A Comparison of Medication Management Between Older and Younger Adults Living with HIV

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A Comparison of Medication Management
Between Older and Younger Adults
Living with HIV

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A Thesis Submitted to The Graduate School at the University of Missouri – St. Louis
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Abstract

The aims of this study were to examine whether there are differences in medication management between older and younger adults living with Human Immunodeficiency Virus and to examine the relationship between age and personal factors including cognitive ability, depression and self-efficacy on medication management.

The research utilized a descriptive-correlational, cross-sectional design to compare medication management between older and younger adults living with HIV and to describe differences in predictive factors of cognition, depression, and self-efficacy on medication management ability between older and younger adults living with HIV. Results indicate both older and younger adults have high rates of mild cognitive impairment, high rates of depression, and high self-efficacy, and both groups have poor medication management ability. In both older and younger adults cognitive ability and depression were predictors of medication management, and each factor was a much stronger predictor for older adults. Overall cognitive ability was the best predictor of medication management for both older and younger adults.

This research contributes to nursing knowledge in that it helps to identify predictive factors impacting medication management in older and younger adults living with HIV. The older adult with HIV demographic is one of the fastest growing segments of persons with HIV, and these individuals have been under represented in previous research. Determining which factors predict medication management, and what is unique
about these factors in the older population of persons living with HIV will contribute to nurses’ and other healthcare workers’ ability to care for this growing population.
Acknowledgements

I would especially like to thank all of those individuals who participated in this research. Their time and effort made this study possible. I would also like to thank the nurses and staff at the AIDS Clinical Trials Unit for their help with this study, and for their ongoing work with HIV/AIDS.

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I would like to thank my parents for their love in allowing me the freedom I needed growing up to become the person I am today. My brothers and sisters, Jill, Chris, John and Michael and their families have played, and continue to play important roles in my life and I thank all of them for their support, understanding and especially love.

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Chapter 1
Introduction

Statement of the Problem

Currently, more than one million people in the United States are living with Human Immunodeficiency Virus (HIV), the virus that causes Acquired Immune Deficiency Syndrome (AIDS), and each year another 50,000 new cases are diagnosed (Prejean et al., 2011). The virus attacks the immune system and people succumb to infections that they can no longer fight off. Not much more than a decade ago, an HIV infection was tantamount to a death sentence. More than 620,000 deaths have been attributed to the disease since it was first identified in 1981 (Prejean et al., 2011). In spite of the tremendous progress that has been made in diagnosis and treatment, in 2009, the most recent year for which data is available, there were still more than 17,000 deaths attributed to AIDS (CDC, 2011a).

Today, with early diagnosis, and effective antiretroviral therapy (ART), a HIV diagnosis is no longer a death sentence. When used properly, ART halts the progression of the virus and keeps HIV from progressing to AIDS. Medications for HIV only work if they are taken correctly 90-95% of the time (Bartlett, 2002). Taking medication correctly 90-95% of the time would be a very difficult task for anyone, but may present a more formidable task for older persons with HIV because of other risk factors prevalent in this population, including cognitive ability, depression, and low self-efficacy, all of which complicate medication management.
This research considered whether the ability to manage medications differs between older and younger adults living with HIV, and if so, which specific factors accounted for or contributed to the age-related differences. This area of study is important because advances in medical research and the development of new medications increase the life expectancy of adults living with HIV. But an increased life expectancy in individuals with HIV depends, in part, upon the individual’s ability and desire to stick with a tedious, rigorous medication schedule for the rest of his or her life. If advancing age in HIV patients affects medication management, then it would be important to identify specific factors that could explain the age-related difference. Once identified, nurses and other healthcare providers could consider these factors as they create strategies related to medication management and that will enable patients to take their medications correctly at least 90-95% of the time.

Background and Definitions

This research examined whether there are differences in medication management between older and younger adults living with HIV. Before delving further into the problem, it would be useful to provide definitions for generally used terms.

**Older adults with HIV** are defined as those individuals 50 years of age and older. This is the definition used by the Centers for Disease Control and Prevention (CDC) and it is the most frequently used definition in HIV research when studying older adults (Avelino-Silva, Ho, Avelino-Silva, & Santos, 2011; CDC, 1993; Gebo, 2006; Joyce, Goldman, Leibowitz, Alpert, & Bao, 2005). **Younger adults with HIV** are
defined as individuals between the ages of 18 and 49, the age range commonly used in HIV research.

**Self-efficacy** is described as a person’s confidence in their ability to perform a particular behavior (Bandura, 1997). High self-efficacy along with cognitive ability and a low level of depression can overcome environmental barriers in order to effectively manage medications (Bandura, 1989). Self-efficacy is a major construct of Social Cognitive Theory. According to Bandura (1989), self-efficacy beliefs are what determine a person’s level of motivation and thereby influence the effort a person will exert on a particular task. When a person has a strong belief in their ability to perform a task, they will endure in spite of difficulties they encounter. However, a person who doubts their ability to successfully perform a task will limit their effort or may eventually abort the attempt altogether when confronted with adversity (Bandura, 1989).

**Medication management** is defined as a desire and an ability to adhere to a medication regimen (Madigan, Farris, Wiens, & Johnson, 2003). Medication management may be adversely affected by age. Cognitive ability, depression, and self-efficacy, measurable factors in older persons with HIV have been shown to adversely affect medication management (DiMatteo, 2004; Dunbar-Jacob & Mortimer-Stephens, 2001; Gellad, Grenard, & Marcum, 2011).

Over time the preferred term used when referring to following a medication treatment has changed. Compliance, a term frequently used in the past, has fallen out of favor because of the perception that it is a value judgment on the patient’s behavior (Wood et al., 2002). Adherence, a term more commonly used today, is defined as the
extent to which patients take medications as prescribed by their health care providers (Osterberg, 2005). Medication management, the term used in this study was chosen because it incorporates both desire and ability to take medications correctly.

**Cognitive Decline** is described as a decrease in memory, language, thinking, and judgment. Cognitive decline can decrease the ability to perform tasks associated with daily functioning (Valcour et al., 2011). In the general population age has been an important predictor of cognitive decline (Bishop, Lu, & Yanker, 2010; Salthouse, 2009). According to Salthouse, cognitive decline begins in early adulthood and accelerates for adults after age 60. Approximately 50% of adults over age 85 are afflicted with cognitive decline and dementia (Bishop, Lu, & Yanker., 2010). Contrast this with the research on older persons with HIV, where studies are finding that cognitive decline in adults with HIV is more extensive and begins at an earlier age than in the general population (Ances et al., 2010). Nurses and other healthcare providers may not be aware of the prevalence and early onset of cognitive decline in the older HIV population, They may overlook subtle signs of decline and miss early opportunities to assess its impact on medication management.

Ances et al. (2010) and Malaspina et al. (2011) found high rates of cognitive decline in adults with HIV as young as 45 years of age. This cognitive decline was related to brain function. The brain function of persons with HIV was found to be similar to that of persons 15 to 20 years older who did not have HIV (Ances, 2010). Malaspina et al. found cognitive decline associated with increased depression and decreased medication management. These findings suggest that cognitive decline at an early age has
implications for medication management in the population of older persons living with HIV.

**Depression** is defined as a mental state or chronic mental disorder characterized by feelings of sadness, loneliness, despair, low self-esteem, and self-reproach (Stedman, 2011). Depression is not unique to persons with HIV. Depression affects people throughout society across all socio-demographic groups. But the rates of depression in adults with HIV appear to be higher than in the general population, and even higher than rates in other chronic diseases (Valente, 2003). The high rate of depression is of concern because depression has been shown to affect medication management in persons living with HIV (Voss, Portillo, Holzemer, & Dodd, 2007).

According to the CDC (2010a), 9% of adults in the United States suffer from depression. The rate of depression in older adults is higher than the rate in the overall population, with about 15% of older adults affected by depression (Ciechanowski et al., 2004). Studies have shown a higher level of depression in persons with chronic illnesses, and rates in older adults with chronic illnesses range from 20 to nearly 50% (Harpole et al., 2005; Krishnan et al., 2002; Reich 2008). In persons with HIV depressive symptoms that are clinically significant are common, with rates reported as high as 30% (Bagulho, 2002; Lyness et al., 2007). In older persons with HIV, depression rates higher than 50% have been reported (Kilbourne et al., 2002; Valente, 2003; Voss et al., 2007).

The rate of depression in the older HIV population is explained in part by the chronic nature of HIV disease, yet other factors are at play resulting in rates higher than in other chronic diseases. Studies by Emlet (2007) found that the stigma associated with
HIV contributes to an increase in depression rates in this cohort. Studies specifically examining depression in older adults living with HIV have found that an association exists between depression and decline in cognitive abilities (Voss et al., 2007). The clinical implications of high depression rates in older patients with HIV and the understanding that depression can affect medication management should signal nurses to be vigilant in assessing depression in their older patients with HIV.

**Significance of Medication Management**

Medication management of antiretroviral therapy (ART) is one of the strongest predictors of whether an individual’s HIV will progress to AIDS and ultimately lead to death (Battaglioli-DeNero, 2006). Where it is available, ART is commonly prescribed to manage HIV. Research studies have shown that the medications must be taken correctly 95% of the time to keep the HIV virus fully suppressed in the body (Bartlett, 2002; Battaglioli-DeNero; Chesney et al., 2000). Medication management has been identified as an important component of taking medications correctly in persons living with HIV (Albert et al., 1999; Sorensen, Mascovich, Wall, Dephilippis, Batki, & Chesney, 1998).

Despite the importance of ART in effectively managing HIV, few studies have focused on medication management and its role in taking medications correctly, and within those few studies, the population of older adults living with HIV has not been a focus of the research. The lack of research on aging and medication management is a significant omission given that persons over the age of 50 are the fastest growing segment of persons living with HIV. In 2005 persons over the age of 50 accounted for only 15%
of new HIV diagnoses (CDC, 2008a). It is estimated that by 2015 over half of all persons living with HIV will be 50 years of age or older (CDC, 2008c).

Studies have found that medication management is affected by factors such as cognitive ability, depression, and self-efficacy (Malaspina et al., 2011; Sarkar, Fisher, & Schillinger, 2006; Voss et al., 2007). Studies have also found that cognitive ability, depression, and self-efficacy are worse in older adults with HIV (Ances et al., 2010; Justice et al. 2004; Karpiak & Shippy, 2006; & Woodward & Wallston, 1987). However there is a gap in the research. To fill that gap this study will consider if cognitive ability, depression and self-efficacy affect medication management differently in older adults with HIV than in younger adults with HIV. This study will contribute to knowledge in HIV and aging research by studying cognitive ability, depression and self-efficacy to determine if their influence on the older population makes their effect on medication management different.

**Human Immunodeficiency Virus**

**Human Immunodeficiency Virus** is a difficult disease to oversee. Medication management involves adapting life-altering changes in order to successfully manage HIV disease. If persons are ill-equipped to manage their medications, it is difficult to take them correctly 90-95% of the time, and overall health will suffer. Self-efficacy is a person’s belief in their ability to succeed in a particular situation (Bandura, 1995). This belief is what determines a person’s level of motivation and thereby influences the effort a person will exert on a particular task (Bandura, 1989). This belief in the ability to successfully manage medications is an integral part of disease management. Nurses who
educate patients about their medications and the importance of medication management can increase self-efficacy in their patients. High self-efficacy is associated with improved self-management in adults with chronic diseases (Brekke, Hjortdahl, & Kvien, 2001; Grembowski et al., 1993; Sarkar, Fisher, & Schillinger, 2006). A low sense of self-efficacy is associated with the development of depression and anxiety (Bandura, 1993). Bandura (1993) found that people do not perform well if they lack the necessary skills, or if they have the skills but lack the efficacy needed to utilize them. Self-efficacy has been found to mediate the impact of low literacy in medication management (Wolf, Davis, Osborn, Skripkauskas, Bennett, & Makoul, 2007).

**Theoretical Framework**

**Social Cognitive Theory** is the theoretical framework used in this study to examine medication management in adults living with HIV. The study also examines the effects of specific factors (i.e., cognitive ability, depression, and self-efficacy) on medication management in older and younger adults in order to determine whether specific factors can predict age-related differences in medication management in persons living with HIV.

**Statement of the Purpose**

The aims of this study were to examine whether there are differences in medication management between older and younger adults living with HIV and examine the relationship between age and personal factors including cognitive ability, depression and self-efficacy on medication management. Influences on medication management for older adults living with HIV become important to nurses and other healthcare providers
as they consider strategies to promote medication management for their patients living with HIV.

Study aim one was achieved through research questions one. Study aim two was achieved through research questions two, three and four.

The specific questions to be answered were:

**Question 1:** Is there a difference in the medication management ability between older and younger adults living with HIV?

**Question 2:** Are there differences in cognitive ability, depression, or self-efficacy between older and younger adults living with HIV?

**Question 3:** What are the associations between personal factors (cognitive ability, depression, and self-efficacy) and medication management among older and younger adults living with HIV, respectively?

**Question 4:** Which personal factors (cognitive ability, depression, and self-efficacy) are the best predictors of medication management among adults living with HIV, controlling for age as a covariate?

**Significance of the Problem**

Recent advances in early diagnosis and medications create the opportunity for persons with HIV to live to an advanced age. Adults over the age of 50 are expected to make up more than half of all persons living with HIV by the year 2015 (CDC, 2008c). A longer life expectancy creates new challenges for older adults living with HIV, and for their health care providers. Much of HIV care is now managed on an outpatient basis and patients are only seen for healthcare visits once every three or four months (Uphold &
Frain, Judy, 2013, UMSL, 17

Mkanta, 2005). Between visits patients are responsible for maintaining their health. An important component of health maintenance is medication management. Nurses play a vital role in educating their patients as to the importance of taking charge of their physical, psychological, and emotional health. Nurses emphasize the importance of medication management, and encourage patients to function independently in refilling prescriptions promptly, assessing side effects of their medications, and notifying the healthcare team when problems develop. Mastering these skills may only be possible if patients are healthy enough both physically and psychologically to master these skills (Hinkin et al., 2002).

Pharmacological advances have contributed to the development of simpler medication regimens for persons with HIV. Paradoxically, improved medication management has not followed. This lack of improvement is an issue because when a person stops taking medications or takes them incorrectly or inconsistently, the HIV virus becomes resistant to those medications and different, more toxic medications may be needed to combat the newly mutated virus (Robbins et al., 2003). Currently, the second-line and third-line medication treatments available come with an increased pill burden, more complicated dosing regimens, and an increase in the number and severity of toxicities, all of which complicate medication management.

Older adults may also have comorbidities that require more complicated HIV medication regimens (Grabar, Weiss, & Costagliola, 2006). Drug to drug interactions between HIV medications and other medications may arise. Additionally, HIV medications sometimes exacerbate conditions, such as cardiac and metabolic problems
that are already more common in the older population (Grabar et al., 2006). Determining what impedes older adults from managing their medications is an area in need of further research. If nurses better understood medication management in the older HIV population and could identify clinical factors associated with medication management problems, they may be able to intervene to improve medication management before medication changes become necessary.

Older individuals may be dealing with cognitive decline, depression, or other comorbidities that increase pill burden and increase dosing schedule, thereby complicating the already difficult task of managing medications effectively. Cognitive decline and depression, along with a more complicated medication schedule potentially present significant and critical issues for older individuals living with HIV because medication management is essential for medications to be effective. Determining if certain variables are associated with medication management may offer nurses insight into how to focus education and intervention efforts to increase the ability to manage medications in older adults living with HIV.

The Variables

Four variables were selected for this study. The three independent variables (ie: cognitive ability, depression and self-efficacy) were selected because they have been shown to have a greater impact on older adults with HIV than on younger adults (Treisman, Angelino, & Hutton, 2001). These independent variables have also been shown to have an effect on medication management in previous research (Clark & Dodge, 1999; Knowlton, Curry, Hua, & Wissow, 2009; Selnes, 2002). Medication
management was chosen as the dependent variable because of its importance in promoting health in persons with HIV. Medication management is an area of HIV care where nurses play an important role. By learning more about what factors influence medication management nurses will be better equipped to recognize when medication management may be an obstacle for their patients, and can use this knowledge to be proactive in improving medication management. The variables used in this study, and the instrument used to measure each variable are discussed in Table 1.

Table 1.

<table>
<thead>
<tr>
<th>Variable and Measure</th>
<th>Importance</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cognitive Ability</strong></td>
<td>Cognitive ability predicts performance (Hunter, 2004).</td>
<td>The brain-based skills needed to carry out tasks, things people are able to do (Mayer &amp; Massa, 2003). Cognitive decline involves changes in memory, language, thinking, and judgment. Cognitive decline can decrease the ability to perform tasks associated with daily functioning (Valcour et al., 2011).</td>
</tr>
<tr>
<td>Montreal Cognitive Assessment (MoCA)</td>
<td>Cognitive decline is seen nearly twice as often in older persons with HIV compared to younger persons (Hinkin, Castellon, Atkinson, and Goodkin, 2001). Hinkin et al. (2004) found that older persons without cognitive decline were better able to manage their medications.</td>
<td></td>
</tr>
<tr>
<td><strong>Depression</strong></td>
<td>Common in persons living with HIV. Several studies report that more than half of persons living with HIV suffer from depression</td>
<td>A mental state or chronic mental disorder characterized by feelings of sadness, loneliness, despair, low self-esteem, and self-</td>
</tr>
<tr>
<td>Studies Depression Scale (CES-D)</td>
<td>and the rate increases in the aging population (Grov et al., 2010, Yun, Maravi, Kobayashi, Barton, &amp; Davidson, 2005). As studies by Grov et al. (2010) and Karpiak and Shippy (2006) have shown, depression affects a person’s ability to perform activities of daily living (ADLs), including medication management.</td>
<td>reproach; accompanying signs include psychomotor retardation (or less frequently agitation), withdrawal from social contact, and vegetative states such as loss of appetite and insomnia (Stedman, 2011)</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Medication Management</td>
<td>Vital to taking medication correctly 90-95% of the time. Identifying factors that affect medication management, especially in the older population with HIV, will provide nurses and other healthcare providers with new information that can be used to formulate plans to improve patients’ medication management.</td>
<td>For purposes of this study, medication management is defined as a person’s desire and ability to utilize their cognitive and functional ability to comply with their medication regimen (Madigan, Farris, Wiens, &amp; Johnson, 2003).</td>
</tr>
<tr>
<td>Medication management task-revised (MMT-R)</td>
<td>Predictive of medication management in chronic diseases (Clark &amp; Dodge, 1999). Later studies that looked specifically at HIV also found self-efficacy to be associated with medication management (Barclay et al., 2007; Gifford et al., 2000; Johnson et al.,</td>
<td>According to Bandura (1995), self-efficacy is a person’s belief in their ability to organize and execute a series of actions necessary to accomplish a task or goal.</td>
</tr>
<tr>
<td>Self-Efficacy for Chronic Disease Scale (SE-CDS)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Though the importance of self-efficacy in medication management has long been recognized, it is not usually assessed during healthcare visits. Such failure in assessment deprives nurses of the opportunity to determine the effect of this variable on a patient’s ability to manage their medications.

Overview of Remaining Chapters

Each chapter in this dissertation begins with an introductory section that identifies the purpose of the study and states the research questions.

Chapter one sets the tone for the research by providing a statement of the problem being studied, the purpose of the study, the research questions being asked, and important definitions. Chapter one also provides an introduction to Social Cognitive Theory, the theoretical framework used in the research study.

Chapter two begins with a brief history of HIV in order to present the scope of the disease. This chapter examines the body of literature focused on the depth and the breadth of the disease. The literature focuses on aging with HIV and special attention is given to the physiological and psychosocial literature that has shown cognitive decline, depression and low self-efficacy to be present in higher rates in the older HIV population. Literature that supports the importance of medication management in maintaining health in persons living with HIV is reviewed, along with a discussion of barriers to medication
management. The theoretical foundation for this study is Bandura’s Social Cognitive Theory, and in chapter two there will be a discussion of how it forms the underpinning for this study.

Chapter three describes the design and methodology used in this study. The instruments used in this study are explained in detail, as are the rationales for the use of each specific instrument, along with the validity and reliability of each instrument. The chapter contains information about the data collection process; the methods used to collect, manage and analyze the data will be explained in detail. The chapter contains information about the research setting, and human subjects’ protection, along with the time frame of the study. Finally, strengths and limitations of the study are discussed in this chapter.

Chapter four contains the findings of the study. It presents the results of the statistical analyses procedures used to answer each of the questions. It is organized into five sections: 1) recruitment and data management, 2) sample characteristics, 3) quality of measures, 4) results to related questions, and 5) discussion.

Chapter five summarizes the findings from the study and discusses the implications and limitations. Lastly, suggestions for future research are presented.
Chapter 2

Review of the Literature

The primary aim of this research was to examine if medication management is different for older adults living with Human Immunodeficiency Virus (HIV) compared to younger adults living with HIV. The secondary aim was to examine the relationship between age, personal factors (cognitive ability, depression, and self-efficacy) and medication management among participants. The two study aims were achieved through the following research questions.

**Question 1:** Is there a difference in the medication management ability between older and younger adults living with HIV?

**Question 2:** Are there differences in cognitive ability, depression, or self-efficacy between older and younger adults living with HIV?

**Question 3:** What are the associations between personal factors (cognitive ability, depression, and self-efficacy) and medication management among older and younger adults living with HIV, respectively?

**Question 4:** Which personal factors (cognitive ability, depression, and self-efficacy) are the best predictors of medication management among adults living with HIV, controlling for age as a covariate?

This area of study has become increasingly significant. Advances in medical research and the development of new medications have slowed the progression of the HIV virus and accompanying opportunistic infections, and thereby increased the life expectancy of adults living with HIV. An increased life expectancy depends, in part,
upon an individual’s ability and desire to stick with a difficult, rigorous medication schedule for the rest of his or her life. If advancing age in HIV patients affects one’s ability to manage medications then it would be important to identify specific factors that are associated with the age-related differences. Once identified, nurses and other healthcare providers could consider these factors as they formulate strategies related to medication management that will enable patients to take their medications correctly at least 90-95% of the time.

**Introduction**

When HIV was first identified in the early 1980s no medications were available that could stop HIV from decimating the immune system and taking over the body (Brodt, 1997). Even persons receiving the best medical care available at the time incurred opportunistic infections that eventually destroyed a weakened immune system and their HIV disease progressed to Acquired Immune Deficiency Syndrome (AIDS) (Wood, Whittet, & Bradbeer, 1997).

In the past thirty years, significant advances have been made in detection and treatment of HIV and the accompanying opportunistic infections. With the advent of antiretroviral therapy (ART) in the late 1980s, healthcare providers were finally able to provide patients with medications that could prolong their lives (CDC, 2007). Still, ART was not a cure and the toxic side effects of the available medications made them difficult to take consistently. Side effects of ART included anemia, neuropathy, and severe gastrointestinal disturbances (Carr & Cooper, 2000). Many of those living with HIV were unable to tolerate the side effects of their medications and they eventually stopped taking
them, even though they may have known the consequences of not taking these medications.

The advent of new medications with less toxic side effects have helped transform a once fatal disease into a chronic, manageable disease. This meant HIV infection was no longer an automatic death sentence and persons living with HIV were now able to attain a near-normal life expectancy (Bhaskaran, et al., 2008; Deeks & Phillips, 2009; Stoff, Khalsa, Monjan, & Portegies, 2004). Yet survival remains dependent upon a person’s ability and willingness to take their prescriptive medications despite the challenge this task presents.

There are factors that contribute to a person’s inability to manage their medications effectively. Three known factors that adversely influence medication management are cognitive ability, depression, and self-efficacy. Adults with HIV experience high rates of depression. They also experience cognitive decline earlier than the general population. These conditions are exacerbated in older persons with HIV (Groev, et al., 2010; Valcour, Shikuma, Shiramizu, et al., 2004). These findings suggest that older adults living with HIV may have more difficulty with medication management than their younger counterparts.

While medical advances in treating HIV over the past thirty years represent the most dramatic change in this epidemic, other changes have also occurred. No longer is HIV considered a disease of young gay men. The demographics of the disease have changed. The disease, HIV, affects men and women, gay and straight. Men who have sex with men remain the group most affected by HIV, but other groups, especially persons of
color have also been disproportionately impacted by this disease (Hutchinson et al., 2006).

The population of older adults living with HIV has steadily increased in a relatively short period of time. In 2005, adults aged fifty and over accounted for 15% of the new HIV/AIDS diagnoses and 24% of persons living with HIV (CDC, 2008a). By 2015, it is expected that more than 50% of persons living with HIV will be over the age of fifty. This is a marked change from the early years of the HIV epidemic. As recently as 2000, only 6.5% of persons living with HIV were aged 55 or older (CDC, 2004).

The number of women living with HIV has increased as well. In fact, women have emerged as one of the fastest growing groups within the population of older adults with HIV. In 2007, over 25% of new HIV diagnoses were in women (CDC, 2010b). According to the most recent data available, women now account for approximately one quarter of the HIV/AIDS cases in the United States (CDC, 2008b). This represents a dramatic increase from just 14% of the cases a decade ago. The number of AIDS cases in women over the age of 50 has nearly tripled in the last 10 years and women aged 50 and over now account for more than 10% of women living with AIDS in the United States (CDC, 2008b).

Both Black men and women have been heavily impacted by HIV. Blacks account for nearly half of all new HIV infections despite making up 12% of the total United States population (Hall et al., 2008). As the number of infections in women continues to climb, women of color are affected disproportionately. Infection rates for Black and
Hispanic women far exceed those for White women in both older and younger populations (CDC, 2011a).

Progress in the fight against HIV has been made on fronts other than more effective medications. An important change in the evolution of HIV care is that testing for the virus is becoming a routine part of medical care in many healthcare facilities. In the past HIV testing was only discussed with those persons deemed to be at risk, and not offered to others (Branson et al., 2006). This change has enabled infections to be discovered earlier and prior to progressing to AIDS (Branson et al., 2006). With early treatment and better medications available people are able to resist the opportunistic infections that were common and often fatal only a decade ago.

Despite progress made in the fight against HIV, the older population has seen an increase in HIV infections and a higher percentage of older persons with HIV have been diagnosed with AIDS compared to the younger population. Early testing, essential in identifying infections, has not been adopted in the older population to the same degree it has in the younger population. Lack of testing creates an unnecessary barrier to early detection and entry into care for older adults. The most recent CDC guidelines (CDC, 2006a) recommend routine opt-out HIV testing for all persons between the ages of 13 and 64. Opt-out testing means a person will be tested for HIV unless they specifically refuse the test. The clinical goal of opt-out testing is early diagnosis and entry into care. Testing for persons age 65 and older has not increased to the same degree it has in the younger age groups since guidelines have not changed for this age group (Tangredi, Danvers, Molony, & Williams, 2008).
Older adults living with HIV have in many ways remained an invisible element in the HIV/AIDS epidemic in spite of their increasing numbers. Older adults are an understudied and underserved group. Clinical trials research on the effectiveness of new HIV medications too often excludes older adults from participation. This limits knowledge of how medications may work differently in the aging population (Linsk, 2000; Manfredi, 2003). Prevention messages continue to target younger adults (Mack & Ory, 2003). The words and the images are geared toward youth to the exclusion of older adults. Health care providers continue to be reluctant to discuss sex and HIV risk factors with their older patients (Sormanti & Shibusawa, 2007). Additionally an HIV diagnosis may be delayed in older persons. Symptoms of HIV, such as weight loss and fatigue, can be similar to ordinary conditions of aging (Siegel, Schrimshaw, & Dean, 1999). These circumstances contribute to older adults being diagnosed later in the disease process, making treatment complex.

This chapter contains an overview of research on HIV and of aging. The literature review includes a discussion of studies addressing physiological and psychosocial aspects of aging with HIV and how these physiological and psychosocial aspects affect medication management. The discussion incorporates research studies on cognitive ability, depression, and self-efficacy in older and younger HIV populations, and the effect cognitive ability, depression and self-efficacy have on medication management. This chapter concludes with a discussion of Social Cognitive Theory as a framework for studying medication management within this research.
Aging with HIV

Thirty years into the HIV epidemic we are recognizing that one of the ripple effects of treatment advances in HIV is the increasing numbers of older adults living with the disease (CDC, 2008c). Based on current projections, more than 50% of the HIV population will be aged 50 years and older by the year 2015 (CDC, 2008c). This figure includes both those infected with HIV at a younger age who are now living longer and adults not diagnosed with HIV until after the age of 50.

The CDC defines older adults with HIV as those 50 years of age and older (CDC, 1993). Early in the epidemic the CDC chose the age of 50 years and older to represent an older cohort. At that time age 50 was much older than the mean age of persons living with HIV (Gebo, 2006). This age made sense because as people reached age 50 they experienced changes related to aging. As scientists and healthcare providers grappled with identifying disease characteristics, this age delineation made sense, the age of 50 and older continues to be used in much of the HIV research focusing on older adults (Avelino-Silva, Ho, Avelino-Silva, & Santos, 2011; CDC, 1993; Gebo, 2006; Joyce, Goldman, Leibowitz, Alpert, & Bao, 2005).

Recognition of the profound impact that HIV has on the older population is a relatively recent phenomenon (Emlet, 2006b; Gebo, 2006; Shah & Mildvan, 2006). The main body of literature on aging with HIV has been developed only within the past decade. Prior to that time HIV was considered a disease of young persons (Fenton, 2007; Riley, 1989). It was thought that older adults generally did not engage in behaviors that would put them at risk for HIV infection (Emlet, 2006b). Transmission of HIV occurs
primarily through unsafe sexual practices and sharing of dirty needles by intravenous drug users. Both of these practices are considered activities engaged in by younger persons. Therefore medical and psychological considerations, prevention strategies, and research dollars were targeted at youth, ignoring the older population.

Another reason that older adults with HIV were not included in research is that there were relatively few older adults available to participate (CDC, 2004). In addition, older adults were generally not discussed as a subpopulation when reporting results of research trials. This strategy may have been reasonable in the early years of the epidemic. At that time due to the combination of young age at time of infection and a short life-expectancy after diagnosis, few older adults with HIV infection were alive. Because there were few treatment options for HIV available there was little practical reason to consider age when developing a plan of care for adults with HIV.

The increase in the number of older adults living with HIV can be attributed in large part to the advent and effective use of antiretroviral therapy (ART). In most patients with an HIV diagnosis ART is able to bolster the immune system and increase life expectancy. The result was that in less than 10 years between 1996 and 2005, life expectancy after an HIV diagnosis more than doubled, going from 10 years to over 20 years (Harrison, Song, & Zang, 2010). The effectiveness of ART has been responsible for changing the classification of HIV from a fatal disease to a chronic disease. Currently persons infected with HIV at a younger age now have the opportunity to live into old age, a phenomenon not seen earlier in the epidemic.
Interestingly there has also been an increase in the number of new HIV infections in persons over age 50. The CDC estimates that in 2005 persons over the age of 50 accounted for about 20% of all new HIV infections (CDC, 2006b). The reasons for this increase in new infections in this age group include infrequent condom use and inadequate discussion between healthcare providers and older patients about sexual practices and HIV risk (Sormanti & Shibusawa, 2007). Condom use is not the norm in older adults because pregnancy is no longer a concern and most older adults do not consider themselves to be at risk for HIV (Lindau et al., 2007; Önen, Shacham, Stamm, & Overton, 2010; Trobst, Herbst, Masters III, & Costa, 2002).

Studies by Lindau, Leitsch, Lundberg, and Jerome (2006) and Nusbaum, Singh, and Pyles (2004) found the majority of sexually active older adults did not discuss sex with their healthcare providers. In failing to initiate this discussion, nurses miss out on opportunities to assess their older patients risk for HIV and are unable to educate them about safer sex practices and the benefits of HIV testing.

Older adults often underestimate their risk for contracting HIV (Lindau et al., 2007). In a study by Coleman and Ball (2007) older adults reported multiple sexual partners and infrequent condom use, yet despite these risk factors they rated their risk of contracting HIV as low. Sormanti and Shibusawa (2007) found that condom use was not only associated with younger adults, but with younger persons of higher socioeconomic status and a higher level of education. These findings regarding condom use suggest that many of those at highest risk for HIV infection, are the very persons least likely to be
using condoms (Coleman & Ball, 2007; Winningham, Corwin, Moore, Richter, Sargent, & Gore-Felton, 2004).

Older Black women have been hard hit by HIV. In 2004, HIV infection was the leading cause of death for Black women between the ages of 45 and 54 (CDC, 2008b). The majority of older Black women are infected with HIV through heterosexual sex (CDC, 2008b). Research suggests that many of these women may be ill-equipped to protect themselves sexually because they lack power in sexual relationships, and have poor sexual negotiation skills (Lindau et al., 2006; Neundorfer, Harris, Britton, & Lynch 2005). These women also reported drug and alcohol use, physical and sexual abuse, and acknowledged taking risks to keep a relationship intact, all circumstances that put them at risk for contracting HIV. Jacobs and Thomlison (2009) and Jacobs and Kane (2011) found that low self-esteem was a risk factor for HIV in women over age 50, reporting that low self-esteem was predictive of increased HIV-risk behaviors. Similar to studies on older adults in general, studies focusing on older women found the women had little knowledge of how HIV was transmitted, and considered themselves to be at low risk for infection (Altschuler, Katz, & Tynan, 2004; Ward, Disch, Schensul, & Levy, 2011).

As the HIV risk in the older adult population is beginning to be recognized, prevention strategies specific to this age group are at last being developed. Testing for HIV is beginning to be offered as a routine part of healthcare (AIDS Alert, 2010). Other prevention strategies are focusing on raising awareness of HIV in the older adult population, including prevention messages that target older adults with both age-appropriate text and images (Obermeyer & Osborn, 2007).
Research on older adults living with HIV is in its infancy. Up until now older adults have been cared for and treated for HIV based on research that targeted a much younger demographic. Current research is finding differences in older and younger persons living with HIV but nurses lack the necessary tools to recognize problems specific to older adults. There is a clear and urgent need for the development of knowledge regarding whether older adults living with HIV face unique and different problems than younger adults with HIV. An area that is in need of research and is vital to caring for this emerging demographic is whether there are differences in medication management between older and younger adults living with HIV.

**Socio-Economic Factors Affecting Older Persons with HIV**

The aging HIV population is changing. Joyce, Goldman, Leibowitz, and Alpert (2005) found two distinct groups of older adults living with HIV: gay men who were well-educated and financially stable and persons from some minority groups, especially Blacks and Hispanics, with limited education and financial resources. The changing demographics of HIV will increase the numbers of persons from these minority groups and persons of lower socioeconomic status aging with this disease. As these Black and Hispanic groups’ age, public and private financial resources will be increasingly strained. Joyce et al. found almost one third of Whites and more than two thirds of Blacks and Hispanics over age 50 stopped working within one year of an HIV diagnosis, taxing an already overburdened Medicare/Medicaid system. Crystal et al. (2003) found that older persons from these minority groups were especially impoverished, which contributes to an elevated relative risk of death in persons with HIV.
Long-term survivorship of persons with HIV is now commonplace in areas where ART is readily available. Long-term survivors are more likely to live in poverty than newly infected older adults. Robinson, Petty, Patton, and Kang (2008) compared long-term survivors and newly infected older adults with HIV. Because of years of living on disability, or a decreased ability to work due to illnesses associated with HIV, older long-term survivors were more likely to live in poverty.

Wood et al. (2002) found socioeconomic status was strongly associated with HIV-related mortality. In this study persons of lower socioeconomic status began treatment later in the disease course than persons of higher socioeconomic status. Mortality was attributed to delayed receipt of ART. One explanation for this disparity in treatment was health care providers’ reluctance to prescribe medications because of concerns that poor medication management in this less stable group could lead to resistance to medications, resulting in fewer treatment options in the future (Wood et al., 2002). However studies have shown providers do little better than chance in correctly predicting which patients will take their HIV medications as prescribed (Bangsberg et al., 2001). Bogart, Catz, Kelly and Benotsch (2001) found healthcare providers may place too much emphasis on socioeconomic factors when predicting adherence.

Unstable housing makes managing HIV a more difficult proposition. Uphold and Mkanta (2005) looked specifically at the health care service needs of older adults with HIV and found that unstable housing was associated with higher medical costs, poorer access to care, and a lack of continuity of care. Studies have found an association between unstable housing and medication adherence (Spire et al. 2002; Tobias et al.
Stewart, Cianfrini, and Walker (2005) found that unstable housing was associated with poorer physical health in persons living with HIV.

In 1990 the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act was implemented to improve quality and access to HIV services for low-income persons with HIV. While services improved under this act, they remained unequal for disadvantaged persons with HIV (McKinney & Marconi, 2002). Marx, Katz, Parks and Gurley (1997), found that in spite of the tremendous influx of government funding, uninsured, minorities, and women remained slower to enter into HIV care. Although once established in care, access to ART was similar for all groups,

Older Black men and women with HIV are challenged to successfully manage their HIV. A study by Heslin, Andersen, Ettner, and Cunningham (2005) found Black patients with HIV less likely than White patients with HIV to have an infectious disease specialist providing their HIV care. Blacks with less education, no health insurance, and lower household incomes were least likely to be cared for by a HIV specialist (Heslin et al., 2005). Korthuis et al. (2008) found racial disparities in access to care and found that these disparities were the result of community-level differences. Blacks living in poor urban areas often only had access to inner-city clinics where there are limited resources. Both Heslin et al. and Korthuis et al. emphasized that limited access to care resulted in poorer outcomes for affected patients.

Previous research has shown Blacks and Hispanics have higher levels of physician distrust than Whites, and lower socioeconomic status exacerbates this distrust (Armstrong, Ravenell, McMurphy, & Putt, 2007). This distrust can result in a delay in
diagnosing HIV infections, since persons distrustful of physicians and the healthcare system often put off healthcare appointments until they are very sick. Kuo, Haukoos, Witt, Babaie, and Lewis (2005) found that older Black men and women who were more distrustful of physicians were likely to have a delayed diagnosis of HIV. This delayed diagnosis led to poorer outcomes for the affected individuals.

**Antiretroviral Therapy and Medication Management**

The advent of ART has had a dramatic impact on the lives of persons with HIV. Successful implementation of ART is responsible for dramatically increasing the life span for those persons living with HIV, provided they have access to these medications and take them as prescribed by their health care provider (Bhavan et al., 2008). To be effective ART must be taken as prescribed 90-95% of the time. A study by Paterson et al. (2000) found that only 22% of persons who took their medications correctly 95% of the time failed treatment. When medications were taken as prescribed 80 to 94.9% of the time 61% failed treatment. And 80% of persons who took medications correctly less than 80% of the time failed treatment. Treatment failure complicates care for persons with HIV. Taking medications incorrectly leads to resistance to entire classes of HIV medications, resulting in the need for new medication combinations that are effective in suppressing the HIV virus. Patients with adherence rates greater than 95% had considerably fewer hospital days than those with less than 95% adherence: 2.6 days per 1000 days versus 12.9 days per 1000 days (Paterson et al.). Second- and third-line medications are used when initial, or first-line treatment fails, and require a difficult dosing schedule (DeFino, Clark, Mogyoros, & Shuter, 2004). Medications may need to
be taken two or three times a day, they may need to be taken with food, taken on an empty stomach, or taken at night. All these requirements make medication management difficult.

Several studies (Cuzin, Delpierre, Gerard, Massip, & Marchou, 2007) found that older adults responded just as well to ART as younger adults if treatment was initiated at a similar point in the disease process. However, because of the lack of testing for HIV in older adults many were diagnosed later in the disease process; leading to disease progression and less immune reconstitution. These results confirmed findings from earlier studies that emphasize the need to be proactive in recognizing the risk of HIV in the older population. Thus reinforcing the need to increase testing in older adults in order that infections are detected earlier and treatment initiated in a timely manner (Nogueras et al., 2006; Tumbarello et al., 2004).

Minority groups, including Blacks, Hispanics and women, are disproportionately affected by HIV and are less likely to take medications correctly (Osborn, Paasche-Orlow, Davis, & Wolf, 2007; Siegel, Karus, & Schrimshaw, 2000; Thrasher, Earp, Golin, & Zimmer, 2008).

Several studies found a difference in medication management between Blacks and Whites. Osborn, Paasche-Orlow, Davis and Wolf (2007) determined that low health literacy inhibited medication management. The authors reported that Blacks were 2.5 times more likely to take their HIV medications incorrectly than were Whites. Siegel, Karus and Schrimshaw (2000) and Thrasher, Earp, Golin and Zimmer (2008) cited lack of trust in the healthcare system in reporting that older Black men were less certain they
could take ART consistently than were older White men. Berg, Cooperman, Newville and Arnsten (2009) and Wolf, Gazmararian and Baker (2005) found self-efficacy affected medication management in all cohorts.

There is no denying the contribution ART has in treating HIV, yet the long-term use of these medications have unintended consequences that can cause an increase in comorbidities (Grabar et al., 2006). Side effects of HIV medications continue to be problematic and contribute to the difficulty of managing medication regimens. Both the side effects of the medications themselves and the increase in pill burden due to an increase in comorbidities make medication management more difficult.

**The Physiological Impact of Aging and its Effect on Medication Management**

The impact of aging on HIV is multifaceted. The interaction of aging and HIV infection is not altogether understood, nor has the scope and impact on the aging population been fully realized. Physiological and psychosocial aspects of aging impact HIV disease and its treatment. Research is beginning to focus on the impact of aging with HIV in the ART era. Earlier research looked at the effect of aging on HIV in the pre-ART era. The results of these studies do not accurately reflect current clinical practice where ART is used routinely resulting in increased survival (Gebo & Justice, 2009). While the significance of aging on HIV is not fully understood, it is becoming apparent that age does impact HIV (Bhavan, Kampalath, & Overton, 2008; Gebo & Justice, 2009). This section offers an overview of research focused on the physiological impact of aging with HIV, with a review of physiological changes that affect medication management.
Although the exact reasons are not understood, several studies have found age to be an independent predictor of clinical progression in HIV (Babiker, Peto, Porter, Walker, & Darbyshire, 2001; Egger et al., 2002). Research has shown that, after adjusting for stage of infection at diagnosis, older adults with HIV have a significantly shorter survival time compared with younger adults with HIV (CDC, 2006a).

Factors that contribute to this survival time include delayed diagnosis, ineffective therapy, a weakened immune system, and an increase in the number of comorbidities, including AIDS-defining illnesses (Emlet, 2004; Kirk & Goetz, 2009; Nguyen & Holodniy, 2008; Rickabaugh & Jamieson, 2010; Vance & Robinson, 2004). Studies have found that older adults experienced rates of viral suppression similar to those of younger adults, yet they have lower levels of CD4 restoration after initiating ART, evidence of a less robust immune system (Goetz, Boscardin, Wiley, & Alkasspooles, 2001; Kalayjian, et al., 2005). A weakened immune system provides a partial explanation of comorbidities found in older adults with HIV.

Studies show that in addition to less restoration of CD4 counts, older adults do not respond to therapy as quickly as younger adults (Silverberg, Leyden et al., 2007; Kirk & Goetz, 2009). This suggests that older adults remain in an immunocompromised state longer than younger adults after starting ART. This long-term immunocompromised state accounts for an increased risk for infections and increased risk for other illnesses (Silverberg, Leyden et al., 2007; Kirk & Goetz, 2009). A host of research confirms that older age is associated with an increase in morbidity in adults infected with HIV (Butt et al., 2001; Hall, McDavid, Ling, & Sloggett, 2006; Inungu, Mokotoff, & Kent, 2001;
Keitz et al., 1996). These same studies found that even when CD4 counts were high, older adults were more prone to AIDS-defining illnesses than their younger counterparts. Infections and other illnesses increase the need for additional medications, leading to an increase in the number of medications and the complexity of dosing.

Results are equivocal as to whether or not an increased pill burden complicates medication management (DeFino, Clark, Mogyoros, & Shuter, 2004; Maggiolo et al., 2002; Mannheimer et al., 2002; Murphy, Roberts, Martin, Marelich, & Hoffman, 2000; Stone, Jordan, Tolson, Miller, & Pilon, 2004; Trotta, 2002). Studies looking strictly at the pill count found that medication management was not affected by pill burden (DeFino, et al., 2004; Mannheimer et al., 2002). While studies looking at pill count and dosing frequency found that increased pill burden complicated medication management (Maggiolo et al., 2002; Murphy et al., 2000; Stone et al., 2004; Trotta, 2002).

Recent research finds the aging process accelerated by HIV (Nunez, Armbruster, Phillips, & Gale, 2003). Nurses and other healthcare providers unaware of this research may be unaware that their patients with HIV are aging faster than their non-infected patients, and that this aging may make them more like non-HIV patients who are 10 to 15 years older (Ances et al., 2010). Bhavan (2008) reports that this accelerated aging results in health problems progressing faster, and diseases associated with aging, such as cardiovascular disease and hypertension, are more severe when found in combination with HIV disease.

A variety of health conditions are associated with the aging HIV population. Diseases such as coronary artery disease, diabetes, hypertension, hypercholesterolemia
and osteoporosis are more common as persons with HIV age (Vance, Mugavero, Willig, Raper, & Saag, 2011). Additionally, ART itself is associated with peripheral neuropathy and cardiovascular disease (Grabar et al., 2006). Not only are diseases associated with aging more common in persons with HIV, but many are being diagnosed at a younger age in adults living with HIV compared with the general population (Deeks & Phillips, 2009).

**Comorbidities**

Adults with HIV have more diseases than adults in the general population and many of these diseases are not specifically HIV- or AIDS-related (Deeks & Phillips, 2009; Goulet et al., 2007). Older adults with HIV report four times the number of comorbidities as younger adults with HIV (Shah & Mildvan, 2006). Comorbidities complicate medication management by impacting overall health, decreasing the ability to perform activities of daily living (ADLs), and increasing pill burden (Roberts et al., 2006). As the number of older adults living with HIV increases, comorbidities become a major component of care.

Among the more common comorbidities prevalent in older adults with HIV are: cardiovascular disease, bone disease, various cancers, peripheral neuropathy, frailty, and neurocognitive disorders (Bhavan et al., 2008; Önen, Overton et al., 2010).

**Cardiovascular Disease**

Cardiovascular disease (CVD) is the leading cause of death in the United States. Many of the medications used to treat the HIV virus, and the virus itself increase the risk for CVD. Several studies found increased risk for CVD associated with the use of ART (Currier et al., 2003; Salyer, Lyon, Settle, Elswick, & Rackley, 2006). Fat redistribution,
an unwanted side effect of HIV and HIV medications, was a predictor of cardiovascular
disease in patients taking ART (Currier et al., 2003; Friss-Moller et al., 2003; Friss-Moller et al., 2007; Hadigan et al., 2001; Hadigan et al., 2003).

Smoking is a known risk factor for cardiovascular disease, and persons living
with HIV have been found to be smokers. Studies found smoking rates ranging from 40
to 74% in persons with HIV (Burkhalter, Springer, Chhabra, Ostroff, & Rapkin, 2005; Mamary, Bahrs, & Martinez, 2002; Miguez-Burbano et al., 2005; Vance, 2011; Webb, Vanable, Carey, & Blair, 2007). This compares to a rate of approximately 20% in the
general population (CDC, 2011b).

Several studies have found an association between smoking and poor medication
management (Feldman et al., 2006; Shutter & Bernstein, 2008). Feldman et al. (2006)
found 68% of smokers report taking medications correctly 95% of the time, while 77% of
non-smokers reported taking their medications correctly 95% of the time. Smokers fared
worse in a study by Shutter and Bernstein (2008), where current smokers took their
medications correctly 63.5% of the time compared to a rate of 84.8% in the non-smokers.

**Bone Disease**

Older adults with HIV are diagnosed with bone diseases at a higher rate than older
adults in the general population (Arnsten et al., 2007; Triant, Brown, Lee & Grinspoon,
2008). Bone fractures are a concern for older adults with HIV. Fractures can start a
cascade of problems including frailty, decrease in quality of life, and a decrease in ADLs,
including medication management. Arnsten et al. (2007) and Triant et al. (2008) found
fracture rates in older adults with HIV increased when compared to non-HIV-infected persons, and these differences increased as the ages of patients increased.

Studies suggest that bone disease, osteoporosis and osteopenia, occurs in persons with HIV regardless of their use of ART. Yet ART, especially protease inhibitors, seems to exacerbate the problem (Moore et al., 2001; Tebas et al., 2000). Several studies found bone mineral density (BMD) lower in older adults with HIV. Amiel et al. (2004), Calmy et al. (2009), and Önen, Overton et al., (2010) found lower BMD in older adults with HIV. Calmy et al. attributed bone loss primarily to the use of protease inhibitors, where Amiel et al. and Önen, Overton et al. identified HIV infection itself as the primary cause of decreased BMD. Irrespective of the cause, bone fractures, especially in older patients, decrease the ability to perform ADLs, including medication management. As this population ages, problems related to bone disease increase as well. Longer time living with an HIV infection, and longer time on ART are both associated with decreased BMD and fractures.

**Cancers**

Before ART, untreated HIV infection was associated with increased risk for Kaposi’s sarcoma and non-Hodgkins lymphoma (Biggar, Chaturvedi, Goedert, & Engels, 2007; Engels et al., 2006). More recently there has been an increase in rates of non-AIDS related cancers (Deeks & Phillips, 2009; Hessol et al., 2007; Patel et al., 2008; Shiels, Cole, Kirk, & Poole, 2009). Long-term immunosuppression is associated with increased cancer risk (Bower et al. 2003; Monforte et al., 2008; Grulich, Leeuwen, Falster, & Vajdic, 2007).
Smoking is a modifiable risk factor for cancer. As mentioned earlier, smoking rates are increased in persons living with HIV. This contributes to the high incidence of some cancers, including lung cancer, in this population (Bazoes, Bower, & Powles, 2008; Chaturvedi et al., 2007). Studies by Bazoes et al. (2008) and Chaturvedi et al. (2007) acknowledge the role of smoking in increased lung cancer rates but determined that other factors, as yet unidentified, may play a role, since smoking rates alone do not account for the disparity in cancer rates between persons living with HIV and those without HIV.

The exact role HIV plays in cancer risk remains inconclusive. Research to understand the cancer-causing mechanism of HIV and immunosuppression is ongoing. Another unexplained influence on cancer-causing mechanisms is long-term use of ART. Cancer treatments suppress the immune system and managing these two diseases together becomes a complicated clinical problem.

**Peripheral Neuropathy**

Peripheral neuropathy remains the most common neurological complication of HIV in the ART era. Ironically there are more instances of ART-induced peripheral neuropathy than disease-induced peripheral neuropathy (Sacktor, 2002; Schifitto et al., 2002). Studies indicate the risk of peripheral nerve disorders increase with low CD4 counts, high plasma viral loads, and increased age (Fellay et al., 2001; Simpson, et al. 2002; So, Holtzman, Abrams, & Olney, 1988). Lichtenstein, et al. (2005), Simpson, Brown and Tobias (2008), and Watters et al. (2004) found an association with aging and peripheral neuropathy, noting that an increase in the number of comorbidities contributed to the increase in peripheral neuropathy in older adults.
The emergence of new medications to treat HIV has decreased instances of peripheral neuropathy (Schifitto et al., 2002). Yet peripheral neuropathy continues to affect a significant portion of adults living with HIV, especially long-term survivors. Most began treatment with medications that caused neuropathy and were the only treatment option available (Lichtenstein et al., 2005). The pain and disability associated with peripheral neuropathy results in high treatment costs, decreased productivity, decreased quality of life, and a decrease in the ability to perform ADLs, including medication management (Berg et al., 2009; Nicholas, et al., 2007; Simpson et al., 2008).

**Frailty**

A recent area of concern for older adults living with HIV is early-onset frailty. Frailty is a syndrome involving loss of muscle mass, weight loss, decreased energy, and low physical activity levels (Henry, 2009). Desquilbet et al. (2007) found HIV infection strongly associated with frailty. In a study by Önen et al. (2009) frailty was associated with more comorbidities and higher hospitalization rates. Research by Ruiz and Cefalu (2011) found 30% of community dwelling HIV patients over age 60 were frail, while less than 20% of community dwelling adults over age 65 without HIV. Desquilbet et al. (2009; 2011) suggested that a compromised immune system was independently associated with frailty, and frailty was predictive of mortality. Frailty complicates a person’s ability to perform ADLs, including medication management.

**Neurocognitive Disorders**

In studies by Barrclay et al. (2007) and Hinkin et al. (2004) older age was associated with successful medication management except when older age was
accompanied by cognitive decline. In the Barclay et al. study, neurocognitive functioning was the best predictor of medication management in adults with HIV over the age of 50.

Neurocognitive disorders are common in adults living with HIV. These HIV-associated neurocognitive disorders are found in about 30% of adults with asymptomatic HIV, and 50% of adults with AIDS (Woods, Moore, Weber, & Grant, 2009). Older adults with HIV suffer neurocognitive disorders at a higher rate than their younger counterparts for several reasons including longer use of ART and poorer immune reconstitution (Cherner et al. 2004). These HIV-associated neurocognitive disorders are different from the neurocognitive decline associated with normal aging (Clifford et al., 2009).

Valcour, Shikuma, Shiramizu et al. (2004) found older adults with HIV were 1.3 to 8 times more likely to have dementia than were younger adults with HIV, unrelated to the duration of their HIV infection. Not only do the rates of neurocognitive disorders increase as HIV disease progresses but the severity of the disorders increase as well. Heaton et al. (2010) found this increase in severity remained even after immune recovery was achieved, suggesting that starting ART earlier may reduce the rate of neurocognitive disorders.

Although ART has improved neurocognitive functioning, milder forms of HIV-associated neurocognitive disorders are present even in those persons with an undetectable viral load (Tozzi, Balestra, Libertone, & Antinori, 2010). Studies by Anthony, Ramage, Carnie, Simmonds, and Bell (2005), Price and Spudich (2008), and Clifford (2008) found significant, ongoing neuroinflammation in patients treated with
ART, warning of the increased probability of future neurocognitive problems for persons living with HIV long term.

In a new area of research, Ances et al. (2010) and Paul et al. (2008) used MRIs to detect changes related to cognitive decline, and found that HIV infection and aging independently affected brain functional demands. This line of research could lead to a noninvasive biomarker of HIV infection in the brain. Currently lumbar punctures, often painful and with risk of injury to the patient, are the only method available in determining the amount of HIV virus in the brain (Clifford, 2008).

Medication management is a vital component of combating HIV disease but is more difficult for persons with neurological impairment (Gorman, Foley, Ettenhofer, Hinkin, & van Gorp, 2009; Selnes, 2002; Woods et al., 2008). Increased fatigue and a decrease in independent functioning, both factors that affect medication management, have been found to be associated with neurological impairment (Waldrop-Valverde, Jones, Gould, Kumar, & Ownby, 2010).

Research is mounting that neurocognitive decline begins earlier in persons living with HIV (Ances et al., 2010; Barclay et al., 2007). There is strong evidence that this decline affects medication management and may be the best predictor of medication management for older adults living with HIV (Barclay et al., 2007). Interestingly, a study by Ettenhofer et al. (2009), agreed that cognitive decline was a strong predictor of poor medication management. Ettenhofer hypothesized that it was suboptimal medication management when persons were younger that contributed to the neurocognitive decline later found in older adults.
Psychosocial Aspects of Aging with HIV

Despite the profound medical effect aging has on older adults living with HIV, many living with the disease would consider the non-medical, psychosocial effects to take a greater toll (Emlet & Farkas, 2001; Sayles, Wong, Kinsler, Martins, & Cunningham, 2009). Older adults living with HIV experience many of the same stressors as younger adults with the disease but are also faced with challenges unique to an aging population (Emlet, 2006b). Feelings of stigmatization and isolation are issues older adults may experience to a greater degree than younger persons. A study by Emlet (2006b) found nearly every person over 50 years of age experienced HIV stigma, and over two-thirds experienced both ageism and HIV stigma.

Herek (1999) defines HIV stigma as prejudice and discrimination directed at persons who have, or are perceived to have, HIV or AIDS. Ageism is defined as a negative attitude toward persons based on the idea that aging makes a person “unattractive, unintelligent, asexual, unemployable, and mentally incompetent” (Atchley & Barusch, 2004, p. 439). Older adults with HIV face double jeopardy in having to deal with both HIV stigma and ageism, effecting both physical and mental health.

A survey by the Kaiser Family Foundation (2011) commissioned as the HIV/AIDS epidemic marked 30 years offered some discouraging results. Although stigmatizing attitudes have decreased, an alarming number of people still acknowledge holding negative views of persons living with HIV. Forty-five percent do not want someone with HIV preparing their food, 29% would not want their children to have a teacher with HIV, and 29% still think if a person contracts HIV it is their own fault.
(Kaiser Family Foundation, 2011). While these percentages are lower than in the early years of the epidemic, the numbers serve as a discouraging reminder of the prejudices and stigma persons living with HIV face daily.

Delayed and decreased access into care has been attributed to HIV stigma (Heckman, Heckman, Kochman, Sikkema, Suhr, & Goodkin, 2002; & Sayles, Wong, Kinsler, Martins, & Cunningham, 2009). Less access to care leads to persons presenting with advanced HIV disease, which complicates care and treatment. (Heckman, Heckman, Kochman, Sikkema, Suhr, & Goodkin, 2002). Nurses and other healthcare providers are perceived to stigmatize persons with HIV according to a study by Kinsler, Wong, Sayles, Davis, and Cunningham (2007), where 25% of participants reported feeling stigmatized during a health care visit.

Black men may be more strongly affected by HIV stigma than any other group. Williams, Wyatt, Resell, Peterson and O’Brien (2004) found Black men perceived stigma as more prevalent and strongly associated with homophobia in the Black community. This stigma caused men who had sex with men to self-identify as heterosexual. Many of the men refusing the label of gay reported having sex with women to maintain their heterosexual identity. This activity increases the risk of HIV infection for Black women and is a contributing factor to the high HIV rates found in Black women (Williams et al., 2004).

Fear of rejection and HIV stigma can prevent people from disclosing their illness to friends and family (Brennan, Emlet, & Eady, 2011). This can result in increased social
isolation and loneliness, both associated with poorer medication management (Emlet, 2006a; Vanable, Carey, Blair, & Littlewood, 2006).

Several studies have found a strong correlation between stigma and depression (Emlet, 2007; Grov, Golub, Parsons, Brennan, & Karpiak, 2010; Heckman, Kochman, & Sikkema, 2002), and depression is strongly associated with poor medication management (Holstad, Foster, DiIorio, McCarty, & Teplinskiy, 2010; Willard, 2006). Levy-Dweck (2005) cautions the double stigma of HIV and ageism could result in lower quality of social services and possible denial into long-term care facilities.

**Depression**

Depression is the most common and heavily studied psychological problem in persons living with HIV. There are many reasons for depression in older adults living with HIV in addition to the burden of living with a chronic illness. Chief among the reasons is the stigma and isolation associated with HIV (Emlet, 2006b). Stigma is often cited by patients as a deterrent to sharing their HIV diagnosis, leading to isolation and a lack of social support, which in turn leads to higher rates of depression and cognitive decline (Cornwell & Waite, 2009; Emlet, 2007).

Adults living with HIV have much higher rates of depression than the general public (Voss, Portillo, Holzemer, & Dodd, 2007). In adults with HIV, depression rates ranged from 50 to nearly 70% (Treisman, Angelino, & Hutton, 2001; Voss, 2007; Vosvick, Martin, Smith, & Jenkins, 2010). Depression in persons with HIV has been associated with poor medication management, higher levels of stress, and increased morbidity and mortality (Knowlton, Curry, Hua, & Wissow, 2009; Springer, Chen, &
Altice, 2009). Several studies on HIV and depression have found that older adults with HIV exhibit higher rates of depression than their younger counterparts (Grov, Golub, Parsons, Brennan, & Karpiak, 2010; Heckman & Heckman et al., 2002; Justice et al., 2004; Karpiak & Shippy, 2006; Shippy & Karpiak, 2005a).

Depression affects health-related quality of life (HRQOL). Studies by Cunningham, Crystal, Bozzette, and Hays (2004) and Murri et al. (2003) found that HRQOL was a strong predictor of survival independent of standard medical measures such as CD4 count and stage of HIV infection. Overall it appears there is an association between older age and lower HRQOL (Hudson, Kirksey, & Holzemer, 2004; Nokes et al., 2011). The majority of the studies, including those by Hays et al. (2000), Jia, Uphold, Zheng et al. (2007), Mowad (2004), and Nokes et al. (2000) determined that decreased social support, depression, and other comorbidities, all of which are more prevalent in older adults living with HIV, were reasons for the lower HRQOL in the older cohorts.

Depression is also associated with disease progression and shortened survival time (Farinpour et al., 2003). Pence, Miller, Gaynes, and Eron (2007) found depression associated with a slower rate of virologic suppression, while Mugavero et al. (2007) found an association between depression and opportunistic infections. Slow virologic response is of special concern for older adults with HIV, since they have a less robust virologic response to treatment than younger adults, and are often diagnosed later in the disease process, leading to longer periods of immunosuppression (Silverberg, Leyden et al., 2007; Kirk & Goetz, 2009).
In studies looking at the association between depression and medication management, Holzemer et al. (1999), Gonzalez et al., (2004), Paterson et al. (2000), and Horberg et al. (2008) found persons with depressive symptoms more likely to exhibit poor medication management. Similarly, in studies focused on older adults, Cruess, Kalichman, Amaral, Swetzes, Cherry and Kalichman (2012) and Wagner et al., (2011) found an increase in depressive symptoms was associated with poor medication management. Studies report that antidepressant medication is efficacious in treating depression in older adults living with HIV (Rabkin, McElhiney, Rabkin, McGrath, & Ferrando, 2006). Furthermore, when depression is treated effectively, medication management improves (Dalessandro et al., 2007; Holzemer et al., 1999; & Horberg et al., 2008).

Unfortunately depression often goes undiagnosed in older adults living with HIV (Voss et al., 2007). Older adults were less likely to report depressive symptoms and depressed older adults were less likely to receive treatment for their depression than were younger adults (Voss et al., 2007; Zanjani, Saboe, & Oslin, 2007). When left untreated depressive symptoms can lead to poorer medication management and poorer health outcomes (Asch et al., 2003).

**Isolation and Social Support**

Studies find that older adults with HIV live alone at almost twice the rate of older adults in the general population, and they also have smaller support networks (Emlet, 2006a; Karpiak & Shippy, 2006; Poindexter & Shippy, 2008; Shippy & Karpiak, 2005a). Isolation has been associated with increased morbidity and mortality, high rates of
depression and cognitive decline (Grov, Golub, Parsons, Brennan, & Karpiak, 2010).

Cornwell and Waite (2009) found isolation and social disconnectedness were independently associated with decreased physical and mental health. Studies by Esterling, Kiecolt-Glaser, and Glaser (1996) and Lutgendorf et al. (2005) found an association between social support and immune function, asserting that social support is an important component of battling HIV disease.

Studies by Nokes et al. (2000), Poindexter and Shippy (2008), Schrimshaw and Siegel (2003), and Shippy and Karpiak (2005a) found older adults with HIV perceived a lack of social support. This perception resulted in a significantly smaller circle of persons in whom they felt they could confide about their illness (Emlet, Tozay, & Raveis, 2011; Karpiak, Shippy, & Cantor, 2006). The lack of social support for older adults with HIV was due in part to self-isolation, choosing not to disclose their HIV status to family or friends because of the fear of stigma (Shippy & Karpaik, 2005a). Shippy and Karpiak (2005b) found older adults with HIV relied on formal care networks instead of traditional informal networks that older adults with other chronic diseases frequently use. Research suggests that these informal networks often formed around other persons with HIV or other chronic diseases. The result was these informal networks were unable to provide needed support because members of the network were debilitated by their own disease and were unable to provide support.

Many studies have found a positive association between social support and medication management (Catz, Kelly, Bogart, Benotsch, & McAuliffe, 2000; Gonzalez et al. 2004; Holstad, Pace, De, & Ura, 2006; Power et al. 2003; Simoni, Frick, Lockhart, &
Liebovitz, 2002; Stirratt, et al., 2006). These studies did not differentiate between support from a partner and other support. However in a study that did make the distinction between partner and other support, Power et al. (2003) found that only social support from a partner was strongly associated with medication management. Support from friends and family was not significantly related to medication management. This is important because older adults living with HIV are less likely to have a life partner.

Older adults with HIV not only have smaller support networks but they also lack the formal support used by older adults with other chronic diseases (Emlet & Poindexter, 2004). In examining formal support networks, Emlet and Poindexter (2004) argue for the integration of gerontological services and HIV services in order to provide holistic care for this emerging demographic. Emlet and Poindexter cite examples of older adults with HIV feeling unwelcome at AIDS Service Organizations (ASOs) that were judged to be geared to younger adults. These older adults felt just as uncomfortable in the aging care network, where staff was often unfamiliar and sometimes uncomfortable with the needs of older adults with HIV.

**Theoretical Framework**

Social Cognitive Theory provides a framework for understanding, predicting, and affecting human behavior. This theory was developed by Bandura (1977) to explain how personal and environmental factors interact to affect human behavior. According to Bandura (1997) it is the combined influences of personal and environmental factors that influence a person’s thoughts and ultimately leads to behavior. A model of social cognitive theory developed for this study is depicted in Figure 1.
In this theoretical model, the interaction between personal and environmental factors influences a person’s thoughts and eventually their behaviors. Interaction between the person and the environment involve the factors of cognition, depression and self-efficacy and how they are continually modified by the environment. The environment, including friends, family, healthcare providers and socio-economic factors like wealth and stable housing is modified by personal factors of cognition, depression and self-efficacy. Both personal and environmental factors require cognitive processing to affect behavior. In this model medication management is being studied. In a reciprocal loop effective medication management in turn affects personal and environmental factors.

Medication management is a complicated set of behaviors. In order to be successful in HIV medication management a person must have knowledge and skills to perform the tasks, but a person must have the belief that they can continue to successfully complete these tasks over a long period of time. The person must then be able to understand the complexity of medication management in order to be successful in medication management.

High self-efficacy along with cognitive ability and low level of depression can overcome environmental barriers in order to effectively manage medications (Bandura, 1989). These determinants are constantly interacting. Self-efficacy is a major construct of Social Cognitive Theory.
Self-efficacy is described as a person’s confidence in their ability to perform a particular behavior (Bandura, 1997). According to Bandura (1989), self-efficacy beliefs are what determine a person’s level of motivation and these beliefs influence the effort a person exerts on a particular task. When a person has a strong belief in their ability to perform a task, they will endure in spite of difficulties they encounter. However, a person who doubts their ability to successfully perform a task limits their effort or may eventually abort the attempt altogether when confronted with adversity (Bandura, 1989).

According to Social Cognitive Theory, perceived self-efficacy and outcome expectancies are important factors that influence behavior (Bandura, 2004). A person will not set a goal of taking their medications correctly 100% of the time if they do not
believe that doing so will result in better health. Antiretroviral therapy is difficult to
tolerate. Persons may abandon ART if they do not have a strong belief in the efficacy of
the medications that make up the therapy. Persons starting ART for the first time or
persons changing their ART regimen may experience diarrhea, nausea, vomiting, fatigue
and rashes. These, along with other debilitating side effects of the medications, can act as
barriers to successfully completing the task of medication management. Persevering
through the difficult initial weeks on therapy is made easier, and better tolerated if a
person understands that the downside of short-term side-effects is outweighed by
successfully achieving the long-term goal of HIV viral suppression.

Medication management is a skill that may become more difficult for older adults
with HIV because of obstacles that impede the successful mastery of this task. Increased
pill burden, depression, and cognitive decline are personal factors that can create self-
doubt and decrease self-efficacy in one’s ability to successfully master the skill of
medication management. This self-doubt may discourage a person from attaining and
maintaining the high level of medication management necessary to prevent virologic
failure, which then can introduce new obstacles to successfully managing their illness.
Chapter 3

Introduction

The primary aim of this research was to examine if medication management was different for older adults living with Human Immunodeficiency Virus (HIV) compared to younger adults living with HIV. The secondary aim was to examine the relationship between age, personal factors (cognitive ability, depression, and self-efficacy) and medication management among participants. The two study aims were achieved through the following research questions.

Question 1: Is there a difference in the medication management ability between older and younger adults living with HIV?

Question 2: Are there differences in cognitive ability, depression, or self-efficacy between older and younger adults living with HIV?

Question 3: What are the associations between personal factors (cognitive ability, depression, and self-efficacy) and medication management among older and younger adults living with HIV, respectively?

Question 4: Which personal factors (cognitive ability, depression, and self-efficacy) are the best predictors of medication management among adults living with HIV, controlling for age as a covariate?

Methodology

Research Design

This research utilized a descriptive-correlational, cross-sectional design in examining whether there was a difference in medication management between older and
younger adults living with HIV. The influence of age was examined in the associations between personal factors (cognitive ability, depression, and self-efficacy) and medication management. The factors (cognitive ability, depression and self-efficacy) have been observed in practice and previously studied in persons living with HIV. However, what was unknown is their influence on medication management among the older HIV population.

A descriptive-correlational cross-sectional design allows the researcher to describe selected variables and study associations between groups (Taylor & Kermode, 2006). It was chosen for this study to compare the characteristics of groups according to selected variables. Variables for this study were selected on the basis of previous studies where cognitive decline, depression and self-efficacy have an effect on medication management. More importantly these factors are found at higher rates in older adults with HIV than in younger adults with HIV. This study adds to nursing knowledge of older adults living with HIV by examining how this population can manage their medication regimens, and what clinical variables predict the ability to manage their medications.

**Instruments**

Participants completed four existing standardized instruments along with a Demographic Form. As shown in Table 2, the four standardized instruments were: the Center for Epidemiological Studies Depression Scale (CES-D), the Medication Management Task-Revised (MMT-R), the Montreal Cognitive Assessment (MoCA), and the Self-Efficacy for Chronic Disease Scale (SE-CDS). The CES-D was used to measure depression (Appendix A). The MMT-R was used to measure medication management
The MoCA was used to measure cognitive ability (Appendix C). The SE-CDS was used to measure self-efficacy (Appendix D). All four instruments have been used in previous studies of persons living with HIV. These particular instruments were chosen for this study not only because of their reliability but their brevity makes them useful in clinical settings. Another reason for choosing these instruments is that they would not be overly burdensome on patients, an important consideration when choosing research instruments. The Demographic Form collected descriptive data about the participants. (Appendix E).

Table 2

<table>
<thead>
<tr>
<th>Instruments</th>
<th>Variable</th>
<th># of Items</th>
<th>Scoring</th>
<th>Completion Time</th>
<th>Reliability</th>
</tr>
</thead>
<tbody>
<tr>
<td>CES-D</td>
<td>Depression</td>
<td>20</td>
<td>Total Score of 0-60</td>
<td>5 minutes</td>
<td>0.90</td>
</tr>
<tr>
<td>MMT-R</td>
<td>Medication Management</td>
<td>10</td>
<td>Total Score of 0-16</td>
<td>10 minutes</td>
<td>0.72</td>
</tr>
<tr>
<td>MoCA</td>
<td>Cognitive Ability</td>
<td>30</td>
<td>Total Score of 0-30</td>
<td>10 minutes</td>
<td>0.83</td>
</tr>
<tr>
<td>Self-Efficacy – Chronic Disease Scale</td>
<td>Self-efficacy</td>
<td>6</td>
<td>Total Score of 1-10</td>
<td>5 minutes</td>
<td>0.91</td>
</tr>
<tr>
<td>Demographic Form</td>
<td>Descriptive Statistics</td>
<td></td>
<td></td>
<td>10 minutes</td>
<td></td>
</tr>
</tbody>
</table>
The researcher administered the MoCA and MMT-R. The CES-D and SE-CDS instruments were self-administered and were completed by the study participants. Information collected on the Demographic Form was collected from study participants and from information gathered from medical records.

The Center for Epidemiological Studies Depression Scale: CES-D

The CES-D (Radloff, 1977) is a 20-item self-administered depression questionnaire. Total scores can range from 0 to 60. The instrument asks participants to consider the past 7 days when answering the questions. Scoring for each item is on a 4-point scale ranging from 0 (rarely or none of the time) to 3 (most or all of the time). Scores on items 4, 8, 12, and 16 are reversed. A higher score indicates a higher level of distress. A score >16 indicates a clinically significant level of distress. Less than 20% of the general population would be expected to score in this range. A score > 23 indicates major depressive symptoms.

The CES-D has been used in many large-scale HIV/AIDS research trials. Reliability and validity have been well-established. Chronbach’s Alpha is 0.94 (Radloff, 1977).

An example of a question is: “I was bothered by things that usually don’t bother me”

Four of the questions have reversed scoring.

An example of a question scored in reverse is: “I felt hopeful about the future”

Study participants who score greater than 16 on the CES-D were referred to their HIV healthcare provider for follow-up.
The Medication Management Task-Revised: (MMT-R)

The MMT-Revised is a performance test designed to assess medication management skills. The MMT-R was developed by Heaton et al. (2004) taking the most valid and reliable items from their original medication management test developed by Albert et al. (1999). Medication management has been defined as “the cognitive and functional ability to self-administer a medication regimen as it has been described” (Madigan, Farris, Wiens, & Johnson, 2003, p. 333).

The MMT-R is a 10-item questionnaire consisting of two components. The questionnaire is administered by the researcher. The pill-dispensing component measures the participant’s ability to dispense a day’s dosage of medications. The medication inference component requires the participant to answer questions about the medications, such as how long a medication prescription will last, and how many times a day a particular medication must be taken. A higher score indicates better medication management. The final question consists of 10 parts that focus on participants’ own medications. Examples of the questions are “how many different medications do you take on a daily basis?” and “how many pills do you take on a daily basis?”

The original MMT reliability ranged from .63 to .74 for the medication inference component, and .78 to .84 for the pill-dispensing component (Albert et al., 1999). In another study using the MMT, it was found that cognitive deficit in persons with HIV was associated with greater risk of error on the MMT (Albert et al., 2003). Albert et al.
also found beliefs about medication efficacy affected scores on the MMT. The MMT-R is a revised version of the original MMT, using only the items deemed most reliable and valid from the pilot work (Heaton et al, 2004). This revised version retains both the pill-dispensing component and the medication inference component found in the original version; however, the total number of questions has been decreased. Completion time has also been shortened to 10-15 minutes, from the 15-25 minute completion time of the original version. The overall reliability of the MMT-R was 0.72 in a study of 193 persons living with HIV (Heaton, 2004).

Items from the medication inference component include questions concerning dosage information, special instructions such as take with food, take on an empty stomach, or how long medication prescriptions will last. The pill dispensing component includes questions about the number of medications taken on a daily basis, the total number of pills and supplements taken daily, and questions about medication aids such as pill organizer and timing devices.

**The Montreal Cognitive Assessment: (MoCA)**

The MoCA is a 30-item assessment tool used as a screening instrument for mild cognitive dysfunction. It was developed by a group of Canadian researchers to assist in detecting mild cognitive decline in the clinical setting (Nasreddine et al., 2005). The test is administered by the researcher. It is designed as a quick screening tool to assess mild cognitive dysfunction, taking only about 10 minutes to complete. The MoCA assesses different cognitive domains: attention, concentration, executive function, memory,
language, visioconstructional skills, conceptual thinking, calculations, and orientation. The total possible score is 30, and a score of 26 or above is considered normal.

The MoCA was first tested in a study that included 94 patients meeting mild cognitive decline criteria, 93 patients with mild Alzheimer’s disease, and 90 healthy elderly controls. It was shown to have sensitivity and specificity (Nasreddine et al., 2005).

Since its initial validation, the MoCA has been used to determine mild cognitive decline in many studies. Recently the MoCA has been used in studies of persons living with HIV (Koski et al., 2011; Musso et al., 2011). In a study of 69 patients with HIV, the MoCA was found to be useful in screening for HIV dementia. However, a slightly lower cutoff of < 24 was proposed (Musso et al., 2011). Koski et al. found the MoCA effective in the geriatric and HIV populations. The MoCA was chosen for this study because it is a quick screening tool that can easily be included in a healthcare visit with immediate results that could alert the healthcare team of mild cognitive impairment, or cognitive changes that may otherwise be missed.

The **Self-Efficacy for Chronic Disease Scale: (SE-CDS)**

This scale was developed by the Stanford Patient Education Research Center. The Center has nearly 20 years of work developing, adapting, and testing self-administered scales. Self-efficacy is an integral component of Social Cognitive Theory, and has been shown to be a predictor of the adoption of healthy behaviors, including medication management (Bandura, 1997). The SE-CDS is a quick screening tool that measures self-efficacy in persons living with chronic diseases. It has been shown to be reliable and
consistent. When tested with 605 persons with chronic disease, internal consistency and reliability was found to be 0.91. The 6 items had an observed range of 1-10, with a mean of 5.17 and a standard deviation of 2.22 (Lorig, Sobel, Ritter et al., 2001). This SE-CDS uses a Likert-like scale with answers ranging from 1 (not at all confident) to 10 (totally confident).

This scale was designed specifically for self-efficacy in managing chronic disease. An example of a question on the scale is: “How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?” Total scores are divided by the number of questions (6), resulting in total scores between one and 10, with higher scores indicating an increased ability to manage chronic disease.

This scale was chosen for this research study as it is minimally burdensome for patients, can provide a quick gauge of a patient’s self-efficacy in a clinical setting, and has been shown to be reliable in past research.

Demographic Form

The Demographic Form will collect data from the participant and from medical records. The information collected includes:

- Participant’s name, date of birth, study visit date and assigned study number
- Study arm (Age 50 and older or Under age 50)
- Current and past alcohol, tobacco, and drug use
- Nadir and current CD4 counts, current HIV viral load
• Year of HIV diagnosis, date of HIV confirmation used for study, time on HIV medications
• ART and other medications
• Diagnoses (other than HIV)
• Race, gender, Hispanic ethnicity
• Years of education completed
• Test scores from completed study instruments

Inclusion and Exclusion Criteria

This study used a convenience sample of adult men and women living with HIV and currently taking antiretroviral medications. The inclusion criteria for this study are listed in Table 3.

The inclusion criteria for study participation included men and women living with HIV who were at least 18 years of age. The HIV infection was determined by a licensed ELISA test and a confirmatory Western Blot documented in the medical record, or two documented detectable HIV viral loads at any time prior to entering the study. Participants must have been on an antiretroviral regimen for at least 16 consecutive weeks prior to entering the study. Sixteen weeks on ART was chosen as the minimum time to be on ART because it may take 16 weeks to determine the effectiveness of the medication. Participants in this study must have had the ability to read and speak English. This requirement was established because the instruments used in this study were all in English, and their reliability has been determined using an English version of the
instrument. Lastly, participants all provided written informed consent of their participation in this study.

Table 3.

*Inclusion Criteria*

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1</td>
<td>Men or Women at Least 18 years of age</td>
</tr>
<tr>
<td>2</td>
<td>HIV infection as documented by a licensed ELISA test and confirmed by a Western Blot or alternatively two documented detectable HIV viral loads at any time prior to study entry</td>
</tr>
<tr>
<td>3</td>
<td>Receipt of antiretroviral regimen for at least 16 consecutive weeks prior to study entry</td>
</tr>
<tr>
<td>4</td>
<td>Ability to read and speak English</td>
</tr>
<tr>
<td>5</td>
<td>Ability and willingness of study participant to provide written informed consent</td>
</tr>
</tbody>
</table>

The exclusion criteria for study participation include persons less than 18 years of age. This age was chosen as 18 is the age commonly used in adult HIV research. Persons were excluded from this study if they did not have a documented HIV infection. Documentation required a positive ELISA and confirmatory Western Blot or two detectable HIV viral loads prior to entry into the study. Persons who had not been on antiretroviral therapy for at least 16 weeks were excluded from the study. Persons who did not read or speak English were not enrolled in this study as the survey instruments used are all written in English, and their reliability has been determined using an English version of the instrument. Lastly, participants were not enrolled in this study if they
refused to provide written informed consent. The exclusion criteria for this study can be found in Table 4.

Table 4.

**Exclusion Criteria**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Less than 18 years of age</td>
</tr>
<tr>
<td>2</td>
<td>No documentation of HIV infection</td>
</tr>
<tr>
<td>3</td>
<td>Less than 16 consecutive weeks on HIV medications</td>
</tr>
<tr>
<td>4</td>
<td>Inability to read and understand English</td>
</tr>
<tr>
<td>5</td>
<td>Unable or unwilling to give written informed consent</td>
</tr>
</tbody>
</table>

There were two groups in this study. Group 1 was comprised of participants 50 years of age and older. Group 2 was comprised of participants between the ages of 18 and 49 years of age. A goal of recruiting 25% women into each group was established in order to resemble national percentages of women living with HIV.

**Sample Size**

To determine sample size for this study, alpha was set at .05 and beta at .80, and calculated on a two-tailed t-test to detect a moderate effect size of medication management between the two groups (Faul, Erdfelder, Lang, & Buchner, 2007). Using the G-power statistical program, a total of 128 participants were required to be enrolled in this study. This number is in line with other rules for calculating sample size (Field, 2005). Therefore, rounding up required enrollment of 130 participants. There were 65
participants in the group of adults age 50 and older and 65 participants in the group of adults age 18 to 49.

**Recruitment**

Participants for this study were recruited from the Infectious Diseases Clinic and the AIDS Clinical Trials Unit (ACTU) at Washington University School of Medicine. The researcher reviewed the clinic and ACTU schedules each day to identify persons potentially eligible for the study. This initial identification was limited to age and HIV status. A research assistant employed by the ACTU was informed of persons potentially eligible for the study. She approached these persons while they were at their healthcare appointment and inquired about their participating in a study designed to examine medication management in persons living with HIV. When a potential volunteer expressed interest in participating they were taken by the recruiter to a private room where they were provided information about the study and given a copy of the informed consent document for the study. When the researcher was available she met with the person at that time and answered any questions they had related to the study requirements. If the potential volunteer and the researcher were both available, the appointment took place at that time.

If the researcher was not available at that time the recruiter notified the researcher of the potential volunteer’s interest in the study, and the researcher contacted the volunteer to answer any questions they had regarding the study. If the potential volunteer agreed to participate in the study an appointment was scheduled at a time convenient to both the researcher and the participant. Recruitment procedures are outlined in Table 5.
Table 5.

*Recruitment Procedures*

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>The researcher will look at the clinic and ACTU appointment calendars for the day and with the use of medical records determine which clients may be eligible for the study.</td>
</tr>
<tr>
<td>2</td>
<td>A research assistant, who is employed as a recruiter for the ACTU will approach clients initially considered to be eligible who are at the Infectious Disease clinic or the ACTU for an appointment and ask them if they would be interested in participating in a study designed to examine medication management in persons living with HIV.</td>
</tr>
<tr>
<td>3</td>
<td>If a person expresses interest in participating, they will be ushered into a private room where they will be provided with more information about the study.</td>
</tr>
<tr>
<td>4</td>
<td>The study will be explained in greater detail, and the volunteer will be provided an informed consent document to read. The researcher will be available to answer any questions at this time.</td>
</tr>
<tr>
<td>5</td>
<td>If the potential participant and researcher are available, enrollment into the study can take place at this time.</td>
</tr>
<tr>
<td>6</td>
<td>A potential participant may also choose to schedule a study visit at a future time convenient to both the participant and the researcher.</td>
</tr>
<tr>
<td>7</td>
<td>At the study appointment, the participant along with the researcher will complete the informed consent process, the researcher will answer any questions the participant may have, and the participant will be given a copy of the informed consent document.</td>
</tr>
<tr>
<td>8</td>
<td>The participant will be able to complete the study in a single visit of about one hour.</td>
</tr>
<tr>
<td>9</td>
<td>Upon completion of the study, the participant will be given $10 cash as remuneration for their time.</td>
</tr>
</tbody>
</table>
Setting

This study took place at the ACTU at Washington University School of Medicine, located in the city of St. Louis, Missouri. The ACTU at Washington University is the major research center for conducting HIV/AIDS research in the St. Louis area. Established in 1987, the unit has operated continuously since that time enrolling volunteers in clinical trials. The trials are predominantly therapeutic but not exclusively so. The majority of participants have been enrolled in studies funded by the National Institute of Allergy and Infectious Diseases (NIAID). In addition Washington University and industry-sponsored studies are offered to participants at this site. The ACTU currently follows more than 800 participants in clinical trials. The ACTU is a referral clinic and draws participants from throughout the states of Missouri and Illinois. The ACTU provides ample parking for volunteers and is conveniently located adjacent to the Metrolink rail line and bus lines.

Located in the same building as the ACTU but in a separate physical space is the Washington University Infectious Disease outpatient clinic. The Infectious Disease clinic is the primary recruitment point for the ACTU. The clinic provides care to well over 1,600 HIV infected individuals. This is a major clinic for persons newly diagnosed with HIV/AIDS in the area, seeing 3-4 new patients per week. Patients followed in the Infectious Disease practice are regularly referred for participation in clinical trials. The researcher has worked for eleven years in HIV clinical research, the last seven of which have been at the ACTU as a clinical research nurse. The researcher has been trained and certified in neurocognitive testing. The researcher has been trained in the use of all the
study instruments. The researcher has also worked extensively in improving medication management with research participants new to and experienced with HIV medications.

**Data Collection Procedures**

Written informed consent was obtained from all participants prior to completing any study-related questionnaires. All study procedures took place in a quiet, private room with adequate lighting and a flat writing surface. After obtaining informed consent, the researcher, together with the participant, completed the Demographic Form. The researcher then administered the MoCA followed by the MMT-R. After completion of these tests, participants completed the following self-administered questionnaires: CES-D and the SE-CDS. The researcher was available to assist the participants if they had questions about either of the instruments. The participants were given as much time as necessary to complete the questionnaires. The duration of the time it takes for a participant to complete the series of questionnaires was expected to be approximately one hour. These study visits ranged from about 45 to 75 minutes. Upon completion, the researcher checked the questionnaires for missing data before the participant left. If it was found that some questions had not been answered, the participant was asked if they were missed or intentionally left blank. Participants were not required to answer any questions they chose not to answer. At the conclusion of the study visit the participant was given $10 cash for their time and participation in the study.

The researcher completed the Demographic Form using self-report from the participant along with accessing the medical records. The Demographic Form included
descriptive statistics along with other information. A copy of the Demographic Form can be found in Appendix E.

If the participant scored higher than 16 on the CES-D the researcher informed the participant of this score and advised them that this information would be provided to their HIV healthcare provider, as stated in the informed consent document.

This study was run by the researcher. The researcher completed IRB training and worked in the past in a research capacity at the ACTU for over seven years. The researcher was trained on administration of all the screening tests included in this study, and was involved in several previous studies utilizing these and other similar screening tests.

Demographic information collected from the participants included age, gender, race, number of years since diagnosis, current CD4 and viral load (VL) counts. Each study packet was coded with a number for confidentiality purposes, and identifying information was not included in the coded data. It was estimated that the researcher would need about two hours to complete data collection for each participant. One hour was spent with the participant, and the second hour consisted of time spent recruiting participants and extracting data from medical records.

**Analysis and Data Management**

Data was input and analyzed using the latest SPSS version available. Descriptive statistics were used to summarize the demographic characteristics of both groups. Data on current and historical use of tobacco, drugs, and alcohol was collected from the
Demographic Form. Current CD4 count and viral load was presented using descriptive statistics.

Independent T-tests were used to compare the difference in continuous variables including age, pill burden, duration of HIV infection, time on Antiretroviral Therapy (ART), CD4 count and viral load between groups. Chi-square tests were used to examine the difference in discrete variables including gender at birth, current and historical use of tobacco, drugs, and alcohol.

The characteristics of study participants were reported as: age (mean years ± standard deviation [SD]), male (%), ethnicity (%), CD4 count at study entry (cells/ml ± SD), viral load at entry (copies per ml ± SD), duration of HIV infection (mean years ± SD), time on ART (mean years ± SD), and pill burden (number of pills per day ± SD). This information gathered on the Demographic Form was used to compare the two groups.

To answer research question one, a two-tailed t-test was used to analyze differences in medication management between older and younger adults with HIV. A two-tailed t-test was used because although it is expected there will be differences in medication management between the two groups, there was not enough data to determine the direction of the difference (Field, 2005).

For research question two, two-tailed t-tests was used to analyze differences in cognitive ability, depression, and self-efficacy between older and younger participants. Effect size of cognitive ability, depression, and self-efficacy was determined through an analysis of mean difference scores between the older and younger groups on all overall
scores on each instrument using Cohen’s d (Cohen, 1988). Effect size quantifies the difference between the means of two groups, and is concerned with the strength of the relationship (Polit & Hungler, 1995).

For research question three, Pearson correlation coefficients were computed for older and younger adults among the three independent variables; MoCA (cognition), CES-D (depression), and SE-CDS (self-efficacy), and the dependent variable, MMT-R (medication management).

To answer research question four, multiple regressions were conducted to analyze the effects of cognitive ability, depression, and self-efficacy on medication management for the older and younger groups respectively. Regression analysis is used to make predictions about phenomena (Polit & Hungler, 1995). In this study multiple regressions were used to make predictions about medication management based on the effects of cognitive ability, depression and self-efficacy. Simultaneous regression, rather than step-wise regression was used because there was not enough data to determine if any one of the variables would have a greater impact on medication management than the other variables.

Data is stored on a hard drive and backed up on the server of the researcher’s computer. The computer is password protected. No identifying data is included in the stored computer data. Hard copies of the completed study visits are stored by the researcher in a locked file cabinet in a locked office.
Strengths and Limitations

Strengths of this study include ready access to the population being studied and the strong research background of the researcher. The researcher is also aware of significant interest in research about the aging HIV community among current research participants and the local community advisory board at the Washington University ACTU. This group is comprised of community members affected by HIV. During monthly meetings held in a conference room within the ACTU building this group discusses current and future research studies. They have been vocal in their support for more studies directed at the aging HIV community. The community advisory board has been instrumental in disseminating information about HIV research studies of interest to the community.

A limitation of this study is that all recruitment was done within a single geographical area, and only English speaking persons were enrolled, making the results of the study less generalizable. Another limitation is item burden; the use of multiple instruments may have placed a time and attention burden on participants.

Human Subjects Protection

This study has undergone full review by the Washington University Human Research Protection Office (HRPO) and the Institutional Review Board at the University of Missouri, St. Louis prior to implementation of the research project. The researcher met with and obtained signed informed consent from each participant in the study. Due to the confidential nature of this study, the consent form emphasized the privacy protections afforded participants in this study. Protected Health Information (PHI) has not, and will
not be disclosed to anyone by the researcher without written consent from the study participant. Participants were assigned an identification number (ID). Confidentiality was maintained by using ID numbers and not participant names. Only the investigator has access to code numbers that link information to a participant’s name. Records are kept in a locked, secured location accessible only to the researcher. Computer data is coded by ID number and does not contain identifying information. It is stored on a password-protected computer.

**Time Frame**

The HRPO approval took about three weeks. It was anticipated, based on experience from previous similarly designed studies, that enrollment goals could be met within four months of study initiation. In fact, the study was completely enrolled within three months. Data input and analysis were completed within two months of completion of study.

**Conclusion**

The purpose of this research study was to consider whether there are differences between medication management in older and younger adults living with HIV. The second purpose of this study was to identify factors that predict medication management so that nurses and other healthcare providers can consider these factors as they create strategies to promote medication management and increase adherence in their patients. In this chapter the methodology used has been identified, described and justified by the researcher. Findings from this study may help nurses and other healthcare providers create better strategies to increase older adults HIV medication management.
Chapter 4

Results

Introduction

The primary aim of this research was to examine if medication management is different for older adults living with Human Immunodeficiency Virus (HIV) compared to younger adults living with HIV. The secondary aim was to examine the relationship between age, personal factors (cognitive ability, depression, and self-efficacy) and medication management among participants. The two study aims were achieved through the following research questions.

**Question 1:** Is there a difference in the medication management ability between older and younger adults living with HIV?

**Question 2:** Are there differences in cognitive ability, depression, or self-efficacy between older and younger adults living with HIV?

**Question 3:** What are the associations between personal factors (cognitive ability, depression, and self-efficacy) and medication management among older and younger adults living with HIV, respectively?

**Question 4:** Which personal factors (cognitive ability, depression, and self-efficacy) are the best predictors of medication management among adults living with HIV, controlling for age as a covariate?

Chapter four is organized into five sections: 1) recruitment and data management, 2) sample characteristics, 3) quality of measures, 4) results to related questions, and 5) discussion.
Recruitment and Data Management

As explained in Chapter 3, participants were recruited from the Infectious Disease Clinic and the AIDS Clinical Trials Unit (ACTU) at Washington University School of Medicine. The researcher reviewed the clinic and ACTU schedules each day, using medical records to determine which persons with scheduled appointments would be eligible for the study. This initial identification consisted solely of age and HIV status. The researcher gave the research assistant employed by the ACTU a list of potentially eligible study participants. Potentially eligible participants were approached by the research assistant during their appointment and asked if they would be interested in participating in a research study designed to examine medication management in adults living with HIV. If interested, potential participants were instructed to come to the ACTU waiting room at the conclusion of their appointment and ask for the medication management researcher. The researcher brought the potential participant into a private room where eligibility was verified and the consent process took place. The majority of participants completed the research study at this time. Some persons interested in participating in the study scheduled appointments at a later date.

Records were not kept on potential participants who declined to participate. In total 131 eligible participants completed the study. Of the eligible participants, one case in the younger group was excluded from analysis due to incomplete HIV-related medical data, resulting in 65 participants in the older group and 65 participants in the younger group for a total of 130 evaluable participants. Data was analyzed using SPSS version 20.0 for Windows.
Table 6.

*Characteristics of the Study Participants (N = 130) and by Groups (n = 65 for Group1; n = 65 for Group2)*

<table>
<thead>
<tr>
<th>Categorical Variables</th>
<th>Male</th>
<th></th>
<th>Female</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All</td>
<td>G1</td>
<td>G2</td>
<td>All</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>95(73%)</td>
<td>51(78%)</td>
<td>44(68%)</td>
<td>35(27%)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All</td>
<td>G1</td>
<td>G2</td>
<td>All</td>
</tr>
<tr>
<td></td>
<td>82(63%)</td>
<td>34(52%)</td>
<td>48(74%)</td>
<td>47(36%)</td>
</tr>
<tr>
<td>Currently</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol use</td>
<td>80(62%)</td>
<td>32(49%)</td>
<td>48(74%)</td>
<td>38(29%)</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>65(50%)</td>
<td>24(37%)</td>
<td>41(63%)</td>
<td>34(26%)</td>
</tr>
<tr>
<td>Drug use</td>
<td>38(29%)</td>
<td>13(20%)</td>
<td>25(39%)</td>
<td>41(32%)</td>
</tr>
<tr>
<td>Numerical Variables</td>
<td>Range</td>
<td>Mean</td>
<td>Standard Deviation</td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>All G1 G2</td>
<td>All G1 G2</td>
<td>All G1 G2</td>
<td></td>
</tr>
<tr>
<td>Age (Years)</td>
<td>20-76 50-76 20-49</td>
<td>46.91 56.17 37.65</td>
<td>11.67 6.01 8.02</td>
<td></td>
</tr>
<tr>
<td>Education (Years)</td>
<td>8-20 8-20 8-20</td>
<td>12.90 12.88 12.92</td>
<td>2.49 2.66 2.33</td>
<td></td>
</tr>
</tbody>
</table>

HIV-Related Medical Data

| Years Since HIV Diagnosis   | 1-30 3-30 1-28 | 13.74 15.80 11.68 | 7.39 7.62 6.60 |
| Years of HIV Meds           | 1-28 1-28 1-27 | 9.28 10.50 08.05 | 6.50 6.55 6.27 |
| Current CD4 Count           | 5-1649 5-1417 8-1649 | 557.85 548.94 566.75 | 303.60 290.87 317.85 |
| Nadir CD4 Count             | 0-1289 0-600 0-1289 | 211.43 161.51 261.35 | 192.20 147.68 218.15 |
| Number of Meds              | 0-19 0-19 0-9 | 4.89 6.40 3.40 | 3.69 3.95 2.69 |
| Number of Other Diagnoses   | 0-12 0-12 0-7 | 3.35 4.55 2.14 | 2.54 2.61 1.78 |

Note: G1 – Group 1 (Older adults); G2 = Group 2 (Younger adults); Number of Meds includes all documented medications other than HIV medications; Other Diagnoses includes all documented diagnoses other than HIV or AIDS
Sample Characteristics

The characteristics of this sample are reflective of the current state of the HIV epidemic in this country (CDC, 2012). The older group consisted of more college educated White males than the younger group. While the majority of older participants were White males, the females enrolled in this group were predominantly Black.

The younger group included more females and more Blacks than the older group. There were more than twice as many Black males as White males in this group, and the females in this group were overwhelmingly Black females. The younger group had higher rates of alcohol, tobacco and drug use than the older group.

Table 6 summarizes demographic information and HIV-related medical data for all participants and each group. The 130 participants in this study each had a positive HIV test documented in their medical records. Among them, 95 (73%) were male and 35 (27%) were female. Eighty-two participants (63%) were Black, 47 (36%) were White, and one self-identified as “other”. Eighty participants (61%) consumed alcohol, 38 (29%) reported past alcohol consumption and 12 (9%) reported never having consumed alcohol. Sixty-five participants (50%) smoked tobacco, 34 (26%) smoked in the past, but not currently, and 31 (24%) never smoked. Thirty-eight participants (29%) used drugs, 41 (31%) had used drugs in the past, but not currently, and 51 (39%) never used drugs. On average, study participants were 46.9 years of age (SD = 11.67), ranging from 20 to 76 years. Their mean years of education was 12.9 years (SD= 2.49), ranging from 8 to 20 years. Overall 103 study participants (79%) had at least a high-school education, and 19
(15%) had college degrees. The average time since HIV diagnosis for all participants was 13.74 years (SD = 7.39), ranging from one to 30 years. On average, study participants have taken HIV medications for 9.28 years (SD = 6.50), ranging from 1 to 30 years. The mean number of HIV medications taken each day was 2.4 (SD = 1.11), ranging from one to five. Overall three-quarters (n = 97; 75%) of the participants had undetectable viral loads, indicating the level of the HIV in the blood is below the level needed for detection, and demonstrating that it is well-controlled in the body. The remaining quarter (n = 33; 25%) had detectable viral loads ranging from 20 to 206,397, indicating that HIV could be found in the blood, and the infection was not fully controlled by medication.

In the older group (n = 65), there were 51 (78.5%) males and 14 (21.5%) females. Among them, 34 (52%) were Black and 31 (48%) were White. Almost half (n = 32; 49%) of the older adults consumed alcohol, 26 (40%) consumed alcohol in the past, but did not currently, and 7 (11%) reported never drinking alcohol. Twenty-four (37%) older adults used tobacco, 26 (40%) used tobacco in the past, but did not currently, and 15 (23%) never used tobacco. Thirteen (20%) older adults used drugs, 22 (34%) used drugs in the past, but did not currently, and 30 (46%) never used drugs.

The average age of the older adults was 56.17 years (SD = 6.01), ranging from 50 to 76 years. On average, they had 12.88 years of education (SD = 2.66), ranging from eight to 20. Three-quarters (n = 49; 75%) had at least a high school education and almost one in five (n = 12; 18%) had earned college degrees. Looking at gender, more than three-quarters (n = 42; 82%) of the older males had at least a high school education, and
less than a quarter (n = 11; 22%) had college degrees. Half (n = 7; 50%) of the older females had at least a high education, and just one (7%) had earned a college degree.

The average time since HIV diagnosis was 15.80 years (SD = 7.62), ranging from 3 to 30 years. The mean number of HIV medications they took each day was 2.35 (SD = 1.14), ranging from 1 to 4 daily medications. The mean number of non-HIV medications taken each day was 6.40 (SD = 3.95), ranging from 0 to 19 non-HIV medications. Over two-thirds (n = 53; 82%) of the older adults had undetectable viral loads. The remaining 12 (18%) had detectable viral loads ranging from 20 to 51,458.

In the younger group (n = 65), there were 44 (68%) males and 21 (32%) females. Forty-eight (74%) participants were Black and 16 (25%) were White. Forty-eight (74%) participants consumed alcohol, 12 (19%) consumed alcohol in the past, but did not currently, and 5 (8%) never consumed alcohol. Forty-one (63%) participants used tobacco, 8 (12%) used tobacco in the past, but did not currently, and 16 (25%) never used tobacco. Twenty-five (39%) participants used drugs, 19 (29%) used drugs in the past, but did not currently, and 21 (32%) never used drugs.

The average age of the younger adults was 37.65 years (SD = 8.02), ranging from 20 to 49 years. On average, they had 12.92 years of education (SD = 2.33), ranging from 8 to 20 years of education. Over three-fourths (n = 54; 83%) had at least a high-school education, and seven (11%) had college degrees. Looking at gender, 37 (84%) younger males had at least a high school education, and seven (16%) had college degrees. Over three-quarters (n = 17; 81%) of the younger females had at least a high school education, none had a college degree.
The average time since HIV diagnosis was 11.68 years (SD = 6.60), ranging from 1 to 28 years. The mean number of HIV medications they took each day was 2.45 (SD = 1.09), ranging from 1 to 5 HIV medications. The mean number of non-HIV medications they took each day was 3.40 medications (SD = 2.69), ranging from 0 to 9. Overall 44 (68%) younger adults had undetectable viral loads. The remaining 21 (32%) had detectable viral loads ranging from 22 to 206,397.

**Instrumentation**

The measures used in this study were chosen because they had been used in other HIV studies, they were reliable and valid, and their brevity insured that participants would not be overly burdened in completing four survey instruments. Another important consideration was choosing instruments that could be transitioned into a clinical setting. Having brief, reliable instruments available would encourage their use during healthcare appointments. Healthcare providers have limited time to spend with their patients, and in order to incorporate survey instruments into a visit the instruments would have to be able to be completed quickly. Two of these instruments, the CES-D and the SE-CDS could be completed by the patient while in the waiting room, or while in the exam room waiting for the clinician. While the other two instruments, the MMT-R and the MoCA could be administered by a trained member of the healthcare team, and would not require a nurse or physician to administer.

Four measures were used in this study: the Montreal Cognitive Assessment (MoCA), the Center for Epidemiological Studies Depression Scale (CES-D), the Medication Management Task-Revised (MMT-R), and the Self-Efficacy for Chronic
Disease Scale (SE-CDS). The reliability of each instrument is documented in Table 7. Cronbach’s alpha was used to measure reliability of the CES-D, the MMT-R and the SE-CDS. Because of the way the MoCA is scored, with varying scales for each of the questions, Cronbach’s alpha was not a good fit in determining reliability. Therefore test-retest was used to determine its reliability. Thirty of the study participants, 15 from each group, completed two separate MoCA tests. The tests were given no less than six months and no more than one year apart and were compared to determine test-retest reliability.

The MoCA was used to measure cognitive ability. Scores on the MoCA range from 0 to 30, with a score of 26 or more considered normal and a score of less than 26 considered mild cognitive impairment (Nasreddine et al., 2005). As shown in Table 6, the average MoCA scores demonstrate mild cognitive impairment for all participants (M = 24.31; SD = 3.54), for the older group (M = 23.77; SD = 3.82), and for the younger group (M = 24.85; SD = 3.17). Individual total MoCA scores classified the study participants into normal cognitive ability (n = 47; 36%), and mild cognitive impairment (n = 83; 64%). Among those with normal cognitive ability, 22 (47%) were older adults and 25 (53%) were younger adults. Among those who exhibited mild cognitive impairment, 43 (52%) were older adults, and 40 (48%) were younger adults.

Regarding gender, more than three-quarters of females (n = 27; 77%) reported mild cognitive impairment, compared to about two-thirds of the males (n = 56; 62%). Similarly, in the older group; almost three-quarters of the females (n = 10; 71%) reported mild cognitive impairment, compared with about two-thirds of the males (n = 33; 65%). Following this trend, in the younger group over three-quarters of the females (n = 17;
81%) reported mild cognitive impairment compared to just over half the males (n = 23; 52%).

The CES-D was used to measure depression. Scores on the CES-D range from 0 to 60, with a score of less than 16 considered no depression, scores of 16 to 22 considered mild depression, and scores of 23 or more considered major depression (Randloff, 1977). As shown in Table 7, the average overall CES-D scores were just below the level specified for clinical depression (M = 15.42; SD = 11.52), for the older group (M = 15.84; SD = 12.80, and for the younger group (M = 15.00; SD = 10.16). Individual total CES-D scores found about half (n = 75; 58%) of the participants were not exhibiting symptoms of clinical depression, about a fifth (n = 28; 21%) of the participants were experiencing mild depressive symptoms, and another fifth (n = 28; 21%) were experiencing major depressive symptoms. Among participants who were not clinically depressed, about half (n = 38; 51%) were older adults and half (n = 37; 49%) were younger adults. For those with mild depressive symptoms, 11 (39%) were older adults and 17 (61%) were younger adults. Of those with major depressive symptoms, 16 (59%) were older adults and 11 (41%) were younger adults.

Regarding gender, about a quarter of the males (n = 23; 24%) reported mild depressive symptoms, compared with 14% of the females (n = 5). However, the percentage of women reporting major depressive symptoms (n = 12; 34%) was more than double that of males (n = 15; 16%). A similar trend was found in the older group; where males (n = 9; 18%) and females (n = 2; 14%) had similar rates of mild depression, but a third of the females (n = 2; 33%) reported major depressive symptoms compared to a
fifth \( (n = 10; 20\%) \) of the males. The trend continued in the younger group, where about one-third of males \( (n = 14; 32\%) \) reported mild depressive symptoms compared to 14% of females \( (n = 3) \), but here again, the percentage of females reporting major depressive symptoms was nearly three times that of males \( (n = 6; 29\% \text{ vs. } n = 5; 11\%) \).

**The MMT-R** was used to measure medication management. Scores on the MMT-R range from 0 to 16. A higher score indicates better medication management (Heaton et al., 2004). Total mean scores for all participants were 12.27 \( (SD = 3.31) \), for the older group the mean score was 12.17 \( (SD = 3.23) \) and for the younger group 12.52 \( (SD = 3.30) \). Regarding gender, the mean score for males was 13.08 \( (SD = 2.83) \) with scores ranging from 4 to 16, and the mean score for females was 10.34 \( (SD = 3.53) \) with scores ranging from 3 to 16.

Education was associated with scores on the MMT-R. Participants with a college degree had mean scores of 15.11 \( (SD = 1.15) \), with scores ranging from 12 to 16. Mean scores of high school graduates were 12.80 \( (SD = 3.29) \), ranging from 4 to 16. Mean scores of participants who did not finish high school were 10.22 \( (SD = 2.55) \), ranging from 3 to 16.

**The SE-CDS** was used to measure self-efficacy. Scores on the SE-CDS range from 0 to 10, with higher scores indicating higher self-efficacy (Lorig et al., 2001). The total mean score was 7.76 \( (SD = 1.98) \), ranging from 1.33 to 10. The mean score for the older group was 12.17 \( (SD = 3.23) \) and for the younger group 12.52 \( (SD = 3.30) \). Regarding gender, the mean scores for males was 7.90 \( (SD = 1.99) \), ranging from 1.33 to 10, and the mean score for females was 7.35 \( (SD = 1.91) \), ranging from 2.83 to 10.
Table 7.

*Descriptive Statistics and Reliability of Study Instruments for All and by Groups*

<table>
<thead>
<tr>
<th>Description</th>
<th>Mean</th>
<th>SD</th>
<th>Reliability</th>
</tr>
</thead>
<tbody>
<tr>
<td>MoCA</td>
<td>24.31</td>
<td>3.54</td>
<td>0.90</td>
</tr>
<tr>
<td>CES-D</td>
<td>15.42</td>
<td>11.52</td>
<td>0.91</td>
</tr>
<tr>
<td>MMT-R</td>
<td>12.27</td>
<td>3.31</td>
<td>0.80</td>
</tr>
<tr>
<td>SE-CDS</td>
<td>7.75</td>
<td>1.98</td>
<td>0.92</td>
</tr>
</tbody>
</table>

Note: G1 = Group 1 (Older group); G2 = Group 2 (Younger group); SD = standard deviation
Results Related to Research Questions

Question 1 - Is there a difference in the medication management ability between older and younger adults living with HIV?

An independent t-test was used to answer research question 1. The t-test was used to compare the mean scores on medication management between the older and younger groups. Data showed that the older group had a mean score of 12.17 (SD = 3.23) on medication management and the younger group had a mean score of 12.52 (SD = 3.30). The older group scored lower in medication management ability than the younger group, however, the difference did not rise to the level of statistical significance and the effect size was minimal (Tables 7, 8).

Question 2 - Are there differences in cognitive ability, depression, or self-efficacy between older and younger adults living with HIV?

An independent t-test was used to answer research question 2. The t-tests were used to compare the mean scores on cognitive ability, depression and self-efficacy between the older and younger group (Table 7). On cognitive ability the mean score for older adults was 23.77 (SD = 3.82), the mean score for younger adults was 24.85 (SD = 3.17). Scores greater than 26 indicate normal cognitive ability, and scores lower than 26 indicate mild cognitive impairment. Both groups had a mean score below the 26 point cutoff, indicating mild cognitive impairment. This difference demonstrated a small effect size and was not statistically significant.

On depression older adults had a mean score of 15.84 (SD = 12.80), younger adults had a mean score of 15.00 (SD = 10.16). Higher scores indicate a higher level of depression, a score higher than 16 indicates clinically meaningful depression. Overall
older adults exhibited more depression than younger adults. Although the difference did not rise to the level of statistical significance and the effect size was minimal.

Scores on self-efficacy can range from 0 to 10. In this study, the mean score on self-efficacy for older adults was 7.68 (SD = 2.06), and the mean score for younger adults was 7.83 (SD = 1.90). Older adults exhibited lower self-efficacy than younger adults, but once again the difference did not reach the level of statistical significance and exhibited a minimal effect size.

In summary, older adults did not perform as well as younger adults on any of the measures examined in this study. Older adults exhibited higher rates of depression, poorer medication management ability, less cognitive ability and lower self-efficacy, although none of the differences reached the level of statistical significance (Table 8).

Table 8.

<table>
<thead>
<tr>
<th></th>
<th>t</th>
<th>Sig</th>
<th>CI</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>-0.67</td>
<td>0.50</td>
<td>-1.52-0.75</td>
<td>0.05</td>
</tr>
<tr>
<td>management</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive</td>
<td>-1.79</td>
<td>0.10</td>
<td>-2.33-0.17</td>
<td>0.15</td>
</tr>
<tr>
<td>ability</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>0.31</td>
<td>0.76</td>
<td>-3.39-4.65</td>
<td>0.04</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>-0.43</td>
<td>0.67</td>
<td>-0.88-0.54</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Note: Sig = significance; SD = standard deviation; CI = confidence interval
Question 3 - What are the associations between personal factors (cognitive ability, depression, and self-efficacy) and medication management among older and younger adults living with HIV, respectively?

Pearson correlation was used to answer research question 3. Table 9 displays the intercorrelations among cognitive ability, depression, and self-efficacy for older adults. Scores for cognitive ability and depression were correlated with medication management, both at $p < .01$; self-efficacy was correlated with depression at the $p < .01$ level. Self-efficacy was not correlated with medication management.

Table 9.

*Correlations Among Predictors of Medication Management in Older Adults*

<table>
<thead>
<tr>
<th>Measures</th>
<th>Medication Management</th>
<th>Cognitive Ability</th>
<th>Depression</th>
<th>Self-Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>-</td>
<td>.641**</td>
<td>-.383**</td>
<td>.111</td>
</tr>
<tr>
<td>Management</td>
<td>-</td>
<td>-</td>
<td>-.212</td>
<td>-.006</td>
</tr>
<tr>
<td>Cognitive Ability</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Depression</td>
<td>-</td>
<td>-</td>
<td>-.586**</td>
<td>-</td>
</tr>
<tr>
<td>Self-Efficacy</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**: Correlation is significant at the 0.01 level (2-tailed)

Table 10 displays the intercorrelations between instruments for younger adults. Similar to older adults, cognition and depression were correlated with medication management, at the $p < .01$. In the younger adults, as in the older adults, self-efficacy was not correlated with medication management. In contrast to the results in older adults, self-efficacy in younger adults was not correlated with depression.
Table 10.

Correlations Among Predictors of Medication Management in Younger Adults

<table>
<thead>
<tr>
<th>Measures</th>
<th>Medication Management</th>
<th>Cognitive Ability</th>
<th>Depression</th>
<th>Self-Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication Management</td>
<td>-</td>
<td>.477**</td>
<td>-.321**</td>
<td>.108</td>
</tr>
<tr>
<td>Cognitive Ability</td>
<td>-</td>
<td>-.109</td>
<td>-</td>
<td>-.029</td>
</tr>
<tr>
<td>Depression</td>
<td>-</td>
<td></td>
<td>-.164</td>
<td>-</td>
</tr>
<tr>
<td>Self-Efficacy</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**: Correlation is significant at the 0.01 level (2-tailed)

**Question 4 - Which personal factors (cognitive ability, depression, and self-efficacy) are the best predictors of medication management among adults living with HIV, controlling for age as a covariate?**

Multiple regressions were used to answer research question 4. Table 11 displays the summary of the model for older adults. As shown in Table 11, this model, with an adjusted $R^2$ of .45 ($p < .001$), suggests that 45% of the variance in medication management ability can be predicted by cognitive ability, depression and self-efficacy. The value of adjusted $R^2$ of .45 is considered to be a moderate to large effect size (Cohen & Cohen, 1983). Table 12 presents the analysis of variance (ANOVA) that indicates the overall significance of the model for the older adults.
Table 11.

_Model Summary Older Adults_

<table>
<thead>
<tr>
<th>Predictor Variable</th>
<th>R</th>
<th>R²</th>
<th>Adjusted R²</th>
<th>F</th>
<th>df</th>
<th>Sig. (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression Model 1</td>
<td>.691*</td>
<td>.478</td>
<td>.452</td>
<td>18.61</td>
<td>3,61</td>
<td>.000</td>
</tr>
</tbody>
</table>

*Predictors: (Constant), Depression, Cognitive Ability, Self-Efficacy

Table 12.

_Analysis of Variance for Model 1*

<table>
<thead>
<tr>
<th>Model</th>
<th>Sum of Squares</th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig. (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression</td>
<td>318.78</td>
<td>3</td>
<td>106.261</td>
<td>18.61</td>
<td>.000**</td>
</tr>
<tr>
<td>Residual</td>
<td>348.36</td>
<td>61</td>
<td>5.711</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>667.14</td>
<td>64</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Dependent Variable: Medication Management

**Predictors: (Constant), Cognitive Ability, Depression, Self-Efficacy

While the total R square indicates the proportion of variance in the model accounted for in medication management, the squared semi-partial correlations (sr²) were employed to detect the variance uniquely accounted for by each individual variable. The unique variance does not include any of the variables shared variance. Results indicate that cognition accounted for 31% (sr²=.312) of the unique variance in medication management scores (β = .58, p < .001). Depression accounted for 6% (sr²=.055) of the unique variance (β = -.30, p < .05), and self-efficacy accounted for .3% (sr² = .003) of the variance (β = .05, p = .55). The results of semipartial correlations (sr²) for each predictor reveal that about 11% of the variance in the model was shared by the three predictors.
The same procedures with the same variables were then performed for younger adults. As shown in Table 13, this model, with an adjusted $R^2$ of .27, ($p < .001$), suggests that medication management can be predicted by cognitive ability and depression. Self-efficacy was excluded from the model for younger adults. Thus, 27% of the variance in medication management can be predicted by cognitive ability and depression for younger adults. The value of adjusted $R^2$ of .27 is considered a small effect size (Cohen & Cohen, 1983). While this result was significant, the predictive value of the three variables (cognition, depression and self-efficacy) for younger adults was considerably smaller than their predictive value for older adults. Table 14 presents the analysis of variance (ANOVA) that indicates the overall significance of the model for the younger adults.

Table 13.

*Model Summary Younger Adults*

<table>
<thead>
<tr>
<th>Predictor Variable</th>
<th>$R$</th>
<th>$R^2$</th>
<th>Adjusted $R^2$</th>
<th>$F$</th>
<th>df</th>
<th>Sig. ($p$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression Model 2</td>
<td>.551*</td>
<td>.304</td>
<td>.270</td>
<td>8.87</td>
<td>3,61</td>
<td>.000</td>
</tr>
</tbody>
</table>

*Predictors: (Constant), Cognitive Ability, Depression, Self-Efficacy*
Table 14.

*Analysis of Variance for Younger Adults*

<table>
<thead>
<tr>
<th>Model</th>
<th>Sum of Squares</th>
<th>Df</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig. (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression</td>
<td>211.49</td>
<td>3</td>
<td>70.50</td>
<td>8.87</td>
<td>.000**</td>
</tr>
<tr>
<td>Residual</td>
<td>484.73</td>
<td>61</td>
<td>7.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>696.22</td>
<td>64</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Dependent Variable: Medication Management
**Predictors: (Constant), Cognitive Ability, Depression, Self-Efficacy

Results of the squared semipartial correlations ($sr^2$) in younger adults indicate that cognition accounted for 20% ($sr^2 = .197$) of the unique variance in medication management scores ($\beta = .45$, $p < .001$); depression accounted for 7% ($sr^2 = .067$) of the variance ($\beta = -.26$, $p < .05$); and self-efficacy accounted for .3% ($sr^2 = .003$) of the variance ($\beta = .05$, $p = .63$). From the results of semipartial correlations ($sr^2$) for each variable, it appears that about 3% of the variance in the model was shared by the three variables.

In order to generalize the findings to the general population, certain assumptions must be met. So, the assumptions of linear regression were tested.

Tests for multicollinearity indicated that a low level of multicollinearity was present in both groups (Field, 2005). Older adults (Tolerance = .61, VIF = 1.63 for depression, Tolerance = .93, VIF = 1.07 for cognition, and Tolerance = .64, VIF = 1.59 for self-efficacy). Younger adults (Tolerance = .97, VIF = 1.04 for depression, Tolerance = .99, VIF = 1.01 for cognition and Tolerance = .97, VIF = 1.03 for self-efficacy).

Therefore, all variables were retained in the prediction models for each group. In older adults, both MoCA and CES-D were shown to be significant predictors of the outcome.
variable, medication management. For MoCA: (B = .488, SE = .081) p < .001, CI = (.326, .650). For CESD: (B = -.076, SE = .30) p < .05, CI = (-.135, -.016). In younger adults, only MoCA was a significant predictor of the outcome variable, medication management. MoCA: (B = .613, SE = .110) p < .001, CI = (.394, .831)

Linearity was tested for each group between the predictors and the outcome variable, medication management. All relationships were linear, so all assumptions were retained in each group. Independence of errors was then tested for each group. A normal distribution was seen, so all the assumptions were retained. Finally, the errors were normally distributed, so all of the assumptions were retained. The data can be generalized to the population of persons living with HIV.

Findings

Results indicate both the older and younger adults have high rates of mild cognitive impairment, high rates of depression, and high self-efficacy, and both groups had poor medication management ability. In both older and younger adults cognitive ability and depression were predictive of medication management, although each variable was a stronger predictor for older adults. Overall, cognitive ability was the best predictor of medication management for both older and younger adults, but again, a stronger predictor for older adults.

Discussion of Results

Differences in medication management ability. This study found no statistically significant difference in medication management between older and younger adults living with HIV. In fact, both older and younger adults performed poorly on the medication management test, answering only about 75% of the questions correctly. Many
participants in this study seemed quite confident in answering medication management questions. Less than a dozen of the 130 participants used the pen and paper provided to work out medication questions requiring calculations. Yet even simple calculations were problematic for many participants. Barely 60% (61.8%) of participants could correctly determine the number of days a refill would last if they were given 30 pills and the prescription on the label called for two pills per day. Only 71 (52%) participants were correctly able to set up one day’s worth of medications that consisted of four different medications, taken once, twice, or three times per day.

In the only other study found that used the MMT-R to compare medication management ability between older and younger adults, Thames et al. (2011) found older adults with HIV performed significantly worse than younger adults (p < .05). In comparing study results, the difference in scores between the younger groups was small, however the older group in Thames’ study scored much worse than the older group in the current study. The demographics of the two older groups were similar, except in the earlier study the mean age of the participants in the older group was 59.4, compared to 56.1 in the current study. Another possibility for the differences between older groups is the ages within the group. The minimum age for the older group was 55 in the earlier study. Perhaps medication management is not affected until cognitive changes are more pronounced, and adults aged 50 to 55 may not be affected as much. Another possibility is that the age gap between the two groups was greater in the earlier study, so perhaps differences between the two groups were more pronounced. The previous study was also much smaller than the current study, with a total of 51 participants, so the results may not be generalizable to other populations.
A study by Waldrop-Valverde, Jones, Jayaweera, Gonzalez, Romero and Ownby (2009) used the original version of the MMT-R. Results were not presented by age, but were broken down by gender. Findings showed females scoring lower than males in medication management (p < .01). Results of this study support Waldrop-Valverde, et al. results. Females scored significantly worse than males (p < .001) in both the older and younger groups. These results of both of these studies emphasize the need to not only include women in HIV studies, but to analyze their data separately to capture differences associated with gender.

This study defines medication management as: “the desire and ability to adhere to a medication regimen” (Madigan, Farris, Wiens, & Johnson, 2003). The majority of medication studies focus on adherence or compliance, and not specifically medication management, yet the goal of these studies remain the same; to determine how accurately medications are taken. Results of previous studies have overwhelming shown that older persons do a better job of taking medications correctly than younger persons (Barclay et al., 2007; Gorman et al., 2009; Hinkin et al., 2004; Maggiolo et al., 2002). These studies have found that older adults who are better able to manage their medications have generally relied on methods of measurement such as pill counts, patient recall or prescription refills. Methods that do not take into account the help some older adults receive in setting up their medications, or remembering to take their medications. Nor do those methods reflect the accuracy of taking medications at the correct time (Murray et al., 2004). Unlike other methods, the MMT-R focuses strictly on the ability to read medication labels and take medications according to instructions (Heaton et al., 2004). While no gold standard exists for measuring medication management, the MMT-R has
been shown to be an accurate measure of how adults take their medications (Albert et al., 2003; Albert et al., 1999; Heaton et al., 2004).

The medication management scores from this study suggest that regardless of age, medication management is a skill that needs to be fostered in adults living with HIV. Given that medication management scores for the older and younger groups averaged 76% and 78% respectively, it is hard to imagine that the requisite 90-95% adherence rate for full viral suppression can be approached for either of these groups (Bartlett, 2002).

An additional concern is that older adults face the added challenge of having to take an increased number of medications due to numerous comorbidities. Studies have found that complex medication regimens are associated with poorer medication management (Hinkin et al., 2002; Maggiolo et al., 2002). This current study found a statistically significant difference in the mean number of medications other than HIV medications taken between older and younger adults; 6.4 versus 3.4 medications respectively (p < .001), suggesting that medication management may be even more important for older adults, since the number of their medications may continue to increase. Furthermore, since poor medication management is a major cause of hospitalizations in the older population (Swanlund, Scherck, Metcalf, & Jesek-Hale, 2008), improving medication management for older adults could decrease the number of hospital admissions with a subsequent decrease the cost of care. A study by Col, Fanale and Kronholm (1990) found that poor medication management accounted for 28% of all hospitalizations among older adults with 11% related to adherence issues. If healthcare providers can identify and work with older adults at risk for poor medication
management before adverse events or hospitalizations occur, then those adults may experience an improved quality of life and potentially decreased healthcare costs.

Interestingly, in spite of poor medication management, mean CD4 counts were within normal range for the majority of participants (558 overall; 549 and 567 for older and younger adults respectively), and three quarters (75%) of participants had undetectable viral loads. The CD4 counts are a measure of the health of the immune system, and viral load is a measure of the amount of HIV virus in the blood. When CD4 counts are above 500 they are considered normal for persons living with HIV. When CD4 counts drop below 200 the immune system is no longer able to resist infections, and an AIDS diagnosis results. This may suggest that HIV medications, even when taken less than optimally, can effectively suppress the HIV virus in the body, and perhaps a less stringent medication adherence goal, rather than the existing goal of 90-95% could be effective in controlling the virus.

**Differences in cognitive ability, depression and self-efficacy.** This study found no statistically significant differences in cognitive ability, depression or self-efficacy between older and younger adults with HIV. However older adults scored lower than younger adults on every variable measured in this study. While it was not unexpected that depression and self-efficacy would be similar between the two groups, it was thought that older adults would have lower cognitive scores than younger adults. Recent research has reported early cognitive changes in adults with HIV (Ances et al., 2010; Malaspinia et al., 2011), and it was thought that decreased cognitive ability would be reflected by lower scores on the MoCA. This was not the case.
Cognitive ability. The scores on the MoCA in this study indicate the prevalence of mild cognitive impairment (scores < 26) in both older and younger adults (Nasreddine et al., 2005). There was a small effect size difference between the older and younger groups. Because recent research has demonstrated high rates of cognitive decline in adults with HIV as young as 45 years of age (Ances et al., 2010; Barclay et al., 2007; Malaspinia et al., 2011), it was thought there would be a significant difference in MoCA scores between the groups. However both groups in this sample had, on average, been diagnosed with HIV for over 10 years, and had been on HIV medications for an average of at least eight years. So it is possible that even the younger group in this sample experienced cognitive decline related to long-term HIV infection (Clifford, 2008; Price & Spudich, 2008). Another possible explanation is that initial cognitive changes related to age may be too small to be detected by the MoCA, and would not show up on cognitive testing until further decline took place.

Gender differences were seen in cognitive ability. When breaking down scores by age and gender, older females scored significantly worse than any of the other groups (p < .05). The scores for younger females were the next lowest. While some studies have explored gender differences in how HIV affects the body, and found slower disease progression for women (Jarrin et al., 2008; Nicastri et al., 2005) no studies were found that explored whether gender influences how HIV affects cognitive ability. These results suggest this may be an important area for future research.

Depression. This study reinforces previous studies of depression in the HIV population in finding that depression rates were higher in adults with HIV than in adults living with other chronic diseases (Emlett, 2006b; Katon et al., 2010; Lichtman et al.,
High rates of depression were found in both the older and younger groups. In comparing older and younger adults living with HIV, there was no statistically significant difference in depression rates, although the rates were slightly higher in the older group. Previous studies have found older adults with HIV had higher rates of depression than younger adults (Kilbourne et al., 2002; Valente, 2003; Voss et al., 2007), yet other studies have reported higher rates in younger persons (Justice et al., 2004; Rabkin, 1996). This study offers no definitive answer as to whether older adults experience higher depression rates than younger adults, but supports previous studies calling attention to the high overall rates of depression for persons living with HIV.

While the overall rates of depression were found to be high in both older and younger adults, the rate of major depressive symptoms was striking. A quarter (n = 16; 25%) of older adults and almost one fifth (n = 11; 17%) of younger adults exhibited major depressive symptoms. Examining men exclusively, major depressive symptoms were nearly twice as prevalent among older men as younger men (20% vs 11% respectively).

Rates of major depressive symptoms in women were even more disturbing; with rates more than double that of men in both the older and younger groups (29% vs 11% and 43% vs 20% respectively). Previous studies using the CES-D have also found higher rates of depression in women living with HIV (Cook et al., 2004; Richardson et al., 2001), these studies associated depression with decreased medication adherence and increased AIDS-related mortality, making managing depression a critical component of caring for persons with HIV.
This current study suggests that despite research emphasizing the benefits of treating depression, depression rates have not declined in the HIV population. Because women represent one of the fastest growing groups of persons living with HIV, and have the highest rates of depression this is a problem that cannot be ignored. These high rates of depression are a reflection of the work that still needs to be done to erase the stigma and shame that continues to be associated with an HIV diagnosis. Furthermore these results suggest a need for more vigilance in diagnosing and treating depression in all persons living with HIV, with a particular focus on women.

**Self-efficacy.** Both older and younger adults registered high scores on the SE-CDS. Surprisingly, these scores were significantly higher than scores reported in previous studies of persons living with chronic diseases. Lorig et al (2001) evaluated persons living with chronic diseases and reported a mean score of 5.17 (SD = 2.22), this compares to a mean score of 7.75 (SD = 1.98) in this sample. High scores indicate increased self-efficacy for dealing with chronic disease, in this case HIV. Curiously, in this study self-efficacy was not strongly correlated with medication management. This result was unexpected because most previous studies identified self-efficacy as important to health maintenance behaviors, including medication management (Brekke, Hjortdahl, & Kvien, 2001; Grembowski et al., 1993; Sarkar, Fisher, & Schillinger, 2006). Bandura (1993) found people did not perform well if they lacked the necessary skills, or if they had the skills but lacked the self-efficacy needed to utilize them. In this study participants appear to have had the self-efficacy needed to perform well at medication management, but they may have lacked the necessary skills to do so.
Social Cognitive Theory postulates that perceived self-efficacy and outcome expectancies are important factors in influencing behavior (Bandura, 2004). However Bandura (1989) also states that along with self-efficacy, cognitive processing is necessary to affect behavior. Both older and younger participants in this study scored high on self-efficacy, and yet in this study neither group performed particularly well on the test of medication management. One possible explanation can be gleaned from the Social Cognitive Theory that underpins this study (Figure 1). High self-efficacy was not enough to overcome the other personal factors (depression and low cognitive ability) that worked against mastery of medication management.

The high self-efficacy shown by both groups in this study is encouraging. It demonstrates a strong belief in the ability to manage HIV, and suggests a willingness to improve medication management as part of overall disease management. However these results also suggest that high self-efficacy alone is not sufficient to master medication management. A person must possess the cognitive ability, in addition to the desire and motivation necessary to effectively manage their medications. Since it appears from these results that persons are motivated to excel at medication management, interventions targeted at improving functional and cognitive skills may prove effective.

The SE-CDS was chosen for this study because it focuses on chronic disease, and its brevity makes it conducive for use in a clinical setting (Lorig et al., 2001). In retrospect, this scale may have been a poor fit for this patient population because the majority of the questions deal with disease symptoms. Though now considered by many to be a chronic disease, HIV differs from other chronic diseases in that persons infected can live for years without experiencing any noticeable, much less debilitating symptoms.
Future studies may benefit from the development of a brief self-efficacy scale tailored specifically for persons living with HIV, or possibly focused specifically on medication management for persons living with HIV.

**Associations between cognitive ability, depression and self-efficacy.** In this study cognitive ability and depression were strongly correlated with medication management for both older and younger adults. This suggests that interventions designed to improve cognitive ability or decrease depression could improve medication management, thereby improving health-related quality of life.

Self-efficacy was strongly correlated with depression for older adults, but had no correlation for younger adults. The strong correlation between depression and self-efficacy found in older adults reinforces findings from previous studies (Bandura, 1993; Emlet, 2007; Grov, Golub, Parsons, Brennan, & Karpiak, 2010). Surprisingly, there was no correlation between depression and self-efficacy in the younger adult group. Overall this group was in relatively good health and had few comorbidities, so this scale may not have effectively measured self-efficacy in relation to HIV disease. The scale measured chronic disease self-efficacy, and it may be that this group’s HIV was largely asymptomatic, so self-efficacy was high in relation to their disease management.

**Predictors of medication management ability.** In both older and younger adults the three independent variables; cognitive ability, depression and self-efficacy were predictors of medication management. However the predictive value of these variables was much stronger for older adults. Together the three independent variables accounted for 45% of the variance in medication management scores for older adults, and 27% of the variance in younger adults. Cognitive ability was the strongest predictor of
medication management in both older and younger groups. But the predictive value was much stronger in older adults, where cognitive ability alone accounted for 31% of the variability in medication management. In contrast, cognitive ability accounted for 20% of the variance in younger adults, and while 20% variance is still a very strong correlation, it is not as robust as in older adults.

This study supports the findings of previous studies by Barclay et al. (2007) and Ettenhofer et al. (2009) that found cognitive ability was the best predictor of medication management in older adults. However while Barclay et al. found cognitive ability the only predictor of medication management, this current study found depression and self-efficacy were also predictive of medication management.

Depression was strongly correlated with medication management, and accounted for about 6 to 7% of the variance in both older and younger groups. This result tracks with previous studies that found a strong association between depression and medication management (Holstad et al., 2010; Willard, 2006). Unexpectedly, self-efficacy accounted for just .3% of the variance in each group, and was not statistically significant. Past studies have shown self-efficacy has a strong correlation with medication management (Bandura, 1989; Horberg et al., 2008). The results of the current study may be reflective of a strong belief in the ability to manage medications, despite the lack of cognitive ability necessary to accomplish this task. Persons in this study appeared confident in their answers when completing the medication management component of the study, even when those answers were wrong.

Another possibility, as mentioned previously, the self-efficacy scale used in this study may have been a poor fit in judging medication management, since it was
developed for chronic illness and not HIV specifically. This may have caused inflated self-efficacy scores due to the asymptomatic nature of HIV.

Social cognitive theory. Results from this study reinforced the personal and environmental factors of Social Cognitive Theory and its influence on behavior. These results add to current thinking about Social Cognitive Theory by emphasizing the role of cognition in behavior. Study findings suggest that the cognitive process of Social Cognitive Theory should be emphasized over personal and environmental factors. While discussion on this theory focuses on the importance of self-efficacy, findings from this current study suggest that high self-efficacy by itself was not enough to successfully overcome high rates of depression and mild cognitive impairment in order to manage medications effectively. Despite the belief of many participants that they were able to answer medication management questions correctly, the average score on the medication management test was approximately 75%. Since medications must be taken correctly 90 to 95% of the time, a score of 75% is indicative of the need to improve medication management. Healthcare providers, more specifically nurses, have the opportunity to impact personal and environmental factors that influence medication management. Recognizing that early assessment of changes in cognitive ability and depression can improve medication management puts nurses on the front line in the battle to improve medication management and adherence. Healthcare providers can also influence environmental factors that affect medication management by involving family members or friends to assist with medications when cognitive ability or depression inhibits the patient’s ability to manage medications on their own.
This study advances Social Cognitive Theory by validating the importance of the cognitive process in behavior. While personal and environmental factors are important in affecting behavior, they cannot operate without the cognitive process. The results of this study suggest that the cognitive process is of primary importance in affecting behavior, and personal and environmental factors play a secondary role. A person must first be able to cognitively process the necessary steps to affect behavior. Nursing science would do best to concentrate on interventions that improve the cognitive process before developing interventions designed to affect personal or environmental factors.
Chapter 5

Summary, Conclusions, and Implications

Summary of the Purpose

The primary aim of this research was to examine if medication management is different for older adults living with Human Immunodeficiency Virus (HIV) compared to younger adults living with HIV. The secondary aim was to examine the relationship between age, personal factors (cognitive ability, depression, and self-efficacy) and medication management among participants. The two study aims were achieved through the following research questions:

**Question 1:** Is there a difference in the medication management ability between older and younger adults living with HIV?

**Question 2:** Are there differences in cognitive ability, depression, or self-efficacy between older and younger adults living with HIV?

**Question 3:** What are the associations between personal factors (cognitive ability, depression, and self-efficacy) and medication management among older and younger adults living with HIV, respectively?

**Question 4:** Which personal factors (cognitive ability, depression, and self-efficacy) are the best predictors of medication management among adults living with HIV, controlling for age as a covariate?

This chapter summarizes the findings from the present study and discusses the implications and limitations. Additionally, recommendations for future research are presented as well.
Implications

This study supports a relationship between personal factors; (cognitive ability, depression and self-efficacy) and medication management in adults living with HIV. Early assessment of cognitive ability and identification and treatment of depression could increase medication management and possibly decrease morbidity and mortality. Utilizing the research instruments at assessment tools at each healthcare appointment could provide a quick, effective way for nurses and other healthcare providers to assess subtle changes in personal factors (cognitive ability, depression and self-efficacy). Recording results at each healthcare visit and comparing scores over time could provide measurable evidence of changes that could affect medication management for patients. Thus, adults living with HIV would benefit from healthcare providers who incorporate these assessments into each patient visit.

Changes in healthcare, along with the improved overall health of adults living with HIV have led to a reduction in the frequency and the duration of healthcare visits for patients living with HIV. As a result, nurses and other healthcare providers have less time for assessing changes in cognitive ability and depression that could adversely affect medication management. Failure to recognize these changes could result in patients taking their medications incorrectly over extended periods of time. Errant or failed medication management may lead to the development of drug resistance and virologic failure, resulting in the need for more complex dosing regimens. A more complex dosing regimen makes medication management even more difficult for patients. This study suggests that early identification and intervention may stop or at least slow down undesirable, possible fatal effects of poor medication management. Findings from this
study also question the need for exacting regimens requiring 90-95% adherence. New medications may be more forgiving than older ART, and perhaps a lower adherence rate will still keep the HIV virus suppressed.

**Suggestions for Future Research**

The results of this study suggest many areas ripe for research (Figure 2). These areas include: age-related factors, cognitive-related factors, depression-related factors, gender-related factors, and understanding the complexity of medication and medication management. Development of an HIV-specific self-efficacy scale, or medication management self-efficacy scale should be considered as well.

It would be interesting to examine medication management in chronic diseases other than HIV to see whether it is similar to or different than in HIV, and whether the predictors of medication management are the same in other chronic diseases. If cognitive ability is the strongest predictor of medication management in other chronic diseases, it could be beneficial to know if other chronic diseases affect cognitive ability.

Future studies could examine age-related cognitive changes that may affect medication management by using more narrowly defined age classifications. As medical advances lead to increases in life expectancy for persons living with HIV, it may make sense for HIV researchers to adopt the age classifications used in social work and gerontological medicine (Hutchison, 2007). In these fields, old age is broken down into young old (65-74), middle old (75-84) and old old (85 and older). Incorporating these classifications into HIV studies may provide a more specific measure of age-related cognitive changes, and could facilitate comparing adults living with HIV to adults living with other chronic diseases.
Results from this study demonstrate that medication management is a problem for both older and younger adults living with HIV. A secondary analysis of the data from this study could show that specific cognitive ability, rather than age related cognitive decline is an indicator of medication management. Using this data to identify those at risk for poor medication management could lead to earlier interventions. Future research could then explore the effectiveness of specific cognitive interventions designed to improve medication management for persons determined to be at risk for poor medication management. Successful early interventions could improve medication management thereby decreasing drug resistance caused by poor adherence.

A recent pilot study by Vance, Fazeli, Ross, Wadley and Ball (2012) examined cognitive remediation therapy on a small group of middle-aged and older adults living with HIV and found that those in the experimental group improved on some cognitive measures, suggesting this type of training might improve cognitive and everyday functioning. This type of training is common in gerontology practice, but has not been used in the aging HIV population. Given the promising results from this pilot study, further research with this type of cognitive training in relation to medication management appears warranted.

Another area for future research would be exploring which cognitive domains tested on the MoCA (attention, concentration, executive function, memory, language, visuoconstructional skills, conceptual thinking, calculations, or orientation) have the greatest impact on medication management. If a secondary analysis found that specific cognitive domains have greater impact on medication management, mental exercises could then be developed for use by patients to help improve cognitive function in that
specific area, with the outcome of improving medication management. It may also be found that while cognitive decline begins earlier in persons living with HIV, those declines are not in areas that greatly affect medication management, but may affect other aspects of living with HIV.

Though this study did not explore the impact of health literacy on medication management, results suggest that many participants experienced difficulties with interpreting prescription labels on medication bottles. Health literacy may have played a role in that difficulty. Future studies on medication management could include a health literacy component to determine if health literacy impacts medication management. It may be that changing the way medications are labeled could improve medication management. It would be worthwhile to test different medication labels to determine if written instructions affect medication management.

Qualitative studies exploring why persons do not take their medications as prescribed have been done in the past. Now that medications are easier to take and side-effects for many have decreased, it may be time to re-examine this issue in order to understand medication management from the patient’s perspective.

Another question for future studies is why depression appears to be so undertreated in this population. Many persons displaying depression were receiving no antidepressant medications. Many who were receiving antidepressant medications still exhibited depressive symptoms. Many persons with depressive symptoms had no diagnosis of depression in their medical records. Qualitative studies may be the best method for considering reasons depression is under-diagnosed and under-treated in this population.
Developing an HIV-specific self-efficacy scale could improve this measure in future studies examining self-efficacy in persons living with HIV. While HIV is considered a chronic disease, it is different enough from other chronic diseases that a scale tailored to the specific problems of living with HIV could be a useful tool for measuring self-efficacy in this population.

This study uncovered substantial differences between men and women living with HIV. Further examination of these differences should be a priority. Women are one of the fastest growing groups of persons living with HIV, and historically women have been underrepresented in HIV research, examining the specific needs of women should be an emphasis area for research.

Although this research was not designed to examine differences between genders, in every measure analyzed women performed worse than men, and in some areas significantly so. Women experienced major depressive symptoms at more than twice the rate of men, and older women were nearly three times more likely to experience major depressive symptoms than were older men. The reasons for this might best be examined through qualitative studies exploring women’s perceptions of living with HIV.

More than three-quarters of the women in this study exhibited cognitive impairment. Since cognitive ability was the best predictor of medication management, these results suggest that medication management will be challenging for women living with HIV. Scores on the medication management component of this study support these findings. Both older and younger women scored significantly lower than men in medication management (p < .001). Qualitative studies focused on women may be the best way to explore women’s perspective about their medications, how much importance
they place on taking their medications, and why they do or do not take them as prescribed.

Women scored lower on the self-efficacy instrument than men. Even though self-efficacy scores were generally high, reasons for this discrepancy could be explored. Qualitative studies where women would have the opportunity to give voice to their ability to effectively manage their HIV may be beneficial. Women should be well-represented in any research designed to develop an effective self-efficacy tool for persons living with HIV

**Figure 2. Future Research**
Study Limitations

There are limitations in the present study. Although the infectious disease clinic and clinical trials unit used for recruitment for this study draw from a sizable area in the Midwest, it is a single geographical site, which makes it more difficult to generalize the findings. However the demographics of the sample in this study are similar to national demographics of adults living with HIV.

Because of the wide variety of instruments used in HIV studies it is difficult to compare results of this study to past studies. The instruments used in this study to measure depression (CES-D), cognitive ability (MoCA) and self-efficacy (SE-CDS) are not HIV-specific instruments, and other studies have used different instruments to measure these variables. While comparisons to other studies can still be made, they may not be as accurate due to the variation in instrumentation.

Another limitation to the study was the higher percentage of women in the younger group may have skewed results in that group. Overall women did not perform as well as men on any of the study instruments. The greater number of women in the younger group may have resulted in lower overall scores in that group than would have been the case if men and women were equally represented in each group. It is worth noting that these percentages are reflective of the national HIV population.

Finally, the self-efficacy scale used in this study may not have been a good fit for this patient population, and may have overestimated the confidence study participants had in managing their medications and their disease. As mentioned previously an HIV-
specific self-efficacy scale may be important in accurately measuring self-efficacy in this population.

**Summary and Conclusion**

This study considered whether there is a difference in medication management ability between older and younger adults living with HIV. It examined the influence of age in the relationships between cognition, depression, and self-efficacy and medication management. Past research suggested that medication management would be influenced by these variables. The literature suggested that these variables would be more pronounced in older adults living with HIV, and therefore affect medication management to a greater extent in that group. The results suggest that older adults have more difficulty managing their medications than younger adults, but the difference did not rise to a statistically significant level. In both groups cognitive ability was the best predictor of medication management, followed by depression and then self-efficacy. Cognitive ability was a stronger predictor in older adults than in younger adults, while depression and self-efficacy were similar between the two groups.

These results emphasize the need to improve medication management for all persons living with HIV, with a particular focus on older adults and women. Older adults, often have numerous comorbidities, and face the challenge of managing their medications even with the complexity of their regimen. Women, one of the fastest growing groups of persons living with HIV, score lowest on medication management, depression and self-efficacy, and may need special attention to help them successfully manage this disease.
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Appendix A

CES-D
Center for Epidemiologic Studies Depression Scale (CES-D), NIMH
Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

<table>
<thead>
<tr>
<th>Week</th>
<th>During the Past</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rarely or none of the time (less than 1 day)</td>
<td>Some or a little of the time (1-2 days)</td>
</tr>
<tr>
<td>Occasionally or a moderate amount of time (3-4 days)</td>
<td>Most or all of the time (5-7 days)</td>
</tr>
<tr>
<td>1. I was bothered by things that usually don’t bother me.</td>
<td>☐</td>
</tr>
<tr>
<td>2. I did not feel like eating; my appetite was poor.</td>
<td>☐</td>
</tr>
<tr>
<td>3. I felt that I could not shake off the blues even with help from my family or friends.</td>
<td>☐</td>
</tr>
<tr>
<td>4. I felt I was just as good as other people.</td>
<td>☐</td>
</tr>
<tr>
<td>5. I had trouble keeping my mind on what I was doing.</td>
<td>☐</td>
</tr>
<tr>
<td>6. I felt depressed.</td>
<td>☐</td>
</tr>
<tr>
<td>7. I felt that everything I did was an effort.</td>
<td>☐</td>
</tr>
<tr>
<td>8. I felt hopeful about the future.</td>
<td>☐</td>
</tr>
<tr>
<td>9. I thought my life had been a failure.</td>
<td>☐</td>
</tr>
<tr>
<td>10. I felt fearful.</td>
<td>☐</td>
</tr>
<tr>
<td>11. My sleep was restless.</td>
<td>☐</td>
</tr>
<tr>
<td>12. I was happy.</td>
<td>☐</td>
</tr>
<tr>
<td>13. I talked less than usual.</td>
<td>☐</td>
</tr>
<tr>
<td>15. People were unfriendly.</td>
<td>☐</td>
</tr>
<tr>
<td>16. I enjoyed life.</td>
<td>☐</td>
</tr>
<tr>
<td>17. I had crying spells.</td>
<td>☐</td>
</tr>
<tr>
<td>18. I felt sad.</td>
<td>☐</td>
</tr>
<tr>
<td>19. I felt that people dislike me.</td>
<td>☐</td>
</tr>
<tr>
<td>20. I could not get “going.”</td>
<td>☐</td>
</tr>
</tbody>
</table>
SCORING: zero for answers in the first column, 1 for answers in the second column, 2 for answers in the third column, 3 for answers in the fourth column. The scoring of positive items is reversed. Possible range of scores is zero to 60, with the higher scores indicating the presence of more symptomatology.
Appendix B

Medication Management Task-Revised
LOPERAMIDE CAPSULES

COMPOSITION:
2 mg loperamide hydrochloride per capsule.

INDICATIONS:
Symptomatic treatment of acute diarrhea.

CONTRA-INDICATIONS:
- Known sensitivity to loperamide.
- Safety in pregnancy and lactation has not been established.
- LOPEROL must not be used when inhibition of peristalsis is to be avoided, in particular where constipation is present or in patients with inflammatory bowel disease. Discontinue use immediately if constipation or abdominal distension develop.

WARNINGS:
Patients with inflammatory bowel disease receiving loperamide should be carefully observed for signs of toxic megacolon.
Keep out of reach of children.

No improvement in acute diarrhea has been observed after 48 hours. LOPEROL should be
Medication Management Task-Revised

INSTRUCTIONS TO THE TESTER:
The MEDICATION MANAGEMENT TEST (MODIFIED) INTERVIEW Section B will NOT be given to the study participant but instead read aloud in a face-to-face interview style format by a clinic staff member to assure comprehension of items, response choices, and completeness of the questionnaire, preferably in a quiet, secluded area (e.g., exam room or other office).

It is important to be familiar with the content and format of the interview before beginning the interview. Prior to the start of the interview, the study participant will be given 5 medication bottles labeled Medication A, Medication B, etc. Prior to question 5, the study participant will be given the insert for Loperam. Prior to question 6, the study participant will be given the medications organizer.

Questions for Participant and Instructions for Tester:
Text in brackets - [ ] = instructions for the tester.

Please begin by telling the study participant:

"During this task I am going to ask you some questions about these 5 medications labeled A through E. [Tester lines up the medication containers in front of the participant] Please answer the questions using the information on the labels. Some questions may require that you open the containers and count the numbers of pills. To open the container you push down the tab and then twist the top off, like this... [Tester demonstrates how to open one of the medication containers - the instructions may vary depending on what type of container is used. Tester then hands the participant a piece of paper and pen or pencil.] Here are paper and pen/pencil in case you would like to take notes to help you answer the questions. It is not required that you do so. This is not a timed test, so take as much time as you need to answer each question. Your answers will help us understand the effects of the study drug you are taking. We appreciate your answers to these questions."

You should briefly go over the format of the questions and how to answer them. For data keying, if the study participant did not answer a question, enter "1." PLEASE COMPLETE SECTION A AFTER THE STUDY PARTICIPANT COMPLETES THE INTERVIEW OR AFTER YOU ASCERTAIN THE INTERVIEW IS NOT POSSIBLE.

SECTION A

1. Was a face-to-face interview conducted? ........................................ (1-Yes, 2-No) □
   If No, complete "a".
   a. If 'No,' please indicate the reason why: ....................................
      1-Participant refused □
      2-Participant missed clinic visit □
      3-There was not enough time □
      9-Other reason, specify [30]: ..............................................

09-16-06
Medication Management Task-Revised

SECTION B

1. Assume that you take these medications every day. Are any of the medicines supposed to be taken with food? If so, please show me which medication or medications you would take with a meal.

   Correctly determines Medication C and Medication E: ................................. No 0 ☐ Yes 1 ☐

2. You are about to run out of Medication B, so you go to the pharmacy to get a refill. According to the prescription on the label, how many days will the refill last?

   Correctly determines 15 days: ........................................................................ No 0 ☐ Yes 1 ☐

3. This question is about Medication A. Listen carefully. Assume you were given a seven-day supply of Medication A three days ago. You have been taking the medicine for the past three days. However, you think you may have forgotten to take one or more doses. You can’t remember. Please check whether you, in fact, forgot to take any pills, and if you have, tell me how many... Please explain your answer to me.
   a. Correctly determines that 18 pills taken/24 remain: .................................... No 0 ☐ Yes 1 ☐
   b. Correctly counts remaining 24 pills: .............................................................. No 0 ☐ Yes 1 ☐
   c. Correctly notes that no doses missed: ......................................................... No 0 ☐ Yes 1 ☐

4. Your doctor then gives you a new prescription for Medication A. The doctor keeps you on the same daily dose you have been taking, but switches you to generic pills to save you money. The generic pills come in 200 mg tablets instead of the 100 mg tablets you have in front of you. With the new prescription, how many pills of the generic 200 mg tablets will you take per day?
   a. Correctly determines 3 pills: ........................................................................ No 0 ☐ Yes 1 ☐

How many milligrams of the medication do you take each day?
   b. Correctly determines daily dosage of 600 mg: ............................................ No 0 ☐ Yes 1 ☐
Medication Management Task-Revised

5. Assume that you are suddenly experiencing diarrhea. You pick up a common over-the-counter anti-diarrhea medication from the local pharmacy. The medicine comes with this package insert. [Tester hands the insert for Loperam to the participant.]

Over the next two days, you find that you must take several doses to control the diarrhea. You’re worried that you may exceed the maximum recommended dosage. What is the maximum limit on the number of pills you can safely take for two days according to the package insert?

Correctly determines 16 capsules/maximum of 8 per day: No 0 □  Yes 1 □

6. Unfortunately, on the third day after starting the medication, you are still experiencing diarrhea. At this point, what does the package insert tell you to do?

Correctly determines discontinue the medication/see a doctor: No 0 □  Yes 1 □

7. This next question is about Medication E. Listen carefully. Assume that in three days from now you are going on a 5-day vacation. You want to make sure you have enough pills to make it through vacation and not run out. Based on the number of pills you have in front of you, do you have enough? Or must you get a refill within the next three days before you leave? Please explain your answer by telling me how many pills you will need and how many you have.

   a. Correctly determines the number of pills (9) required for three days prior to leaving: No 0 □  Yes 1 □

   b. Correctly determines the number of pills (15) required for five days: No 0 □  Yes 1 □

   c. Correctly determines that no refill is needed: No 0 □  Yes 1 □
Medication Management Task-Revised

8. Using this medications organizer, I'd like you to lay out the number of pills for Medications A through D that you will need for Monday. (Tester points to the Monday compartments.) The organizer has compartments marked for time of day, including morning, noon, and evening. (Tester points to the compartments on the organizer, shows how to open them, and then closes them to allow the participant to open the correct compartments.) For medications taken twice a day, assume you need to take them every 12 hours. Do you have any questions? (Participant should only use boxes labeled for Monday. If the participant places beans in the wrong day, correct them and explain the task once more. If participant continues to incorrectly place the beans, allow him/her to complete the task.)

   a. Medication A (two beans in each compartment): .................................................. No 0 □ Yes 1 □

   b. Medication B (one bean in the morning compartment and one in the evening compartment): .................................................. No 0 □ Yes 1 □

   c. Medication C (three beans in each compartment): .................................................. No 0 □ Yes 1 □

   d. Medication D (one bean in the morning compartment and one in the evening compartment): .................................................. No 0 □ Yes 1 □

9. MMT Total Points (maximum 16): .................................................. □ □
Medication Management Task-Revised

10. a. How many different medications do you take on a daily basis? 
   [Do not include vitamins or supplements.]
   [If "0", STOP.
   If more than "0", continue.]

   b. How many pills do you take on a daily basis? 
   [Encourage study participant to calculate how many pills (doses) he/she
   takes per day. Include a dose of an oral solution as one pill (dose). Do not
   include topical solutions.]

   c. Do you take vitamins or supplements on a daily basis?  (1-Yes, 2-No)

   d. How many pills/doses of a supplement do you take daily?

   e. Do you use a pill organizer of any kind?  (1-Yes, 2-No)

   f. Do you use a medication reminder (such as a timing device
   that alerts you to take your next pill)?  (1-Yes, 2-No)

   g. Does anyone help you to remember to take your pills?  (1-Yes, 2-No)

   h. Does anyone assist you with your medication regimen, such as
   counting pills or placing them in an organizer?  (1-Yes, 2-No)

   i. During the past two months, have you run out of any of
   your medications?  (1-Yes, 2-No)

   j. Are you having any more problems now than you've had in the
   past with managing your medications?  (1-Yes, 2-No)

Date Form Keyed (DO NOT KEY): _____ / _____ / _____
Appendix C

Montreal Cognitive Assessment
Montreal Cognitive Assessment (MoCA)

Administration and Scoring Instructions

The Montreal Cognitive Assessment (MoCA) was designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. Time to administer the MoCA is approximately 10 minutes. The total possible score is 30 points; a score of 26 or above is considered normal.

1. Alternating Trail Making:
   Administration: The examiner instructs the subject: "Please draw a line, going from a number to a letter in ascending order. Begin here [point to (1)] and draw a line from 1 then to A then to 2 and so on. End here [point to (E)]."
   Scoring: Allocate one point if the subject successfully draws the following pattern: 1 −A- 2- B- 3- C- 4- D- 5- E, without drawing any lines that cross. Any error that is not immediately self-corrected earns a score of 0.

2. Visuoconstructional Skills (Cube):
   Administration: The examiner gives the following instructions, pointing to the cube: "Copy this drawing as accurately as you can, in the space below".
   Scoring: One point is allocated for a correctly executed drawing.
   • Drawing must be three-dimensional
   • All lines are drawn
   • No line is added
   • Lines are relatively parallel and their length is similar (rectangular prisms are accepted)
   A point is not assigned if any of the above-criteria are not met.

3. Visuoconstructional Skills (Clock):
   Administration: Indicate the right third of the space and give the following instructions: "Draw a clock. Put in all the numbers and set the time to 10 past 11".
   Scoring: One point is allocated for each of the following three criteria:
   • Contour (1 pt.): the clock face must be a circle with only minor distortion acceptable (e.g., slight imperfection on closing the circle);
   • Numbers (1 pt.): all clock numbers must be present with no additional numbers; numbers must be in the correct order and placed in the approximate quadrants on the clock face; Roman numerals are acceptable; numbers can be placed outside the circle contour;
   • Hands (1 pt.): there must be two hands jointly indicating the correct time; the hour hand must be clearly shorter than the minute hand; hands must be centred within the clock face with their junction close to the clock centre.
   A point is not assigned for a given element if any of the above-criteria are not met.
2

4. Naming:
Administration: Beginning on the left, point to each figure and say: “Tell me the name of this animal”.
Scoring: One point each is given for the following responses: (1) lion (2) rhinoceros or rhino (3) camel or dromedary.

5. Memory:
Administration: The examiner reads a list of 5 words at a rate of one per second, giving the following instructions: “This is a memory test. I am going to read a list of words that you will have to remember now and later on. Listen carefully. When I am through, tell me as many words as you can remember. It doesn’t matter in what order you say them”.
Mark a check in the allocated space for each word the subject produces on this first trial. When the subject indicates that (s)he has finished (has recalled all words), or can recall no more words, read the list a second time with the following instructions: “I am going to read the same list for a second time. Try to remember and tell me as many words as you can, including words you said the first time.” Put a check in the allocated space for each word the subject recalls after the second trial.
At the end of the second trial, inform the subject that (s)he will be asked to recall these words again by saying, “I will ask you to recall those words again at the end of the test.”
Scoring: No points are given for Trials One and Two.

6. Attention:
Forward Digit Span: Administration: Give the following instruction: “I am going to say some numbers and when I am through, repeat them to me exactly as I said them”. Read the five number sequence at a rate of one digit per second.
Backward Digit Span: Administration: Give the following instruction: “Now I am going to say some more numbers, but when I am through you must repeat them to me in the backwards order.” Read the three number sequence at a rate of one digit per second.
Scoring: Allocate one point for each sequence correctly repeated, (N.B.: the correct response for the backwards trial is 2-4-7).
Vigilance: Administration: The examiner reads the list of letters at a rate of one per second, after giving the following instruction: “I am going to read a sequence of letters. Every time I
say the letter A, tap your hand once. If I say a different letter, do not tap your hand". Scoring: Give one point if there is zero to one errors (an error is a tap on a wrong letter or a failure to tap on letter A).

Serial 7s: Administration: The examiner gives the following instruction: "Now, I will ask you to count by subtracting seven from 100, and then, keep subtracting seven from your answer until I tell you to stop." Give this instruction twice if necessary. Scoring: This item is scored out of 3 points. Give no (0) points for no correct subtractions, 1 point for one correction subtraction, 2 points for two-to-three correct subtractions, and 3 points if the participant successfully makes four or five correct subtractions. Count each correct subtraction of 7 beginning at 100. Each subtraction is evaluated independently; that is, if the participant responds with an incorrect number but continues to correctly subtract 7 from it, give a point for each correct subtraction. For example, a participant may respond “92 – 85 – 78 – 71 – 64” where the “92” is incorrect, but all subsequent numbers are subtracted correctly. This is one error and the item would be given a score of 3.

7. Sentence repetition:
Administration: The examiner gives the following instructions: “I am going to read you a sentence. Repeat it after me, exactly as I say it [pause]: I only know that John is the one to help today.” Following the response, say: “Now I am going to read you another sentence. Repeat it after me, exactly as I say it [pause]: The cat always hid under the couch when dogs were in the room.” Scoring: Allocate 1 point for each sentence correctly repeated. Repetition must be exact. Be alert for errors that are omissions (e.g., omitting "only", "always") and substitutions/additions (e.g., "John is the one who helped today;" substituting "hides" for "hid", altering plurals, etc.).

8. Verbal fluency:
Administration: The examiner gives the following instruction: “Tell me as many words as you can think of that begin with a certain letter of the alphabet that I will tell you in a moment. You can say any kind of word you want, except for proper nouns (like Bob or Boston), numbers, or words that begin with the same sound but have a different suffix, for example, love, lover,
loving. I will tell you to stop after one minute. Are you ready? [Pause] Now, tell me as many words as you can think of that begin with the letter F. [time for 60 sec]. Stop.”

Scoring: Allocate one point if the subject generates 11 words or more in 60 sec. Record the subject's response in the bottom or side margins.

9. Abstraction:
Administration: The examiner asks the subject to explain what each pair of words has in common, starting with the example: “Tell me how an orange and a banana are alike”. If the subject answers in a concrete manner, then say only one additional time: “Tell me another way in which those items are alike”. If the subject does not give the appropriate response (fruit), say, “Yes, and they are also both fruit.” Do not give any additional instructions or clarification.

After the practice trial, say: “Now, tell me how a train and a bicycle are alike”. Following the response, administer the second trial, saying: “Now tell me how a ruler and a watch are alike”.

Do not give any additional instructions or prompts.

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Scoring: Only the last two item pairs are scored. Give 1 point to each item pair correctly answered. The following responses are acceptable:
Train-bicycle = means of transportation, means of travelling, you take trips in both;
Ruler-watch = measuring instruments, used to measure.
The following responses are not acceptable: Train-bicycle = they have wheels;
Ruler-watch = they have numbers.

10. Delayed recall:
Administration: The examiner gives the following instruction: “I read some words to you earlier, which I asked you to remember. Tell me as many of those words as you can remember.” Make a check mark (✓) for each of the words correctly recalled spontaneously without any cues, in the allocated space.

Scoring: Allocate 1 point for each word recalled freely without any cues.

Optional:
Following the delayed free recall trial, prompt the subject with the semantic category cue provided below for any word not recalled. Make a check mark (✓) in the allocated space if the subject remembered the word with the help of a category or multiple-choice cue. Prompt all non-recalled words in this manner. If the subject does not recall the word after the category cue, give him/her a multiple choice trial, using the following example instruction, “Which of the following words do you think it was, NOSE, FACE, or HAND?”

Use the following category and/or multiple-choice cues for each word, when appropriate:
FACE: category cue: part of the body multiple choice: nose, face, hand
VELVET: category cue: type of fabric multiple choice: denim, cotton, velvet
CHURCH: category cue: type of building multiple choice: church, school, hospital
DAISY: category cue: type of flower multiple choice: rose, daisy, tulip
RED: category cue: a colour multiple choice: red, blue, green

Scoring: **No points are allocated for words recalled with a cue.** A cue is used for clinical information purposes only and can give the test interpreter additional information about the type of memory disorder. For memory deficits due to retrieval failures, performance can be improved with a cue. For memory deficits due to encoding failures, performance does not improve with a cue.

11. Orientation:
Administration: The examiner gives the following instructions: “Tell me the date today”. If the subject does not give a complete answer, then prompt accordingly by saying: “Tell me the [year, month, exact date, and day of the week].” Then say: “Now, tell me the name of this place, and which city it is in.”
Scoring: Give one point for each item correctly answered. The subject must tell the exact date and the exact place (name of hospital, clinic, office). No points are allocated if subject makes an error of one day for the day and date.

**TOTAL SCORE:** Sum all subscores listed on the right-hand side. Add one point for an individual who has 12 years or fewer of formal education, for a possible maximum of 30 points. A final total score of 26 and above is considered normal.
Appendix D

Self Efficacy Scale
Self-Efficacy for Managing Chronic Disease 6-Item Scale

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.
Self-Efficacy for Managing Chronic Disease 6-Item Scale

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?

Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident

Items (using the same format as above):

1. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?
2. How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?
3. How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?
4. How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?
5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?
6. How confident are you that you can do things other than just taking medication to reduce how much your illness affects your everyday life?

Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the scale is the mean of the six items. If more than two items are missing, do not score the scale. Higher number indicates higher self-efficacy.

Characteristics

Tested on 605 subjects with chronic disease.

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<th>No. of items</th>
<th>Observed Range</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Internal Consistency Reliability</th>
<th>Test-Retest Reliability</th>
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Frain, Judy, UMSL, 2013, 185
Source of Psychometric Data


References

Appendix E

Demographic Form
Demographic Form

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<tr>
<th>Name</th>
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<th>Study Number</th>
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<th>CES-D Score</th>
<th>MMT Score</th>
<th>Self-Efficacy Score</th>
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<th>Date of HIV confirmation used for study</th>
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<th>Current CD4</th>
<th>Current HIV VL</th>
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<th>Tobacco Use</th>
<th>Drug Use</th>
<th>Other Diagnoses</th>
<th>HAART Meds:</th>
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<td>Past</td>
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</table>

I accept remuneration: __________________    __________________    ____________
Participant signature       Staff signature Date

I decline remuneration: _________________   ___________________   ____________
Participant signature       Staff signature Date
Appendix F

Consent Form
Project Title: A Comparison of Medication Management Between Older and Younger Adults Living With HIV

Principal Investigator: Judy Frain

Research Team Contact: Judy Frain  314.302.0875

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research participant. By signing this form you are agreeing to participate in this study.

- If you have any questions about anything in this form, you should ask the research team for more information.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have HIV and are taking antiretroviral medications.

The purpose of this research study is to determine if there are significant differences in medication management between older and younger adults living with HIV. The research will look to see if there are differences in cognitive ability, depression and self-efficacy between older and younger adults living with HIV, and if so what effect these have on medication management in these two groups. As more people with HIV are living to an older age determining differences between older and younger people with regard to how they take their medications will help us provide better care for these patients.

WHAT WILL HAPPEN DURING THIS STUDY?

- If you are eligible for the study you will complete the following evaluations:
- A demographic form, which collects information about your age, ethnicity, education, HIV and other diseases you may have, the medications you take, and your alcohol, tobacco and drug history. This takes about 10 minutes.
- The Montreal Cognitive Assessment, which asks questions about how you think. This takes about 10 minutes.
- The Medication Management Task-Revised, which asks questions about taking
medications. This takes about 10 minutes.

- The chronic disease self-efficacy scale, which asks questions about your confidence in performing certain activities. This takes about 5 minutes.
- The Center for Epidemiologic Studies Depression Scale, which asks about your mood over the past week. This takes about 5 minutes.

All questionnaires will be completed in a private exam room in the ACTU.

You may skip any questions that may make you feel uncomfortable.

HOW MANY PEOPLE WILL PARTICIPATE?
Approximately 130 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?
If you agree to take part in this study, your involvement will last for about one hour.

WHAT ARE THE RISKS OF THIS STUDY?
You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

- **Risk of Social Harm**
  Although the study site will make every effort to protect participant privacy and confidentiality, it is possible that participants’ involvement in the study could become known to others, and that social harms may result (i.e., because participants could become labeled as HIV-infected or at “high risk” for HIV infection). For example, participants could be treated unfairly or discriminated against, or could have problems being accepted by their families and/or communities

WHAT ARE THE BENEFITS OF THIS STUDY?
You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because it will increase our understanding of the effects of aging on HIV.

WHAT OTHER OPTIONS ARE THERE?
Taking part in this research study is voluntary. You may choose not to take part in this research study.
WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs/additional costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will receive $10 cash in remuneration for your participation in this study. This will be given to you at the completion of the study visit. You may choose to participate without being paid.

WHO IS FUNDING THIS STUDY?

This study is being funded by a joint grant from Sigma Theta Tau (The Nursing Honor Society) and the Association of Nurses in AIDS Care.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- Your HIV physician will be notified if a score of >16 is obtained on the CES-D
- University representatives, to complete University responsibilities
- Washington University’s Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will assign the information you give us a code number. A master list linking the code number and your identity will be kept separate from the research data. Only the PI and people helping her will be able to see the list. All files will be kept in a locked room in a locked cabinet accessible only by the PI.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent
form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, “How will you keep my information confidential?”.

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University’s Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect
- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:
- You authorize the use of your PHI for this research
- Your signature and this form will not expire as long as you wish to participate.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
- To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at [http://hrpo.wustl.edu](http://hrpo.wustl.edu) (or use the direct link: [http://hrpohome.wustl.edu/participants/WithdrawalTemplate.rtf](http://hrpohome.wustl.edu/participants/WithdrawalTemplate.rtf)) or you may request that the Investigator send you a copy of the letter.
  - If you revoke your authorization:
    - The research team may only use and share information already collected for the study.
    - Your information may still be used and shared if necessary for safety reasons.
    - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?
Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you
decide not to be in this study, or if you stop participating at any time, you won’t be penalized or lose any benefits for which you otherwise qualify.

**What if I decide to withdraw from the study?**
You may withdraw by telling the study team you are no longer interested in participating in the study.

**Will I receive new information about the study while participating?**
If we obtain any new information during this study that might affect your willingness to continue participating in the study, we’ll promptly provide you with that information.

**Can someone else end my participation in this study?**
Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because the study is stopped or cancelled.

**WHAT IF I HAVE QUESTIONS?**
We encourage you to ask questions. If you have any questions about the research study itself, please contact: Judy Frain (Principal Investigator) 314.302.0875. If you feel that you have been harmed in any way by your participation in this study, please contact Michael Klebert 314.454.0058.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office, 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, (314) 633-7400, or 1-(800)-438-0445 or email hrpo@wusm.wustl.edu. General information about being a research participant can be found by clicking “Participants” on the Human Research Protection Office web site, http://hrpohome.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

**Do not sign this form if today’s date is after $STAMP_EXP_DT.**
Statement of Person Who Obtained Consent
The information in this document has been discussed with the participant or, where appropriate, with the participant’s legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

(Signature of Person who Obtained Consent) (Date)

(Name of Person who Obtained Consent - printed)