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An Exploratory Model of Medication Refill Adherence Behavior

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ACCEPTANCE

This dissertation, AN EXPLORATORY MODEL OF MEDICATION REFILL ADHERENCE BEHAVIOR, by GAYLE HOLMES PAYNE, was prepared under the direction of the candidate's Dissertation Advisory Committee. It is accepted by the committee members in partial fulfillment of the requirements for the degree Doctor of Philosophy in the College of Education, Georgia State University.

The Dissertation Advisory Committee and the student's Department Chair, as representatives of the faculty, certify that this dissertation has met all standards of excellence and scholarship as determined by the faculty. The Dean of the College of Education concurs.

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Gayle Holmes Payne

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ABSTRACT

AN EXPLORATORY MODEL OF MEDICATION REFILL ADHERENCE BEHAVIOR
by
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Coronary heart disease (CHD) is the leading cause of death in the United States with over 15.8 million Americans suffering from the chronic disease (U.S. Department of Health and Human Services, 2007). Adherence to medication regimens has been identified as a key mediator between medical practice and patient outcomes (Kravitz & Melnikow, 2004). In this study, participants (N = 355) with CHD completed a questionnaire measuring their background characteristics, cognitive status, health literacy skills, self-efficacy levels, their perceived concerns and necessity beliefs about medication use, and enablers and barriers to their medication-taking behavior. Information regarding each participant's number of medications and presence of disease was obtained from medical charts. Data regarding the dependent variable, cardiovascular medication refill adherence, were collected from pharmacy records. The data were used to see how the various variables work together in a model that explains cardiovascular medication refill adherence behavior. The study aimed to contribute to the body of adherence research by jointly examining all variables found to have an association with medication adherence through a path analysis to explain the determinants of medication refill adherence behavior.

Analyses indicated that the hypothesized model did not fit the data. Additional analysis was conducted using a condensed revised model (age, self-efficacy, perceived concerns and necessity) and a self-reported measure of medication adherence (Adherence to Refills and Medication Scale) as the dependent variable. The revised model fit the data, $\chi^2(5, N = 355) = 6.71, p = .24$. The revised model did not explain a statistically significant amount of the variance in medication adherence, suggesting that there may be other additional factors that may mediate the relationship between independent variables and medication refill adherence. Additional research is needed to reveal all the determinants of medication refill adherence behavior and to identify the most effective measure of adherence behavior. Given the number of people who suffer from CHD, and the often low rates of medication adherence, research that continues to explore and improve medication refill adherence will have a significant impact on morbidity and mortality rates.

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A Dissertation

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ABBREVIATIONS

ARMS	Adherence to Refills and Medication Scale
AHA	American Health Association
ART	Antiretroviral Therapy
BMQ	Beliefs about Medicines Questionnaire
CHD	Coronary Heart Disease
CFI	Comparative Fit Index
CMG	Cumulative Medication Gap
DRUGS	Drug Regimen Unassisted Grading Scale
MARS	Medication Adherence Report Scale
MMC	Medication Management Capacity
MMSE	Mini-Mental State Examination
NAAL	National Assessment of Adult Literacy
NFI	Normed Fit Index
REALM	Rapid Estimate of Adult Literacy in Medicine
RMSEA	Root Mean-Square Error of Approximation
SEAMS	Self-Efficacy for Appropriate Medication Use Scale
SEM	Structural Equation Modeling
TOFHLA	Test of Functional Health Literacy in Adults

CHAPTER 1

THE PROBLEM

Research Question

The aim of this study was to investigate both direct and indirect influences on medication refill adherence from a combination of explanatory variables. The research question was

1. How do the variables background characteristics, cognitive status, health literacy, number of medications, presence of diseases, self-efficacy, patient perceived concerns about medication use, patient perceived necessity for medication use, enablers to medication-taking behavior and barriers to medication-taking behavior work together within a model to explain medication refill adherence?

Purpose

Research on adherence demonstrates the complexity of medication-taking behavior. Medication refill adherence involves more than patients receiving instructions to take medications as directed. Numerous variables have been studied to understand their role in medication refill adherence and the current study examined how these variables work together within a model to explain variation in refill practices.

Significance

Research examining how best to guide disease management and improve health is ubiquitous and scientists have been struggling with this complex issue for decades (Bandura, 2005). Although complex, facilitating the management of appropriate behavior

for patients is vital for optimum health. The potential to improve function and quality of life make it imperative for research to make substantial contributions to understanding medication-taking behavior (Russell & Conn, 2005).

Assumptions and Limitations

An assumption that was associated with the research study was that the findings would provide a better understanding of what determines patient medication refill adherence. A limitation of the study is that, because it is a retrospective cohort, we can not know how medication adherence behavior may change over time; nor can we assess causation. Additionally, because the subjects consisted primarily of urban, African American patients, generalization of results to other populations is limited.

CHAPTER 2

REVIEW OF THE LITERATURE

Patients do not automatically adhere to physicians' recommendations. One example of this is medication adherence. Adherence to, or compliance with, a medication regimen is usually defined as the extent to which patients take medications as prescribed by their physician (Osterberg & Blaschke, 2005). Researchers have been studying adherence to medication regimens over the past half century (Walker et al., 2006). Studies have documented large discrepancies between medication prescriptions and medication-taking behavior among individuals with chronic disease (Balkrishnan, 2005; Dunbar-Jacob et al., 2000).

The number of people suffering from chronic disease swells with the increasing number of men and women surviving into their 70s, 80s and 90s (Maes & Karoly, 2005). With the increased prevalence of chronic disease, medication refill adherence takes on increased urgency as more individuals are placed on long-term prescription regimens (Russell & Conn, 2005). Adherence to medication regimens has been identified as a key mediator between medical practice and patient outcomes (Kravitz & Melnikow, 2004). Chronic disease medication therapy is life-long and, for a patient to be successful, treatment strategies must be sustainable (Gifford & Groessl, 2002). Prescribed medications and recommended regimens can be inconvenient, costly, and complex. Changes in psychosocial functioning such as altered cognitive functions and reduced self-confidence can affect medication behavior (Russell & Conn, 2005). When patients do not

follow prescribed dosages closely, the health consequences can be severe. Studies have found that poor adherence to medication regimens accounts for 33 – 69% of all medication-related hospital admissions in the United States (Osterberg & Blaschke, 2005). Poor medication adherence leads to increased health care costs in the United States, worsening of disease, and death (Senst, Achusim, & Genest, 2001). The range in adherence reported in the research is due to multiple factors, including the lifestyle of the patient and/or the measure of adherence used. For example, medication adherence studies have found that nonadherence rates are around 57% for patients treated for chronic disease (Veazie & Cai, 2007). This is particularly alarming because the quality of life for chronic disease patients is dependent on how accurately and consistently they follow medical regimens. Therefore, if patients lack adherence to medication regimens, it can result in otherwise avoidable adverse health effects, increased utilization of care, and unnecessary financial costs (Veazie & Cai, 2007).

One way researchers explore patient adherence to medication regimens is by measuring medication refill adherence (Kindmalm, Melander, & Nilsson, 2007). Medication refill adherence includes the act of refilling medication prescriptions correctly. It is important for patients to practice medication refill adherence correctly. When patients do not and are non-adherent they may experience gaps or delay between refills, or discontinue taking needed medications (Kripalani, 2007). Given both the magnitude of the importance of refill adherence and the significance of its impact, there is a need to better elucidate the relationships between the explanatory variables and strategies that facilitate the desired behavior.

Adherence Research

Numerous variables have been studied to understand their role in medication adherence in general, and medication refill adherence specifically. However, there are no known studies that examine how these variables work together within a model to explain medication refill adherence behavior. The following studies among adult patients managing chronic diseases describe some of the variables that explain varying amounts of variance in medication adherence. The studies elucidate the relationships found between medication adherence and the study variables background characteristics cognitive status, health literacy, number of medications, presence of diseases, self-efficacy, patient perceived concerns about medication use, patient perceived necessity for medication use, enablers to medication-taking behavior and barriers to medication-taking behavior.

Medication adherence is measured, calculated and defined differently in the literature. Various measures of adherence exist, including patient self-report, prescription refill records, and electronic lids on medication containers that record the actual time at which pill bottles are opened and medications are presumably taken. Calculation can include calculating adherence or calculating non-adherence. However, most studies do not distinguish between “repeat” or major non-adherence and “sporadic” or minor non-adherence. The definition for adherence in the following studies was determined by each individual researcher and varied by study and on the measure used. When provided by the researcher, the method for adherence measurement, calculation and definition is described.

Background characteristics. Some research has focused on background characteristics in relation to medication adherence. For example, researchers (Gatti, Jacobson, Gazmararian, Schmotzer, & Kripalani, 2009) examined age as a factor associated with low self-reported adherence. Self-reported medication adherence was measured using the Morisky eight-item Medication Adherence Scale. The study included 275 patients from an inner-city hospital pharmacy, who completed an in-person, interviewer-assisted questionnaire on adherence and background variables. The average participant age was 53.9 years and approximately half of the patients (52.7%) reported low medication adherence (Morisky > two). Results found that younger age (<65 years) had 2.5 times greater odds of low medication adherence compared with patients age 65 years or older.

Golin and colleagues (2002) assessed variables including age, gender, ,and education, to examine their relationship to medication adherence among a cohort of 117 HIV-infected clinic patients. The study administered a questionnaire to assess the predictor variables. Adherence was computed by the number of doses taken divided by the number of doses prescribed over a four-week period. Bivariate analysis found that patients who were younger, and who had lower education were less likely to adhere to prescribed medications. There was no association found for gender and medication adherence.

Similarly, researchers (Schectman, Bovbjerg, & Voss, 2002) examined the association of medication refill adherence with background characteristics among 1,984 indigent rural patients managing hypertension, hypercholesterolemia, or oral diabetes. Age was assessed along with medication refill adherence which was calculated with two

or more refills for at least one medication during a nine month period. Mean refill adherence was <80% for 33% of the patients. Older respondents had higher mean refill adherence. Age helped explain 6.8% of the variability in mean patient refill adherence.

Another study looked at gender, age, and educational level, (Kalichman, Ramachandran, & Catz, 1999) in relation to medication adherence among 318 patients on HIV drug therapies. Results found that 20% of the participants had missed at least one medication dose during the study period (previous two days). Analysis found that education was significantly associated with treatment adherence. Participants with less than 12 years of education were greater than three times as likely to be non-adherent compared to participants with at least a high school education. Analysis found that gender and age were not associated with adherence.

Gazmararian and colleagues (2006) examined education to understand its role on medication refill adherence among 1,549 cardiovascular Medicare patients over 65 years old. Refill adherence was measured using the cumulative medication gap (CMG) by calculating the number of days the medication was not available between each prescription fill, divided by the number of days between the first and last medication fill during the study period. Results indicated that 40% of the patients had low refill adherence (CMG of 20% or more). Bivariate analyses indicated that education was related to medication refill adherence.

Cognitive status. Researchers (Insel et al., 2006) explored the association between cognitive status and antihypertensive medication adherence among 95 independently living adults aged 67 or older. Cognition was assessed using the Mini-Mental State Examination (MMSE), an instrument that provides a measure of cognitive function.

Medication adherence was defined as the percentage of days that the correct number of doses was taken. Medication adherence was measured over eight weeks for one prescribed medicine with an electronic medication monitoring cap. The average participant medication adherence was 80.4%. Regression analysis found that cognitive status explained a statistically significant 4% of the variance in medication adherence.

A prospective community-based cohort study of 1573 residents 55 years of age or older living in Rotterdam, The Netherlands was conducted to explore the association between cognitive impairment and non-adherence with antihypertensive medication. Researchers (Salas et al., 2001) assessed participants who had two consecutive MMSE assessments between 1991 and 1996 and who had received three or more consecutive antihypertensive prescriptions for at least 6 months. Adherence was estimated by dividing the number of days the participant took medication by the follow-up period in days, and it was expressed as a ratio between zero and one. Participants with at least 80% adherence were considered to have good adherence. Results found that low cognition was associated with twice the risk of non-adherence.

To better understand how even mild cognitive impairment may affect medication adherence, researchers (Hayes et al., 2009) conducted a cross-sectional study of 38 participants aged 65 or older living independently in the community who added a twice-daily vitamin C regimen to their medication routine for five weeks. Cognitive function was measured with the Alzheimer 's Disease Assessment Scale–Cognitive Subtest (ADAS-Cog), an instrument that provides a measure of very mild impairments in cognitive function. Participants were divided into a group with high cognitive function (HCF) or low cognitive function (LCF) based on their scores on the ADAS-Cog.

Adherence to a twice daily vitamin C supplement was estimated as the percentage of days in the trial period in which fewer than the prescribed two doses were taken. Adherence was measured using an electronic seven-day pillbox. Participants with at least 80% adherence were considered to have good adherence. Overall, the LCF group was significantly worse than the HCF group. Only 27.8% of the LCF group had good adherence to their regimen, compared to 75% of the HCF group. The LCF group had four times the risk of poor adherence than the HCF group.

Health literacy. Kalichman, Ramachandran, & Catz (1999) found that health literacy is also an important variable associated with adherence behavior because understanding medical instructions is a necessary condition for adherence. The study found an association between the effects of health literacy on medication adherence to HIV drug therapies among a community sample of 318 participants. The researchers conducted interviews with the participants to elicit health status, factors related to medication adherence, and health literacy. The study used the *Test of Functional Health Literacy in Adults* (TOFHLA) (Parker, Baker, Williams, & Nurss, 1995) to assess health literacy. Participants who scored below 85% on the TOFHLA were defined as possessing lower literacy and participants scoring 86% or better were defined as possessing higher literacy. Results found that 20% of the participants had missed at least one dose of antiviral medication during the previous two days. The individuals who were non-adherent reported lower educational levels and were more likely to be African American. Multivariate logistic regression analysis found no associations between the participants' health status, factors related to treatment, and adherence to HIV drug therapies. Analysis did find that participants with less than 12 years of education were more than three times

as likely to be non-adherent compared to participants with at least a high school education. Participants with lower literacy were almost four times more likely to be non-adherent than those with higher literacy.

Another study (Chew, Bradley, Flum, Cornia, & Koepsell, 2004) found an association between health literacy and adherence with pre-operative medication instructions. Health literacy was assessed using the *Short Test of Functional Health Literacy in Adults* (S-TOFHLA) (Parker et al., 1995) and defined participants scoring inadequate or marginal as having low health literacy. Overall, 12% of the study participants had low health literacy, and age, income, education attainment, employment, and cognitive impairment were all significantly associated with low health literacy. Adherence was defined as patients following pre-operative medication or fasting instructions. Overall, eight percent of patients were not adherent to pre-operative instructions. A higher proportion of patients with low health literacy were not adherent to pre-operative medication instructions. After controlling for age, number of medications, and cognitive function, low health literacy was associated with a twofold increase in the odds of non-adherence to pre-operative medication instructions.

Kripalani and colleagues (Kripalani et al., 2006) explored patients' ability to manage medications using a cross-sectional design with 152 coronary heart disease patients. Literacy skills were assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM) (Davis et al., 1993). The majority of the participants had low health literacy skills (50.7% had inadequate literacy skills and 28.9% had marginal skills). Results found that the patients’ ability to correctly identify and describe medications was significantly associated with literacy. Compared to patients with adequate health literacy,

patients with inadequate health literacy skills were 10 to 18 times more likely of being unable to identify all of their medications.

There were two studies whose findings do not support an association between health literacy and refill adherence. A study by Golin and colleagues (2002) found little association between health literacy and medication adherence. Researchers examined the influence of health literacy and demographic variables on medication adherence among a cohort of 117 HIV-infected clinic patients. The study administered a questionnaire to assess predictor variables including age, gender, education, income, current medications, self-efficacy, and literacy (measured by the *TOFHLA*). Adherence was computed by the number of doses taken divided by the number of doses prescribed over a four-week period. Although bivariate analysis found that patients who were younger, had lower income, and lower education were less likely to adhere to prescribed medications, regression analysis with age, gender, education, income, current medications, self-efficacy and literacy variables found no significance in accounting for the variance in adherence.

Researchers (Gazmararian at al. 2006) looked at medication refill adherence and health literacy. Their participants included 1,549 cardiovascular Medicare patients over 65 years old. Health literacy was assessed using the *S-TOFHLA*. Refill adherence was measured using the cumulative medication gap (CMG) by calculating the number of days the medication was not available between each prescription fill, divided by the number of days between the first and last medication fill during the study period. Overall, 40% of the participants had low refill adherence (CMG > 20%). There was a significant inverse relationship between health literacy level and medication refill adherence. Education was

also significantly related to refill adherence. The unadjusted model indicated that health literacy was significantly associated with medication refill adherence; those with inadequate health literacy skills had 1.37 times the odds of low refill adherence compared with those with adequate health literacy. However, the odds ratios for health literacy and refill compliance were not statistically significant after adjusting for age, gender, and education.

Finally, a longitudinal study (Paasche-Orlow et al., 2006) found an inverse relationship between low health literacy and adherence to antiretroviral therapy (ART). Researchers collected health literacy and adherence information from 235 HIV patients. ART adherence was collected via a self-report questionnaire where patients recorded the names of the antiretroviral medications, the number of doses and the total number of pills prescribed daily. Adherence was defined as a dichotomous variable. During the previous three days patients were either 100% adherent or were considered non-adherent. Health literacy was assessed using the REALM. Overall, 66% of patients exhibited 100% three-day adherence. Logistic regression analysis found that low health literacy was associated with increased adherence.

Number of medications/Presence of diseases. A person who is coping with more than one health problem is more likely to perceive a health threat from an illness than is someone who is experiencing excellent health. This may affect the belief in being able to successfully perform the behavior required to produce the desired outcomes (Burns, 1992). Researchers in a study examining patient health and adherence (Phatak & Thomas, 2006) assessed the total number of medications and non-adherence of patients waiting to see pharmacists at an outpatient pharmacy in a primary care clinic. Non-adherence was

assessed using the *Morisky Medication Adherence Scale* (Morisky, Green, & Levine, 1986). Regression analysis indicated the total number of medications, along with concerns/necessity beliefs, and age, explained 26.5% of the variation in non-adherence to chronic drug therapy.

Self-efficacy & concerns. Self-efficacy is the belief in being able to successfully perform the behavior required to produce a desired outcome, such as those needed for medication refill adherence behavior. Self-efficacy beliefs regulate an individual's behavior through cognitive, motivational, affective, and decisional processes. Self-efficacy affects thinking in either self-enhancing or self-debilitating ways by determining how well individuals motivate themselves and persevere in the face of difficulties (Bandura, 2002).

One study looked at self-efficacy and patient perceived concerns about medication use. Using a cross-sectional study among 309 type-2 diabetes patients enrolled in an outpatient education program, researchers (Aljasem, Peyrot, Wissow, & Rubin, 2001) assessed the concerns along with patient self-efficacy in relation to self-care behaviors. Self-report questionnaires assessed patient's perceived concerns of treatment and patient's judgment of their capability to monitor, plan, and carry out diabetes regimens during daily life. Information on patient adherence was measured through self-reporting of medication-taking behavior. Regression analysis found that greater self-efficacy predicted less frequent skipping of medication, explaining a statistically significant eight percent of the variance. The perceived concerns variable did not significantly contribute to the variance in skipping medication.

Another study (Gatti et al., 2009) examined variables including self-efficacy and beliefs about medication concerns as factors associated with low self-reported adherence. The study included 275 patients from an inner-city hospital pharmacy, who completed an in-person, interviewer-assisted questionnaire on adherence and background variables. Patient self-efficacy was measured using the Self-Efficacy for Appropriate Medication Use Scale (SEAMS). The Beliefs about Medicine Questionnaire (BMQ) was used to assess patients' beliefs about medicines. Self-reported medication adherence was measured using the Morisky eight-item Medication Adherence Scale. Approximately half of the patients (52.7%) reported low medication adherence (score > two). Logistic regression results indicated that patients who reported more concerns about medications were 2.1 times more likely to have low medication adherence compared to patients with fewer concerns. Patients with lower medication self-efficacy had greater odds, 4.3 times, of low medication adherence compared with patients with higher medication self-efficacy.

Concerns/necessity. Some of the research on medication adherence among patients with chronic disease has focused on how individuals weigh the perceived benefits (necessity) of an action against the perceived costs or barriers (concerns); physical pain, unpleasant side effects, or inconveniences that may be associated with the action (Horne, Weinman, & Hankins, 1999). One example is research that focused on concerns/necessity to explore patients' beliefs about the use of prescribed medication for controlling their illness and perceived barriers or their concerns about the potential adverse consequences of taking the medicine. Researchers (Horne & Weinman, 1999) conducted a cross sectional study involving 342 participants with chronic illnesses and

assessed patient concerns/necessity using the *Beliefs about Medicines Questionnaire* (BMQ) (Horne et al., 1999) and medication adherence using a four-item self-report scale. The study found that the majority of the sample (89%) had strong beliefs regarding the necessity of their medication for maintaining health. However, over a third (36%) also had strong concerns about potential negative side effects of using their medication. Researchers created a necessity-concerns differential and found that patients (17.3%) whose concerns scores outweighed their necessity scores reported significantly lower adherence rates. Regression analysis revealed the strongest predictor was patient perceived necessity beliefs about their medicines, accounting for 19% of the variance in reported medication adherence.

Researchers (Byrne, Walsh, & Murphy, 2005) examined illness beliefs about medication among 1,084 coronary heart disease patients to understand the effect on medication adherence. Concerns/necessity were assessed using the BMQ. Adherence was measured using a five-item self-report *Medication Adherence Report Scale 5* (MARS5) (Thompson, Kulkarni, & Sergejew, 2000). Researchers found that a stronger belief that medications are necessary and fewer concerns about the medication were related to higher medication adherence. Using regression analysis, concerns/necessity were statistically significant predictors of medication adherence but only explained seven percent of the variance in the medication adherence behavior of patients.

In another study examining concerns and necessity beliefs using the BMQ, researchers (Phatak & Thomas, 2006) examined the association of medication beliefs along with age and medication use on nonadherence of patients on chronic, multiple medications. A cross-sectional, self-administered survey of patients waiting to see

pharmacists at an outpatient pharmacy in a primary care clinic was conducted. Nonadherence was assessed using the *Morisky Medication Adherence Scale* (Morisky et al., 1986). The study found that together concerns/necessity beliefs, age, and total number of medications explained 26.5% of variation in nonadherence.

Finally, Brownlee-Duffeck and colleagues (1987) examined 143 diabetic outpatients and assessed patient concerns/necessity for adherence to diabetic regimens. Adherence was assessed by self-report measure of adherence to the diabetic regimen, with higher scores indicating greater adherence. Results indicated that the independent variables concerns and necessity both accounted for a statistically significant portion of the self-reported adherence variance.

Enablers to medication-taking behavior. Given that complete adherence is necessary for favorable health outcomes, it is important to examine facilitators patients face in adhering to medication regimens. Using self-report, Svensson and colleagues (2000) studied the role of enablers to medication-taking behavior. Data from 33 interviews indicated that the top reasons for medication adherence included a trust in the physician and a desire to control the condition. These reasons demonstrate that possible ways to improve adherence to medication is to reinforce the patient’s trust in their physician and to focus on improving the quality of patient–physician communication.

Barriers to medication-taking behavior. It is also essential to examine the obstacles patients face in adhering to medication regimens. Barriers to medication-taking behavior have been explored to understand how they play a role in medication adherence. In a longitudinal study (Barber, Parsons, Clifford, Darracott, & Horne, 2004), researchers assessed adherence to new medication among 239 patients managing chronic disease.

Interviews conducted at 10 days and again at four weeks revealed that at 10 days, 70% of the patients were adherent while at four weeks the adherence increased to 75%. Reasons the patients expressed for nonadherence included a substantial and sustained need for further information on the purpose and use of the medication. At 10 days, 61% of the patients said they had further information needs and 51% at four weeks. These results demonstrate that barriers for patients newly started on a chronic disease medication may include needs for information and support.

Additional barriers to adherence were explored in a cross-sectional national survey of Medicare beneficiaries older than 65 years of age (Gellad, Haas, & Safran, 2007). Overall. 41.6% of the sample reported one or more forms of nonadherence to a chronic disease medication during the last 12 months. Among respondents who reported any nonadherence, reasons included: cost (27.6%), skipped doses to make prescription last longer (16.8%), which were both statistically significant.

In another study (George & Shalansky, 2007) researchers sought to identify the barriers associated with medication non-adherence in 350 patients managing congestive heart failure (CHF). A survey was administered to assess reasons for non-adherence. Non-adherence was defined as <90% mean refill adherence with CHF medications. Refill non-adherence was found in 22% of participants. A positive response to a question related to a potential barrier to taking medications, ‘Have you changed your daily routine to accommodate your heart failure medication schedule’ was a statistically significant independent predictor of refill non-adherence.

Conclusion

Summary. Overall, the studies demonstrate how a number of variables explain health behavior related to adherence to medication regimens. Some studies found that the background characteristics education and age were associated with medication adherence (Gatti et al., 2009; Gazmararian et al., 2006; Golin et al., 2002; Kalichman et al., 1999; Schectman et al., 2002). An individual's cognitive status was found to be related to medication adherence (Hayes et al., 2009; Insel, et al., 2006; Salas et al., 2001). Patient health documented by the number of medications or the managing of other diseases were also found to be related to medication adherence (Kalichman et al., 1999; Phatak & Thomas, 2006). Self-efficacy was found to explain adherence variance (Aljasem et al., 2001; Gatti et al., 2009). Other studies examined concerns/necessity and the importance of patient belief in the necessity of medication adherence and found that both patient perceived necessity and perceived concerns are predictors of medication adherence (Brownlee-Duffeck et al., 1987; Byrne et al., 2005; Horne & Weinman, 1999; Phatak & Thomas, 2006). Numerous barriers to medication-taking behavior variables were also found to be associated with medication adherence (Barber et al., 2004; Gellad et al., 2007; George & Shalansky, 2007), as well as enablers to medication-taking behavior (Svensson et al., 2000).

Research on the role of health literacy on adherence to medication regimens has found some associations as well as some conflicting findings. Most health literacy studies previously conducted have found that patients with lower literacy were more likely to be non-adherent than those with higher literacy (Chew et al., 2004; Kalichman et al., 1999). Individuals with low health literacy skills were more likely to be unable to identify all of

their medications (Kripalani et al., 2006). Two studies that looked at medication refill adherence (Gazmararian et al., 2006; Golin et al., 2002) found only a moderate association between health literacy and medication adherence and this association was not statistically significant. Another study (Paasche-Orlow et al., 2006) found that low health literacy was associated with increased adherence. Therefore, further research is needed on the effect of health literacy on patient medication adherence behavior. It may be that health literacy acts as a factor mediating the relationship between other predictor variables and medication adherence. The current study explored the role health literacy may play in medication adherence by examining how medication adherence variables are related to a health literacy variable. The goal was to elucidate the added benefit of health literacy as an explanatory variable to the model.

Limitations. The studies reviewed have several limitations. One limitation was the different methods used to assess medication adherence. Patient self-report was the most common method of assessment used (Aljasem et al., 2001; Barber et al., 2004; Brownlee-Duffeck et al., 1987; Byrne et al., 2005; Gellad et al., 2007; George & Shalansky, 2007; Greene, Weinberger, Jerin, & Mamlin, 1982; Horne & Weinman, 1999; Johnson, Williams, & Marshall, 1999; Svensson et al., 2000) although it is subject to self-presentational and recall biases. A couple of studies did verify self-report through provider or pharmacy records (Greene et al., 1982; Nagy & Wolfe, 1984). Two studies used electronic monitoring devices (Hayes et al., 2009 & Insel et al., 2006) and one study (Phatak & Thomas, 2006) used an adherence scale.

Another limitation stemmed from some of the studies' cross-sectional designs (Aljasem et al., 2001; Andersson, Melander, Svensson, Lind, & Nilsson, 2005; Brownlee-

Duffeck et al., 1987; Byrne et al., 2005; Greene et al., 1982; Hayes et al., 2009; Horne & Weinman, 1999; Insel et al., 2006; Kindmalm et al., 2007; Krigsman, Nilsson, & Ring, 2007; Nagy & Wolfe, 1984; Phatak & Thomas, 2006), which makes it difficult to determine causality. A further limitation was that most studies did not assess the degree of patient comorbidity (other diseases a patient might have) and therefore cannot rule out the possibility that patients were receiving medication for other medical conditions in addition to the medication prescribed for the primary diagnosis.

A major limitation in the adherence studies was that each study only focused on a few variables in their research. No study examined all of the variables jointly to determine their combined explanatory power for adherence behavior among adults who are managing chronic disease. Research is needed to clarify which variables are most responsible for medication refill adherence. This requires an examination of the multiple variables associated with medication refill adherence to identify both their direct and indirect influences on medication adherence.

The variables background characteristics, cognitive status, health literacy, number of medications, presence of diseases, self-efficacy, concerns, necessity, enablers to medication-taking behavior and barriers to medication-taking behavior were all found to be associated with medication adherence and were jointly analyzed in this study. By conducting the study, it was hoped that the findings would provide a better understanding of how variables interact to determine a model of medication refill adherence behavior.

Research Question and Hypothesis:

The specific research question was

1. How do background characteristics, cognitive status, health literacy, number of medications, presence of disease, self-efficacy, concerns, necessity, enablers to medication-taking behavior and barriers to medication-taking behavior work together within a model (Figure 1) to explain medication refill adherence?

The study's hypothesis was that the model would adequately fit the observed data and would account for a substantial portion of the variance in patient medication refill adherence (see Figure 1 for hypothesized model).

Specific Expectations

Exploratory model of medication refill adherence behavior. Increasing medication refill adherence involves a behavior change. Given both the magnitude of the importance of adherence and the significance of its impact, there is a need to better elucidate the relationships between the explanatory variables and strategies that facilitate the desired behavior. Adherence is a particularly complex phenomenon and numerous factors may play a role, making behavior change difficult (Konkle-Parker, 2001). There are several constructs and variables to help explain health behaviors (Veazie & Cai, 2007). An exploratory model of medication refill adherence behavior identified variables that contribute to medication refill adherence behavior. The proposed relationships between the variables were interconnected and complex. It was hypothesized that together they would predict medication refill adherence behavior. The variables, described below, include: background characteristics (age and education), cognitive status, health literacy, number of medications, presence of disease (diabetes, hypertension, hypercholestermia), self-efficacy, concerns, necessity, enablers and barriers to medication-taking behavior, and medication refill adherence.

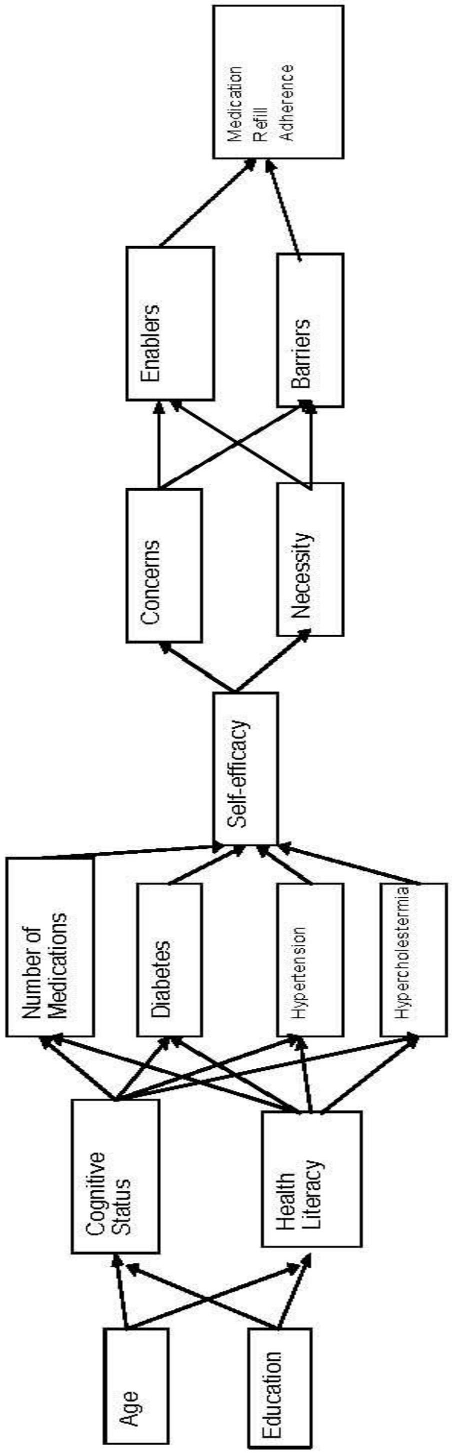

Figure 1. Hypothesized Exploratory Path Model

Background characteristics. Background characteristics of the patient were considered in the proposed model. These characteristics pertain to individual difference

variables that are relatively permanent background traits that affect the behavior process in some predictable manner (Burns, 1992). These factors have long been theoretically proposed as a starting point to distinguish the population in terms of preventive health care behavior (Becker & Janz, 1985; Kasl & Cobb, 1966; Rosenstock, 1966). Empirically, studies found that the variables education and age are associated with medication adherence (Gazmararian et al., 2006; Golin et al., 2002; Kalichman et al., 1999; Kripalani et al., 2006). The proposed exploratory model suggested that background characteristics would directly correlate with cognitive status because an individual's age and education may directly influence his/her cognitive ability. Background characteristics would also directly correlate with health literacy and directly affect these variables. This serves to modify the other variable relationships and affect medication refill adherence only indirectly.

Cognitive status/health literacy. An individual's cognitive status was found to be related to medication adherence (Hayes et al., 2009; Insel, et al., 2006; Salas et al., 2001). Cognitive status may inform the understanding of health decisions and the appropriateness of health decision-making. Therefore, the model proposed that the effects of cognitive status, along with health literacy, will directly affect a patient's management of chronic illness. Research suggests combining a cognitive variable with other theoretically derived variables may improve the understanding of refill adherence behavior of chronic disease patients (Nagy & Wolfe, 1984). Health literacy is an important variable associated with adherence behavior because understanding medical instructions is necessary for medication refill adherence (Kalichman et al., 1999). Health literacy is affected by a person's background characteristics and impacts the ability to

stay healthy. A common definition is, “Health literacy is a constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment” (Parker et al., 1999, p. 553). Studies have shown that many adults who have completed high school still have limited literacy skills and that an individual’s educational status is not always an accurate way to assess literacy ability (Parikh, Parker, Nurss, Baker, & Williams, 1996). Research has established a clear link between health and literacy (Parker, Ratzan, & Lurie, 2003) and according to analysis of the research by Partnership for Clear Health Communication, literacy skills predict an individual’s health status even more strongly than age, income, employment status, educational level, and racial or ethnic group (Wilson, 2003).

Research on the role of health literacy on adherence to medication regimens found some associations as well as some conflicting findings. Some studies found that patients with lower literacy were more likely to be non-adherent than those with higher literacy (Chew et al., 2004; Kalichman et al., 1999). Individuals with low health literacy skills were more likely to be unable to identify all of their medications (Kripalani et al., 2006). Two studies (Gazmararian et al., 2006; Golin et al., 2002) found only a moderate association between health literacy and medication adherence and another study (Paasche-Orlow et al., 2006) found that low health literacy was associated with increased adherence. The current exploratory model proposed that health literacy, along with cognitive status, both indirectly affect refill adherence through their role influencing patient health.

Number of medications/presence of disease. Patient health can be interpreted as illness experiences. The model proposed that patient health may be directly influenced by

a person's background characteristics, cognitive status, and health literacy skills. Patient health is important in that it affects subsequent aspects of health behavior because a person who is coping with more than one health problem is more likely to perceive a health threat from an illness than is someone who is experiencing excellent health. This may affect the belief in being able to successfully perform the behavior required to produce the desired outcomes (Burns, 1992). Therefore, the model proposed that patient health directly influences a person's self-efficacy belief.

Self-efficacy. Self-efficacy refers to whether or not a person believes he or she can implement an action (Bandura, 2002). Bandura conceptualized the concept of self-efficacy to account for an individual's confidence in his or her own ability to reach a desired behavior. The model proposed that an individual's health influences medication refill adherence behavior through self-efficacy because a person's health status may play a role in medication management coping abilities. Theories such as social cognitive theory and the extended health belief model have postulated that self-efficacy directly influences concerns/necessity beliefs (Bandura, 2002; Burns, 1992). Empirical research has shown self-efficacy to be a predictor of medication adherence (Aljasem et al., 2001).

Concerns/necessity. Concerns/necessity beliefs are when a person weighs the believed benefits of the target action against the known or suspected costs, both tangible and intangible, to derive an ultimate value of the action (Leventhal & Cameron, 1987). In relation to medication refill adherence, a patient would weigh the believed effectiveness of medication adherence to reduce the threat of a chronic disease against the known costs or potential negative consequences that may result from taking particular health actions, including physical, psychological, and financial demands. Theoretical models have

postulated that concerns/necessity action is influenced by self-efficacy and influences enablers and barriers to medication-taking behavior (Bandura, 2002; Burns, 1992). Therefore, the model proposed that patient's concerns/necessity directly influences enablers and barriers to medication-taking behavior.

Enablers & barriers to medication-taking. Achieving mediation refill adherence behavior also involves the art of navigating enablers and barriers to medication-taking. Situational factors, such as enablers and barriers, are conditions or circumstances that enable or impede action. Theoretical models have postulated that enablers and barriers to medication-taking are influenced by concerns/necessity beliefs (Bandura, 2002; Burns, 1992). Numerous barriers to medication-taking behavior have been found to be associated with medication adherence (Barber et al., 2004; Johnson et al., 1999), as well as enablers to medication-taking behavior (Svensson et al., 2000) and the proposed model details this direct relationship.

Medication refill adherence. Medication refill adherence, measured by the CMG method, was the desired health behavior result. The model proposed that medication refill adherence would be directly influenced by enablers and barriers, which are directly influenced by concerns and necessity, which are directly influenced by self-efficacy, which is directly influenced by number of medications/diseases, which are directly influenced by cognitive status and health literacy, which are directly influenced by age and educational attainment.

The proposed model of medication refill adherence maps the various interconnected individual, social, and cognitive factors affecting an individual as he or she proceeds to the desired health behavior result. This exploratory study focused on

these explanatory variables of refill medication adherence. It is important to do so because studies on medication refill adherence among chronic disease patients reveal that very few people refill prescriptions accurately and timely (Andersson et al., 2005; Kindmalm et al., 2007; Krigsman et al., 2007). It was hoped that this exploratory theoretical model may serve as a foundation in the continued examination of what factors are most important in facilitating patient medication refill adherence and why they are important.

CHAPTER 3

METHODOLOGY

Participants

Data in this study were gathered from a larger intervention study. The participants in the intervention study included patients in the primary care clinics at Grady Memorial Hospital, an urban teaching hospital serving an indigent minority population in Atlanta, Georgia. From March 30, 2004 through March 2005 (with follow-up data collected through March 2006), consecutive patients with documented coronary heart disease (CHD) who presented to the clinic were recruited for the study. Exclusion criteria included patients who were currently participating in another medication adherence study, did not manage their own medications, had no mailing address or telephone number, were already receiving an intervention, routinely filled prescriptions outside of the hospital's pharmacy system, were unable to communicate in English, were in police custody, or had visual acuity worse than 20/60. Patients with a serious psychiatric illnesses (schizophrenia, schizoaffective disorder, or bipolar disorder), overt delirium, or severe dementia were also excluded from the study.

Of the approximate 968 patients with CHD screened for the intervention study, 490 were deemed eligible. The most common reasons for ineligibility were not filling prescriptions in the hospital's pharmacy system (215), refusal to complete the screening process (approximately 120), having a caregiver who managed the patient's medications (78), and having overt dementia or delirium (13). Out of the 490, 440 agreed to enroll in

the intervention study. Five patients later withdrew consent, leaving the final total of the intervention study with 435 study patients. The current study focused on 355 study patients with complete data sets. Descriptive analysis indicated that the current study's subsample (N = 355) did not significantly differ from the overall intervention study sample (N = 435) in terms of this study's variables of interest (their age, educational level, cognitive status, health literacy skills, number of medications taking, presence of diseases, self-efficacy, perceived concerns and necessity for medication use, and enablers or barriers to medication-taking).

Instrument

For use in the intervention study, a 45 minute medication adherence questionnaire was developed by Dr. Sunil Kripalani, the principle investigator for the intervention study. The questionnaire is a self-report measure comprised of multiple instruments to assess variables related to the dependent variable of medication refill adherence. The current study focuses on a subset of questionnaire items.

To facilitate comprehension and reduce the effect of literacy on questionnaire administration, an interviewer read the questions aloud. For each set of items, the interviewer placed a printed response scale in front of the patient, oriented the patient to the response choices, and allowed the patient to indicate a response verbally or by pointing to the desired choice. The REALM literacy assessment was also administered by providing a copy of the REALM Patient Word List and the interviewer asked the participant to read as many words as possible aloud from the list. Upon completion of the questionnaire, patients were compensated five dollars. The study materials and protocol were approved for Sunil Kripalani by the Emory Institutional Review Board and Grady

Research Oversight Committee. Gayle Payne (the principle investigator for the current study) was added to the IRB protocol so that she would have access to the study data. Permission was also given by Georgia State University's Institutional Review Board to use these data for the current study. Data collected on a selection of the questionnaire instruments are described below.

Background characteristics. The questionnaire assessed age and educational attainment. For the purpose of this study, age was calculated as number of years old and educational attainment was calculated by the total number of years of schooling completed.

Cognitive status. An instrument designed to assess cognition found on the questionnaire is the *Mini Mental State Examination* (MMSE), a brief quantitative measure of cognitive status in adults (Folstein, Folstein, & McHugh, 1975). The MMSE is a 30-item, quantitative measure of cognitive status in adults. It can be used to screen for cognitive impairment, to estimate the severity of cognitive impairment at a given point in time, and to document an individual's response to treatment (Wells et al., 1992). Scores of 23 or lower indicate the presence of cognitive impairment. Originally conceptualized in 1975 (Folstein et al., 1975), the instrument has demonstrated validity and reliability in numerous medical populations (Wells et al., 1992). One example of a test of the instrument's psychometric properties was a validation study among Alzheimer's disease patients (Wells et al., 1992). Linear discriminant analysis was used and it was found that the items distinguished between Alzheimer's disease patients and controls with 96% sensitivity and 98% specificity. For the current study, the maximum possible MMSE raw score (out of 30) was calculated for analysis purposes.

Health literacy. To assess the patient's health literacy, the *Rapid Estimate of Adult Literacy in Medicine* (REALM), was administered (Davis et al., 1993). The REALM is a 66-item word pronunciation test (Paasche-Orlow et al., 2006) using common terms from the health care setting and was developed as a quick screening tool to assist physicians in identifying patients with limited reading skills and in estimating patient reading levels (Davis et al., 1993). The properties of the REALM were measured using 207 adults in six public and private primary care clinics. The test-retest reliability was found to be 0.99. REALM scores correlated highly with those of other standardized reading tests [Peabody Individual Achievement Test-Revised (Lazarus, 1990) and the Slosson Oral Reading Test (Slosson, 1990)]. The REALM, which takes three to five minutes to administer and score, appears to be a practical instrument to estimate patient literacy in primary care, patient education, and medical research (Davis et al., 1993). The score assigns health literacy skills into four categories of grade-equivalent reading level: 0–18 (≤ third grade), 19–44 (fourth to sixth grade), 45–60 (seventh to eighth grade) and 61–66 (≥ ninth grade). For the current study, the maximum possible REALM raw score (out of 66) was calculated for analysis purposes.

Number of medications/presence of disease. Patient health history was taken from medical charts at the time of enrollment. Included in this information was the total number of medications taken and whether they had a diagnosis of hypertension, diabetes, or hypercholesterolemia. For the purpose the current study, the total number of medications and the presence of hypertension (zero, no; one, yes), diabetes (zero, no; one, yes), hypercholesterolemia (zero, no; one, yes) were assessed.

Self-efficacy. The reduced 13-item *Self-Efficacy for Appropriate Medication Use Scale* (SEAMS) was administered to assess self-efficacy. The scale assesses, under a number of different circumstances, the patient level of confidence about taking medications correctly (one = “not confident”, two = “somewhat confident”, and three = “very confident”). The possible scores for the full 21-item scale ranged from 21 to 63. Higher scores indicate higher levels of self-efficacy for medication adherence. Research on the psychometric properties on the SEAMS (Risser, Jacobson, & Kripalani, 2007) was conducted among 436 patients with coronary heart disease. Reliability was evaluated by measuring internal consistency and validity was evaluated by performing a principal components factor analysis. Reliability and validity analyses were also performed separately among patients with low and higher literacy levels to ensure that the scales have consistent performance across all patient groups. Results found that the final 13 items (three, four, five, six, seven, eight, nine, 10, 11, 12, 13, 15, and 16) had good internal consistency reliability (Cronbach’s $\alpha = 0.89$). For the validity assessment, a two factor solution was found to represent two clear dimensions – self-efficacy for taking medications under difficult circumstances and self-efficacy for continuing to take medications when circumstances surrounding medication-taking are uncertain (ie. when normal routine gets off schedule, when doctor changes medicine, when suffering from a cold). These two factors explained 52.3% of the scale’s variance. The scale performed similarly across literacy levels. Therefore, the reduced 13-items SEAMS is a reliable and valid instrument to assess medication self-efficacy in chronic disease management, and it appears appropriate for use in patients with a broad range of literacy skills. For the

purpose of this study, the reduced 13-item maximum possible SEAMS raw score, 39 (from 13, three-point items) was calculated for analysis purposes.

Concerns/Necessity. The *Beliefs about Medicines Questionnaire* (BMQ) was used to measure concerns/necessity beliefs. The BMQ is a questionnaire to assess cognitive representations of medication (Horne et al., 1999). The beliefs are grouped under two core themes: the beliefs about the *necessity* (or benefits) of the prescribed medication for maintaining health and *concerns* (or costs) about the potential adverse effects of taking medication. Respondents indicate their degree of agreement with each individual statement about medications on a five-point Likert scale, ranging from one = “strongly disagree” to five = “strongly agree” for each of the five necessity items and the six concern items). Scores obtained for the individual items within each scale are summed to give a scale score.

Researchers (Horne et al., 1999) evaluated and assessed the psychometric properties of the questionnaire using a sample of 116 cardiac patients. The items in the subsections explained 51.9% of the scale’s variance. Reliability was evaluated by measuring the internal consistency and validity was tested by a one-way analysis of variance (ANOVA). Results found good internal consistency reliability (Cronbach’s α = 0.76 for specific-necessity; Cronbach’s α = 0.76 for specific-concerns). Overall, the results of the evaluation of the questionnaire found it to be a flexible instrument which can be adapted to assess beliefs about all medicines for a particular condition or for individual components of a regimen. Results confirm the value of the BMQ as an appropriate method for assessing beliefs which patients commonly hold about their prescribed medication. For the purpose of this study, the maximum possible concerns raw

score was 30 (from six, five-point items) and the maximum possible necessity raw score was 25 (from five, five-point items).

Enablers to medication-taking. To assess enablers to medication-taking, patients were asked to answer nine yes or no items on ways helpful to remember to take medicine. For the purpose of the current study, the total score from the nine items was calculated for analysis purposes with a maximum possible of score of nine.

Barriers to medication-taking. Barriers to medication-taking were assessed in two sections of the questionnaire. To assess barriers to adherence behavior the *Brief Medication Questionnaire* was included in the questionnaire. The five items comprise a self-report tool that asks patients how difficult it is to conduct some medication regimen tasks. Respondents answer on a three-point scale with answers ranging from “very hard”, “somewhat hard”, and “not hard”. Researchers (Svarstad, Chewning, Sleath, & Claesson, 1999) assessed the validity of the items among 20 patients. Results varied by type of non-adherence, with the regimen and belief items having 80–100% sensitivity for major dosage errors (“repeat” non-adherence) and the recall items having 90% sensitivity for minor dosage errors (“sporadic” non-adherence). Results demonstrate that the brief medication questionnaire appears to be a sensitive tool with regard to type of patient non-adherence and may be useful in identifying and diagnosing adherence problems.

To assess the obstacles patients face in adhering to medication regimens, the questionnaire also examined barriers to refills with three, three-point items created by Kripalani. For the purpose of the current study, the maximum possible score was 24, calculated from the combined eight, three-point items.

Cardiovascular medication refill adherence. The dependent variable of interest was cardiovascular medication refill adherence. Patient cumulative medication gap (CMG) was calculated based on prescriptions obtained in the outpatient pharmacies of the Grady Health System. It was a weighted average of the CMGs of individual medications. Therefore, if the patient took medication A for 100 days and medication B for 200 days, medication B counted double in the calculation of the CMG. Only cardiovascular medications are included in the CMG calculations. Refill adherence figures were available for six months prior to study participant enrollment

Data Analysis Procedures

Analysis of the variables employed the structural equation modeling (SEM) technique of path analysis. The SEM family also includes other standard statistical procedures including multiple regression and additional general linear model techniques, which are all special instances of SEM. However, path analysis differs from multiple regression because where one might need numerous regression equations to test the relationships, a path analysis tests all possible correlations simultaneously. This is advantageous because it does not ignore likely intercorrelations among the criterion variables. Multiple regression would not allow a variable to be represented as both a predictor and a criterion in the same analysis.

Path analysis is an extension of multiple regression and utilizes structural equation modeling techniques with measured variables (Hoyle & Smith, 1994). It is used when there is only a single measure of each theoretical variable and there is a hypotheses about causal relations among these variables. Path analysis begins with the specification of a structural model (Figure 1) and an a priori determination of good model fit using

specific model fit indices. The literature has numerous indices for selecting good model fit (MacCallum, Browne, & Sugawara, 1996). The most commonly used goodness of fit statistics include the chi-square statistic, the root mean-square error of approximation (RMSEA), the normed fit index (NFI), and the comparative fit index (CFI). An acceptable model fit for a path-model is generally indicated by a non-significant chi-square with a low RMSEA (at or below 0.05) and a NFI or CFI at or above 0.95.

The two main goals of path analysis are to understand patterns of correlations among a set of variables and to explain as much of their variance as possible with the model specified by the researcher (Kline, 2005). The analysis for this study specified a model (figure 1) based on expected relationships between the predictor variables and compared the extent to which observed relationships between variables "fit" those that would be expected based on the model. This approach considers how much of the variation in the data can be explained by expected relationships in the model and how this finding compares to what one would find using a model based on chance relationships between variables.

Path analyses generates estimated path coefficients, or standardized linear regression coefficients. Specifically, standardized path estimates reflect the extent to which a one standard deviation unit change in a predictor variable is associated with the corresponding standard deviation change for an outcome variable. Significance is determined by dividing the estimates by their standard estimates and using a t-test (Schillinger, Barton, Karter, Wang, & Adler, 2006).

Path analysis is a powerful analytic tool because it permits the simultaneous estimation of both direct and indirect influences on outcomes (Hoyle & Smith, 1994).

The analysis enables comparison of the explanatory power of competing models and observation of mediational effects by examining changes in the strength of variable relationships across models. For the study purposes, the expectation was to explore the influence of explanatory variables on medication refill adherence.

CHAPTER 4

RESULTS

Descriptive Statistics

Data from 355 participants were included in this study. The majority of the participants, 90.1%, were African American and the remainder was White (7.6%) or Asian/Hispanic/other (2.3%). Table 1 provides a summary of the descriptive statistics of the model variables. The age of the participants ranged from 33 to 90, with a mean age of 63. The mean number of years of education completed was 10.85 ranging from zero to 20 years.

The Mini-Mental Status Examination (MMSE), measuring cognitive status, had a mean score of 24.7 (*SD* 3.17) out of a possible 30 and a range from 16 to 30. The 66-item REALM health literacy assessment mean was 40.97 (*SD* 22.22), which is equivalent to a fourth to sixth grade reading level. Participants had a good range of scores from zero (non-literate) to 66 (high-literacy).

With regard to the participants overall health, respondents reported taking between zero and 18 medications, with a mean of 8.81 (*SD* 2.78). Most respondents were managing hypertension and hypercholestermia (99.2% and 88.7% respectively). Less than half (43.9%) were managing diabetes.

On the Self-Efficacy for Appropriate Medication use Scale (SEAMS), the total score ranged from 14 to 39 with an average of 31.19 (*SD* 6.05). Overall, participants were efficacious about their ability to take medications appropriately. For example, when

Table 1

Variable Means

Variable	Minimum	Maximum	Mean	SD
Age (in years)	33	90	63.20	9.97
Education (in years)	0	20	10.85	3.15
Cognitive Status (as measured by the 30-item MMSE)	16	30	24.76	3.17
Health Literacy (as measured by the 66-item REALM)	0	66	40.97	22.22
No. of Medications	0	18	8.81	2.78
Self-efficacy (SEAMS 21-item four-point Likert scale ranged from 21 to 63)	14	39	31.19	6.05
Concerns (6 items on five-point Likert scale ranged from 6 to 30)	6	30	19.99	4.54
Necessity (5 items on five-point Likert scale ranged from 5 to 25)	5	20	9.38	3.08
Enablers (9 dichotomous items ranging from 0 to 9)	0	8	2.91	1.39
Barriers (Combined 8 items on three-point Likert scale ranging from 8 to 24)	9	24	19.63	3.06
CMG (Continuous variable from 0, *adherent*, to 1, *nonadherent*)	0	.91	.23	0.19

N = 355. The three dichotomous variables (diabetes, hypertension, hypercholestermia) are not included in the table.

asked “how confident they are to take medications correctly”, most participants (76.5%) were very confident: when “taking several different medicines each day”; and when “no one reminds you to take the medicine” (79.3%). Participants (38.4%) were not confident however, “when the medications cause some side effects”.

Results from the Beliefs about Medicines Questionnaire are broken out into 2 subscales, specific concerns (costs) and specific necessity (benefits). For the *Specific Concerns* subscale, participants' scores ranged from 6 to 30 with a mean of 19.99 (*SD*, 4.54). Participants did not have strong beliefs of specific concerns of their prescribed medications. For example, 52.4% of the participants disagreed that "having to take medicines worry me" and 32.8% disagreed that "I sometimes worry about long term effects". For the *Specific Necessity* subscale, participants' scores ranged from 5 to 20 with a mean of 9.38 (*SD* 3.08). More participants have strong beliefs in the necessity and efficacy of prescribed medications. For example, 94.7% of the participants either strongly agreed or agreed that "my current health depends on my medicines" and 87.4% either strongly agreed or agreed that, "my medicines protect me from becoming worse".

The majority of the participants responded negatively to 7 of the 9 enablers to medication-taking items. For example, responses to the items indicated that: 65.3% did not "use a pillbox that helps organize medicine for all the days of the week", 97.5% did not "use a reminder that beeps when it's time to take the medicine" and 91.3% did not "write down the instructions for when you should take each of your medicines". There were two enablers that participants did utilize: 80.4% responded positively to "taking medicine along with meals or other daily events, like brushing your teeth" and 90.5% did "remember to get refills by seeing that container or pillbox is almost empty".

Barriers to medication-taking were assessed using a 5-item Brief Medication Questionnaire and 3 additional items created by Kripalani. Responses to the 5-items indicated that the respondents did not experience barriers represented by the items. For example, 74.8% of respondents found it not hard "to open or close the medication bottle"

and 87.4% found it not hard “to remember to take all the pills”. Two of the 3 additional barrier items did prove to be barriers. For example, 43.7% of participants indicated that it is very hard “to get their medicine when they are expensive” and 44.8% found it very hard “to get their medicine when there is a long wait in line.

The dependent variable, cardiovascular medication refill adherence was expressed as the cumulative medication gap (CMG). CMG was measured 6 months retrospectively from each patient’s date of enrollment. The CMG was calculated as a continuous score ranging from 0 (adherent) to 1 (non-adherent). Participant mean CMG was .23 (*SD* .19) with a range from .0 to .91. As the literature suggests (Steiner & Prochazka, 1997), adequate refill adherence is defined as having an overall CMG less than 20%. Adequate refill adherence was found for 56.3% of participants. This group did not significantly differ from the non-adequate refill adherence participants on this study’s variables of interest (background characteristics, cognitive status, health literacy, number of medications, presence of diseases, self-efficacy, perceived concerns/necessity or enablers and barriers to medication-taking).

Correlations

Correlations among independent variables (except for dummy coded variables diabetes, hypertension, and hypercholesterolemia) and medication refill adherence found several significant results (see Table 2). The dependent variable CMG had significant correlations with age, self-efficacy, concerns, necessity, and barriers. Participants who had higher refill adherence were younger, had high self-efficacy, low concerns about and barriers to taking medication. The beliefs about the necessity of the prescribed

Table 2

Intercorrelations between Independent Variables and CMG

	Age	2	3	4	5	6	7	8	9	10
2. Education	−.318**									
3. Cognition	−.323**	.483**								
4. Health Literacy	−.133**	.617**	.613**							
5. No. of Medications	.100	−.071	−.081	−.043						
6. Self-efficacy	.085	.011	.019	−.032	−.007					
7. Concerns	.117*	−.007	.053	.022	−.031	.303**				
8. Necessity	.011	.003	−.102	−.052	−.053	.010	−.045			
9. Enablers	−.034	−.051	−.136*	−.048	.067	−.168**	−.185**	−.139**		
10. Barriers	.108	−.005	.022	.002	−.047	.474**	.343**	.051	−.164**	
11. CMG	−.168**	.012	−.024	−.074	.029	−.169**	−.110*	.131*	.064	−.140**

N = 355. CMG = Cumulative Medication Gap. The three dichotomous variables (diabetes, hypertension, hypercholestermia) are not included in the matrix.

medication for maintaining health was high among participants with higher refill adherence.

Scatter Plots

Figures 2–11 are scatter plots of each independent variable with the CMG (except for dummy coded variables diabetes, hypertension, and hypercholesterolemia). They visually depict the finding that overall, respondent medication refill adherence was moderate, with little linear relationships between the independent variables and the dependent variable, CMG. For example, the largest correlation is $r = -.169$, indicating that 2.8% of the variance in CMG is explained by concerns. Overall, the findings suggest that regardless of the independent variable, they have very little linear relationship with CMG.

Regression Analysis

A series of regression analyses were conducted to determine the amount of variance in medication refill adherence accounted for by the independent variables. Regression analysis found that together, the independent variables explained a statistically significant 11.9% of the variance in medication refill adherence, $F(14, 354) = 3.27$, $p = .00$ (see Table 3). Stepwise regression found that the variables self-efficacy, age, necessity, and hypertension together explained a statistically significant 8.8% of the variance in medication refill adherence, $F(4, 354) = 8.49$, $p = .00$. Self-efficacy accounted for 2.9% of the variance, age accounted for 2.4% of the variance, necessity accounted for 1.8% of the variance and hypertension accounted for 1.8% of the variance.

Additional regression analyses were conducted to determine if results mirrored findings from the reported literature review. For example, Phatak’s (2006) regression

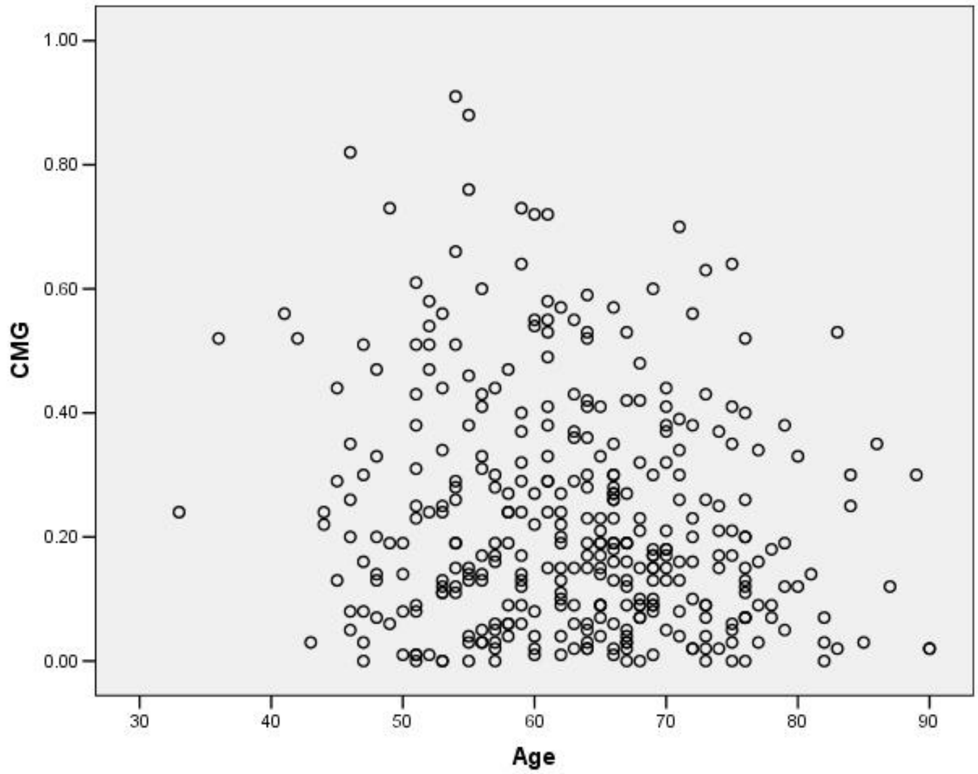

Figure 2. Respondents' Age and CMG.

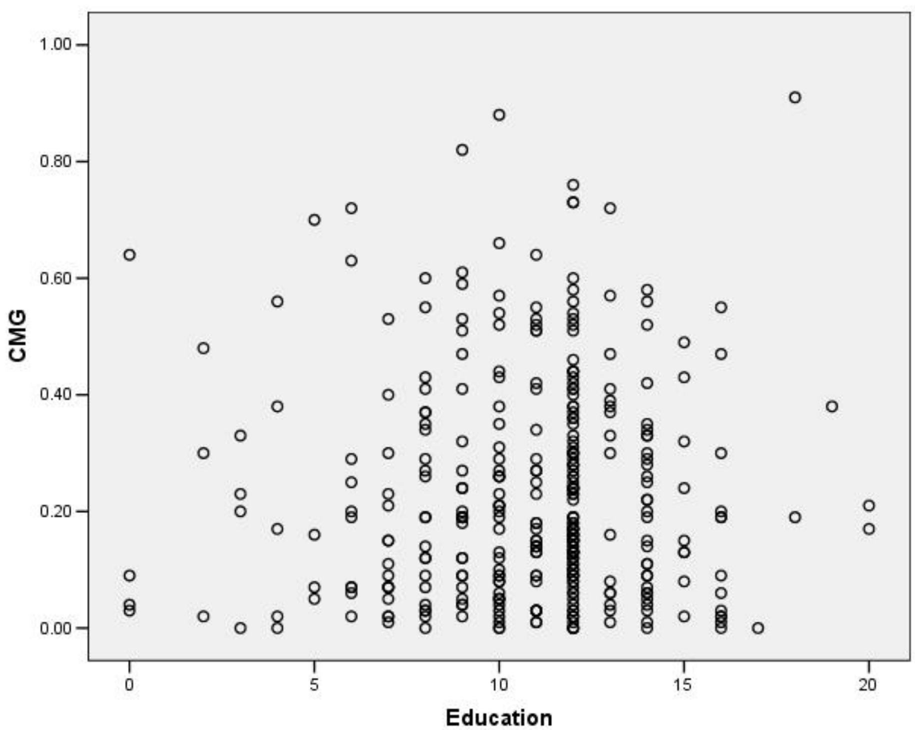

Figure 3. Respondents' Education and CMG.

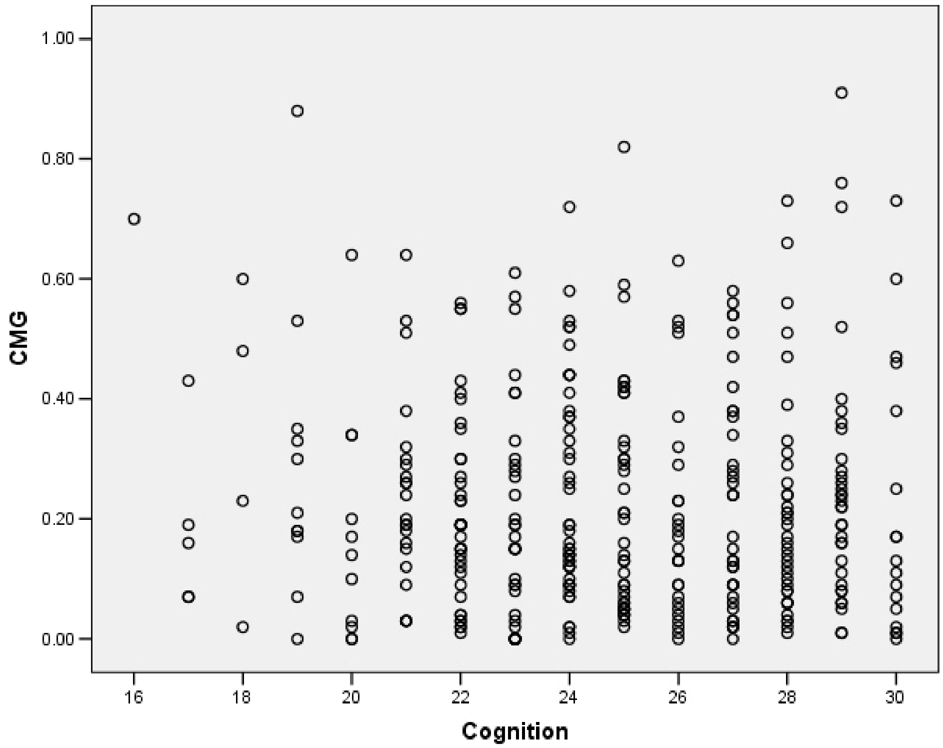

Figure 4. Respondents' Cognition and CMG.

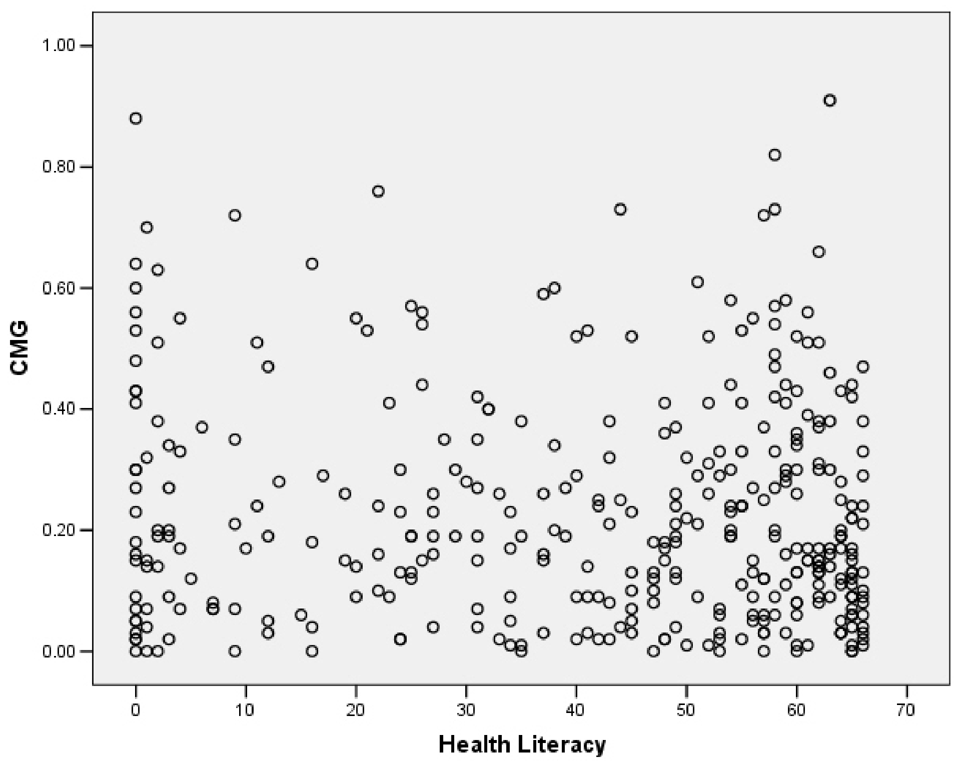

Figure 5. Respondents Health Literacy and CMG.

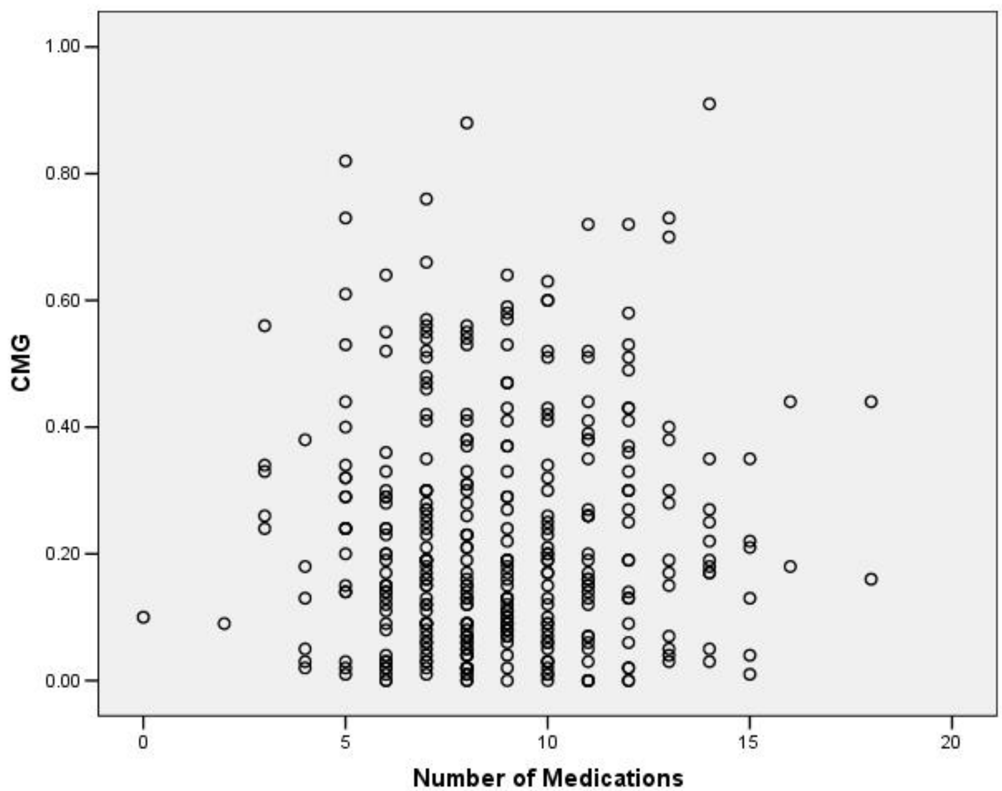

Figure 6. Respondents' Number of Medications and CMG.

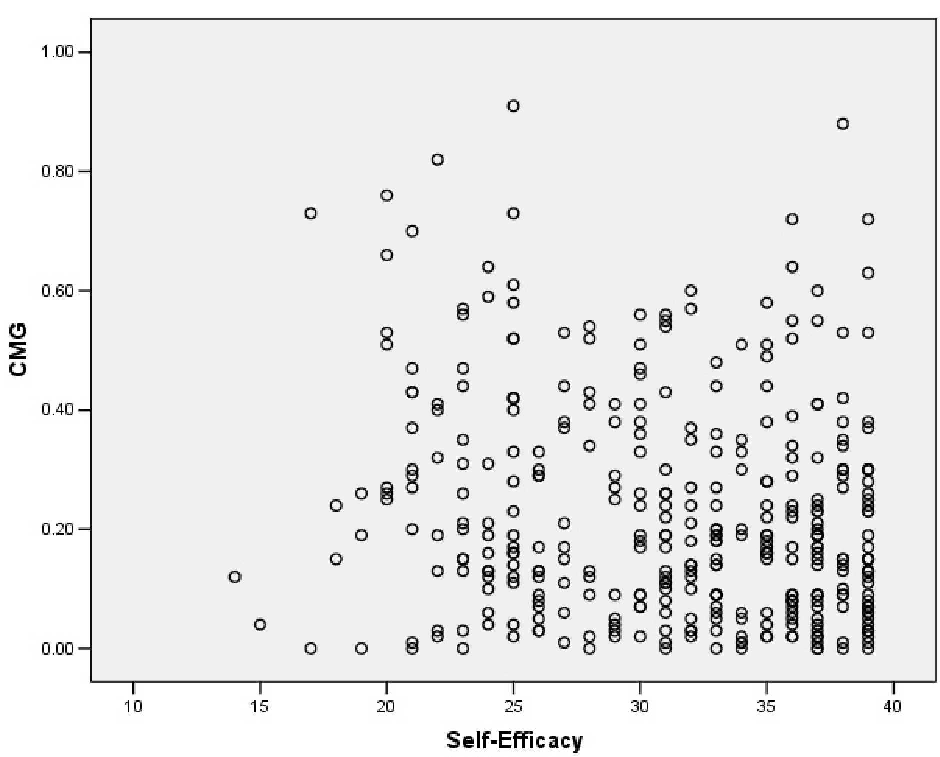

Figure 7. Respondents' Self-Efficacy and CMG.

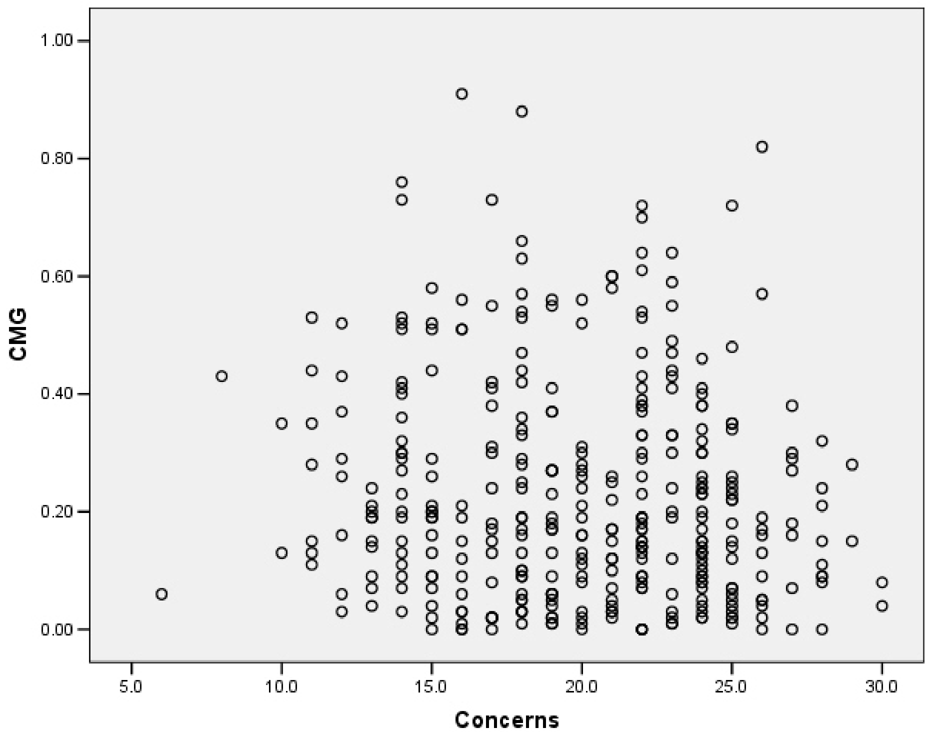

Figure 8. Respondents' Concerns and CMG.

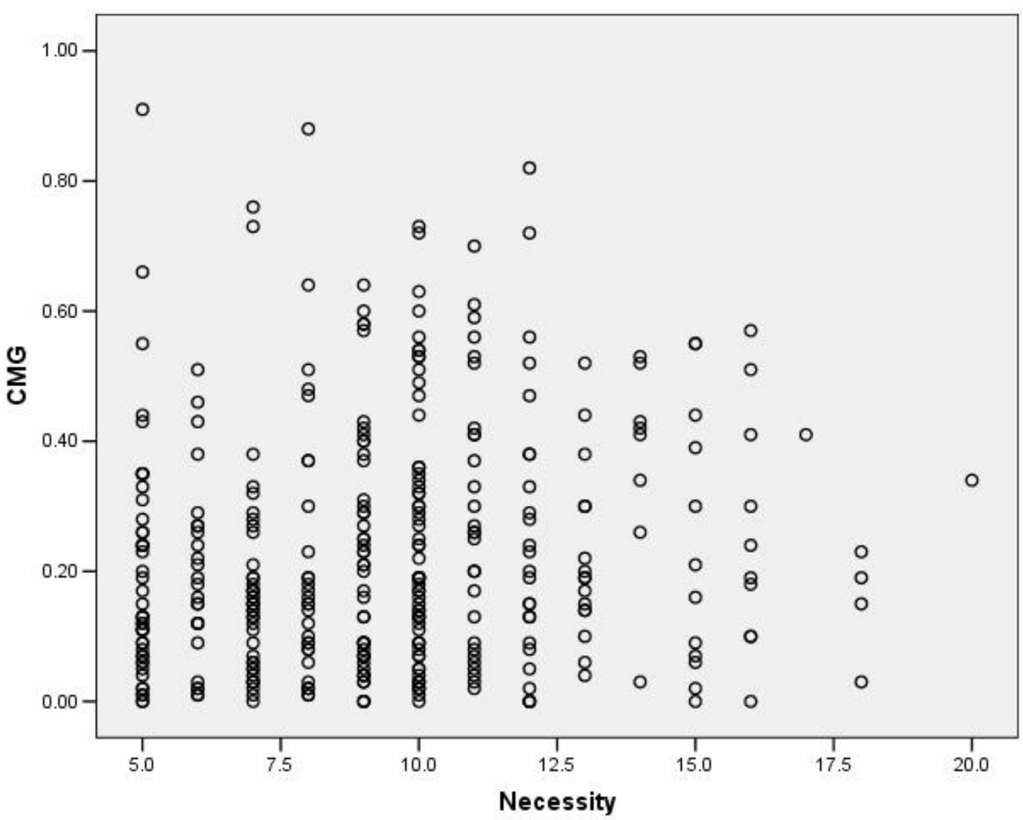

Figure 9. Respondents' Necessity and CMG.

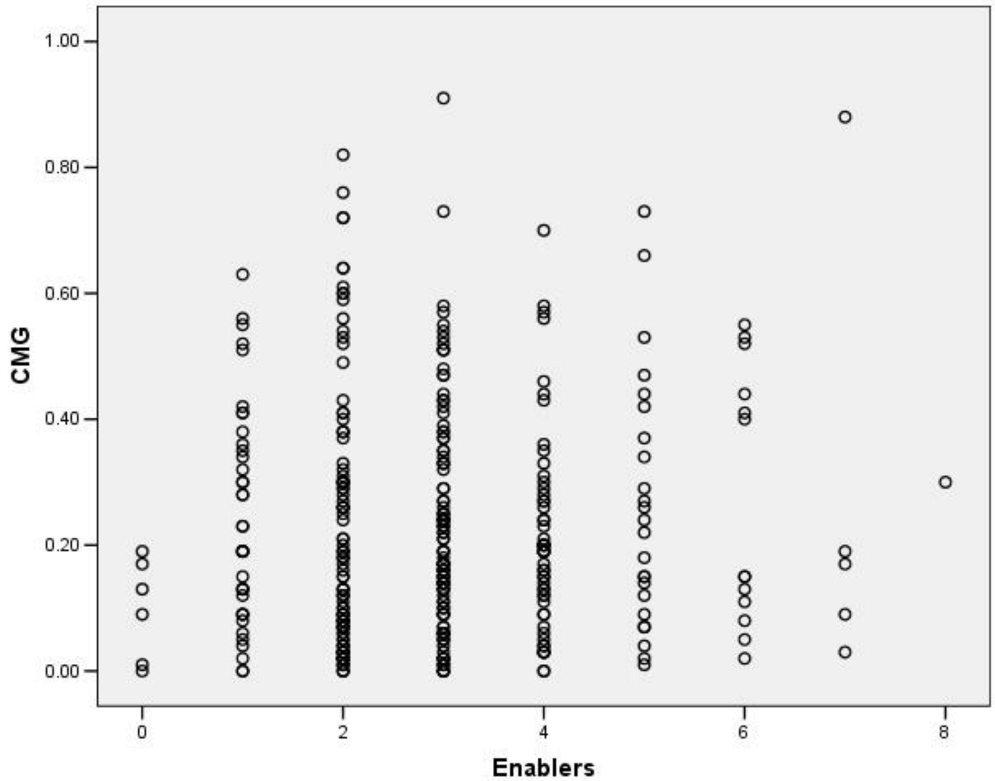

Figure 10. Respondents' Enablers and CMG.

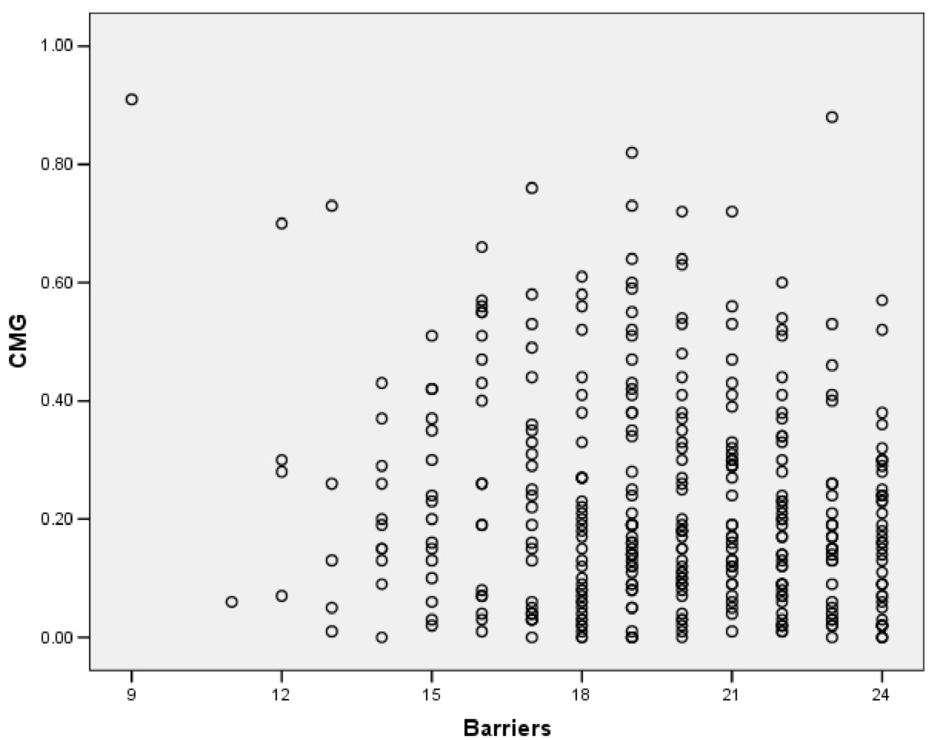

Figure 11. Respondents' Barriers and CMG.

Table 3

Summary of Regression Analysis for Variables Predicting Medication Refill Adherence

Variable	*B*	*SE B*	β
Age	-.003	.001	-.173**
Education	.003	.004	.059
Cognitive Status	.000	.004	-.007
Health Literacy	-.001	.001	-.119
No. of Medications	.002	.003	.025
Diabetes	-.014	.019	-.036
Hypertension	.303	.108	.149**
Hypercholestermia	-.062	.030	-.105*
Self-Efficacy	-.004	.002	-.123*
Concerns	-.001	.002	-.021
Necessity	.009	.003	.142**
Enablers	.004	.007	.033
Barriers	-.004	.004	-.061
R^2		.119	
F		3.274**	

*p < .05. **p < .01. N = 355.

analysis indicated the total number of medications, along with concerns/necessity beliefs, and age, explained 26.5% of the variation in non-adherence. The same analysis with the current study found that a statistically significant 5.6% of the variation in adherence was explained. Previous research regression analysis found that necessity (Horne & Weinman, 1999) and concerns/necessity (Byrne et al., 2005) explained 19% and 7% respectively of the variation in medication adherence. The current study found that together patient perceived concerns and perceived necessity for medication accounted for a statically significant 2.8% of the variance in medication refill adherence.

Path Analysis

Path analysis (computed with Mplus) was used to study the relationship between 13 psychosocial and behavioral factors and medication refill adherence (Table 4 & Figure 12). An acceptable model fit for a path model is generally indicated by a nonsignificant chi-square value with a low root mean square error of approximation (RMSEA) (at or below .05), and a CFI at or above .95. The statistical results describing model fit for the model were a significant chi-square, $\chi^2(66, N = 355) = 272.68$, $p = .00$; RMSEA = .094, CFI = .65, indicating that the model did not fit the data. Additionally, overall, the relationships of the variables in the model did not explain a statistically significant amount of the variance in medication refill adherence.

Additional Path Analyses

In an attempt to explore other possible paths explaining medication refill adherence, three additional path models were examined. However, they also did not result in any significant findings. The first revised model was run without a path delineated a priori (Figure 13). The model was not identified (degrees of freedom were negative). A second model was run based on a variation of paths identified by the researcher (Kripalani) responsible for collecting the intervention study data (Figure 14). The model variables included the following: background factors of educational attainment, age, and cognitive status (MMSE); health literacy (measured with the REALM); necessity; concerns; self-efficacy (measured with the SEAMS); barriers; and adherence (CMG). The statistical results describing model fit were a significant chi-square, $\chi^2(21, N = 355) = 144.61$, $p = .00$, RMSEA = 0.129, and CFI = 0.713, indicating that the model did not fit the data. A third revised model (Figure 15), based on variables

Table 4

Hypothesized Model Path Analysis

Model Variable	*Unstandardized*	*Standardized*	*Sig.*
Age			
Cognitive status	-0.06	0.02(-3.93)	0.00
Health Literacy	0.16	0.10 (1.61)	0.12
Education			
Cognitive status	0.43	0.05 (8.82)	0.00
Health Literacy	4.51	0.31 (14.57)	0.00
Cognitive status			
# of Medications	0.00	0.00 (0.24)	0.81
Diabetes	-0.00	0.01 (-0.25)	0.80
Hypertension	0.00	0.01 (0.22)	0.82
Hypercholestermia	-0.08	0.06 (-1.31)	0.19
Health Literacy			
# of Medications	0.00	0.00 (-0.09)	0.93
Diabetes	0.00	0.00 (1.59)	0.11
Hypertension	-0.00	0.00 (-1.15)	0.25
Hypercholestermia	0.00	0.01 (0.16)	0.88
# of Medications			
Self-efficacy	8.57	3.50 (2.5)	0.01
Diabetes			
Self-efficacy	0.21	0.64 (0.32)	0.75
Hypertension			
Self-efficacy	1.92	1.00 (1.92)	0.06
Hypercholestermia			
Self-efficacy	-0.05	0.12 (-0.40)	0.69
Self-efficacy			
Concerns	0.23	0.04 (5.99)	0.00
Necessity	0.01	0.03 (0.18)	0.86
Concerns			
Enablers	-0.06	0.02 (-3.71)	0.00
Barriers	0.23	0.03 (6.95)	0.00
Necessity			
Enablers	-0.07	0.02 (-2.86)	0.00
Barriers	0.07	0.05 (1.34)	0.18
Enablers	0.01	0.01 (0.79)	0.43
Barriers	-0.01	0.00 (-2.49)	0.01

Note. Unstandardized, Standardized, and Significance Levels for Model in Figure 11 (Standard Errors in Parentheses; N = 355). RMSEA = .094; CFI = .65

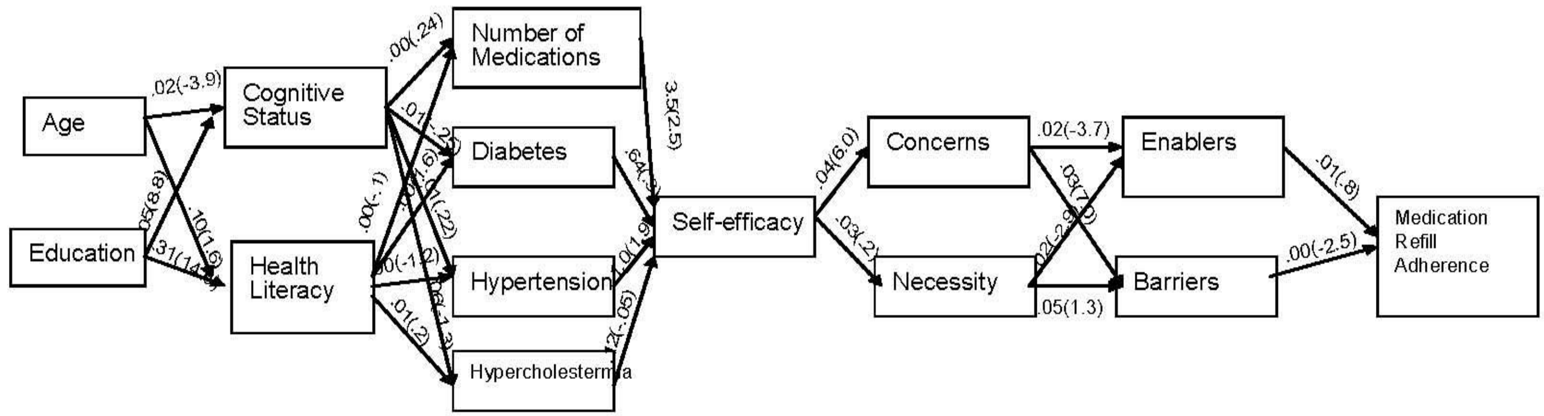

Figure 12. Hypothesized Exploratory Path Model

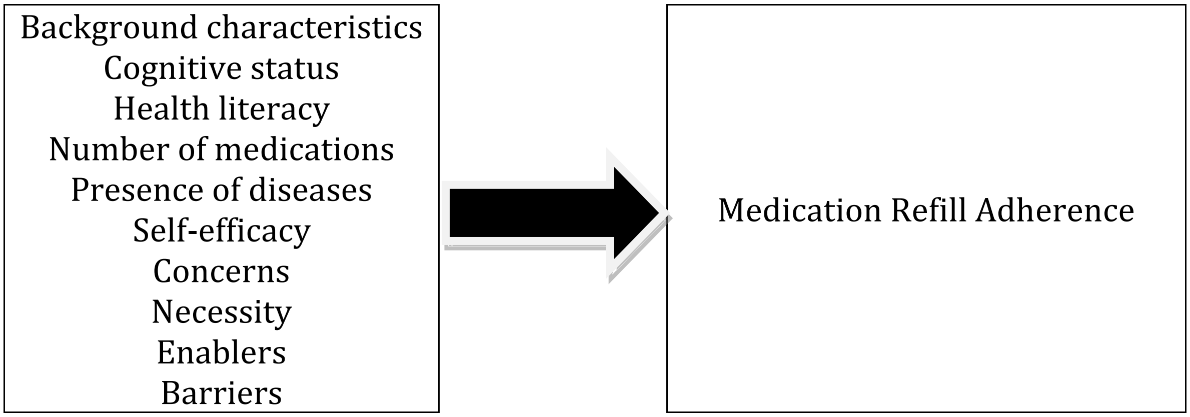

Figure 13. Revised Model #1.

found to explain a significant amount of the variance in medication adherence from the literature (self-efficacy, concerns, necessity, and age) was also explored. The statistical results describing model fit were a significant chi-square, $\chi^2(5, N = 355) = 20.75$, $p = .00$, RMSEA = 0.094, CFI = 0.727, indicating that the model did not fit the data.

Study II

Because the hypothesized model did not fit the data, another medication adherence variable present in the intervention study database was examined as the dependent variable. Originally, CMG was selected because it does not rely on self-report, is objective in nature, and easy to collect from administrative sources. The Adherence to Refills and Medications Scale (ARMS) was selected to further explore the relationship between the independent variables identified for this study and refill adherence. This alternative measure of adherence was developed by researchers to provide an accurate self-reported measure of adherence that can be administered to low-literate populations (Kripalani, Risser, Gatti, & Jacobson, 2009). The 12-item Likert scale includes responses of “none,” “some,” “most,” or “all” of the time. Values ranged from one (“none”) to four (“all”), with lower scores indicating better medication adherence. The scale was validated

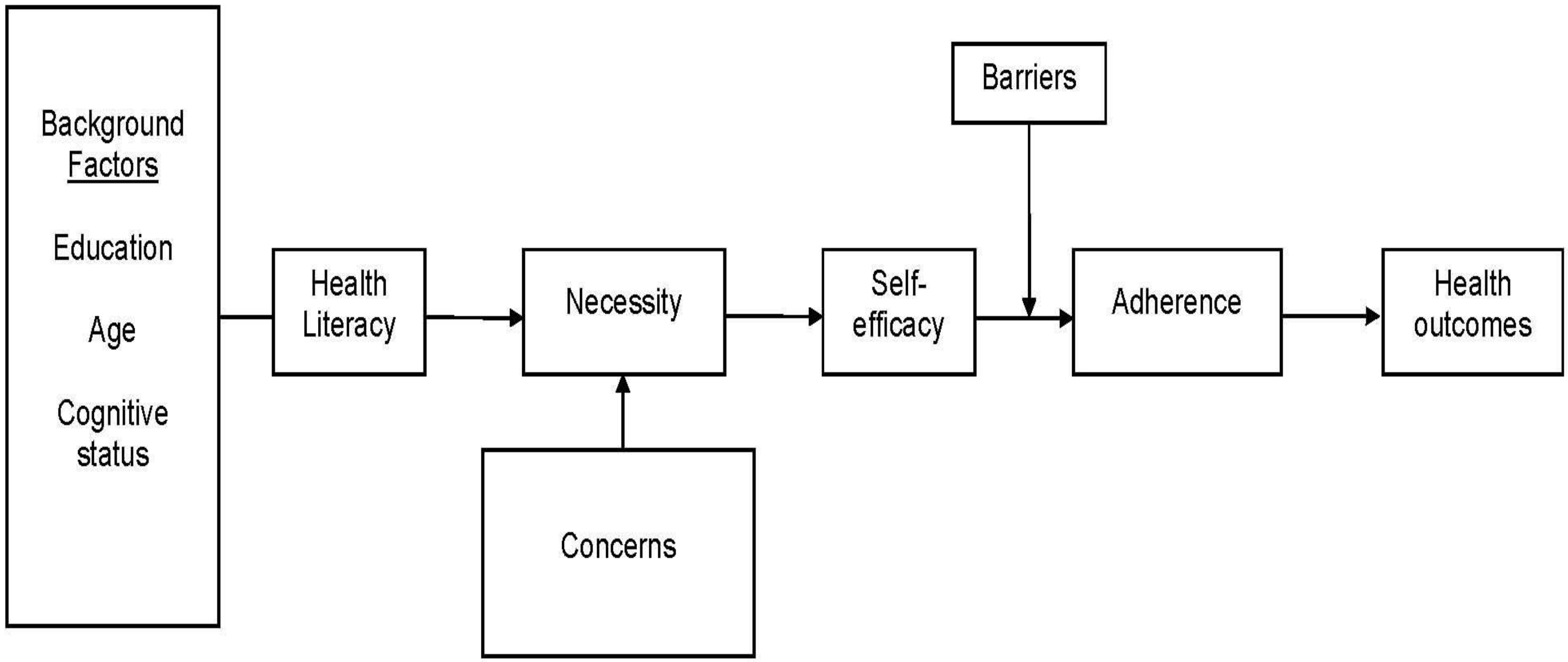

Figure 14. Revised Model #2

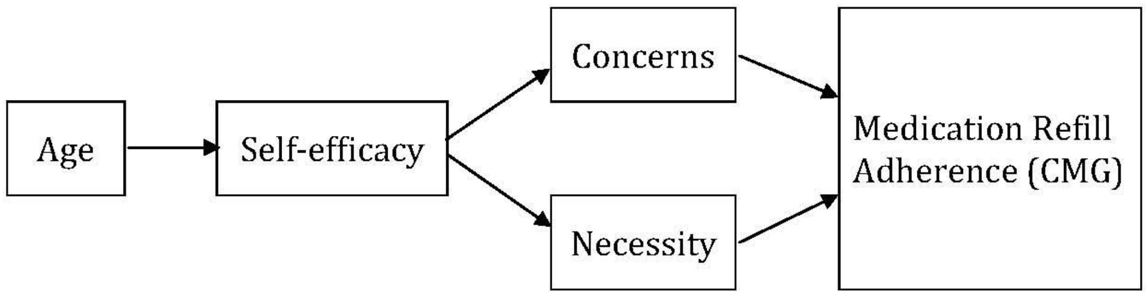

Figure 15. Revised Model #3.

with 435 patients, 55.6% female, mean age of 63.7 years, and 91% African American. It contains eight items that assess adherence to correctly taking medications and four items that assess adherence to refilling medications on schedule. Validation of the scale found that for the first subscale, Cronbach's alpha was 0.794 and the item-total correlations ranged from 0.344 to 0.598. For the second subscale, Cronbach's alpha was 0.641 and the item-total correlation ranged from 0.408 to 0.514 (Kripalani et al., 2009).

Study II Results

The total ARMS score ranged from 12 to 34 with an average of 16.32 (*SD* 3.963). Overall, participants self-reported as adherent. Figure 16 depicts the positively-skewed distribution of the ARMS variable. Path analysis with the proposed exploratory model was used to study the relationships between the independent variables with ARMS as the dependent variable. However, similar to the initial models' analysis, the proposed exploratory model of medication refill adherence did not fit the data. The statistical results describing model fit were a significant chi-square, $\chi^2(66, N = 355) = 243.31$, $p = .00$, RMSEA = 0.087, CFI = 0.68.

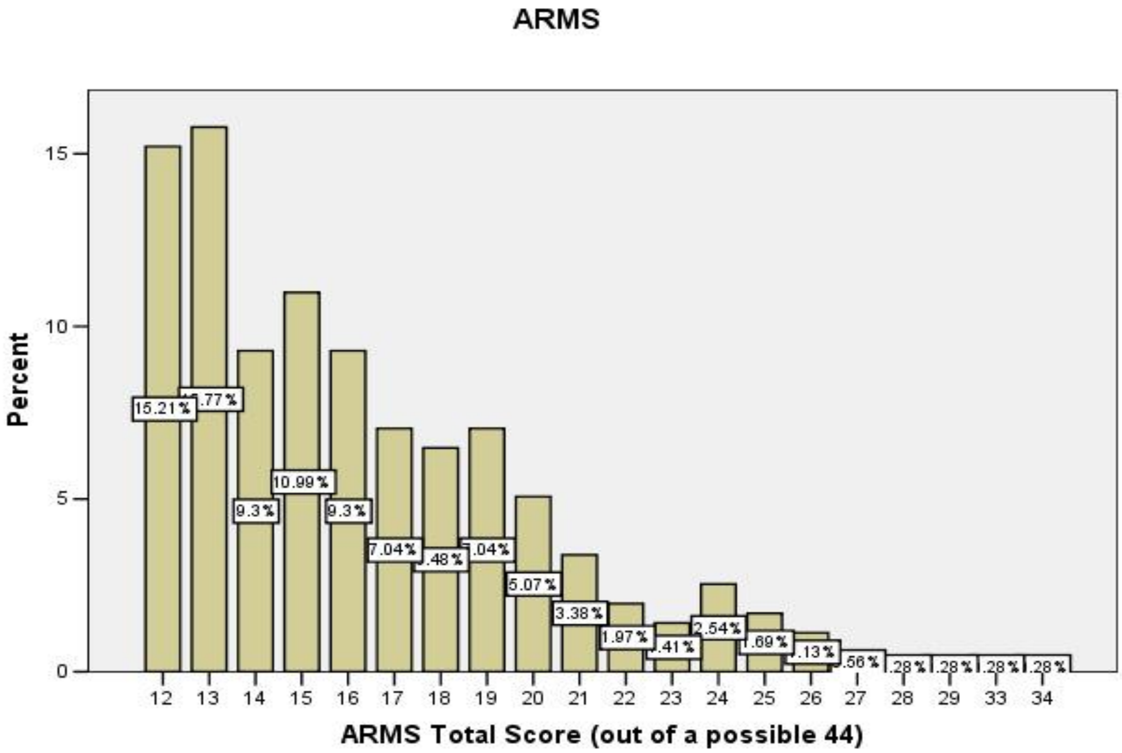

Figure 16. ARMS total score.

Correlations among independent variables (except for dummy coded variables diabetes, hypertension, and hypercholesterolemia) and ARMS found several significant results (Table 5). The dependent variable ARMS had significant correlations with age, self-efficacy and concerns.

Given the correlation findings, the scatter plots with ARMS visually depicted strong linear relationships with variables age, self-efficacy, perceived concerns about medication and perceived necessity about medication-taking (see Figures 17–20). These scatter plots indicated that as age increases, medication adherence decreases; as self-efficacy increases, medication adherence decreases; as perceived concerns for medication increases, medication adherence decreases; and as perceived necessity for medication

Table 5

Intercorrelations between Independent Variables and ARMS

Variable	Age	2	3	4	5	6	7	8	9	10
2. Educ.	-.318**									
3. Cognit.	-.323**	.483**								
4. H.Lit.	-.133**	.617**	.613**							
5. Meds	.100	-.071	-.081	-.043						
6. S.Effic.	.085	.011	.019	-.032	-.007					
7. Conc.	.117*	-.007	.053	.022	-.031	.303**				
8. Neces.	.011	.003	-.102	-.052	-.053	.010	-.045			
9. Enabl.	-.034	-.051	-.136*	-.048	.067	-.168**	-.185**	-.139**		
10. Barriers	.108	-.005	.022	.002	-.047	.474**	.343**	.051	-.164**	
11. ARMS	.261**	.027	-.046	-.060	.032	.550**	.308*	-.042	.023	.002

Note. N = 355. Educ. = Education; Cognit. = Cognition; H. Lit. = Health Literacy Meds = Number of Medications; S.Effic. = Self-Efficacy; Conc. = Concerns; Neces. = Necessity; Enabl. = Enablers. The three dichotomous variables (diabetes, hypertension, hypercholestermia) are not included in the matrix.

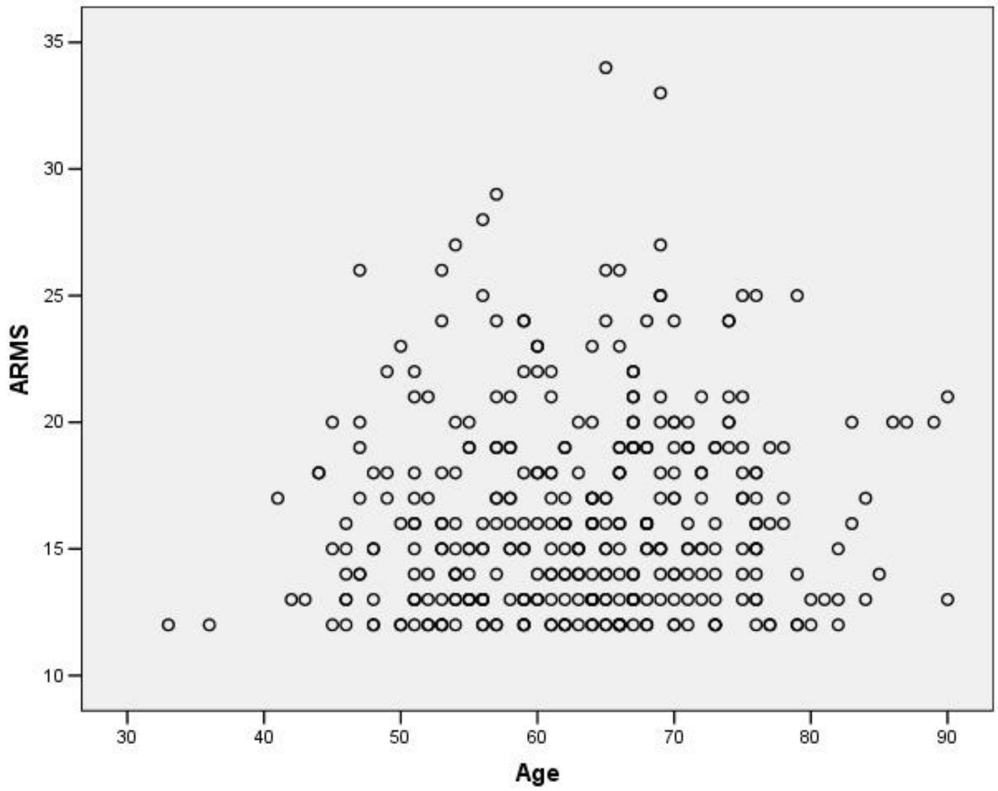

Figure 17. Respondents' Age and ARMS.

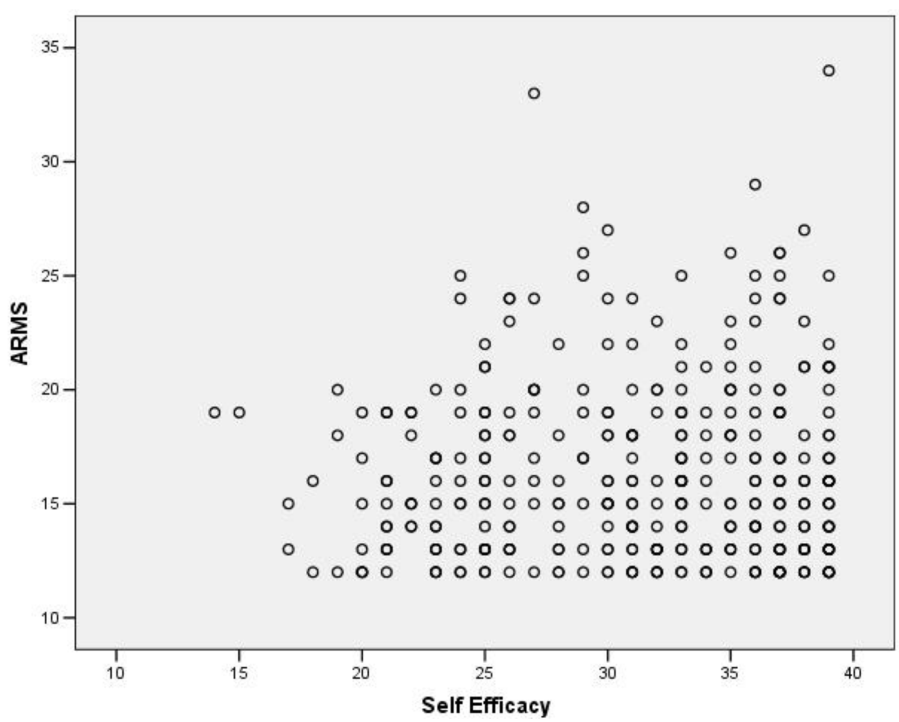

Figure 18. Respondents' Self-efficacy and ARMS.

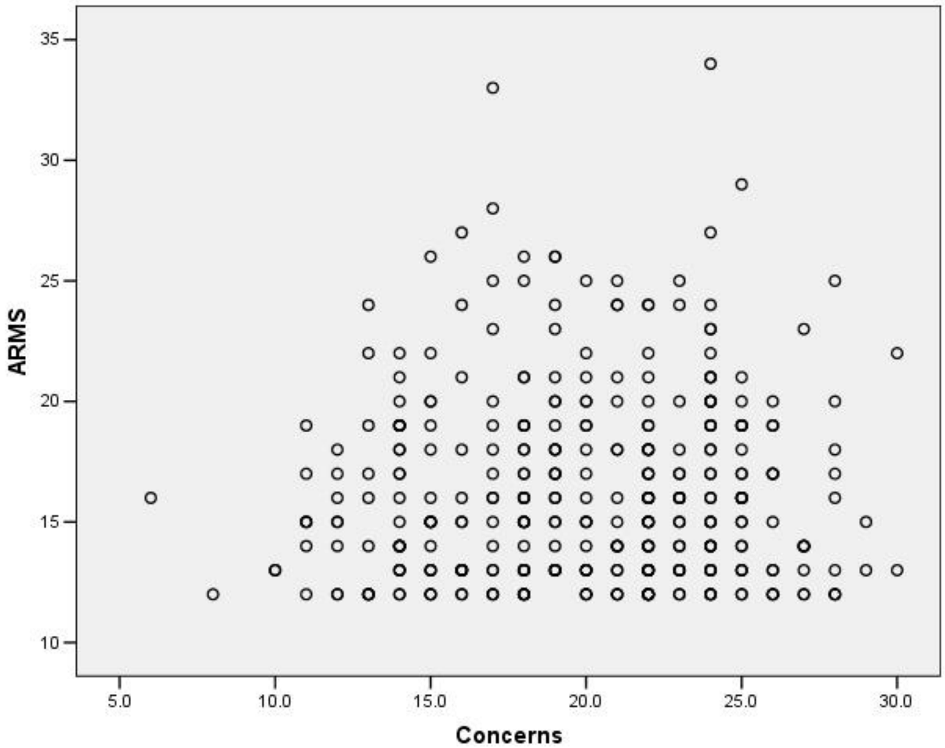

Figure 19. Respondents' Concerns and ARMS.

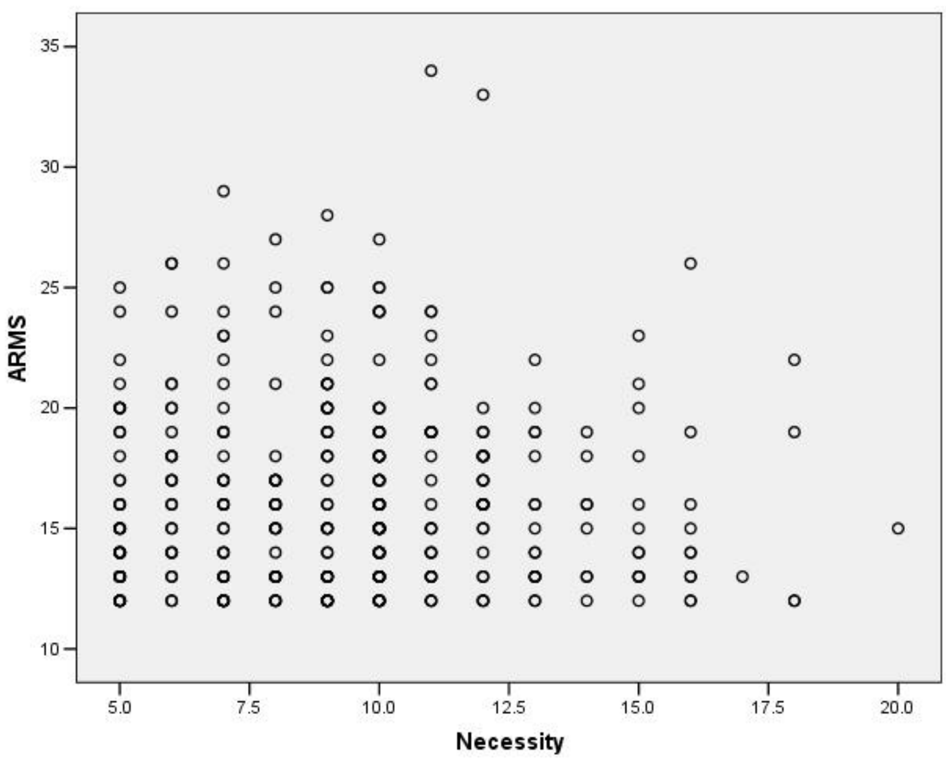

Figure 20. Respondents' Necessity and ARMS.

increases, medication adherence increases. Overall, the scatter plots suggested that because of the stronger relationship between the independent variables and the ARMS variable, compared to the CMG variable, the independent variables age, self-efficacy, perceived concerns and perceived necessity had some effect on self-reported adherence behavior.

Support for the scatter plot findings can be found in the literature. Age (Schectman et al., 2002), self-efficacy (Aljasem et al., 2001), concerns (Byrne et al., 2005; Phatak & Thomas, 2006), and necessity (Horne & Weinman, 2009; Phatak & Thomas, 2006) were all found to explain a statistically significant amount of variability in medication adherence. Therefore, these variables were used in a condensed revised path analysis model (Figure 15) to test for fit with the ARMS scale as the dependent variable.

The ARMS dependent variable was regressed on patient concerns and patient necessity. Patient concerns and necessity were regressed on self-efficacy. Self-efficacy was regressed on age. Although the revised model did not explain a statistically significant amount of the variance in medication adherence, the condensed revised model did fit the data. Results describing the model fit were a non-significant chi-square, $\chi^2(5, N = 355) = 6.71$, $p = .24$, RMSEA = 0.31, and CFI = .95 (Table 6, Figure 21). There was one statistically significant direct effect on patient concerns from self-efficacy, $\beta = .23$, $p = .00$.

Table 6

Revised Model Path Analysis

Model variable	*Unstandardized*	*Standardized*	*Sig.*
Age	0.05	0.032 (1.61)	0.12
Self-Efficacy			
Concerns	0.23	0.04 (5.99)	0.00*
Necessity	0.01	0.03 (0.18)	0.86
Concerns	0.03	0.05 (0.72)	0.47
Necessity	−0.02	0.07 (−0.22)	0.83

Note. Unstandardized, Standardized, and Significance Levels for Model in Figure 21 (Standard Errors in Parentheses; N = 355). RMSEA = .094; CFI = .65.
* p < .05

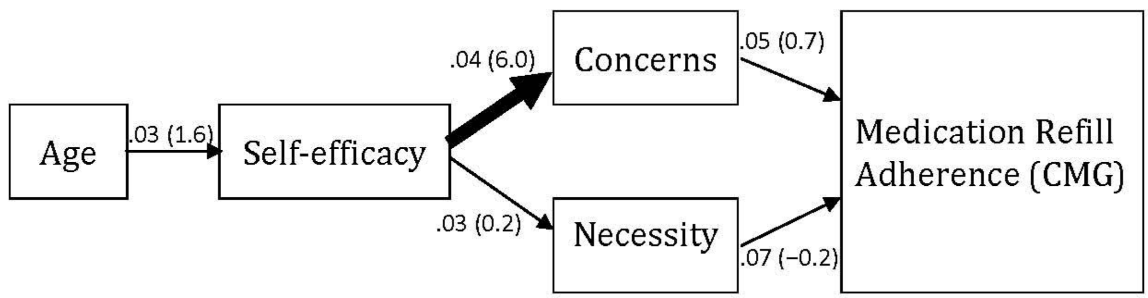

Figure 21. Condensed Revised Path Model (with ARMS). The denser line indicates the statistically significant path.

CHAPTER 5

DISCUSSION

Summary

As the population ages and individuals are more frequently placed on long-term prescription regimens, understanding factors associated with medication refill adherence behavior is an important endeavor. Utilizing data collected from patients managing CHD, independent variables including background characteristics, cognitive status, health literacy, number of medications, presence of diseases, self-efficacy, patient perceived concerns about medication use, patient perceived necessity for medication use, enablers to medication-taking behavior and barriers to medication-taking behavior were examined through a path analysis to see how effectively they work together in a model that explains the determinants of medication refill adherence behavior. Overall, the hypothesized model (with CMG as the dependent variable) did not fit the data. However, there were some interesting findings that help elucidate the relationships between the independent variables and medication refill adherence behavior.

In the hypothesized model, background characteristics were proposed to directly affect cognitive status and health literacy. The variable age was significantly correlated with cognitive status, $r = -.323$ ($p = .00$). Age was also significantly correlated with health literacy, $r = -.133$ ($p = .01$). Education was significantly correlated with both cognitive status, $r = .483$ ($p = .00$) and health literacy, $r = .617$ ($p = .00$).

The hypothesized model proposed that the effects of a person's cognitive status, along with their health literacy, directly correlate with the ability to manage chronic illness, specifically, the number of medications taking and managing co-morbidities such as diabetes, hypertension, and hypercholestermia. The current study did not find any significant correlations to this effect.

The hypothesized model proposed that patient health, including number of medications taking and presence of co-morbidities such as diabetes, hypertension, and hypercholestermia, would directly influence self-efficacy. Additionally, Phatak's (2006) regression analysis found that the total number of medications, along with concerns/necessity beliefs, and age, explained 26.5% of the variation in non-adherence. The same analysis with the current study found that 5.6% of the variation in adherence was explained, and this finding was statistically significant.

Self-efficacy was proposed to directly influence patient perceived concerns and perceived necessity for medication use. Results indicated that self-efficacy significantly correlated with patient perceived concerns, $r = .303$ (p=.00). Similar to Aljasem's (2001) study where regression analysis found that greater self-efficacy accounted for statistically significant 8% of the variance in less frequent skipping of medication, and Gatti's (2009) study findings that patients with lower self-efficacy had greater odds of low medication adherence compared with patients with higher medication self-efficacy, the current study found through regression analysis that self-efficacy accounted for statistically significant 2.9% of the variance in refill adherence.

The model proposed that patient perceived concerns and perceived necessity for medication use would influence enablers and barriers to medication-taking behavior.

There were significant correlations between perceived concerns and enablers, $r = -.185$ (p=.00) and barriers, $r = .343$ (p=.00). There was a significant correlation with perceived necessity and enablers, $r = -.139$ (p=.01). Previous research regression analysis found that necessity (Horne & Weinman, 1999) and concerns/necessity (Byrne et al., 2005) explained 19% and 7% respectively, the variation in adherence. Similarly, the current study found that together patient perceived concerns and perceived necessity for medication accounted for a statically significant 2.8% of the variance in medication refill adherence. In another study (Phatak & Thomas, 2006), concerns/necessity beliefs, age and total number of medications explained 26.5% of the variance in non-adherence to medication. The current study found that together concerns/necessity beliefs, age and total number of medications explained a statistically significant 5.6% of the variation in medication refill adherence.

Enablers and barriers to medication-taking were proposed to directly influence medication adherence. More work needs to be conducted examining enablers as an explanatory variable for medication refill adherence. Only one study (Svensson et al., 2000) examined enablers and it found that the top reasons for medication adherence were physician trust and desire to control the condition. When examined in the literature, barriers to medication-taking behavior included a need for information and support (Barber et al., 2004) and changing a daily routine (George & Shalansky, 2007). Gellad (2007) found both cost and skipping doses statistically significant in explaining refill adherence. The current study found that barriers significantly correlated with, self-efficacy, concerns and enablers, $r = .47$ (p=.00), $r = .34$ (p=.00), $r = -.16$(p=.00), respectively. George and Shalansky (2007) found the barrier of changing a daily routine

to accommodate taking medications a statistically significant independent predictor of refill non-adherence. The current study found that barriers to taking medications explained a statistically significant 1.9% of the variance in refill adherence.

Because the hypothesized model did not fit the data, the ARMS self-report measure of adherence was analyzed with the independent variables. A major advantage of the ARMS is its appropriateness for use among minority populations and patients with limited literacy skills (Kripalani, 2009). The current study participants included 90.1% African-Americans whose mean health literacy was equivalent to a fourth to sixth grade reading level. In this study, the ARMS variable had greater linear relationships with the independent variables than the CMG variable. The ARMS variable did not fit the hypothesized model. However, there were stronger linear relationships between ARMS and age, self-efficacy, concerns, and necessity variables when compared to CMG. These relationships are substantiated and supported by the literature. Therefore, these four variables were tested in a revised path model with the ARMS dependent variable and results found that this revised model fit the data.

Strengths and Limitations

A major strength of this study is that, for the first time, all variables found to have an association with medication adherence were tested together in a model of determinants of medication refill adherence behavior. Unfortunately, this hypothesized model did not work. However, the condensed revised model, using ARMS as the dependent variable, was successful in fitting a smaller group of variables.

A limitation to this study was that the independent variables were self-reported (except for number of medications and presence of diseases, which were collected from

medical records). A second limitation was that the participants were predominately African-American attending a pharmacy in a large urban city, resulting in limited generalization possibilities. A third limitation of the study was that the unsuccessful exploratory model was based on research that looked at two different constructs, medication adherence and medication refill adherence. It may have been fruitful to tease out a model that was purely based on either medication refill adherence specifically or medication adherence in general.

Conclusion

Overall, the study found that the proposed interactions in the hypothesized model of refill adherence behavior did accurately reflect some of the relationships between the independent variables. However, the present findings do not support the hypothesized model of refill adherence behavior. The ARMS variable had greater linear relationships with the independent variables than the CMG variable. Although the hypothesized model did not fit the data, a condensed revised model using age, self-efficacy, concerns, and necessity variables with ARMS as the dependent variable successfully fit the data. However, the revised model did not explain a statistically significant amount of the variance in medication adherence.

Future research needs to identify additional variables that may also be associated with medication refill adherence. This is especially salient given that studies examining variables that play a role in adherence to medication regimens did not predict high levels of variance in adherence. Overall, the studies demonstrated that the proportions of variance in adherence explained was low, including 6.8% for age and other background characteristics (Schectman et al., 2002), 4% for cognition (Insel et al., 2008), 7% for

concerns/necessity, 8% for self-efficacy (Aljasem et al., 2001), 19% for necessity (Horne & Weinman, 1999), and 26.5% for number of medications, concerns/necessity, and age (Phatak & Thomas, 2006). Additional research is needed in this area to reveal all the determinants of medication refill adherence behavior and to identify the most appropriate measure of adherence behavior.

A better understanding of the motivational and behavioral factors that influence medication refill adherence will assist the development of effective strategies to improve patient adherence. Given the number of people who suffer from chronic diseases such as CHD, diabetes, hypertension, and hypercholestermia, and the often low rates of medication adherence, research that continues to explore and improve medication refill adherence will have a significant impact on morbidity and mortality rates.

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