FUNCTIONAL HEALTH LITERACY, MEDICATION-TAKING SELF-EFFICACY AND HIV MEDICATION ADHERENCE

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ABSTRACT

Health literacy has been shown to be related to multiple health outcomes and may be an issue of great importance in the management of a chronic and complicated disease like HIV. Functional health literacy (FHL) may be a factor that affects medication adherence in people living with HIV/AIDS.

This study sought to describe FHL in people living with HIV/AIDS who are taking antiretroviral medication and to investigate functional health literacy and medication taking self-efficacy as possible predictors of HIV medication adherence. Additionally, the study explored the relationship between FHL and selected variables from SCT.

This secondary data analysis was a cross-sectional descriptive study. The sample included 335 individuals living with HIV who were taking antiretroviral medications. Measures of central tendency and variance were used to describe continuous variables. Bivariate analyses and logistic regression were conducted to examine the univariate relationships between and

among the key variables of interest. Multivariate logistic regression was used to jointly examine potential predictors of adherence.

Overall, 10.4% (n=35) of the participants were classified as having inadequate/marginal FHL. Race, educational level, and the interaction between race and educational level predicted FHL in this sample. Sixty seven percent (n=223) of participants had adherence rates less than 85%, based on days with correct intake. In bivariate analysis, FHL was not significantly related to medication adherence, although there was a non-significant trend suggesting that people with lower FHL may demonstrate lower adherence ($\chi 2 = 3.17$, $p=.075$). FHL was also not related to self-efficacy beliefs. In multivariate logistic regression, non-white participants, people with lower self-efficacy beliefs, and younger individuals were more likely to demonstrate poorer adherence.

Using multivariate logistic regression, medication adherence was significantly related to mental health functioning, role of state of mind in controlling illness, negative self-image related to HIV-stigma, and two interaction terms (mental health functioning and negative self-image related to HIV-stigma; personalized stigma and FHL), after controlling for race and age.

The proportion of people with lower FHL was lower than expected. Further research is needed to fully understand the scope and breadth of FHL issues for people living with HIV. Further research is needed to understand the disparate findings related to FHL and treatment adherence. Finally, these results indicate that there remains much work to be done in identifying true predictors of medication adherence in people living with HIV.

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PREFACE

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1.0 INTRODUCTION

Health literacy is defined in the Healthy People 2010 Objectives as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (U.S. Department of Health and Human Services, 2000, Ch.11, p. 20) Health literacy is a significant societal issue, and is even more critical for the person living with a chronic disorder or health problem, who probably has more frequent and complicated interactions with all aspects of the health care delivery system (U.S. Department of Health and Human Services, 2000). Current research examining health literacy and health outcomes estimates that at least one in five individuals in the United States has inadequate health literacy (Artinian, Lange, Templin, Stallwood, & Hermann, 2001a; Lindau et al., 2002; Montalto & Spiegler, 2001; Montaque, Okoli, & Guerrier-Adams, 2003; Rudd, Kirsch, & Yamamoto, 2004; Sharp, Zurawski, Roland, O'Toole, & Hines, 2002). The scope of the problem of health literacy is broad and far-reaching. Although researchers may use slightly different definitions for and assessments of health literacy, their studies attempt to quantify the magnitude of the crisis.

For people living with HIV/AIDS—a multi-dimensional, chronic, infectious disease—health literacy becomes critically important because successful management of their disease requires strict adherence to a complex medication regimen. Current research shows that viral suppression may require nearly 100% adherence; rates greater than 95% translate into less than

one missed dose per week for a patient on a twice-a-day pill regimen (Deeks et al., 1999; Paterson et al., 2000). The "non-adherent" patient on highly active antiretroviral therapy (HAART) is 3.5 times more likely to experience treatment failure and 3.87 times more likely to die than an adherent patient on the same therapy (de Olalla et al., 2002; Ickovics et al., 2002). HIV treatment has evolved significantly over the past 20 years, and recent findings from Bangsberg (2006) suggest that newer, more potent regimens may actually require lower levels of adherence for viral suppression, possibly varying between 54 and 100 percent. However, Bangsberg noted that the probability of viral suppression, reduced disease progression and reduced mortality are increased with greater adherence levels, supporting continued efforts to maximize adherence in people living with HIV/AIDS. Actual adherence rates in the HIV/AIDS population are estimated to vary from 30% to 90% (Catz, Kelly, Bogart, Benotsch, & McAuliffe, 2000; Dunbar-Jacob et al., 2000; Erlen, Sereika, Cook, & Hunt, 2002; Golin et al., 2002; Howard et al., 2002; McNabb, Nicolau, Stoner, & Ross, 2003; Riera et al., 2002). A recent meta-analysis on adherence in HIV/AIDS reports rates in North America of approximately 55% (Mills et al., 2006). These rates, when examined in the context of HIV disease management, demand that continued attention be paid to medication taking behaviors and the mechanisms of medication adherence. Health literacy may be one of the myriad factors influencing the disease-management behaviors of people living with HIV. Although there is no available research examining the nature of the relationship between these two variables, two studies have shown lower HIV medication adherence to be associated with lower health literacy (Kalichman, Catz, & Ramachandran, 1999; Kalichman, Ramachandran, & Catz, 1999).

To date, health literacy research has been limited to primarily descriptive work with different populations, as researchers seek to define health literacy levels and identify possible

correlates of low health literacy. Advancing the science in this area requires a more in-depth understanding about the breadth of low health literacy, including possible predictors of health literacy and factors that protect those with lower health literacy against negative health outcomes. Additionally, there needs to be a more comprehensive understanding of the impact of health literacy on outcomes, such as self-efficacy and treatment adherence. Finally, researchers need to explore the potential role of health literacy using well-established, theoretically based approaches to explain health behavior, as there is very little published literature in this area.

This study addresses two current, critical problems: 1) low health literacy and 2) poor HIV medication adherence. Healthy People 2010 Objectives related to health literacy assert that the burden for change in health literacy, in the short term, lies with healthcare providers, public health professionals, and healthcare systems; however long-term educational programs may be best suited to raise health literacy levels in the general population (U.S. Department of Health and Human Services, 2000). While research in health literacy has illustrated the potentially deleterious effects of low health literacy on health outcomes, little attention has been paid to the mechanism by which this occurs. Very few studies were found that examined the relationship between health literacy and self-efficacy. This study attempted to address these identified gaps in the literature by examining the relationships among health literacy and other variables within Albert Bandura's Social Cognitive Theory (1986). An increased understanding of predictors and variables related to low health literacy may make an important contribution to the body of literature exploring health literacy and related health outcomes. There is a lack of research exploring the possible role of health literacy in theoretically-based approaches of health behavior and the results of this analysis, specifically the model testing, may lay the groundwork for future work in this area.

This study also built upon existing research by using a more comprehensive and accurate approach to measuring adherence that utilizes electronic event monitoring, rather than the less reliable self-report and recall used frequently in other studies. An improved understanding of health literacy, self-efficacy and medication adherence has the potential to be translated into effective interventions designed specifically for individuals with lower health literacy. These intervention protocols, in turn, may lead to improved health outcomes related to medication adherence, disease knowledge, transmission, service utilization, symptom control, and quality of life.

1.1 SIGNIFICANCE OF THE PROBLEM

In 2003, Surgeon General Carmona called health literacy "the currency for success for everything we do in primary and preventive medicine" (Carmona, 2003). Without adequate "currency", individuals may not achieve the same health goals as others with higher proficiency levels. Low health literacy has been linked with several important health outcomes such as higher rates of hospitalization, less disease-specific knowledge, and poorer glycemic control and higher rates of retinopathy in diabetics (Baker, Gazmararian, Williams et al., 2002; J. A. Gazmararian, Williams, Peel, & Baker, 2003b; Hicks, Barragan, Franco-Paredes, Williams, & del Rio, 2006; Lindau et al., 2002; Dean Schillinger et al., 2002). People with low health literacy are at higher risk of acquiring gonorrhea and yet less likely to seek care for sexually transmitted diseases (J. D. Fortenberry et al., 2001). In patients with HIV/AIDS, lower health literacy has also been associated with poorer health outcomes—specifically, lower CD4 cell count and higher viral load (Kalichman & Rompa, 2000b). Researchers examining reading levels in an HIV-

positive population found that two-thirds of those reading below a ninth-grade reading level did not know how to take their medications correctly and one-third of them could not name their medications (Wolf et al., 2004). Researchers are just now starting to understand the scope of the issue, and researchers and clinicians are recognizing the critical role of health literacy in the lives of patients.

Health literacy has emerged as a significant component of the current U.S. health care agenda. Prominent and influential governmental entities and healthcare organizations have issued the call for increased health literacy out of concern for patient safety, quality of care, and patient satisfaction. In 2004, the Agency for Healthcare Research and Quality (AHRQ) published an evidence report describing the impact of inadequate health literacy. This report clearly demonstrated that low health literacy is related to poor health outcomes; AHRQ urgently recommended increased attention and priority to the issue (Berkman et al., 2004).

Prior to the report from AHRQ, the Institute of Medicine of the National Academies identified health literacy as a priority for improving the quality and delivery of health care. Their report *Priority Areas for National Action: Transforming Health Care Quality* listed 20 areas, of which health literacy was one of two areas classified as "cross-cutting" because it affects patients across many conditions. That report asserted that efforts to improve health literacy are necessary and critical for both self-care of individuals and for collaborative care provided by healthcare professional (Adams & Corrigan, 2003). One critical area of self-management is medication adherence.

The American Nurses Association (ANA) and the American Medical Association (AMA) also have recognized the importance of health literacy. The AMA Foundation's Ad Hoc Committee on Health Literacy issued a report stating that the professional and public awareness

of the health literacy issue must be increased, educational programs related to health literacy should be introduced in training health care providers, and public and private funding should be allocated to investigate health literacy (Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, 1999). In 2002 the AMA helped to create the Partnership for Clear Communication, a coalition of high-visibility health organizations addressing the problem of low health literacy. The ANA, the American Pharmacists Association, the American Public Health Association, and other professional organizations have partnered with the AMA on this project (Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, 1999). In 2005 the AMA published "Understanding Health Literacy: Implications for Medicine and Public Health," a comprehensive resource designed to help clinicians and researchers understand this healthcare challenge and to provide a comprehensive look at the existing research on health literacy. This textbook was written in an atttempt to both improve practice and stimulate research in this area (Schwartzberg, VanGeest, & Wang, 2005).

Healthy literacy, as it has been conceptualized, is a critical component in the care of people with chronic diseases such as HIV. Researchers currently estimate that 20-25% of people living with HIV/AIDS demonstrate inadequate or marginal health literacy, a rate similar to that of the general population (Kalichman et al., 2000; Kalichman & Rompa, 2000b; Rudd, Kirsch, & Yamamoto, 2004). The Centers for Disease Control and Prevention (CDC) estimate that 1 million people are living with HIV in the U.S. and approximately 40,000 new people are infected annually (Centers for Disease Control and Prevention, 2003b). Prolonged survival, attributed almost exclusively to the advent of antiretroviral treatment, requires strict adherence to medication therapy and places significant demands on individuals with low health literacy (D. R. Bangsberg et al., 2001; Carrieri et al., 2003; de Olalla et al., 2002). Additionally, the unique

pressures of this chronic and infectious disease, such as preventing transmission and maintaining healthy behaviors, create a higher demand for self-management ability. Medication adherence is a critical issue in the management of HIV/AIDS because poor rates of adherence can lead to unsuccessful viral suppression, resistance to medication, opportunistic infections, overall poor health, decreased quality of life, and potentially death (D. R. Bangsberg et al., 2001; Carballo et al., 2004; Erlen & Mellors, 1999; McNabb, Nicolau, Stoner, & Ross, 2003). Therefore, persons with HIV/AIDS who also have inadequate health literacy are even more vulnerable and at greater risk for poor health outcomes.

Despite the increase in information about health literacy and its effect on health outcomes, considerable confusion remains about the mechanism by which health literacy affects outcomes and potential intervention points for nurses and other healthcare providers. In their report in 1999, the Ad Hoc Committee on Health Literacy of the AMA made specific recommendations about particular policy and research issues related to health literacy. One of these calls to action highlighted the importance of further research into the casual pathway, detailing specifically how health literacy may affect health. However, in their editorial, *"Beyond the Institute of Medicine Health Report: Are the Recommendations Being Taken Seriously?"* Parker and Kindig (2006) asserted that, despite some advancement, greater attention needs to be paid to reducing the negative effects of health literacy including research into the mechanism by which health literacy influences health. In light of the significant evidence supporting health literacy's role, researchers investigating health outcomes must consider how health literacy can be represented theoretically in a framework that explains the mechanism by which it may affect health outcomes. Albert Bandura's Social Cognitive Theory (1986) attempts to explain how people behave, and posits that behavior is influenced by the environment, individual factors, and

aspects of the behavior itself. This theory, in which the three domains are constantly influencing each other, may provide valuable guidance for this line of inquiry. This study, guided by the constructs of Bandura's Social Cognitive Theory (1986), examined the relationship between functional health literacy, medication-taking self-efficacy, and adherence to prescribed medication therapy in people living with HIV.

1.2 PURPOSE

The primary purposes of this descriptive study, guided by Bandura's Social Cognitive Theory (1986), were to describe functional health literacy in people living with HIV/AIDS who are taking antiretroviral medication and to examine the relationships among functional health literacy, medication-taking self-efficacy, and HIV medication adherence. Secondarily, the study sought to generate hypotheses by investigating inter-relationships among functional health literacy and selected factors related to medication adherence within the constructs of Bandura's Social Cognitive Theory: individual factors, environmental factors, and health behavior.

1.3 SPECIFIC AIMS AND RESEARCH HYPOTHESIS

The specific aims were to:

1. Examine functional health literacy rates in people living with HIV who are taking antiretroviral medication.

H1: Inadequate/marginal health literacy levels in the sample population are similar to health literacy levels seen in other tested populations (i.e. approximately 20%).

2. Examine the associations between selected socio-demographic variables (age, gender, race, educational background, marital status, employment, income, and current alcohol/drug use), HIV disease history variables (CD4 count, viral load, and number of HIV medications) and functional health literacy.

H2.1: There is an association between functional health literacy and educational background.

H2.2: There is no association between functional health literacy and the remaining socio-demographic variables (age, gender, race, marital status, employment, income, and current alcohol/drug use).

H2.3: There is no association between health literacy and HIV disease factors (CD4 count, viral load, and number of HIV medications).

3. Describe the relationships among functional health literacy, medication-taking self-efficacy, and HIV medication adherence in persons living with HIV.

H3.1: Functional health literacy has a direct positive effect on medication-taking self-efficacy.

H3.2: Functional health literacy has an indirect, positive mediating effect on HIV medication adherence, through medication-taking self-efficacy.

4. Investigate the inter-relationships among health literacy and selected factors related to adherence within the constructs of Bandura's Social Cognitive Theory: a) individual factors (functional health literacy, medication taking self-efficacy,

functional health status, depressive symptoms, and perceived burden of illness); b) environmental factors (social support, HIV-related stigma, and relationship with health care provider); and c) the health behavior (HIV medication adherence).

1.4 DEFINITION OF TERMS

1.4.1 Functional Health Literacy

Researchers in health literacy have proposed several definitions of health literacy; all describe the concept as a constellation of skills that together constitute the ability to function in the health-care environment (Berkman et al., 2004). This study used the definition of the Healthy People 2010 Objectives, which defines health literacy as the "degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (U.S. Department of Health and Human Services, 2000, Ch. 11, p. 20). Functional health literacy was assessed using the Short Test for Functional Health Literacy (S-TOFHLA) (Baker, Williams, Parker, Gazmararian, & Nurss, 1999). The terms "health literacy" and "functional health literacy" are used interchangeably in the published literature. For the purposes of this report, the two terms are used and refer to the same thing.

1.4.2 Socio-demographic Variables

Socio-demographic data included age, gender, race, educational background, marital status, employment, income, and current alcohol/drug use. This information was collected using the Center for Research in Chronic Disorders (CRCD) Socio-demographic Questionnaire and Medical Record Review (completed by self-report and medical record review, respectively).

1.4.3 HIV Disease History

HIV Disease history included CD4 count, viral load (dichotomized to detectable/undetectable), and number of prescribed HIV medications. This information was collected using the Health Survey Questionnaire and Medical Record Review. Self-report measurement has been shown to be a valid and reliable measure for CD4 count and for viral load when it is dichotomized between detectable and undetectable (Kalichman, Rompa, & Cage, 2000).

1.4.4 Medication Adherence

Adherence is broadly defined as the degree to which one follows or conforms to the prescribed therapeutic regimen (Sackett & Haynes, 1979; Wright, 2000). In this study, adherence was the health behavior of interest and was limited to medication therapy, as successful medication taking behaviors have a significant impact on long-term prognosis, extending life expectancy, reducing opportunistic infections, and increasing quality of life for those living with

HIV/AIDS. Adherence was assessed using electronic event monitoring (EEM), augmented by paper diary self-report.

1.4.5 Medication Taking Self-Efficacy

Theorist Albert Bandura defines self-efficacy as individuals' belief in their own capacity to organize and execute an action required to produce specific results. Self-efficacy influences human functioning through the choices people make, effort expenditure, persistence, thought patterns, and emotional reactions (Bandura, 1997). In this study, self-efficacy was conceptualized as medication taking self-efficacy beliefs, or one's belief in his/her ability to plan and execute successful medication taking. Self-efficacy was measured using the Self-Efficacy Beliefs and Outcomes Expectancies subscales of the Erlen HIV Self-Efficacy Scale for Medication Study (Erlen, Cha, & Sereika, 2003).

1.4.6 Individual Factors

Individual factors included functional health literacy (described above), medication-taking self-efficacy (described above), functional health status, depressive symptoms, and perceived burden of illness.

Functional Health Status. Functional status, defined by the National Quality Measures Clearinghouse as "a measure of an individual's ability to perform normal activities of life," was once studied as a predictor of morbidity and mortality (Outcomes section, para 3). Recently it has received more attention as a critical component of quality of life. Declines in functional status can affect various areas, including physical mobility, role functioning, activities of daily

living (ADL) and independent activities of daily living (IADL). Functional health status was measured using the Physical Health Summary Score (PHS) of the Medical Outcomes Study HIV Health Survey (Revicki, Sorensen, & Wu, 1998), a health status measure that has been used extensively in HIV/AIDS.

Depressive Symptoms. Depression is most significantly characterized by "persistent and impairing changes on mood that represent a significant change from baseline" (Fishman & Treisman, 1997, para. 4). Clinical findings include: sadness, anxiety, irritability, apathy, sleep disturbances, anhedonia, low energy, decreased appetite, decreased interest in sex, worthlessness, and thoughts of death or suicide (Bangsberg, 2004, Fishman and Treisman, 1997). Depressive symptoms are the manifestations of depression, and are usually regarded on a continuum of severity, such as mild, moderate, or severe. Depressive symptoms was measured using the Beck Depression Inventory-II (BDI-II) (Beck, Steer, & Brown, 1996).

Perceived Burden of Illness. The treatment of HIV includes a complex and demanding treatment regimen. Perceived burden of illness assessed the participant's perceptions about the burden of the illness on their life, specifically as it related to complexity of their regimen and the severity of side effects they experience. This variable was measured using two visual analog scales developed for the parent study. The first scale asked the subject to rate the complexity of their medication regimen, on a scale ranging from 0 (not complex) to 100 (very complex). The second scale asked participants to rate the impact of side effects on daily life from 0 (no effect) to 100 (greatly effects).

1.4.7 Environmental Factors

Environmental factors included social support, HIV-related stigma, and relationship with healthcare provider.

Social Support. Social support refers to the network of people and resources available to an individual. Specifically, social support refers to the system of family, friends, neighbors, and community members that are available to provide psychological, physical, and financial help (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). Social support was measured using the composite score of the Interpersonal Support Evaluation List (ISEL) (Cohen, Mermelstein, Kamarck, & Hoberman, 1985).

HIV-Related Stigma. The concept of stigma as it relates to social identity was first introduced by Erving Goffman (1963). In his highly influential book, *Stigma: Notes on the Management of a Spoiled Identity*, Goffman (1963) defined stigma as "an attribute that is deeply discrediting" (Goffman, 1963, p. 3). Stigma was measured using the HIV-related Stigma Scale**,** which uses four sub-scales to assess the perception by persons that they (or others with HIV) are being viewed as different by society because they possess traits viewed negatively (Berger, Ferrans, & Lashley, 2001).

Relationship with Healthcare Provider. Relationship with the healthcare provider is the patient's perception of the quality of their relationship with their healthcare provider. This variable was assessed using a one-item questionnaire that asks participants to rate their relationship with their healthcare provider on a scale from 1 (very poor) to 10 (excellent).

2.0 LITERATURE REVIEW

This chapter presents a model of health behavior that seeks to explain, among other things, the mechanism by which pertinent individual factors such as health literacy and self-efficacy (among others) may affect medication adherence in the person living with HIV/AIDS. The review of literature provides a comprehensive definition of health literacy and critical analysis of the recent literature examining the relationship between health literacy and health outcomes. This chapter includes a review of the most recent national survey on health literacy in the United States and provides an overview of the current HIV/AIDS epidemic in America including a description of the populations currently disproportionately affected by HIV/AIDS. Additionally, the review provides evidentiary support for the investigation of the proposed relationships between health literacy and self-efficacy, specifically as they relate to medication taking, and health literacy and medication adherence in this population. Finally, this chapter provides support for exploring the relationships among functional health literacy, medication-taking self-efficacy, medication adherence, and other pertinent individual (depression and perceived burden of illness) and environmental (social support, HIV-related stigma, and relationship with health care provider) factors identified in the literature.

2.1 THEORETICAL FRAMEWORK

Health behavior, and specifically the ways by which health behavior can be modified or changed, has become an increasingly important issue. Over the last 50 years, the major health concerns in the country have become those that can be influenced by changes in lifestyle. Health behavior theories provide a way to target interventions meant to alter behavior or establish health habits. To date, no published literature has presented health literacy conceptualized within an established theory. Such a framework would be valuable in designing interventions, to improve health literacy or use health literacy as a means for changing other health behavior.

Schillinger and Davis (2006) proposed a model for improving chronic disease care based on health literacy that attempts to explain the relationship between health literacy and health outcomes. However, this model is predominantly focused at the systems level, and therefore, is difficult to apply to the individual. The framework postulates that enhanced patient-provider communication, expanded home-based monitoring (e.g. good self-management practices) and improved community factors (access to health care, public health messages) can improve health outcomes if health literacy barriers in each area can be overcome. The authors provided numerous ways to enhance the three domains, but the model does not address the way in which health literacy acts as a barrier. For example, is poor heath literacy a direct barrier to good health outcomes, or does a low health-literacy level decrease the individual's self-efficacy, which then results in poorer health outcomes?

There are several existing theories related to health behavior that apply to the individual that potentially could be used to explain and guide interventions related to health literacy and medication adherence in the HIV population. Two possible models, Social Cognitive Theory (SCT) and the Information, Motivations and Behavior Skills (IMB) Model, are presented to

demonstrate how it may be possible to investigate health literacy within a theoretical framework at the individual level. These two theories were chosen for comparison because they represent two different ways to approach the application and use of theoretical frameworks. One--SCT--is specifically an educational theory. The other--the IMB model--is a more pragmatic, direct-to-practice approach for changing health behaviors. Because the concept of "health literacy" is quite new, there are no existing models that describe health literacy's causal relationship to health behaviors. Additionally, the concept is not an existing part of either of the models presented.

Social Cognitive Theory, refined in 1977 by Albert Bandura to include self-efficacy, attempts to explain how people behave, and posits that behavior is influenced by the environment, individual factors, and aspects of the behavior itself. These three factors are constantly influencing each other. The theory holds that learning occurs through modeling, problem solving, and reinforcements, and attempts to explain this education process through a number of "constructs." Environment refers to the social (family members, friends, co-workers) and physical environment. Self-efficacy is the belief in one's ability to successfully change one's behavior. Outcome expectations are the benefits the individual can expect to receive in response-changing behavior. Reciprocal determinism describes the dynamic relationship between the individual, the behavior, and the environment (Bandura, 1986, 2001).

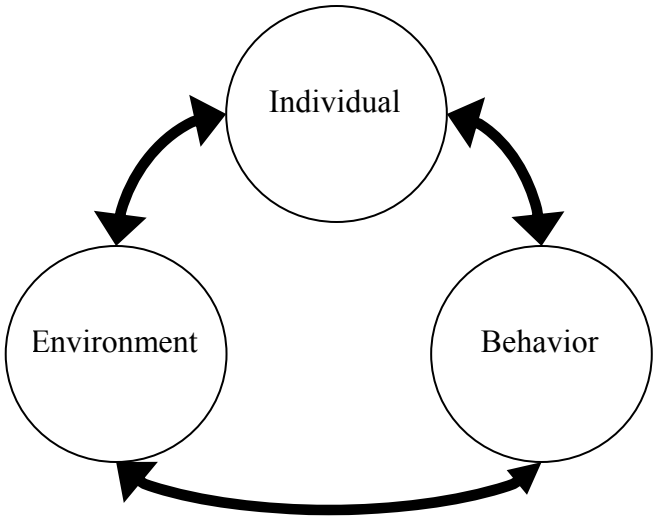

Figure 1: Bandura's Social Cognitive Theory

SCT is widely used in descriptive, correlational, and intervention studies and has empirical support in a wide variety of populations. Recent studies that used SCT to explain variances in behaviors or to guide the design of interventions that are also related to adherence and/or HIV have examined the relationship between various motivational interventions and adherence to an exercise program (Annessi & Otto, 2004; Hallam & Petosa, 2004), predictors of physical activity adherence (Netz & Raviv, 2004; Petosa, Suminski, & Hortz, 2003), interventions to improve HIV medication adherence (Fourney & Williams, 2003; Smith, Rublein, Marcus, Brock, & Chesney, 2003), and HIV prevention programs (Kalichman, 2005).

In contrast, the IMB model (W. A. Fisher, Fisher, & Harman, 2003), a conceptualization of health behavior, is an approach to understanding and promoting health-related behaviors and predictors. This model posits that, armed with the appropriate information, motivation, and behavior skills, an individual can achieve certain desired health outcomes. (W. A. Fisher, Fisher, & Harman, 2003). The IMB model's assumptions (not including health literacy) have empirical

support and have been tested in HIV-prevention studies in a variety of populations including homosexual men, heterosexual university males and females (J. D. Fisher, Fisher, Misovich, Kimble, & Malloy, 1996; Jaworski & Carey, 2001; Singh, 2003), low-income African American women (Carey et al., 1997), indigenous people of the Amazon basin (Linn et al., 2001), and truck drivers from the Indian subcontinent (Bryan, Fisher, & Benziger, 2001).

For this dissertation, the chosen model had to meet several conditions. The model had to accommodate a reciprocal relationship between the main variables, as each may have an affect on the other. The IMB model provides more specificity about the directional relationships between key constructs, which limits its usefulness (W. A. Fisher, Fisher, & Harman, 2003). In contrast, SCT has as one of its defining characteristics the reciprocity between the key variables. Also, due to the significant amount of research showing a strong relationship between adherence and self-efficacy, the model had to have a clear and direct link between these two variables. Both of these models posit a direct link (the IMB through "behavior skills", which has traditionally been operationalized to mean self-efficacy). However, the more complex SCT posits a number of feedback loops and significant inter-relationships between the environment, the individual, and the behavior in question. SCT allows for a more comprehensive view of the individual's perceptions about his or her own abilities to be successful. Specifically, self-efficacy's central position in Bandura's model demonstrates the critical role, now well-supported in the literature, that self-efficacy has in health behavior. This direct relationship creates important opportunities for interventions designed to increase self-efficacy and medication adherence. The IMB model includes self-efficacy as a potential variable, but the concept is embedded in behavior skills, which also include other variables that influence likelihood or intention to act, as opposed to the direct relationship between self-efficacy and health behavior described in Bandura's model.

As this review demonstrates in subsequent sections, there is limited literature available to explain the mechanism by which health literacy is related to health outcomes, although there is a clearly established relationship between them. Therefore, an appropriate theory had to allow for a deeper understanding and investigation into possible explanatory hypotheses. The IMB model may be too parsimonious to account for the potential relationships between variables, which could lead to a less sophisticated understanding of the connection between health literacy and medication adherence.

In summary, SCT is a complex approach to explaining health behaviors that examines the inter-relationships among the environment, the individual, and the behavior in question. Highly supported with empirical research, SCT became an appropriate and applicable theory for this line of inquiry. The IMB model was a less appropriate fit primarily because it may be difficult to isolate the role of health literacy and separate it from the other constructs in the model. Although there may be a relationship between health literacy and the constructs of IMB model, the SCT provides a stronger causal pathway congruent with the relationships in question for this study; ultimately, this was the driving force behind the selection of an appropriate model.

This study, guided by the tenets of SCT, examined the relationships between two individual factors (health literacy and self-efficacy) and the health behavior (HIV medication adherence) in an attempt to identify potential points for interventions designed to promote adherence. Secondarily, the study examined the inter-relationships between five individual factors (functional health literacy, medication taking self-efficacy, functional health status, depression, and perceived burden of illness), three environmental factors (social support, HIV-related stigma, and relationship with health care provider), and the health behavior (medication adherence). This secondary examination was undertaken to identify potential relationships that

may identify predictors or outcomes of low health literacy and generate hypotheses for further testing. Although the study did not directly test SCT as a model, it did incorporate the constructs of the theory, as well as the relationships among these constructs, into this research. Specifically, the theory provided much of the rationale for the specific aims. The purpose of the dissertation was to generate hypotheses for future testing of a model, and ultimately interventions for changing health behaviors related to the self-management of HIV.

The following description provides a general overview of how the tenets of SCT informed the research questions and provided the basis for the line of inquiry. The primary aim of the study was to describe health literacy in the HIV/AIDS population, and then to examine the relationships between health literacy and 1) socio-demographic variables, 2) HIV-health status variables, 3) self-efficacy, and 4) adherence to medication. When applied to Bandura's model, these variables are the foundation for work examining several of the relationships between selected individual characteristics and the health behavior (Figure 2). Although these relationships exist within Bandura's triadic reciprocal model, it is both possible and responsible to examine just a segment of the theory to gain an understanding of the interactions of the variables. According to Bandura (1986), these factors "do not operate simultaneously as a holistic entity;" and "it is the various subsystems and interrelations, rather than the entity, that are analyzed" (p. 25). The value of this study, using Bandura's rationale, was "clarifying how the various subsystems function interactively advances understanding of how the superordinate system operates" (p. 25).

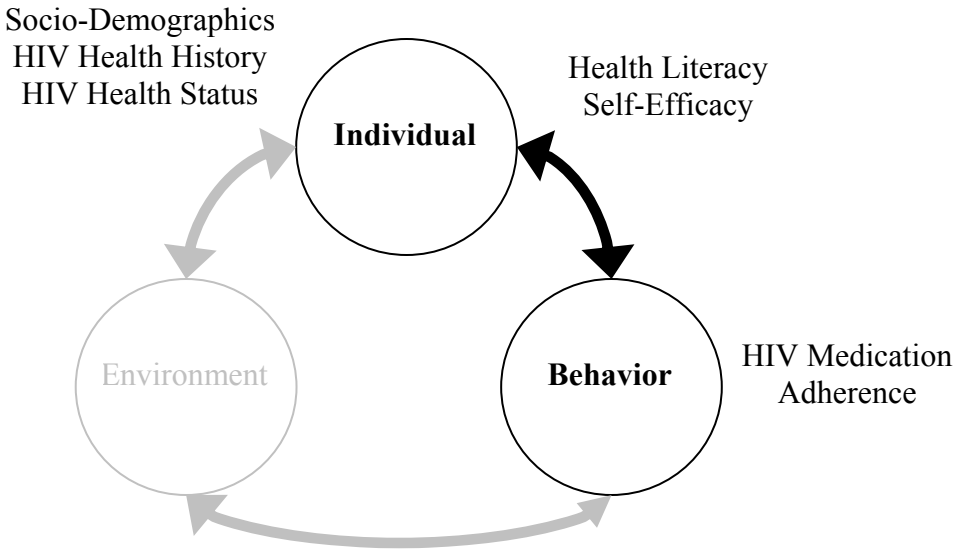

Figure 2: SCT and Primary Aims

The secondary aims allowed for an exploratory investigation of the model on a broader level, using selected variables shown in previous research to have a significant relationship with one or more of the primary variables (health literacy, self-efficacy, and medication adherence). This model included variables from the individual and the environment, as well as the identified health behavior (Figure 3). The goal was to explore interrelationships within the subsystems in order to gain insight into the model as a whole.

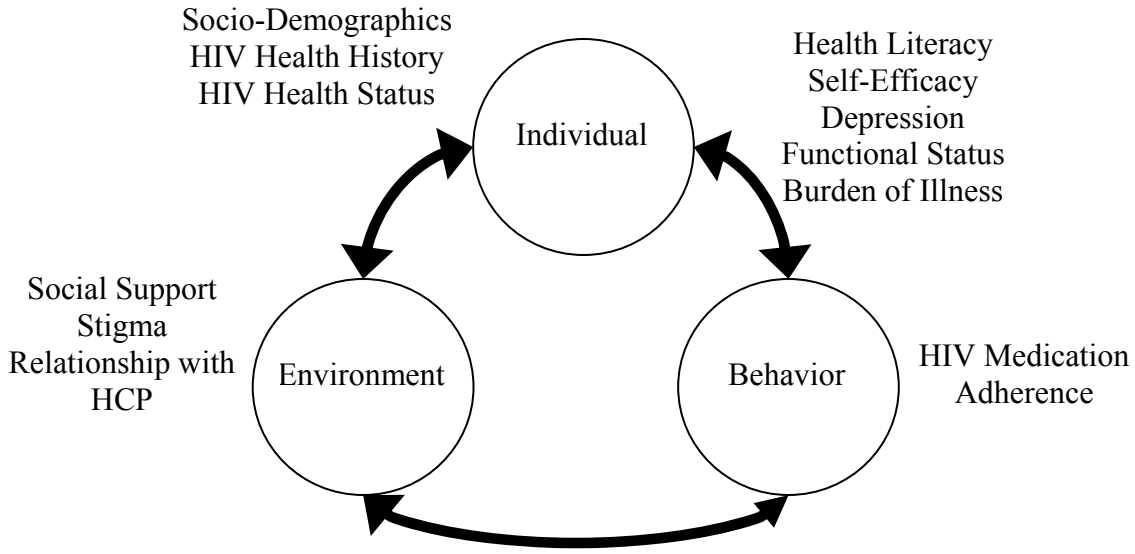

Figure 3: SCT with Selected Variables

2.2 HEALTH LITERACY

Health literacy is a relatively new concept that is often used to describe how various personal factors can be aggregated to conceptualize how well an individual is able to access and navigate the health care system and manage health-related issues. Researchers have not yet reached consensus on a definition of health literacy, but several important stakeholders have put forth their interpretations. The World Health Organization (1998) has defined health literacy as the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand, and use information in ways which promote and manage good health. The Healthy People 2010 Objectives have defined health literacy as the "degree to which individuals have the capacity to obtain, process, and understand basic health information and services

needed to make appropriate health decisions" (U.S. Department of Health and Human Services, 2000, Ch. 11, p. 20). Increased attention to health literacy has lead to a broadening of the definition by some to include self-efficacy, disease process, and motivation for political action regarding health issues (Nutbeam, 2000). However, the existing assessment tools do not capture these data, and while the concepts are clearly related to health literacy, they may be more appropriately investigated as potentially moderating or mediating variables affecting health literacy.

Although the specific term "health literacy" is a recent addition to the health care lexicon, issues related to patient-provider communication and health education are not new. It is important to recognize that health literacy is a measurable concept that indicates how well individuals are able to be successful in health care situations: for instance, how well they read prescription bottles, navigate health care benefits and bureaucracy, and apply abstract health-education guidelines in their day-to-day lives. According to Ratzan (2001), the term "health literacy" was first used in a 1974 article by Simonds on social policy and education. Simonds explicated the importance of including age-appropriate health education in the general education curriculum. After remaining obscure for nearly 20 years, health literacy began to gain national prominence in 1992 as a product of the 1992 National Assessment of Adult Literacy (NAAL), the first rigorous test of literacy in the United States. The survey tested "functional literacy," or the literacy skills most commonly used in everyday activities. Results indicated that over 90 million adults lacked the basic functional literacy skills required in everyday life, and that literacy level was not always associated with educational level (R. M. Parker, Ratzan, & Lurie, 2003). The NAAL report underscored the importance of functional health literacy to the health

and well-being of the population. Results of the most recent 2006 NAAL survey are provided later in this review.

Despite the different definitions of health literacy, there are some components that are shared across definitions. In reality, all individuals have some degree of "health literacy," however low that level may be. The critical attributes of health literacy can be derived from examining the definitions of the concept and discerning the defining characteristics. The individual with an ideal health literacy level must be able to demonstrate the ability to:

1. access and utilize the health care system, including understanding benefits, being able to clearly communicate with providers and other professionals, filling out forms, providing an accurate medical history;
2. navigate the health care system, including understanding how the health care system works and the individual's rights and responsibilities; and
3. perform activities associated with maintaining and improving health, preventing disease, and engaging in self-care, especially applying abstract concepts, recommendations and guidelines to actual health-related activities (Nutbeam, 2000; R. Parker & Gazmararian, 2003; U.S. Department of Health and Human Services, 2000).

Health literacy is a dynamic and potentially modifiable descriptor encompassing a complementary set of skills and abilities related to an individual's functional abilities in the healthcare environment. The health literacy level of an individual indicates how that individual 1) accesses and navigates the health care system and 2) gains access to, understands, and uses information in ways which promote and manage good health. Health literacy is regarded as both a characteristic of the individual—which means care must be provided in a manner that meets

the specific health literacy needs of that individual—and as a potential health outcome that can, theoretically, be altered through intervention.

The most suitable approach for intervention remains unclear. The authors of the Healthy People 2010 objectives (2000) stated that although long-term educational programming may be best suited to raise literacy levels in the general population, the burden for change in health literacy, at least in the short term, lies with healthcare providers, public health professionals, and healthcare systems. As with other issues of health disparities and service delivery, health literacy is an ethical issue for nurses (Erlen, 2004). A "blame the patient" philosophy that regards health literacy as the patient's problem to fix is incongruous with the way nursing approaches service delivery. Patient education is a cornerstone to nursing practice. Thus, it is critical that nurses be fully able to provide teaching to their patients in an effective way; from a patient-centered perspective, this teaching involves interventions tailored to fit the health literacy demands of the patient (American Nurses Association, 2002). To that end, health literacy must be approached in two ways: 1) to meet the overall goal of increasing health literacy, and 2) to provide needed immediate health information in a way appropriate for people at all levels.

2.2.1 Health Literacy versus Literacy

Literacy is broadly defined as the ability to read, write and comprehend (U.S. Department of Health and Human Services, 2000). Literacy is often mentioned in conjunction—and sometimes interchangeably—with health literacy; this relationship is complicated further by the fact that literacy is probably an antecedent to a "high" health literacy level. The word literacy is also often used to convey a level of knowledge about a particular topic or field, such as "computer literacy," or the more recently coined "information literacy." The two terms, literacy

and health literacy, are different in that one is a more general statement about an individual's abilities, while the other is a content- and knowledge- specific term, used to describe similar abilities related to health and health care.

For further clarification, and to illustrate how health literacy differs from reading literacy or traditional patient health education, health literacy can be classified as three key types of health information and services (see Table 1). Researchers can use these classifications to guide research in health literacy and to identify issues or problems within populations for targeted intervention.

Table 1: Health Literacy Classifications and Definitions

Type	Definition	Examples
Clinical	Activities associated with the interactions between healthcare provider and patient, diagnosis and treatment of illness, and medication.	Filling out medical forms; Understanding dosing instructions on medications; Providing accurate verbal or written medical history.
Preventive	Activities associated with maintaining and improving health, preventing disease, and engaging in self-care.	Follow guidelines for preventive health services; Changing lifestyle habits to prevent disease.
Navigational	Activities associated with understanding how the healthcare system works and individual rights and responsibilities.	Understanding covered and non-covered benefits; Determining eligibility for public assistance programs.

Note. Adapted from U.S. Department of Health and Human Services. *Healthy People 2010*. 2nd ed. With Understanding and Improving Health and Objectives for Improving Health. 2 vols. Washington, DC: U.S. Government Printing Office, November 2000.

2.2.2 NAAL Report on Health Literacy

In September, 2006 the U.S. Department of Education released the report *The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy* (NAAL). The report provided the results of the items designed specifically to measure health literacy in adults. The assessment included tasks adults were likely to encounter in their daily lives. The report used definitions of health literacy provided by the Institute of Medicine and Healthy People 2010 (Kutner, Greenberg, Jin, & Paulsen, 2006).

The NAAL report (2006) is divided into three scales: prose, document, or quantitative. Prose literacy involves the skills to search, comprehend and use information from continuous texts, such as brochures and instructional materials. Document literacy refers to the knowledge and skills required to search, comprehend, and use information from non-continuous texts such as job applications and drug labels. Quantitative literacy refers to the knowledge and skills required to identify and perform computations such as balancing a checkbook or determining percentages. These same scales were used in the health literacy components but were distinguished by their content related to health.

Three domains of health—clinical, prevention, and navigation of the health system—were described in the assessment. The materials selected were expressly chosen to reflect real-world health-related information. The clinical domain included activities associated with the provider/patient interaction, treatment of illness, and medication tasks such as filling out the

patient information form, understanding dosing instructions for medications, and following recommendations regarding the diagnostic test. The prevention domain encompassed activities associated with maintaining and improving health such as following guidelines for age-appropriate preventive care, recognizing signs and symptoms of health problems, and understanding how certain behaviors may decrease risk for developing serious illness. The final domain, navigation of the healthcare system, involved those activities related to understanding the healthcare system. These activities include tasks such as understanding what a health insurance plan will and will not pay for, providing informed consent, and determining eligibility for assistance programs. The health system navigation assessment, although thorough with regard to print literacy, did not assess ability to obtain information from non print sources. This means that certain components of health literacy, as defined by the report's authors, were not assessed (Kutner, Greenberg, Jin, & Paulsen, 2006).

According to the NAAL report, the majority of adults (53 percent) had intermediate health literacy. Twelve percent of adults had proficient health literacy, 22% had basic health literacy, and the final 14% were assessed at below basic health literacy. The findings translate to approximately 1 in 7 adults being unable to understand the most basic health information, while only 1 in 8 adults are able to understand these same materials at a proficient level. The assessment was scored in a range from 0-500, with 500 being a perfect score. In terms of health literacy tasks, the proficient individual (score 310-500) would be able to use abstract inference and compare multiple documents, such as evaluating legal documents to determine which was appropriate in a health care situation. In contrast, the individual scoring below the basic health literacy level (0-184) would not be able to read a clearly written brochure, and then, based on that information, give two reasons why a person with no symptoms of a specific disease should

be tested for the disease. To achieve a score of approximately 100 on the assessment, one must be able to circle the date of a medical appointment on a hospital appointment slip. Finally, to score in the intermediate range (226-309), one must identify three substances that may interact with an over-the-counter drug, using information provided on the drug label. At least 36% of the adult population in the United States falls below the intermediate level of health literacy (Kutner, Greenberg, Jin, & Paulsen, 2006).

The NAAL report examined health literacy levels across selected demographic variables. Results indicated that women had a slightly higher average health literacy than men (below basic health literacy of 12% versus 16%, respectively). Black, Hispanic, American Indian/Alaska native, and multiracial adults had lower average health literacy than white and Asian/Pacific Islander adults. Age also appeared to be related to health literacy. Adults over the age of 65 years had lower average health literacy than adults younger than 65 years. Additionally, adults living below the poverty level had lower average health literacy than adults living above the poverty level (Kutner, Greenberg, Jin, & Paulsen, 2006).

Tables 2-4 provide selected results from the 2006 NAAL report. The assessment was scored as follows: Proficient 310-500; Intermediate 226-309; Basic 185-225; Below Basic 0-184.

Table 2: Health Literacy Scores by Level

	Adults (≥18 years)	**Males**	**Females**	**Adults over 65 years**
Below Basic	14%	16%	12%	29%
Basic	22%	22%	21%	30%
Intermediate	53%	51%	55%	38%
Proficient	12%	11%	12%	3%
Mean Score	*not available*	242	248	214

Note. Adapted from Kutner, M., Greenberg, E., Jin, Y., and Paulsen, C. (2006). *The Health Literacy of America's Adults: From the 2003 National Assessment of Adult Literacy (NCES 2006-483)*. Washington, DC: National Center for Education Statistics. Totals may not equal 100% due to rounding.

Table 3: Health Literacy Level and Mean by Race

	African American	**Caucasian**	**Hispanic**	**Asian/ Pacific Islander**	**American Indian/ Alaskan Native**	**Multi-racial**
Below Basic	24%	9%	41%	13%	25%	9%
Basic	34%	19%	25%	18%	23%	28%
Intermediate	41%	58%	31%	52%	45%	59%
Proficient	2%	14%	4%	18%	7%	3%
Mean Score	216	256	197	255	227	238

Note. Adapted from Kutner, M., Greenberg, E., Jin, Y., and Paulsen, C. (2006). *The Health Literacy of America's Adults: From the 2003 National Assessment of Adult Literacy (NCES 2006-483)*. Washington, DC: National Center for Education Statistics. Totals may not equal 100% due to rounding.

Table 4: Health Literacy Level and Mean by Educational Level

	Less than High School	HS Graduate	Some College	Bachelor's Degree	Graduate Studies/Degree
Below Basic	49%	15%	5%	3%	3%
Basic	27%	29%	20%	10%	8%
Intermediate	23%	53%	67%	60%	57%
Proficient	1%	4%	8%	27%	33%
Mean Score	184	232	253	280	287

Note. Adapted from Kutner, M., Greenberg, E., Jin, Y., and Paulsen, C. (2006). *The Health Literacy of America's Adults: From the 2003 National Assessment of Adult Literacy (NCES 2006-483)*. Washington, DC: National Center for Education Statistics. Totals may not equal 100% due to rounding.

2.2.3 Assessing Functional Health Literacy

Assessing functional health literacy is complicated and controversial. Tools used in research include the Rapid Evaluation of Adult Literacy in Medicine (REALM), the Wide Range Achievement Test (WRAT), and the Test of Functional Health Literacy (TOFHLA). The REALM requires the participant be given a series of medical terms and asked to pronounce each one. Reading level is ascertained with a total score based on the number of words correctly pronounced (Kellerman & Weiss, 1999). The WRAT is an overall reading and comprehension test occasionally used in health care and other settings (Fetter, 1999). Although both of these

tests attempt to approximate reading level, neither captures the functional aspect of health literacy.

Recent research on functional health literacy frequently uses the TOFHLA (Baker, Williams, Parker, Gazmararian, & Nurss, 1999). The TOFHLA uses materials a patient may encounter in the healthcare setting. The test is in two parts: 1) a 36-item test using a modified Cloze procedure (every fifth to seventh word is omitted and four choices are offered) on health-related documents (e.g. hospital instructions, Medicare enrollment forms; and dietary guidelines), and 2) a 4-item test using hospital forms and prescription bottles. Scores on the TOFHLA are classified into adequate, marginal, and inadequate levels (R. M. Parker, Baker, Williams, & Nurss, 1995). The TOFHLA is the only functional health literacy instrument that includes materials encountered in the health care context. Additionally, the TOFHLA assesses comprehension, and measures the ability to read and understand both narrative information and items involving numbers.

Even though the TOFHLA is more comprehensive than the REALM and WRAT, it is not feasible for use in clinical settings because it takes an average of 12-20 minutes to complete. In response to this issue of time, researchers devised the Short Test of Functional Health Literacy in America (S-TOFHLA). With the new tool, maximum administration time is reduced from 22 minutes to 12 minutes. (Baker, Williams, Parker, Gazmararian, & Nurss, 1999).

Differences between the REALM and the S-TOFHLA were highlighted when the two were compared by the researchers. The REALM at times both underestimated and overestimated participants' literacy skills when compared to the S-TOFHLA. For example, some participants are able to correctly pronounce words, but have difficulty when assessed for comprehension using the TOFHLA. Overall, the correlation between the REALM and the S-TOFHLA is

moderately high (.80), which is only slightly lower than the correlation between the REALM and the longer TOFHLA (.84). However, the correlation between the numeracy items and the REALM is significantly lower (.61), further supporting the claim that the TOFHLA and S-TOFHLA perform an assessment that is substantively different from the REALM (Baker, Williams, Parker, Gazmararian, & Nurss, 1999).

Despite the advances in tools developed to measure functional health literacy, researchers agree that more comprehensive tests are needed to investigate the concept fully (Baker, 2006). The TOFHLA and S-TOFHLA allow for assessment of functional activities, but not the more abstract activities related to verbal communication and critical thinking. Although the existing research does not state or reflect this, one could argue that a true measure of functional health literacy also needs to include some clinical outcomes (e.g. body weight, cholesterol level, smoking cessation), as the individual who is truly able to apply abstract concepts or guidelines of health-promoting behavior needs to be able to demonstrate results through the clinical outcome measurements.

2.3 FUNCTIONAL HEALTH LITERACY AND OUTCOMES

There is considerable research examining the relationship between functional health literacy and health outcomes. The findings are contradictory, alluding to the complex and not-yet-understood relationship between functional health literacy and health outcomes. Examples of some of the health behaviors and outcomes associated with functional health literacy in the published literature are listed in Table 5, along with the sample size and the instrument used to

assess functional health literacy. Two of the larger studies, and their conflicting results, are highlighted in the subsequent narrative.

Table 5: Lower Functional Health Literacy and Outcomes

Author	Outcome	Sample Size	Tool
(Baker, Parker, Williams, Clark, & Nurss, 1997)	Hospitalization in the previous year and self-reported poor health	2650	TOFHLA
(Sharp, Zurawski, Roland, O'Toole, & Hines, 2002)	Increased levels of distress among women at high risk for developing cervical cancer	130	REALM
(Lindau et al., 2002)	Decreased knowledge related to cervical cancer screening	529	REALM
(S. P. Kim et al., 2001)	Prostate cancer knowledge	30	REALM
(J. D. Fortenberry et al., 2001)	Decreased probability of having a gonorrhea test in the past year	809	REALM
(Kaufman, Skipper, Small, Terry, & McGrew, 2001)	Lower incidence of exclusive breast-feeding during the first 2 months	61	REALM
(J. Gazmararian, Williams, Peel, & Baker, 2003a)	Decreased knowledge about own chronic disease (asthma, diabetes, congestive heart failure, or hypertension)	653	S-TOFHLA

Author	Outcome	Sample Size	Tool
(Hicks, Barragan, Franco-Paredes, Williams, & del Rio, 2006)	Decreased HIV knowledge	372	REALM
(Baker et al., 2004)	Increased rates of emergency department use	3260	S-TOFHLA
(J. A. Gazmararian, Parker, & Baker, 1999)	Increased likelihood to want to know more about birth control methods and to have incorrect knowledge about when they were most likely to get pregnant	406	S-TOFHLA
(Chew, Bradley, Flum, Cornia, & Koepsell, 2004)	Lower adherence to preoperative medication instructions	332	TOFHLA
(Endres, Sharp, Haney, & Dooley, 2004)	Increased likelihood to have an unplanned pregnancy and decreased likelihood to have either discussed pregnancy ahead of time with an endocrinologist or obstetrician or taken folic acid	74	TOFHLA

Author	Outcome	Sample Size	Tool
(Fang, Machtinger, Wang, & Schillinger, 2006)	In patient's taking warfafin, incorrect answers to questions on warfarin's mechanism, side-effects, medication interactions, and frequency of monitoring	179	S-TOFHLA
(Mancuso & Rincon, 2006)	In asthma patients, worse quality of life, worse physical function, and more emergency department utilization for asthma over 2 years	175	TOFHLA

Scott, Gazmararian, Williams and Baker (2002) examined functional health literacy and health outcomes in a sample of 2,722 Medicare-managed care enrollees (aged 65-79 yrs). Individuals with inadequate functional health literacy reported a greater lack of preventive services, including never having an influenza vaccination (29% versus 19%); never having a pneumococcal vaccination (65% vs. 54%); no mammogram in the last 2 yrs (24% vs. 17%); never having a Papanicolaou smear (10% vs. 5%). Even after adjusting for demographics, years of school completed, income, number of physician visits, and health status, there were still significant differences between those with adequate and those with inadequate functional health literacy (Scott, Gazmararian, Williams, & Baker, 2002). This study is especially significant because the findings, after controlling for other confounding variables, seem to lend credence to the proposition that functional health literacy alone may have an impact on health outcomes. In a

separate, kin study (same Medicare-managed care sample as above) researchers found that Mini-Mental Status Exam (MMSE) scores were linearly related to functional health literacy scores across all levels of literacy and all items on the MMSE. This relationship also held after controlling for chronic conditions and self-reported overall health (Baker, Gazmararian, Sudano et al., 2002). In both studies, functional health literacy was assessed using the more comprehensive S-TOFHLA.

Morris, MacLean and Littenberg (2006) assessed the functional health literacy of over 1000 individuals with Type 2 diabetes and examined several disease management and progression markers, including glycolated hemoglobin, blood pressure, lipid levels, or self-reported diabetes complications. The authors found that people with lower functional health literacy were more likely to report retinopathy, stroke, or coronary artery disease. They were also more likely to take medication for diabetes and hypertension. However, these differences disappeared after controlling for confounders, such as age, race, sex, depression, and length of time diagnosed with diabetes. Limitations of the study relate to the population being studied. The scores on the S-TOFHLA with this population were quite high; the median score across the entire sample was 34 (out of a possible 36). Additionally, the sample was predominately white, relatively well-educated, and included people who demonstrated good glycemic control (a very significant consideration when considering the results related to complications of diabetes) (Morris, MacLean, & Littenberg, 2006). These results are in conflict with a 2003 study (D. Schillinger et al., 2003) of 38 physician participants and 124 patient participants that did find functional health literacy to be associated with good glycemic control. In this study testing an interactive communication intervention, authors found good glycemic control was associated with higher functional health literacy levels (OR, 3.97, $p = .04$).

In the HIV+ population, functional health literacy has been studied in relation to several other disease-related outcomes. Kalichman et al. (2000) found in their study of 228 HIV-positive individuals that those participants with lower functional health literacy were significantly less likely to have an undetectable HIV viral load and somewhat less likely to know their CD4 cell count. In addition to clinical outcomes, this study also demonstrated a link between functional health literacy and understanding about HIV. Lower levels of functional health literacy were related to misperceptions that HIV medications reduce the risk of transmitting HIV and beliefs that anti-HIV treatments means individuals can relax safer-sex practices (Kalichman et al., 2000). Hicks et al. (2006) also found that people with lower functional health literacy, as measured using the REALM, had significantly less knowledge about HIV/AIDS. Clearly, these gaps in knowledge may have a significant impact on transmission of the disease for the individual with limited functional health literacy. In this study, functional health literacy was assessed using the TOFHLA. Although these findings associated the individual's deficient knowledge with functional health literacy (assessed with the more comprehensive measure), they do not provide insight into the mechanism of how the variables are related. Like many of the studies testing links between functional health literacy and health outcomes, this study provides the rationale for continued examination of how the variables are related and how interventions can be designed to improve outcomes.

2.4 TRENDS IN HIV/AIDS IN THE UNITED STATES

The Centers for Disease Control and Prevention (CDC) estimated that at the end of 2003 (the date of the most recent data available) there were between 1,039,000 and 1,185,000 people

living with HIV in the United States (diagnosed and undiagnosed), and approximately 40,000 new people are infected every year. Nearly 530,000 people in the United States have died from AIDS since the beginning of the epidemic (CDC, 2006). The most accurate reporting of HIV/AIDS statistics is compiled based on data collected from the 35 areas (33 states, Guam, and the U.S. Virgin Islands) with integrated HIV and AIDS surveillance since 2000. At the end of 2004, an estimated 462,792 people were living with HIV/AIDS, from name-based confidential data gathered for the 35 areas (48% black, 34% white, 17% Hispanic, and <1% each were American Indian/Alaskan Native and Asian/Pacific Islander) (CDC, 2005). Despite large declines in numbers of AIDS diagnoses in the past 5 years, most AIDS cases still occur in men, especially intravenous drug users (IDUs) and men who have sex with men (CDC, 2006).

Racial disparities, which have existed since the disease was first discovered, have worsened over the last 20 years. In 2004, blacks accounted for approximately 12% of the U.S. population and for 50% of all HIV/AIDS cases diagnosed. African-American women are 13 times more likely to die of HIV/AIDS than their white counterparts (CDC, 2003a). Recent data suggest there may be some change in these statistics: from 2001-2004, the estimated number of HIV/AIDS cases decreased among blacks and Hispanics, but increased for whites, Asians/Pacific Islanders, and American Indians/Alaska Natives. Notably, the estimated numbers of AIDS cases (separate and distinct from total HIV/AIDS cases) increased among all racial groups (CDC, 2005).

Socioeconomic factors are also increasingly significant in relation to the demographics of those affected by HIV. More than 40% of AIDS diagnoses during 1999 were among residents of the poorest counties, although these counties represented only one quarter of the 1998 population. (Karon, Fleming, Steketee, & De Cock, 2001) The changing demographics

associated with HIV/AIDS also include a shift in the educational attainment levels of those infected, and lower educational level has been shown to be associated with higher mortality and poorer health status for people infected with the virus (Lewden et al., 2002; Regidor, De Mateo, Calle, & Dominguez, 2002; Stoskopf, Richter, & Kim, 2001). These disturbing patterns may exacerbate existing health disparities in vulnerable populations.

Of particular relevance to the discussion of functional health literacy are the statistics showing that more people than ever before are living with HIV disease. This has a direct impact on the need for prevention, treatment, and care services for HIV-positive individuals. According to the CDC, in 1998 there were approximately 275,000 people living with AIDS; in 2000, there were approximately 323,000; in 2002, 385,000, and in 2004, that number rose to 415,000 (CDC, 2006). The total number of new cases of HIV/AIDS in the United States decreased slightly from 2001-2004; however, the number of people living with HIV/AIDS increased (CDC, 2005). These prolonged survival rates, attributed almost exclusively to the advent of HAART, require strict adherence to a medication therapy regimen which places clear demands on individuals with low functional health literacy (D. R. Bangsberg et al., 2001; Carrieri et al., 2003; de Olalla et al., 2002).

2.5 SELF-EFFICACY

Self-efficacy, defined as the individuals' belief in his/her own capacity to organize and execute an action required to produce specific results, influences the choices and motivations of individuals (Bandura, 1997). Bandura asserts that self-efficacy is the self-assurance with which individuals approach tasks and behavior; self-efficacy determines whether or not people make

good use of their capabilities and can ultimately be successful. Additionally, self-regulation over one's thought processes, motivation, and emotional states is also influenced by self-efficacy. Self-efficacy, in turn, influences human functioning through the choices people make, effort expenditure, persistence, thought patterns, and emotional reactions (Bandura, 1997). Functional health literacy may play a significant part in individuals' development of self-assurance within the context of health. More specifically, the lived experience of individuals with lower functional health literacy, who are trying to navigate the health care system and manage their health and the health of their family, may have a significant influence on their belief in their own capacities.

2.6 MEDICATION ADHERENCE

2.6.1 Defining Adherence

The term adherence often elicits debate from researchers, clinicians, and ethicists, each of whom have their own preferred term, be it adherence, compliance, concordance, or treatment maintenance. For the purposes of this review, however, the term "adherence" is used with the expressed understanding that this may not be the best or most appropriate term; it is, simply, the term most often used in the literature today. This broad review is also limited to *medication adherence*, as opposed to general *treatment adherence*, which includes additional factors such as appointments and health-promoting behaviors.

2.6.2 Medication Adherence and HIV

Adherence to a complex, dynamic treatment regimen is a significant issue faced by the person living with HIV/AIDS, and is influenced by emotional, cognitive, and behavioral factors (Remien et al., 2003). It can be defined broadly as the degree to which one follows or conforms to the prescribed therapeutic regimen (Sackett & Haynes, 1979; Wright, 2000). For the person with HIV/AIDS, unsuccessful viral suppression, resistance to medication, opportunistic infections, overall poor health, quality of life, and potentially death can result from poor adherence (D. R. Bangsberg et al., 2001; Carballo et al., 2004; Erlen & Mellors, 1999; McNabb, Nicolau, Stoner, & Ross, 2003).

Given the changing demographics and the critical importance of adherence to successful management of HIV/AIDS, findings from studies examining HIV medication adherence and socio-demographic factors are conflicting. Active substance abuse is frequently cited as a factor related to poor adherence (Bouhnik et al., 2002; Sharpe, Lee, Nakashima, Elam-Evans, & Fleming, 2004; Visnegarwala, Graviss, Sajja, Lahart, & White, 2004); other factors such as income, race, and gender have, for the most part, not been shown to be significantly related to HIV medication adherence (Cox, 2002; DiMatteo, 2004; Kleeberger et al., 2001; McGinnis et al., 2003; J. M. Simoni, Frick, Lockhart, & Liebovitz, 2002; Stone et al., 2001). However, race has been shown to be significantly related to morbidity/mortality and initiation of treatment (Crystal, Sambamoorthi, Moynihan, & McSpiritt, 2001; McGinnis et al., 2003).

2.6.3 Assessing Medication Adherence

Like adherence itself, assessing and measuring adherence is a complex issue. Studies have used multiple approaches, including self-report, direct observation, pill counts, pharmacy refills, and electronic monitoring. Each of these methods has its own particular advantages and disadvantages. The two most common methods currently used for measuring adherence to HIV medications are self-report recall and electronic event monitoring.

Three studies comparing self-report and electronic event monitoring, all in HIV-positive populations assessing adherence to antiretroviral medication, have shown that self-report tends to over-estimate adherence by two- to four-fold (Arnsten, Demas, & Farzadegan, 2001; Liu, Golin, & Miller, 2001; Melbourne et al., 1999). Lui, Golin and Miller (2001) also report improvement in predictive ability of electronic monitoring when supplemented with self-report data.

Wagner (2002) examined various predictors of adherence across several methods of measuring adherence. A sample of 180 HIV-positive participants was randomized to one of three methods: electronic event monitoring, patient medication diaries, or three-day recall self-report. The three methods revealed varying levels of adherence; moderate levels for electronic monitoring (80.6%) and high for self-report (93.7%) and diaries (92.7%). The self-report and diary scores were computed using a weighted formula, whereby errors (missed doses, doses outside the interval range, partial doses) were counted and weighed, with missed doses having the greatest weight. The adherence score was one minus the proportion of the sum of errors divided by the total possible number of errors. This number was then multiplied by 100 to achieve a percent. The EEM uses a computer program to compute an adherence score based on the percentage of prescribed doses taken and a therapeutic coverage variable. Results of Wagner's study demonstrated that the EEM provides a wider range of scores associated with

adherence, as well as a greater sensitivity to non-adherence. Diaries and three-day recall, on the other hand, provide more skewed data. This discrepancy resulted in findings that associated adherence—as measured with EEM—with more variables. Although the results did demonstrate fair consistency across assessment methods, EEM was shown to be accurate and specific (Wagner, 2002).

Although all methods of measurement have their unique problems, EEM, currently considered the "gold standard" for indirectly monitoring adherence, is believed to be the most appropriate tool for intervention studies (like the parent study) and offers more information over time than biologic assays (Turner, 2002). EEMs consist of a medication cap containing a micro-electronic circuit that fits on a standard medication bottle and records the time and date each time the cap is opened.

EEM, though, is not infallible. Turner and Hecht (2001) point out that EEM assessment cannot demonstrate definitively that pills were actually taken by the participant, and must function on the assumption that the opening of the bottle represents the patient taking the medication at approximately the same time the bottle is opened. Additionally, participants may refuse to participate in studies using EEM because it may require them to eliminate use of adherence tools such as pillboxes, resulting in a selection bias. Finally, improper use or damage to the devices may limit the usefulness and availability of data (Turner & Hecht, 2001). Despite these limitations, EEM assessment is able to provide valuable insight into the individual's capacity to create and maintain a consistent medication-taking behavior.

The measurement of adherence is a complicated and controversial issue, and may create problems for individuals with lower functional health literacy who are expected to provide information about their adherence levels. In turn, this may have an effect on studies investigating

adherence. In a qualitative study of 25 HIV+ patients (75% with lower functional health literacy as assessed by the REALM), Wolf et al. (2005) examined the relationship of literacy and the participants' responses to HIV medication-adherence questionnaires. The authors' analysis revealed several themes related to format, administration and visual aids. The majority of respondents thought that adherence defined as recall over three days was not accurate. Additionally, most believed they would require one-on-one assistance in order to accurately complete a self-report measure. Finally, the majority of respondents reported increased difficulty with multiple-response items, especially Likert-type scales (Wolf, Bennett, Davis, Marin, & Arnold, 2005). These findings raise significant issues about the validity of self-report as a measure of adherence in people with lower functional health literacy. If additional work in this area, with larger sample sizes and more subjective measurement strategies, finds similar results, there would be significant questions raised about studies that rely on self-report for people with lower functional health literacy.

2.7 DESCRIPTION OF THE MODEL: FUNCTIONAL HEALTH LITERACY, SELF-EFFICACY AND MEDICATION ADHERENCE

2.7.1 Increased Functional Health Literacy Demands for People Living with HIV/AIDS

Researchers currently estimate that 20-25% of people living with HIV/AIDS demonstrate inadequate or marginal functional health literacy, a rate similar to that of the general population

(Kalichman et al., 2000; Kalichman & Rompa, 2000b; Rudd, Kirsch, & Yamamoto, 2004). Prolonged survival rates for people with HIV/AIDS, attributed almost exclusively to the advent of antiretroviral treatment, require strict adherence to medication therapy, placing significant demands on individuals with low functional health literacy.(D. R. Bangsberg et al., 2001; Carrieri et al., 2003; de Olalla et al., 2002) Additionally, this chronic and infectious disease's unique pressures, such as preventing transmission and maintaining healthy behaviors, create a higher demand on self-management ability, and therefore functional health literacy, making persons with HIV/AIDS even more vulnerable and at greater risk for poor health outcomes.

2.7.2 Functional Health Literacy and HIV Medication Adherence

Six published studies (Golin et al., 2002; Graham, Bennett, Holmes, & Gross, 2006; Kalichman, Catz, & Ramachandran, 1999; Kalichman, Ramachandran, & Catz, 1999; Paasche-Orlow et al., 2006; Wolf et al., 2004) have looked directly at the relationship between functional health literacy and medication adherence in people living with HIV. Three of these studies assessed the relationship of functional health literacy to HIV medication adherence and showed that lower functional health literacy is related to poorer adherence. The first of the studies was conducted in a community setting and had 318 participants (Kalichman, Ramachandran, & Catz, 1999). The authors conducted both univariate and multivariate testing and reported that those with lower functional health literacy were nearly four times as likely to be non-adherent (i.e. miss at least one dose in the last two days). The second included 85 African-American men and 53 African-American women; this study also found that those with lower functional health literacy were significantly more likely to be non-adherent (Kalichman, Catz, & Ramachandran, 1999). Both studies used the more comprehensive TOFHLA to measure functional health

literacy. These studies did not measure adherence with electronic event monitoring (EEM) but with two-day recall, which has potential problems with memory and recall bias (Turner, 2002). The third study used the REALM to measure functional health literacy and found that in their sample of 87 people living with HIV, reading grade level was associated with lower adherence. Adherence was measured using a pharmacy refill surrogate marker and the median adherence rate in the study was 95%; 95% was also the cut-off point between higher and lower adherence (Graham, Bennett, Holmes, & Gross, 2006).

Golin et al. (2002), conversely, did not find a significant relationship between functional health literacy and HIV medication adherence in their longitudinal study. The prospective, cohort study had 140 participants, 117 of whom had data used in the analysis. This study used the TOFHLA to assess functional health literacy and electronic monitors to assess adherence over time (up to 48 weeks). However, in the discussion section of the published article, the authors stated that while there was not a significant relationship between functional health literacy and adherence, the functional health literacy assessment "may have been compromised in this evaluation because of a large number of imputed values" (Golin et al., 2002, p.763). The authors do not specify what imputation method was used or why it may be considered compromised. Unfortunately, this makes any generalizability of their findings suspect.

Paasche-Orlow et al. (2006) also found that low functional health literacy was not associated with lower odds of adherence or viral suppression in a population of 235 individuals who were HIV-positive and had a history of alcohol problems. In fact, rather counter-intuitively, the authors reported a non-significant trend that lower functional health literacy might be associated with better adherence and virologic suppression (adjusted OR 1.93, 95% CI 0.86-

4.31). Their study, however, used both the less comprehensive REALM tool to measure functional health literacy and the less reliable 3-day self report of adherence.

Finally, Wolf et al. (2004) found that functional health literacy, as assessed using the REALM, was not associated with medication adherence. This study examined 157 people with HIV in a Southern U.S. clinic. Adherence was assessed using self-report and participants who missed more than one dose in the last week were considered to be non-adherent. This study was limited, much like the others, because it used the less comprehensive REALM and self-report measure for adherence.

In 2007, Wolf and colleagues published a report on a study examining the relationships between functional health literacy, self-efficacy and medication adherence. Their results are presented later, under "Functional Health Literacy and Self-Efficacy."

The role of functional health literacy and its association with HIV is further demonstrated in two additional studies examining knowledge and adherence. Miller et al. (2003) found that poor knowledge of medication regimen, assessed at 8 weeks after medication therapy was started, was associated with both lower adherence during the study period ($p=.05$) and lower functional health literacy ($r=.31$, $p=.005$). This study is highlighted because it used both the more comprehensive S-TOFHLA to measure functional health literacy and electronic event monitoring to assess adherence (Miller, Liu, & Hays, 2003). Weiss et al. (2003) also found HIV-disease knowledge to be related to adherence, measured using self-report. In their study of 997 participants, those individuals who got 0-1 answers correct on the five-item knowledge tool were nearly three times as likely to report missed doses ($OR=2.92$, $p<.05$). Those with 2 or 3 correct responses were nearly twice as likely ($OR=1.72$, $p<.05$), while those who got 4 or 5 answers correct were not more likely to miss doses ($OR=1.00$) (L. Weiss et al., 2003). This study was

limited because adherence was measured using only self-report. The Healthy People 2010 definition of health literacy suggests that higher levels of health literacy require an increased knowledge about disease and disease process. Therefore, the studies by (2000) Miller and colleagues (2003), and Weiss and colleagues (2003) contribute to an increased understanding about the depth and breadth of functional health literacy's influence on health outcomes.

There is also a need to understand how functional health literacy is related to medication adherence within the context of other socio-demographic variables. For example, Osborn et al (2007) found that race moderated the relationship between health literacy and HIV medication adherence. However, this study uses the same sample as work from Wolf and colleagues (2005) discussed previously, and the results need further verification because of the limitations in the original research related to assessing functional health literacy and medication adherence. As pointed out by Osborn, et al (2007), the relationship between functional health literacy and socio-demographic variables, such as race or income, may be an important component in research that seeks to reduce racial disparities in health and health care.

Clearly, there are conflicting findings about the relationship between HIV medication adherence and functional health literacy. These results support further investigation of the issue, especially investigation using more comprehensive health literacy instruments (TOFHLA and S-TOFHLA) and the "gold standard" for adherence measures, electronic event monitoring. There is a need to have adequate sample sizes and more comprehensive data that truly reflect the constructs being measured.

2.7.3 Functional Health Literacy and Self-Efficacy

There was one published study examining the relationship between functional health literacy and self-efficacy in a population of people living with HIV identified in a literature search of Ovid Medline from 1966, CINAHL from 1992, Pysch-Info from 1967, and the Cochrane Database of Systematic Reviews through May, 2007. Wolf et al. (2006) examined the relationship between literacy, self-efficacy and HIV medication adherence. Their study of 204 people with HIV used the REALM to assess functional health literacy and a revised version of the Patient Medication Adherence Questionnaire (PMAQ) to measure adherence. The PMAQ is a self-report measure that asks respondents to report doses missed in the last 4 days. Results initially showed an association between functional health literacy and adherence; however with further analysis the authors found that self-efficacy mediated this relationship. This study is limited because of the use of self-report measures. Also, the authors stated that the REALM may not provide enough precision to adequately examine the relationship between functional health literacy and adherence.

The available research on functional health literacy and self-efficacy in other populations is limited to one published study. Sarkar, Fischer and Schillinger (2006) examined 408 ethnically diverse people diagnosed with type 2 diabetes to determine the effect of self-efficacy on self-management, and whether this relationship varied across functional health literacy levels. Over 53% of their participants demonstrated lower functional health literacy, as assessed by the S-TOFHLA. The researchers did not find significant interactions between self-efficacy regarding health management (diet, exercise, blood glucose monitoring, foot care, or medication adherence) and functional health literacy.

Despite the lack of available literature in this area, investigation into this relationship is well supported by the important role that self-efficacy has shown to have in producing and maintaining health behaviors, including HIV medication adherence, as demonstrated below. Additionally, several researchers have identified that self-efficacy is an important link that is missing in the available literature.

2.7.4 Medication Adherence and Self-Efficacy

Results from several studies have supported the relationship between higher self-efficacy and better HIV medication adherence (Buchmann, 1997; Catz, Kelly, Bogart, Benotsch, & McAuliffe, 2000; M. O. Johnson et al., 2003; Debra A. Murphy, Greenwell, & Hoffman, 2002; J. M. Simoni, Frick, Lockhart, & Liebovitz, 2002) providing the rationale for continued inquiry into the relationship between self-efficacy and adherence. This relationship is supported across diverse HIV+ populations. For example, both Murphy, Greenwell and Hoffman (2002) and Kalichman et al. (2001) found that for women, decreased self-efficacy was associated with missing medication doses, as measured by self report (Kalichman et al., 2001; Debra A. Murphy, Greenwell, & Hoffman, 2002). Another study in Australia with 200 participants found that self-efficacy was related to self-reported adherence and viral load. Adherence was measured using self-report for the past 4, 7, and 28 days. In terms of self-efficacy, non-adherence was specifically associated with being sure one would be able to take the medications as directed (OR 0.2) and being sure that missing doses of HIV medication will result in drug resistance (OR 0.4) (Wilson, Doxanakis, & Fairley, 2004).

Pinheiro et al. (2002) studied of 195 participants with HIV in Brazil. Univariate analysis showed that those with greater self efficacy were three and a half times as likely to report better

adherence (OR = 3.50, 95% CI 1.90-6.55). Multivariate analysis showed that those with higher self-efficacy had three times the odds of reporting higher adherence levels (OR = 3.33, 95% CI 1.69-6.56) than people with lower self-efficacy, making self-efficacy the single best predictor of adherence in this study (Pinheiro, de-Carvalho-Leite, Drachler, & Silveira, 2002).

In their study on HIV+ youths, ages 16-24, Naar-King et al. (2006) found that self-efficacy was significantly correlated with adherence measured by self-report for the last month and the last three months ($r=.62$, $p<.01$). Self-efficacy was operationalized using three items to determine the degree to which the participant was confident they could take the right medications at the right time. In a regression model self-efficacy predicted adherence ($p<.01$); when combined with psychological distress, self-efficacy explained 47% of the variance in adherence. Despite the small sample size (n=24), these results underscore the significance of self-efficacy and adherence in various populations, including young adults.

Of particular interest in the study of self-efficacy may be the baseline levels at which participants report self-efficacy prior to beginning HIV medications. This starting point is significant as it may help to identify predictors of non-adherence and allow for the development of proactive interventions to maximize medication taking behaviors. Reynolds et al. (2004) conducted a study with over 900 individuals naive to HIV medication treatments. These researchers found that lower self-efficacy about adherence was associated with increased stress, depression, and symptom distress. Additionally, higher self-efficacy was associated with higher functional health, social support, and higher education (all $p < .001$) (Reynolds et al., 2004).

The Sarker, Fisher and Schilligger (2006) study described in the previous section that examined the effect of self-efficacy on diabetes self-management (five different outcomes) found that self-efficacy and the five outcomes were related across ethnicities and functional health

literacy levels. Interestingly, they also found a trend toward increased self-efficacy and increased medication adherence (one of the five self-management outcomes) in African-American and white participants, but not the other ethnic groups. This cross-sectional study was limited by the use of self-report adherence measures; however, the results add to the body of literature supporting the relationship between self-efficacy and adherence (Sarkar, Fisher, & Schillinger, 2006).

Longitudinal data further support the importance of self-efficacy. In a study of mainly African-American and Puerto Rican men and women with HIV/AIDS, self-efficacy to adhere at baseline predicted self-reported adherence at 3 months (Jane M. Simoni, Frick, & Huang, 2006).

In addition to a direct relationship, self-efficacy has also been studied as a potential mediator of adherence. The findings of a study of 2,765 individuals with HIV who were on antiretroviral medications supported a model in which adherence self-efficacy was the mechanism for the relationship between positive provider interactions and adherence (Mallory O. Johnson et al., 2006). Interactions between providers and patients are a significant component of functional health literacy, in theory and in practice. Therefore, the results from the study by Johnston et al. (2006) have even more salience when the implications are considered within the context of functional health literacy.

As important as it is to understand the relationship between self-efficacy and adherence, the question for researchers is whether or not increasing self-efficacy will have an effect on adherence, and thereby improve health outcomes. In their study with 56 women with HIV, Ironson et al. (2005) found that their cognitive-behavioral intervention resulted in increases in AIDS self-efficacy (operationalized as ability to prevent transmission to others and ability to

prolong their own life) that were significantly related to increases in CD4 and decreases in viral load.

2.8 INDIVIDUAL FACTORS

The SCT model component of the individual, according to Bandura (1986), may include the individual's vulnerability to anxiety, stress, depression or fatigue in relation to the treatment-adherence behavior as well as physical functioning. To date, there is very little literature specifically examining the relationship between these variables and functional health literacy; however, there is a significant amount of data highlighting the relationship between these variables and HIV/AIDS disease management.

2.8.1 Depression

Depression is one of the most common, yet under-diagnosed, diseases in the general population and in HIV in particular; the prevalence of depression is 8-14% in the general population and 18-20% in HIV+ individuals (Bangsberg, 2004, Bing, Burnam and Longshore 2001, Sambamoorthi, Walkup, Olfson and Crystal, 2000). Depression is the most common psychiatric illness seen in HIV-infected populations, and depressive symptoms associated with adjustment disorder are found in 18% of people with HIV (Rabkin, 1997, Angelino, 2002).

Depression is commonly found to be related to poor adherence (Avants, Margolin, Warburton, Hawkins, & Shi, 2001; Bouhnik et al., 2002; Catz, Kelly, Bogart, Benotsch, & McAuliffe, 2000; Larney, 2002; Perry & Karasic, 2002; Starace et al., 2002; Tucker, Burnam,

Sherbourne, Kung, & Gifford, 2003; Turner, Laine, Cosler, & Hauck, 2003). This strong relationship suggests that any model of medication adherence needs to include this variable.

However, the link between depression and functional health literacy is not well understood. Lincoln et al. (2006) found that low functional health literacy was associated with increased depressive symptoms. Other researchers have reported that those with inadequate functional health literacy were more than twice as likely to report depressive symptoms; however, this relationship was not significant after controlling for health status (J. Gazmararian, Baker, Parker, & Blazer, 2000). Morris, McLean and Littenberg (2006) also found that those individuals with lower functional health literacy were more likely to report depression. These findings provide some insight into the complexity of the relationship between functional health literacy and depression, suggesting that depressive symptoms may be related to lower functional health literacy.

The above proposition has been supported in research within the HIV+ population as well. In a study of 294 HIV+ individuals, Kalichman and Rompa (2000) found lower functional health literacy was related to greater symptoms of depression. This study is especially interesting because it also examined the coping strategies of individuals by using hypothetical situations of poor health related to HIV. Participants were provided two different vignettes detailing good and bad clinical events (increased or decreased viral load). Affective reactions and coping strategies were then assessed. Individuals with low functional health literacy more strongly endorsed negative affective states and maladaptive coping strategies compared to persons with higher health-literacy skills (Kalichman & Rompa, 2000a). This study offers insight into not only the relationship between depressive symptoms and functional health literacy, but also the role of functional health literacy on an individual's response to their own disease process over time.

More research is needed to increase this understanding in order to design interventions to influence behaviors to change disease progression.

Taking this line of inquiry into possible interventions, Weiss et al. (2006) compared depressive symptoms and functional health literacy (using the REALM) to determine if interventions to increase literacy can have an impact on depression. They found that those who received education to increase literacy plus standard depression treatment did have significantly more improvement in their depressive symptoms (B. D. Weiss, Francis, Senf, Heist, & Hargraves, 2006). These authors maintained that this was the first study to provide evidence that a health outcome can be improved with literacy education and standard depression treatment. This knowledge contributes support to the continued investigation of the relationships between functional health literacy and depression, using the reciprocal SCT model.

2.8.2 Burden of Illness

The treatment of HIV includes a complex and demanding treatment regimen. In this study, perceived burden of illness assessed participants' perceptions about the complexity of their medication regimen and the impact of side effects on their daily life. The daily medication regimen, once an arduous task that involved taking up to 30 different pills a day, has dramatically changed over the last 20 years. Currently some people taking antiretroviral medications may take only two pills, twice a day. A significant amount of research has demonstrated a relationship between regimen complexity and adherence rates (Graney, Bunting, & Russell, 2003; Spire et al., 2002). For example, Maggiolo et al. (2005) found that adherence (4-day recall, self-reported) was significantly influenced by both the number of pills and daily doses received. Research has also shown that participants taking newer, simplified regimens that

contain fixed dose combination pills (i.e. multiple drugs in one pill), as opposed to separate pills are three times more likely to achieve adherence rates greater than 95% (Legorreta et al., 2005). There does remain, however, considerable variation in the different regimens being prescribed and for people who have been living with HIV for an extended period there may be a dramatic difference in the complexity and burden of the regimens they have been taking over time.

Pill burden and regimen complexity are only one part of the daily medication management of HIV. For many of those people taking the potent combination therapy, side effects have a dramatic impact on their lives. Ammassari et al. (2001) found the frequency of moderate to severe symptoms or side effects ranging from 3.6% to 30%. Furthermore, they found that in their sample of 358 people, non-adherent individuals had higher symptoms and side effects scores compared to adherent participants. Adherence was measured using three-day recall (Ammassari et al., 2001). In their qualitative study on adherence in people living with HIV, Remien et al. (2003) identified a theme of intentional non-adherence in their participants, usually found in response to physical side effects. Several other studies have supported the relationship between decreased adherence rates and increased number or severity of side effects (Catz, Kelly, Bogart, Benotsch, & McAuliffe, 2000; Graney, Bunting, & Russell, 2003; Spire et al., 2002). Because of the highly individualized and subjective experience of both regimen complexity and impact of side effects, this study looked at the individual's perception of the burden of illness on their daily lives.

There are no published studies examining the relationship between functional health literacy and perceived burden of illness. This study allowed for such an examination.

2.8.3 Functional Health Status

Functional health status, defined as "a measure of an individual's ability to perform normal activities of life" (National Quality Measures Clearinghouse, 2004, section titled Outcomes, para 5), was once studied as a predictor of morbidity and mortality, but has received more recent attention as a critical component of quality of life. There are no published studies reporting the relationship between functional status and functional health literacy. However, functional status is a significant part of the lived experience of the person living with HIV.

Overall, the person with HIV/AIDS experiences at least one acute illness that is physically debilitating and subsequently experiences symptoms like fatigue, weakness, anemia, or wasting that reduces physical functioning abilities (Fleishman & Crystal, 1998). In a national representative study, greater functional limitation was associated with older age, lower educational attainment, and more advanced disease. In this same study, more than 80% of those with AIDS (as opposed to HIV) were limited in vigorous activity and 72% were limited at least some of the time in work, school or housework (Crystal, Fleishman, Hays, Shapiro, & Bozzette, 2000). Although there are no published studies comparing functional health and functional health literacy, the association with lower educational attainment suggests that this may be a fruitful line of inquiry.

In one multi-ethnic study specifically examining economically disadvantaged patients with HIV/AIDS, the authors found that overall work-related functioning was significantly impaired and that this status held true for every social, demographic, and behavioral group studied; ethnic minority groups, moreover, reported poorer physical functioning than whites (Vidrine, Amick, Gritz, & Arduino, 2003). These decreases in functional health status may

ultimately influence self-management behaviors, including adherence (Fleishman & Crystal, 1998).

2.9 ENVIRONMENTAL FACTORS

According to Bandura (1986), environmental factors are those factors that may affect behavior but are external to the individual. These can include family members, friends, peers, healthcare providers, and society at large. Bandura also includes *situation* as an environmental factor. Situation refers to the individual's cognitive representation of the environment, real or imagined.

2.9.1 Social Support

Studies have consistently shown significant associations between social support and medication adherence in a variety of disease processes (Brook et al., 2001; Carrieri et al., 2003; Catz, Kelly, Bogart, Benotsch, & McAuliffe, 2000; Catz, McClure, Jones, & Brantley, 1999; Graney, Bunting, & Russell, 2003; R. Power et al., 2003; Roberts, 2000; J. M. Simoni, Frick, Lockhart, & Liebovitz, 2002) . This relationship is further supported for people living with HIV. In fact, the literature indicates a strong relationship, among diverse sample populations. In their study with low-income, Spanish-speaking, HIV-positive Latino men (n = 85), Van Servellen and Lombardi (2005) found that social support was significantly associated with level of dose adherence.

In their study on the predictors of adherence, Gorillo (1999) found that those individuals who perceived high levels of social support were twice as likely to have adherence rates greater than 90%, as measured by pill counts. Furthermore, Simoni et al. (2002) reported that absence of social support was related to acknowledged non-adherence. Additionally, this relationship was mediated by self-efficacy and depressive symptoms, two other factors under consideration in this study. Again, these findings are limited because adherence was assessed using self-report (J. M. Simoni, Frick, Lockhart, & Liebovitz, 2002).

There is qualitative work also supporting the role of social support in successful adherence. In a study of individuals who were 100% adherent to their medications over 30 days, Lewis, Colbert, Erlen and Meyers (2006) found that participants relied on the support and encouragement they received from family and friends. Bontempi, Burleson, and Lopez (2004) conducted focus groups and also found that social support is a key ingredient to adherence success.

Despite this empirical support, there may be some HIV+ populations for whom social support is less influential. In a study of 16-24 year olds infected with HIV, social support was not significantly correlated with adherence ($r=.18$, no p-value provided). However, this same study did show that social support specific to medication taking was related to self-efficacy ($r=.43$, $p<.05$) (Naar-King et al., 2006). Although the study was limited by a very small sample size ($n=24$), the findings suggest that social support is regarded and weighed differently among different groups.

There are no published studies examining the relationship between functional health literacy and social support; yet, this relationship must be considered in a model examining the relationship between functional health literacy and health outcomes. This relationship is critically

important because individuals may develop formal or informal compensatory measures to buffer themselves from the effects of lower functional health literacy and to hide any of these problems from health care providers or other members of their social support framework.

2.9.2 Stigma

The concept of stigma as it relates to social identity was first introduced by Erving Goffman in 1963. In his highly influential book, *Stigma: Notes on the Management of a Spoiled Identity*, he defined stigma as "an attribute that is deeply discrediting" (Goffman, 1963, p. 3). He identified three different types of stigma: "abominations of the body," "blemishes of individual character" and "tribal stigma of race, nation, and religion" and recognized that the issue does not exist separate from the context in which it resides, immediately noting that the term requires a "language of relationships, not attributes" (Goffman, 1963, p. 3).

Living with HIV/AIDS carries a significant burden of stigma; despite better understanding about the disease, stigma persists, and it may have an effect on how one views one's own ability to be successful (Herek, Capitanio, & Widaman, 2002, 2003). HIV disease-related stigma is associated with negative self-perceptions (Frable, Wortman, & Joseph, 1997), lower rates of HIV-status disclosure (Clark, Lindner, Armistead, & Austin, 2003; Vanable, Carey, Blair, & Littlewood, 2006), decreased health care utilization (Reece, 2003), and lower rates of HIV and STD testing and disclosure (J.D. Fortenberry et al., 2002; Vanable, Carey, Blair, & Littlewood, 2006).

The experience of stigma and its relationship to HIV medication adherence is supported in published literature. Vanable et al. (2006) conducted a study with 221 participants. Adherence was assessed using a 7-day, self-report recall tool. Using bivariate regression analysis, the

authors found adherence to be a predictor of stigma-related experiences (b= -.24, p<.01). Multivariate regression analysis revealed that even after controlling for background variables, adherence remained a robust predictor of stigma (b= -.20, p<.01). Despite these findings, the exact mechanism by which these relationships occur is not known.

There are no studies examining the relationship between stigma and functional health literacy; however, the demonstrated connection between stigma and outcomes, including adherence, suggests that such an investigation is appropriate. First, low functional health literacy itself may be stigmatizing for the individual. Secondly, it seems possible that if an individual struggles with management of their disease or has a difficult time understanding the disease process—as might be the case for someone with low functional health literacy—that they may also have a higher level of stigma. For example, in the relationship between stigma and adherence, it is possible that functional health literacy may act as a mediating variable between these two variables, potentially protecting those with higher functional health literacy from some of the detrimental effects of stigma.

2.9.3 Relationship with Health Care Provider

Research has demonstrated the effect of positive healthcare provider relationships on medication adherence (Bogart, Bird, Walt, Delahanty, & Figler, 2004; Graney, Bunting, & Russell, 2003; Meredith, Jeffe, Mundy, & Fraser, 2001; D. A. Murphy, Roberts, Martin, Marelich, & Hoffman, 2000; Spire et al., 2002). Several empirical studies have examined this relationship specifically within the HIV-positive population. The results from these studies all

underscore the relevance of the patient-provider relationship in the management of chronic disease.

Golin et al. (2002) found that patients who reported a high level of trust in their provider reported higher adherence. However, the researchers did not find a significant relationship between adherence in provider continuity, counseling behaviors, or overall satisfaction. Another group of researchers did not find a significant relationship between adherence and satisfaction with provider, however over 93% of respondents reported satisfaction with their provider, which may have had made it difficult to reach statistical significance. The authors did not provide odds ratios or p-values for this bivariate analysis (Gordillo, del Amo, Soriano, & Gonzalez-Lahoz, 1999).

In a study of Latino men and women, investigators found that the quality of physician-patient communications or relationships was significantly associated with adherence to medication schedule ($p < .001$). Even more significantly, the quality of patient-physician relationship accounted for 22% of the variance in adherence to medication schedule (van Servellen & Lombardi, 2005). Heckman et al. (2004) also found a good patient-provider relationship to be predictive of self reported adherence in a rural U.S. population.

Scheider et al. (2004) conducted a cross-sectional study with over 550 participants to investigate which aspects of a provider-patient relationship are associated with better adherence rates in people living with HIV. In their study, seven measures of interpersonal care (communication, HIV-specific information, participatory decision making, overall physician satisfaction, willingness to recommend, trust, and adherence dialogue) were all associated with better adherence. Bivariate relationships were strongest between adherence and communication ($r = .17$, $p < .0001$), overall satisfaction ($r = .17$, $p<.0001$) and adherence dialogue ($r = .21$,

p<.0001). Functional health literacy, in terms of the level of the individual and the capacity of the provider to provide care at the appropriate level, may play a part in the development and maintenance in these particular aspects of the patient-provider relationship.

2.10 SUMMARY

Overall, there was significant existing literature available to support the primary line of inquiry. However, there were significant gaps in the literature, several of which were addressed specifically in this study. In addition to several areas where there is no published literature, that which is available demonstrates a lack of longitudinal adherence data, collected using electronic monitoring methods. Most of the published studies measured adherence with self-report using a recall method. Second, many of the studies used the least comprehensive REALM (or, less often, another measure) to assess functional health literacy. This study attempted to address both of these significant issues in an effort to answer questions about the effect of functional health literacy on medication adherence. In addition, the exploratory aims of the study allowed for the initial examination of other variables related to adherence in this population.

While reported functional health literacy rates in the United States are less than adequate across populations, ranging from 15-71% (Artinian, Lange, Templin, Stallwood, & Hermann, 2001a; Lindau et al., 2002; Montalto & Spiegler, 2001; Montaque, Okoli, & Guerrier-Adams, 2003; Nurss et al., 1997; Rudd, Kirsch, & Yamamoto, 2004; Sharp, Zurawski, Roland, O'Toole, & Hines, 2002), functional health literacy may also be affecting certain vulnerable populations disproportionately. To ascertain which socio-demographic factors are related to functional health literacy, Chapter Two provides a systematic review of the literature exploring the relationships

between functional health literacy and various socio-demographic variables, providing support for the continued exploration of these factors.

3.0 PRELIMINARY STUDY

3.1 BACKGROUND

Existing studies examining functional health literacy have primarily described rates and possible socio-demographic correlates. Individually, these articles describe functional health literacy within a specific population or sample; however, collectively, they may be able to describe more about the scope and weight of the functional health literacy problem in the United States. This preliminary study combined several studies done in significantly different populations (as illustrated in Table 6); however, examining them together may provide some direction for further research. By calling the findings "overall" functional health literacy rates and effect sizes, and given the relatively immaturity of this research arena, the author is referring only to a mathematical computation. It should not be inferred that these numbers accurately reflect the characteristics of the United States population as a whole. The purpose of this preliminary study was to estimate the rates of functional health literacy and explore the relationship between functional health literacy and selected socio-demographic factors (socio-economic status, age, educational level, and race).

3.2 METHODS

3.2.1 Data Sources

In order to achieve the stated objective of the integrative review, a search of English-language literature was completed, using both electronic and manual methods. The electronic search was done using the keywords "health literacy" and a combined search using "health" and "literacy." The databases searched were Ovid Medline from 1966, CINAHL from 1992, Pysch-Info from 1967, and the Cochrane Database of Systematic Reviews. Additionally, a manual check of the references in published reviews of functional health literacy and the Institute of Medicine's published bibliography on functional health literacy was performed. The cut-off date for retrieval of articles was March 23, 2005; no articles published after that date were included.

3.2.2 Literature Screening and Study Selection

Studies were selected for inclusion in the systematic review and meta-analysis based on pre-specified criteria. Existing literature was screened and sorted at two separate levels. The first level was a review of citations and abstracts for the following exclusion criteria: review articles, letters or comments, brief mentions of other published works, studies limited to children or adolescents (less than 18 years of age), and functional health literacy measurement tools other than the Test of Functional Health Literacy in Adults (TOFHLA). Full articles were then obtained for the studies not excluded at level 1. Articles reviewed at level 2 were screened for the above exclusion criteria and the following inclusion criteria: reported outcomes on functional health literacy levels and socio-demographic factors, use of the TOFHLA to measure functional

health literacy, and study conducted in the United States with English- or Spanish-speaking samples. Study samples were also closely scrutinized at level 2 to identify "kin" studies—multiple studies that described the same or overlapping samples—so that samples were only included in the analysis once.

3.2.3 Functional Health Literacy Measurement

The measurement of functional health literacy was a critical part of this analysis. A discussion of the assessment of functional health literacy was included in Chapter 2. Only studies that used the TOFHLA or the S-TOFHLA were included in this study.

3.2.4 Statistical Analysis

Analyses were performed only on the studies in the final inclusion subset. Study, patient sample, and functional health literacy levels were summarized using basic descriptive statistics. For the meta-analysis examining the effect of socio-demographic factors on functional health literacy, effect sizes (phi) were computed from the provided p-values for each variable. These results were then averaged for a combined analysis without weighting and without transformation, to determine a combined effect size in the procedure for effect size estimation (Rosenthal, 1991).

3.3 RESULTS

3.3.1 Data Retrieval

A flow diagram illustrating the systematic review process is provided (Figure 4). The initial literature review identified 585 citations to be screened. Of these 510 were rejected based on the exclusion criteria. Seventy-five articles were retrieved for more a detailed review; 59 studies were rejected for the following reasons: 12 used measures other than the TOFHLA or S-TOFHLA, 9 were reviews or letters, 24 had different outcomes than those being examined, 3 were not able to be retrieved, and 11 were "kin" studies. Ultimately, 16 articles were included in the integrative review.

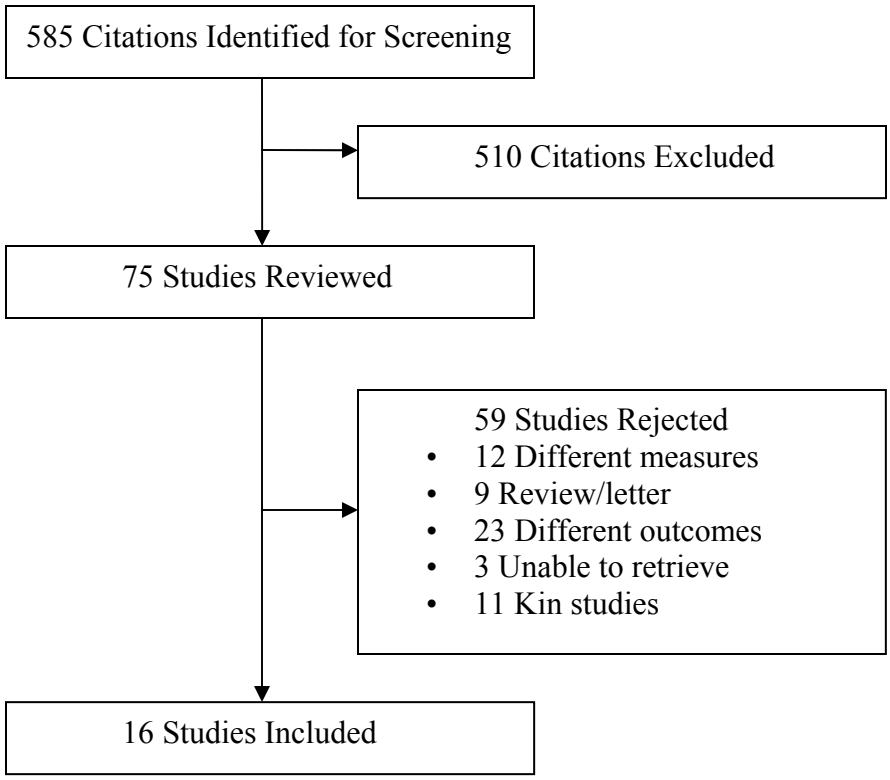

Figure 4: Study Attrition Diagram

3.3.2 Participant Functional Health Literacy Levels

Functional health literacy rates, sample size and the population being studied are reported for each of the studies in Table 6. Functional health literacy was collapsed into a dichotomized variable—adequate or marginal/inadequate—as several of the studies only reported results in those two levels. Overall (N=9,926) the functional health literacy rates for the included studies were 38% inadequate/marginal and 62% adequate. The variability in functional health literacy rates among studies is illustrated in Figure 5. The highest rates were seen in the Gazmariarian, et al. (2004) study of women aged 19-45 years who were seeking contraception services. An

inadequate/marginal functional health literacy rate of 9.6% was reported for a sample size of 406. Conversely, the lowest rates were reported by Nurss et al (1997) in their study at a diabetes outpatient clinic; 71% of the participants (mean age 58.2) scored at the inadequate/marginal level.

Table 6: Functional Health Literacy Rates Across Studies

Author	Sample	N	#Inadequate/Marginal	#Adequate
(Artinian, Lange, Templin, Stallwood, & Hermann, 2001b)	Primary care, VA	92	26 (28.3%)	66 (71.7%)
(Baker, Parker, Williams, & Clark, 1998)	ED patients, 18 yrs and older, English-speaking	958	455 (47.5%)	503 (52.5%)
(Baker, Gazmararian, Williams et al., 2002)	Medicare managed care enrollees	3260	1166 (35.8%)	2094 (64.2%)
(Benson & Forman, 2002)	Retirement community	93	28 (30.1%)	65 (69.1%)
(Chew, Bradley, Flum, Cornia, & Koepsell, 2004)	Preoperative Patients	332	40 (12%)	292 (88%)
(Endres, Sharp, Haney, & Dooley, 2004)	Pregnant women with gestational diabetes	74	16 (21.6%)	58 (78.4%)
(J. A. Gazmararian, Parker, & Baker, 1999)	Women 19-45	406	39 (9.6%)	367 (90.4%)
(Kalichman & Rompa, 2000b)	HIV	339	83 (24.5%)	256 (75.5%)
(Kalichman et al., 2000)	HIV	294	50 (17%)	244 (83%)

Author	Sample	N	#Inadequate/Marginal	#Adequate
(S. Kim, Love, Quistberg, & Shea, 2004)	Diabetes education class participants, 18 yrs or older	92	21 (22.8%)	71 (77.2%)
(Montalto & Spiegler, 2001)	Rural primary care	70	10 (14.3%)	60 (85.7%)
(Nurss et al., 1997)	Diabetes outpatient clinic	131	93 (71%)	38 (29%)
(Parikh, Parker, Nurss, Baker, & Williams, 1996)	ED	202	86 (42.6%)	116 (57.4%)
(Dean Schillinger et al., 2002)	Type 2 DM, 30 yrs and older	408	210 (51.5%)	198 (48.5%)
(Williams et al., 1995)	Presenting for acute care	2659	1138 (42.8%)	1521 (57.2%)
(Williams, Baker, Parker, & Nurss, 1998)	HTN General Medicine clinic	402	246 (61.2%)	156 (38.8%)
(Williams, Baker, Parker, & Nurss, 1998)	DM General Medical Clinic	114	63 (55.3%)	51 (44.7%)
TOTAL NUMBERS		9926	3770 (37.98%)	6156 (62.02%)

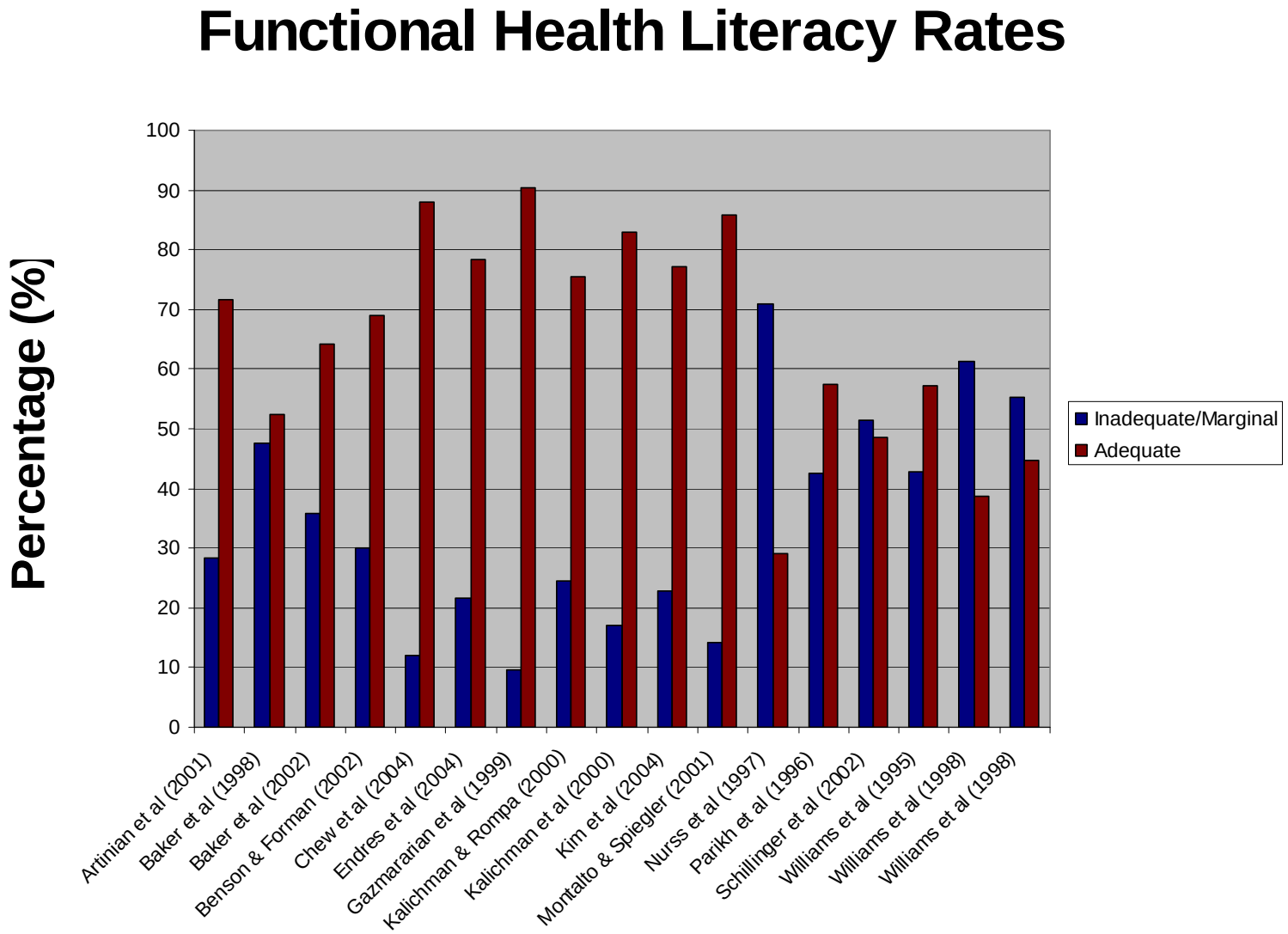

Figure 5: Functional Health Literacy Rates

3.3.3 Socio-demographic Factors

Sixteen studies were analyzed to explore the effect size of the relationships between functional health literacy and four socio-demographic factors: socioeconomic status, age, educational level and race. Individual study results showing p-values and effect sizes of socio-demographic factors are displayed in Table 7. A combined analysis of the socio-demographic factors showed mostly small to low-moderate effect sizes. Most notable in the combined analysis was the relatively small effect size of educational level in relation to functional health literacy; the analysis of sixteen studies with appropriate results demonstrated a small to moderate effect size ($\varphi = .219$), the largest effect size found. Eight separate studies examined the relationship between socio-economic status (measured using either income or insurance status) and functional health literacy; a small effect size was found ($\varphi = .178$). The significance of increasing age was noted in 13 separate studies; overall, the effect size of age was small to moderate ($\varphi = .208$). Race, reported in eight studies, had the smallest effect size of all the socio-demographic factors ($\varphi = .108$). Results of the meta-analysis of the socio-demographic factors are illustrated in Figure 6.

Table 7: Socio-demographic Factors Related to Functional Health Literacy

Author	N	Age		Race		Socio-econ status		Education level	
		p	φ	*p*	φ	*p*	φ	*p*	φ
(Artinian, Lange, Templin, Stallwood, & Hermann, 2001b)	92	<.001	.344	.046	.208	.018	.247	.002	.322
(Baker, Parker, Williams, & Clark, 1998)	958	<.001	.106	.03	.07	<.001	.106	<.001	.106
(Baker, Gazmararian, Williams et al., 2002)	3260	<.01	.045	<.01	.045	<.01	.045	<.01	.045
(Benson & Forman, 2002)	93	.04	.213					.0005	.361
(Boswell, Cannon, Aung, & Eldridge, 2004)	149							<.001	.27
(Chew, Bradley, Flum, Cornia, & Koepsell, 2004)	332	<.001	.181	.30	.057	<.01	.142	<.01	.142
(Endres, Sharp, Haney, & Dooley, 2004)	74	.001	.383			.001	.383	.001	.383

Author	**N**	**Age**		**Race**		**Socio-econ status**		**Education level**	
		p	**φ**	***p***	**φ**	***p***	**φ**	***p***	**φ**
(J. A. Gazmararian, Parker, & Baker, 1999)	406	.596	.026	.088	.085	.537	.031	.001	.163
(Kalichman & Rompa, 2000b)	339							.01	.161
(Kalichman et al., 2000)	294			.01	.150			.01	.150
(S. Kim, Love, Quistberg, & Shea, 2004)	92	.001	.343	.379	.092	.001	.343	<.001	.344
(Montalto & Spiegler, 2001)	70	.0003	.432					.0005	.416
(Nurss et al., 1997)	131	.06	.164					<.05	.173
(Parikh, Parker, Nurss, Baker, & Williams, 1996)	202	<.01	.182					<.01	.182
(Dean Schillinger et al., 2002)	408	<.0001	.163	<.001	.163	.009	.129	<.001	.163
(Williams et al., 1995)	2659	<.001	.118					<.001	.118
Raw Total			2.7		.87		1.426		3.499

Author	N	Age		Race		Socio-econ status		Education level	
		p	φ	*p*	φ	*p*	φ	*p*	φ
# of studies	16		13		8		8		16
Mean φ			.208		.109		.178		.219

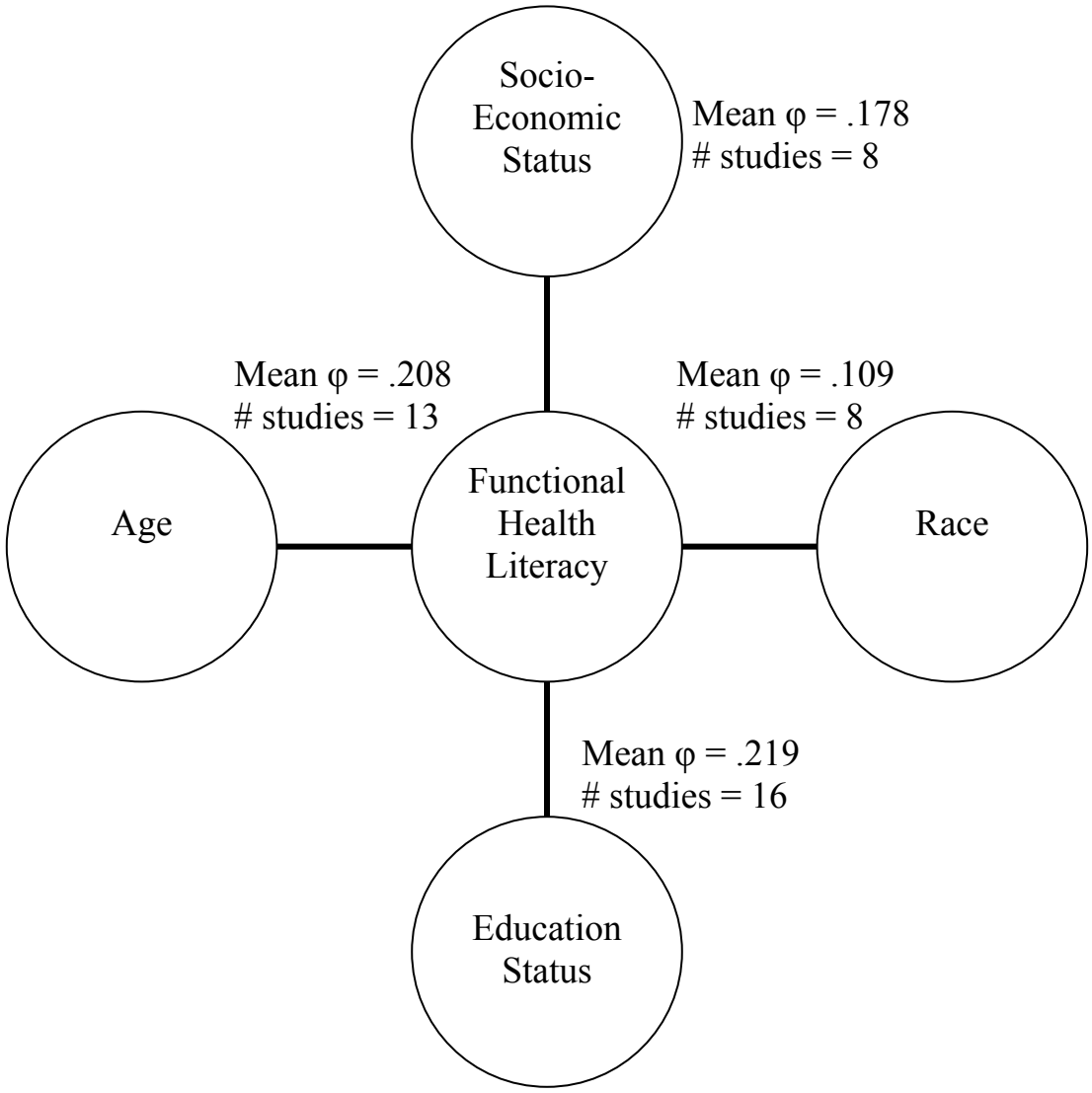

Figure 6: Relationship of Functional Health Literacy to Age, Race, Education Level, and Socioeconomic Status

3.4 DISCUSSION

This systematic review of relevant literature indicated that almost one third of the populations studied may have inadequate or marginal functional health literacy levels when functional health literacy was measured using the more comprehensive TOFHLA. Socio-demographic factors, noted in these studies to have a statistically significant relationship with functional health literacy, had relatively small effect sizes. These results indicate that functional health literacy is indeed an issue that health care providers need to recognize, but that traditional assumptions about who is at risk for low functional health literacy—especially as it relates to educational level, socio-economic status, age, or race may be unwarranted and inaccurate. This study indicated that a comprehensive meta-analysis on existing literature (both published and unpublished) would be appropriate in order to provide a better understanding of the pervasiveness of the problem. Continued study needs to include special attention to the populations with high functional health literacy demands, such as people living with chronic illness, co-morbidities, or severe illness, and primary caregivers of people with significant health needs. Continued research needs to examine the correlates of low functional health literacy—including socio-demographic, health-specific, and cognitive factors—and the development of interventions appropriate for the low-health literate person.

There were several limitations to this study. First, the relative immaturity of the health literacy concept and lack of rigorous science makes it difficult to draw conclusions about the population as a whole. Additionally, statistics were not reported for most non-significant relationships, and the inconsistency of some reporting within studies suggests that some relationships may have not been reported. The results may have also been affected by a publication bias, wherein a choice was made not to publish if research showed primarily non-

significant results. Health literacy research, in general, faces a number of limitations by its very nature. Participants with low functional health literacy may opt not to participate in research, thereby creating a selection bias, or research materials and procedures may not be written or performed at a level for people with low functional health literacy to comprehend, thereby creating systematic biases. These are important considerations for all aspects of research in this area.

4.0 METHODS

4.1 RESEARCH DESIGN

4.1.1 Secondary Data Analysis

The design of this study was a cross-sectional, descriptive secondary analysis using data from the parent study (described below). Variables examined included: functional health literacy, medication adherence, medication taking self-efficacy, depressive symptoms, burden of illness, social support, HIV-related stigma, functional health status, and relationship with healthcare provider.

4.1.2 Description of the Parent Study

The parent study, "Improving Adherence to Antiretroviral Therapy" (2R01 NR04749), is a randomized clinical trial testing the efficacy of two interventions designed to promote and sustain adherence when people with HIV are taking antiretroviral medicine. The 5-year study based on social cognitive and self-efficacy theory is comparing the effect of two intervention groups (structured and individualized) relative to usual care on adherence to antiretroviral therapy over time. A sample of 354 people living with HIV taking antiretroviral therapy was randomly assigned to one of three study arms. Those in the structured intervention received a 12

week structured telephone delivered intervention and a 3-month tapered maintenance program; half were then randomized to receive 3 boosters over the next 6 months. Those in the individualized group received a 12 week individualized telephone delivered intervention based on their self identified needs and a 3-month tapered maintenance program; half were randomized to receive 3 boosters over the next 6 months. The usual care group received their regular care. Data collection procedures are described in Section 4.4.

4.2 SETTING AND SAMPLE

4.2.1 Setting

Participants were recruited from clinics and HIV/AIDS service organizations in Western Pennsylvania and Northeaster Ohio, and through self-referral. A previous study using the same population (1R01 NR04749) resulted in the following sample characteristics: 67.5% male; and 54.5% White, 34% African American, and 11.5% multi-racial/other. Based on that study, the parent study expected to recruit women (33%) and minorities (Latino, 5%; African American, 44%) in numbers that reflected the composition of the affected populations in those geographical areas. Demographic characteristics of the sample for this secondary data analysis are presented in Chapter 5.

4.2.2 Sample

All participants from the parent study who completed screening, enrollment and baseline data collection and who also completed the functional health literacy tool and had electronic event monitoring data collected were included in the secondary analysis. The total number of participants for this analysis was 335. In order to have been eligible for the parent study, participants had to be 18 years of age or older; able to speak, write, and read English; free from HIV-related dementia as evidenced by assessment using an HIV dementia screening instrument (C. Power, Selnes, Grim, & McArthur, 1995); prescribed HIV medications; self-administering prescribed HIV-antiretroviral medication; and not living with a current participant in the study.

4.3 MEASUREMENTS

4.3.1 Functional Health Literacy

Functional health literacy was measured using the Short Test for Functional Health Literacy (S-TOFHLA) (Baker, Williams, Parker, Gazmararian, & Nurss, 1999). The S-TOFHLA is a shorter version of the standard TOFHLA which uses materials a patient may encounter in the healthcare setting. The test has two parts: 1) a timed 36-item test using a modified Cloze procedure (every fifth to seventh word is omitted and four choices are offered; and 2) a 4-item test using hospital forms and prescription bottles. There are two reading comprehension sections, one written at the 4^{th} grade level and the other at the 10^{th} grade level. The S-TOFHLA is scored on a scale of 0 to 100. Developers of the tool categorized participants as having adequate

functional health literacy if the score was 67-100, marginal functional health literacy if it was 54-66, and inadequate functional health literacy if the score was 0-53 (Baker, Williams, Parker, Gazmararian, & Nurss, 1999).

There is general agreement that functional health literacy (especially as measured using the existing instruments such as the REALM and S-TOFHLA) is best analyzed as a categorical variable, in order to properly recognize its "threshold" effect. However, there is some discrepancy across studies about the appropriate cut-off point between functional health literacy levels. The studies that examined functional health literacy in an HIV-positive population differ. Kalichman, Ramanchandran, and Catz (1999) used an amended version of the S-TOFHLA that included an HIV-specific reading comprehension section along with two of the standard reading sections and the numeracy items. The authors considered those with greater than 85% correct to have higher functional health literacy, and those with 85% or less to have lower functional health literacy in their study examining medication adherence. In a different study assessing HIV-knowledge, Kalichman et al (2000) used a cut-off of 80% as the distinction between higher and lower functional health literacy. Golin (2002), conversely, used the S-TOFHLA reading comprehension section as a continuous variable in model testing. The most recent study, Paasche-Orlow et al. (2006) and Wolf et al (2007) both used the REALM, with grade level cut-off points (less than 6^{th} grade as inadequate, 7^{th}-8^{th} grade as marginal, and 9^{th} grade and higher as adequate). Studies using the S-TOFHLA in other populations have used cut-off points varying from 67-75% for inadequate/marginal. The developers of the S-TOFHLA established cut-points of 0-53 as inadequate, 54-66 as marginal, and 67 or greater as adequate. For comparison purposes and to fully describe the functional health literacy of the sample, functional health literacy was examined as a continuous variable and as a categorical variable with various cut-off

points. The variable was examined as a continuous variable in the descriptive analysis. For further analysis the scores were dichotomized, with scores or 75 and lower indicating lower functional health literacy. This point was selected to allow for comparing results with the other related studies in adherence.

In a sample of 211 urgent care patients given the S-TOFHLA, Cronbach's alpha was .68 for the 4 Numeracy items and .97 for the 36 items in the 2 prose passages. The correlation (Spearman) between the S-TOFHLA and the REALM was .80, which is only slightly lower than the correlation between the REALM and the longer TOFHLA (.84) (Baker, Williams, Parker, Gazmararian, & Nurss, 1999). Data collected using the S-TOFHLA are continuous, interval level data. For this sample, Cronbach's alpha was .953 for the entire tool, .300 for the 4 Numeracy items and .955 for the 36 items in the 2 prose passages. A copy of the instrument can be found in Appendix C.

4.3.2 Socio-Demographics Variables and HIV Disease History

Socio-demographic and HIV health history information were collected using the CRCD Socio-demographic Questionnaire and the Medical Record Review (completed by self-report and medical record review, respectively) which included questions about age, years of education completed, income level, health insurance, race, history of IV drug use, and gender. Self-report of CD4 count, viral load (dichotomized to detectable/undetectable), AIDS diagnosis (CD4<200, or history of opportunistic infections) were collected. Self-report measurement has been shown to be a valid and reliable measure for CD4 count and for viral load (when it is dichotomized between detectable and undetectable) (Kalichman, Rompa, & Cage, 2000). Age, years of

education, and CD4 count are ratio-level data. All other variables are categorical. Copies of these instruments can be found in Appendix C.

4.3.3 HIV Medication Adherence

Adherence was assessed using electronic event monitoring (EEM), augmented by paper diary self-report. Although all methods of measurement for medication adherence have their unique problems, EEM, currently considered the "gold standard" for indirectly monitoring adherence, is recognized as the most appropriate tool for intervention studies (like the parent study) and offers more information over time than biologic assays (Turner, 2002). The EEM consists of a medication cap containing a micro-electronic circuit that fits on a standard medication bottle and records the time and date each time the cap is opened. In the parent study, participants were asked to put one of their HIV antiretroviral medications (randomly selected using a computer-based program) in the special bottle with the EEM cap; therefore one medication from the HIV regimen was monitored throughout the course of the study. Participants were also asked to keep a daily paper diary, recording the date and time they removed their HIV medications from their bottles and when they actually took the medications, to allow for pocket dosing. Data from paper diaries were inserted into the EEM data when the participant noted in the paper diary that a medication was removed from the bottle at one time and then actually taken at another. In these instances, the EEM data were supplemented by the medication-taking diary data before summarizing data to adherence indices. Adherence data were interpreted using these adherence indices to explain and describe medication adherence. One such index is the "percentage of prescribed doses taken," defined as the actual number of cap openings divided by

the prescribed number of doses during a designated time period, multiplied by 100 to convert to a percentage. Other indices were derived to better capture information regarding the timing of doses, such as "percentage of days with correct intake," "percentage of days with the correct number of administrations and timing," and "variability in the time of administrations." The final adherence score is continuous, ratio level data.

4.3.4 Medication Taking Self-Efficacy

Bandura's conceptualization of self-efficacy prescribes a very clear set of criteria measuring self-efficacy. He asserts that self-efficacy "is not a contextless global disposition assayed by an omnibus test " but rather something to be measured in "terms of particularized judgments of capability" (Bandura, 1997, p.42). Therefore, researchers developing scales measuring self-efficacy need to have a clear understanding of what is required to be successful in a given task. The behavior of interest in this study was HIV medication adherence. According to Bandura, in order to accurately measure medication-taking self-efficacy, the tool must measure the participant's beliefs about their abilities to execute different levels of medication adherence.

Self-efficacy measures must also be able to distinguish variances in self-efficacy level, generality, and strength (Bandura, 1997). Level refers to complexity of a task and falls on a continuum that ranges from simple to extremely challenging. Generality, in contrast, allows the individual to rate their ability across a wide range of activities, versus a small segment of tasks required within a certain domain. For medication taking, that translates to assessing the individual's ability to take medications as prescribed in a wide variety of circumstance (i.e. unplanned interruptions, crisis, vacation, etc). Finally, strength refers to the strength of the perceived self-efficacy for the individual. Bandura states that the greater the strength of the

perceived self-efficacy, the more likely the behavior will be performed successfully (Bandura, 1997).

Self-Efficacy was conceptualized as medication-taking self-efficacy beliefs, or one's belief in his/her ability to plan and perform a desired behavior. Self-efficacy was measured using the Self-Efficacy and Outcomes Expectancy subscales of the Erlen HIV Self-Efficacy Scale for Medication Study. The tool is a 26-item scale developed for the parent study, collecting continuous, interval level data. In testing performed by the researchers of the parent study with an HIV-positive population, the tool total score demonstrates internal consistency of .96 (n=190) based on Cronbach's alpha. Cronbach's alpha for the self-efficacy subscale was .96 (n=190); the outcome expectancies was .95 (n=213) (J.A. Erlen, personal communication, November 20, 2006). This tool meets the criteria established by Bandura for appropriate structure for self-efficacy scales. The content relates specifically to the behavior or interest and measures the level, generality and strength of medication taking self-efficacy. Cronbach's alpha was .945 for the overall tool in the study population. The self-efficacy subscale Cronbach's alphas were: self efficacy, .948; and outcome expectancy, .938. A copy of the instrument can be found in Appendix C.

4.3.5 Functional Health Status

Functional health status was measured using the Physical Health Summary Score (PHS) of the Medical Outcomes Study HIV Health Survey, a health status measure that has been used extensively in HIV/AIDS. The MOS-HIV (distributed by the Medical Outcomes Trust) contains 35 items that cover 11 dimensions of health. The 10 dimensions included in the PHS are: physical functioning, mental health, health distress, quality of life, cognitive functioning, vitality,

pain, role functioning, social functioning, and general health. The health transition dimension (comparing current health to health 4 weeks ago) is not included in this summary score. The PHS is scored using a method that transforms the scores to a T-score (a mean of 50 and a standard deviation of 10). Mean PHS scores above or below 50 can be interpreted as having better or worse health-related quality of life than the HIV-infected patient sample from which the summary measures were developed; patients reporting worsening health status had significantly lower mean PHS scores than patients reporting stable or improving health status (Revicki, Sorensen, & Wu, 1998). In testing performed by the researchers of the parent study, the MOS-HIV's subscales had Cronbach's alphas ranging from .67-.93. The mental health subscale had the lowest score (.67) followed by the role functioning scale (.84) (J.A. Erlen, personal communication, November 20, 2006). The Cronbach's alpha for the MOS-HIV with the study sample was .702. A copy of the instrument can be found in Appendix C.

4.3.6 Depressive Symptoms

Depressive symptoms were measured using the Beck Depression Inventory II (BDI-II). The BDI-II can be used to detect depressive symptoms in a primary care setting, and is intended to measure the intensity, severity and depth of the depressive symptoms. The BDI-II includes depressive symptoms like hopelessness and irritability, cognitions such as guilt or feelings of being punished, and physical symptoms (e.g. fatigue and weight loss). The BDI-II is a 21-item self-report tool assessing the degree of self-reported depression over the prior 2 weeks. The tool collects continuous, approximately interval level data. There is extensive research support for the reliability and validity of this measure. In research conducted by the tool developers, the alpha coefficient was .92 and the BDI-II showed high content and construct validity. (Beck, Steer, &

Brown, 1996). In testing performed by the researchers of the parent study with an HIV-positive population, the BDI-II had a Cronbach's alpha of .91 (n=212) (J.A. Erlen, personal communication, November 20, 2006). For this study sample, the Cronbach's alpha was .942. A copy of the instrument can be found in Appendix C.

4.3.7 Perceived Burden of Illness

Perceived burden of illness was measured using two visual analog scales developed for the parent study that ask the subject to score the impact of regimen complexity and side effects on their daily lives. The first asks the subject to rate the complexity of their medication regimen on a scale ranging from 0 (not complex) to 100 (very complex). Participants are also asked to rate the impact of side effects on daily life from 0 (no effect) to 100 (greatly effects). Data from the visual analog scale are continuous, approximately interval level data. A copy of the instrument can be found in Appendix C.

4.3.8 Social Support

Social support was measured using the composite score of the Interpersonal Support Evaluation List (ISEL) (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). The ISEL was designed to assess the perceived availability of four separate functions of social support as well as providing an overall support measure. The items which comprise the ISEL fall into four 10-item subscales. The total score was used in the analysis. ISEL scores are continuous, approximately interval level data. The "tangible" subscale is intended to measure perceived availability of material aid; the "appraisal" subscale assesses the perceived availability of

someone to talk to about one's problems; the "self-esteem" subscale assesses the perceived availability of a positive comparison when comparing one's self to others; and the "belonging" subscale assesses the perceived availability of people one can do things with. This 40-item tool focuses on available resources; higher scores suggest higher social support. Cohen et al. report alpha coefficients of .88-.90 for the whole scale (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). In testing performed by the researchers of the parent study with an HIV-positive population, the ISEL total score's Cronbach's alpha was .96 (n=205) (J.A. Erlen, personal communication, November 20, 2006). The Cronbach's alpha on the total ISEL for the study sample was .956. The subscale Cronbach's alphas were: appraisal, .880; belonging, .864; tangible, .872; and self esteem, .786. A copy of the instrument can be found in Appendix C.

4.3.9 HIV-Related Stigma

Stigma was measured using the HIV-related Stigma Scale to assess the perception by persons that they (or others with HIV) are being viewed as different by society because they possess traits viewed negatively. The 40-item tool has four subscales: personalized stigma, disclosure concerns, negative self-image, and concern over public attitudes toward people with HIV. Each subscale collects continuous, approximately interval level data. Personalized stigma is the experience of actually being rejected or perceiving rejection based on HIV status. Disclosure concerns refer to whether or not an individual tells others of their diagnosis. Negative self-image is whether or not having HIV makes one feel badly about oneself (i.e. shame, feeling "unclean"). Concern over public attitudes toward people with HIV includes discrimination, employability and the reactions of the public to people with HIV. All items are answered using a 4-point Likert-type scale (*strongly disagree, disagree, agree, and strongly agree*). The scale has

coefficient alphas ranging from .90-.93 (subscales) to .96 (whole scale) (n=318) (Berger, Ferrans, & Lashley, 2001). In testing performed by the researchers of the parent study, the Cronbach's alpha of the stigma sub-scales ranged from .89-94 (J.A. Erlen, personal communication, November 20, 2006). The Cronbach's alpha for the study sample was .954. The subscale Cronbach's alphas were: personalized stigma, .925; disclosure, .857; negative self image, .851; and public perceptions about HIV, .892. A copy of the instrument can be found in Appendix C.

4.3.10 Relationship with Healthcare Provider

A one-item questionnaire that asks participants to rate their relationship with their healthcare provider on a scale from 1 (very poor) to 10 (excellent) was used to assess relationship with health care provider. The data collected are continuous, ratio level data.

4.4 DATA COLLECTION PROCEDURES

The data used in this study were obtained during the baseline data collection session of the parent study. At the first visit, subjects gave informed consent, were screened for inclusion, and then enrolled into the study. They were instructed in the use of the diary and the electronic event monitor (EEM). One month later participants were mailed a booklet of questionnaires, allowing the subject to complete the measures at home. Participants were contacted via telephone to ascertain whether they received the booklet and to schedule their appointment with the data collector. The subject then returned for baseline data collection at which time the data from the

EEM were downloaded, the functional health literacy tool was administered, and the remaining questionnaires were completed. These data were collected prior to randomization in the parent study.

4.5 PROTECTION OF HUMAN SUBJECTS

Internal Review Board (IRB) approval under exempt status was obtained from the University of Pittsburgh Institutional Review Board prior to beginning this secondary analysis using existing data from "Improving Adherence to Antiretroviral Therapy" (2R01 NR04749) (see Appendix A for IRB approval letter). Only baseline data (questionnaires, subject profile, and electronic-event-monitoring data) were used. The data were collected between 2004 and 2007 and were stored in the Principal Investigator's (Dr. J. Erlen) secure database at the School of Nursing. All data were de-identified (free of all identifying information) as required to meet criteria for IRB exempt status. Any risks associated with this planned study were believed to be minimal. All data were compliant with the most current guidelines of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. This information was for study purposes only. All data were kept in a secure and locked file cabinet. All data were obtained specifically for research purposes and for future dissemination of findings. All data were reported as group data to ensure participant confidentiality and anonymity. Separate IRB approval was obtained for this secondary data analysis.

4.6 DATA SCREENING PROCEDURES

The data from the parent study were collected using pre-coded forms and processed using Teleform®, a Windows-based software for automated data entry. Oracle (version 9i, Oracle Corporation, Redwood Shores, CA) was used for data management. Event data from the AARDEX EEM caps were downloaded using PowerView and merged into an Oracle database. SPSS (version 15.0, SPSS Inc., Chicago, IL 2006) was used for the majority of the analysis. SAS (version 9.1.3, SAS Institute, Inc., Cary, North Carolina, 2004), was used for the exact estimation logistic regression modeling required for Specific Aim 2.

A detailed descriptive analysis of all quantitative data was performed, involving the summarization of data and the use of inferential and graphical exploratory data analytic techniques. All univariate data were initially screened for accuracy of input using frequency reports, means, and standard deviations. Bivariate correlations were examined for expected direction, based on existing literature. Mean scores on the functional health literacy tool were significantly higher that expected. Entered data were checked against original data, scoring was confirmed, and the administration procedure for the tool was assessed for accuracy and standardization across examiners to ensure accuracy of the data. This further examination did not reveal any problems with accuracy on the S-TOFHLA tool and the data were deemed accurate and reliable. Examination of the remaining statistics did not identify problems with data accuracy.

The information obtained from this preliminary investigation was used to: 1) describe univariate and bivariate sample distributions of the data; 2) identify the interrelationships between variables (i.e., need for covariate adjustment); and 3) check for the violation of

assumptions underlying identified statistical techniques (e.g. normality, linearity, homoscedasticity).

4.6.1 Normality

Normality was assessed using SPSS descriptive statistics, histograms, residual distributions, skewness and kurtosis. Data transformation (e.g. square root transformation, categorizing data) was considered for any variable not meeting this underlying assumption. Functional health literacy had a non-normal distribution, but was categorized for the correlation and logistic regression analyses. Other variables demonstrating non-normality did not approximate normality with transformation.

Most SEM estimation methods assume multivariate normality (e.g., ML, GLS) (Kline, 2005). The change in the analysis made it unnecessary to complete this data screening procedure. Measured variables would have been examined for multivariate and univariate outliers (as above), including inspection of skewness and kurtosis through visual inspection of frequency distributions and skewness and kurtosis indexes. EQS also screens for multivariate normality. If statistical assumptions were severely violated, data transformations or more statistically robust procedures (i.e., Satorra-Bentler scaled chi-square, or Browne's asymptotic distribution free) would have been employed. Certain variables, such as depressive symptoms, were expected to have non-normal distributions in the population; with these variables, the analysis would have employed an estimation that specifically addresses non-normality (Ullman, 2001). Non-normality is addressed in the analysis section for Specific Aim #3.

4.6.2 Univariate and Multivariate Outliers

A visual screening of histograms and box plots was used to identify univariate outliers, while multivariate outliers were evaluated statistically using Mahalanobis distance. Mahalanobis distance at $p < .001$ was used as the cut-off criteria (Ullman, 2001). Outliers were evaluated for possible omission; this included assessment of missing data patterns, addressed below. All identified outliers were deemed to be valid members of the population and representative of the variability in the scales.

4.6.3 Linearity and Homoscedasticity

Linear relationships among pairs of measured variables were evaluated through visual inspection of bivariate scatter plots. Problems with homoscedasticity would have been corrected using data transformations, but this was not necessary.

4.6.4 Missing Data

Analysis of incomplete data to determine patterns of missing data were completed using the Missing Value Analysis in SPSS. Less than 5% of subjects were missing data on all variables. Evaluation of the patterns of missing data indicated that the data were missing at random. Mean imputation was used to estimate missing values on all continuous variables.

4.6.5 Multicollinearity

If intercorrelations between variables are too high, certain mathematical operations are not possible; this may occur because separate variables are actually measuring the same thing. Multicollinearity was assessed by evaluating 1) the correlation matrix for all of the variables, identifying correlations >.90; 2) tolerance values, with values <.10 indicating multicollinearity; and 3) variance inflation factor (VIF), with values >10 indicating possible multicollinearity (Kline, 2005; Ullman, 2001). None of the variables had inter-correlations greater than .90 and all tolerance and VIF factors fell within the acceptable limits. Interaction terms (used in logistic regression) typical demonstrate problems with multicollinearity. To avoid this problem, continuous variables entered as interaction terms in the logistic regression model were centered. Multicollinearity was not found to be a problem with the measures in this study.

Preliminary analysis also examined 1) population representativeness of the sample as a result of exclusions or dropouts, and 2) the internal consistency and validity of established scales. The internal consistency of scales was estimated using Cronbach's coefficient alpha or, if items were binary, Kuder-Richardson formula 20.

4.7 DESCRIPTIVE STATISTICS

Descriptive statistics included frequencies, measures of central tendency, and variability, and exploration of relationships. Choice of the measure of central tendency (mean, median or mode) was based on the distribution of data and which statistic provided the most meaningful

information. Frequencies are provided for all categorical variables (socio-demographic variables, and detectable viral load). Continuous variables that had a skewed distribution were assessed using a median; this included functional health literacy, adherence, self-efficacy, depression, and CD4 counts. Mean scores were used with continuous variables with distributions approximating normal.

Specific Aim 1: Examine functional health literacy rates in people living with HIV who are taking antiretroviral medication.

Analysis: Appropriate descriptive statistics (e.g., mean, median, standard deviation, range) based on the empirical distribution of the data were used to characterize the sample of people living with HIV with respect to functional health literacy as measured by the two S-TOFHLA scales, reading and numeracy. Additionally, subjects were classified as having adequate or marginal/inadequate levels of functional health literacy. For each level of functional health literacy, frequency counts and percentages were computed. In addition to point estimates, corresponding interval estimates (95% confidence intervals) were obtained.

4.8 INFERENTIAL STATISTICS

Specific Aim 2: Examine the associations between selected socio-demographic variables (age, gender, race, educational background, marital status, employment, income, and current alcohol/drug use), HIV disease history variables (CD4 count, viral load, and number of HIV medications) and functional health literacy.

Analysis: Contingency table analyses with chi-square test for independence or Fisher's exact test (with sparse cell numbers), and non-parametric group parametric analysis using Mann-

Whitney U were conducted to discern bivariate relationships between selected socio-demographic factors and functional health literacy (two S-TOFHLA scales and the derived levels of functional health literacy) based on the level of measurement and the empirical distributions of variables under investigation. Univariate binary logistic regression analyses were performed to estimate crude odds ratios and then multivariate binary logistic regression was used to examine the joint relationship of functional health literacy (dichotomized) with socio-demographic factors showing a moderately significant relationship with functional health literacy ($p<.2$). Categorical factors (e.g., gender, race) were dummy coded for the regression analyses. Main effects and interactions effects were evaluated for each of the sociodemographic variables as predictors of functional health literacy.

Due to the distribution of the functional health literacy data and the small numbers of subjects having inadequate/marginal functional health literacy, exact estimation (in SAS using PROC LOGISTIC) was used to examine the models with functional health literacy as the dependent variable. Exact inference is the appropriate analytic technique when sample or cell sizes are very small or unbalanced. The results of the exact procedures are not reliable for overall goodness of fit because some of the cells contained no cases; therefore these models were evaluated based only on odds ratios and their respective p-values. The two-tailed statistical significance level was set a priori at .05.

4.9 STRUCTURAL EQUATION MODELING

NOTE: The following discussion reflects the original analysis plan for the study. Due to limitations imposed by the distribution of the data, specifically very high functional health

literacy rates, the proposed SEM analysis was not possible. Instead the Specific Aims were accomplished using the contingency plan (found at the end of this chapter) that was implemented upon detection of the issue. Both the original plan and the contingency plan are included here for clarity and comprehensiveness.

Specific Aim 3: Describe the relationships among functional health literacy, medication-taking self-efficacy, and HIV medication adherence in persons living with HIV.

Analysis: Path analysis was to be used to fit the hypothesized model suggested by Bandura's Social Cognitive theory, where the relationship between functional health literacy and HIV medication adherence is mediated by medication taking self-efficacy. Path analysis was originally chosen because it allows for the simultaneous testing of the model, whereby regression weights predicted by the model are compared with the observed correlation matrix for the variables, and a goodness-of-fit statistic is calculated. The best-fitting of two or more models is selected by the researcher as the best model for advancement of theory (Kline, 2005). For this model the researcher would have assumed that the variables in the model were measured without error, residuals (unexplained variance in endogenous variables of medication taking self-efficacy and HIV medication adherence) were uncorrelated, and the model was recursive (i.e., flows in one direction; no feedback). Functional health literacy would have been assessed by a composite score of the two subscales of the S-TOFHLA. Medication self-efficacy would have been assessed using the Erlen Medication Self Efficacy Tool, self-efficacy subscale. Adherence would have been measured using EEM adherence indexes. Each measurement tool would have yielded one score to be used in the path analysis. All instruments are described in detail in the measurement section. EQS (available version) would have been used to fit the path analysis model.

In path analysis, the steps are model 1) specification; 2) estimation; 3) evaluation; and 4) modification (Ullman, 2001). Each step is outlined below.

Model Specification Figure 7 is the visual representation of the proposed model.

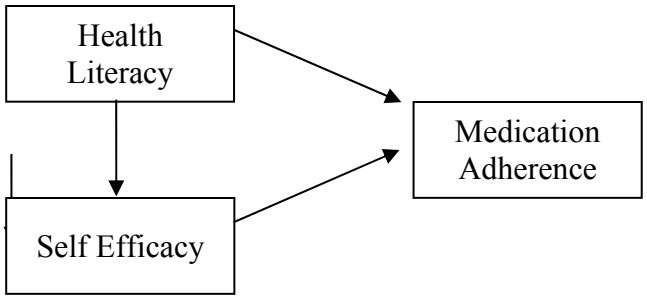

Figure 7: Path Analysis for Specific Aim #3

Model Estimation Path coefficients would have been estimated to summarize the impact of one variable on another. The correlations among the variables specified in the model would have been decomposed into direct, indirect, and total effects (= direct effects + indirect effects). This recursive path model would have been estimated using maximum likelihood (ML) estimation, in which the estimators are those that maximize the likelihood that the data from the sample were drawn from the population. Each of the measured variables in the model was continuous and was expected to be normally distributed (or able to be transformed to approximate normality). In the event that the data failed to demonstrate multivariate non-normality and could not be suitably transformed, a more robust approach for parameter estimation would have been considered (e.g., the Bollen-Sline bootstrap and Satorra-Bentler adjusted chi-square for inference of exact structural fit in EQS) (Kline, 2005; Ullman, 2001).

Model Evaluation R-squared values would have been estimated to determine the amount of variance in the endogenous variables (medication taking self-efficacy, HIV medication adherence) accounted for by variables in the model. Residuals would have been estimated to summarize the amount of variance not explained by the variables in the model. Following model fitting, the adequacy of the model would have been evaluated in terms of the feasibility of parameter estimates and appropriateness of standard errors as well as the importance of the parameter estimates. To assess the importance of parameters estimated, t-statistics, computed as the ratio of the estimated parameters to their standard errors, would have been used to determine whether parameter estimates are statistically different from zero at a significance level of .05. The goodness-of-fit of the path model would have been assessed using two credible fit indices: the comparative fit index (CFI) and the root mean square error of approximation (RMSEA). Bentler's (1990) CFI estimates the proportion of improvement of the specified covariance model beyond the null model (Bentler, 1990). CFI also adjusts for bias due to sample size. Values of CFI range between 0 and 1, with a value greater than .95 suggesting that the model fits reasonably well. Steiger and Lind's (1980) RMSEA provides information on how the specified structure does not fit the estimated population values (Steiger & Lind, 1980). A RMSEA value of .08 or less indicates reasonable error of approximation in the sample, while values less than .05 represent a close fit. Confidence intervals for RMSEA would have been estimated to assess its precision and tests of closeness of fit. Other goodness-of-fit indices (e.g., NNFI, GFI) would have been be considered as appropriate, including Satorra-Bentler scaled chi-square and cut-off criteria recommended by Hu and Bentler (Hu & Bentler, 1998, 1999). Hu and Bentler (1999) recommend evaluation of models with a two-index strategy that include MFI for samples with

less than 250 subjects. None of the goodness-of-fit indices would have been credible given the small proportion of people with less than adequate functional health literacy.

Model Modification The resultant model would have been modified with the goal of finding a parsimonious model that fits the data reasonably well. Model misspecification would have been investigated by thoroughly examining residuals (discrepancies between the restricted covariance matrix as implied by the hypothesized model and the observed sample covariance matrix) and modification indices. The basic methods of modification would have been change in chi-square, Lagrange multiplier tests (LM) and Wald tests. The change in chi-square evaluates the difference in chi-square and degrees of freedom between two nested models. The change is evaluated to determine if there is a statistically significant difference when a specific parameter(s) is added and/or freely estimated in a subsequent fitting of the model. The LM test provides information on parameters that should be added to the model to improve the fit. Parameters would have been added to the model only if, in addition to improved model fit, the addition makes theoretical sense according to the existing literature as substantive criteria are more important than statistical criteria. Alternatively, the Wald test provides an evaluation of which parameters should be deleted to improve the fit of the model. Again, substantive criteria are more important than statistical (Ullman, 2001). These modification indices would have been used for exploratory post hoc analyses (i.e., specification searches) to develop revised structural equation or path models for future confirmation in an independent study. When fitting the path model, the need for covariates (e.g., age, gender, highest education level) would have been considered as indicated by the findings of the preliminary analysis and the research literature.

Specific Aim 4: Investigate the inter-relationships among the factors related to adherence within the constructs of Bandura's Social Cognitive Theory: a) individual

factors (functional health literacy, medication taking self-efficacy, functional health status, depressive symptoms, and perceived burden of illness); b) environmental factors (social support, HIV-related stigma, and relationship with health care provider); and c) the health behavior (HIV medication adherence).

Analysis: A similar analytic approach conducted to address Specific Aim 3 would have been performed to investigate the hypothesized role of functional health literacy, including the mediational effect of medication taking self-efficacy on the relationships between the observed endogenous variables of depression, burden of illness, social support, HIV-related stigma, physical health status, and relationship with health care provider and the observed endogenous variable HIV medication adherence. Because of the limitations of the available research in health literacy, this analysis was exploratory in nature, and was considered to be potentially hypothesis generating. Figure 8 is the visual representation of the proposed model. Additionally, when fitting these models, the need for covariates (e.g., age, gender) would have been explored by evaluating correlations and relationships among the variables.

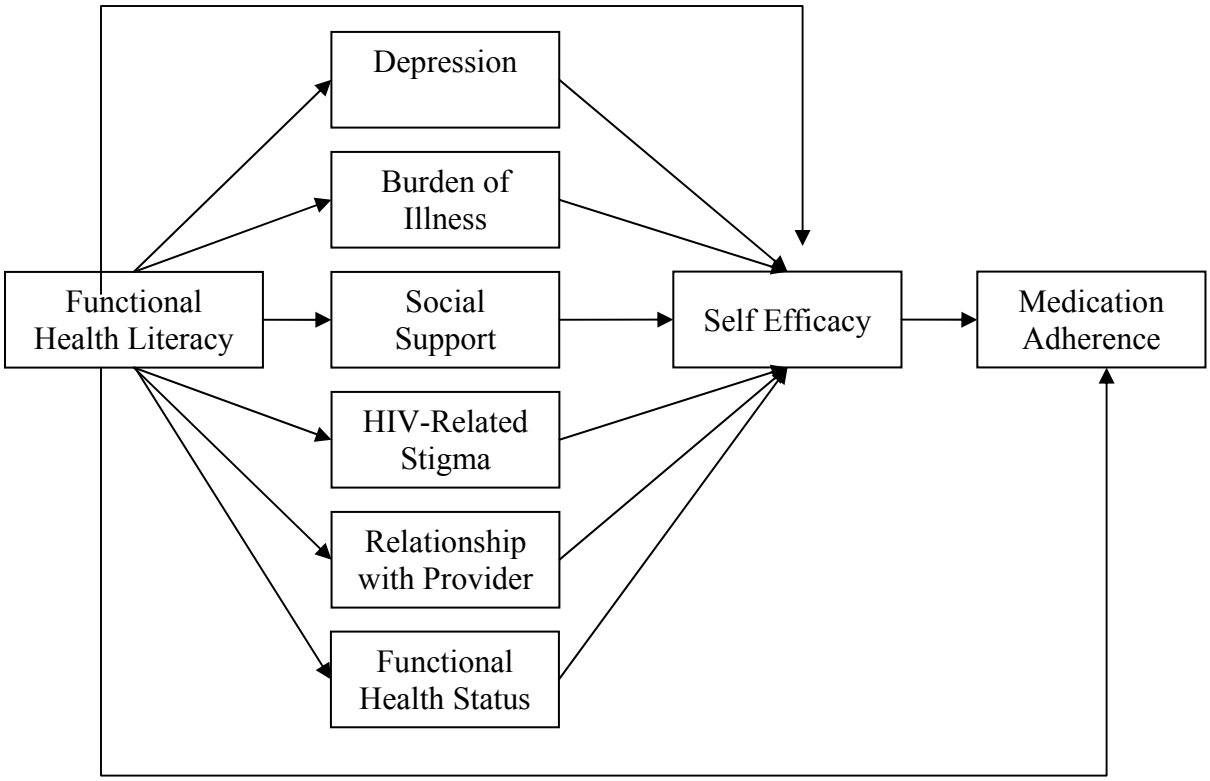

Figure 8: Path Analysis for Specific Aim #4

The same steps for model specification, estimation, evaluation and modification outlined in Specific Aim #3 would have been employed. As for Specific Aim 3, modification would have been used for exploratory post hoc analyses to develop revised structural equation models to be tested in future studies.

4.10 SAMPLE SIZE CONSIDERATIONS

The sample size for this study was pre-determined by the maximum sample size of the parent study (up to 350). Hence the expected precision of estimators and the minimum detectable effect size were determined. Since some missing data were to be expected, a minimum complete sample size of 240 was conservatively set to investigate the expected precision of estimators and the minimum detectable effect size. For a confidence coefficient of .95 with a minimum of 240 subjects, mean S-TOFHLA scores may be estimated with .127σ precision (or margin of error), where σ is the population standard deviation for functional health literacy based on the S-TOFHLA, while proportions for functional health literacy levels may be estimated with .053 precision, assuming a baseline proportion of 18-20%. When investigating associations between socio-demographic factors and functional health literacy, bivariate correlation coefficients as small as .180 and multiple correlation coefficients (based on models with at most 5 predictor variables) as small as .042 may be detected with .80 power with a minimum of 240 subjects at a significance level of .05. For more complicated multiple regression models (> 5 predictor variables) slightly larger multiple correlation coefficients (.053 for models including 10 predictors and .061 for models including 15 predictors) would be detectable with .80 power at a two-tailed significance level of .05. In terms of fitting a path analysis model, Bentler and Chou (1987) recommend at least a 5:1 ratio of cases to parameters when using SEM with elliptical (normal) distributions. A larger ratio of cases to parameters, on the order of 10 to 15:1, should be considered when data are non-normal or incomplete (Bentler & Chou, 1987). Boomsma (1983) has also recommended a sample size of about 200 when fitting small to medium sized structural equation models as proposed in this study (Boomsma, 1983). For the path analysis in specific aim #3 there were six parameters to be estimated (3 regression coefficients, 2 residual variances,

1 exogenous variance). For specific aim #4 there were 24 parameters to be estimated (15 regression coefficients, 8 residual variances, 1 exogenous variable). According to ratios detailed above, both of the proposed path analyses reach optimal ratios for adequate sample size. Hence, the projected sample size of at least 300 subjects would permit the stable estimation of the 15 parameters specified in the model, with 15 degrees of freedom, as well as allow for the omission of up to 60 cases (20.0%) due to extensive missing data (240 complete cases), if the hypothesized functional health literacy rate had been assessed to be 80% or less. However, the final proportion of high functional health literacy over 90% prevented the stable estimation of the parameters via SEM.

4.11 CONTINGENCY PLAN

The proposed data analysis plan was predicated on one major assumption about the data being collected: low functional health literacy rate in the sample population would fall relatively close to the published rates in similar populations (18-20%). Since this was not the case, it became necessary to adjust the analysis plan for this study. The following contingency plan, delineated for each specific aim, explains the alternative approach.

4.11.1 Specific Aim 1

Examine functional health literacy rates in people living with HIV who are taking antiretroviral medication.

Analysis: This analysis remained the same, as described above.

4.11.2 Specific Aim 2

Examine the associations between selected socio-demographic variables (age, gender, race, educational background, marital status, employment, income, and current alcohol/drug use), HIV disease history variables (CD4 count, viral load, and number of HIV medications) and functional health literacy.

Analysis: This analysis remained the same, as described above.

4.11.3 Specific Aim 3

Explore the relationships among functional health literacy, medication-taking self-efficacy, and HIV medication adherence in persons living with HIV.

Analysis: Due to the small sample size of persons with lower functional health literacy level, path analysis could not be employed for Specific Aim 3.

A descriptive analysis that included measures of central tendency (mean median, mode), range, and standard deviation was conducted to describe functional health literacy and medication adherence in this sample. Bivariate analyses were again conducted to examine the relationships between functional health literacy and various subject characteristics, based on the level of measurement and the empirical distributions of variables under investigation. Independent sample t-tests were used for continuous variables and χ^2 analyses for categorical variables.

Logistic regression was employed to fully examine the relationships among functional health literacy, self-efficacy, and medication adherence. Socio-demographic and health history variables that were determined to be significantly related to functional health literacy ($p<.2$) in

the bivariate analysis results were included in the full model. Initially, univariate analysis examined the individual relationships between the variables. Then all possible two-way interactions were assessed, entering individual interaction terms in the full model containing the full set of candidate predictors. Separate hierarchical logistic regression models were produced to include age, gender, race and educational level as covariates, with adherence again as the dependent variable. Finally, the resultant models were evaluated and modified to include only significant relationships and to provide the most parsimonious model.

Employment of the data analysis contingency plan required that the data meet different assumptions and conduct separate diagnostics than the original plan. Assumptions that were met immediately by the characteristics of the sample included: 1) adequate sample size to number of predictors and 2) independence of all cases. Logistic regression does not depend on normality or linearity of the predictors, although this may enhance power. The data set was tested for multicollinearity (as described in the previous section) and linearity in the logit. Linearity in the logit describes a linear relationship between continuous predictors and the logit transformation of the dependent variable. This was tested by running a logistic model with the DV (adherence dichotomized) predicted by each of the continuous variables (age, years of education, and self efficacy) plus the interactions between each predictor and its natural log. None of the values were significant (all p–values were less than.120); therefore this assumption was not violated.

4.11.4 Specific Aim 4

Investigate the inter-relationships among the factors related to adherence within the constructs of Bandura's Social Cognitive Theory (SCT): a) individual factors (functional health literacy, medication taking self-efficacy, functional health status, depressive

symptoms, and perceived burden of illness); b) environmental factors (social support, HIV-related stigma, and relationship with health care provider); and c) the health behavior (HIV medication adherence).

Analysis: Due to the small sample size of persons with lower functional health literacy level, path analysis was not possible with this sample. The relationships between functional health literacy and the individual SCT factors related to adherence identified were investigated using descriptive statistics and the bivariate analysis used for Specific Aim #3. The relationships among functional health literacy, medication-taking self efficacy, and medication adherence were explored in great detail in Specific Aim #3. The limited sample precluded the more advanced path analysis; therefore, this analysis was restricted only to functional health literacy and the remaining factors, and in a separate analysis, adherence and the remaining factors. Bivariate relationships were assessed using the same approach as Specific Aim #3. In order to differentiate the potential additional explanatory power of functional health literacy over educational level, the analysis included a comparison between the two.

Finally, a set of logistic regression models with adherence as the dependent variable were used to assess the predictive power of the significant variables. Variables that demonstrated a significant relationship ($p<.2$) with adherence were then entered into a logistic regression model to estimate the strength of the relationship. A hierarchical logistic regression model then tested the same set of candidate predictor variables after controlling for those socio-demographic factors shown to be associated with adherence in Specific Aim #3.

The analysis also included examining the bivariate relationship between the SCT variables and the 8-item Numeracy Scale, comprised of all 8 items of the original TOFHLA (4 of which are used to score the S-TOFHLA). The approach included a psychometric analysis of the

Numeracy Scale. The purpose of the additional psychometric analysis was to examine the reliability and the factor structure for the Numeracy Scale. Reliability was assessed using Cronbach's alpha, item analysis and inter-item correlations. Exploratory factor analysis was performed to assess the construct validity and dimensionality of the Numeracy Scale. Principal component analysis with a varimax rotation was the extraction method used.

5.0 MANUSCRIPT: #1 RESULTS AND DISCUSSION

(Preliminary title: "A Descriptive Analysis of Functional Health Literacy in People Living with HIV/AIDS")

This manuscript provides the results for Specific Aims 1 and 2. The document was prepared as an original report to be submitted to a journal with an HIV/AIDS clinician readership.

5.1 ABSTRACT

Health literacy has been shown to be related to multiple health outcomes and may be an issue of great importance in the management of a chronic and complicated disease like HIV. The objectives of the study were to describe functional health literacy in people living with HIV/AIDS who are taking antiretroviral medications and to examine potential socio-demographic predictors of functional health literacy.

The study was a cross-sectional, secondary data analysis of 335 people living with HIV/AIDS who were taking antiretroviral medications. We measured functional health literacy using the S-TOFHLA, and collected additional socio-demographic and HIV health history information. Measures of central tendency and dispersion were used to describe functional health literacy. Bivariate analyses and logistic regression were conducted to examine the relationships between functional health literacy and various participant characteristics. Multivariate logistic

regression was used to examine the socio-demographic and HIV health history predictors of lower functional health literacy.

Overall, 10.4% (n=35) of the participants were classified as having inadequate/marginal functional health literacy, based on a cut-off of 75 on the S-TOFHLA. Race, educational level, and the interaction between race and educational level predicted functional health literacy in this sample. Univariately, income also predicted functional health literacy, but this was not significant in the multivariate model when other factors were included.

Further research is needed to fully understand the scope and breadth of functional health literacy issues for people living with HIV. These results indicate that people disproportionately represented in the HIV population, such as African-Americans and those with less education, may be more at risk due to issues related to functional health literacy.

5.2 INTRODUCTION

In 2003, Surgeon General Richard Carmona called health literacy "the currency for success for everything we do in primary and preventive medicine" (Carmona, 2003). Without adequate "currency," individuals may not achieve the same health goals as others with higher proficiency levels. Low functional health literacy is a significant societal issue, and is even more critical for the person living with a chronic disorder or health problem such as HIV/AIDS, who probably has more frequent and complicated interactions with all aspects of the health care delivery system (U.S. Department of Health and Human Services, 2000).

Researchers currently estimate that 20-25% of people living with HIV/AIDS demonstrate inadequate or marginal functional health literacy, a rate similar to that of the general population

(Kalichman et al., 2000; Kalichman & Rompa, 2000b; Rudd, Kirsch, & Yamamoto, 2004). The Centers for Disease Control and Prevention (CDC) estimates that 1 million people are living with HIV in the U.S. and approximately 40,000 new people are infected annually (Centers for Disease Control and Prevention, 2003b). Prolonged survival, attributed almost exclusively to the advent of antiretroviral treatment, requires strict adherence to medication therapy and places significant demands on individuals with low functional health literacy (D. R. Bangsberg et al., 2001; Carrieri et al., 2003; de Olalla et al., 2002). Additionally, the unique pressures of living with chronic disease, such as preventing transmission and maintaining healthy behaviors, create a higher demand for self-management ability.

In patients with HIV/AIDS, lower functional health literacy has also been associated with poorer health outcomes—specifically, lower CD4 cell count and higher viral load (Kalichman & Rompa, 2000b). Researchers examining reading levels in an HIV-positive population found that 2/3 of those reading below a ninth-grade reading level did not know how to take their medications correctly and 1/3 of them could not name their medications (Wolf et al., 2004). Several studies have shown functional health literacy to be associated with decreased knowledge about HIV and the treatment regimen (Hicks, Barragan, Franco-Paredes, Williams, & del Rio, 2006; Kalichman et al., 2000; Kalichman & Rompa, 2000b). The importance of this finding is highlighted when viewed in the context of work from Miller, Lui, and Hays (2003) and Weiss et al. (2003); the two research teams found decreased knowledge to be associated with poorer medication adherence.

There are several demographic variables potentially associated with functional health literacy. In order to design interventions to improve health outcomes, it may be useful to have a better understanding of which individuals are at higher risk for having lower functional health

literacy. Researchers describing health literacy in people living with HIV have found a significant relationship between functional health literacy and race (Kalichman et al., 2000; Wolf et al., 2005) and functional health literacy and socio-economic status (Wolf et al., 2007). Socio-demographic variables may also provide some additional information regarding the relationship between functional health literacy and health behaviors or outcomes. For example, Osborn et al (2007) found that health literacy moderated the relationship between race and HIV medication adherence. As pointed out by Osborn, et al (2007), the relationship between functional health literacy and socio-demographic variables, such as race or income, may be an important component in research that seeks to reduce racial disparities in health and health care.

An increase in research related to functional health literacy has resulted in significant variance in the way that the concept is assessed and reported. There is general agreement that functional health literacy, especially as measured using the existing instruments such as the Rapid Estimate of Adult Literacy in Medicine (REALM) and Test of Functional Health Literacy in America (TOFHLA) is best analyzed as a categorical variable, in order to properly recognize its "threshold" effect. Developers of the S-TOFHLA tool categorized participants as having adequate functional health literacy if the score was 67-100, marginal functional health literacy if it was 54-66, and inadequate functional health literacy if the score was 0-53 (Baker, Williams, Parker, Gazmararian, & Nurss, 1999). However, there is some discrepancy across studies about the appropriate cut-off point between functional health literacy levels. Kalichman, Ramanchandran, and Catz (1999), using an amended version of the S-TOFHLA with HIV specific content added, considered those with greater than 85% correct to have higher functional health literacy. In a different study examining HIV knowledge, Kalichman et al. (2000) used a cut-off of 80% as the distinction between higher and lower functional health literacy. Golin

(2002), conversely, used the S-TOFHLA reading comprehension section as a continuous variable in model testing. In more recent studies, Paasche-Orlow et al. (2006) and Wolf et al. (2006) both used the REALM, with grade level cut-off points (less than 6^{th} grade as inadequate, 7^{th}-8^{th} grade as marginal, and 9^{th} grade and higher as adequate). Studies using the S-TOFHLA in other populations have used cut-off points varying from 67-75 for inadequate/marginal. These variations make it difficult to compare results across studies and suggest a need for further descriptive research into the functional health literacy status of people living with HIV/AIDS.

The primary purposes of this descriptive study were to describe functional health literacy in people living with HIV/AIDS who are taking antiretroviral medication and to examine the potential socio-demographic and HIV health history predictors of functional health literacy. Based on the existing literature, it was hypothesized that 18-20% of this sample would have lower functional health literacy. Additionally, we hypothesized that functional health literacy would be univariately associated with educational level, but not other socio-demographic variables (age, gender, race, marital status, employment, income, and current alcohol/drug use) or HIV health history variables (CD4 count, viral load, or number of HIV medications). Finally, we explored the potential of the Numeracy Scale as an assessment tool for describing functional health literacy is this sample, using 8-items from the expanded health literacy tool.

5.3 METHODS

5.3.1 Design

The design of this secondary analysis was descriptive and cross-sectional. The parent study, "Improving Adherence to Antiretroviral Therapy" (2R01 NR04749), is an ongoing randomized clinical trial testing the efficacy of two interventions designed to promote and sustain adherence when people with HIV are taking antiretroviral medicine. Separate Institutional Review Board approval (IRB) was obtained for both the parent study and this secondary data analysis. For this secondary analysis, an honest broker was used to de-identify all data before they were provided to the researcher.

5.3.2 Procedure

Participants for the parent study were recruited from Western Pennsylvania and Northeastern Ohio via clinics and community organizations serving people living with HIV/AIDS. All participants from the parent study who completed the functional health literacy assessment were included. In order to be eligible for the parent study, participants had to be 18 years of age or older, able to speak and understand English, free from HIV-related dementia as evidenced by assessment using an HIV dementia tool (C. Power, Selnes, Grim, & McArthur, 1995), prescribed HIV medications, self-administering the prescribed HIV-antiretroviral medication, and not living with a current participant in the study. The sample for this secondary analysis was 335 participants.

The data used in this study were obtained during the baseline data collection session for all participants. At the first visit, subjects were asked to give informed consent, and were then screened for inclusion and enrolled into the study. They were instructed in the use of the diary and the electronic event monitor (EEM). One month later participants were mailed a booklet of questionnaires, allowing them to complete the self-administered measures at home. The subjects then returned for baseline data collection, at which time the data from the EEMs were downloaded, the functional health literacy tool was administered, and the remaining questionnaires that required face to face format or that they be timed were completed. These data were collected prior to randomization in the parent study.

5.3.3 Instrumentation

Socio-demographic information was collected using the Center for Research in Chronic Disorders (CRCD) Socio-demographic Questionnaire which included questions about age, race, gender, years of education completed, marital status, income level, health insurance, and primary language. The Medical Record Review was used to collect data on CD4 count, viral load, alcohol/drug use history, and medication regimen. Self-report of CD4 count and viral load (dichotomized to detectable/undetectable) were collected using the Health Survey. The primary source for CD4 count and detectable/undetectable viral load data was the medical record; where available, self-report provided an additional data source.

Functional health literacy was measured using the Short Test for Functional Health Literacy (S-TOFHLA) (Baker, Williams, Parker, Gazmararian, & Nurss, 1999). The S-TOFHLA is a shorter version of the standard TOFHLA, which uses materials a patient may encounter in the healthcare setting. The test has two parts: 1) a 36-item test using a modified Cloze procedure

where every fifth to seventh word is omitted and four choices are offered on health-related documents (e.g. hospital instructions, Medicare enrollment forms; and dietary guidelines), and 2) a 4-item test using hospital forms and prescription bottles. For comparison with other research and to fully describe the functional health literacy of the sample, we examined functional health literacy as assessed by the S-TOFHLA both as a continuous variable and a categorical variable. The continuous variable was used in the analyses of central tendency, variance, and dispersion. For further analysis, we dichotomized functional health literacy at a cut-off value of 75—less than or equal to 75 indicating lower functional health literacy and higher than 75 equaling higher functional health literacy. For this sample of 335, Cronbach's alpha was .953 for the S-TOFHLA tool.

The researchers had a special interest in the numeracy items from the long version of the TOFHLA; these items are specific to the act of medication taking (i.e. reading and interpreting prescription labels). Four additional questions were included in the assessment of numeracy, for a total of 8 items. These additional items are not included in the S-TOFHLA score; thus the results were analyzed separately. All of the numeracy items are listed in Table 13.

5.3.4 Statistical Analysis

A descriptive analysis that included computing measures of central tendency (mean median, mode) and variance was conducted to describe the continuous functional health literacy data. Bivariate analyses were conducted to examine the associations between the dichotomized functional health literacy levels and various subject characteristics. Independent sample t-tests or the nonparametric Mann-Whitney U test was used for continuous subject characteristics to

examine difference between functional health literacy levels. Chi-square test of independence or Fisher's exact test was used for categorical participant descriptors.

Logistic regression was used to univariately and multivariately examine the relationships among the demographic/health history variables and the dependent variable of functional health literacy dichotomized at the 75-point cut-off score. Initially, univariate logistic regression was used to examine and estimate the relationships between functional health literacy and each of the individual descriptors determined to be significantly related to functional health literacy ($p<.2$) in the bivariate analysis (the candidate predictors). All of these candidate predictors were then entered simultaneously in a multivariate logistic regression model. Then all possible two-way interactions were assessed, entering individual interaction terms hierarchically into the multivariate model with the full set of candidate predictors. Finally, the resultant models were evaluated and modified to include only significant relationships ($p<.05$) and to identify the most parsimonious model.

Analysis was performed using SPSS (version 15.0, SPSS Inc., Chicago, IL) and SAS (version 9.1.3, SAS Institute, Inc., Cary, NC). Due to the distribution of the functional health literacy data, exact estimation (in SAS using PROC LOGISTIC) was used to examine the models with functional health literacy as the dependent variable. Exact inference is the appropriate analytic technique when sample or cell sizes are very small or unbalanced. The results of the exact procedures are not reliable for overall goodness of fit because some of the cells contained no cases; therefore these models were evaluated based only on odds ratios and their respective p-values. The two-tailed statistical significance level was set a priori at .05.

5.4 RESULTS

5.4.1 Sample Characteristics

Three hundred thirty-five (n=335) participants were assessed using the S-TOFHLA. The sample was primarily male (70.1%), with a mean age of 43.64 years. Over half (56.7%) of the participants were African-American. In subsequent sections, the classifications are white and non-white, as collected with self-report. Of those designated non-white (n=196, 58.5%), 96.9% (n=190) were African American. On average, participants had 13 years of formal education. Nearly 71% (n=237) reported household income of less than $13,000 per year, and 82.% (n=276) were not employed. Table 8 provides additional descriptive information about the total sample.

5.4.2 Functional Health Literacy, Socio-demographics, and HIV Health History

The findings in regard to describing functional health literacy in people living with HIV demonstrated that overall, 10.4% (n=35) of the participants were classified as having inadequate/marginal functional health literacy. S-TOFHLA total scores ranged from 7 to 100 and, as expected, were heavily negatively skewed, with a mean score of 90.01 (SD=12.97, 95%CI=88.62-91.41), median of 94 and mode of 98. Fifty-nine participants (17.6%) scored 100, and 69% scored 90 or above. Using the classifications delineated by developers of the S-TOFHLA, 2.1% of the participants (n=7, range 7-50) were classified as having inadequate functional health literacy, 3.8% (n=13, range 54-66) as marginal, and 94.1% (n=315, range 67-100) as adequate. These findings were much less than expected; based on previously work in this area, we anticipated that 18-20% of this sample would have lower functional health literacy.

Table 8 displays the difference in selected characteristics between the two functional health literacy levels, inadequate/marginal (≤75) and adequate (>75). Non-white participants and those individuals with less than a high school education were more likely to demonstrate lower functional health literacy (χ^2=7.437, p=.006 and χ^2=16.484, p<.001, respectively). Also, people with income less than $13,000/year were also more likely to have lower functional health literacy (χ^2=6.368, p=.012).

Although educational level and years of education were both significantly related to functional health literacy; the two variables do not completely overlap. In fact, 7.5% (n=21) of those individuals with a high school degree or GED had marginal or inadequate functional health literacy. Additionally, 74.1% (n=40) of those with less that a high school diploma or GED had adequate functional health literacy.

Participants had an average CD4 count of 449.94 (SD=316.45), and viral load was undetectable in 40.3% (n=135) of participants. These clinical indicators did not vary significantly between the two functional health literacy groups (Mann-Whitney U=3205.0, p=.950 and χ^2=.510, p=.475, respectively). Participants were taking an average of 2.7 medications daily (mode = 3, range 1-5); there was no difference between the two groups (Mann-Whitney U=5155.5, p=.852).

These findings led us to reject our second hypothesis, at least in some part, which stated that functional health literacy would be univariately associated with educational level, but not other socio-demographic variables or HIV health history variables. Functional health literacy was univariately associated with educational level, race, and income, but none of the HIV history variables.

Table 8: Socio-demographic and Health History Variables of Interest for the Total Sample and by Dichotomized Functional Health Literacy (FHL) Categories (≤75, >75)

	Sample N=335		Inadequate/ Marginal, ≤75 n=35		Adequate, >75 n=300		Difference Between FHL Categories	
Variable	**n**	**%**	**n**	**%**	**n**	**%**	χ^2	***p-value***
Gender							0.37	.545
Male	235	70.1	23	65.7	212	70.8		
Female	100	29.9	12	34.3	88	29.3		
Ethnicity							7.44	.006
White	139	41.5	7	20.0	132	44.0		
Non-White	196	58.5	28	80.0	168	56.0		
Age (in years)							0.24	.887
20-30	20	6.0	2	5.7	18	6.0		
31-54	289	86.3	31	88.6	258	86.0		
55 and up	26	7.8	2	5.7	24	8.0		
Educational Level							16.48	<.001
≥GED/HS Graduate	281	83.9	14	40.0	40	86.7		
< HS, No GED	54	16.1	21	60.0	260	13.3		

	Sample N=335		Inadequate/ Marginal, ≤75 n=35		Adequate, >75 n=300		Difference Between FHL Categories	
Variable	**n**	**%**	**n**	**%**	**n**	**%**	χ^2	***p-value***
Employment Status							3.24	.072
Yes	59	17.6	10	28.6	49	16.3		
No	276	82.4	25	71.4	251	83.7		
Current Drug Use							2.29[b]	.165 [a]
Yes	27	8.1	5	14.3	22	7.3		
No	167	49.9	15	42.9	152	50.7		
Unknown/Missing	141	42.1	15	42.9	126	42.0		
Current Alcohol Abuse							0.10[b]	1.000 [a]
Yes	13	3.9	1	2.9	12	4.0		
No	181	54.0	19	54.3	162	54.0		
Unknown/Missing	141	42.1	15	42.9	126	42.0		
Marital Status							0.46 [b]	.795
Never married	180	53.7	20	57.1	160	53.3		
Married/living w/	73	21.8	6	17.1	67	22.3		
Divorced/Separated/ Widowed	82	24.5	9	25.7	73	24.0		

	Sample N=335		Inadequate/ Marginal, ≤75 n=35		Adequate, >75 n=300		Difference Between FHL Categories	
Variable	**n**	**%**	**n**	**%**	**n**	**%**	χ^2	***p-value***
Detectable Viral Load							0.17 [b]	.684
Yes	135	40.3	14	40.0	121	40.3		
No	167	49.9	15	42.9	152	50.7		
Unknown/Missing	33	9.9	6	17.1	27	9.0		
Income							6.37 [b]	.012
<$13,000	237	70.7	30	85.7	207	69.0		
≥$13,000	91	27.2	3	8.6	88	29.3		
Unknown/Missing	7	2.1	2	5.7	5	1.7		
Health Insurance							3.02	.155 [a]
Yes	311	92.8	35	100	276	92.0		
No	24	7.2	0	0.0	24	8.0		
English as Primary Language [a]							0.25	.487 [a]
Yes	329	98.2	34	97.1	295	98.3		
No	6	1.8	1	2.9	5	1.7		

	Sample N=335		Inadequate/ Marginal, ≤75 n=35		Adequate, >75 n=300		Difference Between FHL Categories	
Variable	**n**	**%**	**n**	**%**	**n**	**%**	χ^2	***p-value***
Recruitment Site							0.87	.344
Western PA	205	61.2	24	68.6	181	60.3		
Northeastern OH	130	38.8	11	31.4	119	39.7		

	Sample n=335		Inadequate/ Marginal, ≤75 n=35		Adequate, >75 n=300		Difference Between FHL Categories	
Variable	**Mean Median**	**SD**	**Mean Median**	**SD**	**Mean Median**	**SD**	**U z**	***p-value***
Age (years)	43.64	4.93	42.37	8.46	43.79	7.87	4918.0	.540
Range: 20-66	44.00		44.00		44.00		-0.61	
Education (years)	13.01	2.85	11.40	2.33	13.20	2.85	3303.5	<.001
Range: 3-26	12.00		12.00		12.00		-3.67	
CD4 Count (n=280)	449.84	316.45	401.14	245.31	455.25	323.34	3335.5	.636
Range: 4-2148	378.00		361.50		380.00		-0.47	

	Sample n=335		Inadequate/ Marginal, ≤75 n=35		Adequate, >75 n=300		Difference Between FHL Categories	
Variable	**Mean Median**	**SD**	**Mean Median**	**SD**	**Mean Median**	**SD**	**U z**	***p-value***
Total # of HIV Meds Range: 1-5	2.70 3.00	.86	2.71 3.00	0.86	2.69 3.00	0.86	5155.5 -0.19	.852

[a]Fisher's Exact test
[b]Missing cases excluded from chi-square analysis

The results of the logistic regression univariate analysis for all candidate predictors that met the screening value of p<.20 are presented in Table 9. Non-white individuals had three times the risk of white individuals to have inadequate/marginal functional health literacy (OR=3.13, *p*=.009, 95%CI: 1.29-8.77). Participants with less than a high school education had over four times the odds as those with a high school degree or GED of having inadequate/marginal functional health literacy (OR=4.31, *p*<.001, 95%CI: 0.62-2.28). Also, those with income less than $13,000/year had over three times the odds as those with income greater than or equal to $13,000/year of demonstrating inadequate/marginal functional health literacy (OR=3.26, *p*=.019, 95%CI: 1.11-13.09). Notably, people who were not employed were more than twice as likely to have inadequate/marginal functional health literacy as those who were employed, but that relationship did not reach statistical significance (OR=2.04, *p*=.077, 95%CI: 0.83-4.76).

Table 9: Univariate Analysis, Predicting Inadequate/Marginal Functional Health Literacy[a]

	Test Statistic	***p-value***	***Estimate***	***df***	**Odd Ratio (OR)**	***p-value***	**95% CI for OR**
Race: Non-White	7.41	.003	1.14	1	3.13	.009	1.29-8.77
Educational Level: < High School, No GED	16.44	<.001	1.46	1	4.31	<.001	.62-2.28
Employment Status: Employed	3.23	.04	-0.71	1	2.04	.077	0.83-4.76
Income: <$13,000/yr	5.18	.01	1.18	1	3.26	.019	1.11-13.09
Health Insurance: No	3.01	.06	1.45	1	4.27	.092	0.72-Infinity

[a]Exact methods for estimation used; test statistics and estimates are from the exact results. CI for the Odds Ratio may include one, negative infinity or infinity due to sparse cells.

The mulitvariate model included all of the candidate predictor variables from the univariate analysis entered into the model at the same time (see Tale 10). This model indicated that race and educational level remained strongly associated with functional health literacy (OR=3.68, *p*=.004, 95%CI: 1.44-10.79 and OR=3.81, *p*=.003 95%CI: 1.57-9.16, respectively).

Income, employment status, and health insurance were not significantly related to functional health literacy in the multivariate model.

Table 10: Full Mulitvariate Model with all Candidate Predictors, No Interactions, Predicting Inadequate/Marginal Health Literacy[a]

	Test Statistic	***p-value***	***Estimate***	***df***	**Odds Ratio (OR)**	***p-value***	**95% CI for OR**
Race: Non-White	8.82	.001	1.30	1	3.68	.004	1.44-10.79
Educational Level: < High School, No GED	11.74	.001	1.34	1	3.81	.003	1.57-9.16
Employment Status: Employed	3.70	0.03	-.82	1	2.27	.103	0.85-5.56
Income: <$13,000/yr	3.34	.034	1.00	1	2.71	.098	0.87-11.29
Health Insurance: No	2.91	.075	-1.41	1	0.24	.151	0.0-1.506

[a]Test statistics and estimates are based on the exact results. CI for the Odds Ratio may include one, negative infinity or infinity due to sparse cells.

Two interactions demonstrated statistical significance in the multivariate model. Non-white participants without a high school degree or GED had 18 times the odds of having inadequate/marginal functional health literacy than whites with a high school degree or GED (OR=18.06, *p*=.008, 95%CI: 2.03-Infinity, based on exact analysis). In fact, 7 non-white individuals fell into this category, but none of the white individuals did. Of those seven, all were African-American and all spoke English as their primary language. Additionally, education and employment demonstrated a marginally significant interaction effect (p=.083). Specifically, individuals who were employed but had a high school education or GED were more likely to have inadequate/marginal health literacy. These two interactions and the other candidate predictor variables were included in the full multivariate model (Table 11). Not surprisingly, the main effects for race and education were no longer statistically significant after the interaction terms based on these variables were included in the model.

Table 11: Multivariate Model, with All Candidate Predictors and Significant Two-Way Interactions, Predicting Inadequate/Marginal Health Literacy[a]

	Test Statistic	***p-value***	***Estimate***	***df***	**Odds Ratio (OR)**	***p-value***	**CI for OR**
Race: Non-White	0.07	0.258	-.18	1	0.83	1.000	0.17-3.96
Educational Level: < High School, No GED	<.001	.234	0.02	1	1.02	1.000	0.24-3.55

	Test Statistic	***p-value***	***Estimate***	***df***	**Odds Ratio (OR)**	***p-value***	**CI for OR**
Employment Status: Employed	9.57	.004	-2.08	1	7.69	.009	1.58-47.62
Income: <$13,000/yr	2.55	.054	0.89	1	2.43	.163	0.77-10.27
Health Insurance: No	3.83	.039	-1.74	1	0.18	.079	0.00-1.78
Race* Education: Non-white* <HS, No GED	8.96	.004	2.89	1	18.06	.008	2.03-Infinity
Education* Employment: <HS, No GED* Employed	4.48	.038	2.00	1	7.42	.083	0.82-87.67

[a]Exact methods for estimation used; test statistics and estimates are from the exact estimation methods. CI for the Odds Ratio may include one, negative infinity or infinity due to sparse cells.

A parsimonious model (Table 12) was obtained after evaluating each predictor for statistical significance. Again, the interaction term for race and education was the strongest predictor of functional health literacy (OR= 18.88, p<.01, 95%CI: 2.25-Infinity). Again, not surprisingly, race and education are no longer statistically significant when this two-way interaction is entered into the multivariate model. Due to small cell numbers, these exact results are only used to examine odds ratios. The traditional model fit statistics (chi-square, classification tables, r-squared, and the Hosmer and Lemeshow) are not reliable and could not be used.

Table 12: Final Parsimonious Multivariate Model Predicting Predicting Inadequate/Marginal Health Literacy[a]

	Test Statistic	***p-value***	***Estimate***	***df***	**Odds Ratio (OR)**	***p-value***	**95% CI for OR**
Race: Non-White	.03	.240	-.10	1	.906	1.00	0.22-3.66
Educational Level: < High School, No GED	3.05	.051	.84	1	2.32	.156	0.74-6.59
Race* Education	9.44	.002	2.94	1	18.88	.005	2.25-Infinity

[a]Exact methods for estimation used; test statistics and estimates are from the exact results. CI for the Odds Ratio may include one, negative infinity or infinity due to sparse cells.

*denotes an interaction term

Finally, we explored how the numeracy items may be used to describe functional health literacy in this population. Analyses of all of the numeracy items (8 total, four of which are used to compute the S-TOFHLA score) revealed that 57% of participants answered at least two of the questions incorrectly. Approximately 26% (n=86) answered all the questions correctly. There was a statistically significant difference in the percent correct between functional health literacy levels in 7 of the 8 items and a non-significant trend in the remaining item (item #3). Eighty percent of people with lower functional health literacy answered five or fewer items correctly; conversely, 23% of those with higher functional health literacy answered five or less correctly. Details about the individual questions on the numeracy portion for the whole sample and for each functional health literacy level can be found in Table 13.

Table 13: Numeracy Items and Scores for the Sample and Each FHL Level

	Sample n=335		**Inadequate/ Marginal n=35**		**Adequate n=300**		**Difference between levels**	
S-TOFHLA Numeracy Question	**Incorrect**		**Incorrect**		**Incorrect**		**χ^2**	***p*-value**
	n	**%**	**n**	**%**	**n**	**%**		
Pill bottle with prescription and dosing information								

	Sample n=335		Inadequate/ Marginal n=35		Adequate n=300		Difference between levels	
S-TOFHLA Numeracy Question	**Incorrect**		**Incorrect**		**Incorrect**		χ^2	***p-value***
	n	**%**	**n**	**%**	**n**	**%**		
1. If you were to take your first tablet at 7 am when should you take the next one?*	41	12.2	10	28.6	31	10.3	9.71	.005[a]
2. And the next one after that?	147	43.9	22	62.9	125	41.7	5.72	.017
3. What about the last one for the day?	198	59.1	26	74.3	172	57.3	3.73	.054
Blood sugar reading with normal range provided								
4. If this were your score, would your blood sugar be normal?*	62	18.5	21	60.0	41	13.7	44.61	<.001
Appointment card with time and location								
5. When is your next appointment?*	18	5.4	7	20.0	11	3.7	16.45	.001 [a]

	Sample n=335		Inadequate/ Marginal n=35		Adequate n=300		Difference between levels	
S-TOFHLA Numeracy Question	**Incorrect**		**Incorrect**		**Incorrect**		χ^2	***p-value***
	n	**%**	**n**	**%**	**n**	**%**		
6. Where should you go?	16	4.8	6	17.1	10	3.3	13.14	.003 [a]
Pill bottle with prescription and dosing information								
7. If you eat lunch at noon and want to take meds before lunch, when should you take it?*	54	16.1	19	54.3	35	11.7	42.11	<.001
8. If you forgot before lunch, when should you take it?	74	22.1	23	65.7	51	17.0	43.22	<.001

[a]Fisher's Exact test
*Only starred items are included in computation of the S-TOFHLA score.

Note. Permission to print the exact numeracy items from the TOFHLA was obtained from the author of the tool, Dr. David W. Baker. See Appendix B.

5.5 DISCUSSION

Functional health literacy scores, as measured with the S-TOFHLA and the participants classified as having functional health literacy using the standard cut-off points established by the tool developers, were significantly higher than expected; 2.1% of the sample had inadequate functional health literacy and 3.8% were classified as having marginal. With the alternative cut-off points ($\leq$75 or >75), the number of people with inadequate or marginal functional health literacy did increase from 20 to 35, but even this represented only 10.45% of the sample. Our findings did not approach the hypothesized 18-20% of people living with HIV, which was based on the existing literature (Kalichman et al., 2000; Kalichman & Rompa, 2000b; Rudd, Kirsch, & Yamamoto, 2004). However, the cut-off points for levels of functional health literacy vary in the published literature, making comparisons across studies difficult. Additionally, other studies describe functional health literacy in this population using the REALM, which reports levels based on grade level; therefore results of studies using the REALM cannot easily be compared with studies using the S-TOFHLA. Researchers who studied functional health literacy in people living with HIV that used the TOFHLA or the S-TOFHLA have reported functional health literacy results closer to the findings in this study, ranging from 15-28% (Kalichman et al., 2000; Kalichman, Catz, & Ramachandran, 1999; Kalichman, Ramachandran, & Catz, 1999; Mayben et al., 2007). Yet, the cut-off points for dichotomizing between higher and lower functional health literacy were different in these studies (74-85). Results from studies with similar samples that used the REALM, however, had much higher rates of lower functional health literacy, ranging from 30-50%; all of these studies used the same cut-off point of less than 9th grade (Graham, Bennett, Holmes, & Gross, 2006; Paasche-Orlow et al., 2006; Wolf et al., 2007; Wolf et al., 2005; Wolf et al., 2004). Findings from these studies seem to suggest that the method used to

assess functional health literacy may have an effect on the final results, despite the fact that criterion-related validity testing of the REALM has shown it to be comparable with the TOFHLA (Baker, Williams, Parker, Gazmararian, & Nurss, 1999). Possibly, these two tools measure two separate components of health literacy, particularly in a younger sample or in people with higher educational levels.

Race and educational level were the participant characteristics that were significantly predictive of functional health literacy in this sample, supporting findings from other studies in people living with HIV (Kalichman et al., 2000; Kalichman & Rompa, 2000b; Osborn, Paasche-Orlow, Davis, & Wolf, 2007). In fact, non-additivity or interaction was found suggesting that those two variables together are most predictive of functional health literacy. The influence of the interaction in the model is notable. In this sample, white individuals with a high school degree or GED had higher functional health literacy. These results support much of the published literature which reports functional health literacy to be associated with race and educational level (Golin et al., 2002; Graham, Bennett, Holmes, & Gross, 2006; Kalichman, Ramachandran, & Catz, 1999; Paasche-Orlow et al., 2006; Wolf et al., 2007; Wolf et al., 2005). However, none of those earlier studies identified this particular interaction. Our results indicate that people over-represented in the HIV population compared to the general population, such as African-Americans and those with less education, may be more at risk if lower functional health literacy has an impact on healthcare management and health outcomes, thereby increasing disparities in those populations.

In addition, this study explored how researchers may use the numeracy items from the entire TOFHLA instrument to describe health literacy. The 8-item Numeracy Scale analysis revealed interesting deficiencies in the abilities of the participants. This sample demonstrated

more difficulty with these questions than the reading comprehension section, as evidenced through the greater variability in the number of items incorrect for people with both higher and lower functional health literacy. No other published studies have specifically examined these items; our results do suggest that these pragmatic questions may offer some additional information about functional health literacy, distinct from the reading comprehension part of the S-TOFHLA. For example, the majority of the sample had difficulty with the timing of all three doses of the thrice daily medication (questions 1-3, Table 9). The items were included in the study because they seemed especially relevant to the daily practice of medication taking, specifically following dosing instructions and timing doses.

There are several potential explanations for the high functional health literacy rate finding that highlight some of the study limitations, most notably the potential selection bias that exists in the parent study. That intervention study is a longitudinal, 18-month study that requires participants to be currently taking HIV medication, which requires at least a minimal engagement in care. Possibly these study specific requirements attracted a different cohort of patients than a cross-sectional study examining another aspect of HIV-disease management that does not require active engagement in medical care (such as disease transmission or knowledge). Additionally, recruitment methods relied heavily on printed materials such as posters, brochures and flyers, thereby necessitating a minimal level of reading ability. Although the study did not explicitly exclude people unable to read and write, the protocol may have inadvertently prohibited participation from those who were either unable to read or felt insecure about their abilities. Because this study was a secondary data analysis, we were limited to the sample available through the parent study. There is also the possibility that this sample accurately reflects the population in this region of the country (the smaller cities of the Midwest). The high

health literacy rates may also be related to the very high proportion of people in this area with English as their primary language.

Because this is a secondary data analysis, there may be limitations related to the selection of tools, specifically those that could have offered some further explanation of our findings. For example, there were no data available on the length of time since HIV diagnosis or the duration of HIV treatment, both of which may have some explanatory power related to health literacy or adherence. Additionally, there were limited data available on educational history beyond highest level completed. A more detailed examination of educational progress that included type of education (public or private), geographic setting (urban, rural or suburban) and some value estimate related to success in school may offer important information regarding the basic reading and comprehension skills of the participants.

Future research on the functional health literacy levels of people living with HIV needs to focus on two key areas. First, it is critically important to continue to assess the actual functional health literacy levels of the HIV-positive population to determine if these findings occurred because of limitations in the design of the study (e.g. selection bias), or if they truly reflect the population's competencies. There is also a need for future research to explore the psychometric properties of the S-TOFHLA and the REALM in people living with HIV, specifically their construct validity as assessors of functional health literacy. This continued assessment needs to include examination of the construct of functional health literacy and innovative measurement strategies available. Second, researchers need to design a study that effectively recruits and retains a higher proportion of individuals with a lower functional health literacy level. This could be accomplished by expanding recruitment activities to include people currently not in care or

not taking medications, or by targeting more disenfranchised populations, such as incarcerated adults or people with active addictions.

In addition to those two areas, our findings support further research on the numeracy items from the TOFHLA, or similar assessment tools that measure the practical knowledge related to medication taking. Continued research in this area, examining how skills for timing medication doses are related to medication adherence and understanding of treatment regimen, is needed and could offer additional insight into self-management behaviors.

This study demonstrates that functional health literacy is a problem for some people living with HIV and that functional health literacy may be disproportionately affecting already vulnerable populations such as those with less education or African-Americans living with HIV. Further assessment of the scope of the functional health literacy problem is needed, including additional attention to the definition and measurement of the construct.

6.0 MANUSCRIPT #2: RESULTS AND DISCUSSION

(Preliminary title: "Functional Health Literacy and Medication-Taking Self-Efficacy as Predictors of Medication Adherence in People Living with HIV/AIDS")

This manuscript provides the results for Specific Aim 3. The document was prepared to be submitted to a multi-disciplinary journal with a history of publishing work related to health literacy.

6.1 ABSTRACT

Background Medication adherence is critical to successful HIV/AIDS self-management. Despite simplified regimens and the availability of tools to assist with medication-taking, adherence remains a challenge for many people living with HIV/AIDS. Bandura's Social Cognitive Theory can provide guidance for examining the mechanisms of certain health behavior.

Objective This study, guided by Bandura's Social Cognitive Theory, investigated functional health literacy and medication taking self-efficacy as possible predictors of HIV medication adherence.

Methods The study was a cross-sectional, secondary data analysis of 335 people living with HIV/AIDS who were taking antiretroviral medications. Adherence was measured using electronic event monitors with self-report diary data inserted to correct for "pocket dosing" and

medication refills. Adherence rates were dichotomized as < 85% or ≥85%. Bivariate analyses and univariate logistic regression were conducted to examine the relationships between functional health literacy, medication-taking self-efficacy, and HIV medication adherence. Multivariate logistic regression was used to examine possible predictors of adherence jointly. Socio-demographic and HIV health history variables were considered extraneous variables to be controlled for in the multivariate model.

Results Sixty-seven percent (n=223) of participants had adherence rates less than 85%, based on days with correct intake. In bivariate analysis, functional health literacy was not significantly related to medication adherence, although there was a non-significant trend suggesting that people with lower functional health literacy may demonstrate lower adherence ($\chi 2 = 3.17$, p=.075). Functional health literacy was also not related to self-efficacy beliefs. In multivariate analyses, non-white individuals, people with lower self-efficacy beliefs, and younger individuals were more likely to demonstrate poorer medication adherence.

Conclusions Adherence rates in this sample were sub-optimal and functional health literacy was not a statistically significant predictor of adherence. Further research is needed to understand the disparate findings related to functional health literacy and treatment adherence in this and other studies examining this relationship.

6.2 INTRODUCTION

Successful self-management of HIV requires significant effort on the part of the individual because of the need for consistent and effective medication taking behaviors. Research has shown that viral suppression may require nearly 100% adherence. Maintaining

rates greater than 95% translate into less than one missed dose per week for a patient on a twice-a-day pill regimen (Deeks et al., 1999; Paterson et al., 2000). However, more recent research is suggesting that the level of adherence required for viral suppression may be actually lower. Recent findings from Bangsberg (2006) suggest that the newer, more potent regimens may actually achieve viral suppression with lower levels of adherence; potentially varying between 54 and 100 percent. Functional health literacy may be one of the myriad factors influencing the disease-management behaviors of people living with HIV. The purpose of this descriptive study, guided by Bandura's Social Cognitive Theory (1986), was to examine functional health literacy and medication-taking self-efficacy as possible predictors of HIV medication adherence.

6.3 BACKGROUND

Bandura's Social Cognitive Theory guided the selection of variables of interest for this study; this framework focuses heavily on the role of self-efficacy in behavior. Self-efficacy, defined as the belief of individuals in their own capacity to organize and execute an action required to produce specific results, influences the choices and motivations of individuals (Bandura, 1997). Bandura asserts that self-efficacy is the self-assurance with which individuals approach tasks to accomplish a specific behavior; self-efficacy determines whether or not people make good use of their capabilities and can ultimately be successful. Additionally, self-regulation over one's thought processes, motivation, and emotional states is also influenced by self-efficacy. Self-efficacy, in turn, influences human functioning through people's choices, effort expenditure, persistence, thought patterns, and emotional reactions (Bandura, 1997). Functional health literacy may play a significant part in an individual's development of self-

assurance within the context of health. More specifically, the lived experience of individuals with lower functional health literacy, who are trying to navigate the health care system and manage their health and the health of their family, may have a significant influence on their belief in their own capacities.

Medication adherence is a critical issue in the management of HIV/AIDS because poor rates of adherence can lead to unsuccessful viral suppression, resistance to medication, opportunistic infections, overall poor health, decreased quality of life, and potentially death (D. R. Bangsberg et al., 2001; Carballo et al., 2004; Erlen & Mellors, 1999; McNabb, Nicolau, Stoner, & Ross, 2003). Therefore, persons with HIV/AIDS who have inadequate functional health literacy are even more vulnerable in regards to accessing health services and are at greater risk for poor health outcomes.

Results from several studies have supported the relationship between higher self-efficacy and better HIV medication adherence (Buchmann, 1997; Catz, Kelly, Bogart, Benotsch, & McAuliffe, 2000; M. O. Johnson et al., 2003; Debra A. Murphy, Greenwell, & Hoffman, 2002; J. M. Simoni, Frick, Lockhart, & Liebovitz, 2002) providing a rationale for continued inquiry into the relationship between self-efficacy and adherence. This relationship is supported across diverse HIV+ populations. For example, both Murphy, Greenwell and Hoffman (2002) and Kalichman et al. (2001) found that for women, decreased self-efficacy was associated with missing medication doses, as measured by self report. Pinheiro et al. (2002) reported in their study of 195 individuals living with HIV in Brazil that those with greater self efficacy had three-and-a-half times the odds of reporting better adherence (OR = 3.50, 95% CI=1.90-6.55). Multivariate analysis showed that those with higher self-efficacy three times the odds of reporting higher adherence levels (OR = 3.33, 95% CI 1.69-6.56), suggesting that self-efficacy is

the single best predictor of adherence in that study (Pinheiro, de-Carvalho-Leite, Drachler, & Silveira, 2002).

Six published studies (Golin et al., 2002; Graham, Bennett, Holmes, & Gross, 2006; Kalichman, Catz, & Ramachandran, 1999; Kalichman, Ramachandran, & Catz, 1999; Paasche-Orlow et al., 2006; Wolf et al., 2004) have directly examined the relationship between functional health literacy and medication adherence in people living with HIV. Three of these studies assessed the relationship of functional health literacy to HIV medication adherence and showed that lower functional health literacy is related to poorer adherence (Graham, Bennett, Holmes, & Gross, 2006; Kalichman, Catz, & Ramachandran, 1999; Kalichman, Ramachandran, & Catz, 1999). Two of these studies used the S-TOFHLA to measure functional health literacy and two-day recall to measure adherence (Kalichman, Catz, & Ramachandran, 1999; Kalichman, Ramachandran, & Catz, 1999). The third study used the REALM to measure functional health literacy and found that in their sample of 87 people living with HIV, reading grade level was associated with lower adherence. Adherence was measured using a pharmacy refill surrogate marker; 95% was the cut-off point between higher and lower adherence (Graham, Bennett, Holmes, & Gross, 2006).

Conversely, three of these six studies did not find lower functional health literacy to be associated with lower medication adherence. Golin et al. (2002) did not find a significant relationship between functional health literacy and HIV medication adherence in their longitudinal study with 140 participants. This study used the TOFHLA to assess functional health literacy and electronic monitors to assess adherence over time (up to 48 weeks). In discussing the findings, the authors stated that while there was not a significant relationship between functional health literacy and adherence, the functional health literacy assessment "may

have been compromised in this evaluation because of a large number of imputed values" (Golin et al., 2002, p.763). Paasche-Orlow et al. (2006) also found that low functional health literacy was not associated with lower odds of adherence or viral suppression in a population of 235 individuals who were HIV-positive and had a history of alcohol problems. In fact, the authors reported a non-significant trend that lower functional health literacy might be associated with better adherence and virologic suppression (adjusted OR 1.93, 95% CI 0.86-4.31). Their study used the REALM to measure functional health literacy and a 3-day self-report of adherence. Wolf et al. (2005) also found functional health literacy, as measured with the REALM, not to be significantly associated with medication adherence.

Wolf et al. (2006) examined the relationship between functional health literacy, self-efficacy and HIV medication adherence. Their study of 204 people with HIV used the REALM to assess functional health literacy and a revised version of the Patient Medication Adherence Questionnaire (PMAQ) to measure adherence (self-report, 4-day recall). Results initially showed an indirect association between functional health literacy and adherence; however, with further analysis the authors found that self-efficacy partially mediated this relationship.

Given that the results in prior studies are inconsistent and the measurement strategies varied, the aim of this study was to examine functional health literacy and medication taking self-efficacy as potential predictors of adherence to HIV medication. Using the published literature and Bandura's theory, we hypothesized that 1) functional health literacy has a direct positive effect on medication-taking self-efficacy; and 2) functional health literacy has an indirect, positive mediating effect on HIV medication adherence, through medication-taking self-efficacy. Understanding the relationships among these variables may contribute to an increased

understanding of medication taking behaviors in persons with HIV and assist in the development of novel interventions to improve HIV medication adherence.

6.4 METHODS

6.4.1 Design

This secondary data analysis was a descriptive study that used de-identified baseline data obtained from an honest broker from the parent study, "Improving Adherence to Antiretroviral Therapy" (2R01 NR04749), to address the aims of the study and to test the hypotheses. The ongoing parent study is a randomized clinical trial testing two nurse delivered telephone interventions designed to improve HIV medication adherence. Institutional Review Board approval (IRB) was obtained for the secondary data analysis; the parent study had separate IRB approval.

6.4.2 Sample Procedure

The sample and recruitment procedures for this study and the parent study have been described elsewhere (Chapter 5). Three-hundred and fifty-four participants were enrolled in the parent study; 16 were excluded from the secondary analysis because the functional health literacy assessment was not completed. An additional three participants were excluded due to a lack of electronic adherence data; all three of these participants were classified as having

adequate functional health literacy. Therefore, the final sample for this study was 335 participants.

6.4.3 Measures

Functional health literacy was measured using the Short Test for Functional Health Literacy (S-TOFHLA) (Baker, Williams, Parker, Gazmararian, & Nurss, 1999). The S-TOFHLA is a shorter version of the standard TOFHLA which uses materials a patient may encounter in the context of healthcare, such as patient instructions for surgery and a prescription bottle. Functional health literacy was dichotomized as inadequate/marginal ($\leq$75) or adequate (>75). This cut-off point was selected based on the comparable literature published in this population. The S-TOFHLA has demonstrated good internal reliability, with a Cronbach's alpha of .953.

Adherence was objectively assessed using electronic event monitors (EEM), augmented by paper daily diary self-report. EEM consists of a medication cap containing a micro-electronic circuit that fits on a standard medication bottle and records the time and date each time the cap is opened. In the parent study, participants were asked to put one of their HIV antiretroviral medications (randomly selected using a computer-based program) in the bottle with the EEM cap; therefore one medication from the HIV regimen was continuously monitored throughout the course of the study. Participants were also asked to keep a daily paper diary, recording the date and time they removed their HIV medications from their bottles and when they actually took the medications, to allow for pocket dosing. Data from paper diaries were inserted into EEM data when the participant noted in the paper diary that a medication was removed from the bottle at one time and then actually taken at another. The documentation of refills allowed the omission of

these extraneous events from the EEM data set. In these instances, the EEM data were supplemented by the medication-taking diary data before summarizing data to adherence indices.

For analysis, adherence was reported as both a continuous variable (percentage of days with the correct intake or number of prescribed administrations) and a categorical variable (less than 85% adherence, greater than or equal to 85% adherence). This cut-off was chosen because it reflects a moderate to high-level of adherence. Although the traditional cut-off point in HIV is often 95-100%, the lower threshold for "higher" adherence may be more consistent with Bangberg's (2006) research demonstrating effectiveness of medications at lower levels of adherence.

Self-efficacy was conceptualized as medication-taking self-efficacy beliefs, or one's belief in his/her ability to plan and perform a desired behavior. Self-efficacy was measured using the Self-Efficacy Beliefs subscale of the Erlen HIV Self-Efficacy Scale for Medication Taking. The self-administered, self-report instrument is a 26-item scale developed for the parent study; 17 of those items comprise the Self-Efficacy Belief subscale. The content relates specifically to medication taking and measures the level, generality and strength of medication taking self-efficacy. Questions on the scale asked participants to rate their confidence about medication taking behaviors, such as following their own treatment regimen and planning to take medication in times of crisis. The total score for the self-efficacy beliefs subscale ranges from 17 to 170. The subscale demonstrated good reliability; the Cronbach's alpha was .948.

Two investigator-developed tools, the Health Survey and Medical Record Review were used to collect HIV health history information. To provide the most accurate data possible, we first used available medical records to obtain CD4 counts and detectable/undetectable viral load data. When available, we used self report as additional data. The Center for Research in Chronic

Disorders (CRCD) Socio-demographic Questionnaire was used to collected socio-demographic information.

6.4.4 Statistical Analysis

Analysis was performed using SPSS (version 15.0, SPSS Inc., Chicago, IL 2006). Measures of central tendency and dispersion were used to summarize the patient descriptors, medication adherence and self-efficacy. Functional health literacy in this sample was described in detail elsewhere (Chapter 5). Bivariate analyses were conducted to examine the independent relationships between dichotomized medication adherence (<85%, ≥85%) and selected socio-demographic factors and HIV-health history information. Independent sample t-tests or the nonparametric Mann-Whitney U-test were used for continuous variables and χ^2 analysis was used for categorical variables.

Binary logistic regression was employed to examine the relationships among functional health literacy, medication-taking self-efficacy, and medication adherence (the dependent variable). Candidate predictors that were determined to be significantly related to the adherence ($p<.2$) in the above described bivariate analyses were included in the multivariate model. Initially, univariate logistic regression analysis examined the individual relationships between the variables. Then all possible two-way interactions were assessed, by entering them hierarchically into the multivariate model containing all of the candidate predictors. Finally, the resultant models were evaluated and modified to include only significant relationships and to identify the most parsimonious model. Model fit was evaluated using change in chi-square statistics, classification tables, pseudo r-squared values (Cox & Snell and Nagelkerke), and the

Hosmer and Lemeshow Test for adequate fit of the data. Significance levels were set a priori at .05, except where indicated.

6.5 RESULTS

6.5.1 Sample Characteristics

The sample was comprised of 335 participants. Primarily male (70.1%), the sample had a mean age of 43.64 years (SD 4.93) and had an average of 13.01 years of education (SD=2.85). Over 70% of the sample reported household incomes of less than $13,000 per year. Additionally, 56.7% of the participants were African-American. Although the racial distribution in the study reflected that of the geographic area, the very small numbers in some cells necessitated that some of the racial groups be collapsed for statistical analysis; therefore racial data were analyzed as white and non-white, as collected with self-report. Of those designated non-white, 96.9% (n=190) were African American.

6.5.2 Functional Health Literacy

Approximately 10% (n=35) of the participants demonstrated inadequate/marginal functional health literacy. Scores for functional health literacy ranged from 7 to 100 and the mean score was 90.01 (SD 12.97, 95%CI 88.62-91.41), with a median of 94 and a mode of 98.

6.5.3 HIV Medication Adherence, Functional Health Literacy, and Medication-Taking Self-Efficacy

The mean adherence score for the sample was 60.07% (the average percent of days with the correct number of doses taken) and were highly variable between the subjects (SD=31.60). There was no significant difference in the rates of adherence between the inadequate/marginal and adequate functional health literacy levels (U = 441.5, *p*=.149). Measures of central tendency and mean number of days with no medications being taken for each level of functional health literacy are displayed in Table 14.

Table 14: Profiles of Adherence to Medication in the Sample and Compared Between Functional Health Literacy Categories

Adherence	Sample	Inadequate/ Marginal	Adequate	Difference Between Means
Mean	60.07 (SD 31.60)	53.63 (SD 31.97)	60.83 (SD 31.53)	U: 4471.5 Z: -1.44 *p:* .149
95% CI for Means	56.68-63.47	54.03-57.14	57.24-64.41	
Median	71.43	57.14	71.43	
Mode	92.86	0.0[a]	92.86	
Minimum-Maximum	0.0-100	0.0-100	0.0-100	
Percentiles				
25	35.71	28.57	35.71	
50	71.43	57.14	71.43	
75	85.71	78.57	85.71	
Mean % of days with no meds taken	20.72 (SD 26.69)	27.83 (SD 30.56)	19.93 (SD 26.14)	U: 4477.0 Z: -1.47 *p:* .142

[a]Multiple modes exist. Smallest value is shown.

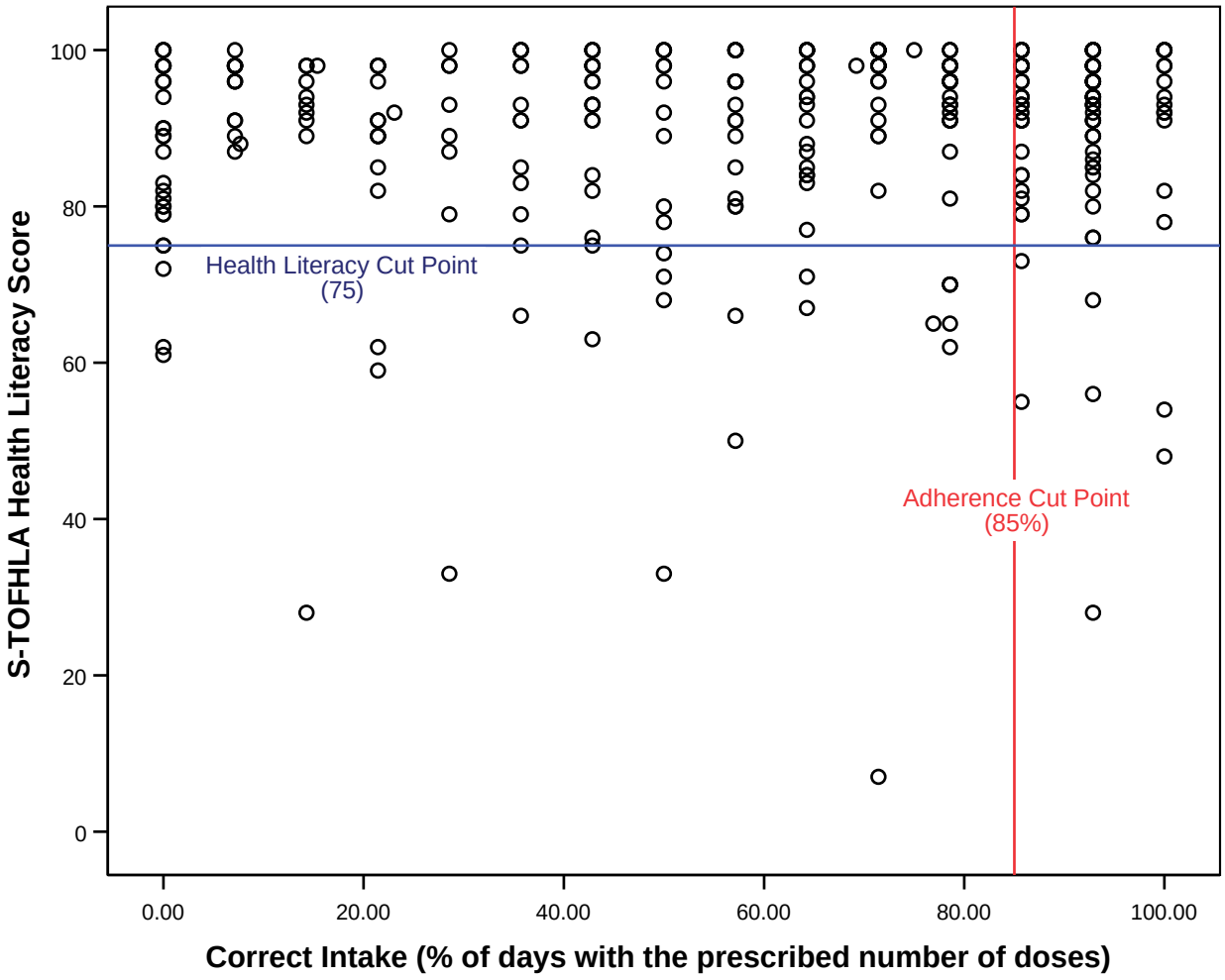

Figure 9: Adherence Rates and Health Literacy Scores

In contrast to the functional health literacy scores, adherence levels in the sample were highly variable. Figure 9 illustrates this variability plotted against the relatively homogenous functional health literacy scores.

Adherence, as dichotomized as <85% or ≥85%, was only significantly related to four of the included socio-demographic and HIV health history variables examined in this study: race, viral load, income, and age. Non-whites and individuals with a household income less than $13,000 per year were more likely to demonstrate lower adherence ($\chi^2 = 6.124$, p=.013 and $\chi^2 = 4.127$, p=.042, respectively). Additionally, those participants with poorer adherence were less likely to report an undetectable viral load ($\chi^2 = 6.160$, p=.013). However, CD4 counts did not differ significantly between the two groups (t=-1.762, p=.079).

The mean self-efficacy beliefs score was 139.57 (SD 29.06), with scores ranging from 17 to 170, suggesting a moderately high level of self-efficacy beliefs. Self-efficacy belief scores did not differ between inadequate/marginal and adequate functional health literacy levels (U=-4992.0, p=.634). Because these two variables did not have a significant relationship and because functional health literacy was not significantly related to medication adherence, we rejected both of the stated hypotheses. Specifically, that 1) functional health literacy has a direct positive effect on medication-taking self-efficacy; and 2) functional health literacy has an indirect, positive mediating effect on HIV medication adherence, through medication-taking self-efficacy.

Table 15: Variables of Interest—Differences Between Dichotomized Adherence Levels

	<85% Adherence n=223		≥85% Adherence n=112		Difference Between Adherence Levels	
Variable	**n**	**%**	**n**	**%**	χ^2	***p***
Gender					0.82	.367
Male	160	71.7	75	67.0		
Female	63	28.3	37	33.0		
Ethnicity					6.12	.013
White	82	36.8	57	50.9		
Non-White	141	63.2	55	49.1		
Age (years)					0.48	.788
20-30	12	5.4	8	7.1		
31-54	193	86.5	96	85.7		
55 and up	18	8.1	8	7.1		
Educational Level					1.63	.202
< HS, No GED	40	17.9	14	12.5		
GED/HS Graduate	183	82.1	98	87.5		
Employment Status					0.69	.407
Yes	42	18.8	17	15.2		
No	181	81.2	95	84.8		

	<85% Adherence n=223		≥85% Adherence n=112		Difference Between Adherence Levels	
Variable	**n**	**%**	**n**	**%**	χ^2	***p***
Current Illicit Drug Use					1.79[a]	.181
Yes	21	9.4	6	5.4		
No	108	48.4	59	52.7		
Missing	94	42.2	47	42.0		
Current Alcohol Abuse					1.00[a]	.317
Yes	7	3.1	6	5.4		
No	122	54.7	59	52.7		
Missing	94	42.2	47	42.0		
Marital Status					0.52	.770
Never married	121	54.3	59	52.7		
Married/co-habitating	50	22.4	23	20.5		
Divorced/Separated/ Widowed	52	23.3	60	6.8		
Viral Load Detectable					6.16[a]	.013
Yes	97	43.5	38	33.9		
No	97	43.5	70	62.5		
Unknown/Missing	29	13.0	4	3.6		

	<85% Adherence n=223		≥85% Adherence n=112		Difference Between Adherence Levels	
Variable	**n**	**%**	**n**	**%**	χ^2	***p***
Income					4.13[a]	.042
<$13,000	166	74.4	71	63.4		
≥$13,000	53	23.8	38	33.9		
Missing/Unknown	4	1.8	3	2.7		
Health Insurance					0.21	.646
Yes	206	92.4	10	93.8		
No	17	7.6	7	6.3		
English Primary Language					0.77[b]	.380
Yes	218	97.8	111	99.1		
No	5	2.2	1	0.9		
Recruitment Site					0.68	.411
Western PA	133	59.6	72	64.3		
Northeastern OH	90	40.4	40	35.7		
Functional health literacy					3.17	.075
Inadequate/Marginal (≤75)	28	12.6	7	6.3		
Adequate (>75)	195	87.4	105	93.8		

	<85% Adherence n=223		≥85% Adherence n=112		Difference Between Adherence Levels	
Variable	**Mean**	**SD**	**Mean**	**SD**	**t-value**	***p-value***
Age (years) Range: 20-66	42.74	7.90	45.44	7.74	-2.96	.003
Education (years) Range: 3-26	12.85	2.71	13.34	3.09	-1.49	.136
CD4 Count (n=281) Range: 4-2148	425.28	323.91	494.73	298.74	-1.76	.079
Self-Efficacy Beliefs	136.40	31.54	145.90	22.13	-3.20[b]	.002
Total # of HIV Meds	2.68	.91	2.72	.74	-0.45[b]	.654

[a]Missing data were not included in the bivariate analyses

[b]unequal variances assumed between groups

To address the second hypothesis, we used logistic regression to determine if functional health literacy and self-efficacy were related to adherence level. All variables of interest that met the screening criteria ($p<.20$) were evaluated univariately with adherence. In the univariate analysis adherence was significantly related to self–efficacy beliefs (OR: .987, *p*=.005, 95%CI=.979-.996). Those with lower functional health literacy had over two times the risk of having poorer adherence; however, this odds ratio did not reach statistical significance (OR: 2.154, *p*=.081, 95%CI=.910-5.098). Complete results are displayed in Table 16.

Table 16: Univariate Analysis Predicting Poorer Adherence (<85%)

	b	***SE***	***Wald***	***df***	***p-value***	**Odds Ratio (OR)**	**95% CI for OR**
Race: Non-White	.58	.24	6.07	1	.014	1.78	1.13-2.82
Income: <13,000/yr	.51	.25	4.14	1	.042	1.67	1.02-2.74
Functional health literacy: Inadequate/ Marginal	.77	.44	3.05	1	.081	2.15	0.91-5.10
Age (years)	-.04	.01	8.39	1	.004	0.96	0.93-.99
Education (years)	-.06	.04	2.20	1	.138	0.94	0.87-1.02
Self-Efficacy	-.01	.01	7.72	1	.005	0.99	0.98-.99

Results similar to the univariate analysis were found for the adjusted estimates when all candidate predictors were included in the multivariate model (Table 17). This model demonstrated a fair fit with the data, as assessed using the model chi-square and pseudo R-squared statistics (model $\chi^2 = 23.561$, df=6, p=.001; Cox & Snell R^2 =.068; and Nagelkerke R^2=

.094). The Hosmer and Lemeshow Test was insignificant, suggesting that the data fit the model adequately (χ^2 = 8.569, df=8, *p*=.380). The model correctly classified 66.6% of participants: 15.2% of those with better adherence and 92.4% of those with poorer adherence.

Table 17: Multivariate Model Containing All Candidate Predictors, Predicting Poorer Adherence (<85%)

	b	***SE***	***Wald***	***df***	***p-value***	**Odds Ratio (OR)**	**95% CI for OR**
Race: Non-White	.44	.25	3.20	1	.074	1.55	0.96-2.50
Income: <$13,000/yr	.36	.27	1.79	1	.182	1.43	0.85-2.43
Functional health literacy: Lower	.52	.46	1.26	1	.263	1.67	0.68-4.12
Age (continuous)	-.04	.02	5.47	1	.019	0.96	0.93-0.99
Years of Education (continuous)	.00	.04	.00	1	.991	1.00	0.92-1.09
Self-Efficacy (continuous)	-.01	.01	4.63	1	.031	0.99	.98-.99

To ascertain the appropriate final model to test, we explored the inclusion of all of the two-way interactions with the candidate predictor variables in the multivariate model. None of the interactions was statistically significant. The results of the analysis were then used to evaluate and test the final model. Variables from the fully saturated model that were not statistically significant were removed one by one. The removal of years of education and income had no effect on the model; however, removing functional health literacy resulted in race becoming significant. This finding suggests that functional health literacy may modify the relationship between race and adherence, but the interaction was not significant (OR=1.723, p=.601 95%CI=.224-13.256). The final model showed that self-efficacy is an independent predictor of medication adherence, after controlling for race and age (See Table 18). Non-white participants had over 1.5 times the odds as a white participant to demonstrate poorer adherence. The model also demonstrated that poorer adherence is associated with younger age.

Model fit results were similar to the fully saturated model. The more parsimonious version indicated that the overall model demonstrated a fair fit with the data (χ^2 = 19.986, df=3, p<.001); however, only a relatively small proportion of the variance was explained (Cox & Snell R^2 =.058 and Nagelkerke R^2= .080). The Hosmer and Lemeshow Test was insignificant, meaning that the data fit the model adequately (χ^2 = 8.569, df=8, p=.380). The model correctly classified 67.5% of the total sample: 15.2% of those with higher adherence and 93.7% of those with lower adherence. The final model was evaluated for undue influence by outliers that may influence the fit of the model using residuals, deviance values and change in χ^2. None of the cases was found to have a significant influence on the fit of the model.

Table 18: Final Parsimonious Model Predicting Poorer Adherence (<85%)

	b	***SE***	***Wald***	***df***	***p-value***	**Odds Ratio (OR)**	**95% CI for OR**
Race: Non-White	.51	.24	4.42	1	.036	1.66	1.04-2.65
Age (continuous)	-.04	.02	5.93	1	.015	0.96	0.93-0.99
Self-Efficacy (continuous)	-.01	.01	5.70	1	.017	0.99	0.98-0.99

6.6 DISCUSSION

This study, guided by Bandura's Social Cognitive Theory, sought to investigate the potential relationship between functional health literacy, self-efficacy, and HIV medication adherence. The findings indicated that there is not a statistically significant relationship between HIV medication adherence and functional health literacy, as measured using the S-TOFHLA. However, there was a non-statistically significant trend indicating that those with lower functional health literacy were more likely to have poorer adherence rates, when adherence was dichotomized at the moderate cut-off point (85%). This is one of only a few published investigations to combine the use of the S-TOFHLA and electronic monitoring to examine this relationship in people living with HIV/AIDS.

These results are contrary to both of our original hypotheses. Functional health literacy was not related to medication-taking self-efficacy. The non-significant relationship between functional health literacy and medication adherence leads to the rejection of our second hypothesis; medication-taking self-efficacy did not mediate the relationship between functional health literacy and HIV medication adherence. The results do support one of the primary relationships in Bandura's theory; specifically, the critical role of self-efficacy in predicting behavior.

Although there was a trend to indicate an association between functional health literacy and medication adherence, these results support the work of Golin et al. (2002), Wolf et al. (2004) and Paasche-Orlow et al. (2006), which all reported no significant relationship between HIV medication adherence and functional health literacy. Our results contradict three earlier separate research studies that did find a significant relationship (Graham, Bennett, Holmes, & Gross, 2006; Kalichman, Catz, & Ramachandran, 1999; Kalichman, Ramachandran, & Catz, 1999). This discrepancy may be attributable to the various ways in which functional health literacy and adherence were assessed. Five out of the six studies used measured adherence using self-report which has potential problems with memory and recall bias (Turner, 2002). Golin et al. (2002) used the most comprehensive assessment of adherence, a composite score using electronic monitoring, pill counts, and self –report. Although all methods of measurement for medication adherence have their unique problems, electronic event monitoring, used in this study, is recognized as the most appropriate tool for intervention studies and offers more information over time than biologic assays (Turner, 2002). Golin et al. reported a mean adherence rate similar to ours, 71.3%.

To assess functional health literacy, researchers used the 36- reading comprehension items from the S-TOFHLA, but none of the numeracy items; however they imputed data on 34 out of 140 patients, nearly 25%. In addition to the differences in the measure for adherence, these contradictory results may be attributable to the different ways functional health literacy was measured. Wolf et al. (2006) noted that, in their study, the REALM may not provide enough precision to adequately examine the relationship between functional health literacy and adherence.

In multivariate analysis, functional health literacy was not found to be an independent predictor of adherence; however self-efficacy did predict adherence, even after controlling for socio-demographic co-variates. Additionally, in the model we tested, self-efficacy and functional health literacy were not significantly related to one another. These results contradict the work of Wolf (2006), who found statistically significant relationships between functional health literacy and medication adherence that was mediated by self-efficacy. These results may be the result of differences in the measurement strategy. Wolf et al. used 4-day recall self report to measure adherence and dichotomized results as 100% or less than 100%; they also used the REALM to measure functional health literacy. Our results do support, however, the broad body of research that has found self-efficacy to be associated with adherence.

Adherence, in contrast to functional health literacy, was quite variable within the sample, ranging from 0.0 to 100%, with a mean of 61% (31.6) and median of 71.4%. This finding supports reports of sub-optimal adherence to HIV medication, such as Mills' (2006) meta-analysis that showed average HIV medication adherence to be approximately 55%. While there may be variation in the adherence levels required for viral suppression, Bangsberg (2006) noted that the probability of viral suppression, reduced disease progression and reduced mortality are

increased with greater adherence levels, thereby supporting continued efforts to maximize adherence in people living with HIV/AIDS.

Several limitations to this study must be noted. Although electronic event monitoring is considered the gold standard for measuring adherence, EEM is not infallible. Turner and Hecht (2001) point out that EEM assessment does not demonstrate definitively that pills were actually taken by the participant; EEM assessment functions on the assumption that the opening of the bottle represents the patient taking the medication at approximately the same time the bottle is opened. Additionally, participants may refuse to participate in studies using EEM because they may need to discontinue use of adherence tools such as pillboxes and thus, result in a selection bias. Finally, improper use or damage to EEM may limit the usefulness and availability of data (Turner & Hecht, 2001). Despite these limitations, EEM assessment is able to provide valuable insight into the individual's capacity to create and maintain a consistent medication-taking behavior. Our work is one of only a few studies to examine functional health literacy and adherence with electronic monitoring.

The study is also limited because it is a secondary data analysis, and therefore the methodology and measurement tools were selected to address other primary research questions. However, the tools and methodology addressed gaps in the literature and were appropriate to the framework and the research question of this study.

The results of this study identify several areas for further research. Although there is limited conclusive data about the relationship between functional health literacy and HIV medication adherence, our findings suggest that if there were a greater proportion of individuals with lower functional health literacy, the relationship may be more pronounced. It would be worthwhile to design a study that seeks to address specifically some of the limitations of this

study that may have served as a deterrent to those with limited functional health literacy, such as reading demands on recruitment and study materials. Also, additional research specifically targeted to the lower functional health literacy group may help contribute to a better understanding of medication adherence in that particular population. For example, researchers need to design a study exploring the specific medication taking practices and habits for someone with lower functional health literacy in order to identify unique barriers and compensatory efforts of the person functioning with lower functional health literacy.

Finally, there may be a need to improve on the measurement strategy for functional health literacy. Additional areas may need to be assessed. The individual with an "ideal" health literacy level must be able to demonstrate the ability to:

1. access and utilize the health care system, including understanding medical benefits, being able to clearly communicate with providers and other professionals, filling out forms, providing an accurate medical history;
2. navigate the health care system, including understanding how the health care system works and the individual's rights and responsibilities; and
3. perform activities associated with maintaining and improving health, preventing disease, and engaging in self-care, especially applying abstract concepts, recommendations and guidelines to actual health-related activities (Nutbeam, 2000; R. Parker & Gazmararian, 2003; U.S. Department of Health and Human Services, 2000).

With this in mind, the results of this study lead to the following question: can people living with HIV who are not taking their medication as prescribed be considered to have "adequate functional health literacy?" No matter what the reason for the less than optimal

adherence (barring, perhaps, personal choice), poorer adherence alone suggests at least some degree of difficulty with managing their health. While the S-TOFHLA may be able to measure part of the functional health literacy construct—specifically reading comprehension—it may not be able to adequately measure all of the components. This is consistent with continued calls from researchers for different and more comprehensive ways to measure functional health literacy, including tools that are disease specific.

6.7 CONCLUSION

Contrary to our original hypothesis, functional health literacy was not significantly related to medication taking self-efficacy or HIV medication adherence in a cohort of individuals currently engaged in care and taking antiretroviral medication, although there was a trend suggesting that those with lower functional health literacy had lower adherence. The participants demonstrated higher-than-expected functional health literacy levels and highly variable adherence rates. Also contrary to the original hypotheses, functional health literacy was not related to medication taking self-efficacy, but self-efficacy was an independent predictor of adherence. These findings indicate a need to further explore functional health literacy and medication regimen management, and to investigate alternative predictors of sub-optimal medication adherence in people living with HIV. Additionally, this study also highlights the need for expanded attention to how the functional health literacy construct is being defined and measured.

7.0 RESULTS: SPECIFIC AIM #4

This chapter presents the results for Specific Aim #4. The purpose of this exploratory aim was to generate hypotheses by investigating inter-relationships among functional health literacy and selected factors related to medication adherence within the constructs of Bandura's Social Cognitive Theory (SCT): individual factors, environmental factors, and health behavior. The analysis included examining the relationship between functional health literacy and those SCT factors shown to be associated with HIV medication adherence, and then examining the relationships between those factors and medication adherence. The analysis also included exploring the relationships among the SCT variables (functional health status, depressive symptoms, perceived burden of illness, social support, HIV-related stigma, and relationship with health care provider), and educational level and the 8 numeracy items from the full TOFHLA (the Numeracy Scale). This was done to ascertain if either educational level or the numeracy score provided additional explanatory power over functional health literacy. Finally, the analysis included a psychometric evaluation of the Numeracy Scale.

Specific Aim #4: Investigate the inter-relationships among the factors related to adherence within the constructs of Bandura's Social Cognitive Theory: a) individual factors (functional health literacy, medication taking self-efficacy, functional health status, depressive symptoms, and perceived burden of illness); b) environmental factors (social support, HIV-

related stigma, and relationship with health care provider); and c) the health behavior (HIV medication adherence).

7.1 PREDICTING MEDICATION ADHERENCE USING SCT VARIABLES

The Mann-Whitney U test was used to assess the bivariate relationships between functional health literacy and selected Social Cognitive Theory (SCT) variables. Functional health literacy, as measured using the S-TOFHLA, was only significantly related to the visual analog scale assessing state of mind ("My state of mind plays a _____ part in managing my illness (0-10, minor-major)") and the negative self-image subscale of the HIV-related stigma scale (Berger, Ferrans, & Lashley, 2001). Individuals with low functional health literacy were more likely to report that their state of mind played a smaller part in controlling their illness (U=3984.0, p=.019) and to display higher negative self-image (U=4167.0, p=.045). There was also a non-statistically significant trend indicating that people with lower functional health literacy reported a more complex medication regimen (U=4349.5, p=.096). Table 19 provides a detailed description of the selected SCT variables and the differences between functional health literacy levels (overall and by functional health literacy groups).

Table 19: Descriptive Statistics: Social Cognitive Theory Variables of Interest for the Total Sample and Between Functional Health Literacy Levels

	Sample N=335			Inadequate/Marginal n=35			Adequate n=300			Difference Between FHL Levels	
Variable	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**U z**	***p-value***
Depressive Symptoms (BDI-II) Range: 0.0-60.0	14.00	16.01	12.28	17.00	16.27	11.81	14.00	16.08	12.35	5067.0 -0.34	.736
Social Support (ISEL Total) Range: 6.15-120.0	78.00	75.44	23.09	72.00	71.93	23.91	78.00	75.85	22.99	4693.0 -1.03	.304
Appraisal	20.00	19.80	6.95	20.00	18.71	7.18	21.00	19.93	6.92	4730.5 -0.96	.337
Belonging	19.00	18.31	6.79	18.00	17.68	7.16	19.00	18.38	6.75	4934.5 -0.58	.560

	Sample N=335			Inadequate/Marginal n=35			Adequate n=300			Difference Between FHL Levels	
Variable	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**U z**	***p-value***
Tangible	18.29	18.29	7.23	18.00	17.37	7.35	19.00	18.40	7.22	4785.0 -0.86	.391
Self-Esteem	19.0	19.04	5.19	18.00	18.12	5.29	20.00	19.14	5.18	4647.0 -1.11	.265
Physical Functioning (MOS-HIV Physical Health Summary) Range: 17.98-63.37	43.19	43.19	11.77	40.64	42.57	13.12	43.58	44.85	11.75	5092.0 -0.29	.771

	Sample N=335			Inadequate/Marginal n=35			Adequate n=300			Difference Between FHL Levels	
Variable	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**U z**	***p-value***
Mental Health Functioning (MOS-Mental Health Summary Score) Range: 10.38-67.78	44.82	44.56	11.98	41.29	42.04	13.77	45.24	44.85	11.75	4569.0 -1.26	.209
Burden: Living with HIV has become _____ (0-10, easier – more difficult)	8.00	7.02	2.94	8.20	6.58	3.71	7.90	7.07	2.84	5208.0 -0.08	.938

	Sample N=335			Inadequate/Marginal n=35			Adequate n=300			Difference Between FHL Levels	
Variable	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**U z**	***p-value***
There is _____ I can do to control my HIV (0-10, little – much)	8.70	7.51	2.80	8.00	6.56	3.67	8.70	7.63	2.66	4712.5 -0.99	.321
My state of mind plays a _____ part in managing my illness (0-10, minor-major)	9.20	8.37	2.17	8.20	6.93	3.38	9.20	8.54	1.92	3984.0 -2.34	**.019**
Complexity of medication regimen (0-10, not complex-very complex)	1.70	3.23	3.34	5.10	4.44	3.70	1.55	3.09	3.27	4349.5 -1.66	.096

	Sample N=335			Inadequate/Marginal n=35			Adequate n=300			Difference Between FHL Levels	
Variable	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**U z**	***p-value***
Effect of side effects on daily life (0-10, small effect-large effect)	2.50	3.44	3.28	3.70	4.04	3.79	2.40	3.37	3.16	5108.5 -0.26	.794
Stigma: Personalized Range: 0-44	26.00	26.26	7.88	28.00	27.07	7.87	26.00	26.16	7.89	4788.0 -0.85	.394
Stigma: Disclosure Range: 11-44	31.36	31.19	6.85	31.36	31.93	6.45	31.36	31.11	6.91	4889.5 -0.67	.506
Stigma: Public perceptions Range: 3-36	25.00	24.88	5.85	25.00	25.23	6.02	25.00	24.84	5.84	5157.5 -0.17	.864

	Sample N=335			Inadequate/Marginal n=35			Adequate n=300			Difference Between FHL Levels	
Variable	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**U z**	***p-value***
Stigma: Negative self-image Range: 8-30	17.00	17.17	5.36	19.00	18.73	5.23	17.00	16.99	5.35	4167.0 -2.00	**.045**
Self-Efficacy: Self-efficacy Range: 17-170	148.00	139.57	29.06	139.00	134.93	32.95	148.00	140.12	28.59	4992.0 -0.48	.634
Self-Efficacy: Outcome expectancy Range: 9-90	81.00	76.03	16.39	77.00	73.31	18.14	81.00	76.35	16.18	4774.5 -0.88	.377

	Sample N=335			Inadequate/Marginal n=35			Adequate n=300			Difference Between FHL Levels	
Variable	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**Median**	**Mean**	**SD**	**U z**	***p-value***
Satisfaction with HCP (0-10, not at all satisfied to very satisfied)	10.00	8.90	1.84	10.00	8.94	1.76	10.00	8.88	1.85	5081.5 -0.35	.727

However, when these same variables were evaluated using educational level (dichotomized as high school degree/GED or higher or less than high school degree/GED), different relationships were found to be significant. People without a high school degree or GED reported significantly more depressive symptoms (U=6041.0, *p*=.018), lower physical functioning scores (U=6216.5, *p*=.036), and lower mental health functioning scores (U=6098.5, *p*=.022). Of particular note, those with no high school diploma/GED reported significantly higher levels of perceived complexity of the regimen (U=5403.5, *p*=001); however these groups did not differ in terms of the number of pills in their regimen (χ^2=0.00, *p*=1.00). See Table 20 for the complete results for those variables between the two educational levels.

Table 20: Descriptive and Group Comparative Statistics for SCT Variables Between Educational Levels

	<HS n=54		**HS or GED n=281**		**Difference Between Educational Levels**	
Variable	**Mean**	**SD**	**Mean**	**SD**	**U z**	***p-value***
Depressive Symptoms (BDI-II) Range: 0.0-60.0	20.54	14.78	15.25	11.57	6041.0 -2.37	**.018**

	<HS n=54		HS or GED n=281		Difference Between Educational Levels	
Variable	**Mean**	**SD**	**Mean**	**SD**	**U z**	***p-value***
Social Support (ISEL Total) Range: 6.15-120.0						
Appraisal	18.88	7.04	19.98	6.93	6967.5 -0.95	.341
Belonging	17.68	6.55	18.42	6.84	7267.0 -0.49	.623
Tangible	18.06	7.01	18.33	7.28	7432.5 -0.24	.812
Self-Esteem	18.56	5.61	19.13	5.12	7190.5 -0.61	.542
Physical Functioning (MOS-HIV Physical Health Summary) Range: 17.98-63.37	40.24	12.10	43.76	11.64	6216.5 -2.10	**.036**

	<HS n=54		HS or GED n=281		Difference Between Educational Levels	
Variable	**Mean**	**SD**	**Mean**	**SD**	**U z**	***p-value***
Mental Health Functioning (MOS-Mental Health Summary Score) Range: 10.38-67.78	41.18	11.42	45.21	12.00	6098.5 -2.28	**.022**
Burden: Living with HIV has become _____ (0-10, easier – more difficult)	7.27	3.17	6.97	2.90	6636.0 -1.46	.144
There is _____ I can do to control my HIV (0-10, little – much)	6.65	3.61	7.68	2.59	6791.0 -1.22	.222
My state of mind plays a _____ part in managing my illness (0-10, minor-major)	8.35	2.31	8.38	2.14	7387.0 -0.31	.758

	<HS n=54		HS or GED n=281		Difference Between Educational Levels	
Variable	**Mean**	**SD**	**Mean**	**SD**	**U z**	***p-value***
Complexity of medication regimen (0-10, not complex-very complex)	4..88	3.68	2.91	3.18	5403.5 -3.35	**.001**
Effect of side effects on daily life (0-10, small effect-large effect)	4.42	3.55	3.25	3.13	6384.0 -1.85	.065
Stigma: Personalized Range: 0-44	28.10	8.30	25.90	7.76	6498.0 -1.67	.094
Stigma: Disclosure Range: 11-44	32.08	5.82	31.02	7.03	7067.5 -0.80	.425
Stigma: Public perceptions Range: 3-36	25.40	5.97	24.79	5.84	7063.5 -0.80	.421

	<HS n=54		HS or GED n=281		Difference Between Educational Levels	
Variable	**Mean**	**SD**	**Mean**	**SD**	**U z**	***p-value***
Stigma: Negative self-image Range: 8-30	18.07	5.55	17.00	5.84	6712.0 -1.35	.179
Self-Efficacy: Self-efficacy Range: 17-170	134.27	31.82	140.59	28.45	6816.5 -1.18	.237
Self-Efficacy: Outcome expectancy Range: 9-90	76.80	15.75	75.89	16.54	7204.0 -0.59	.554
Satisfaction with HCP (0-10, not at all satisfied to very satisfied)	8.79	2.11	8.91	1.79	7505.5 -0.14	.888

The data were also examined using all 8 items from the numeracy portion of the S-TOFHLA (4 of which are used to compute the S-TOFHLA score). Scores on this scale were

dichotomized to less than or equal to 62.5% correct (five or fewer items correct) and greater than 62.5% correct (six or greater items). No other published literature was identified that used these 8-items as a separate tool for analysis. The 62.5% cut-off was chosen because it approximated the original tool developers' cut-off for the TOFHLA tool in its entirety (scores of 67 and below indicating lower functional health literacy) and because it was a more conservative approach to classifying people in the lower category.

People with numeracy scores less than or equal to 62.5% were more likely to report a higher level of complexity in their regimen ($t=3.954$, $df=333$, $p<.001$). However, again, there was no significant difference in the number of pills in their HIV regimen between these two groups ($t=-1.192$, $df=333$, $p=.234$). There was also a non-statistically significant trend indicating that people with lower scores on the numeracy score reported that their state of mind played less of a role in managing their illness than those with higher scores ($t=-1.960$, $df=333$, $p=.052$). See Table 21 for complete results for the relationships between the SCT variables and the Numeracy Scale (dichotomized at 62.5%).

Table 21: Descriptive and Group Comparative Statistics for SCT Variables Between Numeracy Levels

	≤62.5% Numeracy (n=97)		>62.5% Numeracy (n=238)		Difference Between Numeracy Levels	
Variable	**Mean**	**SD**	**Mean**	**SD**	**t-value**	***p-value***
Depressive Symptoms (BDI-II) Range: 0.0-60.0	16.18	12.15	16.07	12.35	0.07	.941
Social Support (ISEL Total) Range: 6.15-120.0						
Appraisal	19.89	6.52	19.76	7.13	0.15	.878
Belonging	18.46	6.58	18.24	6.89	0.27	.788
Tangible	17.84	6.53	18.47	7.50	-0.77	.445[a]
Self-Esteem	18.45	5.11	19.28	5.22	-1.33	.185
Physical Functioning (MOS-HIV Physical Health Summary) Range: 17.98-63.37	43.38	12.35	43.11	11.55	0.19	.850

	≤62.5% Numeracy (n=97)		>62.5% Numeracy (n=238)		Difference Between Numeracy Levels	
Variable	**Mean**	**SD**	**Mean**	**SD**	**t-value**	***p-value***
Mental Health Functioning (MOS-Mental Health Summary Score) Range: 10.38-67.78	44.12	12.49	44.74	11.79	-0.42	.672
Burden: Living with HIV has become _____ (0-10, easier – more difficult)	6.80	3.26	7.11	2.80	-0.81	.418[a]
There is _____ I can do to control my HIV (0-10, little – much)	7.13	3.21	7.67	2.60	-1.47	.144[a]
My state of mind plays a _____ part in managing my illness (0-10, minor-major)	7.97	2.60	8.54	1.95	-1.96	**.052**[a]

	≤62.5% Numeracy (n=97)		>62.5% Numeracy (n=238)		Difference Between Numeracy Levels	
Variable	**Mean**	**SD**	**Mean**	**SD**	**t-value**	***p-value***
Complexity of medication regimen (0-10, not complex-very complex)	4.38	3.49	2.76	3.17	3.95	**<.001**[a]
Effect of side effects on daily life (0-10, small effect-large effect)	3.60	3.45	3.37	3.14	0.58	.562
Stigma: Personalized Range: 0-44	26.43	7.54	26.19	8.03	0.26	.798
Stigma: Disclosure Range: 11-44	30.83	6.75	31.34	6.90	-0.62	.537
Stigma: Public perceptions Range: 3-36	24.42	6.32	25.07	5.66	-0.93	.353
Stigma: Negative self-image Range: 8-30	18.01	5.15	16.83	5.41	1.83	.068

	≤62.5% Numeracy (n=97)		>62.5% Numeracy (n=238)		Difference Between Numeracy Levels	
Variable	**Mean**	**SD**	**Mean**	**SD**	**t-value**	***p-value***
Self-Efficacy: Self-efficacy Range: 17-170	135.34	33.37	141.30	26.99	-1.56	.120[a]
Self-Efficacy: Outcome expectancy Range: 9-90	76.97	17.11	75.65	16.11	0.67	.505
Satisfaction with HCP (0-10, not at all satisfied to very satisfied)	8.82	2.02	8.92	1.76	-0.42	.674

[a]Unequal variances assumed between the two groups

These same variables of interest were analyzed with respect to their relationship to higher and lower adherence levels (dichotomized as discussed in Chapter 6). Individuals with adherence levels greater than or equal to 85% reported that side effects had made a significantly greater impact on their daily lives (t=2.252, *p*=.025). Individuals with higher adherence also reported higher medication-taking self-efficacy (t=-3.198, *p*=.002) and a larger role for their state of mind

in managing their illness (t=-2.596, *p*=.003). Table 22 presents the full details of this analysis, including mean scores of measures for both levels of adherence.

Table 22: SCT Variables Compared Between Dichotomized Adherence Levels

	<85% Adherence n=223		**≥85% Adherence n=112**		**Difference Between Adherence Levels**	
Variable	**Mean**	**SD**	**Mean**	**SD**	**t-value**	***p-value***
Depressive Symptoms (BDI-II) Range: 0.0-60.0	16.27	11.81	16.08	12.35	0.19[a]	.848
Social Support (ISEL Total) Range: 6.15-120.0	71.93	23.91	75.85	22.99	-1.08	.283
Appraisal	18.71	7.18	19.93	6.92	-1.07	.287
Belonging	17.68	7.16	18.38	6.75	-0.75	.560
Tangible	17.37	7.35	18.40	7.22	-0.48	.635
Self Esteem	18.12	5.29	19.14	5.18	-1.71	.088
Physical Functioning (MOS-HIV Physical Health Summary) Range: 17.98-63.37	42.57	13.12	44.85	11.75	-0.46	.648

	<85% Adherence n=223		≥85% Adherence n=112		Difference Between Adherence Levels	
Variable	**Mean**	**SD**	**Mean**	**SD**	**t-value**	***p-value***
Mental Health Functioning (MOS-Mental Health Summary Score) Range: 10.38-67.78	42.04	13.77	44.85	11.75	-1.43	.152
Burden: Living with HIV has become _____ (0-10, easier –more difficult)	6.58	3.71	7.07	2.84	-0.06	.954
There is _____ I can do to control my HIV (0-10, little – much)	6.56	3.67	7.63	2.66	-1.38	.169
My state of mind plays a _____ part in managing my illness (0-10, minor-major)	6.93	3.38	8.54	1.92	-2.60[a]	**.003**
Complexity of medication regimen (0-10)	4.44	3.70	3.09	3.27	0.73	.469
Effect of side effects on daily life (0-10)	4.04	3.79	3.37	3.16	2.25	**.025**

	<85% Adherence n=223		≥85% Adherence n=112		Difference Between Adherence Levels	
Variable	**Mean**	**SD**	**Mean**	**SD**	**t-value**	***p-value***
Stigma: Personalized Range: 0-44	27.07	7.87	26.16	7.89	1.70	.089
Stigma: Disclosure Range: 11-44	31.93	6.45	31.11	6.91	0.61	.540
Stigma: Public perceptions Range: 3-36	25.23	6.02	24.84	5.84	0.88	.378
Stigma: negative self-image Range: 8-30	18.73	5.23	16.99	5.35	1.31	.193
Self Efficacy: Self-Efficacy Range: 17-170	134.93	32.95	140.12	28.59	-3.20[a]	**.002**
Self-Efficacy: Outcome Expectancy Range: 9-90	73.31	18.14	76.35	16.18	-1.26[a]	.210
Satisfaction with HCP Range: 1-10	8.94	1.76	8.88	1.85	-0.84	.402

[a]Unequal variances assumed between the two groups.

Logistic regression models were run to evaluate the ability of the selected variables to predict higher adherence (greater than or equal to 85%). All variables that were related at a significance level of p<.20 and below in the bivariate analysis were included in this analysis. The variables meeting this criterion were: self-esteem subscale of the ISEL, mental health summary score, perceived control over illness, degree to which state of mind manages illness, impact of side effects, personalized stigma, negative self-image subscale of HIV stigma, self-efficacy beliefs, and functional health literacy.

Each variable was evaluated independently for its ability to predict higher medication adherence. Individuals who reported that their state of mind had a greater part in managing their illness were more likely to have higher adherence (OR=5.252, p=.012 95%CI=1.430-19.291). Additionally, those who reported a smaller impact of side effects and higher self-efficacy were also more likely to have higher adherence (OR=0.432, p=.026, 95%CI=.206-.904 and OR=1.013, p=.005 95%CI=1.004-1.022, respectively). Table 23 provides the full results for the univariate analysis.

Table 23: Univariate Analysis, Predicting Higher Adherence (≥85%)

	b	***se***	***Wald***	***df***	***p-value***	**Odds Ratio (OR)**	**95% CI for OR**
ISEL: Self Esteem Subscale	0.04	0.02	2.90	1	.089	1.04	.99-1.09
MOS: Mental Health Summary (MHS)	0.01	0.01	2.05	1	.153	1.01	.99-1.03

	b	*se*	*Wald*	*df*	*p-value*	Odds Ratio (OR)	95% CI for OR
There is _____ I can do to control my HIV (0-10, little – much)	0.598	0.44	1.88	1	.170	1.82	.77-4.28
My state of mind plays a _____ part in managing my illness (0-10, minor-major)	1.66	0.66	6.24	1	.012	5.25	1.43-19.29
Impact of Side Effects	-0.84	0.38	4.96	1	.026	0.43	0.21-0.90
Personalized Stigma	-0.03	0.02	2.87	1	.090	0.98	0.95-1.00
Stigma—Negative Self Image	-0.03	0.02	1.70	1	.192	0.97	0.93-1.02
Self-Efficacy	0.01	0.01	7.72	1	.005	1.01	1.00-1.02
Functional health literacy (higher is reference)	0.77	0.44	3.05	1	.081	2.15	0.91-5.10

The multivariate model included the full set of candidate predictors that were individually assessed in the prior analysis. This model demonstrated a fair fit with the data, as demonstrated the model chi-square and the pseudo R-squared statistics (χ^2 = 20.986, df=9, p=.013; Cox &

Snell R^2 =.061; and Nagelkerke R^2= .084). The Hosmer and Lemeshow Test was not significant, suggesting that the data fit the model adequately, i.e. good-fit (χ^2 = 5.967, df=8, *p*=.651). The model correctly classified 65.7% of participants: 8.0% of those with higher adherence and 94.6% of those with lower adherence. See Table 24 for the results of the multivariate logistic regression model which includes all of the candidate predictors meeting the screening criteria.

Table 24: Results of Multivariate Regression Model Predicting Higher Adherence (≥85%)

	b	***se***	***Wald***	***df***	***p-value***	**Odds Ratio (OR)**	**95% CI for OR**
ISEL: Self Esteem Subscale	0.01	0.03	0.02	1	.884	1.00	0.95-1.07
MOS: Mental Health Summary (MHS)	-0.01	0.01	0.17	1	.682	0.99	0.97-1.02
There is _____ I can do to control my HIV (0-10, little – much)	-0.19	0.51	0.13	1	.718	0.83	0.30-2.27
My state of mind plays a _____ part in managing my illness (0-10, minor-major)	1.56	0.71	4.82	1	.028	4.75	1.18-19.09
Impact of Side Effects	-0.65	0.43	2.25	1	.133	0.52	0.23-1.22

	b	***se***	***Wald***	***df***	***p-value***	**Odds Ratio (OR)**	**95% CI for OR**
Personalized Stigma	-0.02	0.02	0.76	1	.382	0.98	0.95-1.02
Stigma—Negative Self Image	0.00	0.03	0.00	1	.957	1.00	0.94-1.06
Self-Efficacy	0.01	0.01	5.04	1	.025	1.01	1.00-1.02
Functional Health Literacy: Higher	0.54	0.46	1.39	1	.238	1.72	0.70-4.24

To ascertain the appropriate final model to test, all of the interactions with the fully saturated model were evaluated one by one. All continuous predictor variables were centered before interaction terms were created to avoid problems with multicollinearity. Three of the interactions were statistically significant (i.e. odds ratio p-values less than .05): mental health summary score by belief about ability to control disease, mental health summary score by negative self-image sub-scale of the stigma scale, and personalized stigma subscale by functional health literacy. Those three interactions were simultaneously added to the multivariate model with the candidate predictor variables. Table 25 displays the complete results for the analysis of the resultant model.

Table 25: Multivariate Model with Interactions and All Candidate Predictor Variables, Predicting Higher Adherence (≥85%)

	b	***se***	***Wald***	***df***	***p-value***	**Odds Ratio (OR)**	**95% CI for OR**
ISEL: Self Esteem Subscale	-0.01	0.03	0.16	1	.694	0.99	0.93-1.05
MOS: Mental Health Summary (MHS)	-0.01	0.02	0.10	1	.755	1.00	0.97-1.03
There is _____ I can do to control my HIV (0-10, little – much)	-0.96	0.62	2.36	1	.124	0.38	0.11-1.30
My state of mind plays a _____ part in managing my illness (0-10, minor-major)	2.65	0.87	9.25	1	.002	14.09	2.56-77.47
Impact of Side Effects	-0.72	0.44	2.64	1	.104	0.49	0.20-1.16
Personalized Stigma	0.17	0.08	4.30	1	.038	1.18	1.01-1.39
Stigma—Negative Self Image	0.00	0.03	0.00	1	.989	1.00	0.94-1.06
Self-Efficacy	0.01	0.01	5.58	1	.018	1.01	1.00-1.02

	b	*se*	*Wald*	*df*	*p-value*	Odds Ratio (OR)	95% CI for OR
Functional health literacy (higher level is reference)	0.91	0.61	2.23	1	.136	2.49	0.75-8.21
MHS* There is _____ I can do to control my HIV [a] Interaction	-0.07	0.05	2.54	1	.111	0.93	0.85-1.02
MHS* Stigma—Negative Self Image [a] Interaction	0.01	0.00	5.47	1	.019	1.00	1.00-1.01
Personalized Stigma*Functional Health Literacy [a] Interaction	-0.20	0.08	5.94	1	.015	0.82	0.69-0.96

[a] Continuous predictor variables were centered before interaction terms were created.

The multivariate model, including the candidate predictor variables and three interactions, was evaluated for fit, predictive ability, and parsimony. Predictor variables that were non-significant in the multivariate model were removed individually and the model was

evaluated at each step using the Step value of Model χ^2. The self-esteem sub-scale of the ISEL was removed (Step χ^2 = .155, df=1, *p*=.694), then the impact of side effects (Step χ^2 = 2.767, df=1, *p*=.096), the interaction of the mental health sub-scale and the perception of control over illness (Step χ^2 = 2.735, df=1, *p*=.098), and finally the perception of control over illness (Step χ^2 = .97, df=1, *p*=.481). The results for the model after removing these non-significant variables are presented in Table 26.

Table 26: Modified Multivariate Model Predicting Higher Adherence (≥85%)

	b	***se***	***Wald***	***df***	***p-value***	**Odds Ratio (OR)**	**95% CI for OR**
MOS: Mental Health Summary (MHS)	-0.00	0.01	0.10	1	.750	1.00	0.97-1.02
My state of mind plays a _____ part in managing my illness (0-10, minor-major)	1.92	0.71	7.33	1	.007	6.79	1.70-27.20
Personalized Stigma	-0.04	0.02	3.56	1	.059	0.96	0.93-1.00
Stigma—Negative Self Image	0.01	0.03	0.10	1	.759	1.01	0.95-1.07
Self-Efficacy	0.01	0.01	5.02	1	.025	1.01	1.00-1.02

	b	*se*	*Wald*	*df*	*p-value*	Odds Ratio (OR)	95% CI for OR
Functional health literacy (higher is reference)	-0.94	0.60	2.47	1	.116	0.39	0.12-1.26
MHS* Stigma—Negative Self Image[a]	0.01	0.00	7.81	1	.005	1.01	1.00-1.01
Personalized Stigma*Functional health literacy[a]	0.19	0.08	5.61	1	.018	1.21	1.03-1.42

[a] Continuous predictor variables were centered before interaction terms were created.

The above model was then tested, controlling for race and age (the two socio-demographic variables found to be related to adherence in earlier analysis). After adding the controlling variables, personalized stigma became a statistically significant independent predictor of higher adherence. Self-efficacy beliefs, conversely, was no longer a statistically significant predictor of higher adherence. Results for the model controlling for race and age are presented in Table 27.

Table 27: Modified Multivariate Model Predicting Higher Adherence (≥85%), Controlling for Race and Age

	b	***se***	***Wald***	***df***	***p-value***	**Odds Ratio (OR)**	**95% CI for OR**
Race	-0.55	0.25	4.66	1	.031	0.58	0.35-0.95
Age	0.04	0.02	6.06	1	.014	1.04	1.01-1.08
MOS: Mental Health Summary (MHS)	0.00	0.01	0.03	1	.867	1.00	0.97-1.02
My state of mind plays a _____ part in managing my illness (0-10, minor-major)	2.06	0.74	7.72	1	.005	7.84	1.83-33.54
Personalized Stigma	-0.04	0.02	4.70	1	.030	0.96	0.92-1.00
Stigma—Negative Self Image	0.02	0.03	0.61	1	.437	1.02	0.97-1.09
Self-Efficacy	0.01	0.00	3.31	1	.069	1.01	1.00-1.02
Functional health literacy (higher is reference)	-0.80	0.63	1.60	1	.206	0.45	0.13-1.55
MHS* Stigma—Negative Self Image[a]	0.01	0.00	7.89	1	.005	1.00	1.00-1.01

	b	*se*	*Wald*	*df*	*p-value*	Odds Ratio (OR)	95% CI for OR
Personalized Stigma*Functional health literacy[a]	0.20	0.09	5.14	1	.023	1.22	1.03-1.44

[a] Continuous predictor variables were centered before interaction terms were created.

The model-fit statistics for these two models (the modified model and the modified model controlling for race and age) are presented in Table 28. The model controlling for age demonstrated a better fit to the data and classifies a greater percentage of the total. The full model alone only correctly classified 16.1% of those with higher adherence, but after controlling for race and age, the model correctly classified 26.8%.

Table 28: Model Fit Comparison Predicting Higher Adherence (≥85%)

Model	Fit Statistics
Modified Model (Table 26)	Model χ^2 =34.433 (*df* = 8, *p* <.001) Hosmer-Lemeshow χ^2 =7.033 (*df* = 8, *p* = .533) Cox-Snell R^2 =0.098 Nagelkerke R^2 =0.136 Classification Total =67.2% Lower Adherence (<85%) =92.8% Higher Adherence =16.1%
Modified Model, Controlling for Race and Age (Table 27)	Model χ^2 =32.549 (*df* = 8, *p* <.001) Hosmer-Lemeshow χ^2 =9.052 (*df* = 8, *p* = .338) Cox-Snell R^2 =.129 R^2 Nagelkerke R^2 =.179 Classification Total =68.7% Lower Adherence (<85%) =89.7% Higher Adherence =26.8%

The final modified model was evaluated for undue influence by outliers that may influence the fit of the model using residuals and change in χ^2. Subjects with deviance values greater than 2 were evaluated as possible outliers; three cases fit those conditions. The model was tested with those three cases removed individually. One of the cases had inadequate/marginal functional health literacy and appeared to be a multivariate outlier, suggesting that this model did not adequately fit profiles similar to this case. However, the relatively small number of participants with inadequate/marginal functional health literacy (n=35) makes it less probable that there will be a group of people displaying those particular characteristics. Removal of these cases did not result in a significant change in χ^2 for the model; therefore it was concluded that none of the cases had undue influence on the model.

7.2 PSYCHOMETRIC PROPERTIES OF THE TOFHLA NUMERACY SCALE

The psychometric properties of the 8-item Numeracy Scale (comprised of all 8 items from the original long-form TOFHLA) were evaluated. Reliability was assessed using Cronbach's alpha, item analysis and inter-item correlations. Exploratory factor analysis was performed to assess the construct validity and dimensionality of the Numeracy Scale. Principal component analysis with a varimax rotation was the extraction method used.

Reliability analysis yielded a Cronbach's alpha of .578 for the 8 items of the Numeracy Scale. The weak internal consistency of the instrument was further demonstrated in the item-to-item correlations. The inter-item correlation mean was .147, with a range of .028 to .576, and a variance of .016. Table 29 displays the full inter-item correlation matrix.

Table 29: Inter-Item Correlation Matrix

	1	2	3	4	5	6	7	8
Pill bottle with prescription and dosing information								
1. If you were to take your first tablet at 7 am when should you take the next one?*		.331	.162	.057	.032	.130	.084	.152
2. And the next one after that?			.576	.028	.029	.056	.070	.066
3. What about the last one for the day?				.084	.091	.044	.117	.092
Blood sugar reading with normal range provided								
4. If this were your score, would your blood sugar be normal?*					.057	.182	.167	.172
Appointment card with time and location								
5. When is your next appointment?*						.257	.148	.128
6. Where should you go?							.130	.252
Pill bottle with prescription and dosing information								

	1	2	3	4	5	6	7	8
7. If you eat lunch at noon and want to take meds before lunch, when should you take it?*								.432
8. If you forgot before lunch, when should you take it?								

* Questions included in S-TOFHLA computation

To further test the reliability of the Numeracy Scale, item analysis was done on the 8 items of the subscale. For all versions of the scale (i.e. a scale with each item removed individually) the Cronbach's alpha was between .509 and .576. Although reliability testing indicated that eliminating any of the items resulted in a decrease in the alpha, a few of the items had a greater decrease. Item 4 had the smallest effect on the alpha coefficient when it was deleted, indicating that it was a relatively less informative item, while item 3 was the most informative item. It is important to note that these differences were very minor, and that the coefficient alpha remained very similar with the deletion of any of the items.

A three-factor model was supported with initial eigenvalues of 2.064, 1.492, and 1.013. This model accounted for 57.11% of the variance. The three factors were described as: 1) prescription dosing instructions; 2) complicated instructions with applied numeracy; and 3) simple instructions containing numbers. Items did not appear to cross-load on the identified factors. See Table 30 for items and their factor loadings.

Table 30: Factor Loadings Obtained Via Exploratory Factor Analysis, Varimax Rotated Component Matrix of Numeracy Items from TOFHLA

	Factor 1	Factor 2	Factor 3
Pill bottle with prescription and dosing information			
1. If you were to take your first tablet at 7 am when should you take the next one?*	**.538**	.154	.071
2. And the next one after that?	**.887**	-.018	-.006
3. What about the last one for the day?	**.812**	.035	.032
Blood sugar reading with normal range provided			
4. If this were your score, would your blood sugar be normal?*	.033	**.481**	.119
Appointment card with time and location			
5. When is your next appointment?*	.042	.014	**.826**
6. Where should you go?	.049	.244	**.729**
Pill bottle with prescription and dosing information			
7. If you eat lunch at noon and want to take meds before lunch, when should you take it?*	.077	**.791**	.007
8. If you forgot before lunch, when should you take it?	.078	**.792**	.121

* Questions included in S-TOFHLA computation

To explore the construct validity of the tool, each numeracy item was also assessed for its individual relationship with medication adherence. Only question 7 (participant is given the labeled prescription bottle and asked, "If you eat lunch at noon and want to take meds before lunch, when should you take it?") showed some degree of association with dichotomized

medication adherence, although it was not statistically significant (χ^2=3.635, *p*=.057). Table 31 displays the full results of this analysis.

Table 31: Numeracy Items Relationships to Dichotomized Medication Adherence Based on Percentage of Days with Correct Intake

	<85% Adherence n=223		**≥85% Adherence n=112**		**Difference Between Adherence Levels**	
	Incorrect		**Incorrect**			
Items	**n**	**%**	**n**	**%**	**χ^2**	***p-value***
Pill bottle with prescription and dosing information						
1. If you were to take your first tablet at 7 am when should you take the next one?*	27	12.11%	14	12.5%	.01	.918
2. And the next one after that?	98	43.95%	49	43.5%	.00	.973
3. What about the last one for the day?	128	57.40%	70	62.5%	.80	.370
Blood sugar reading with normal range provided						
4. If this were your score, would your blood sugar be normal?*	43	19.28%	19	16.96%	.27	.606

	<85% Adherence n=223		≥85% Adherence n=112		Difference Between Adherence Levels	
	Incorrect		Incorrect			
Items	**n**	**%**	**n**	**%**	χ^2	***p-value***
Appointment card with time and location						
5. When is your next appointment?*	10	4.48%	8	7.14%	1.04	.309
6. Where should you go?	13	5.83%	3	2.68%	1.63	.202
Pill bottle with prescription and dosing information						
7. If you eat lunch at noon and want to take meds before lunch, when should you take it?*	42	18.83%	12	10.71%	3.64	.057
8. If you forgot before lunch, when should you take it?	54	24.22%	20	17.86%	1.75	.186

8.0 DISCUSSION, CONCLUSIONS AND IMPLICATIONS

The primary purpose of this study was to examine the relationships between functional health literacy, self-efficacy, and medication adherence. The discussion of the findings, implications for future research, and limitations of that analysis were described in the two manuscripts in Chapters 5 and 6. This chapter focuses primarily on the other variables introduced for the expanded analysis in the exploratory aim as described in Chapter 7.

8.1 DISCUSSION OF FINDINGS FOR SPECIFIC AIM #4

Specific Aim #4 sought to investigate the inter-relationships among the factors related to adherence within the constructs of Bandura's Social Cognitive Theory: a) individual factors (functional health literacy, medication taking self-efficacy, functional health status, depressive symptoms, and perceived burden of illness); b) environmental factors (social support, HIV-related stigma, and relationship with health care provider); and c) the health behavior (HIV medication adherence).

Previous chapters described the sample and the results of the first three specific aims. In summary, the sample was comprised of 335 people living with HIV. The sample was primarily male (70.1%), with a mean age of 43.64 ($\pm$ 4.93) years. Over half (56.7%) of the participants were African-American. Approximately 10% (n=35) of the sample demonstrated inadequate or

marginal health literacy. Overall medication adherence rates were suboptimal, with an average of approximately 60%. Functional health literacy was not related to medication taking self-efficacy or HIV medication adherence. Medication taking self-efficacy was significantly related to HIV medication adherence.

Functional health literacy, as measured by the S-TOFHLA did not demonstrate statistically significant relationships with the majority of the Social Cognitive Theory (SCT) variables related to HIV disease management. This study did not find functional health literacy to be related to depressive symptoms. These results contradict some previously published research by Lincoln et al. (2006) and Morris, McLean and Littenberg (2006) who found low functional health literacy to be associated with increased depressive symptoms. This dissertation study was one of the first studies to look at the relationship between functional health literacy and the other SCT variables of interest, so this information cannot be compared against the published literature. Only disease burden, as measured by the degree that state of mind affects ability to manage disease, and the negative self-image sub-scale of the HIV-stigma tool were significantly related to health literacy. It is interesting to note that these two variables were included in the final logistic regression models predicting higher adherence in this sample.

This study also explored the potential usefulness of educational level and the Numeracy Scale (two variables closely related to health literacy) as factors related to adherence that may offer additional explanatory information. Educational level, dichotomized as less than high school or GED or high school/GED or greater, was associated with more of the variables from SCT included in this analysis than functional health literacy. Specifically, educational level was significantly associated with depressive symptoms, physical functioning, mental health functioning, burden of the disease, perceived complexity of the medication regimen, and

perceived impact of side effects on daily life. The results of this exploratory aim are similar to work from Paasche-Orlow et al. (2005) who found that educational level and not functional health literacy was associated with HIV risk behavior. These results lend support to the proposition that functional health literacy and educational attainment are separate characteristics.

The expanded 8-item Numeracy Scale did have a significant association with one of the variables of interest (complexity of the medication regimen) and a borderline relationship with two other variables (impact of state of mind on controlling illness and negative self-image related to HIV-stigma). These results suggest that those individuals with lower numeracy skills perceive things to be more complicated than those with higher numeracy skills. They also suggest that there is some value to continuing to study this area, in particular the different ways that complexity of regimen is interpreted by people with higher and lower health literacy, and the potential impact of those perceptions on attitudes about taking their medicines and medication adherence. However, the psychometric analysis of the Numeracy Scale revealed that, as currently constructed, this tool does not have good reliability; therefore these results are questionable.

The degree to which state of mind controls illness was an important variable in this study. The characteristic was related to health literacy, numeracy (as a non-statistically significant trend), and was the most promising predictor of adherence in this study. These findings may offer some insight into medication adherence, and how the perception of the individual influences adherence; it may also offer some explanation into the relationship between health literacy and adherence, even though functional health literacy was not an independent predictor of adherence. Potentially, people with higher health literacy believe that their outlook and perspective toward HIV has an impact on their health outcomes; potentially that awareness leads

those individuals to be more cognizant of how they are approaching their own health management, leading to better adherence. It is interesting to note that functional health literacy was significantly related to state of mind, but not to self-efficacy beliefs or the statement "There is little/much I can do to control my illness." This suggests that state of mind may be something separate and distinct from control or confidence in one's abilities.

This study allowed for the continued exploration of some of the theoretical relationships suggested by Bandura's Social Cognitive Theory (SCT) (1986) that have been supported in previous studies. As theorized in the model and much of the published literature, self-efficacy was significantly related to medication adherence. This relationship is one of the key components of the theory, so these results support that particular pathway.

Bandura's theory attempts to explain how people behave, using three categories of factors: environmental, individual, and aspects of the behavior itself. The behavior being investigated here was HIV medication adherence. In addition to self-efficacy, the individual factors that demonstrated, on their own, a significant relationship with functional health literacy included race, age, and impact of state of mind in controlling illness. Personalized stigma was the only environmental variable to demonstrate a significant relationship with adherence.

According to Bandura (1986), the three factors (individual, environment, and health behavior) continually influence each other so one would expect interactions between variables. This study found two significant interactions: mental health functioning (individual) by negative self image related to HIV-stigma (environmental), and functional health literacy (individual) by personalized stigma (environmental). Specifically, people with higher mental health functioning and lower negative self image related to HIV stigma were more likely to report better adherence. Also, those with higher functional health literacy and lower personalized stigma were more

likely to demonstrate better adherence. Personalized stigma, in this context, is the experience of actually being rejected or perceiving rejection based on HIV status. Since the primary aims of this study examined the influence of health literacy on medication adherence, this last interaction is of particular interest and may suggest that factors related to the environment may serve as a buffer for the detrimental effects of functional health literacy on medication adherence.

8.2 LIMITATIONS

The limitations of this secondary analysis were discussed in Chapters 5 and 6. This more exploratory analysis does reveal one additional limitation related to cognitive function and its potential relationship to functional health literacy and medication adherence in persons living with HIV. This study did include a screening measure for HIV-related dementia, but the broader analysis did not include an examination of cognitive functioning in general, and how cognitive functioning may influence disease management in this population. Therefore, these findings are not able to adequately separate issues of cognitive function from those related specifically to functional health literacy. Additionally, there is not yet a good empirical understanding of the difference between cognitive functioning and health literacy. Further exploration of this issue is warranted in order to make clear the distinction between the two and to investigate how each are related to health behavior and disease management.

Due to the limited proportion of participants with adequate or marginal health literacy, the analysis plan needed to be amended. The required change in the data analysis plan presented a unique challenge. Although this was not necessarily a limitation, the contingency plan was a

significant deviation from the original plan. The final distribution of the functional health literacy data required the amended model; however, this analytical approach was less useful, in that it did not allow for full-scale testing of the model.

8.3 IMPLICATIONS FOR FUTURE RESEARCH

The exploratory analysis provides several potential areas for further research. This includes several potential lines of inquiry to generate further hypotheses on the mechanism by which functional health literacy may be related to medication adherence or disease management in this population.

First, while the relationship between functional health literacy and medication adherence was not statistically significant, there are trend data to warrant further examination. Of particular interest is the interactive effect of functional health literacy and the personalized stigma sub-scale of the HIV-stigma tool. Functional health literacy may potentially moderate or mediate the impact of personalized stigma on medication adherence. In turn, such a relationship might suggest that adherence interventions that include components related to dealing with stigma may be beneficial for people with lower health literacy.

Second, the pronounced effect that the perceived influence of state of mind on managing illness has on medication adherence is notable for many reasons. This variable was significantly related to functional health literacy, had a borderline relationship with the Numeracy Scale, and was included in the final logistic regression model predicting higher adherence. Individuals reporting that state of mind had a great part to play in managing adherence were both more likely to report higher functional health literacy and demonstrate higher adherence. Additional work is

needed to explore how "state of mind" is interpreted by this population, and the way in which this perception influences medication adherence in particular and disease management in general.

Finally, the work as a whole suggests that while there are some factors consistently related to adherence, it may be necessary to revisit some of the traditional predictors of medication taking behavior. Given the significant literature presented in Chapter 2 supporting the relationship between medication adherence and social support, depression, regimen burden, and stigma, one would have expected to see more significant relationships between the selected variables in this study. These results, combined with the highly variable adherence rates, contradict much of that literature. Furthermore, the results suggest that medication adherence in people living with HIV may be too variable and subject to too many different influences for one model to offer comprehensive explanatory power. This study supports continued targeted research in specific sub-populations of people with HIV, such as individuals with lower functional health literacy.

Future research needs to continue to test the models proposed and evaluated in this study, using a more sophisticated analytic approach such as structural equation modeling. In order to accomplish this, researchers will need to focus on recruiting a greater proportion of individuals with HIV who demonstrate lower functional health literacy. This may be accomplished by targeting recruitment activities and removing potential barriers to the participation of those with lower functional health literacy (high literacy demands or a research protocol that may be perceived as too complicated or difficult).

Despite significant limitations, the present research does offer some insight into the relationship between functional health literacy and HIV medication adherence. Continued

research that includes incorporating more theoretical approaches as well as measurement and methodological considerations would help advance knowledge in this area. Additionally, focused research more closely examining a population of people identified with lower functional health literacy, may provide additional guidance on how to best intervene with this particular sub-set of people living with HIV.

APPENDIX A: IRB APPROVAL

University of Pittsburgh

Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
http://www.irb.pitt.edu

Memorandum

TO: ALISON COLBERT
FROM: SUE BEERS, PhD, Vice Chair
DATE: 4/27/2007
IRB#: PRO07040093
SUBJECT: Health Literacy, Self-Efficay and HIV Medication Adherence

---

The above-referenced project has been reviewed by the Institutional Review Board. Based on the information provided, this project meets all the necessary criteria for an exemption, and is hereby designated as "exempt" under section 45 CFR 46.101(b)(4).

Please note the following information:

- If any modifications are made to this project, please contact the IRB Office to ensure it continues to meet the exempt category.
- Upon completion of your project, be sure to finalize the project by submitting a termination request.

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

APPENDIX B: APPROVAL TO USE TEST OF FUNTIONAL HEALTH LITERACY (TOFHLA) NUMERACY ITEMS

Current Folder: **INBOX** **Sign Out**

Compose Addresses Folders Options Search Help

Message List | Delete Previous | Next Forward | Forward as Attachment | Reply | Reply All

Subject: RE: TOFHLA
From: "Baker, David, M.D." <DBaker1@nmff.org>
Date: Tue, November 13, 2007 3:58 pm
To: amc38@pitt.edu
Priority: Normal
Options: View Full Header | View Printable Version

That's fine
db
David W. Baker, MD, MPH
Michael A. Gertz Professor in Medicine
Chief, Division of General Internal Medicine
Associate Director, Institute for Healthcare Studies
Feinberg School of Medicine, Northwestern University
750 N. Lake Shore Drive, 10th Floor
Chicago, IL 60611
312-503-6407

Assistant: Tahitia Young 312-503-6400
Clinical Office: 312-695-8630

-----Original Message-----
From: amc38+@pitt.edu [mailto:amc38+@pitt.edu]
Sent: Tuesday, November 13, 2007 2:29 PM
To: Baker, David, M.D.
Subject: TOFHLA

Dr. Baker:

My name is Alison Colbert. I am a doctoral candidate at the University of Pittsburgh School of Nursing, completing my dissertation research in functional health literacy and HIV medication adherence. We corresponded several years ago when I was in the planning stage of this study, as we use the S-TOFHLA and we had some questions about scoring. The tool is included as part of a large RCT on an adherence intervention, and my study is a secondary data analysis of that dataset.

In my dissertation, I look at a number of different things, including an analysis of all of the 8 numeracy items from the long version of the TOFHLA. I am seeking permission from you to include the exact working of those 8-items in my dissertation document and subsequent manuscripts. If you would prefer I didn't, I will paraphrase or offer an alternative description for each of the items (and if you have any preferences about that, please let me know).

Thank you for your time and consideration.

Sincerely,

Alison

Alison Colbert, PhD(c), MSN, APRN-BC
University of Pittsburgh School of Nursing

APPENDIX C: INSTRUMENTS

Instrument Number: 302
(For internal use only)

(staple here)

Study ID: 071

Sociodemographic Questionnaire

Center for Research in Chronic Disorders
University of Pittsburgh

ID Number: _____ Administration Date: ___ / ___ / ____
(month) (day) (year)

Time: 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○

(FOR STAFF USE ONLY)

Directions: The information requested is important to understand more about you and your health. A person's characteristics have been shown to influence health, either through heredity or current and past lifestyle practices. The information that you provide will be used for research purposes only and will be held in **confidence**. For each question, please select the response that best describes you. If you do not know the information requested, mark "Do Not Know" or "Unknown" as indicated. If you feel that a question does not apply to you, mark "Not Applicable."

1. What is your sex?

○ (1) Male
○ (2) Female

2. What is your date of birth?

___ / ___ / ____
(month) (day) (year)

3. What is your age? *(Please list your age at your last birthday.)*

___ (years)

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4. Which one of the following best describes your current marital status?

- O (1) Never married
- O (2) Currently married
- O (3) Living with partner/significant other
- O (4) Widowed
- O (5) Separated
- O (6) Divorced
- O (7) Other (specify) ----> [ ]

5. How many years have you been at your current marital status? *(If less than one year, please write "00")*

[ ] [ ] (years)

Given the ever-increasing ethnic diversity of the population in the United States of America, the following questions are being asked to gather information on your racial/ethnic background....

6. Do you consider yourself to be Hispanic or Latino, that is, of Mexican, Puerto Rican, Cuban, Caribbean, or of Latin American descent?

- O (1) Yes
- O (2) No
- O (3) Do Not Know

7. What is your race? *(Please choose ALL categories that apply)*

(a.) White	O (1) Yes
(b.) Black or African American	O (1) Yes
(c.) American Indian	O (1) Yes
Please specify the tribe: _____	
(d.) Alaska Native	O (1) Yes
(e.) Native Hawaiian or other Pacific Islander	O (1) Yes
(f.) Asian	O (1) Yes
(g.) Unknown	O (1) Yes
(h.) Other	O (1) Yes
Please specify: _____	

8. Is English your primary language (the one you speak most often)?

- O (1) Yes
- O (2) No -----> Please specify language: _____

(for office use only) [ ] [ ] [ ]

9. Where do you live?

a. Please enter the 5-digit ZIPCODE of your PRIMARY RESIDENCE:
(where you live most of the time)

b. Please enter the 5-digit ZIPCODE of your SECONDARY RESIDENCE:
(where you live second most of the time)

○ **N/A**
(No Secondary Residence)

10. In what type of area did you live most of your childhood?

- ○ (1) Urban, large city
- ○ (2) Urban, small city
- ○ (3) Suburb of large city
- ○ (4) Suburb of small city
- ○ (5) Rural, farm
- ○ (6) Rural, non-farm
- ○ (7) Other (please specify) ---> _____

(for office use only)

11. How many years of formal education have you completed?

(For example, if you completed high school in the USA, you would have had 12 years of education.)

(years)

12. What is your educational background? *(Please complete to the highest level of education attained.)*

School:	Number of years attended:	Did you finish this school?	If earned a degree, specify the major area of emphasis:
a.) **Grade school** *(Grades 1 - 8)*	1)	2) ○ (1) Yes	*(Not Applicable)*
b.) **High school** *(Grades 9 - 12)*	1)	2) ○ (1) Yes	*(Not Applicable)*
c.) **Earned G.E.D.** *(Graduate Equivalent Diploma)*	*(Not Applicable)*	2) ○ (1) Yes	*(Not Applicable)*
d.) **Vocational / Technical school**	1)	2) ○ (1) Yes	_____
e.) **2 year college** *(Associate's level)*	1)	2) ○ (1) Yes	_____
f.) **4 year college** *(Bachelor's level)*	1)	2) ○ (1) Yes	_____
g.) **Graduate school** *(Master's level)*	1)	2) ○ (1) Yes	_____
h.) **Professional school** *(ex: MD, D.V.M., JD)*	1)	2) ○ (1) Yes	_____
i.) **Graduate school** *(Doctoral level) (ex: Ph.D., Ed.D.)*	1)	2) ○ (1) Yes	_____
j.) **Other;** *please specify:* _____	1)	2) ○ (1) Yes	_____

13. What is your current employment status?

○ (1) Full time (working at least 35 hours a week)
○ (2) Part time (working less than 35 hours a week)
○ (3) Laid off or unemployed, but looking for work
○ (4) Laid off or unemployed, but not looking for work
○ (5) Retired, not working at all
○ (6) Retired, but working part or full time
○ (7) Disabled/unable to work
○ (8) Full time homemaker
○ (9) Student
○ (10) Other (specify) ---->

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14. Are you currently employed?

○ (1) Yes ——> a.) What is your primary occupation? (the one where you work the most hours per week):

Write in job title: _____ (for office use only) | | | |

b.) Has this been your primary occupation for most of your working life?

○ (1) Yes

○ (2) No ----> c.) What was your primary occupation?

Write in job title: _____ (for office use only) | | | |

d.) Did you change occupations since your illness?

○ 1 Yes ----------> e.) Select all that apply:

1. Because of the **physical** demands of my job. ○ (1) Yes
2. Because of the **mental** demands of my job. ○ (1) Yes
3. Other (specify) ○ (1) Yes

V

_____

○ 2 No; my change in occupation was not because of my illness.

○ (2) No ——> f.) When you were employed, what was your primary occupation?

Write in job title: _____ (for office use only) | | | |

g.) When was the last year that you were employed? | | | | |

h.) Did you stop working because of your illness?

○ 1 Yes ----------> i.) Select all that apply:

1. Because of the **physical** demands of my job. ○ (1) Yes
2. Because of the **mental** demands of my job. ○ (1) Yes
3. Other (specify) ○ (1) Yes

V

_____

○ 2 No; my stopping work was not because of my illness.

○ (3) I have NEVER been employed

15. Do you have any children?

- O (1) Yes ----> a.) Please specify the number of children: ☐☐
- O (2) No

16. How many people *presently* live in your household including yourself?

a. ☐☐ (adults)

b. ☐☐ (children under age 18)
If NONE, enter 00.

17. Do you have a religious background or preference?

- O (1) Yes ----> a.) Please specify: (Choose one response only)
  - O (1) Catholic (ex: Roman Catholic)
  - O (2) Jewish
  - O (3) Protestant (ex: Lutheran; Presbyterian; Methodist; Unitarian)
  - O (4) Other (specify) ----> _____

  (for office use only) ☐☐☐

  b.) To what extent do you follow the customs and practices of your religion?
  - O (1) Never
  - O (2) Sometimes
  - O (3) Frequently
  - O (4) Always
- O (2) No

18. How important is religion or spirituality in your life?

- O (1) Not at all important
- O (2) Somewhat important
- O (3) Extremely important

19. Do you have health care insurance?

○ (1) Yes --->
○ (2) No

a.) What type(s) of insurance do you have? (Choose all that apply.)

1.) Medicare	○ (1) Yes
2.) Medicaid	○ (1) Yes
3.) SSI	○ (1) Yes
4.) Veterans Administration	○ (1) Yes
5.) Workers Compensation	○ (1) Yes
6.) Private health insurance	○ (1) Yes
7.) Other (specify) V _____	○ (1) Yes

b.) Does your insurance cover the cost of <u>medication</u>?

○ (1) Yes, all
○ (2) Yes, some of the cost ---> Please specify in what way: _____
○ (3) No
○ (4) Unknown

c.) Does your insurance cover the cost of <u>health care</u>?

○ (1) Yes, all
○ (2) Yes, some of the cost ---> Please specify in what way: _____
○ (3) No
○ (4) Unknown

The following questions concern family and individual income. We recognize the sensitive nature of these questions. This information is important in order to understand the economic impact of the chronic illness on the family and individual. Your answers will be held in strict confidence.

20. What are all the sources of <u>your own</u> total gross <u>annual</u> income (before taxes and deductions):

(a.) Wages, salaries, commisions, bonuses, or tips from all jobs	O (1) Yes
(b.) Self-employment income from farm or non-farm business	O (1) Yes
(c.) Interest, dividend, net rental income, royalty income, or income from estates or trusts	O (1) Yes
(d.) Social security or railroad retirement	O (1) Yes
(e.) Supplemental security income or other public assistance income	O (1) Yes
(f.) Retirement, survivor, or disability pensions	O (1) Yes
(g.) Other (specify): _____	O (1) Yes

21. If you are currently employed, please select <u>your own</u> gross annual income from <u>wages only</u> (before taxes and deductions):

O (1) Under $10,000
O (2) $10,000 to $14,999
O (3) $15,000 to $19,999
O (4) $20,000 to $29,999
O (5) $30,000 to $39,999
O (6) $40,000 to $49,999
O (7) $50,000 to $59,999
O (8) $60,000 to $69,999
O (9) $70,000 to $79,999
O (10) $80,000 to $99,999
O (11) $100,000 to $150,000
O (12) Over $150,000
O (13) Unknown
O (14) Refused

O **N/A (Not Employed)**

22. If you are not currently employed, but were employed in the past, please select your own gross annual income from wages (before taxes and deductions) for the last year you worked:

- O (1) Under $10,000
- O (2) $10,000 to $14,999
- O (3) $15,000 to $19,999
- O (4) $20,000 to $29,999
- O (5) $30,000 to $39,999
- O (6) $40,000 to $49,999
- O (7) $50,000 to $59,999
- O (8) $60,000 to $69,999
- O (9) $70,000 to $79,999
- O (10) $80,000 to $99,999
- O (11) $100,000 to $150,000
- O (12) Over $150,000
- O (13) Unknown
- O (14) Refused

O N/A (Never Employed)

23. What is the total gross annual income for your household from all sources (before taxes and deductions):

- O (1) Under $10,000
- O (2) $10,000 to $13,000
- O (3) $13,000 to $20,000
- O (4) $20,000 to $30,000
- O (5) $30,000 to $50,000
- O (6) Over $50,000

24. Does your current household income meet your basic needs (such as food, housing, utilities, and health care):

- O (1) Yes
- O (2) No

Instrument Number: 303
(For internal use only)

(staple here)

Study ID: 071

Sociodemographic Questionnaire (continued)

Center for Research in Chronic Disorders
University of Pittsburgh

ID Number: | | | | | | | | | | |

Administration Date: (month) / (day) / (year)

Time: 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○

(FOR STAFF USE ONLY)

25. How difficult is it to pay for your basic needs?

- ○ (1) Not at all difficult
- ○ (2) Somewhat difficult
- ○ (3) Extremely difficult

62520

Instrument Number: 822
(For internal use only)

Study ID: 071

HEALTH SURVEY

Center for Research in Chronic Disorders

ID Number: | | | | | | | | | | |

Administration Date: | | / | | / | | | | |
(month) (day) (year)

Time: 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○

(FOR STAFF USE ONLY)

Please complete the following questions to the best of your ability.

1. Most recent CD4 T-Cell Count:

2. Is your viral load detectable?

○ 1 Yes ------> a. Most recent viral load:

○ 2 No

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3. Current medications and dosages:

(a) Medication		(b) Doses/day	(c) # of Pills/dose
(1.) _____	(for office use only)		
(2.) _____	(for office use only)		
(3.) _____	(for office use only)		
(4.) _____	(for office use only)		
(5.) _____	(for office use only)		
(6.) _____	(for office use only)		
(7.) _____	(for office use only)		
(8.) _____	(for office use only)		
(9.) _____	(for office use only)		
(10.) _____	(for office use only)		

(continued on next page)

3. Current medications and dosages: *(continued)*

Medication	(a) (for office use only)	(b) Doses/day	(c) # of Pills/dose
(11.) _____			
(12.) _____			
(13.) _____			
(14.) _____			
(15.) _____			

Please complete the following questions. We are interested in obtaining information since _____ .

4. Hospitalizations?

○ 1 Yes ------> a. Reason(s):

(1.) _____

(2.) _____

(3.) _____

(4.) _____

(for office use only)

5. Emergency room visits?

○ 1 Yes ------> a. Reason(s):

(1.) _____

(2.) _____

(3.) _____

(4.) _____

(for office use only)

6. Missed medical appointments?

○ 1 Yes ------> a. How many? ☐☐

○ 2 No

b. Reason(s):

(1.) _____

(2.) _____

(3.) _____

(for office use only) ☐☐☐ ☐☐☐ ☐☐☐

7. Do you have any current infections related to HIV?

○ 1 Yes ------> a. Please list:

(1.) _____

(2.) _____

(3.) _____

(for office use only) ☐☐☐ ☐☐☐ ☐☐☐

8. Are you currently involved in a clinical trial or research study, <u>other than this one</u>?

○ 1 Yes ------> a. Please list:

(1.) _____

(2.) _____

(for office use only) ☐☐☐ ☐☐☐

9. Do you currently use any alternative therapies or treatments for HIV infection?

○ 1 Yes ------> a. Are you currently using any of these:

○ 2 No

Yes (1)		Yes (1)	
○	1. Yoga	○	5. Vitamins
○	2. Meditation	○	6. Acupuncture
○	3. Herbal therapy	○	7. Aromatherapy
○	4. Exercise	○	8. Other

10. Are you currently involved in <u>one-on-one</u> counseling?

○ 1 Yes
○ 2 No

11. Are you currently involved in <u>group counseling</u> or support groups?

○ 1 Yes ------> a. Please list:

(1.) _____

(2.) _____

(for office use only)

○ 2 No

12. Do you currently receive assistance from a community-based organization?

○ 1 Yes ------> a. Please list:

(1.) _____

(2.) _____

(for office use only)

○ 2 No

13. How satisfied are you with your relationship with your health care provider?

1	2	3	4	5	6	7	8	9	10
○	○	○	○	○	○	○	○	○	○

Not Satisfied ***Very Satisfied***

Instrument Number: 3 1 1
(For internal use only)

Study ID: 0 7 1

CO-MORBIDITY QUESTIONNAIRE

Center for Research in Chronic Disorders

ID Number: | | | | | | | | | | | Administration Date: | | / | | / | | | | |
(month) (day) (year)

Time: 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○

(FOR STAFF USE ONLY)

Please keep these rules in mind when responding to the questions....

Shade circles like this: ● ⊘
Not like this: ⊗ ✓

If you mark the wrong answer, put an X over it and mark the desired response.

For optimum accuracy, it is recommended that characters be written block style without touching the sides of the blocks, such as in the following examples. Place only one letter or one number in each box as shown....

0	1	2	3	4	5	6	7	8	9

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z

Some people have more than one health condition. We are interested in your health history. The following is a list of conditions and symptoms you may have experienced. Please complete the following questions for each condition.

1. Have you ever had a heart attack? (myocardial infarction or MI)

○ 2 No ----> Go to question 2.

○ 1 Yes ----> Please complete the following questions. This condition:

a. was diagnosed by a healthcare provider:	b. was present in the last 5 years:	c. is currently treated with the following:	d. required hospital admission:	e. has decreased your quality of life:
○ 1 Yes ○ 2 No	○ 1 Yes ○ 2 No	1. Drugs ○ 1 Yes 2. Diet ○ 1 Yes 3. Exercise ○ 1 Yes 4. Other ○ 1 Yes 5. None ○ 1 Yes	○ 1 Yes ○ 2 No	○ 0 Not at all ○ 1 Slightly ○ 2 Moderately ○ 3 Greatly ○ 4 Extremely

38096

37. Are you HIV positive?

○ 2 No ----> Go to question 38.

○ 1 Yes ----> This condition:

a. was diagnosed by a healthcare provider:	b. was present in the last 5 years:	c. is currently treated with the following:	d. required hospital admission:	e. has decreased your quality of life:
○ 1 Yes ○ 2 No	○ 1 Yes ○ 2 No	1. Drugs ○ 1 Yes 2. Diet ○ 1 Yes 3. Exercise ○ 1 Yes 4. Other ○ 1 Yes 5. None ○ 1 Yes	○ 1 Yes ○ 2 No	○ 0 Not at all ○ 1 Slightly ○ 2 Moderately ○ 3 Greatly ○ 4 Extremely

f. Do you have Acquired Immune Deficiency Syndrome (AIDS)?

○ 1 Yes
○ 2 No
○ 3 Don't know

Please answer the following questions regarding the medical conditions listed below as they pertain to you.

	Medical Condition	a. Do you have this condition? Yes 1 / No 2	b. was diagnosed by a healthcare provider: Yes 1 / No 2	c. was present in the last 5 years: Yes 1 / No 2	d. is currently treated with the following: 1 = Drugs, 2 = Diet, 3 = Exercise, 4 = Other, 5 = None — 1 2 3 4 5	e. required hospital admission: Yes 1 / No 2	f. has decreased your quality of life: 0 = Not at all, 1 = Slightly, 2 = Moderately, 3 = Greatly, 4 = Extremely — 0 1 2 3 4
38.	**Skin Disorders** (examples: Acne; Eczema) *Specify condition(s):* _____ ☐☐☐	○ ○	○ ○	○ ○	○ ○ ○ ○ ○	○ ○	○ ○ ○ ○ ○
39.	**Depression**	○ ○	○ ○	○ ○	○ ○ ○ ○ ○	○ ○	○ ○ ○ ○ ○
40.	**Anxiety**	○ ○	○ ○	○ ○	○ ○ ○ ○ ○	○ ○	○ ○ ○ ○ ○
41.	**Other Mental Problems** *Specify condition(s):* _____ ☐☐☐	○ ○	○ ○	○ ○	○ ○ ○ ○ ○	○ ○	○ ○ ○ ○ ○

42. Other health conditions?

○ 1 Yes ----> Please specify condition(s): _____

○ 2 No

Instrument Number: 795
(For internal use only)

Study ID: 071

Test of Functional Literacy in Adults
TOFHLA - 12 pt

Center for Research in Chronic Disorders

ID Number: | | | | | | | | | | |

Administration Date: ___ / ___ / ____
(month) (day) (year)

Time: 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○

(FOR STAFF USE ONLY)

NUMERACY

HAND PATIENT PROMPT FOR EACH QUESTION. THEN READ EACH QUESTION AND RECORD RESPONSES. STOP AT THE END OF 10 MINUTES.

PREFACE FIRST QUESTION WITH:

"These are directions you or someone else might be given at the hospital. Please read each direction to yourself. I will ask you some questions about what it means."

PREFACE SUCCEEDING QUESTIONS WITH:

"Have a look at this one." -or- "Here is another direction you might be given."

PROMPT 1:

If you take your first tablet at 7:00 am, when should you take the next one?

_____

N-1 ○ (1) ○ (0)

And the next one after that?

_____

N-2 ○ (1) ○ (0)

What about the last one for the day; when should you take that one?

_____

N-3 ○ (1) ○ (0)

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PROMPT 2:

If this were your score, would your blood sugar be normal today?

_____

N-4
○ (1) ○ (0)

PROMPT 3:

When is your next appointment?

_____

N-5
○ (1) ○ (0)

Where should you go?

_____

N-6
○ (1) ○ (0)

PROMPT 4:

If you eat lunch at 12:00 noon, and you want to take this medicine before lunch, what time should you take it?

_____

N-7
○ (1) ○ (0)

If you forgot to take it before lunch, what time should you take it?

_____

N-8
○ (1) ○ (0)

Comments

56787

READING COMPREHENSION

HAND PATIENT THE READING COMPREHENSION PASSAGES TO BE COMPLETED.

PREFACE THE READING COMPREHENSION EXERCISE WITH:

"Here are some other medical instructions that you or anybody might see around the hospital. These instructions are in sentences that have some of the words missing. Where a word is missing, a blank line is drawn and 4 possible words that could go in the blank appear just below it. I want you to figure out which of those 4 words should go in the blank, which word makes the sentence make sense. When you think you know which one it is, fill in the circle in front of that word, and go on to the next sentence. When you finish the page, turn to the next page and keep going until you finish all the pages."

STOP AT THE END OF 7 MINUTES.

PASSAGE A:	**X-RAY PREPARATION**
PASSAGE B:	**MEDICAID RIGHTS AND RESPONSIBILITIES**

PASSAGE A

1. **Your doctor has sent you to have a ____ X-ray.**

   - O a. stomach
   - O b. diabetes
   - O c. stitches
   - O d. germs

2. **You must have an ____ stomach when you come for ____.**

O a. asthma	O a. is
O b. empty	O b. am
O c. incest	O c. if
O d. anemia	O d. it

3. **The X-ray will ____ from 1 to 3 ____ to do.**

O a. take	O a. beds
O b. view	O b. brains
O c. talk	O c. hours
O d. look	O d. diets

READING COMPREHENSION

(continued)

THE DAY BEFORE THE X-RAY

4. For supper have only a ____ snack of fruit, ____ and jelly, with coffee or tea.

O a. little	O a. toes
O b. broth	O b. throat
O c. attack	O c. toast
O d. nausea	O d. thigh

5. After ____, you must not ____ or drink anything at ____ until *after* you have ____ the X-ray.

O a. minute	O a. easy	O a. ill	O a. are
O b. midnight	O b. ate	O b. all	O b. has
O c. during	O c. drank	O c. each	O c. had
O d. before	O d. eat	O d. any	O d. was

THE DAY OF THE X-RAY

6. Do not eat ____.

- O a. appointment
- O b. walk-in
- O c. breakfast
- O d. clinic

7. Do not ____, even ____.

O a. drive	O a. heart
O b. drink	O b. breath
O c. dress	O c. water
O d. dose	O d. cancer

8. If you have any ____, call the X-ray ____ at 616-4500.

O a. answers	O a. Department
O b. exercises	O b. Sprain
O c. tracts	O c. Pharmacy
O d. questions	O d. Toothache

THE DAY BEFORE THE X-RAY (continued)

PASSAGE B

9. I agree to give correct information to ____ if I can receive Medicaid.

- O a. hair
- O b. salt
- O c. see
- O d. ache

10. I ____ to provide the county information to ____ any statements given in this ____ and hereby

O a. agree	O a. hide	O a. emphysema
O b. probe	O b. risk	O b. application
O c. send	O c. discharge	O c. gallbladder
O d. gain	O d. prove	O d. relationship

give permission to the ____ to get such proof.

- O a. inflammation
- O b. religion
- O c. iron
- O d. county

11. I ____ that for Medicaid I must report any ____ in my circumstances within ____ (10) days of

O a. investigate	O a. changes	O a. three
O b. entertain	O b. hormones	O b. one
O c. understand	O c. antacids	O c. five
O d. establish	O d. charges	O d. ten

becoming ____ of the change.

- O a. award
- O b. aware
- O c. away
- O d. await

PASSAGE B (continued)

12. I understand ____ if I DO NOT like the ____ made on my case, I have the ____ to a fair hearing.

O a. thus	O a. marrital	O a. bright
O b. this	O b. occupation	O b. left
O c. that	O c. adult	O c. wrong
O d. than	O d. decision	O d. right

13. I can ____ a hearing by writing or ____ the county where I applied.

O a. request	O a. counting
O b. refuse	O b. reading
O c. fail	O c. calling
O d. mend	O d. smelling

14. If you ____ AFDC for any family ____, you will have to ____ a different application form.

O a. wash	O a. member	O a. relax
O b. want	O b. history	O b. break
O c. cover	O c. weight	O c. inhale
O d. tape	O d. seatbelt	O d. sign

15. ____, we will use the ____ on this form to determine your ____.

O a. Since	O a. lung	O a. hypoglycemia
O b. Whether	O b. date	O b. eligibility
O c. However	O c. meal	O c. osteoporosis
O d. Because	O d. pelvic	O d. schizophrenia

Instrument Number: 7 2 2
(For internal use only)

Study ID: 0 7 1

Self-Efficacy Scale

Center for Research in Chronic Disorders

ID Number: | | | | | | | | | | |

Administration Date: ___ / ___ / ____ (month) (day) (year)

Visit Number: 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○

Administration Time: ___ : ___ (hr) (min)

Part A:

Please rate the following items on a scale of 1 ("not at all confident") to 10 ("totally confident"):

How confident are you	Not at all confident 1	2	3	4	5	6	7	8	9	Totally confident 10
1. that you can keep your clinic appointment?	○	○	○	○	○	○	○	○	○	○
2. that you can follow your overall treatment regimen?	○	○	○	○	○	○	○	○	○	○
3. that you can follow the plan of care for taking your HIV medication?	○	○	○	○	○	○	○	○	○	○
4. that you can take your HIV medication the same time each day?	○	○	○	○	○	○	○	○	○	○
5. that you can take the correct dose of your HIV medication each day?	○	○	○	○	○	○	○	○	○	○
6. that you can follow the plan for taking your HIV medication										
a. at work?	○	○	○	○	○	○	○	○	○	○
b. on a weekday?	○	○	○	○	○	○	○	○	○	○
c. on a weekend?	○	○	○	○	○	○	○	○	○	○
d. at a social outing?	○	○	○	○	○	○	○	○	○	○
e. at a party?	○	○	○	○	○	○	○	○	○	○
f. at a planned event?	○	○	○	○	○	○	○	○	○	○
g. at an unplanned event?	○	○	○	○	○	○	○	○	○	○
h. when you travel?	○	○	○	○	○	○	○	○	○	○
i. when you feel well?	○	○	○	○	○	○	○	○	○	○
j. when you feel ill?	○	○	○	○	○	○	○	○	○	○
k. when you have side effects from your medications?	○	○	○	○	○	○	○	○	○	○
l. when you are experiencing a crisis?	○	○	○	○	○	○	○	○	○	○

Part B:

Please rate the following items on a scale of 1 ("not at all confident") to 10 ("totally confident"):

How confident are you	Not at all confident									Totally confident
7. that HIV medication will	1	2	3	4	5	6	7	8	9	10
a. improve your health?	○	○	○	○	○	○	○	○	○	○
b. improve your quality of life?	○	○	○	○	○	○	○	○	○	○
c. improve your ability to function?	○	○	○	○	○	○	○	○	○	○
d. allow you to live a long life?	○	○	○	○	○	○	○	○	○	○
e. enable you to lead a near normal life?	○	○	○	○	○	○	○	○	○	○
f. decrease the likelihood of developing HIV-related symptoms?	○	○	○	○	○	○	○	○	○	○
g. decrease your viral load?	○	○	○	○	○	○	○	○	○	○
h. increase your T-cell count?	○	○	○	○	○	○	○	○	○	○
i. prevent you from requiring hospitalization?	○	○	○	○	○	○	○	○	○	○

Instrument Number: 259
(For internal use only)

Study ID: 071

ISEL

Center for Research in Chronic Disorders

ID Number: | | | | | | | | | | |

Administration Date: ___ / ___ / ____
(month) (day) (year)

Time: 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○

Administration Time: ___ : ___
(hr) (min)

(FOR STAFF USE ONLY)

Please keep these rules in mind when responding to the questions....

Shade circles like this: ●
Not like this: ⊗ ✓

***Instructions*: This scale is made up of a list of statements each of which may or may not be true about you. For each statement, fill in the circle that corresponds to the response which best describes you. For example, choose "definitely true" if you are sure it is true about you; choose "probably true" if you think it is true but are not absolutely certain. Similarly, choose "definitely false" if you are sure the statement is false; choose "probably false" if you think it is false but you are not absolutely certain. Please fill in only one circle for each statement.**

	DEFINITELY FALSE 0	*PROBABLY FALSE* 1	*PROBABLY TRUE* 2	*DEFINITELY TRUE* 3
1. There are several people that I trust to help solve my problems.	○	○	○	○
2. If I needed help fixing an appliance or repairing my car, there is someone who would help me.	○	○	○	○
3. Most of my friends are more interesting than I am.	○	○	○	○
4. There is someone who takes pride in my accomplishments.	○	○	○	○
5. When I feel lonely, there are several people I can talk to.	○	○	○	○
6. There is no one that I feel comfortable talking to about intimate personal problems.	○	○	○	○

(continued on next page)

18429

ID Number: _ _ _ _ _ _ _ _ _ _ _ _ (for internal use only)

Date: _ _ / _ _ / _ _ (for internal use only)

Study ID: 0 7 1

	DEFINITELY FALSE 0	PROBABLY FALSE 1	PROBABLY TRUE 2	DEFINITELY TRUE 3
7. I often meet or talk with family or friends.	○	○	○	○
8. Most people I know think highly of me.	○	○	○	○
9. If I needed a ride to the airport very early in the morning, I would have a hard time finding someone to take me.	○	○	○	○
10. I feel like I'm not always included by my circle of friends.	○	○	○	○
11. There really is no one who can give me an objective view of how I'm handling my problems.	○	○	○	○
12. There are several different people I enjoy spending time with.	○	○	○	○
13. I think that my friends feel that I'm not very good at helping them solve their problems.	○	○	○	○
14. If I were sick and needed someone (friend, family member, or acquaintance) to take me to the doctor, I would have trouble finding someone.	○	○	○	○
15. If I wanted to go on a trip for a day (example: to the mountains, beach, or country), I would have a hard time finding someone to go with me.	○	○	○	○
16. If I needed a place to stay for a week because of an emergency (for example: water or electricity out in my apartment or house), I could easily find someone who would put me up.	○	○	○	○
17. I feel that there is no one I can share my most private worries and fears with.	○	○	○	○
18. If I were sick, I could easily find someone to help me with my daily chores.	○	○	○	○
19. There is someone I can turn to for advice about handling problems with my family.	○	○	○	○
20. I am as good at doing things as most other people are.	○	○	○	○

(continued on next page)

	DEFINITELY FALSE 0	PROBABLY FALSE 1	PROBABLY TRUE 2	DEFINITELY TRUE 3
21. If I decide one afternoon that I would like to go to a movie that evening, I could easily find someone to go with me.	○	○	○	○
22. When I need suggestions on how to deal with a personal problem, I know someone I can turn to.	○	○	○	○
23. If I needed an emergency loan of $100, there is someone (friend, relative, or acquaintance) I could get it from.	○	○	○	○
24. In general, people do not have much confidence in me.	○	○	○	○
25. Most people I know do not enjoy the same things that I do.	○	○	○	○
26. There is someone I could turn to for advice about making career plans or about changing my job.	○	○	○	○
27. I often don't get invited to do things with others.	○	○	○	○
28. Most of my friends are more successful at making changes in their lives than I am.	○	○	○	○
29. If I had to go out of town for a few weeks, it would be difficult to find someone who would look after my house or apartment (the plants, pets, garden, etc.).	○	○	○	○
30. There is really no one I can trust to give me good financial advice.	○	○	○	○
31. If I wanted to have lunch with someone, I could easily find someone to join me.	○	○	○	○
32. I am more satisfied with my life than most people are with theirs.	○	○	○	○
33. If I was stranded 10 miles from home, there is someone I could call who would come and get me.	○	○	○	○
34. No one I know would throw a birthday party for me.	○	○	○	○
35. It would be difficult to find someone who would lend me their car for a few hours.	○	○	○	○

(continued on next page)

	DEFINITELY FALSE 0	PROBABLY FALSE 1	PROBABLY TRUE 2	DEFINITELY TRUE 3
36. If a family crisis arose, it would be difficult to find someone who could give me good advice about how to handle it.	○	○	○	○
37. I am closer to my friends than most other people are to theirs.	○	○	○	○
38. There is at least one person I know whose advice I really trust.	○	○	○	○
39. If I needed some help in moving to a new house or apartment, I would have a hard time finding someone to help me.	○	○	○	○
40. I have a hard time keeping pace with my friends.	○	○	○	○

Instrument Number: 1 0 4
(For internal use only)

Study ID: 0 7 1

MOS-HIV HEALTH SURVEY

Center for Research in Chronic Disorders

ID Number: | | | | | | | | | | |

Administration Date: (month) / (day) / (year)

Time: 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○

(FOR STAFF USE ONLY)

Please use the following example to answer all questions:

Shade circles like this: ●
Not like this: ⊗ ✓

INSTRUCTIONS TO PATIENT: Please answer the following questions by filling in ONE circle for each question that corresponds best to your response.

1. In general, would you say your health is: *(Choose ONE response only.)*
   - ○ 1 Excellent
   - ○ 2 Very good
   - ○ 3 Good
   - ○ 4 Fair
   - ○ 5 Poor

2. How much bodily pain have you generally had during the past 4 weeks? *(Choose ONE response only.)*
   - ○ 1 None
   - ○ 2 Very mild
   - ○ 3 Mild
   - ○ 4 Moderate
   - ○ 5 Severe
   - ○ 6 Very severe

3. During the past 4 weeks, how much did pain interfere with your normal work (or your normal activities, including work outside the home and housework)? *(Choose ONE response only.)*

   ○ 1 Not at all
   ○ 2 A little bit
   ○ 3 Moderately
   ○ 4 Quite a bit
   ○ 5 Extremely

4. The following questions are about activities you might do during a typical day. Does your health **now** limit you in these activities? If so, how much? *(Choose ONE response on each line.)*

	YES, limited a lot	**YES, limited a little**	**NO, not limited**
	1	2	3
a. The kinds or amounts of vigorous activities you can do, like lifting heavy objects, running, or participating in strenuous sports	○	○	○
b. The kinds or amounts of moderate activities you can do, like moving a table, carrying groceries, or bowling	○	○	○
c. Walking uphill or climbing (a few flights of stairs)	○	○	○
d. Bending, lifting, or stooping	○	○	○
e. Walking one block	○	○	○
f. Eating, dressing, bathing, or using the toilet	○	○	○

5. Does your health keep you from working at a job, doing work around the house, or going to school? *(Choose ONE response only.)*

   ○ 1 Yes
   ○ 2 No

6. Have you been unable to do certain kinds or amounts of work, housework, or schoolwork because of your health? *(Choose ONE response only.)*

   ○ 1 Yes
   ○ 2 No

For each of the following questions, choose the ONE answer that comes closest to the way you have been feeling during the past 4 weeks.

7. How much of the time during the past 4 weeks has your health limited your social activities (like visiting with friends or close relatives)?

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5	6
○	○	○	○	○	○

8. How much of the time during the past 4 weeks:

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
	1	2	3	4	5	6
a. have you been a very nervous person?	○	○	○	○	○	○
b. have you felt calm and peaceful?	○	○	○	○	○	○
c. have you felt downhearted and blue?	○	○	○	○	○	○
d. have you been a happy person?	○	○	○	○	○	○
e. have you felt so down in the dumps that nothing could cheer you up?	○	○	○	○	○	○

For each of the following questions, choose the ONE answer that comes closest to the way you have been feeling during the past 4 weeks.

9. How often during the past 4 weeks:

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
	1	2	3	4	5	6
a. did you feel full of pep?	○	○	○	○	○	○
b. did you feel worn out?	○	○	○	○	○	○
c. did you feel tired?	○	○	○	○	○	○
d. did you have enough energy to do the things you wanted to do?	○	○	○	○	○	○
e. did you feel weighed down by your health problems?	○	○	○	○	○	○
f. were you discouraged by your health problems?	○	○	○	○	○	○
g. did you feel despair over your health problems?	○	○	○	○	○	○
h. were you afraid because of your health?	○	○	○	○	○	○

10. How much of the time during the past 4 weeks:

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
	1	2	3	4	5	6
a. did you have difficulty reasoning and solving problems (for example, making plans, making decisions, learning new things)?	○	○	○	○	○	○
b. did you forget things that happened recently (for example, where you put things and when you had appointments)?	○	○	○	○	○	○
c. did you have trouble keeping your attention on any activity for long?	○	○	○	○	○	○
d. did you have difficulty doing activities involving concentration and thinking?	○	○	○	○	○	○

11. Please respond to the following statements by choosing how "True" or "False" each statement is for you. *(Choose ONE response only per statement.)*

	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
	1	2	3	4	5
a. I am somewhat ill.	○	○	○	○	○
b. I am as healthy as anybody I know.	○	○	○	○	○
c. My health is excellent.	○	○	○	○	○
d. I have been feeling bad lately.	○	○	○	○	○

12. How has the quality of your life been during the past 4 weeks? That is, how have things been going for you? *(Choose ONE response only.)*

- O 1 Very well; could hardly be better
- O 2 Pretty good
- O 3 Good and bad parts about equal
- O 4 Pretty bad
- O 5 Very bad; could hardly be worse

13. How would you rate your physical health and emotional condition **now** compared to 4 weeks ago? *(Choose ONE response only.)*

- O 1 Much better
- O 2 A little better
- O 3 About the same
- O 4 A little worse
- O 5 Much worse

Instrument Number: 502
(For internal use only)

Study ID: 071

BDI - II

Center for Research in Chronic Disorders

ID Number: _____ Administration Date: ___ / ___ / _____
(month) (day) (year)

Time: 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○

Administration Time: ___ : ___
(hr) (min)

(FOR STAFF USE ONLY)

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the *one statement* in each group that best describes the way you have been feeling during the *past two weeks, including today*. Blacken in the circle next to the statement you have picked. If several statements in the group seem to apply equally well, choose the highest number for that group.

Please be sure that you do not choose more than one statement for any group, including Question 16 (Changes in Sleeping Pattern) or Question 18 (Changes in Appetite).

1. Sadness

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

2. Pessimism

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

3. Past Failure

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

4. Loss of Pleasure

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

5. Guilty Feelings

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

6. Punishment Feelings

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

7. Self-Dislike

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

8. Self-Criticalness

- O 0 I don't criticize or blame myself more than usual.
- O 1 I am more critical of myself than I used to be.
- O 2 I criticize myself for all of my faults.
- O 3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

- O 0 I don't have any thoughts of killing myself.
- O 1 I have thoughts of killing myself, but I would not carry them out.
- O 2 I would like to kill myself.
- O 3 I would kill myself if I had the chance.

10. Crying

- O 0 I don't cry anymore than I used to.
- O 1 I cry more than I used to.
- O 2 I cry over every little thing.
- O 3 I feel like crying, but I can't.

11. Agitation

- O 0 I am no more restless or wound up than usual.
- O 1 I feel more restless or wound up than usual.
- O 2 I am so restless or agitated that it's hard to stay still.
- O 3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

- O 0 I have not lost interest in other people or activities.
- O 1 I am less interested in other people or things than before.
- O 2 I have lost most of my interest in other people or things.
- O 3 It's hard to get interested in anything.

13. Indecisiveness

- O 0 I make decisions about as well as ever.
- O 1 I find it more difficult to make decisions than usual.
- O 2 I have much greater difficulty in making decisions than I used to.
- O 3 I have trouble making any decisions.

14. Worthlessness

- O 0 I do not feel I am worthless.
- O 1 I don't consider myself as worthwhile and useful as I used to.
- O 2 I feel more worthless as compared to other people.
- O 3 I feel utterly worthless.

15. Loss of Energy

- O 0 I have as much energy as ever.
- O 1 I have less energy than I used to have.
- O 2 I don't have enough energy to do very much.
- O 3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

- O 0 I have not experienced any change in my sleeping pattern.
- O 1a I sleep somewhat more than usual.
- O 1b I sleep somewhat less than usual.
- O 2a I sleep a lot more than usual.
- O 2b I sleep a lot less than usual.
- O 3a I sleep most of the day.
- O 3b I wake up 1-2 hours early and can't get back to sleep.

17. Irritability

- O 0 I am no more irritable than usual.
- O 1 I am more irritable than usual.
- O 2 I am much more irritable than usual.
- O 3 I am irritable all the time.

18. Changes in Appetite

- O 0 I have not experienced any change in my appetite.
- O 1a My appetite is somewhat less than usual.
- O 1b My appetite is somewhat greater than usual.
- O 2a My appetite is much less than before.
- O 2b My appetite is much greater than usual.
- O 3a I have no appetite at all.
- O 3b I crave food all the time.

19. Concentration Difficulty

- O 0 I can concentrate as well as ever.
- O 1 I can't concentrate as well as usual.
- O 2 It's hard to keep my mind on anything for very long.
- O 3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

- O 0 I am no more tired or fatigued than usual.
- O 1 I get more tired or fatigued more easily than usual.
- O 2 I am too tired or fatigued to do a lot of the things I used to do.
- O 3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

- O 0 I have not noticed any recent change in my interest in sex.
- O 1 I am less interested in sex than I used to be.
- O 2 I am much less interested in sex now.
- O 3 I have lost interest in sex completely.

Instrument Number: 817
(For internal use only)

Study ID: 071

Perceived Burden of Medication Regimen

Visual Analog Scale

Scoring Sheet

Center for Research in Chronic Disorders

ID Number: ☐☐☐☐☐☐☐☐☐☐

Administration Date: ☐☐ / ☐☐ / ☐☐☐☐ (month) (day) (year)

Time: 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○

(FOR STAFF USE ONLY)

DIRECTIONS: Place a vertical line on the lines below each that best describe your perception of the statements.

1. Complexity of medication regimen

0 ***100***

Not Complex ***Very Complex***

☐☐☐.☐☐☐

2. Impact of side effects on daily life

0 ***100***

No Affect ***Greatly Affects***

☐☐☐.☐☐☐

BIBLIOGRAPHY

Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, A. M. A. (1999). Health Literacy: Report of the Council on Scientific Affairs. *JAMA, 281*(6), 552-557.

Adams, K., & Corrigan, J. (Eds.). (2003). *Priority Areas for National Action: Transforming Health Care Quality*. Washington, DC: National Academies Press.

American Nurses Association. (2002). Nursing-Sensitive Indicators for Community-based Non-Acute Care Settings and ANA's Safety & Quality Initiative. Retrieved July 10, 2004, 2004, from http://www.ana.org/readroom/nurssens.htm

Ammassari, A., Murri, R., Pezzotti, P., Trotta, M. P., Ravasio, L., de Longis, P., et al. (2001). Self-reported symptoms and medication side effects influence adherence to highly active antiretroviral therapy in persons with HIV infection. *Journal of Acquired Immune Deficiency Syndromes, 28*(5).

Annessi, J., & Otto, L. (2004). Relationship between number of exercise counseling sessions attended and adherence to a new exercise program. *Psychological Reports, 94*, 907-908.

Arnsten, J., Demas, P. A., & Farzadegan, H. (2001). Antiretroviral therapy adherence and viral suppression in HIV-infected drug users: comparison of self-report and electronic monitoring. *Clinical Infectious Diseases, 33*, 1417-1423.

Artinian, N. T., Lange, M. P., Templin, T. N., Stallwood, L. G., & Hermann, C. E. (2001a). Functional health literacy in an urban primary care clinic. *Internet Journal of Advanced Nursing Practice., 5*(2), 11p.

Artinian, N. T., Lange, M. P., Templin, T. N., Stallwood, L. G., & Hermann, C. E. (2001b). Functional health literacy in an urban primary care clinic. *Internet Journal of Advanced Nursing Practice, 5*(2).

Avants, S., Margolin, A., Warburton, L. A., Hawkins, K. A., & Shi, J. (2001). Predictors of nonadherence to HIV-related medication regimens during methadone stabilization. *American Journal on Addictions, 10*(1), 69-78.

Baker, D. W. (2006). The meaning and the measure of health literacy. *Journal of General Internal Medicine, 21*(8), 878-883.

Baker, D. W., Gazmararian, J., Sudano, J., Patterson, M., Parker, R., & Williams, D. (2002). Health literacy and performance on the Mini-Mental State Examination. *Aging & Mental Health, 6*(1), 22-29.

Baker, D. W., Gazmararian, J. A., Williams, M. V., Scott, T., Parker, R. M., Green, D., et al. (2002). Functional health literacy and the risk of hospital admission among Medicare managed care enrollees. *American Journal of Public Health, 92*(8), 1278-1283.

Baker, D. W., Gazmararian, J. A., Williams, M. V., Scott, T., Parker, R. M., Green, D., et al. (2004). Health literacy and use of outpatient physician services by Medicare managed care enrollees.[see comment]. *Journal of General Internal Medicine, 19*(3), 215-220.

Baker, D. W., Parker, R. M., Williams, M. V., Clark, W., & Nurss, J. (1997). The relationship of patient reading ability to self-reported health and use of health services. *American Journal of Public Health, 87*(6), 1027-1030.

Baker, D. W., Parker, R. M., Williams, M. V., & Clark, W. S. (1998). Health literacy and the risk of hospital admission.[see comment]. *Journal of General Internal Medicine, 13*(12), 791-798.

Baker, D. W., Williams, M. V., Parker, R. M., Gazmararian, J. A., & Nurss, J. (1999). Development of a brief test to measure functional health literacy. *Patient Education & Counseling, 38*(1), 33-42.

Bandura, A. (1986). *Social foundation of thought and action*. Upper Saddle River, NJ: Prentice Hall.

Bandura, A. (1997). *Self-efficacy: The Exercise of Control*. New York: W.H. Freeman and Co.

Bandura, A. (2001). Social cognitive theory: an agentic perspective. *Annual Review of Psychology, 52*, 1-26.

Bangsberg, D. R. (2006). Less than 95% adherence to nonnucleoside reverse-transcriptase inhibitor therapy can lead to viral suppression.[see comment]. *Clinical Infectious Diseases, 43*(7), 939-941.

Bangsberg, D. R., Perry, S., Charlebois, E., Clark, R., Robertson, M. D., Zolopa, A., et al. (2001). Non-adherence to highly active antiretroviral therapy predicts progression to AIDS. *AIDS, 15*(9), 1181-1183.

Beck, A. T., Steer, R. A., & Brown, G. K. (1996). *BDI-II Manual*. San Antonio: The Psychological Corporation, Harcourt Brace and Company.

Benson, J. G., & Forman, W. B. (2002). Comprehension of written health care information in an affluent geriatric retirement community: Use of the test of functional health literacy. *Gerontology, 48*(2), 93-97.

Bentler, P. M. (1990). Comparative fit indices in structural models. *Psychological Bulletin, 107*, 238-246.

Bentler, P. M., & Chou, C. P. (1987). Practical issues in structural modeling. *Sociological Methods and Research, 1*(16), 78-117.

Berger, B. E., Ferrans, C. E., & Lashley, F. R. (2001). Measuring stigma in people with HIV: psychometric assessment of the HIV stigma scale. *Research in Nursing & Health, 24*(6), 518-529.

Berkman, N. D., DeWalt, D. A., Pignone, M. P., Sheridan, S. L., Lohr, K. N., Lux, L., et al. (2004). *Literacy and Health Outcomes*. Rockville, MD: Agency for Healthcare Research and Quality.

Bogart, L. M., Bird, S. T., Walt, L. C., Delahanty, D. L., & Figler, J. L. (2004). Association of stereotypes about physicians to health care satisfaction, help-seeking behavior, and adherence to treatment. *Social Science & Medicine, 58*(6), 1049-1058.

Bontempi, J. M. B., Burleson, L., & Lopez, M. H. (2004). HIV medication adherence programs: the importance of social support. *Journal of Community Health Nursing, 21*(2), 111-122.

Boomsma, A. (1983). *On the Robustness of LISREL (Maximum Likelihood Estimation) against Small Sample Size and Nonormality*. Amsterdam: Sociometric Research Foundation.

Boswell, C., Cannon, S., Aung, K., & Eldridge, J. (2004). An application of health literacy research. *Applied Nursing Research, 17*(1), 61-64.

Bouhnik, A.-D., Chesney, M., Carrieri, P., Gallais, H., Moreau, J., Moatti, J.-P., et al. (2002). Nonadherence among HIV-infected injecting drug users: the impact of social instability. *Journal of Acquired Immune Deficiency Syndromes: JAIDS, 31 Suppl 3*, S149-153.

Brook, M. G., Dale, A., Tomlinson, D., Waterworth, C., Daniels, D., & Forster, G. (2001). Adherence to highly active antiretroviral therapy in the real world: experience of twelve English HIV units. *AIDS Patient Care & Stds, 15*(9), 491-494.

Bryan, A. D., Fisher, J. D., & Benziger, T. J. (2001). Determinants of HIV risk among Indian truck drivers. *Social Science & Medicine, 53*(11), 1413-1426.

Buchmann, W. F. (1997). Adherence: a matter of self-efficacy and power. *Journal of Advanced Nursing., 26*(1), 132-137.

Carballo, E., Cadarso-Suarez, C., Carrera, I., Fraga, J., de la Fuente, J., Ocampo, A., et al. (2004). Assessing relationships between health-related quality of life and adherence to antiretroviral therapy. *Quality of Life Research, 13*(587-599).

Carey, M. P., Maisto, S. A., Kalichman, S. C., Forsyth, A. D., Wright, E. M., & Johnson, B. T. (1997). Enhancing motivation to reduce the risk of HIV infection for economically disadvantaged urban women. *Journal of Consulting & Clinical Psychology, 65*(4), 531-541.

Carmona, R. (2003). *Remarks.* Paper presented at the American Medication Association House of Delegates Meeting.

Carrieri, M. P., Chesney, M. A., Spire, B., Loundou, A., Sobel, A., Lepeu, G., et al. (2003). Failure to maintain adherence to HAART in a cohort of French HIV-positive injecting drug users. *International Journal of Behavioral Medicine, 10*(1), 1-14.

Catz, S. L., Kelly, J. A., Bogart, L. M., Benotsch, E. G., & McAuliffe, T. L. (2000). Patterns, correlates, and barriers to medication adherence among persons prescribed new treatments for HIV disease. *Health Psychology, 19*(2), 124-133.

Catz, S. L., McClure, J. B., Jones, G. N., & Brantley, P. J. (1999). Predictors of outpatient medical appointment attendance among persons with HIV. *AIDS Care, 11*(3), 361-373.

Centers for Disease Control and Prevention. (2003a). *Cases of HIV infection and AIDS in the United States by race/ethnicity, 1998-2002*. Rockville: Center for Disease Control and Prevention.

Centers for Disease Control and Prevention. (2003b). *A Glance at the HIV Epidemic*. Rockville, MD: Centers for Disease Control and Prevention.

Centers for Disease Control and Prevention. (2006). *A Glance at the HIV Epidemic*. Rockville, MD: Centers for Disease Control and Prevention.

Centers for Disease Control and Prevention, T. (2005). *HIV/AIDS Surveillance Report, Volume 16*. Atlanta: U.S. Department of Health and Human Services.

Chew, L. D., Bradley, K. A., Flum, D. R., Cornia, P. B., & Koepsell, T. D. (2004). The impact of low health literacy on surgical practice. *American Journal of Surgery, 188*(3), 250-253.

Clark, H. J., Lindner, G., Armistead, L., & Austin, B. J. (2003). Stigma, disclosure, and psychological functioning among HIV-infected and non-infected African-American women. *Women & Health, 38*(4), 57-71.

Cohen, S., Mermelstein, R., Kamarck, T., & Hoberman, H. (1985). Measuring the functional components of social support. In I. G. Sarason & B. R. Sarason (Eds.), *Social Support: Theory, Research and Application*. The Hague, Holland: Martinus Nijhoff.

Cox, L. E. (2002). Social support, medication compliance and HIV/AIDS. *Social Work in Health Care, 35*(1-2), 425-460.

Crystal, S., Fleishman, J. A., Hays, R. D., Shapiro, M. F., & Bozzette, S. A. (2000). Physical and role funtioning among persons with HIV. *Medical Care, 38*(12), 1210-1223.

Crystal, S., Sambamoorthi, U., Moynihan, P. J., & McSpiritt, E. (2001). Initiation and continuation of newer antiretroviral treatments among medicaid recipients with AIDS. *Journal of General Internal Medicine, 16*(12), 850-859.

de Olalla, P. G., Knobel, H., Carmona, A., Guelar, A., Lopez-Colomes, J. L., & Cayla, J. A. (2002). Impact of adherence and highly active antiretroviral therapy on survival in HIV-infected patients. *Journal of Acquired Immune Deficiency Syndromes: JAIDS, 30*(1), 105-110.

Deeks, S. G., Hecht, F. M., Swanson, M., Elbeik, T., Loftus, R., Cohen, P. T., et al. (1999). HIV RNA and CD4 cell count response to protease inhibitor therapy in an urban AIDS clinic: response to initial and salvage therapy. *AIDS, 13*, F35-F43.

DiMatteo, M. R. (2004). Variations in patients' adherence to medical recommendations: a quantitative review of 50 years of research.[see comment]. *Medical Care, 42*(3), 200-209.

Dunbar-Jacob, J., Erlen, J. A., Schlenk, E. A., Ryan, C. M., Sereika, S. M., & Doswell, W. M. (2000). Adherence in chronic disease. *Annual Review of Nursing Research, 18*, 48-90.

Endres, L. K., Sharp, L. K., Haney, E., & Dooley, S. L. (2004). Health literacy and pregnancy preparedness in pregestational diabetes. *Diabetes Care, 27*(2), 331-334.

Erlen, J. A. (2004). Functional health illiteracy. Ethical concerns. *Orthopaedic Nursing, 23*(2), 150-153.

Erlen, J. A., Cha, E., & Sereika, S. (2003). Self-efficacy scale of medication taking. *Unpublished*.

Erlen, J. A., & Mellors, M. P. (1999). Adherence to combination therapy in persons living with HIV: balancing the hardships and the blessings. *Journal of the Association of Nurses in AIDS Care, 10*(4), 75-84.

Erlen, J. A., Sereika, S. M., Cook, R. L., & Hunt, S. C. (2002). Adherence to antiretroviral therapy among women with HIV infection. *JOGNN - Journal of Obstetric, Gynecologic, & Neonatal Nursing, 31*(4), 470-477.

Fang, M. C., Machtinger, E. L., Wang, F., & Schillinger, D. (2006). Health literacy and anticoagulation-related outcomes among patients taking warfarin. *Journal of General Internal Medicine, 21*(8), 841-846.

Fetter, M. S. (1999). Recognizing and improving health literacy. *MEDSURG Nursing, 8*(4), 226-227.

Fisher, J. D., Fisher, W. A., Misovich, S. J., Kimble, D. L., & Malloy, T. E. (1996). Changing AIDS risk behavior: effects of an intervention emphasizing AIDS risk reduction information, motivation, and behavioral skills in a college student population. *Health Psychology, 15*(2), 114-123.

Fisher, W. A., Fisher, J. D., & Harman, J. (2003). The Information-Motivation-Behavioral Skills model: a general social psychological approach to understanding and promoting health behavior. In J. Suls & K. Wallston (Eds.), *Social Psychological Foundations of Health and Illness*. Malden: Blackwell Publishing.

Fishman, M., & Treisman, G. L. (1997). A guide to the use of antidepressants in HIV [Electronic Version]. *The Hopkins HIV Report*. Retrieved June 4, 2006 from http://www.hopkins-aids.edu/publications/report/may97_4.html.

Fleishman, J. A., & Crystal, S. (1998). Functional status transitions and survival in HIV disease: evidence from the AIDS costs and service utilization survey. *Medical Care, 36*(4), 533-543.

Fortenberry, J. D., McFarlane, M., Bleakley, A., Bull, S., Fishbein, M., Grimley, D., et al. (2002). Relationships of stigma and shame to gonorrhea and HIV screening. *American Journal of Public Health, 92*(3), 378-381.

Fortenberry, J. D., McFarlane, M. M., Hennessy, M., Bull, S. S., Grimley, D. M., St Lawrence, J., et al. (2001). Relation of health literacy to gonorrhoea related care. *Sexually Transmitted Infections, 77*(3), 206-211.

Fourney, A. M., & Williams, M. L. (2003). Formative evaluation of an intervetnion to increase compliance to HIV therapies: the ALP project. *Health Promotion Practices, 4*(2), 165-170.

Frable, D. E., Wortman, C., & Joseph, J. (1997). Predicting self-esteem, well-being, and distress in a cohort of gay men: the importance of cultural stigma, personal visibility, community networks, and positive identity. *Journal of Personality, 65*(3), 599-624.

Gazmararian, J., Baker, D., Parker, R., & Blazer, D. G. (2000). A multivariate analysis of factors associated with depression: evaluating the role of health literacy as a potential contributor. *Archives of Internal Medicine, 160*(21), 3307-3314.

Gazmararian, J., Williams, M. V., Peel, J., & Baker, D. (2003a). Health literacy and knowledge of chronic disease. *Patient Education & Counseling, 51*, 267-275.

Gazmararian, J. A., Parker, R. M., & Baker, D. W. (1999). Reading skills and family planning knowledge and practices in a low-income managed-care population. *Obstetrics & Gynecology, 93*(2), 239-244.

Gazmararian, J. A., Williams, M. V., Peel, J., & Baker, D. W. (2003b). Health literacy and knowledge of chronic disease. *Patient Education & Counseling, 51*(3), 267-275.

Goffman, E. (1963). *Stigma: notes on the management of a spoiled identity*. Englewood Cliffs, NJ: Prentice-Hall, Inc.

Golin, C. E., Liu, H., Hays, R. D., Miller, L. G., Beck, C. K., Ickovics, J., et al. (2002). A prospective study of predictors of adherence to combination antiretroviral medication.[see comment]. *Journal of General Internal Medicine, 17*(10), 756-765.

Gordillo, V., del Amo, J., Soriano, V., & Gonzalez-Lahoz, J. (1999). Sociodemographic and psychological variables influencing adherence to antiretroviral therapy. *AIDS, 13*, 1763-1769.

Graham, J., Bennett, I. M., Holmes, W. C., & Gross, R. (2006). Medication beliefs as mediators of the health literacy-antiretroviral adherence relationship in HIV-infected individuals. *AIDS and Behavior, 11*(3), 385-392.

Graney, M. J., Bunting, S. M., & Russell, C. K. (2003). HIV/AIDS medication adherence factors: inner-city clinic patient's self-reports. *Tennessee Medicine, 96*(2), 73-78.

Hallam, J. S., & Petosa, R. (2004). The long-term impact of a four-session work-site intervention on selected social cognitive theory variables linked to adult exercise adherence. 88-100.

Heckman, B. D., Catz, S. L., Heckman, T. G., Miller, J. G., & Kalichman, S. C. (2004). Adherence to antiretroviral therapy in rural persons living with HIV disease in the United States. *AIDS Care, 16*(2), 219-230.

Herek, G. M., Capitanio, J. P., & Widaman, K. F. (2002). HIV-related stigma and knowledge in the United States: prevalence and trends, 1991-1999.[see comment]. *American Journal of Public Health, 92*(3), 371-377, 2002 Mar.

Herek, G. M., Capitanio, J. P., & Widaman, K. F. (2003). Stigma, social risk, and health policy: public attitudes toward HIV surveillance policies and the social construction of illness. *Health Psychology, 22*(5), 533-540.

Hicks, G., Barragan, M., Franco-Paredes, C., Williams, M. V., & del Rio, C. (2006). Health literacy is a predictor of HV/AIDS knowledge. *Family Medicine, 38*(10), 717-723.

Howard, A., Arnsten, J., Yungtai, L., Vlahov, D., Rich, J., Schumna, P., et al. (2002). A prospective study of adherence and viral load in a large multi-center cohort of HIV-infected women. *AIDS, 16*(2175-2182).

Hu, L.-t., & Bentler, P. M. (1998). Fit indices in covariance structure modeling: sensitivity to underparametereized model misspecification. *Psychological Methods, 3*(4), 424-453.

Hu, L.-t., & Bentler, P. M. (1999). Cutoff criteria for fit indexes in covariance structure analysis: conventional criteria versus new alternatives. *Structural Equation Modeling, 6*(1), 1-55.

Ickovics, J. R., Cameron, A., Zackin, R., Bassett, R., Chesney, M., Johnson, V. A., et al. (2002). Consequences and determinants of adherence to antiretroviral medication: results from Adult AIDS Clinical Trials Group protocol 370. *Antiviral Therapy, 7*(3), 185-193.

Ironson, G., Weiss, S., Lydston, D., Ishii, M., Jones, D., Asthana, D., et al. (2005). The impact of improved self-efficacy on HIV viral load and distress in culturally diverse women living with AIDS: the SMART/EST Women's Project. *AIDS Care, 17*(2), 222-236.

Jaworski, B. C., & Carey, M. P. (2001). Effects of a brief, theory-based STD-prevention program for female college students. *Journal of Adolescent Health, 29*(6), 417-425.

Johnson, M. O., Catz, S. L., Remien, R. H., Rotheram-Borus, M. J., Morin, S. F., Charlebois, E., et al. (2003). Theory-guided, empirically supported avenues for intervention on HIV medication nonadherence: findings from the Healthy Living Project. *AIDS Patient Care & Stds, 17*(12), 645-656.

Johnson, M. O., Chesney, M. A., Goldstein, R. B., Remien, R. H., Catz, S., Gore-Felton, C., et al. (2006). Positive provider interactions, adherence self-efficacy, and adherence to antiretroviral medications among HIV-infected adults: A mediation model. *AIDS Patient Care & Stds, 20*(4), 258-268.

Kalichman, S. C. (2005). The other side of the healthy relationships intervention: mental health outcomes and correlates of sexual risk behavior change. *AIDS Education & Prevention, 17*(1 Suppl A), 66-75.

Kalichman, S. C., Benotsch, E., Suarez, T., Catz, S., Miller, J., & Rompa, D. (2000). Health literacy and health-related knowledge among persons living with HIV/AIDS. *American Journal of Preventive Medicine, 18*(4), 325-331.

Kalichman, S. C., Catz, S., & Ramachandran, B. (1999). Barriers to HIV/AIDS treatment and treatment adherence among African-American adults with disadvantaged education. *Journal of the National Medical Association, 91*(8), 439-446.

Kalichman, S. C., Ramachandran, B., & Catz, S. (1999). Adherence to combination therapies in HIV positive patients of low health literacy. *Journal of General Internal Medicine, 14*.

Kalichman, S. C., & Rompa, D. (2000a). Emotional reactions to health status changes and emotional well-being among HIV-positive persons with limited reading literacy. *Journal of Clinical Psychology in Medical Settings, 7*(4), 203-211.

Kalichman, S. C., & Rompa, D. (2000b). Functional health literacy is associated with health status and health-related knowledge in people living with HIV-AIDS. *Journal of Acquired Immune Deficiency Syndromes: JAIDS, 25*(4), 337-344.

Kalichman, S. C., Rompa, D., & Cage, M. (2000). Reliability and validity of self-reported CD4 lymphocyte count and viral load test results in people living with HIV/AIDS. *International Journal of STD & AIDS, 11*(9), 579-585.

Kalichman, S. C., Rompa, D., DiFonzo, K., Simpson, D., Austin, J., Luke, W., et al. (2001). HIV treatment adherence in women living with HIV/AIDS: research based on the Information-Motivation-Behavioral Skills model of health behavior. *Journal of the Association of Nurses in AIDS Care, 12*(4), 58-67.

Karon, J. M., Fleming, P. L., Steketee, R. W., & De Cock, K. M. (2001). HIV in the United States at the Turn of the Century: An Epidemic in Transition. *American Journal of Public Health, 91*(7), 1060-1068.

Kaufman, H., Skipper, B., Small, L., Terry, T., & McGrew, M. (2001). Effect of literacy on breast-feeding outcomes. *Southern Medical Journal, 94*(3), 293-296.

Kellerman, R., & Weiss, B. D. (1999). Health literacy and the JAMA Patient Page.[comment]. *JAMA, 282*(6), 525-526; author reply 526-527.

Kim, S., Love, F., Quistberg, D. A., & Shea, J. A. (2004). Association of Health Literacy with self-management behavior in patients with diabetes. *Diabetes Care, 27*(12), 2980-2982.

Kim, S. P., Knight, S. J., Tomori, C., Colella, K. M., Schoor, R. A., Shih, L., et al. (2001). Health literacy and shared decision making for prostate cancer patients with low socioeconomic status. *Cancer Investigation, 19*(7), 684-691.

Kleeberger, C. A., Phair, J. P., Strathdee, S. A., Detels, R., Kingsley, L., & Jacobson, L. P. (2001). Determinants of heterogeneous adherence to HIV-antiretroviral therapies in the Multicenter AIDS Cohort Study. *Journal of Acquired Immune Deficiency Syndromes: JAIDS, 26*(1), 82-92.

Kline, R. B. (2005). *Principles and Practices of Structural Equation Modeling* (Second ed.). New York City: The Guilford Press.

Kutner, M., Greenberg, E., Jin, Y., & Paulsen, C. (2006). *The Health Literacy of America's Adults: From the 2003 National Assessment of Adult Literacy (NCES 2006-483)*. Washington, DC: National Center for Education Statistics.

Larney, L. C. (2002). *Do depression, anxiety, hostility, coping style and dispositional outlook predict adherence to prescribed rehabilitation program and recovery outcomes for cardiac rehabilitation outpatients?* , State U New York At Albany, US, 1.

Legorreta, A., Yu, A., Chernicoff, H., Gilmore, A., Jordan, J., & Rosenzweig, J. C. (2005). Adherence to combined lamivudine and zidovudine versus individual components: a community-based retrospective medicaid claims analysis. *AIDS Care, 17*(8), 938-948.

Lewden, C., Raffi, F., Cuzin, L., Cailleton, V., Vilde, J. L., Chene, G., et al. (2002). Factors associated with mortality in human immunodeficiency virus type 1-infected adults initiating protease inhibitor-containing therapy: role of education level and of early transaminase level elevation (APROCO-ANRS EP11 study). The Antiproteases Cohorte Agence Nationale de Recherches sur le SIDA EP 11 study. *Journal of Infectious Diseases, 186*(5), 710-714.

Lewis, M. P., Colbert, A., Erlen, J., & Meyers, M. (2006). A qualitative study of persons who are 100% adherent to antiretroviral therapy. *AIDS Care, 18*(2), 140-148.

Lincoln, A., Paasche-Orlow, M. K., Cheng, D. M., Lloyd-Travaglini, C., Caruso, C., Saitz, R., et al. (2006). Impact of health literacy on depressive symptoms and mental health-related: quality of life among adults with addiction. *Journal of General Internal Medicine, 21*(8), 818-822.

Lindau, S. T., Tomori, C., Lyons, T., Langseth, L., Bennett, C. L., & Garcia, P. (2002). The association of health literacy with cervical cancer prevention knowledge and health behaviors in a multiethnic cohort of women. *American Journal of Obstetrics & Gynecology, 186*(5), 938-943.

Linn, J. G., Garnelo, L., Husaini, B. A., Brown, C., Benzaken, A. S., & Stringfield, Y. N. (2001). HIV prevention for indigenous people of the Amazon basin. *Cellular & Molecular Biology, 47*(6), 1009-1015.

Liu, H., Golin, C., & Miller, L. G. (2001). A comparison study of multiple measures of adherence to HIV protease inhibitors. *Annals of Internal Medicine, 134*(968-977).

Mancuso, C. A., & Rincon, M. (2006). Impact of health literacy on longitudinal asthma outcomes. *Journal of General Internal Medicine, 21*(8), 813-817.

Mayben, J., Kramer, J., Kallen, M., Franzini, L., Lairson, D., & Giordano, T. (2007). Predictors of delayed diagnosis in a recently diagnosed cohort. *AIDS Patient Care & Stds, 21*(3), 195-204.

McGinnis, K. A., Fine, M. J., Sharma, R. K., Skanderson, M., Wagner, J. H., Rodriguez-Barradas, M. C., et al. (2003). Understanding racial disparities in HIV using data from the veterans aging cohort 3-site study and VA administrative data. *American Journal of Public Health, 93*(10), 1728-1733.

McNabb, J. J., Nicolau, D. P., Stoner, J. A., & Ross, J. (2003). Patterns of adherence to antiretroviral therapy predicts biologic outcomes for human immunodeficiency virus-infected persons in clinical trials. *Clinical Infectious Diseases, 34*(8), 1115-1121.

Melbourne, K. M., Geletko, S. M., Brown, S. L., Willey-Lessne, C., Chase, S., & Fisher, A. (1999). Medication adherence in patients with HIV infection: a comparison of two measurement methods. *AIDS Reader, 9*(5), 329-338.

Meredith, K. L., Jeffe, D. B., Mundy, L. M., & Fraser, V. J. (2001). Sources influencing patients in their HIV medication decisions. *Health Education & Behavior, 28*(1), 40-50.

Miller, L. G., Liu, H., & Hays, R. D. (2003). Knowledge of antiretroviral regimen dosing and adherence: a longitudinal study. *Clinical Infectious Diseases, 36*(4), 514-518.

Mills, E. J., Nachega, J. B., Buchan, I., Orbinski, J., Attaran, A., Singh, S., et al. (2006). Adherence to antiretroviral therapy in sub-Saharan Africa and North America: a meta-analysis. *JAMA, 296*(6), 679-690.

Montalto, N. J., & Spiegler, G. E. (2001). Functional health literacy in adults in a rural community health center. *West Virginia Medical Journal, 97*(2), 111-114.

Montaque, M. C., Okoli, A. U., & Guerrier-Adams, S. (2003). Functional health literacy in African Americans with diabetes mellitus. *Joceps: the Journal of Chi Eta Phi Sorority., 49*(1), 16-20.

Morris, N. S., MacLean, C. D., & Littenberg, B. (2006). Literacy and health outcomes: a cross-sectional study in 1002 adults with diabetes. *BMC Family Practice, 7*, 49.

Murphy, D. A., Greenwell, L., & Hoffman, D. (2002). Factors associated with antiretroviral adherence among HIV-infected women with children. *Women & Health, 36*(1), 97-111.

Murphy, D. A., Roberts, K. J., Martin, D. J., Marelich, W., & Hoffman, D. (2000). Barriers to antiretroviral adherence among HIV-infected adults. *AIDS Patient Care & Stds, 14*(1), 47-58.

Naar-King, S., Templin, T., Wright, K., Frey, M., Parsons, J. T., & Lam, P. (2006). Psychosocial factors and medication adherence in HIV-positive youth. *AIDS Patient Care & Stds, 20*(1), 44-47.

National Quality Measures Clearinghouse. (2004). Glossary. Retrieved May 22, 2004, from http://www.qualitymeasures.ahrq.gov/resources/glossary.aspx

Netz, Y., & Raviv, S. (2004). Age difference in motivational orientatin toward physical activity: an application of social cognitive theory. *Journal of Psychology, 138*(1), 35-48.

Nurss, J. R., el-Kebbi, I. M., Gallina, D. L., Ziemer, D. C., Musey, V. C., Lewis, S., et al. (1997). Diabetes in urban African Americans: functional health literacy of municipal hospital outpatients with diabetes. *Diabetes Educator, 23*(5), 563-568.

Nutbeam, D. (2000). Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promotion International, 15*(3), 259-267.

Osborn, C. Y., Paasche-Orlow, M. K., Davis, T. C., & Wolf, M. S. (2007). An overlooked factor in understanding HIV health disparities. *American Journal of Preventive Medicine, 33*(5), 374-378.

Paasche-Orlow, M. K., Cheng, D. M., Palepu, A., Meli, S., Faber, V., & Samet, J. H. (2006). Health literacy, antiretroviral adherence, and HIV-RNA suppression: a longitudinal perspective. *Journal of General Internal Medicine, 21*(8), 835-840.

Parikh, N. S., Parker, R. M., Nurss, J. R., Baker, D. W., & Williams, M. V. (1996). Shame and health literacy: the unspoken connection. *Patient Education & Counseling, 27*(1), 33-39.

Parker, R., & Gazmararian, J. (2003). Health literacy: essential for health communication. *Journal of Health Communication, 8*, 116-118.

Parker, R. M., Baker, D. W., Williams, M. V., & Nurss, J. R. (1995). The test of functional health literacy in adults: a new instrument for measuring patients' literacy skills. *Journal of General Internal Medicine, 10*, 537-541.

Parker, R. M., & Kindig, D. A. (2006). Beyond the Institute of Medicine health literacy report: are the recommendations being taken seriously? *Journal of General Internal Medicine, 21*(8), 891-892.

Parker, R. M., Ratzan, S. C., & Lurie, N. (2003). Health literacy: a policy challenge for advancing high-quality health care. *Health Affairs, 22*(4), 147-153.

Paterson, D. L., Swindells, S., Mohr, J., Brester, M., Vergis, E., Squier, C., et al. (2000). Adherence to protease inhibitor therapy and outcomes in patients with HIV infection. *Annals of Internal Medicine, 133*(1), 21-30.

Perry, S., & Karasic, D. (2002). Depression, adherence to HAART, and survival. *Focus: a Guide to AIDS Research, 17*(9), 5-6.

Petosa, R., Suminski, R., & Hortz, B. (2003). Predicting vigorous physical activity using social cognitive theory. *American Journal of Health Behavior, 27*(4), 301-310.

Pinheiro, C. A. T., de-Carvalho-Leite, J. C., Drachler, M. L., & Silveira, V. L. (2002). Factors associated with adherence to antiretroviral therapy in HIV/AIDS patients: a cross-sectional study in Southern Brazil. *Brazilian Journal of Medical & Biological Research, 35*(10), 1173-1181.

Power, C., Selnes, O., Grim, J. A., & McArthur, J. (1995). HIV dementia scale: a rapid screening tool. *Journal of Acquired Immune Deficiency Syndromes, 8*(3), 273-278.

Power, R., Koopman, C., Volk, J., Israelski, D. M., Stone, L., Chesney, M. A., et al. (2003). Social support, substance use, and denial in relationship to antiretroviral treatment adherence among HIV-infected persons. *AIDS Patient Care & Stds, 17*(5), 245-252.

Reece, M. (2003). HIV-related mental health care: factors influencing dropout among low-income, HIV-positive individuals. *AIDS Care, 15*(5), 707-716.

Regidor, E., De Mateo, S., Calle, M. E., & Dominguez, V. (2002). Educational level and mortality from infectious diseases. *Journal of Epidemiology & Community Health, 56*(9), 682-683.

Remien, R. H., Hirky, A. E., Johnson, M. O., Weinhardt, L. S., Whittier, D., & Le, G. M. (2003). Adherence to medication treatment: a qualitative study of facilitators and barriers among a diverse sample of HIV+ men and women in four US cities. *AIDS & Behavior, 7*(1), 61-72.

Revicki, D., Sorensen, S., & Wu, A. W. (1998). Reliability and validity of physical and mental health summary scores from the Medical Outcomes Study HIV Health Survey. *Medical Care, 36*, 126-137.

Reynolds, N. R., Testa, M. A., Marc, L. G., Chesney, M. A., Neidig, J. L., Smith, S. R., et al. (2004). Factors influencing medication adherence beliefs and self-efficacy in persons naive to antiretroviral therapy: a multicenter, cross-sectional study. *AIDS & Behavior, 8*(2), 141-150.

Riera, M., de la Fuente, L., Castanyer, B., Puigventos, F., Villalonga, C., Ribas, M. A., et al. (2002). Adherence to antiretroviral therapy measured by pill count and drug serum concentrations: variables associated with bad adherence. *Medicina Clinica, 119*(8), 286-292.

Roberts, K. J. (2000). Barriers to and facilitators of HIV-positive patients' adherence to antiretroviral treatment regimens. *AIDS Patient Care & Stds, 14*(3), 155-168.

Rosenthal, R. (1991). *Meta-analytic procedures for social research* (Vol. 6). Newbury Park, CA: Sage Publications.

Rudd, R., Kirsch, I., & Yamamoto, K. (2004). *Literacy and Health in America*. Princeton: Educational Testing Services.

Sackett, D., & Haynes, R. B. (1979). *Compliance with Therapeutic Regimens*. Baltimore: Johns Hopkins University Press.

Sarkar, U., Fisher, L., & Schillinger, D. (2006). Is self-efficacy associated with diabetes self-management across race/ethnicity and health literacy? *Diabetes Care, 29*(4), 823-829.

Schillinger, D., Grumbach, K., Piette, J., Wang, F., Osmond, D., Daher, C., et al. (2002). Association of health literacy with diabetes outcomes.[see comment]. *JAMA, 288*(4), 475-482.

Schillinger, D., Piette, J., Grumbach, K., Wang, F., Wilson, C., Daher, C., et al. (2003). Closing the loop: physician communication with diabetic patients who have low health literacy. *Archives of Internal Medicine, 163*(1), 83-90.

Schwartzberg, J. G., VanGeest, J. B., & Wang, C. (Eds.). (2005). *Understanding healh literacy: implications for medicine and public health*. Chicago: AMA Press.

Scott, T. L., Gazmararian, J. A., Williams, M. V., & Baker, D. W. (2002). Health literacy and preventive health care use among medicare enrollees in a managed care organization. *Medical Care, 40*(5), 395-404.

Sharp, L. K., Zurawski, J. M., Roland, P. Y., O'Toole, C., & Hines, J. (2002). Health literacy, cervical cancer risk factors, and distress in low-income African-American women seeking colposcopy. *Ethnicity & Disease, 12*(4), 541-546.

Sharpe, T. T., Lee, L. M., Nakashima, A. K., Elam-Evans, L. D., & Fleming, P. L. (2004). Crack cocaine use and adherence to antiretroviral treatment among HIV-infected black women. *Journal of Community Health, 29*(2), 117-127.

Simoni, J. M., Frick, P. A., & Huang, B. (2006). A longitudinal evaluation of a social support model of medication adherence among HIV-positive men and women on antiretroviral therapy. *Health Psychology, 25*(1), 74-81.

Simoni, J. M., Frick, P. A., Lockhart, D., & Liebovitz, D. (2002). Mediators of social support and antiretroviral adherence among an indigent population in New York City. *AIDS Patient Care & Stds, 16*(9), 431-439.

Singh, S. (2003). Study of the effect of information, motivation and behavioural skills (IMB) intervention in changing AIDS risk behaviour in female university students. *AIDS Care, 15*(1), 71-76.

Smith, S. R., Rublein, J. C., Marcus, C., Brock, T. P., & Chesney, M. A. (2003). A medication self-management program to improve adherence to HIV therapy regimens. *Patient Education & Counseling, 50*(2), 187-199.

Spire, B., Duran, S., Souville, M., Leport, C., Raffi, F., Moatti, J.-P., et al. (2002). Adherence to highly active antiretroviral therapies (HAART) in HIV-infected patients: from a predictive to a dynamic approach. *Social Science & Medicine, 54*(10), 1481-1496.

Starace, F., Ammassari, A., Trotta, M. P., Murri, R., De Longis, P., Izzo, C., et al. (2002). Depression is a risk factor for suboptimal adherence to highly active antiretroviral therapy. *Journal of Acquired Immune Deficiency Syndromes: JAIDS, 31*(Suppl 3), S136-139.

Steiger, J., & Lind, J. (1980). *Statisically based tests for the number of common factors.* Paper presented at the Paper presented at the Annual Spring Meeting of the Psychometric Society, Iowa City, Iowa.

Stone, V. E., Hogan, J. W., Schuman, P., Rompalo, A. M., Howard, A. A., Korkontzelou, C., et al. (2001). Antiretroviral regimen complexity, self-reported adherence, and HIV patients' understanding of their regimens: survey of women in the her study. *Journal of Acquired Immune Deficiency Syndromes: JAIDS, 28*(2), 124-131.

Stoskopf, C. H., Richter, D. L., & Kim, Y. K. (2001). Factors affecting health status in African Americans living with HIV/AIDS. *AIDS Patient Care & Stds, 15*(6), 331-338.

Tucker, J. S., Burnam, M. A., Sherbourne, C. D., Kung, F. Y., & Gifford, A. L. (2003). Substance use and mental health correlates of nonadherence to antiretroviral medications in a sample of patients with human immunodeficiency virus infection. *American Journal of Medicine, 114*(7), 573-580.

Turner, B. J. (2002). Adherence to antiretroviral therapy by human immunodeficiency virus infected patients. *Journal of Infectious Diseases, 185*(Supplement 2), 143-151.

Turner, B. J., & Hecht, F. M. (2001). Improving on a coin toss to predict patient adherence to medication. *Annals of Internal Medicine, 134*(10), 1004-1006.

Turner, B. J., Laine, C., Cosler, L., & Hauck, W. W. (2003). Relationship of gender, depression, and health care delivery with antiretroviral adherence in HIV-infected drug users. *Journal of General Internal Medicine, 18*(4), 248-257.

U.S. Department of Health and Human Services. (2000). *Healthy People 2010. 2nd ed*. Washington, D.C.: U.S. Government Printing Office.

Ullman, J. B. (2001). Structural Equation Modeling. In B. G. Tabachnick & L. S. Fidell (Eds.), *Using Multivariate Statistics* (Fourth ed.). Boston: Allyn & Bacon.

van Servellen, G., & Lombardi, E. (2005). Supportive relationships and medication adherence in HIV-infected, low-income Latinos. *Western Journal of Nursing Research, 27*(8), 1023-1039.

Vanable, P. A., Carey, M. P., Blair, D. C., & Littlewood, R. A. (2006). Impact of HIV-related stigma on health behaviors and psychological adjustment among HIV-positive men and women. *AIDS and Behavior, Online First*.

Vidrine, D. J., Amick, B. C., Gritz, E. R., & Arduino, R. C. (2003). Functional status and overall quality of life ina multiethnic HIV-positive population. *AIDS Patient Care & Stds, 17*(4), 187-197.

Visnegarwala, F., Graviss, E. A., Sajja, P., Lahart, C. J., & White, A. C., Jr. (2004). Determinants of sustained virological suppression in indigent, HIV-infected patients: is single protease inhibitor-based antiretroviral therapy truly highly active? *HIV Clinical Trials, 5*(3), 117-124.

Wagner, G. (2002). Predictors of antiretroviral adherence as measured by self-report, electronic monitoring, and medication diaries. *AIDS Patient Care & Stds, 16*(12), 599-608.

Weiss, B. D., Francis, L., Senf, J. H., Heist, K., & Hargraves, R. (2006). Literacy education as treatment for depression in patients with limited literacy and depression. *Journal of General Internal Medicine, 21*, 823-828.

Weiss, L., French, T., Finkelstein, R., Waters, M., Mukherjee, R., & Agins, B. (2003). HIV-related knowledge and adherence to HAART. *AIDS Care, 15*(5), 673-679.

Williams, M. V., Baker, D. W., Parker, R. M., & Nurss, J. R. (1998). Relationship of functional health literacy to patients' knowledge of their chronic disease. A study of patients with hypertension and diabetes. *Archives of Internal Medicine, 158*(2), 166-172.

Williams, M. V., Parker, R. M., Baker, D. W., Parikh, N. S., Pitkin, K., Coates, W. C., et al. (1995). Inadequate functional health literacy among patients at two public hospitals.[see comment]. *JAMA, 274*(21), 1677-1682.

Wilson, K. J., Doxanakis, A., & Fairley, C. K. (2004). Predictors for non-adherence to antiretroviral therapy. *Sexual Health, 1*(4), 251-257.

Wolf, M. S., Bennett, C., Davis, T. C., Marin, E., & Arnold, C. (2005). A qualitative study of literacy and patient response to HIV medication adherence questionnaires. *Journal of Health Communication, 10*, 509-517.

Wolf, M. S., Davis, T., Osborn, C. Y., Skripkauskas, S., Bennett, C., & Makoul, G. (2007). Literacy, self-efficacy, and HIV medication adherence. *Patient Education & Counseling, 65*, 253-260.

Wolf, M. S., Davis, T. C., Arozullah, A. M., Penn, R., Arnold, C., Sugar, M., et al. (2005). Relation between health literacy and HIV treatment knowledge among patients on HAART regimens. *AIDS Care, 17*(7), 863-873.

Wolf, M. S., Davis, T. C., Cross, J. T., Marin, E., Green, K. W., & Bennett, C. (2004). Health literacy and patient knowledge in a Southern U.S. health clinic. *International Journal of STD & AIDS, 15*(11), 747-752.

Wright, M. T. (2000). The old problem of adherence: research on treatment adherence and its relevance for HIV/AIDS. *AIDS Care, 12*(6), 703-710.