disparately high rates of chronic illnesses coupled with severe co-morbidities (Cutler et al., 2008; Lagu et al., 2009).

Healthcare Outcomes from Cumulative Disadvantage and Multiple-Jeopardy

Research substantiates the fact that cumulative disadvantage and multiple jeopardy translate to psychological and physiological stress, which frequently lead to negative healthcare outcomes (Berkman et al., 2003; Williams, 1998). Similarly, a compounding of negative effects compromises health and frequently leads to stress and depression which are significant correlates of medication adherence (Bane, Hughes, & McElnay, 2006; Reynolds, et al., 2004). Stress precipitates and exacerbates depression which affects about 20% of patients with coronary artery disease (CAD), and depression is an important risk factor for death and acute coronary syndrome (ACS) (Berkman et al., 2003; Steptoe et al., 2006). Cumulative disadvantage and multiple-jeopardy often cascade into precipitating factors which contribute to burgeoning racial and ethnic disparities. These disparities will now be addressed in greater detail.

Racial and Ethnic Disparities

The evidence of racial and ethnic disparities was almost always consistent across a range of illnesses and healthcare services (Smedley, Stith, & Nelson, 2003). Although the disparities seemed to be related to socio-economic differences, the differences often disappeared when socio-economic factors were controlled for (Schillinger, Barton, Karter, Wang, & Adler, 2006). Nevertheless, AA adults are less likely to have health insurance than Whites (Nelson, 2003; US Census Bureau, 2001a), and AA adults are

more likely to use publicly funded insurance such as Medicaid (The Henry, J. Kaiser Family Foundation, 2000). African American adults frequently are not afforded the same options or privileges in emergency procedures or CV interventions as their White counterparts (Fiscella, Franks, Gold, & Clancy, 2000; Smedley, Stith, & Nelson, 2003). When AA adults cannot afford quality health insurance, they are often relegated to generalists not specialists, and this limits their access to care (Smedley, Stith, & Nelson, 2003). The emerging evidence suggests that racial and ethnic health disparities may be linked to social and economic inequality, persistent racial and ethnic societal discrimination, and subsequently differences in care from biases, prejudice, or stereotyping (Nelson, 2003). The following statistics provide evidence of racial and ethnic disparities which have been shown to contribute to a perpetuation of negative healthcare outcomes for AA adults.

According to Census (2001b) data, 22.3% of AA over 65 years old fall below the poverty line compared to 8.9% of White older adults. In urban areas, 43% of White older adults over 65 years old and 27% of AA over 65 years old had greater than a 9th grade education. Census data reveals that 37% of White older adults and 17% of African American older adults obtained the General Education Diploma, while 27% of White older adults compared to 8% of AA older adults actually graduated from high school. Research suggests that most independent living older AA live in poverty (U.S. Census, 2001b). In addition, Census data showed that African American adults use far less social and health services than their White counterparts. It is believed that these aforementioned personal and environmental factors, if left unrecognized and untreated in

middle age, set the stage for a perpetuation of negative health care outcomes for AA middle-aged adults in later life.

Significance of the Study for Nursing

Low medication adherence is a pervasive and complex problem and a hidden epidemic in our society today (Balkrishnan et al., 2004; Haynes et al., 2005; Paasche-Orlow, Parker, Gazmararian, Nielsen-Bohlman, et al., 2005). Nurses need to study this problem of low MA to identify those AA adults who are at risk, and to intervene early to promote positive healthcare outcomes in terms of morbidity and mortality. In fact, low medication adherence is strongly influenced by the patient, the patient's social support system, the practice of health care providers, and the effectiveness of the healthcare delivery systems (Berkman et al., 2003). Moreover, the evidence is consistent that medication non-adherence is common among patients, regardless of the kind or the severity of the disease (Paasche-Orlow et al., 2005; Peterson & McGhan, 2005; Vermeire, Hearnshaw, Van Royen, & Denekens, 2001).

Although MA research spans several decades, a paucity of the research addresses this topic in a cultural context (Vermiere et al., 2001). In fact, very little MA research addresses the topic from an AA perspective. Sudano and Baker (2001) found that AA adults (73%) were less likely to follow medication regimen when compared with their White counterparts (64%). This is of great concern to healthcare providers given that AA adults experience significantly higher incidences of chronic illnesses for which medications constitute the most common therapeutic interventions (Haynes, McGibbon, Kanani, Brouwers & Oliver, 2005; Vermiere, Hearnshaw, Van Royen & Denekens, 2001). For example, AA adults have a disproportionately higher incidence of

hypertension and are twice as likely as older Whites to have diabetes (Powell, Hill, & Clancy, 2007; Safeer & Keenan, 2005; Sarkar, Fisher, & Schillinger, 2006; Webster & Perry, 2005).

Ramifications of Low Medication Adherence

An important component of low medication adherence is low self-management behavior. Low self-management behavior is reflected in poor lifestyle choices that contribute to the obesity epidemic. It is well-documented that obese persons incur medical expenditures 40% higher than normal weight individuals (Curtis et al., 2007). Obesity significantly contributes to uncontrolled high blood pressure. Empiric evidence reveals that in African American adults, low hypertension medication adherence results in uncontrolled blood pressure that accounts for nearly 8,000 preventable deaths per year from cardiovascular events (Fiscella & Holt, 2008). Uncontrolled blood pressure has economic consequences as well. For example, the escalating cost of hypertension treatment approaches \$70 billion (Rosamond et al., 2008). Similarly, uncontrolled blood pressure has been shown to increase morbidity and mortality along with an increase in health care expenditures of more than \$100 billion a year (Frishman, 2007).

Low medication adherence is reflected in improper medication use that may result in adverse effects such as dizziness, which frequently leads to falls. Fall-related injuries among older people cost more than \$20.2 billion annually (Centers for Disease Control and Prevention [CDC], 2004). Falls also cause 90% of hip fractures, which cost \$10 billion a year, and by 2020, the total annual cost of these injuries is expected to reach \$32.4 billion (CDC, 2004). Toren et al. (2008) provided evidence that low medication adherence frequently leads to increased emergency department visits and re-

hospitalizations because diseases got out of control. Similarly, Bosworth et al. (2006) found that unscheduled surgeries are needed because of uncontrolled high blood pressure. Finally, in a related study, low medication adherence was associated with disease progression in a population with uncontrolled diabetes (Schillinger et al., 2006).

Negative Healthcare Outcomes

Voluminous literature documents the negative effects of medication non-adherence on AA adults' medical outcomes (Chew, Bradley, & Boyko, 2004; Morris, McLean, & Littenberg, 2006; Reynolds et al., 2004). In a cohort of renal transplant patients, Nevins, Kruse, Skeans, and Thomas (2001) found that non-adherence to medications led to acute transplant rejection and adverse outcomes. Similarly, Bosworth et al. (2006), found that non-adherence with antihypertensive medication was a key factor in the failure of antihypertensive therapy.

Moreover, empiric evidence reveals that even after controlling for similarities in age, education, and occupational opportunities, African American adults still have higher incidences of both mortality and morbidity compared to their White counterparts. It is therefore not surprising that although CVD mortality has declined overall over the past decade, AA continue to suffer a disproportionate burden of CVD disease mortality and morbidity (Mensah, Mokdad, Ford, Greenlund, & Croft, 2005). In fact, although AA adults have lower rates of MetS, their history of CVD puts them at greater risk for mortality from CHD and stroke (Chobanian et al., 2003; Grundy et al., 2008).

The purpose of this study was to examine hypertension medication adherence in AA adults with MetS by determining the relationships among personal characteristics, behavioral capability, barriers, and environmental factors. The study purpose was

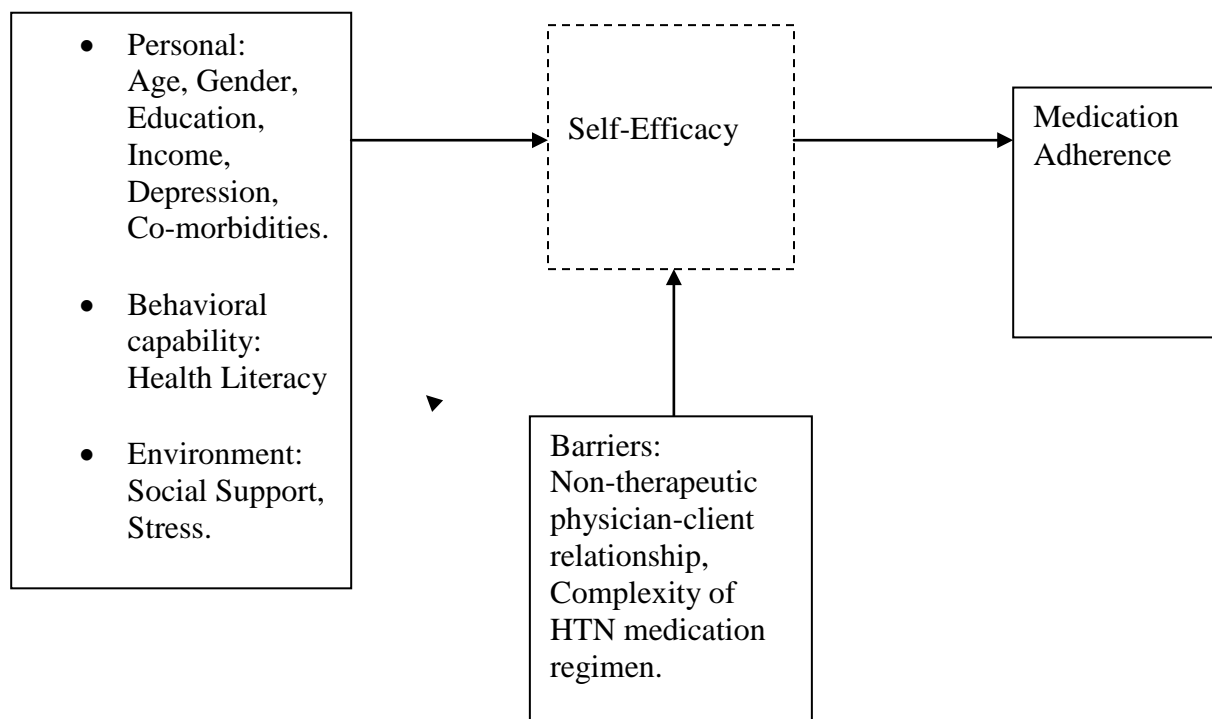
accomplished by using a learning theoretical framework, the Social Cognitive Theory (SCT) to guide this secondary analysis. Currently, SCT is one of the most influential and widely used theoretical frameworks for studying health behaviors (Bosworth et al., 2006; Gallant, 2003).

Theoretical Framework

According to Bandura (1986), the SCT is focused on the social influences that affect learning (e.g. ethnicity, situation, and culture). It is well-established that the SCT is a dynamic interplay of personal factors: a) cognition, affect and biological events; b) behavioral capability, and c) environmental influences which create interactions that result in behavior change (Bandura, 1977a, b). The SCT proposes that motivation to perform a behavior is a strong predictor of performing that behavior (Vogt, Hall, Hankins, & Marteau, 2009). Empirical evidence supports the existence of a relationship among the SCT variables and MA health behavior (See Figure 1).

Figure 1

Social Cognitive Theory to Predict Medication Adherence in AA with MetS

**SCT Overview**

The SCT is a learning theory which is based on the premise that health behavior is influenced by personal characteristics, environmental factors, self-efficacy, outcome expectations, and behavioral capability (Bandura, 2008). In order to engage in recommended health actions, the individual must be confident in their ability to perform the desired behavior, and the environment must be supportive to facilitate and motivate the behavior (Bandura, 1986).

The SCT has many objective empiric indicators that make it suitable for a kaleidoscope of quantitative research in variety of clinical populations. The SCT can be used to explain when and if people will perform health behaviors. Research supports the

causal relationships between the predictors or determinants of the outcome behavior (e.g., Bosworth et al., 2006; Quinn, 2005).

This study focused on personal characteristics, environmental factors, and behavioral capability which are major variables within the SCT. Based on the current review of the literature, predictors for the SCT are consistently associated with healthcare outcomes in a variety of clinical populations (Bosworth et al., 2006). The conceptualizations for SCT model can be seen in Figure 1. Frequently, SCT is used as the framework for many studies that address national health imperatives such as medication adherence and other health behaviors (e.g. Quinn, 2005). SCT demonstrates usefulness in its applicability to various patient populations such as adults with hypertension (HTN) (Bosworth, et al., 2006) and cardiac rehabilitation (Lau-Walker, 2006). Moreover, SCT constructs are tested frequently in medication self-management studies relating to blood pressure control (Bosworth et al., 2006). The salience of empiric findings in diverse clinical populations supports the pragmatic utility of the SCT in research with AA with MetS.

Major Concepts of SCT

The major concepts of the SCT are personal characteristics, environmental factors, behavioral capability, barriers, self-efficacy (SE), and outcome expectations. The behavioral outcome of interest in this study was medication adherence. Self-efficacy has been found to be significantly associated with self-management behaviors in vulnerable populations and SE was found to be one of the strongest predictors of medication adherence in chronic illnesses (Gallant, 2003; Sarkar, Fisher, & Schillinger, 2006; Schoenthaler & Ogedegbe, 2008). The literature showed that SE for medication-taking improved self-management behavior based on health literacy levels (Lau-Walker, 2006;

Schoenthaler et al., 2006). Similarly, Reynolds et al. (2004) found that participants (n=980) with confidence in their abilities to take all their medications were more adherent in their medication regimens. No gaps for medication-taking SE were identified in the literature and the review of literature identified SE variables related to medication adherence. There were no measures of medication-taking self-efficacy in the larger study therefore SE was not tested in this secondary analysis.

Personal Factors

Personal factors include predisposing characteristics such as age, education, gender, ethnicity, co-morbidities, and income. The personal characteristics of African American adults determine the quantity and quality of personal resources that predict healthcare access (Vaglio et al., 2004). Hendrix, Riehle, & Egan (2005) found that demographic characteristics of patients such as age, gender, and ethnicity were associated with significant differences in diagnostic testing, treatment, and control of disease components in primary care. Age, education, income, depression, and co-morbidities may affect medication adherence through factors such as general and health-specific cognitive faculties (Murray et al., 2004a). Research suggests that age, income, and education are significant predictors of health behavior (Davis et al., 2006; Gazmararian et al., 2006; Murray et al., 2004b). Notably, Cavanaugh et al. (2008) found that in diabetic patients (n=398) lower diabetes numeracy scores (ability to calculate blood sugar numbers) were associated with older age, nonwhite race, fewer years of education, lower reported income, lower literacy and general numeracy skills, lower perceived self-efficacy, and worse self-management behaviors.

Depression

Reynolds et al. (2004) provided evidence that depression was the strongest correlate of medication non-adherence, and medications to treat chronic illnesses may intensify depression. Moreover, it is well established that non-adherence subsequent to depression, negatively influences individuals' perceptions about health and quality of life (Bane, Hughes, & McElnay, 2006; Schoenthaler, Ogedegbe, & Allegrante, 2007).

Behavioral Capability

Behavioral capability includes knowledge and skills necessary to perform a behavior (Bandura, 1986). Knowledge and skills are key components of health literacy. If adults have adequate knowledge, they may be more empowered to be active participants in their health care decisions (Bandura, 1986). If adults are going to take their medications, they need to know how to read and understand their health instruction/information and how to take their medications correctly. Powell et al. (2007) assessed the relationship between diabetes knowledge and readiness to take action and found a positive expected relationship. It is well documented that simple mathematical skills are important components of adequate health literacy which significantly predicts positive health outcomes (Gazmararian et al., 2006). Research suggests that adequate health literacy was a strong predictor of hypertension medication adherence in adults with chronic illnesses such as high blood pressure and diabetes (Bosworth et al., 2006; Gazmararian et al., 2006; Ngamvitroj & Kang 2007, Ogedegbe et al., 2004). Persons with MetS must know what their blood pressure numbers and blood glucose levels mean. It is expected that a similar relationship will be found in African American adults with MetS.

Environmental Factors

Environmental factors include external conditions such as home and community composition and the level of social support derived from these sources (Schoenthaler, Ogedegbe, & Allegrante, 2007; Murray, et al., 2004a). Within supportive environments, middle-aged adults have opportunities to observe others achieve success, thus influencing their likelihood of performing the same behaviors (Vaglio et al., 2004). When an adult receives verbal encouragement from his family for taking his medications, this accomplishment is more likely to re-occur. This motivation initiates a reciprocal feedback loop for predicting positive health behaviors (Bandura, 1986).

Social Support

Haslam, Pakenam, and Smith (2006) defined social support (SS) as interpersonal transactions that provide individuals with esteem, stress-related aid, and emotional assistance. Social support has been assessed in numerous ways, including different types and sources of social support. Types of social support include instrumental, emotional, appraisal and informational (Whitfield & Wiggins, 2003). Sources of social support include the social network of family, friends, coworkers, healthcare, church, and community (Murray et al., 2004b). The critical component of the social network is the level of satisfaction perceived by the recipient since social support has been linked to positive health behavior (Gallant, 2003; Lee & Sharp, 2007). Chronic illnesses such as diabetes and hypertension are a continual source of stress and social support is essential to successful management of chronic illness (Gallant, 2003; Karslen, Idsoe, & Hanestad, 2004).

Social Support and Chronic Illness Management

The effect of social support on individual agency, coping resources, and health behaviors has been widely explored (Gallant, 2003; Lee & Sharp, 2007; Whitfield & Wiggins, 2003). The literature shows the protective effects of social support for positive healthcare outcomes and health behaviors (Lee & Sharpe, 2007; Collie et al., 2005). Therefore, social support is an important factor in chronic illness management (Haslam et al., 2006). In a recent study, Ogedegbe, Harrison, Robbins, Mancuso, & Allegrante (2004) found that hypertensive AA's (n=106) reported facilitators to medication adherence were good social support and satisfaction with the patient-doctor relationships. In several populations, it has been demonstrated that personal control frequently leads to confidence in seeking medical information and complying with the medical regimen (Collie et al., 2005; Lucove, Kaufman & James, 2008; Ngamvitroj & Kang, 2007). Similarly, Reynolds et al. (2004) found that social support was an important explanatory variable of high hypertension medication adherence. Adequate SS has been linked to access to resources that help solve problems thus leading to confidence, personal control of chronic illness, increased self-management behavior, and general control over life (Lucove, Kaufman, & James, 2008). When stressors are experienced, having enough social capital increases likelihood that stressors will be handled appropriately.

Stress

Empiric evidence suggests that environmental demands predispose individuals to psychological stress (Berkman et al., 2003; Cohen, Kamarck, & Mermelstein, 1983; Steptoe et al., 2006; Williams, 1998). In addition, the availability of healthcare management resources impact stress, which frequently leads to negative health outcomes

(Williams, 1998). Knox and colleagues (2008) posited that depression in AA is very prevalent due to a convergence of societal and biological factors related to stress. Stress may be caused by racial discriminations and institutionalized racism in healthcare or in the workplace (Williams, 1998). Empiric evidence showed that stress was linked to depression which frequently resulted in low medication adherence (Berkman et al., 2003; Cohen et al., 1983).

Medication Adherence Barriers

Quality of Physician-Client Relationship or Health Care Climate

The definition of the quality of the therapeutic relationship between doctor and patient is the degree of autonomy and the level of satisfaction the patient experiences with the health care provider. Quality of the physician-client relationship was used interchangeably with the term, health care climate (HCC). Adequate autonomy support or satisfaction with the health care provider indicates that the relationship is positive or therapeutic. The client who is not satisfied with the HCC may perceive that the HCC is non-therapeutic. Safer and Keenan (2005) found that the quality of the HCC was often reflected in low MA because patients did not feel empowered to make informed choices about their care. The patients were given orders and expected to comply with no opportunity for discussion..

Similarly, Smith and Haggerty (2003) found that the way medication information was disseminated by the healthcare provider impacted medication non-adherence. Good communication between the patient and the health care provider will lead to greater adherence and improved health outcomes (Friedman et al., 2008; Praska, Kripalana, Seright, & Jacobson, 2005). Knowledge of the medication therapy can empower patients

by promoting the understanding of medical problems and by increasing the patients' involvement in decisions regarding their health.

Satisfaction with the healthcare climate or a therapeutic physician-client relationship has been associated with more favorable medical outcomes for patients with chronic diseases (Shea, Guerra, & Ravenell, 2004). Research suggests that information-sharing between physician and client as well as seeking and understanding medical information determined the therapeutic level of the HCC (Hoffman & McKenna, 2006; Williams, McGregor, & King, 2005). Finally, Murray et al. (2004a) found that many adults often lacked adequate transportation to the healthcare system for care and medications and for follow up visits. It is believed that broken appointments impact the continuity in care and strain the therapeutic relationship (Murray et al., 2004a).

Complexity of Medication Regimens

Complexity of the medication regimen was conceptualized as multiple drug therapy including frequent dosing schedules. MetS requires multiple treatment regimens including combination drug therapy and frequent dosing medications (Davis et al., 2006; Grundy, 2008). Moreover, AAs with MetS frequently report multiple health co-morbidities and must take multiple prescription medications including angiotensin receptor blockers (ARB), angiotensin converting-enzyme (ACE) inhibitors, and diuretic combination medications (Lagu et al., 2009; White, 2008; Williams et al., 2007). In a recent study, Shaya et al. (2009) found that patients (n=568) on fixed-dose combination therapy were more likely to display medication adherence than patients with higher co-morbidities and on separate agents. Nevertheless, Lagu et al. (2009) (n=327) found that antihypertensive prescriptions written for patients with five or more co-morbidities were

significantly more likely to be filled versus persons with fewer co-morbidities. In a recent study (n=498), complex regimens from multiple co-morbidities were associated with poor blood pressure control in hypertensive AA (McDonald, Pezzin, Peng & Feldman, 2009). Alternating dosing schedules produced 50% medication adherence while weekly dosing resulted in 29% medication adherence (Risser, Jacobson, & Kripalani, 2007). The research suggests that simpler medical regimens and satisfaction with healthcare climate improved self-efficacy and led to more positive outcomes (Williams et al., 2005).

Similarly, Banning (2009) found that reduction of quantity of medications reduced medication complexity and led to more adherence success. Banning reported that reduction in the quantity of medications improved medication adherence up to 20% and increased medication adherence rates 90% versus 82%, ($p < 0.01$). Similarly, Haynes et al. (2005) noted that complex medication regimens are precursors to non-adherence, due to patients forgetting to take their medication or omission of doses.

Assumptions

Bandura (1986) found that personal factors, environmental factors, and behavioral capability intersect in triadic reciprocity to predict health-seeking behaviors. The following assumptions are an integral part of the theoretical framework: 1) SCT is a model of reciprocal interaction among cognitive factors, environment, and behaviors; 2) adults are active learners; and, 3) adults learn in social contexts.

In addition, the SCT accounted for a greater variance (23%) in health behaviors compared to the Health Beliefs Model, suggesting a potentially greater usefulness for this theory (Bosworth, et al., 2006). The SCT has demonstrated usefulness in its applicability

to various patient populations and its constructs are tested frequently in medication self-management studies (e.g., Bosworth et al., 2006).

The SCT will be used to examine the relationship among medication adherence, personal, environmental, and behavioral variables in AA adults with MetS. If African American adults with MetS follow their medical regimen, morbidity and mortality will decline and more positive outcomes will occur (Poon et al., 2009). The SCT variables have been examined in a variety of clinical populations and have successfully predicted health behavior. A secondary analysis of SCT variables may yield similar results in a cohort of African American adults with MetS.

Summary

Although hypertension medication adherence is a self-management behavior that can greatly reduce risks for negative outcomes such as CVD, the research suggests that AA often do not adhere to medication regimens as well as their White counterparts. In fact, medication non-adherence is more prevalent in minority populations and it is well documented that medication adherence may be more difficult for African American adults than White adults. This finding is of great concern to healthcare providers given that middle-aged African American adults have worse healthcare outcomes than their White counterparts, and they continue to experience disparately high rates of chronic illnesses.

Although prescription medications are the primary therapeutic regimen for AA with multiple co-morbidities, these adults use substantially less prescription medications than White older adults (Lagu et al., 2009). Therefore, interventions are needed to increase health behaviors and promote more positive healthcare outcomes for these vulnerable

adults.

Finally, empiric evidence shows that non-adherence to medication regimens significantly contributes to burgeoning healthcare costs as well as perpetuating health disparities. Given that the relationship among personal characteristics, environmental factors, and medication adherence in AA adults with MetS remains unclear, an investigation of these factors using a learning theoretical framework will advance the science in this research area. The social cognitive theory provided the theoretical framework for examining hypertension medication adherence in this population.

Chapter II

Review of Literature

Metabolic Syndrome Overview

Although the pathophysiology of metabolic syndrome (MetS) is still not clearly or consistently defined (Grundy et al., 2008; Lann, Gallagher, & Leroith, 2008; Wilson & Grundy, 2003), this accumulation of cardiovascular disease (CVD) risk factors is associated with being overweight with large abdominal circumference (Grundy et al., 2008; Mosca et al., 2006; Wright et al., 2008). Moreover, research suggests that MetS is a cluster of metabolic abnormalities that increases the susceptibility to risks of coronary heart disease (CHD) and CVD (Brown et al., 2008; Grundy, 2005). Data from Framingham Risk Scores (FRS) suggested that MetS triples the relative risk of CVD (Wilson, 2004). Similarly, Curtis et al. (2007) found that MetS was associated with a 38% greater risk of CVD events.

Abdominal Obesity

Abdominal obesity is commonly associated with MetS (Perry, Wang, & Kuo, 2008; Ryan et al., 2008). Abdominal obesity presents as increased waist circumference (≥ 102 cm in men and ≥ 88 cm in women) (National Heart Lung Blood Institute [NHLBI], 2004).

It is well documented that individuals with a body mass index (BMI) of 25 to 29.9 kg/m² are considered overweight, and individuals with a BMI \geq 30 kg/m² are considered obese (Rocha, 2008; NHLBI, 2004). All overweight and obese adults with a BMI \geq 25 kg/m² are considered at risk for developing MetS (Lechleitner, 2008; Perry et al., 2008).

Atherogenic dyslipidemia

Atherogenic dyslipidemia is a triad of lipid abnormalities that includes elevated triglycerides (greater than 150 mg/dl), decreased high density lipoprotein (HDL)-cholesterol levels (less than 40 mg/dl), and a preponderance of small, dense low density lipoprotein (LDL) particles ($>$ 130 mg/dl) (Lechleitner, 2008; Ryan et al., 2008).

Hypertension

Hypertension (HTN) is associated with obesity and insulin resistance (Brietzke, 2007; Preiss & Sattar, 2007). The clinical criteria for HTN include a systolic blood pressure (SBP) \geq 140 mmHg and a diastolic blood pressure (DBP) \geq 90 mmHg (Bosworth et al., 2006; Chobanian et al., 2003). AA adults have a greater prevalence of high blood pressure (39%) than Whites (29%) (Cutler et al., 2008; Ong et al., 2007). Moreover, uncontrolled HTN in AA accounts for nearly 8,000 preventable deaths per year from CVD events (Fiscella & Holt, 2008; Gu, Burt, Paulose-Ram, Yoon, & Gillum, 2008).

Insulin Resistance

Insulin resistance (IR) is defined as Type II diabetes mellitus (DM), impaired fasting glucose (IFG), impaired glucose tolerance (IGT), or normal fasting glucose levels greater than 110 mg/dl (Lann, Gallagher, & Leroith, 2008; Ren & Kelley, 2009). Insulin resistance is strongly associated with metabolic risk factors and increases CVD risk

significantly (Lann et al., 2008). Invariably persons with MetS are insulin-resistant, and this insulin resistance progresses to Type II Diabetes Mellitus (Ford, Abbasi, & Reaven, 2005; Martins, et al., 2008).

Pro-inflammatory State

A pro-inflammatory state is recognized clinically as elevations of C-reactive protein (CRP) and is most frequently observed in persons with MetS (Ren & Kelley, 2009). One underlying cause of pro-inflammation is obesity because excess adipose tissue releases inflammatory cytokines that result in higher CRP levels (Wilson & Grundy, 2003).

Pro-thrombotic State

A pro-thrombotic state, manifested as increased plasma plasminogen activator inhibitor (PAI) and fibrinogen, is associated with MetS (Brietzke, 2007; Wilson & Grundy, 2003). These authors found that fibrinogen like CRP rises in the presence of elevated inflammatory cytokines. Research suggests that metabolically, proinflammation and prothrombotic states are interconnected (Brietzke, 2007; Reaven, 2002).

Prevalence of MetS

MetS is a major public health problem in the United States, and according to the U.S. Department of Health and Human Services (2004), about 50 million adults have MetS. Currently, one fourth of U.S. adults, 20 years of age or older, meet the clinical criteria for the diagnosis of MetS. (Brown et al., 2008; Lechleitner, 2008). Furthermore, in overweight persons, MetS increases significantly to rates of over 50% (Ford, 2006; Park et al., 2003).

According to Ford (2006) males and females display comparable rates of MetS, although it is estimated that 31% of Mexican Americans, 24% of Whites, and 22% of AA have MetS (Park et al., 2003). Moreover, Clark & El-Atat (2007) found that although the age-adjusted prevalence of MetS in AA (21.6%) is similar to that in overall U.S. population (23.7%), AA women have an approximately 57% higher prevalence of MetS than their male counterparts (25.7% versus 16.4%) (Appel, Moore, & Giger, 2006). The prevalence of MetS increases with increasing age (44% of adults >50 years old) (Grundy, 2005; Lechlietner, 2008). Similarly, Ren & Kelley (2009) found that MetS was more prevalent in menopausal women than in pre-menopausal women. Ren & Kelley attributed this gender dimorphism to female sex hormones.

Diagnosis of MetS

Clinical Criteria

Given the various definitions by health organizations, it is unclear whether the diagnosis of MetS is greater than the sum of its components (Lann, Gallagher, & Leroith, 2008). Diagnostic criteria for MetS are based on measurements done in persons who have fasted for 12 hours or more (Brietzke, 2007; Ren & Kelley, 2009; Wilson & Grundy, 2003). Four organizations have defined clinical criteria for the diagnosis of MetS: 1) National Cholesterol Education Program's (NCEP) Adult Treatment Panel III or (ATP III), 2) International Diabetes Foundation (IDF), 3) American Association of Clinical Endocrinologists (AACE), and 4) World Health Organization (WHO).

According to the criteria from the ATP III (1997), MetS is clinically present when three or more of the following conditions are met: 1) waist circumference greater than 102 cm in men and 88 cm in women; 2) serum triglyceride (TG) level of at least 1.7 mmol/L (\geq

150 mg/dl); 3) HDL cholesterol level < 40mg/dl in men and < 50mg/dl in women; 4) blood pressure \geq 130 mm Hg systolic or \geq 85 mmHg diastolic ; and 5) fasting plasma glucose level \geq 110mg/dl (Anuurad, Chiem, Pearson & Berglund , 2007). The diagnostic criteria used by the IDF are similar to that of the ATP III; however, the IDF uses body mass index \geq 30 kg/m² instead of waist circumference (\geq 102 cm in men and \geq 88 cm in women) to define MetS (Vaidya et al., 2007).

The AACE proposes a third set of clinical criteria for MetS (Grundy et al., 2008). The authors suggest these criteria are a hybrid of the ATP III and the WHO criteria; however only clinical judgment is needed for diagnosis; therefore, no defined number of risk factors is provided. The World Health Organization (2003) views insulin resistance as a required component for diagnosis.

Controversies with MetS Diagnosis

In addition to insulin resistance, the World Health Organization (WHO) indicates that two other factors are sufficient for diagnosis of MetS. The WHO requires higher blood pressure parameters than ATP III and like IDF, WHO uses BMI instead of waist circumference for diagnosis. Research suggests that the prevalence of MetS did not vary based on differences in IDF and the ATP III criteria for waist circumference (Ryan, Fenster, Abbasi, & Reaven, 2008). The requirement for clinical presence of insulin resistance, however, is believed to predict diabetes mellitus more strongly than ATP III (Lann, et al., 2008).

Consistent with ATP III criteria, the WHO suggests that the presence of Type II DM does not exclude a diagnosis of MetS. A disadvantage of the WHO criteria is that special testing for glucose is needed beyond the routine clinical assessment to diagnose MetS.

The ATP III did not find evidence to recommend routine measurement of insulin resistance (for e.g., increased fasting blood insulin) in their clinical criteria (Vaidya et al., 2007).

Grundy et al. (2008) found that the use of ATP III criteria directs the focus from insulin resistance abnormalities to focus on whether or not a patient has MetS. Grundy found that persons can be hypertensive and hypercholesterolemic and still not meet the ATP II criteria for MetS. This conclusion may explain why many AA are diagnosed with MetS after the disease has already progressed (Norris et al., 2006). Moreover, in a recent study, (n=6938), Mosca et al. (2006) found that when diagnostic criteria included waist circumference in addition to Framingham Risk Scores (FRS), 41% of women who were previously classified as low risk were diagnosed with three or more MetS risk factors.

Emerging Issues Related to MetS Diagnoses

Although adipose tissue in obese people is insulin-resistant, it is recognized that some people who are not obese by traditional measures may be insulin-resistant, and insulin-resistance is one essential cause of MetS (Reaven, 2002). Meis, Schuster, Gaillard, & Osei, (2006) and Perseghin et al. (1997) found that individuals with two diabetic parents or one diabetic parent and one or two close diabetic relatives may have abnormal levels of metabolic risk factors. Similarly, Grundy et al. (2005) found that a genetic component was responsible for MetS susceptibility also.

Reaven (2002) concluded that failure to focus on the central role of IR often led to interventions that increase, not decrease CHD risk. The ATP III approach to MetS suggests that CHD risk is not limited to hypercholesterolemia, and that IR/hyperinsulinemia and defects in insulin metabolism must be considered to decrease

CHD risk (Grundy et al., 2008). Research suggests it is important to focus on the cluster of metabolic abnormalities since they are more likely to occur together than separately (Reaven, 2002).

The American Diabetes Association (ADA) recommended that the lower limit for the diagnosis of impaired fasting glucose be changed from 6.1 mmol/L to 5.6 mmol/L (Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2008). Tai et al. (2004) found that the association between impaired glucose tolerance and CVD morbidity and mortality is stronger than the association between impaired fasting glucose and CVD. It is believed that the lower cutoff identifies more subjects at risk for diabetes and CVD (Tai et al., 2004).

Health Disparities Related to Diagnosis

The disproportionate levels of obesity in AA translate into a disproportionate burden of cardiovascular disease (CVD) morbidity and mortality (Lechleitner, 2008; Mensah et al., 2005; Rocha, 2008; Ryan et al., 2008). According to NHANES III data, AA women have the highest rate of abdominal obesity when compared to other ethnic groups in the United States (Brown et al., 2008; Meis, Schuster, Gaillard, & Osei, 2006; Park et al., 2003; Williams et al., 2007).

The disparity in number of AA diagnosed with MetS relative to the prevalence in hypertension and obesity-related disorders may be due to failure to focus on the role of IR (Reaven, 2002). The lower prevalence of MetS among AA has been explained by the fact that two separate lipid criteria are defined by the NCEP (high triglycerides and low HDL cholesterol), which offset higher rates of HTN and glucose intolerance in AA (Reaven, 2002).

Health Disparities Related to Treatment

The presence of multiple physiological determinants underlying the cluster of MetS abnormalities supported a variety of therapeutic regimens. Brietzke (2007) however, provided evidence that treatment of MetS should target the syndrome rather than the components of the syndrome to reduce risks of DM and CVD.

Although AA are notably absent from many of the large clinical outcomes trials of lipid-lowering therapy, the magnitude of LDL-C reduction with statins appears to be similar in AAs and Whites (Grundy et al., 2008; Clark & El-Atat, 2007). In the lipid lowering component of the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial ([ALLHAT-LLT], Clark & El-Atat, 2007) (n=3491) (38% AA), statin therapy more effectively lowered the risk of CHD and nonfatal myocardial infarction in AA than in non-AA (RR 0.73 vs. 1.02, p=0.03); the 27% relative reduction in CHD events among AA treated with pravastatin versus usual care was statistically significant (ALLHAT, 2002). Clark and El-Atat (2007) found that older AA adults were less likely to be treated with lipid-lowering drugs than their White counterparts.

In a recent study with veterans (n=56,561), Poon et al. (2009) found that despite national practice guidelines recommendation of the use of angiotension converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARB) for patients with diabetes, AA with hypertension and diabetes were less likely to receive these drugs. Although AA in this veterans' cohort had more contraindications like hyperkalemia and angioedema, which may have precluded ACE inhibitors, AA were still much less likely than their counterparts to receive beta-blockers as first line therapy. Furthermore, previous studies found that AA required a greater number of anti-hypertensives, and even

with combination therapy, had much poorer blood pressure control than Whites (Giles et al., 2007; White, 2008; Williams et al., 2007). Prevalence of uncontrolled hypertension among AA remains significantly high, and the high use of mono-therapy in AA is questionable (Chobanian et al, 2003; Lagu et al., 2009; White, 2008).

MetS Long and Short-Term Health Outcomes

Consequences of Uncontrolled MetS

MetS is categorized by multiple risk factors that confer greater risks for adverse clinical outcomes compared to a single factor (Blank & Brunton, 2008; Chen et al., 2004). In one study (n=3323) Wilson (2004) found that MetS alone predicted 25% of all new onset CVD. Similarly, Curtis et al. (2007) found that MetS was associated with a 38% greater risk of CVD events. Also, almost half of the population's attributable risk for diabetes was explained by MetS (Wright et al., 2008).

Coronary Heart Disease/Cardiovascular Disease

The ATP III viewed CVD, the largest cause of death in the United States (American Heart Association [AHA], 2007), as the primary clinical outcome of MetS. MetS increases CVD risk 4-fold (Clark & El-Atat, 2007). Research suggests that AA have the highest mortality rate from CHD of any ethnic group, especially at younger ages (Anuurad, et al., 2007; Hilgers & Mann, 2008; Wright et al., 2008).

Diabetes Mellitus (DM)

In a recent study, Yatskar et al., (2008) (n=510) found that MetS predicted development of diabetes mellitus (DM) for patients who did not have DM at baseline. Type 2 DM is the second leading cause of death in AA women. Insulin resistance is present in most people with MetS. Insulin resistance is associated with other metabolic

risk factors and increases CVD risk significantly (Grundy et al., 2008). Research suggests the associations underlying the link to CVD risk factors are unclear, so the ATP III classifies IR as an emerging risk factor. According to Grundy and colleagues, persistent IR accelerates glucose intolerance, another emerging risk factor in MetS. Glucose intolerance frequently leads to DM-level hyperglycemia, a significant independent risk factor for CVD. DM is diagnosed in 10.3 million Americans, and it is projected that 5.4 million Americans are undiagnosed (Expert Committee, 2008). The American Diabetes Association (Expert Committee, 2008) estimates that 2.8 million (13%) AAs have DM, and another 7% has impaired fasting glucose (IFG) which is a precursor to DM.

Other MetS Clinical Sequelae

MetS is a significant contributor to End-Stage Renal Disease (ESRD) (Gilbertson et al., 2007). Although AAs comprise 12% of the US population they represent almost 30% of those with ESRD (Gilbertson et al., 2007). Other clinical sequelae associated with MetS are chronic kidney disease (CKD) (Appel et al., 1997; 2008), nonalcoholic fatty liver disease (NAFLD), and obstructive sleep apnea (OSA) (Grundy et al., 2008).

MetS Summary

The literature shows that MetS is a significant determinant of CVD (e.g. Annurad, Chiem, Pearson, & Berglund, 2007; Blank & Brunton, 2008; Shaista et al., 2004). In a Framingham follow up study (n=3323), Wilson (2004) found that MetS alone predicted 25% of all new onset CVD; and for both genders, almost half of the population attributable risk for diabetes was explained by MetS. Similarly, Shaista and colleagues looked at the impact of MetS on mortality from CHD/CVD and all causes in US adults.

The authors found that MetS was associated with hazard risk (HR) of 2.02 after controlling for age, gender, smoking status, and total cholesterol. Patients with MetS had HR of CHD mortality of 1.65. HR for CHD mortality was 2.1 for persons with one or two risk factors, compared with those with no MetS (Shaista et al., 2004).

Although CVD mortality has declined overall over the past decade, AA continue to suffer a disproportionate burden of CVD disease mortality and morbidity (Wright et al., 2008; Hilgers & Mann, 2008; Annurad, et al., 2007). In fact, AAs have the highest death rates of any of America's racial and ethnic groups related to CVD events: 319 per 100,000 person years for AA women and 423 per 100,000 for AA men compared to 278 per 100,000 person years for all other ethnicities combined (CDC, Vital Statistics Report, 2006; Henderson et al., 2007). The literature review reveals that a significant contributor to health disparities is low medication adherence; this important healthcare issue will now be addressed in detail.

Medication Adherence

Overview

Medication adherence (MA) is the extent to which medical orders and health recommendations are followed as defined by the healthcare provider (Osterberg & Blaschke, 2005; Vlasnik et al., 2005). Medication non-adherence may be a deliberate or an unintentional deviation from therapeutic regimens and medical interventions (George & Shalansky, 2007; Nyatanga, 1997; Reynolds et al., 2004). Some older adults may forget to take their medications because of memory impairments, while others choose not to take the medication. Intentional medication non-adherence implies that patients refuse to comply with the regimen, or fail to carry out or deviate from specific behaviors after

making an informed choice (Nyatanga, 1997). Often, when older adults encounter unfavorable effects, they may stop taking the medication without consulting with their health care provider; others stop taking the medication the moment they start feeling better.

Causes of Medication Non-Adherence

Medication non-adherence in older adults has many causes, including: 1) stress, 2) depression, 3) low health literacy, 4) poor quality of the therapeutic relationship, 5) complexity of the medication regimen, and 6) lack of adequate social support.

Stress

It is believed that chronic illnesses predispose individuals to stress and stress leads to medication non-adherence (Cohen et al., 1983; Sewitch et al., 2003). The stress of doing blood sugar checks or blood pressure checks may cause patients not to engage in self-management behavior and thus they become non-adherent in their medical regimen. For example, Sewitch et al. (2004) found that patients (n=182) who were not taking their medications had more elevated stress than those who took their medications; the exact mechanisms underlying this relationship between stress and MA were unclear.

Research suggests that several MetS components have been linked to adrenocortical and autonomic disturbances (Berkman et al., 2003; Virtanen et al., 2003). In fact, the relationship between stress induced neuro-hormonal abnormalities, visceral fat, and insulin resistance is well-established (Berkman et al., 2003). Since psychosocial factors explained some of these associations, it was suspected that stress-induced activation of the sympathoadrenal system or the hypothalamic-pituitary-adrenocortical (HPA) axis may contribute to MetS or that stress may be etiologically linked to MetS (Berkman,

Blumenthal, Burg, et al, 2003).

In addition, research provided evidence that negative situations frequently lead to psychological and physiological stress, which contribute to negative healthcare outcomes (Berkman et al., 2003; Cohen, Kamarck, & Mermelstein, 1983; Williams, 1998). A compounding of negative effects compromises health and frequently leads to stress and depression which are significant correlates of medication adherence (Bane, Hughes, & McElnay, 2006; Reynolds et al., 2004). Cumulative disadvantage and multiple-jeopardy often cascade into stressful precipitating factors which contribute to burgeoning racial and ethnic disparities (Dannefer, 2003).

Furthermore, the literature suggests that environmental demands predispose individuals to psychological stress (Berkman et al., 2003; Cohen et al., 1983; Steptoe et al., 2006; Williams, 1998). Research suggests that the availability of healthcare management resources impact stress, which frequently alters bio-behavioral responses that contribute to increased risk factors for cardiovascular disease (Williams, 1998). In fact, CHD patients were found to have more elevated stress hormones and were more likely to be depressed (Steptoe et al., 2006). In addition, stress precipitates and exacerbates depression which affects about 20% of patients with coronary artery disease (CAD) and depression is an important risk factor for death and acute cardiac syndrome (ACS) (Berkman et al., 2003; Steptoe et al., 2006). Notably, Williams (1998) found that the added effects of race, discrimination, and low economic capital contributed to stress and negative health outcomes for AA adults. Finally, it was well-documented that psychological stress is linked to depression in a variety of clinical populations (Berkman et al., 2003; Knox et al., 2008; Steptoe et al., 2006).

Depression

Depression is associated with a failure to activate neural circuitry including the areas of the medial prefrontal cortex and the hippocampus, which prevent inputs to the amygdala (Strike et al., 2006). Inhibition of the amygdala frequently leads to peripheral activation of the cardiovascular and neuro-hormonal responses through the hypothalamus-pituitary-adrenal (HPA) axis and the sympathetic nervous system (SNS) (Strike et al., 2006). These pathways increase the risk of mental stress ischemia and contribute to both damage of the vasculature, especially endothelial tissue, and vascular resistance in CAD patients with depression (Berkman et al., 2003).

Research suggests that depression appears to increase the risk of heart disease and is associated with poorer prognosis among cardiac patients (Steptoe et al., 2006). Current data supported a positive association between depression and CHD, although the mechanisms mediating these associations remain unclear (Knox et al., 2008).

Predictors of Depression

Low Health Literacy

Low health literacy is a powerful predictor of depression symptomatology in older adults (Baker, Gazmararian, Sudano & Patterson, 2002; Gazmararian, Baker, Parker, & Blazer, 2000). Some research shows that older adults with poor health literacy are more likely to show major depressive symptoms than their counterparts with adequate health literacy (Baker et al., 2000; Gazmararian et al., 2000). In fact, the research suggests that adults with inadequate health literacy are more than twice as likely to be depressed compared to their health literate counterparts.

Stress-related Factors

Knox and colleagues (2008) posited that depression in AA is very prevalent due to a convergence of societal and biological factors related to stress. This stress may be caused by racial discriminations and cumulative disadvantage from a lifetime of elusive opportunity structures or income and education (Williams, 1998). Moreover, the stigma of mental health in AA precludes traditional therapy and compounds health disparities related to CVD and DM.

In a recent study (n=112), Artinian et al (2009) found that AA starting phase II cardiac rehabilitation with depression symptoms at or above threshold had more stress and fewer stress-resilience factors than their White counterparts. Similarly, Knox and colleagues (2008) found that AA showed significant associations between history of depression and diabetes that did not exist in Whites, and AA women had significantly more episodes of depression than any other group. Moreover, the associations of depression with body mass index and physical activity were consistent across racial groups. In addition, HDL-cholesterol and LDL-cholesterol levels were associated with depression. In fact, these data indicated that there were positive associations between depression and factors that predispose to stress and cardiovascular risk (Knox et al., 2008; Sud et al., 2005). The association of depression and medication adherence will now be examined.

Depression and Medication Adherence

Reynolds et al. (2004) provided evidence that depression was the strongest correlate of non-adherence, and medications to treat chronic illnesses may intensify depression. These researchers noted that physiological changes with aging may also intensify the

effects of antidepressant medications. In addition, depression from multiple medications often masks symptoms for other chronic conditions (Reynolds et al., 2004). For example, symptoms from dementia, stroke, and Parkinson's disease overlap or mimic symptoms of depression.

Research shows that medication non-adherence because of depression negatively influences individuals' perceptions about health and quality of life (Bane et al., 2006). Similarly, Schoenthaler and colleagues (2007) found that self-efficacy mediated the relationship between depression and medication adherence in hypertensive AAs. Moreover, it is well established that non-adherence subsequent to depression, negatively influences individuals' perceptions about health and quality of life (Bane et al., 2006; Schoenthaler et al., 2007).

Nyatanga (1997) argued that medication non-adherence should not be construed as an act of defiance. Nyatanga (1997) found that psychosocial theories such as depression were helpful in explaining and understanding non-adherence in medication regimens. Nyatanga posited that depression was associated with non-adherence with medication regimens. Similarly, Gazmararian et al. (2000) interviewed 3260 Medicare enrollees over a six-month period. These adults had a high prevalence of chronic conditions. The authors found that 13% of the respondents were classified as depressed. Gazmararian et al. (2000) noted that individuals with low health literacy were 2.7 times more likely to be depressed relative to adults with adequate health literacy skills.

The results of these studies provided evidence that adults with depression were more likely to be non-adherent with their medications and adults with low health literacy skills were more likely to report major depressive symptomatology (Schoenthaler et al., 2007).

In fact, health literacy was consistently linked to negative healthcare outcomes (Baker et al., 2002; Gazmararian et al., 2000). Health literacy will now be addressed in greater detail.

Health Literacy

Definition

Health literacy, as defined by the Institute of Medicine (IOM) (2004) in *Healthy People 2010*, is “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” Low health literacy is a lack of ability to obtain and understand health information in a way that helps people take charge of their health (Gazmararian, et al. 2003).

Low Health Literacy

The research reveals that older adults frequently display low health literacy (Murray et al, 2004). Low health literacy limits knowledge of risk factors and causes of disease, and it limits individuals’ ability to seek health information that may promote health and prevent disease (Davis et al., 2006; Smith & Haggerty, 2003; Wallace et al., 2006). Research suggests that low health literacy may reduce one’s ability to manage health (Hoffman & McKenna, 2006; Nath, Sylvester, Yasek & Gunel, 2001). In fact, health literacy may be linked to utilization of treatments that may be available to individuals (Lauber, Nordt, Falcato, & Rossler, 2003; Montalto & Spiegler, 2001). It appears that in the absence of adequate health literacy skills, appropriate health-seeking behavior diminished considerably (Davis et al., 2006).

Low Health Literacy and Patient Knowledge

According to Hixon (2004) and Safeer and Keenan (2005), lower levels of health literacy are associated with less knowledge about chronic disease conditions, poorer health status, and increased rates of hospitalization, which result in higher healthcare costs. Recently, the Mayo clinic found that 15% of patients were unaware they were being prescribed a new medication; only half knew specific information about their medications related to dosage, dosing schedules, and purpose (Kripalani et al., 2006).

In a related study (N=130) Toren, Kerzman, Koren, and Baron-Epel (2005) examined patients' knowledge regarding medication therapy and the association with health services utilization. Patients were discharged with new prescriptions for long term medications. About 60% of patients reported receiving no counseling regarding their new medications. The authors found that 18% of the patients visited the emergency department during the month after discharge, of whom 35% visited twice or more. The findings indicated that higher levels of patient knowledge were associated with higher levels of health services utilization (OR = 4.76, 95% CI: 1.74-13.06).

Prevalence of Low Health Literacy

National Statistics

The Institute of Medicine (IOM) and the National Academies of Science (2001) estimated that 90 million adults have low health literacy (IOM, 2004). Health literacy research findings include the results from the 2003 National Assessment of Adult Literacy (Rudd, Kirsch, & Yamamoto, 2004) which indicated that up to 20% of the total population demonstrated skills in the lowest levels of literacy of prose, document, and quantitative literacy, while 25-28% of the nation scored in the lowest levels of literacy

scales. Although low health literacy appears to transcend educational level, gender, socio-economic status, and health status (Benson & Forman, 2002; Schillinger, Barton, Karter, Wang, & Adler, 2006), minority groups consistently scored 43 to 73 points lower than Euro-Americans on health literacy, while 71% of older adults ages 65 and older scored in the two lowest levels of literacy (National Center for Educational Statistics, 2003; Rudd et al., 2004).

Low Health Literacy and Socioeconomic Status

Although low health literacy is frequently linked to low socioeconomic status, research showed that the problem of poor health literacy was present in affluent, predominantly college-educated communities (Benson & Forman, 2002). In this study, 93 residents were administered the Test of Functional Health Literacy in Adults (TOFHLA). The residents had a mean age of less than 70 years, were not acutely ill, had no known loss of mental functioning, were better educated, and had a high standard of living compared to national standards. The authors found that 30% of the group was unable to adequately comprehend common written health care information as measured by the TOFHLA. These researchers were especially alarmed by the poor comprehension of an informed consent document. They demonstrated that of those with poor comprehension, only 68% could understand prescription directions as labeled on medication bottles (Benson & Forman, 2002).

Low Health Literacy and Older Adults

The researchers noted that older adults were more likely to have inadequate functional health literacy and chronic and co-morbid health conditions (Baker, et al., 2000; Paasche-Orlow et al., 2005). Some evidence indicates that low health literacy in

older adults may be related to perceptual, sensory, and cognitive decline that occurs with normal aging (Hertzog & Hultsch, 2000).

In fact, older adults had lower health literacy compared with young adults and were more likely to have difficulty reading labels and understanding instructions (Benson & Forman, 2002 ; Davis et al., 2006; Hoffmann & McKenna, 2006). Sorrell (2004) showed that in older adults knowledge deficits included lack of information regarding adverse drug reactions and interactions, lack of information on efficacy of specific therapies, and general uncertainties regarding the medications.

Low Health Literacy in African American Adults

African American adults continue to report significant levels of poor functional health literacy, which may be linked to disparate rates of medication non-adherence and poor health outcomes (Davis et al., 2006; Gazmararian et al., 2006; Georges, Bolton, & Bennett, 2004; Schillinger et al., 2006). AAs with MetS frequently have multiple co-morbidities and must take multiple prescription medications including Angiotensin II Receptor Blockers (ARB), Angiotensin-Converting Enzyme (ACE) inhibitors and diuretic combination medications (Hendrix et al., 2005; Lagu et al., 2009). Therefore, on a daily basis, AA adults must read and understand a variety of health information related to their medical regimen (Sentell & Halpin, 2006; Wolf et al., 2006).

Health Literacy and Cognitive Status

Other studies (Baker et al., 2002; Gazmararian et al., 2000) have shown that adults with low health literacy reported lower scores on the Mini Mental Status Exam (MMSE), indicating that low health literacy, measured using the Short Test of Functional Health Literacy in Adults (S-TOFHLA) may result from true differences in cognitive

functioning. The researchers found that functional health literacy was related to MMSE scores across the entire range of S-TOFHLA scores (Baker et al., 2002). MMSE scores were not adjusted for an individual's functional health literacy because the researchers felt that it would mask true differences in cognitive functioning.

As indicated previously, health literacy is not necessarily a function of educational attainment or poverty status (Baker et al., 2000; Benson & Forman, 2002; Gazmararian et al., 2000). Declines in memory predispose older people to low health literacy because older people have more difficulty remembering and must employ strategies to compensate for memory deficits (Hertzog & Hultsch, 2000). These researchers found that older adults also seem to be disadvantaged with regard to time-based prospective memory tasks. As noted by the researchers, prospective memory involves remembering to do something or perform an action in the future. Health literacy is important to the general health status of older adults, since, on a daily basis, they must understand various types of spoken and written discourse that pertains to their health (Benson & Forman, 2002; Gazmararian et al., 2006).

Importance of Adequate Health Literacy in Older Adults

Webster and Perry (2005) stated that medication self-administration in older adults needs more attention because positive health outcomes were frequently compromised by the prevalence of medication errors (Hoffman & McKenna, 2006; Morris et al., 2006). Webster and Perry noted that, in older adults, outpatient medication errors are four times those of inpatient errors and suggested that this problem is under-diagnosed because of providers' limited gero-pharmacology knowledge. For older people, medications constitute the most common therapeutic interventions for diseases

and are very common as a part of health promotion and disease prevention (Haynes, et al., 2005; Vermiere et al., 2001).

Adequate health literacy is important because older adults must understand various types of spoken and written discourse that pertains to their health (Haynes et al., 2000; Hixon, 2004; Krousel-Wood et al., 2004; Montalto & Spiegler, 2001; Sorrell, 2004). According to Lauber, et al. (2003), for proper health maintenance and health promotion, it is critical that older adults understand the following: (1) instructions for taking their medications; (2) adherence with medication regimen; (3) purpose of drug, action, and side effects; and (4) food and drug interactions. The ability to read and understand health information has been identified as a critical factor in maintaining independent activities of daily living in older adults (Benson & Forman, 2002; Johnson, Diab, Kim, & Kirschblum, 2005; Meadows, 2000).

Researchers are consistent in the finding that adequate health literacy and knowledge about health, health care, hospitalization, and chronic diseases affected health outcomes (Baker et al., 2007; Davis et al., 2006; Kutner, Greenberg, Ying, & Paulsen, 2006; Paasche-Orlow & Wolf, 2007; Peterson & McGhan, 2005; Schillinger et al., 2006). For example, Safeer and Keenan (2005) found that in a diabetes Type 2 population, participants with low health literacy reported more negative health outcomes such as poorer glycemic control and higher levels of diseases of the retina compared to their counterparts with adequate health literacy. In a related study (n=398), Cavanaugh et al. (2008) found that lower diabetes numeracy scores (knowledge of blood glucose levels and sliding scales) were associated with older age, nonwhite race, fewer years of

education, lower reported income, lower literacy and general numeracy skills, lower perceived self-efficacy, and worse self-management behaviors.

Health Literacy and Medication Adherence

Voluminous literature revealed that medication non-adherence in older people was due in large part to low health literacy (Davis et al., 2006; Gazmararian et al., 2000; Gazmararian et al., 2006; Haynes et al., 2005; Morris et al., 2006; Roth & Ivey, 2005; Sentell & Halpin, 2006; Wallace et al., 2006). These researchers found that adults with adequate health literacy were more adherent to medical regimens than those with low health literacy.

Health Literacy, Medication Adherence and Chronic Illnesses

Although the relationship between low functional health literacy and low medication adherence has been documented in several populations with chronic illnesses (Gazmararian et al., 2006; George & Shalansky, 2007; Kurella, Lo, & Chertow, 2005; Mochari et al., 2007), this relationship has not been investigated in a MetS population. Given the multiple risk factors of MetS and its complicated etiology, the relationship between MetS outcomes and health literacy warrants further elucidation. For example, in a recent study, poor hypertension control was directly linked to the failure of patients to understand medical recommendations and dietary requirements (Osterberg & Blaschke, 2005; Shea, Guerra, & Ravenell, 2004). Similarly, in a related study, (n=84) Kripalani et al., (2006) found that patients delay filling prescriptions and have difficulty understanding medical regimen after discharge; interventions, such as discharge counseling, might be beneficial. The authors found that medication non-adherence was significantly more common among patients who reported difficulty understanding the

discharge instructions (71%) versus those who had no difficulty (41%) ($p = .02$) (Kripalani et al., 2006).

Medication Adherence Barriers

Quality of Therapeutic Relationship or Health Care Climate

Safeer and Keenan (2005) found that the quality of the physician-client relationship was reflected in non-adherence with the medication regimen. Similarly, Smith and Haggerty (2003) found that the way medication information was disseminated by the healthcare provider impacted medication non-adherence. For example, the physician sometimes made verbal changes to the regimen without communicating the change to the pharmacy, or the physician did not have complete information about the patient's current medications. Patients' misuse and lack of understanding of medical terminology also led to medication non-adherence (Davis et al., 2007; Friedman et al., 2008; Shea et al., 2007). Physicians may make behavioral errors by ordering prescriptions over the phone without examining the patients, by inappropriate dosing, and by failing to get a history of medications and current drug use from older clients (Chew et al., 2004; Davis & Wolf, 2004). Often, physicians do not instruct the patients adequately about the condition for which the drug is used, the pharmacodynamics of the drugs, adverse effects, and how long the drug should be taken (Chew et al., 2004; Kim, Hill, Bone, & Divine, 2000; Davis & Wolf, 2004). Much generalization in how medication is administered exists, especially in geriatric populations (Davis et al., 2006; Reynolds et al., 2004). This means that clinicians frequently use a "one size fits all" approach instead of using an individualized approach for older adults.

Knowledge of medication therapy can empower patients by promoting the understanding of medical problems and by increasing involvement in decisions regarding their health (Toren et al., 2005). Inaccurate lay public understanding of hypertension and its sequelae contributes to decreased rates of adherence with medical regimen (Hilgers & Mann, 2008; Middleton, 2009). African American adults with MetS frequently lacked the cognitive abilities to understand their health information to make informed choices (Hilgers & Mann, 2008). Older adults sometimes forgot to take their medications or lacked resources to navigate the healthcare delivery system effectively (Banning, 2009; Rudd, Kirsch, & Yamamoto, 2004).

Emerging research suggests that a lack of information about disease process in AA adults with MetS contributes to low medication adherence (Grundy et al., 2005). Toren et al. (2005) examined patients' (n=130) knowledge regarding medication therapy and the association with health services utilization. The authors found that higher levels of patient knowledge were associated with higher levels of health services utilizations (OR = 4.76, 95% CI: 1.74-13.06). In addition, evidence supported the positive relationship between knowledge and positive health behaviors (Middleton, 2009). It is expected that older AA's knowledge of MetS etiology and knowledge about the medication regimen will play a critical role in improving medication adherence (Toren et al. 2005).

Effective patient-provider communication has been associated with more favorable medical outcomes for patients with chronic diseases (Shea et al., 2007; Williams, 1998). Williams (1998) provided evidence that an autonomy supportive environment was critical to positive health care outcomes. Moreover, research suggests that patients' seeking and understanding medical information is a crucial aspect of information sharing between

physician and client (Hoffman & McKenna, 2006). Murray et al. (2004a) found that older adults often lacked adequate transportation to the healthcare system for care and medications, and for follow up visits. It is well established that broken appointments impact the continuity in care and strain the therapeutic relationship (Murray, et al., 2004b).

Complexity of Medication Regimens

It is well-documented that AAs with MetS must take multiple prescription medications including ARB, ACE inhibitors, and diuretic combination medications (White, 2008; Williams et al., 2007). Consistent with JNC7 recommendations, White (2008) found that combination therapy was a strategy that simplified the regimen while providing first line therapy in high-risk patients. In a recent study, Shaya et al. (2009) found that patients (n=568) on fixed-dose combination therapy were more likely to display medication adherence than patients with higher co-morbidities and on separate agents. Nevertheless, Lagu et al. (2009) found that antihypertensive prescriptions written for patients (n=327) with five or more co-morbidities were significantly more likely to be filled versus prescriptions written for persons with fewer co-morbidities. Prescription medications are the primary therapeutic regimen for AA adults with multiple co-morbidities (Lagu et al., 2009). On the other hand, AA adults use substantially less prescription medications despite having a higher incidence of chronic illness. Consequently, morbidity and mortality increase, coupled with an increase in healthcare expenditures of more than \$100 billion a year (Frishman, 2007).

MetS requires collaborative treatment including combination drug therapy and frequent dosing medications (Davis et al., 2006; Grundy, 2008). In a recent study

(n=498), complex regimens from multiple co-morbidities were associated with poor blood pressure control in hypertensive AA (McDonald et al., 2009). Alternating dosing schedules produced 50% medication adherence while weekly dosing resulted in 29% medication adherence (Risser et al., 2007). The research suggests that simpler medical regimens and satisfaction with healthcare climate improved self-efficacy and led to more positive outcomes (Williams et al., 2005).

Similarly, Banning (2009) found that reduction of quantity of medications reduced medication complexity and led to more adherence success. Banning reported that reduction in the quantity of medications improved medication adherence up to 20% and increased medication adherence rates 90% versus 82%, ($p < 0.01$). Similarly, Haynes et al. (2005) noted that complex medication regimens are precursors to non-adherence, due to patients forgetting to take their medication or omission of doses. Older people must take medications for longer periods of time and utilize drugs differently based on age-related pharmacokinetics. Also, they have to assimilate more medication information with more deficits in memory and cognition (Wilson, 2000).

Environmental Factors

It is well established that self-management occurs in a context of social networks including healthcare providers, family, and informal social network members (Breny-Bontempi, Burleson & Lopez, 2004; Gallant, 2003). Moreover, MetS is a lifelong chronic disease that is punctuated with frequent consultations with healthcare providers for ongoing education and social support (Gallant, 2003). Family and friends are sources of emotional and instrumental social support as they provide encouragement to highlight positive outcomes (Lee & Sharpe, 2007).

Social Support

Haslam, Pakenam, and Smith (2006) defined social support as interpersonal transactions that provide individuals with esteem, stress-related aid, and emotional assistance. The external environment includes the AA adults' home, community, social capital, and the level of support derived from these resources (Murray et al., 2004a). Social support is frequently linked to medication adherence. For example, Schillinger et al. (2006) found a positive relationship between social support and self-efficacy in diabetic populations. Similarly, research shows the positive effects of social support such as greater self-regulation, more involvement in the health care regimen, and greater medication adherence in populations with chronic illnesses (Bosworth et al., 2006; Gallant, 2003; Lee & Sharp, 2007; Murray et al., 2004a).

In a related study, Ogedegbe et al. (2004) found that hypertensive AA (n=106) reported facilitators to medication adherence were good social support and good patient-doctor relationships. This empiric work suggests that older adults with MetS who express high levels of social support will express high levels of confidence in their abilities to manage their medications. If African American adults are empowered to be actively involved in their healthcare decisions, they will be more likely to follow their medical regimen as prescribed. Similarly, African American adults with greater confidence in their medication-taking ability will be more likely to take their medications as prescribed.

Consequences of Medication Non-adherence

Negative Effects on Health Outcomes

Medication non-adherence has negative effects on health outcomes because AA adults frequently have chronic conditions and are subject to multiple co-morbidities (Fang, Machtiger, Wang, & Schillinger, 2006). In a cohort of renal transplant patients, Nevins et al. (2001) found that medication non-adherence led to acute rejection and outcomes. Similarly, Bosworth et al. (2006) found that non-adherence with antihypertensive medication was a key factor in the failure of antihypertensive therapy. In addition, low medication adherence to antihypertensive regimens contributed to additional health care costs, reduction in therapeutic value, and increases in the risk for complications from MetS (Frishman, 2007; Osterberg & Blaschke, 2005). Safer & Keenan (2005) found that many hospital admissions due to medication non-adherence resulted in an additional \$69 billion in healthcare costs annually. Treatment costs for uncontrolled hypertension approach \$100 billion a year (Frishman, 2007); therefore, medication non-adherence is a critical issue for AA adults.

Medication adherence consistently predicts positive health outcomes (Schillinger et al., 2006), and it is well documented that hypertension medication non-adherence may be implicated in disparately high rates of CVD morbidity and mortality in African American adults (Angell et al., 2008; Munger, Van Tassell, & Lafleur, 2007; Wright et al., 2008). Research illuminating the factors that predict hypertension medication adherence in AA adults is the next step that is needed in advancing the science in health disparities research.

Predicting Hypertension Medication Adherence

Predicting self-management behaviors, including medication adherence, has been the aim of numerous empirical studies (Gallant, 2003; Gazmararian et al., 2006; Kripalani et al., 2006). Many variables which consistently predict health behaviors have been identified in these studies. In particular, several factors have been found to influence the decision to take prescription medications as prescribed by the healthcare provider. These factors include personal characteristics, health knowledge, and medication-taking barriers such as complexity of medication regimen, and low satisfaction with the healthcare climate (Bosworth et al., 2006; Gallant, 2003; Gazmararian et al., 2006; Kripalani et al., 2008; Williams et al., 2000). Finally, it is well established that low health literacy is associated with medication non-adherence (Davis et al., 2006; Gazmararian et al., 2003).

Medication adherence has been examined in a variety of patient populations, including those with cancer, diabetes, hypertension, CHD, as well as patients with CVD. Given that MetS is associated with an elevated burden of diabetes mellitus (DM) and CVD, self-efficacy for hypertension medication-taking is an integral part of interventions for improving MetS and its components (Hilgers & Mann, 2008; Wright et al., 2008). In a related study, Bosworth et al. (2006) found that non-adherence with antihypertensive medication was identified as a key factor in the failure of antihypertensive therapy. Similarly, Ngamvitroj and Kang (2007) provided evidence that knowledge, social support, and self-efficacy were significant independent predictors of medication adherence. For persons with MetS, poor adherence to blood pressure medications can lead to CVD (Bosworth et al., 2006; Ford, 2006). Phelan, Wadden, & Berkowitz (2007) examined the effects of lifestyle modification and pharmacotherapy in MetS patients

(n=224), and found that MA resulted in reduced MetS prevalence. However, the literature revealed that the problem of medication non-adherence is very prevalent in minority populations (Baker et al., 2007; Chobanian et al., 2003; Schillinger et al., 2006). In particular, research shows that AA adults frequently displayed low medication adherence behavior although prescription medications were the primary therapeutic regimen for their chronic illnesses (Murray et al., 2004a). This finding is important because AA adults continue to experience significant health disparities including shorter life expectancies. Therefore, factors that influence medication adherence in this population warrant further investigation. Finally, it is critical that risk factors for low medication adherence be identified early so that interventions can be implemented to promote positive healthcare outcomes for AA adults.

Literature Review Summary

Multiple physiological determinants are responsible for the cluster of abnormalities known as MetS (Grundy, et al., 2008; Ren & Kelley, 2009;). The risk, however, for MetS is highest in persons with diabetes, or pre-existing CVD, but persons with MetS incur a significant risk for CVD events (Ren & Kelley, 2009; Brietzke, 2007; Preiss & Sattar, 2007). Sudano and Baker (2001) found that middle-aged AA (73%) were less likely to follow medication regimens compared with their White counterparts (64%). The authors conducted a comparative study but did not provide rationale for this behavior except to suggest that the behavior was predicted by personal factors.

It is well-established that poor hypertension medication adherence leads to disease progression. For example, uncontrolled hypertension leads to MetS which is a primary determinant of CVD (Grundy et al., 2005). Emerging research suggests that low

hypertension medication adherence may contribute to disparately worse health outcomes for middle-aged AA with MetS. Of particular concern to healthcare providers is the finding that individuals diagnosed with MetS are at considerable risk for acute coronary events. Moreover, empiric evidence suggests relationships among low health literacy, stress, depression, a poor healthcare climate, and complexity of the medication regimen and medication non-adherence may contribute to negative healthcare outcomes in a variety of clinical populations. However, the research is inconclusive and further investigation is warranted. It is suspected that a lack of information about the disease process and MetS etiology, limited knowledge of hypertension, and a complex medication regimen are predictors of low hypertension medication adherence in adults with MetS (Grundy et al., 2005; Toren et al., 2005). Therefore, it is believed that if AA adults with MetS are provided with clear, simple health information, they will be more likely to follow their hypertension medication regimens which will result in reduced morbidity and mortality in later life, and thus facilitate more positive outcomes for them (Poon et al., 2009).

Gaps in Literature

AA adults were noticeably absent from many of the large clinical outcomes trials of lipid-lowering therapy. In fact, although many epidemiological studies included samples of adolescents and few middle-aged adults; the sample populations lacked diversity, as they were primarily White.

Moreover, medication adherence research spans over 30 years, yet little of this research addressed the topic from an AA perspective. In fact, AA adults are still grossly under-represented in much of the literature that examines health literacy and medication

adherence in other clinical populations (Osterberg & Blaschke, 2005). In addition, most studies looking at MetS outcomes have been examined in populations outside the U.S. (Shaista et al., (2004).

Medication adherence barriers specific to AAs with MetS were not well-addressed in the literature, nor was the association among social support, health literacy, and self-management behaviors. Although extensive research has been conducted to examine the relationships between social support and positive health outcomes, little of the research has examined the relationship between social support and health literacy in terms of health outcomes in AA adults with MetS. In addition, few research studies included theoretical frameworks to guide research related to African Americans' MetS health outcomes.

Research Questions

Based on the literature review describing links among personal characteristics and environmental factors, the following research questions were posed:

Question 1: What is the relationship of personal factors (age, gender, income, depression, co-morbidities, and education), behavioral capability (health literacy), and medication adherence in African American adults with MetS?

Question 2: What is the relationship between environmental factors (stress and social support), barriers (complexity of the medication regimen and quality of the therapeutic relationship) and medication adherence in African American adults with MetS?

Question 3: Will age, gender, income, education, health literacy, complexity of the medication regimen, and quality of the therapeutic relationship explain a greater variance in medication adherence over and above social support, stress, and depression in African

American adults with MetS?

Question 4: Will African American adults with adequate behavioral capability (health literacy) report greater medication adherence than those with inadequate behavioral capability (health literacy)?

Chapter III

Methods

Study Design of Proposed Study

A secondary analysis of data from a large collaborative participatory action research study, the *Morehouse and Emory are Teaming up to Eliminate Cardiovascular Health Disparities* (META- Health) (U.S. Department of Health and Human Services [HHS], 2004 -2010) was conducted. META-Health is a collaborative study with multiple aims designed to investigate racial disparities in African Americans (AAs) with metabolic syndrome (MetS) at risk for cardiovascular events in a larger southeastern urban community. The secondary analysis identified relationships that might suggest areas where healthcare providers could intervene, as well as identified some specific personal characteristics and environmental factors that healthcare providers need to be cognizant of in order to provide more culturally congruent care to promote more positive health outcomes for vulnerable persons such as this cohort of AA adults with MetS.

The proposed secondary analysis used a cross-sectional, correlational design to investigate the relationship between personal characteristics, behavioral capability, environmental factors, and HTN medication adherence in AA adults with MetS. Although the larger META-health study used longitudinal data, the proposed secondary analysis only used the baseline data collected from the larger study.

Description of Original Study

The original META-health study had three aims: Aim I) to define the influence of psychosocial/cultural factors and biologic mediators as determinants of ethnic disparities in obesity and MetS in a bi-racial cohort (Whites and AA); Aim II) to define the effectiveness of patient-centered lifestyle interventions to enhance the health of AAs with MetS based on community clinical practices; and Aim III) to assess the impact of innovative lifestyle intervention strategies on conventional and novel biomarkers of vascular disease risk in AAs.

Baseline Aim II data collected prior to randomization was used for the secondary analysis in the proposed study. Aim II in the original META-health study focused on lifestyle interventions related to diet and exercise to improve health outcomes for AA with MetS. At the baseline visit of the larger study, 203 potential participants were screened. Screening included an oral glucose tolerance test (OGTT) to identify participants with undiagnosed impaired glucose tolerance. Participants had to be fasting for at least 12 hours. Baseline blood draws for plasma glucose were done at fasting, after which each participant was given 75mg of glucola. Blood draws were done 30 minutes after the glucola was given and again at 2-hours. Eighty-three participants were excluded from the study because they did not meet screening criteria based on clinical data related to fasting glucose, insulin, and cholesterol levels. Participants who successfully completed a treadmill stress test (no ST-elevations, ischemia or hypertensive response on baseline EKG) were randomized to the study.

Incentives

Participants received monetary incentives in the form of gift cards for \$25 to \$40 depending on the visit. The participants were also compensated for parking or given tokens for public transportation.

Procedures for Original Study

After obtaining Institutional Review Board (IRB) approval, subjects were referred through the Community Practitioner Network (CPN) according to HIPAA guidelines. Potential participants who met inclusion criteria were contacted, screened for eligibility by phone, and provided with a detailed explanation of the study; the participants who agreed to participate were invited to a private interview where they completed the questionnaires. After completing the questionnaires, the participants were randomized to one of two groups based on a computer generated list of random numbers. The participants retained the right to discontinue or withdraw participation at any time.

Participants' baseline data were collected during a face-to-face interview at two local clinical research centers. Self-report information on participants' education level, income, health history, living arrangements, family health history, and medical history were obtained. Objective data on participants' weight and height (without shoes), waist circumference, and blood pressure were obtained by trained research nurses and study coordinators. Blood samples were obtained to ascertain clinical values for fasting glucose, insulin, and cholesterol levels. After the baseline data were collected, participants were randomized to intervention (education) or usual care, and followed over a 12-month period. There were four data time-points including baseline, 3-month, 6-

month, and 12-month. The baseline and 12-month measurements were comprised of two clinic visits each, one for blood work and one for a treadmill stress test, while the 3-month and 6-month measurements had one visit each. Therefore, participants committed to a total of six clinic visits.

Procedure for the Proposed Study

Since the proposed study was a secondary analysis of existing data from the Meta-Health study, participants were not re-contacted. The baseline data were cleaned and analyzed based on established statistical methodology.

Sample Criteria

Sample Size for Original Study

A sample size of 306 was proposed for the original study based on established research data; however, due to challenges in recruiting and after attrition, a sample size of 120 was attained. Both male and female participants, ages 21 to 70 years were recruited because MetS increases with age, and AA typically report earlier onset of chronic illnesses which frequently occur at older ages (Grundy et al., 2008).

Sample Size for Proposed Study

Since only data from AA adults ages 45 years and older were examined, the sample size for the proposed study (n=91) was smaller than the original study (n=120). The data for 29 participants from the original study were excluded because those participants were less than 45 years old and therefore not considered middle-aged. Moreover, adults greater than or equal to 45 years old were considered because the prevalence of MetS increases with advancing age, and 44% of those over 50 have MetS (Grundy, 2005; Lechlietner, 2008).

It is well documented that African American adults typically report earlier onset of chronic illnesses which frequently occur at older ages, and AA adults have the highest mortality rates from CHD, a primary outcome of uncontrolled MetS, than any other ethnic groups or races, especially at younger ages (Clark & El-Etat, 2009; Grundy et al., 2005).

Recruitment for the Original Study

After receiving approval from the Emory University Institutional Review Board (IRB), the study staff posted flyers across several large metropolitan university campuses, including historically black campuses, church bulletin boards, and assisted living facilities. In addition, the participants were recruited from the Community practice network (CPN), a practice-based consortium designed to eliminate disparities in healthcare. The CPN consists of over 40 clinical practices with over 300,000 patient visits throughout metropolitan Atlanta.

Over a three year period, participants were recruited from health fairs, large university campuses including historically Black college campuses with over 50% AA traditional and non-traditional students enrolled and over 80% minority faculty, and several AA churches in the metropolitan Atlanta area that have a large diverse ethnic population. Moreover, the targeted health fairs catered to the needs of persons who are predominantly AA, and the targeted AA churches served a predominantly AA congregation of various ages. Each AA church had a published congregation of over 700 members with over 60% of the membership aged 50 years or older. Therefore, it was expected that a representative sample of AA would be recruited in the various settings, thus reducing threats to external validity.

Inclusion Criteria for Original Study

The participants self-identified as African American, were able to read, write, and speak English, were 21-70 years of age, and were required to be diagnosed with hypertension in addition to two of the six components of MetS [1) waist circumference greater than 102 cm in men and 88 cm in women; 2) body mass index (BMI) > 25 and < 60 ; 3) serum triglyceride level of at least 1.7 mmol/L (≥ 150 mg/dl); 4) high density lipoprotein (HDL) cholesterol level < 40 mg/dl in men and < 50 mg/dl in women; 5) blood pressure (BP) of at least 130 mmHg systolic or 85 mmHg diastolic and 6) fasting plasma glucose level greater than 110 mg/dl and less than 130 mg/dl].

Inclusion Criteria for Proposed Study

The participants self-identified as African American, were able to read, write, and speak English, were 45-70 years of age, and were diagnosed with three of the six components of MetS [1) waist circumference greater than 102 cm in men and 88 cm in women; 2) body mass index (BMI) > 25 ; 3) serum triglyceride level of at least 1.7 mmol/L (≥ 150 mg/dl); 4) high density lipoprotein (HDL) cholesterol level < 40 mg/dl in men and < 50 mg/dl in women; 5) blood pressure (BP) of at least 130 mmHg systolic or 85 mmHg diastolic; and, 6) fasting plasma glucose level greater than 110 mg/dl and less than 130 mg/dl].

Exclusion Criteria for Original and Proposed Study

Exclusion criteria included pregnancy, psychoses, recent abdominal surgery, cardiovascular interventions or history of myocardial infarction. Although MetS is found in children, self-management behaviors related to medication adherence are developmentally linked. Children were not included in the original study because they

lack the cognitive and developmental capability to self-administer medications and understand complex medical regimens and more effort would be required to include children.

Although the Third National Health and Nutrition Examination Survey (NHANES III) data indicated that 25% of the US adult population 20 years and older and up to 44% of those over 50 years meet the diagnostic criteria for MetS (Grundy et al., 2008), participants older than 70 years were excluded because they were more likely to have other chronic illnesses or experience cognitive deficits or visual changes that may impact their ability to complete questionnaires. Participants with a current diagnosis of clinical depression or mental illness were excluded from this study, as these diagnoses may affect participants' ability to provide informed consent, complete questionnaires, or take medications without supervision. Therefore, potential participants with vision impairments, terminal illnesses, or depression and psychosis as determined by health history and current medication regimen were excluded from the study.

Data Collection for Original Study

Self-report survey data and clinical measures were used to address questions related to the problem of hypertension medication non-adherence in a population of AAs with MetS. Before the baseline visit, each participant self-reported being diagnosed by a physician with high blood pressure and high cholesterol. In addition, each participant reported being on a prescription medication regimen for at least three months.

Although the diagnosis of MetS remains controversial, MetS was diagnosed according to NCEP/ATP III diagnostic criteria. At the baseline visit, the investigator obtained anthropometrics by measuring participants' waist circumference and verifying

participants' heights and weights in order to calculate body mass index (BMI) (weight in kilograms divided by height in meters squared) (Third Report of NCEP, 2002).

First, the research staff used a stadiometer with calibrated scale to obtain height and weight of each participant without shoes. A flexible measuring tape was used to measure waist circumference and hip to waist ratio. Demographic data and information about medications and participants' overall rating of health were obtained through the health history form. Demographic/clinical variables consisted of age, gender, marital status, living arrangements, income, education, and co-morbidities. A medication sheet captured medication use according to past and current use of prescription and non-prescription medications including anti-hypertensives and lipid-lowering medications.

The participants committed to at least three hours for the baseline visit. Participants had an hour and a half down time while they waited for the final OGTT blood draw (two hours after the fasting blood draw). The questionnaires were usually completed during this down time. Each questionnaire was administered in approximately 5-10 minutes. Each participant was offered a brief respite and resumed completing the questionnaires when they indicated they were ready to do so. The participants retained the right to withdraw from the study at any time and did not lose any benefits if they withdrew from the study.

Assessment Tools for Proposed Study

The variables and instruments used for the study were: 1) hypertension medication adherence - Hill Bone Compliance Scale; 2) depression - Beck Depression Inventory II (BDI-II), 3) stress - Perceived Stress Scale (PSS), 4) provider and patient relationship - Health Care Climate Questionnaire (HCCQ); 5) complexity of medical regimen -

Medication sheet, 6) health literacy - Rapid Estimate of Adult Literacy in Medicine (REALM); 7) social support – Enhanced Social Support Inventory (ESSI); and 8) demographic information - Demographic /health history questionnaire.

Hypertension Medication Adherence (Hill Bone Compliance Scale)

Hypertension medication adherence was measured using the Hill Bone Compliance Questionnaire (Appendix A). Medication adherence conceptually meant following the medication regimen as prescribed by the physician. Operationally hypertension medication adherence meant taking the prescribed number of medicine doses at the frequency prescribed by healthcare provider and refilling medications as ordered. In this study, medication adherence only focused on adherence to hypertension medications associated with MetS.

The medication-taking sub-scale of the Hill Bone Compliance Questionnaire was used to measure hypertension medication adherence (Kim, Hill, Bone & Devine, 2000). Adequate reliability has been reported for the Hill Bone compliance scale (Cronbach's alpha .74 – .84), and adequate construct and predictive validity were established in one study (Kim et al., 2000). There were no reported reliability and validity for the individual subscales. For the current study, Cronbach's alpha was .71.

The original Hill Bone scale consists of 14 items with subscales that measure the frequency of behaviors related to medication taking (9 items, possible scores of 0 - 18); appointment keeping (2 items, possible score of 0 - 4), and salt intake (3 items, possible score of 0 - 6). For purposes of this study, only the hypertension medication adherence subscale was used. Three possible responses categories for the 9-item medication taking subscale were used and these response categories score from 0 to 2 for each item (0=

none of the time, 1= some of the time, and 2 = all of the time). Total scale scores ranged from 0 to 18, with higher scores indicating less hypertension medication adherence.

Depression (Beck Depression Inventory II)

Depression was measured using the Beck Depression Inventory II (Appendix B). Depression, the fourth leading cause of early death and disease burden worldwide, has complex etiology. Clinical depression may be caused by both genetic and non-genetic factors. The Beck Depression Inventory-II (BDI-II) is a self-administered 21-item scale (Beck, Steer, & Brown, 1996). Higher scores indicated more depressive symptoms and item nine captured suicidal ideation. If participants' BDI scores were > 20 or if they scored ≥ 2 on item nine, they were immediately referred to a licensed mental health professional. The BDI-II has adequate validity and reliability, has acceptable sensitivity and specificity relating to Diagnostic and Statistical Manual (DSM) criteria for major depression, and also provides a continuum of depressive symptoms (Beck et al., 1996). The BDI-II has been used in many CHD studies (Beck et al., 1996). For the current study, the Cronbach's alpha was .91.

Stress (Perceived Stress Scale)

Psychological stress was measured with the Cohen's Perceived Stress Scale (PSS) (Appendix C) (Cohen, Kamarck, & Mermelstein, 1983). The PSS is a widely used psychological instrument for measuring the perception of stress. It measures the degree to which situations in one's life are appraised as stressful. The scale measures the levels of stress experienced in addition to how overwhelming respondents find their lives. Higher PSS scores are associated with greater vulnerability to depressive symptoms as a result of stressful life-events (Cohen et al, 1983). The PSS is a 10-item survey validated

in multi-ethnic populations with a reliability of coefficient alpha of 0.86. For the current study, the alpha was .89. PSS scores are obtained by reversing responses (e.g. 0 = 4, 1 = 3, 2 = 2, 3 = 1, and 4 = 0) to the four positively stated items (items 4, 5, 7, and 8) and then responses are summed across all scale items. Possible range of scores are 0-40 and higher scores indicate more perceived stress.

Physician-Client Relationship (Health Care Climate Questionnaire)

The quality of the therapeutic relationship between patient and client was assessed with the Health Care Climate Questionnaire (HCCQ) (Williams, 1998).

The conceptual definition was the quality of the therapeutic relationship between doctor and patient, and operationally, it was the degree of autonomy and satisfaction the patient experienced with the healthcare provider.

The HCCQ (Appendix D) was developed to assess the level of autonomy experienced by the patient and supportiveness of the healthcare climate (HCC) created by the healthcare staff with their patients; it has been adapted for use in numerous settings. The HCCQ was validated in a study of patients visiting their primary care physician and was first used in a study of obese patients. The instrument displays adequate validity and reliability and is easily administered in various settings. Alpha reliability has been consistently above 0.90 (Williams, 1998). For the current study, the Cronbach's alpha was .95.

The original questionnaire is a 15-item measure that assesses patient's perceptions of their satisfaction with their healthcare provider and whether the physician-patient relationship is conducive to healthy behavior. Responses are structured in a 7-point Likert-format. The original HCCQ has been modified to a short 7-item scale where

responses are summed, and higher scores indicate a more therapeutic relationship with healthcare providers. The range of scores is 0- 42. The mean scores are reported. The short HCC scale demonstrated adequate reliability of 0.90 (Williams, 1998). The strength of the instrument is that it was validated in a population of obese patients and was well suited to this study population. The instrument is easily administered in a variety of settings.

Complexity of Medication Regimen (Medication Sheet)

Complexity of medication regimen was obtained from the information in the medication sheet (Appendix E). The medication sheet provided information on the number of prescription and non-prescription medications, as well as the dosing schedule. Constitutionally, complexity of the medication regimen was defined as the difficulty or challenge posed by the medical regimen in terms of multiple dosing frequencies of medications and multiple medications. Operationally, complexity was defined as the number of prescription medications and number of doses (Banning, 2009; McDonald, Pezzin, Peng & Feldman, 2009). The complexity of the medication regimen was dichotomously coded as “1” for complex regimen (more than one prescription medication and more than one dose) and “0” for simple regimen (one prescription medication and a single dose of the prescription medication).

Health Literacy (Rapid Estimate of Adult Literacy in Medicine)

Health literacy (HL) was measured by the Rapid Estimate of Adult Literacy in Medicine (REALM) questionnaire (Davis et al., 1991) (See Appendix F). Constitutionally, health literacy was defined as the ability to understand health instructions in a way to take charge of one’s health. Operationally, HL was the ability to

read and understand health instructions and lay terms encountered in a medical setting.

The REALM is a screening instrument used to assess an adult patient's ability to read words, such as lay terms for body parts and illnesses frequently encountered in a medical setting (Davis et al., 1991). The REALM was originally validated in 207 primary care patients and field tested with 203 adult patients in four public hospital primary care clinics. Adequate reliability (0.84) for the REALM has been reported (Davis et al., 1991). The REALM has been correlated with other standardized tests of health literacy and reading comprehension; the REALM is highly correlated with the Wide Range of Assessment Test-Revised (WRAT-R) ($r = 0.88$), the revised Slosson Oral Reading Tests (SORT-R) ($r = 0.96$), and the test of Functional Health Literacy in Adults (TOFHLA) (0.84). The REALM demonstrated concurrent validity with the TOFHLA with a correlation coefficient of 0.84 ($p < .001$). Test-retest reliability was high (coefficient 0.99) for the REALM in a sample of 100 adult inmates (Davis et al., 1991).

The possible range of scores was 0-66. Score cut-offs were to be included based on the identified scoring categories. The number of correct words in the list was counted, and the number was then recorded as the raw score. The total raw score was then matched with its grade equivalent (Davis et al., 1991). For example, scores \geq than 60 were coded as \geq high school reading level, and scores < 60 were coded as $<$ high school reading level. Score cut-offs were included: middle-aged AA with raw scores of 0-18 were counted as third grade reading level; scores of 19-44 were equated to fourth to sixth grade reading level; and scores of 45-60 were equated to seventh to eighth grade reading levels. Reading equivalency level of high school or greater (score of ≥ 61 out of a

possible 66) indicated that an individual should read and understand most healthcare information, since healthcare information is commonly written at tenth grade reading level (Safeer & Keenan, 2005). For analysis, scores were dichotomized as scores $< 60 = 0$ (inadequate HL), and scores $\geq 60 = 1$ (adequate HL) (Davis et al., 1991).

The REALM is one of the best word recognition tests and is still widely used today to assess patients' HL. The strength of the REALM for this study was its time and ease of administration in various settings and across diverse populations. Moreover, researchers do not need to be trained before they administer the REALM. The instrument only takes about two minutes to administer.

Social Support (*Enrichd* Social Support Scale)

Social support was measured using the *Enrichd* Social Support Inventory (ESSI) (Appendix A). Constitutionally, Haslam et al. (2006) define social support (SS) as interpersonal transactions that provide individuals with esteem, stress-related aid and emotional assistance. Operationally, social support is the degree of emotional and verbal encouragement from one's social network such as family, friends, and co-workers.

The ESSI was developed for a study called Enhancing Recovery in Coronary Heart Disease (ENRICHHD) (Berkman et al., 2003). Internal consistency for the ESSI was found to be adequate (Cronbach's alpha of 0.86-0.88) (Vaglio et al., 2004). For the current study, the alpha was .87. The ESSI correlated strongly and significantly with the Perceived Social Support Scale (PSSS) ($r = .63, p < .0001$). Concurrent and predictive validity were established using the SF-36 and the Seattle Angina Questionnaire (SAQ) Quality of Life (QOL) scale at baseline and 6 months in patients undergoing percutaneous coronary intervention (PCI) (Vaglio et al., 2004). The ESSI and the SF-36

Social Functioning subscale, the SF-36 Physical and Mental Component scores correlated modestly ($r = 0.19$, $p = 0.002$). The ESSi consists of seven statements of social and emotional support with responses in a 5-point Likert format. The categories range from 1 (none of the time) to 5 (all of the time) for the first 6 items and item seven (living with spouse) scored 4 for “yes” and 2 for “no.” Individual items were summed for a total score, with higher scores indicating greater social support. The range of scores is from 8-34. Items elicit information on the availability of someone to provide structural support, emotional (caring) support, informational support, and instrumental social support. The social support variable was interval level of measurement.

Data Analysis for Proposed Study

Data were analyzed using the Statistical Analysis Software (SAS) application version 9.0. Frequencies were run for all study variables before specific analyses were conducted. Descriptive statistics including measures of central tendency and variability such as the mean and standard deviation, for sample characteristics and main variables of interest were reported. . The extent of missing data were estimated and handled by imputation based on the valid values of other cases or variables in the sample. Thus, a group mean was inserted for the missing values by mean item substitutions.

The types of analyses were dependent on the level of data (nominal or continuous). Each variable of interest for this study was examined for its univariate distribution and to identify outliers for those variables measured on a continuous scale. Therefore, data were examined for normality. Each variable was analyzed for normal distribution in an initial data screening based on histogram, skewness, extent of kurtosis, box plots and tests for

outliers in order to determine whether parametric or non-parametric testing was appropriate. Cut-off points for outliers were determined using three standard deviations above or below the mean as criterion. Bivariate correlation was assessed to identify highly correlated variables that may have caused collinearity problems in multiple regressions. Correlational analysis was used to examine relationships between key variables as appropriate. Measures of central tendency were used to describe the sample in terms of age (mean and range), height, weight, BMI, gender, complexity of medication regimen, and co-morbidities. The dependent variable (DV) was hypertension medication adherence and the independent variables (IV) were social support, stress, depression, complexity of medication regimen, quality of the therapeutic relationship, and health literacy.

For Research Question 1: *“What is the relationship of personal factors (age, gender, income, depression, co-morbidities, and education), behavioral capability (health literacy), and medication adherence in AA adults with MetS?”* Chi square analyses were used to examine the relationships between key variables after categorizing participants based on meaningful cut-points for each variable.

For Research Question 2: *“What is the relationship between environmental factors (stress and social support), barriers (complexity of the medication regimen, and non-therapeutic health care climate), and medication adherence in AA adults with MetS?”* Chi square analysis was used to analyze data after categorizing the participants based on meaningful cut-points for each variable.

Logistic regression was used to answer Research Question 3: *“Will age, gender, income, education, health literacy, complexity of the medication regimen,*

and quality of the therapeutic relationship explain a greater variance in medication adherence over and above social support, stress, and depression in AA adults with MetS?”

For Research Question 4: “*Will AA adults with adequate behavioral capability (health literacy) report greater medication adherence than those with inadequate behavioral capability (health literacy)?*” Independent samples *t*-tests were used to compare mean scores on medication adherence between the participants with high functional health literacy (REALM scores greater than or equal to 61 out of a possible 66 score) and those who had low functional health literacy (REALM scores less than 61 out of a possible 66 score).

Human Subject Consideration

The META-health study is a multi-site collaboration with investigators from Georgia State University, Dr. Pat Clark; Emory University, Dr. Sandi Dunbar; Dr. Arshed Quyyumi and Dr. Viola Vaccarino, Emory University; Dr. Gary Gibbons and Dr. Priscilla Pemu, Morehouse School of Medicine. IRB approval was obtained prior to analysis of existing data.

Risks

For the proposed study there were no interactions between the student researcher and the participants because participants were not re-contacted for the secondary analysis.

Confidentiality

Participant confidentiality was maintained by keeping personal information private. The consent forms were stored in separate locked file cabinets away from the other study data which were also stored in locked file cabinets. A study number rather than

participant name was used on the original study records. Data from the original study as well as the current study were stored on firewall- and password-protected computers.

Summary

While research on health literacy and hypertension medication adherence is limited, the current research fails to address the topic from the perspective of middle-aged AA with MetS. The study presented a unique opportunity to address gaps in the literature to gain a fuller understanding of the relationship between personal and environmental factors and hypertension medication adherence in a cohort of middle-aged AA with MetS. A huge body of literature shows that nearly half of American adults have difficulty understanding health information in a way to take charge of their health. In particular, older AA report disparately high rates of low functional health literacy, even higher rates of medication non-adherence, and disparately high rates of chronic illnesses for which prescription medications are the primary therapeutic regimen. It is well-established that health literacy is a priority area for self-management for adults with chronic illnesses who take multiple medications to prevent negative health outcomes. Study findings may provide a deeper understanding of the correlation between study variables and medication adherence in AA adults with MetS. Identifying factors which are associated with low hypertension MA, which may lead to negative healthcare outcomes for AAs with MetS, will allow healthcare providers to identify AAs at risk early.

Chapter IV

Results

Data were analyzed using the Statistical Analysis Software (SAS) software application version 9.0. Descriptive statistics were calculated, including measures of central tendency and variability such as the mean and standard deviation, for sample characteristics and main variables of interest. The dependent variable was hypertension medication adherence and the independent variables were personal factors (age, gender, income, co-morbidities, depression), behavioral capability (health literacy), environmental factors (stress, social support), and barriers (health care climate, and complexity of the medical regimen). Reliability was assessed for all instruments using Cronbach's alpha for scales as appropriate and reported in Table 4.

The personal characteristic and environmental factor variables such as age, gender, income, depression, stress, social support, health care climate, and education were originally collected in a continuous format. However, based on distributional properties, it was decided to dichotomize the variables, thus making Chi-square and logistic regression the most appropriate analysis methods.

The sample size of 91 was large enough to provide a minimum power of .80 with alpha of .05 for the multiple regression with ten independent variables (k) (Research Question 3). Warner (2008) recommends a minimum of $N > 50 + 8k$ or $N > 104 + k$ to identify significant independent predictors. However, several variables were found to have non-normal distributions and were therefore converted to categorical variables, including the primary outcome variable, medication adherence, which was dichotomously coded (adherent was coded with "1"; not adherent was coded "0").

Therefore, logistic regression was used to answer this question.

For Research Question 1, *“What is the relationship of personal factors (age, gender, income, depression, co-morbidities, and education), behavioral capability (health literacy), and medication adherence in AA adults with MetS?”*

Chi-square analysis was used to answer this research question because it allowed for meaningful comparisons about how groups such as males and females, low income and high income, and high school reading equivalency and less than high school reading equivalency, differed in terms of proportions reporting hypertension medication adherence and non-adherence.

Although it is often better to use variables in a continuous format, the categorization of continuous variables in this case was based on the distributional properties of the variables and the categories used still provided for meaningful comparisons. For example, although age was continuous data, the variable was dummy coded to categorize those over 50 years old and those less than 50 years old. The research suggests that adults over 50 years old are less likely to report MA (Gazamararian et al., 2000). Moreover, the risk for MetS increases significantly in adults over 50 years old compared to those less than 50 years old (Grundy et al., 2004; Lechlietner, 2008). Consistent with the literature using 14 as the standard cutoff, depression scores were dichotomized into no depressive symptoms (< 14) or elevated depressive symptoms (≥ 14) (Berkman et al, 2003).

For Research Question 2: *“What is the relationship between environmental factors (stress and social support), barriers (complexity of the medication regimen, and non-therapeutic health care climate), and medication adherence in AA adults with*

MetS?” Chi square statistics were used to examine these relationships. Chi square analysis was most appropriate because the decision was made to categorize continuous variables after inspection of their distributions. Reference groups included those with more complex regimens compared to those with simple regimens, and those who reported more autonomy or satisfaction with their healthcare climate (HCC) (HCC score of >3) compared to those with less satisfaction with their health care climate (score of ≤ 3) and the proportions of each group that reported greater medication adherence (score of < 10).

The original plan was to use multiple hierarchical regression to answer Research Question 3: “*Will age, gender, income, education, health literacy, complexity of the medication regimen, and quality of the therapeutic relationship explain a greater variance in medication adherence over and above social support, stress, and depression in AA adults with MetS?*” However, due to non-normal distribution of several variables including the outcome variable, logistic regression was used to address this question.

For Research Question 4: “*Will AA adults with adequate behavioral capability (health literacy) report greater medication adherence than those with inadequate behavioral capability (health literacy)?*” The non-parametric counterpart of the independent samples *t*-test, the Wilcoxon rank sum test was used to compare ranks on hypertension medication adherence between the participants with high functional health literacy (REALM scores greater than or equal to 61) and those who had low functional health literacy (REALM scores less than 61).

Descriptive Statistics of Sample

Demographic Information

In the cohort of AA adults with MetS (N=91), 72 were female (79%) while 19 were male (21%). Participants ranged in age from 45 to 70 years, with an average age of 53.2 (SD = 6.3) years. Nine participants (10%) reported attaining a high school education or General Educational Development (GED) Certificate, while 63 participants (69%) reported acquiring some college education. The participants reported various household income levels; a few (13%) reported low income (< \$19,000); several (25%) reported incomes in the range of \$40,000-60,000, while others (13%) had incomes above \$60,000 and \$80,000. Table 1 provides further categorization of demographic variables.

Table 1

Descriptive Statistics of Sample Characteristics

Variables	n(%)
Age	
45-50 years old	30 (33)
≥ years old	61 (67)
Gender	
Male	19 (21)
Female	<u>72 (79)</u>
	91 (100)
Education	
High School/GED	9 (10)
Technical School (vocational school)	17 (19)
College	<u>63 (69)</u>
	89 (98)

(Table 1 Continues)

(Table 1 Continued)

Variables	n(%)
Household Income	
≤\$19,999	12 (13)
\$20,000 - \$39,999	22 (24)
\$40,000 - \$59,999	21 (23)
\$60,000 - \$79,000	12 (13)
≥ \$80,000	12 (13)
Don't know	3 (3)
Prefer not to answer	<u>8 (9)</u>
	90 (99)
Marital Status	
Married	37 (41)
Divorced	21 (23)
Separated	3 (3)
Widowed	9 (10)
Single	<u>20 (22)</u>
	90 (99)

Clinical Characteristics

Over half (n = 46) presented with uncontrolled high blood pressure (BP ≥ 130/80), while 12% (n=11) presented with dyslipidemia. The mean systolic BP was 127 mm Hg; the mean diastolic BP was 79 mm Hg (SD 6.3). Other clinical characteristics are shown in Table 2.

Table 2

Clinical Variables for Sample and by Gender

	Male n=19 (21%)	Female n=72 (79%)	Total sample n=91
B/P > 130.80	9 (48)	37 (52)	46 (50.5)**
Fasting Glucose			
<100 mg/dl	12 (63)	29 (40.3)	41 (45.1)
100-125 mg mg/dl	4 (21)	42 (58.3)	46 (50.5)
≥ 126 mg/dl	<u>3 (16)</u>	<u>1 (1.4)</u>	<u>2 (2.2)</u>
	19 (100)	72 (100)	89 (98)
BMI (kg/m ²) n (%);			
25-29.9	3 (15.8)	5 (7.0)	8 (8.8)
≥ 30	<u>16 (84.2)</u>	<u>67 (93.0)</u>	<u>83 (91.2)</u>
	19 (100)	72 (100)	91 (100)
WC M (SD)	109.42 (11.52)	106.59 (13.52)	107 (13.82)
HC M (SD)	114.28 (7.89)	121.01 (16.10)	120 (14.95)
HDL – M (SD)	47.5 (12.8)	50.5 (11.8)	49.6 (11.9)
LDL M (SD)	109.2 (29.8)	117.8 (34.6)	116.2 (34.3)

Note: WC = waist circumference, HC = hip circumference.

**The number of participants who presented with uncontrolled BP.

Medication Regimens

Almost three quarters of the sample (74%) reported simple medication regimens, that is, taking only one prescription medication and single dosing, while the remainder (26%) reported combination therapy or complex medication regimens of taking two or more prescription medications with multiple dosing. The majority of the participants (71%) took their hypertension prescription medications once daily and the others (29%) took prescription medications twice or more daily (see Table 3). The most frequently used hypertension medications were diuretics (74%), calcium channel blockers (28%),

angiotensin converting enzyme (ACE) inhibitors (22%), angiotensin receptor blockers (ARBs) (15%), and beta-blockers (15%).

Table 3

Complexity of Medication Regimen and Medication Classification

Number of Agents	Total – n (%)
Monotherapy	67 (74)
Dual therapy	21 (23)
Triple therapy	3 (3)
Number of doses – n (%)	
One dose	67 (74)
More than one dose	24 (26)
Medication classification	
ACE/ARB – n (%)	34 (36)
Diuretic	67 (74)
β-Blocker –	14 (15)
Calcium Channel Blocker	26(29)

Note: Complex regimen = dual or triple therapy and/or multiple dosing; Simple regimen = monotherapy and/or single dosing.

Descriptive Statistics for Major Study Variables

Descriptive statistics and adequate reliability coefficients for the major study variables are shown as appropriate in Table 4. Higher scores indicate greater levels of the variable, except for medication adherence, where higher scores indicate less hypertension medication adherence. Most (83%) of the sample reported low depressive symptoms, 94% reported low stress, 95% reported adequate HL, 85% reported adequate social support, while 94% reported satisfaction with HCC.

Table 4

Descriptive Statistics and Reliability Coefficients for Major Study Variables (N = 91)

Variables	<i>M(SD)</i>	Observed Min/Max	Potential Min/Max	Cronbach's Alpha
BDI-II: Test of depressive symptomatology	7.64 (7.3)	2-43	0-63	.91
PSS: Test of perceived stress	15.08 (7.34)	9-33	0-40	.89
REALM: Test of reading recognition	63.00 (3.31)	40-66	0-66	n/a
HCC: Test of autonomy and satisfaction with health care climate	5.04 (1.16)	5-6	0-6	.95
ESSI: Test of Social Support	26.00 (6.05)	23-32	2-40	.87
Hill Bone: Test of hypertension medication adherence	11.5 (2.56)	9-18	9-36	.71

Note: Min = minimum; Max = maximum.

Health Literacy

The mean score on the REALM was 63.67 (SD=3.31) indicating that on average participants displayed greater than a high school reading level (REALM score \geq 61). Of the 87 participants who reported a high school degree or higher, four had less than a high school reading level according to the REALM classification. The range of scores was 40-66; therefore the reading equivalency levels ranged from third grade (1%) to high school or greater (94%).

Hypertension Medication Adherence

Participants' scores on the hypertension medication-taking subscale of the Hill Bone Compliance scale ranged from 9-18 out of a possible range of 9-36. Thus, overall the mean was low (11.5, SD= 2.6) indicating relatively good hypertension medication adherence. However, based on the strict ranges for scoring the Hill Bone Compliance subscale (adherent = a score of 9, non-adherent= score of ≥ 10), nearly one-third (30%) of the participants were not adherent with hypertension medication taking (Kim et al., 2000). The scores were dichotomized to facilitate the logistic regression analysis and to provide more meaningful comparisons of the sample.

Relationship of Hypertension Medication Adherence with Sample Characteristics

Relationships among key variables were explored using chi square analysis. There was no significant difference in hypertension medication adherence between men and women [$\chi^2 (1, n = 90) = 0.0096, p = 0.92$].

Research Question 1

Initial data screening indicated that the data were not normally distributed. Therefore, several of the personal factor variables were dichotomously coded. Chi square analysis was then used to examine relationships between these key variables.

The categorizations for income were problematic because two of the categories were "don't know" and "prefer not to answer" and so income was not truly ordinal level data. Chi square analysis allowed for comparisons about how groups such as males and females, low income and high income, and high school reading equivalency and less than high school reading equivalency, differed in terms of proportions reporting medication adherence and non-adherence.

Therefore, Chi-square analysis was used to answer Research Question 1: “*What is the relationship of personal factors (age, gender, income, depression, co-morbidities, and education), behavioral capability (health literacy), and medication adherence in AA adults with MetS?*” to allow for more meaningful comparisons because gender, income, and education were nominal and ordinal levels of measurement.

The results indicated that older (≥ 50 years old) participants were less likely to report hypertension medication adherence [$\chi^2 (1, n = 90) = 6.71, p = 0.0096$] than younger ones (< 50 years old). However there were no other significant relationships between personal factors, behavioral capability and hypertension medication adherence as shown in Table 5.

Table 5

Comparison of Personal Factors and Hypertension Medication Adherence

Variable	DF	Chi-square	Probability
Age (≥ 50 years)	1	6.71	.0096
Gender (0=male, 1=female)	1	.0014	.9704
Education (HS or greater reading level)	1	2.11	.6461
Low Income (<\$19,999)	1	1.16	.2816
Depression (score of >14)	1	.1739	.6767

Results indicated that Research Question 1 was only partially supported as there was only one significant relationship, that of age and hypertension medication adherence [$\chi^2 (1, n = 90) = 6.71, p = 0.0096$]. Middle-aged African Americans with MetS (≥ 50 years) were more likely to report less hypertension medication adherence than those < 50 years old.

Co-morbidities

Table 6

Participants (N = 91) Co-morbidities and Inclusion Components

Variable	N (%)	M/SD
Co-morbidities:	91 (100)	1.20 (0.3)
High BP ($> 130/80$ mmHg)	46 (51)	127/79 (6.3)
Impaired Fasting Glucose (IFG) (FPG >100 mg/dl)	46 (53)	95.8 (15.5)
LDL cholesterol (> 126 mg/dl)	11 (12.0)	116.2 (34.3)
HDL cholesterol (<50 mg/dl)	12 (13.0)	49.6 (11.9)
Triglycerides (>150 mg/dl)	12 (13.0)	133.2 (90.0)

(Table 6 Continues)

(Table 6 Continued)

Variable	N (%)	M(SD)
Total cholesterol (>200 mg/dl)	12 (13)	193 (37)
Obesity (BMI >30kg/m ²)	83 (91)	36.5 (6)
Waist Circumference	80 (89)	107.2 (13.8)

Note: B/P = blood pressure. BMI = body mass index. HDL or LDL = high or low density lipoprotein.

The co-morbidities listed above (Table 6) were part of the metabolic syndrome, thus they are not typical Charleston co-morbidities but were components of the inclusion criteria. Given that hypertension MA was the outcome measure, hypertension was excluded while the other co-morbidities were counted for each person. The number of co-morbidities was analyzed to see if there was an association with hypertension medication adherence. Table 6 provides additional descriptions of sample co-morbidities. Of the 91 participants more than half (51%) presented with uncontrolled high blood pressure (>130/80 mm Hg). Although two participants (3%) reported a history of diabetes (fasting glucose levels >125 mg/dl), over half of the sample (53%) presented with impaired fasting glucose levels (fasting plasma glucose levels > 100 mg/dl) despite having no known history of diabetes. Moreover, several participants had elevated lipoprotein levels but were not on lipid-lowering medications. On average, women had HDL levels at the low end of the acceptable range of <50 mg/dl, while men on average were slightly above the 40 mg/dl acceptable range for men. Most participants (91%) were obese (BMI >30 kg/m²). Because of the small numbers of participants who

fell in the diabetes, overweight class, and dyslipidemia categories, it was not meaningful to conduct further analyses for co-morbidities.

Research Question 2

To answer Research Question 2: “*What is the relationship between environmental factors (stress and social support), barriers (complexity of the medication regimen, and non-therapeutic health care climate), and medication adherence in AA adults with MetS*?”, Chi-square analysis was used to compare groups based on cut-off scores. Chi square analysis allowed for comparisons about how groups such as low stress and high stress, low social support and high social support, complex and simple regimens, and therapeutic and non-therapeutic healthcare climate differed in terms of proportions reporting medication adherence and non-adherence. Among the environmental factors and barriers, stress [$\chi^2 (1, n = 90) = 6.28, p = .012$] and social support [$\chi^2 (1, n = 90) = 4.10, p = .04$] had the only significant relationships with hypertension medication adherence. Therefore the research question was only partially answered. Table 7 provides further comparisons of variables to hypertension medication adherence.

Table 7

Comparison of Stress, Social Support, Health Care Climate, Complexity of Regimen, and Hypertension Medication Adherence

Variable	Adherence N (%)	Chi-square	Probability
Low Stress (n=85)	A 60 (70) NA 25 (30)	4.62	0.03
Adequate Social support (n=77)	A 54 (70) NA 23 (30)	4.10	0.04
Simple Regimen (n=67)	A 60 (90) NA 7 (10)	1.21	0.27
Good HCC (n=86)	A 73 (85) NA 13 (15)	2.46	0.12

Note: HCC – Health Care Climate; A = Adherent; NA = Non-adherent

Research Question 3

Logistic regression was used to answer Research Question 3: “*Will age, gender, income, education, health literacy, complexity of the medication regimen, and quality of the therapeutic relationship explain a greater variance in medication adherence over and above social support, stress, and depression in AA adults with MetS?*”

Since the dependent variable was dichotomized to reflect adherence and non-adherence (1= adherent versus 0 = not adherent) logistic regression analysis was appropriate. Moreover, the dependent variable (MA) was dichotomous (1= adherent versus 0 = not adherent). The goal of the regression was to determine if a certain group of independent predictors were able to predict non-adherence.

In comparing adults with high stress and those with low stress (OR=0.848, 95% confidence interval .731-.983, $p = .0291$), highly stressed adults had a 15% reduction in the odds of adherence. Similarly, adults with a low income were 5.8 times more likely to be non-adherent (OR 5.828, 95% confidence interval 1.014-33.493, $p = .0482$). While adults with low social support had a 9% reduction in the odds of adherence, social support trended to significance (OR .914, 95% confidence interval .823-1.016, $p = .09$). African Americans of older age were more likely to be non-adherent (OR 1.12, 95% confidence interval 1.028-1.220, $p = .0096$), indicating that older AA with MetS were 12% more likely to be non-adherent with their hypertension medication regimens. The Wald statistic is the value tested for significance in logistic regression to determine which variables affect the probability of an event. In this analysis, the Wald was not significant. Thus, depression and social support were not significant predictors of hypertension medication adherence over and above the other predictors. In fact, age was more significant than stress, social support, or depression. Therefore, partial support was provided for the research question.

Research Question 4

Medication Adherence and Health Literacy

Research Question 4: “*Will AA adults with adequate behavioral capability (health literacy) report greater medication adherence than those with inadequate behavioral capability (health literacy)?*” Because the adherence variables were not normally distributed, Wilcoxon rank sum test was used to compare mean rank scores on medication adherence between the participants with high functional health literacy (REALM scores greater than or equal to 61) and those who had low functional health

literacy (REALM scores less than 61).

Of the 91 participants, most of the sample (95%) had attained health literacy levels equivalent to high school or greater. These reading equivalencies corresponded to REALM scores of 61 or greater out of a maximum score of 66. Given that 95% of the sample reported adequate health literacy, the comparison of health literacy groups should be interpreted with considerable caution. Results from the Wilcoxon rank sum test for independent samples was not significant ($p=0.6192$). For those with higher HL ($n=87$), the median MA score was 11, range of 9-13 compared to those with low HL ($n=4$) who had a median score of 10, range of 10-18 ($z=139.5$, $p=0.619$).

Summary

The sample ($N=91$) was primarily female, middle aged, [M 53.2 years (SD 6.3)], relatively well-educated, and married, with variability in household income (< \$19,000 to over \$80,000). Most participants presented with uncontrolled high blood pressures and reported several co-morbidities including obesity, elevated fasting glucose levels, and dyslipidemia. In addition, almost a quarter of the sample reported elevated lipoprotein levels. Although the vast majority of the sample displayed adequate health literacy, 30% of the sample was non-adherent to their hypertension medication regimen because of the strict scoring for the Hill Bone Scale.

Research Question 1 was addressed. Results indicated that a considerable number of older (>50 years) African American adults ($n=43$, 70%) with MetS were non-adherent to their hypertension medications. There were no other significant relationships between personal characteristics, behavioral capability, barriers and environmental factors and MA.

Research Question 2 and Question 3 were partially answered. High stressed middle-aged adults were significantly more likely to be non-adherent or had a 15% reduction in the odds of hypertension medication adherence. Similarly, middle-aged adults with a low income were 5.8 times more likely to be non-adherent (OR 5.828, 95% confidence interval 1.014-33.493, $p = .0482$), while middle-aged adults with low social support had a 9% reduction in the odds of hypertension medication adherence; social support trended to significance (OR.914, 95% confidence interval .823-1.016, $p = .09$). Older AA were more likely to be non-adherent (OR 1.12, 95% confidence interval 1.028-1.220, $p = .0096$) than middle-aged AA adults. Finally, given that 95% of the sample reported adequate health literacy, the comparison of health literacy groups should be interpreted with considerable caution.

Chapter V

Discussion and Conclusion

Uncontrolled hypertension in African Americans (AA) accounts for nearly 8,000 preventable deaths per year from cardiovascular events (Fiscella & Holt, 2008; Gu, Burt, Paulose-Ram, Yoon, & Gillum, 2008). In fact, AA adults have the highest mortality rate from cardiovascular disease (CVD) of any ethnic group, and especially at younger ages (CDC, 2007; Lechlietner, 2008). Moreover, vascular disease and its CVD complications carry a significant increase in morbidity and mortality in AA compared to their White counterparts (Anuurad, Chiem, Pearson & Berglund, 2007; Hilgers & Mann, 2008; Wright et al., 2008). Given that CVD is the largest cause of death (AHA, 2007) and the primary clinical outcome of MetS (Clark & El-Atat, 2007), it is important that AA adults with MetS take their hypertension medications as prescribed by their healthcare provider to prevent worse health care outcomes as they get older. It is well established that AA have worse health care outcomes than any other ethnic group. Interventions such as education about making proper lifestyle choices and appropriate medication-taking may be beneficial in the long term for this vulnerable population with its history of multiple-jeopardy. Moreover, early interventions such as making combination therapy the first line of defense for AA adults with MetS may aid in halting the cycle of cumulative disadvantage in old age.

Using baseline data collected from a convenience sample of 91 African Americans over 44 years old, the investigator found a significant relationship between certain personal and environmental factors and hypertension medication adherence (MA).

Personal Characteristics

The literature showed, that in studies which examined self-management behavior, personal characteristics were found to influence hypertension medication adherence. These study findings were consistent with the literature. Age was significantly associated with hypertension medication adherence. The sample was relatively younger (mean age 53 years) than other samples in self-management studies (Benson & Forman, 2002). In addition, the sample in this study was mostly female (79%), married, obese, and reporting uncontrolled diastolic and systolic blood pressure. Although the majority of the sample was recruited from a community practice network, most participants reported relatively high incomes which have been found to have a positive influence on medication adherence (Benson & Forman, 2002; Murray et al., 2004). People with higher income tend to receive healthcare on a more regular basis than those with lower incomes.

It is well-established that older adults with lower income and low education are more likely to display medication non-adherence (Fiscella & Holt, 2008). Consistent with the literature (Benson & Forman, 2002), this study sample was middle-aged, relatively well-educated and reported a good income; therefore the majority of the participants (70%) were adherent with their hypertension medication regimens.

Co-morbidities

MetS is a cluster of metabolic abnormalities including high blood pressure, dyslipidemia, insulin resistance, and obesity. Yatskar et al. (2007) found that MetS predicted development of diabetes for patients who did not have diabetes at baseline. In addition, insulin resistance is present in most people with MetS (Reaven et al., 2002). It is well documented that older adults diagnosed with MetS frequently display severe co-

morbidities (Grundy et al., 2008). Moreover, the literature suggests that persons with severe co-morbidities are more likely to display medication non-adherence (Lagu et al., 2009). In the current sample, the cluster of MetS risk factors was well-represented; however, the majority of the participants only reported co-morbidities which were in fact components of the inclusion criteria. Moreover, despite being on hypertension medications, more than half of the sample presented with uncontrolled high blood pressure; more than 10% presented with dyslipidemia; about 25% reported impaired fasting glucose levels; almost all were obese (BMI >30). Although most participants reported impaired fasting glucose levels, only a small number of participants (3%) were diabetic. It would appear that the majority of the participants were unaware of their risk for diabetes, a negative health care outcome frequently associated with uncontrolled MetS. Most of the components of the cluster of metabolic abnormalities of MetS were well represented in this cohort of middle-aged AA with MetS. However, except for participants in the high blood pressure group, there were only small numbers of participants with true co-morbidities outside of the components of the inclusion criteria. In fact, the Charlston co-morbidity index was not used in the larger study so there was no true measure of co-morbidities in the current study.

In the current study, the majority of the sample was adherent with their hypertension medication regimens and that behavior may be explained by the fact that the majority of the sample was primarily on mono-therapy and simple regimens, as well as reporting good incomes. However, over half of the sample presented with uncontrolled high blood pressure. This anomaly may be explained by the monotherapy. Although this sample self-reported HTM medication adherence, the medication regimens did not appear

to effectively control high blood pressure. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7) recommends combination therapy as the first line of defense for controlling high blood pressure in AA. The current study findings are consistent with the literature which shows that AA are still frequently placed on monotherapy, despite the well-documented success of combination therapy in controlling high blood pressure in this vulnerable population (Chobanian et al., 2003; Poon et al., 2009). Healthcare providers need to be more vigilant in making sure that there is increase in combination therapy for these AA adults.

Depression

Reynolds et al. (2004) provided evidence that depression was the strongest correlate of medication non-adherence, and medications to treat chronic illnesses may intensify depression.

Psychosocial factors such as depression are helpful in explaining and understanding non-adherence with medication regimens (Bane, Hughes, & McElnay, 2006; Schoenthaler, Ogedegbe, & Allegrante, 2007). Given that medication non-adherence may be tied to depression, healthcare providers need to understand the psychosocial reasons for non-adherent behavior to prevent lapses in the medical regimens. It is well documented that depression is widely implicated in non-adherent behavior (Bane et al., 2006).

Williams (1998) found that higher incidences of chronic health, economic strain, discrimination and disparities in the healthcare delivery system may lead to depression, which influences medication adherence. It appears that a lack of health insurance or

inadequate health insurance coverage and the inability to afford costly medications frequently increases stress which leads to depression.

However, in the current study, the association of depression and medication adherence was inconclusive given that increasing depressive symptoms were an exclusion criterion in the larger study. In fact, in the current study most of the sample was relatively well educated and most reported incomes greater than \$40,000, so it was not surprising that 70 participants (83%) reported no depressive symptoms based on their socio-economic status (SES). This is not to say that high SES precludes depressive symptoms. Inferential statistics showed that there was no significant relationship between depression and hypertension medication adherence. It is notable that due to the higher BDI cut-off scores (less than 21) for study inclusion compared to lower cut-off scores (less than 15) in other studies (Berkman et al., 2003) for depressive symptoms, the majority of the sample did not report depressive symptoms.

Behavioral Capability

Health Literacy

In the current study, health literacy was measured using the REALM. The REALM is a reading recognition test, not a test of reading comprehension, so participants who attain high school reading level may not always display adequate functional health literacy or good comprehension of health information (Benson & Forman, 2002). Additionally, participants with higher education do not always display good reading recognition as measured by the REALM.

The participants overwhelmingly reported high school reading levels which were consistent with their educational attainment. Consequently, the results were not

significant for the analyses comparing those with adequate functional health literacy (95%) (score of 61 or greater on the REALM) and those with inadequate HL (5%) (score of 60 or less out of a possible 66 on the REALM). Although the results indicated that the overwhelming majority of individuals (95%) should easily read and understand most healthcare information which is written at 10th grade level or greater (Safeer & Keenan, 2005), almost one-third (30%) of the participants were not adherent with their medication regimens as measured by the Hill Bone medication-taking subscale. This anomaly may have occurred because of the strict scoring of the Hill Bone Scale; an all or nothing score (score of 9 indicates adherence, >9 indicates non-adherence; range 9-18). According to the results from the National Adult Literacy Survey, 22% of US adults function at the lowest literacy skill level (3rd grade equivalent) (Benson & Forman, 2002). Safeer and Keenan noted that although most health care materials are written at 10th grade level or higher, most adults read between the eighth and ninth grade level. These researchers found that participants with a reading equivalency of at least high school level as measured by the REALM were able to read most patient education materials.

The sample in this study displayed remarkably high health literacy skills. In fact, the majority of the participants attained at least high school formal education, and 95% of the sample achieved good reading recognition on the REALM. Based on these findings, one would expect that most of the participants in this current sample should be able to read and understand healthcare information allowing them to take charge of their health. As expected, 70% of the participants reported adherence to medication taking as measured by the Hill Bone hypertension medication- taking subscale.

Georges, Bolton, and Bennett (2004) found that patients with inadequate functional health literacy had difficulty reading, understanding, and interpreting health information and medication instructions. In the current study, although the participants overwhelmingly reported adequate health literacy (95%), no significant relationship between high health literacy scores and hypertension medication adherence were found because there was little or no variation in health literacy hindering the ability to find any relationship. In a study by Benson & Forman (2002) it was found that in a population of affluent, well-educated older adults, 30% of the participants displayed poor functional health literacy.

In a related study by Hixon (2004) patients with inadequate functional health literacy invariably were non-adherent with their medication regimen. Hixon found that patients without formal education displayed inadequate functional health literacy; frequently attained less than high school reading levels, and did not know how to take their medications properly. In the current study, the participants with higher health literacy were mostly adherent with their regimens but the findings are inconclusive given that the majority of the sample reported adequate health literacy. Given that only hypertension medication adherence was measured, it would be beneficial to explore all medication adherence in persons with MetS. Further study is warranted.

Barriers

Complexity of the medication regimen

Research suggests that factors associated with medication non-adherence appear to be the complexity of the medication regimen, the degree of medication supervision, monitoring by healthcare providers, health status of the patient, and available social

support (Murray et al., 2004; Safeer & Keenan, 2005). Previous research has shown that better medication adherence is associated with single dosing while multiple dosing frequently leads to non-adherence (Hilgers & Mann, 2008; Safeer & Keenan, 2005; Wright et al., 2008). Consistent with this finding, in the current study, 25% (n=23) of the sample was on multiple dosing regimens, and more than a quarter (n=27) of the sample was non-adherent with their regimens. Conversely, in the current study, the majority (70%) of the study participants were on single dosing regimens, and most of the participants (n=64; 70%) were adherent.

Similarly, in a study by Safeer and Keenan (2005) the sample on simple medication regimens reported more medication adherence. It is notable that although the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: The JNC-7 Report (JNC7) (Chobanian et al., 2003) recommends combination therapy as the first line of defense in controlling BP, almost 70% of the participants were on monotherapy. It is therefore not surprising that half of the sample presented with uncontrolled BP (>130/90 mmHg) despite being on antihypertensive medication regimens.

Health Care Climate

The literature showed that barriers to MA include personal and institutional barriers. Absence of a healthy therapeutic relationship between the physician and the patient due to lack of trust or lack of culturally sensitive care may influence MA. Institutional barriers such as discrimination and prejudice may prevent older adults from receiving adequate information or even preclude involvement in their healthcare decision making. If there is no satisfaction with the healthcare climate, or if the healthcare

environment precludes autonomy, individuals may not feel accountable and may deviate from the medication regimen (Chiriboga et al., 2005, Williams et al., 1998). Moreover, it is well documented that open communication is a critical component of the healthcare climate (Friedman et al., 2008; Veazie & Cai, 2007).

In the current study, the median health care climate score was 5.5 (range 4.5 - 6.0) which indicated that majority of the sample (94%) reported autonomy and satisfaction with the therapeutic relationship. However, it is not clear how well this autonomy or satisfaction with the healthcare provider translates to involvement in the healthcare, or how effective the health communication is between the participants and their healthcare providers. For example, although more than a half (n=48) had fasting blood glucose levels above 100 mg/dl, only three participants were diagnosed with impaired fasting glucose. Last, although the majority of the sample (n=86; 94%) reported a feeling of autonomy or satisfaction with the therapeutic relationship, there was no significant relationship between healthcare climate and MA.

Environmental Factors

Stress

Empiric evidence suggests that environmental demands predispose individuals to psychological stress (Berkman et al., 2003; Cohen, Kamarck, & Mermelstein, 1983; Steptoe et al., 2008; Williams, 1998). In addition, the availability of healthcare management resources impact stress, which frequently leads to negative health outcomes (Williams, 1998). Knox and colleagues (2008) posited that depression in AAs is very prevalent due to a convergence of societal and biological factors including obesity, anxiety, anger and resultant morbidity related to stress. Stress may be caused by racial

discrimination and institutionalized racism in healthcare or in the workplace (Williams, 1998). Empiric evidence showed that stress was linked to depression which frequently resulted in low medication adherence (Berkman et al., 2003; Cohen et al., 1983). Health disparities may be related to the socio-demographic and cultural factors of stress exposure including financial strain and variations in adaptive resources, inadequate social support systems, and the stigma of mental health such as depression (Chiroboga et al., 2005; Williams, 1998). Findings from the current study showed that the majority of the sample (94%) had low stress.

In the current study, there was a trend toward improved medication adherence with lower stress scores, Cohen et al. (2006) found that individuals who reported low stress were more likely to engage in health-seeking behaviors and appeared more knowledgeable about their health problems, and displayed more medication non-adherence. In previous research individuals who were categorized as having high stress (PSS score greater than or equal to 20), were less likely to engage in health behaviors and were less knowledgeable about their health problems (Cohen et al., 2006).

Social Support

The literature shows the protective effects of social support for positive healthcare outcomes and health behaviors (Collie, Wong, Tiltson et al, 2005; Lee & Sharpe, 2007;). Therefore, social support is an important factor in chronic illness management (Haslam, Pakenam, & Smith (2006). In the current study, almost one half of the participants were married, and less than a quarter were single. However, it was not clear what percentage of the remaining participants were living with significant others. Notwithstanding, the sample reported adequate available social support (mean score of 26, out of a possible

34), which is an important explanatory variable of high medication adherence. Consistent with the literature (Gallant et al, 2003; Vaglio et al., 2004), there was a significant relationship between social support and medication adherence in the current sample. Adequate social support has been linked to access to resources that help solve problems thus leading to confidence, personal control of chronic illness, increased self-management behavior, and general control over life (Baker et al., 2002; Lucove, Kaufman, & James, 2007). These authors concluded that when stressors are experienced, having enough social capital increases likelihood that stressors will be handled appropriately.

Limitations

Although this research will add to the limited literature concerning middle-aged African Americans' non-adherence with medical regimens, this research is still preliminary and has several limitations. First, a threat to external validity was that the sample was a convenience sample of self-reported MetS patients whose medication-taking behavior may not be representative of the general population. Because this study sample was a convenience sample, the unknown unique characteristics of volunteers was a limiting factor in this study. Moreover, the sample was a homogenous sample from a larger convenience sample, which may bias the findings. The sample was not representative of a typical AA population experiencing health disparities. These participants were primarily middle-aged African Americans; therefore the findings may not be generalizable to other races or persons in different age categories.

Because the study was based on self-reports, medication adherence may have been over- or under-reported. For example, over half (n=46) of the participants presented with

elevated BP despite being on anti-hypertensive medications, suggesting their BP was uncontrolled. The instruments for measuring HL and MA were not objective. More objective measures such as pill counts or Medication Electronic Monitoring (MEM) would give more accurate reports of medication adherence (Balkrishnan et al., 2004). Lastly this cross-sectional study only analyzed baseline data so did not capture change over time.

Despite these limitations, study findings may provide a deeper understanding of the relationship among personal characteristics, environmental factors, and medication adherence in African Americans. The study is important because the results showed that low MA was a fairly frequent occurrence with adults, especially those with chronic illnesses such as MetS. Since African Americans experience huge disparities with chronic illnesses, particularly early onset of cardiovascular diseases and diabetes (Henderson et al., 2007; Safeer & Keenan, 2005; Sorrell, 2004); interventions may be implemented to improve medication adherence in AA with MetS. These interventions would lead to more positive healthcare outcomes for AA adults.

Implications for Health Practices

The study has several implications for nursing practice and patient outcomes. First, more collaboration is needed so that at each stage of the health delivery process, healthcare professionals assume advocacy roles for each patient. A therapeutic healthcare climate and health information provided at the appropriate level will lead to greater medication adherence and improved healthcare outcomes (Friedman et al., 2008; Praska et al., 2005). A therapeutic HCC will be created when AA adults are given the opportunity to discuss their concerns and to have meaningful discussion with their

healthcare providers, rather than being passively involved in their healthcare decisions. Clinicians need to spend more time answering questions and have patients return demonstrate that they understand their medical instructions. According to Kripalani et al. (2006) patients complained that they felt rushed by their doctors and they complained that they were not fully instructed on new medications use, side effects or indications. In fact, these many patients reported excessive re-hospitalizations due to inappropriate medication dosing (Toren et al., 2005). It is well established that simpler regimens will lead to more effective outcomes (Lagu et al., 2009). Moreover, the healthcare delivery system needs to be improved so that a collective effort is made to provide qualified advice, in order for patients to receive sufficient information about their own drug therapy. Research suggests that a more individualized versus generalized approach in medication administration for AA adults is needed (Toren et al., 2005).

The current study provided evidence that adequate health literacy, available social support, and satisfaction with the healthcare climate may influence medication adherence. When adults can afford their medications, have adequate health insurance, supportive social networks, and autonomy support from their HCC, they will be more likely to take charge of their health. Hixon (2004) and Gazmararian et al. (2003) found that inadequate health literacy may lead to medication non-adherence because adults may have problems accessing healthcare, following medication instructions, and remembering to take their medications. If patients do not know that “three times a day” means every eight hours they will take their HTN medications at arbitrary times, and never achieve therapeutic effectiveness. Educational attainment is not always the best assessment of readiness to understand health information. Health care providers should not assume that having a

college education automatically makes one ready to understand health information. Although 95% of the sample read at high school level or greater, only 70% reported adequate HTN medication adherence. Results from this current study suggest that there is a dynamic interplay of general literacy, health literacy, and medication adherence. The participants in the current study were well educated, reported good income and were more likely to adhere to their medication regimen. It is also well established that poor health communication or ineffective interaction with the healthcare provider is associated with low medication adherence (Friedman et al., 2008). The findings for the current study are inconclusive because the overwhelming majority (94%) of the sample reported satisfaction with their healthcare climate, yet there was no significant relationship was found between medication adherence and healthcare climate. Currently, a critical need exists for research such as this to identify patients at risk for inadequate health literacy and low hypertension medication adherence, and to intervene early to predict more positive healthcare outcomes.

Implications for Future Research

Future research could use longitudinal design to capture hypertension MA behavior change over time. In addition, future research could examine hypertension medication non-adherence from a gender perspective because the literature suggests that AA women have approximately 57% higher prevalence of MetS than their male counterparts (25% versus 16%) (Appel et al., 2006; Clark & El-Etat, 2007; Ford, 2006).

Although 69% of the sample attained a college education, 95% of the sample read at high school reading level or greater. More objective methods of eliciting and measuring health literacy would be meaningful. For example, although more expensive, the Test of

Functional Health Literacy in Adults (TOFHLA) and the Medication Event Monitoring caps would be more objective instruments for assessing both reading recognition and understanding both written and numeric health information in a way that allows AAs to take charge of their health care. Lastly, future research could be conducted with well-educated AAs versus less educated AAs with MetS to describe the differences.

Comparison of Findings to SCT Framework

Conceptually, using the SCT framework, the key study variables should predict medication adherence in the cohort of AA adults with MetS. The SCT was useful for this cohort of AA adults with MetS. The participants' personal characteristics displayed a triadic reciprocity with the environmental factors, and behavioral capability. For example, the participants were well-educated, reported good income, low stress, relatively low depression, adequate social support and behavioral capability (high health literacy), and several co-morbidities. Barriers with medication adherence were minimal since the overwhelming majority of the participants reported simple medication regimens and high satisfaction with their healthcare climate. However, many of the key variables were not significantly associated with medication adherence, moreover it was not meaningful to do further comparisons related to health literacy and gender due to a lack of variability.

Notably, consistent with the SCT, the study findings suggested that changes in one construct (personal characteristics) appeared to influence other constructs such as behavioral capability and environmental factors. For example, higher education was significantly associated with better health literacy; higher income was significantly

associated with low stress; while adequate social support was significantly associated with low stress, low depression, and high health literacy.

The association of barriers to expected outcomes was consistent with the framework. Consistent with the literature, these AA adults with MetS were mostly on simple regimens and reported good hypertension medication adherence (Poon et al, 2009). In addition, the participants reported high satisfaction with their healthcare climate and would be expected to report good medication adherence (Williams et al., 2005). However, the relationship between healthcare climate, complexity of regimen, and hypertension medication adherence was not significant so the research question was not answered. Although the majority of the participants reported high satisfaction with their healthcare providers, it was not clear to what degree satisfaction with the healthcare climate influenced medication taking behavior. Further study is needed to explore the mediating pathways between personal characteristics, environmental factors, behavioral capability, barriers, and hypertension medication adherence.

Conclusion

Data were collected from 91 participants as part of a larger intervention study to reduce CVD disparities in minorities. The purpose of this study was to examine medication adherence in AA adults with MetS by determining the relationships among personal characteristics, behavioral capability, and environmental factors. Personal characteristics included age, gender, income, and education; behavioral capability was conceptualized as health literacy, while environmental factors included stress, depression, social support, and barriers included complexity of the medication regimen, and quality of the therapeutic relationship. Research suggests that AA adults are more likely to have

inadequate functional health literacy than younger adults. However, in the current study, most of the older participants reported adequate health literacy. Moreover, it is well-documented that a significant relationship exists among medication adherence and key study variables in a variety of clinical populations. In fact, in study populations such as cancer, high blood pressure, renal populations, and diabetic populations, researchers provided evidence that key study variables positively influenced medication adherence (Rothman et al., 2005; Bosworth et al., 2006; Schillinger et al., 2006). Surprisingly, in the current study, an investigation of key study variables did not yield similar findings to those unearthed in other study populations.

Given that the research questions were only partially answered, further research is warranted to more clearly define the suspected relationships using more objective measures to assess medication adherence and possibly to include another measure such as the Test of Functional Health Literacy in Adults (TOFHLA) which captures reading comprehension, not just reading recognition as demonstrated in the REALM. These findings suggest that further investigation of the relationships and potential mediating pathways between personal characteristics, environmental factors, and behavioral capability that may contribute to hypertension medication non-adherence in African American adults with MetS is needed.

Although current sample was homogenous in both personal and environmental factors and not representative of a typical AA cohort with MetS, study findings were consistent with the literature. The study results provided evidence that AA adults are still receiving inappropriate medication regimens for their chronic illnesses. It is therefore not surprising that although CVD morbidity and mortality have decreased over the last

decade, the incidences of CVD morbidity and mortality for AAs continue to rise. Health care providers continue to disregard the recommendations of the JNC7 for combating uncontrolled high blood pressure in AAs. Disparities in diagnoses and treatment need to be more adequately addressed. For example, health care providers and insurance companies need to be held more accountable for inadequate treatment of chronic illnesses in AAs. African American adults must be more actively involved in decisions regarding their care, by being more educated to ask good questions and not being afraid to talk with their healthcare providers. It was very surprising that 70% of the current sample was on monotherapy. Unless drastic changes are implemented in the way AAs receive care for their chronic illnesses, AA s will continue to have worse healthcare outcomes than any other group.

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Appendix A
Hill Bone Compliance Scale

Appendix A

Hill Bone Compliance Scale

META-Health Study	Participant ID <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	Date(mmddyy) <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>
	Visit # <input type="text"/> <input type="text"/>

Hill-Bone Compliance Scale

Item: Please mark the frequency with which each situation happens.	None of the time	Some of the time	Most of the time	All of the time
1. How often do you forget to take your HBP (High Blood Pressure) medicine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. How often do you decide not to take your HBP medicine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. How often do you eat salty food?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. How often do you shake salt on your food before you eat it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. How often do you eat fast food?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. How often do you make the next appointment before you leave the doctor's office?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. How often do you miss scheduled appointments?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. How often do you forget to get prescriptions filled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. How often do you run out of HBP pills?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. How often do you skip your HBP medicine before you go to the doctor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. How often do you miss taking your HBP pills when you feel sick?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. How often do you miss taking your HBP pills when you feel better?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. How often do you take someone else's HBP pills?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. How often do you miss taking your HBP pills when you are careless?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RA Initials

Appendix B

Beck Depression Inventory-II (BDI-II)

Appendix B

Beck Depression Inventory-II (BDI-II)

META-Health Study	Participant ID: □ □ □ □	Visit #: □ □	
	Date(mmddyy): □ □ / □ □ / □ □		Researcher's initials: □ □ □

Beck Depression Inventory

INSTRUCTIONS: This Questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the **one statement** in each group that best describes the way you have been feeling during the **past 2 weeks, including today**. Mark the box beside the statement you have picked (). If several statements in the group seem to apply equally well, mark the highest number for that group. Be sure that you do not choose more than one statement for any group, including item 16 (Changes in Sleeping Pattern) or item 18 (Changes in Appetite).

1. Sadness

- 0 I do not feel sad.
 1 I feel sad much of the time.
 2 I am sad all of the time.
 3 I am so sad or unhappy that I can't stand it.

2. Pessimism

- 0 I am not discouraged about my future.
 1 I feel more discouraged about my future than I used to be.
 2 I do not expect things to work out for me.
 3 I feel my future is hopeless and will only get worse.

3. Past Failure

- 0 I do not feel like a failure.
 1 I have failed more than I should have.
 2 As I look back, I see a lot of failures.
 3 I feel like I am a total failure as a person.

4. Loss of Pleasure

- 0 I get as much pleasure as I ever did from the things I enjoy.
 1 I don't enjoy things as much as I used to.
 2 I get very little pleasure from the things I used to enjoy.
 3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

- 0 I don't feel particularly guilty.
 1 I feel guilty over many things I have or should have done.
 2 I feel quite guilty most of the time.
 3 I feel guilty all of the time.

6. Punishment Feelings

- 0 I don't feel I am being punished.
 1 I feel I may be punished.
 2 I expect to be punished.
 3 I feel I am being punished.

7. Self-Dislike

- 0 I feel the same about myself as ever.
 1 I have lost confidence in myself.
 2 I am disappointed in myself.
 3 I dislike myself.

Appendix C

Perceived Stress Scale (PSS)

Appendix C

Perceived Stress Scale (PSS)

META-Health
Study

Participant ID Date(mmddyy) / / Visit #

Perceived Stress Scale

Instructions: The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by checking how often you felt or thought a certain way.

	Never	Almost Never	Some- times	Fairly Often	Very Often
1. In the last month, how often have you been upset because of something that happened unexpectedly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. In the last month, how often have you felt that you were unable to control the important things in your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. In the last month, how often have you felt nervous and "stressed"?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. In the last month, how often have you felt confident about your ability to handle your personal problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. In the last month, how often have you felt that things were going your way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. In the last month, how often have you found that you could not cope with all the things that you had to do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. In the last month, how often have you been able to control irritations in you life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. In the last month, how often have you felt that you were on top of things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. In the last month, how often have you been angered because of things that were outside of your control?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RA Initials

Appendix D

Health Care Climate Questionnaire (HCCQ)

Appendix D

Health Care Climate Questionnaire (HCCQ)

META-Health
Study

Participant ID Visit #
Date(mmddyy) / /

Health Care Climate Questionnaire

The statements below are about your relationship with the doctors and nurses who have spoken to you about making healthy changes in your lifestyle (diet and exercise). Think about your **LAST TWO VISITS** and pick how strongly you agree or disagree. If you have talked to more than one doctor or nurse about making lifestyle changes, pick the one that best describes your overall experience.

1. I feel that my health care provider has provided me choices and options about managing my lifestyle changes.

Strongly Moderately Slightly Neutral Slightly Moderately Strongly
Disagree Disagree Disagree Agree Agree Agree

2. I feel my health care provider understands how I see things with respect to managing my lifestyle changes.

Strongly Moderately Slightly Neutral Slightly Moderately Strongly
Disagree Disagree Disagree Agree Agree Agree

3. My health care provider conveys confidence in my ability to make lifestyle changes necessary to be healthy.

Strongly Moderately Slightly Neutral Slightly Moderately Strongly
Disagree Disagree Disagree Agree Agree Agree

4. My health care provider encourages me to ask questions about lifestyle changes I need to make.

Strongly Moderately Slightly Neutral Slightly Moderately Strongly
Disagree Disagree Disagree Agree Agree Agree

Appendix E
Medication Sheet

Appendix E

Medication Sheet

MEDICATIONS			
Participant ID:	Date(mmddyy):	Visit #:	Researcher's initials:
<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/>	<input type="text"/>
Frequency Legend:			
QOD=every other day	BID=twice a day	QID=four times a day	
QD=once a day	TID=three times a day	PRN=as needed	
Alpha Blocker	<input type="radio"/> Yes <input type="radio"/> No	Name <input type="text"/> Frequency <input type="checkbox"/> QOD <input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN	Dose(mg) <input type="text"/> Dose changed from last visit? <input type="radio"/> Yes <input type="radio"/> No
Beta Blocker	<input type="radio"/> Yes <input type="radio"/> No	Name <input type="text"/> Frequency <input type="checkbox"/> QOD <input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN	Dose(mg) <input type="text"/> Dose changed from last visit? <input type="radio"/> Yes <input type="radio"/> No
ARB	<input type="radio"/> Yes <input type="radio"/> No	Name <input type="text"/> Frequency <input type="checkbox"/> QOD <input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN	Dose(mg) <input type="text"/> Dose changed from last visit? <input type="radio"/> Yes <input type="radio"/> No
ACE	<input type="radio"/> Yes <input type="radio"/> No	Name <input type="text"/> Frequency <input type="checkbox"/> QOD <input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN	Dose(mg) <input type="text"/> Dose changed from last visit? <input type="radio"/> Yes <input type="radio"/> No
Ca Blocker	<input type="radio"/> Yes <input type="radio"/> No	Name <input type="text"/> Frequency <input type="checkbox"/> QOD <input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN	Dose(mg) <input type="text"/> Dose changed from last visit? <input type="radio"/> Yes <input type="radio"/> No
Statin	<input type="radio"/> Yes <input type="radio"/> No	Name <input type="text"/> Frequency <input type="checkbox"/> QOD <input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN	Dose(mg) <input type="text"/> Dose changed from last visit? <input type="radio"/> Yes <input type="radio"/> No
Other lipid lowering medication	<input type="radio"/> Yes <input type="radio"/> No	Name <input type="text"/> Frequency <input type="checkbox"/> QOD <input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN	Dose(mg) <input type="text"/> Dose changed from last visit? <input type="radio"/> Yes <input type="radio"/> No
Oral Hypoglycemic	<input type="radio"/> Yes <input type="radio"/> No	Name <input type="text"/> Frequency <input type="checkbox"/> QOD <input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN	Dose(mg) <input type="text"/> Dose changed from last visit? <input type="radio"/> Yes <input type="radio"/> No
Coumadin	<input type="radio"/> Yes <input type="radio"/> No	Name <input type="text"/> Frequency <input type="checkbox"/> QOD <input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN	Dose(mg) <input type="text"/> Dose changed from last visit? <input type="radio"/> Yes <input type="radio"/> No
Aspirin	<input type="radio"/> Yes <input type="radio"/> No	Name <input type="text"/> Frequency <input type="checkbox"/> QOD <input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN	Dose(mg) <input type="text"/> Dose changed from last visit? <input type="radio"/> Yes <input type="radio"/> No
NSAIDS	<input type="radio"/> Yes <input type="radio"/> No	Name <input type="text"/> Frequency <input type="checkbox"/> QOD <input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN	Dose(mg) <input type="text"/> Dose changed from last visit? <input type="radio"/> Yes <input type="radio"/> No
Diuretic	<input type="radio"/> Yes <input type="radio"/> No	Name <input type="text"/> Frequency <input type="checkbox"/> QOD <input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN	Dose(mg) <input type="text"/> Dose changed from last visit? <input type="radio"/> Yes <input type="radio"/> No
Diuretic	<input type="radio"/> Yes <input type="radio"/> No	Name <input type="text"/> Frequency <input type="checkbox"/> QOD <input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> TID <input type="checkbox"/> QID <input type="checkbox"/> PRN	Dose(mg) <input type="text"/> Dose changed from last visit? <input type="radio"/> Yes <input type="radio"/> No

Appendix F

Rapid Estimate of Adult Literacy in Medicine (REALM)

*Appendix F**Rapid Estimate of Adult Literacy in Medicine (REALM)***Rapid Estimate of Adult Literacy in Medicine**

Patient name _____ Date of birth _____ Reading level _____

List 1Fat Flu Pill Dose Eye Stress Smear Nerves Germs Meals Disease Cancer Caffeine Attack Kidney Hormones Herpes Seizure Bowel **List 2**Fatigue Pelvic Jaundice Infection Exercise Behavior Prescription Notify Gallbladder Calories Depression Miscarriage Pregnancy Arthritis Nutrition Menopause Appendix Abnormal Syphilis **List 3**Allergic Menstrual Testicle Colitis Emergency Medication Occupation Sexuality Alcoholism Irritation Constipation Gonorrhea Inflammatory Diabetes Hepatitis Antibiotics Diagnosis Potassium Anemia

Asthma Hemorrhoids Obesity Rectal Nausea Osteoporosis Incest Directed Impetigo

List 1 score _____

List 2 score _____

List 3 score _____

Raw score _____

Appendix G

Enriched Social Support Inventory (ESSI)

Appendix G

Enriched Social Support Inventory (ESSI)

Meta-Health
Study

Participant ID Date(mmddyy) / / Visit #

Enriched Social Support Inventory (ESSI)

INSTRUCTIONS: Please read the following questions and mark the response that most closely describes your current situation.

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
1. Is there someone available to you whom you can count on to listen to you when you need to talk?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is there someone available to give you good advice about a problem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Is there someone available who shows you love and affection?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is there someone available to help you with daily chores?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Can you count on anyone to provide you with emotional support (talking over problems or helping you make a difficult decision)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Do you have as much contact as you would like with someone in whom you can trust and confide?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. Are you currently married?

 Yes NoRA Initials

Appendix H
Data Use Agreement

DATE: July 1, 2009

Emory University Nell Hodgson Woodruff School of Nursing

Data Use Agreement

The following is a listing of terms for the use of the data set gathered in the NHLBI funded research grant entitled Morehouse and Emory Team Up to Eliminate Cardiovascular Health Disparities under the direction of Sandra B. Dunbar, RN, DSN, FAAN. These terms are intended to insure that there is a common result from the thesis or research project.

1) The data are to be used solely for the study of the research questions

contained in the research project. The data or syntax developed for the project may

not be released by the student in any form to anyone other than Dissertation

Committee or the project statistician at any time. In this project the specific aims are

to: 1) Determine the relationships among personal factors, environmental factors,

medication adherence barriers (complexity of medication regimen and quality of

therapeutic relationship) and expected outcome (medication adherence) in a population of

older African Americans with Metabolic Syndrome (METs).The following hypotheses

are postulated:

1) Low health literacy, stress, depression and low social support will be significant predictors of low medication adherence.

2) Low medication adherence will be related to greater complexity of the medication regimen and lesser satisfaction with the physician–client relationship.

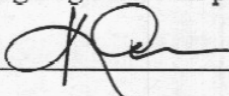
3) Social support will mediate the relationship of health literacy and medication adherence.

4) Health literacy will account for a greater percentage of the variance in medication adherence over and above stress, depression and social support, controlling for

age and other demographic variables.

- 2) The student agrees to destroy any copies of the data and remove from any storage devices copies of the data set and syntax at the conclusion of the project or dissemination effort.
- 3) The student must clear with and obtain approval from the PI, Sandra B. Dunbar, RN, DSN, FAAN any effort to disseminate the findings from the project. Efforts to disseminate include but are not limited to: manuscripts for journal submission, abstracts for presentations or posters, presentation of findings for employment interviews, presentation of data or results on web sites, etc. This includes the intent to disseminate and review/approval of the actual product (poster, presentation, abstract, e-report, manuscript, or other publication)
- 4) If the findings from the project are deemed publishable, (Sandra B. Dunbar, RN, DSN, FAAN) agrees to work with the student to develop a manuscript for submission, with the student as first author. If the student declines to participate in this process or fails to submit a manuscript within 6 months following completion of the research residency or experience (June 30, 2010) Sandra B. Dunbar may use any part of data analysis and writings for dissemination; the student will be invited to serve as secondary author.

By signing below all parties, agree to comply with these terms,

 _____ 7/23/09

Karen A. Armstrong

Date

 _____ 7-24-09

Sandra B. Dunbar

Date

*This may need more
specifically added once
dissemination proposal is
accepted by student's
committee. SD*

Appendix I
Institutional Review Board Approval



Appendix I

INSTITUTIONAL REVIEW BOARD

Mail: P.O. Box 3999
Atlanta, Georgia 30302-3999

In Person: Alumni Hall
30 Courtland St, Suite 217

Phone: 404/413-3500
Fax: 404/413-3504

June 8, 2010

Principal Investigator: Grindel, Cecelia Marie

Student PI: Armstrong, Karen A.

Protocol Department: B.F. Lewis School of Nursing

Protocol Title: The Relationship of Personal Characteristics, Behavioral Capability, and Environmental Factors to Medication Adherence in Older African Americans with Metabolic Syndrome.

Submission Type: Protocol H10483

Review Type: Exempt Review

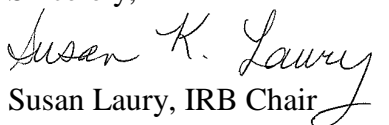
Approval Date: June 8, 2010

The Georgia State University Institutional Review Board (IRB) reviewed and approved your IRB protocol entitled The Relationship of Personal Characteristics, Behavioral Capability, and Environmental Factors to Medication Adherence in Older African Americans with Metabolic Syndrome. The approval date is listed above.

Exempt protocols do not require yearly renewal. However, if any changes occur in the protocol that would change the category of review, you must re-submit the protocol for IRB review. When the protocol is complete, a Study Closure Form must be submitted to the IRB.

Any adverse reactions or problems resulting from this investigation must be reported immediately to the University Institutional Review Board. For more information, please visit our website at www.gsu.edu/irb.

Sincerely,


Susan Laury, IRB Chair

Federal Wide Assurance Number: 00000129