PSYCHOLOGICAL AND PHYSIOLOGICAL PREDICTORS OF ADHERENCE TO ANTIRETROVIRAL MEDICATIONS FOR WOMEN WITH HIV/AIDS

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Submitted to the Graduate Faculty of

School of Nursing in partial fulfillment

of the requirements for the degree of

Doctor of Philosophy

University of Pittsburgh

2007

This study was funded in part by a predoctoral fellowship from the National Institute of Nursing Research, F31 NRO7537-01 and grants from Sigma Theta Tau International, Beta Omega, Northern Illinois University, School of Nursing, and Sigma Theta Tau International,

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UNIVERSITY OF PITTSBURGH

SCHOOL OF NURSING

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ABSTRACT

As the HIV/AIDS epidemic has entered the third decade, a gap remains regarding the uniqueness of women with disease. Although the course of HIV disease management has changed with the development of antiretroviral medications women were not initially in these medication trials. Therefore, much of what is known regarding women's adherence to these medications has been based upon research and clinical trials with HIV positive men. The purpose of this research was to examine selected psychological factors (depressive symptomatology, social support, and perceived stigma) and selected physiological factors (CD-4, viral load, HIV disease symptoms, and physical well-being) as predictors of self-reported adherence among women with HIV who were prescribed antiretroviral medications. In addition, this study examined the mediating effect of self-efficacy on the relationships between the selected psychological and physiological variables and self-reported adherence to antiretroviral medications.

This convenience sample consisted of 44 HIV positive women. White subjects (55%) were women living in rural areas of eastern Ohio or western Pennsylvania. Approximately 80% of the women had a high school education or its equivalent; 30% of the women were married or in a significant relationship, 80% of the women reported their insurance as coming from public assistance, and most identified her disease exposure as being through heterosexual contact.

Standard measures were used for data collection and a demographic measure. Within the larger study, a sample of ten women used the electronic event monitor (MEMS cap) for a period of 29 days. There were significant relationships between depressive symptomatology, perceived stigma, CD 4, HIV disease symptoms, and self-reported adherence. Self-efficacy beliefs had a mediating effect for depressive symptoms and CD 4 and self-reported adherence to antiretroviral medications. This study is one of the first to explore the relationship between perceived stigma and self-reported adherence to antiretroviral medications in women. For this study, one's self-efficacy beliefs mediated self-reported adherence to antiretroviral medications for women with depressive symptomatology.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

PREFACE

I would like to thank the Dissertation Committee Members: Dr. Judith A. Erlen, Dr. Sandra Engberg, Dr. Elizabeth Schlenk, and Dr. Clement Stone. This study was made possible in part through the liaisons at the University of Pittsburgh, Falk Clinic, in particular, Dr. Deborah McMahan, and Rocco Caldararo, Research Recruiter and the staff at the Northwest AIDS Alliance of Pennsylvania, Leah Magagnotti, RN and Julie Whiting, RN. I would like to acknowledge Dr. Donna Caruthers and Mrs. Michelle Meyer for their support and efforts toward recruitment. In addition, I would like to thank all the women that participated in this study, who have contributed to a better understanding of adherence to antiretroviral medications for women with HIV/AID. I would like to thank my nurse colleagues, Carolyn Schubert and Marie Bright-Cobb for keeping me focused on my goals to contribute to nursing. And finally, I would like to thank my husband, Michael for his continual support and encouragement, as well as our children, Matthew, Paula, Adam, Alyssa, and Peter. It was truly their faith in me that has allowed me to pursue my education.

1.0 CHAPTER ONE

1.1 SIGNIFICANCE

As the Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) epidemic has entered the third decade, health care providers and researchers have not completely grasped the full impact of the disease for women or women's unique issues in disease manifestation and disease management. Research has identified a lack of understanding among health care providers regarding the particular needs of women with HIV (Hudson, Kirksey, & Holzemer, 2004). This is due in part to the failure of researchers to include women in clinical trials and the lack of funding to address unique and often-extreme conditions in which some of these women live (Bova, 2000; Liu et al., 2006).

Research has shown that disease exposure is associated with risk taking behaviors, such as early sexual activity, multiple sex partners, unprotected sex, and drug and alcohol use (Diamond & Buskin, 2000; Lansky, Fleming, Byers, Karon, & Wortley, 2001). Females infected with HIV are three times more likely to engage in unprotected sex and to have had numerous sex partners compared to women who are not HIV-positive (Centers for Disease Control and Prevention [CDC], 2001a, 2004; Hader, Smith, Moore, & Holmberg, 2001). Alcohol and/or drugs including intravenous drug use (IDU) have been identified as secondary causes of HIV through unprotected sex with a partner whose history includes IDU (Hader et al.; Israel, Romeis,

& Spitz, 2005). Approximately 79% of women with HIV report becoming infected from heterosexual contact or unknown exposure risk (CDC, 2004). In addition, women are not always successful in negotiating safe-sex practices, which creates opportunities for infection (Israel et al.). Women who have HIV infected male partners are 17.5 times more likely to become infected from the disease than males who have HIV infected female partners (Abercrombie, 1996). Women may be more susceptible to HIV infection through heterosexual contact because there is a greater concentration of viral DNA in the semen of their male sex-partners (Hader et al.; Marlow, Ziskind, & Jones, 2000).

The early manifestations of HIV infection occur within the first two weeks of exposure. During this time as the viral load is increasing, the person may complain of flu-like symptoms such as sore throat, fatigue, and nightsweats. Women often ignore these symptoms because of more pressing issues including child care, home management, and meeting the basic needs of their children and themselves such as acquiring food, clothing, medication, and shelter (Abercrombie, 1996; Carey, Bratten, Jaworski, Durant, & Forsyth, 1999; Hudson et al., 2004 Holzemer, 2004; Lehman-Trzynka & Erlen, 2004). Marginalized women with HIV often focus more on meeting their essential everyday needs rather than symptoms of illness (Abercrombie; Carey et al.; CDC, 2006; Greene, Frey, & Derlega, 2002; Hader et al., 2001; Simoni & Cooperman, 2000; Simoni & Ortiz, 2003). Regardless of the illness, women often ignore their symptoms and delay entry into treatment (Hader et al.).

Late entry into treatment for HIV infection may be related to women's treatment for other infections such as candidiasis, human papillomavirus (HPV), or infections due to dramatic changes in CD 4. As candidiasis and/or HPV become more unmanageable, health care practitioners unfamiliar with the unique manifestations of HIV in women treat only the

candidiasis and not the underlying cause of the infection. The result is that the CD 4 continues to decrease in these women and the risk of opportunistic infections increases; HIV disease progresses (Abercrombie, 1996; Tapper, Daar, Piliero, Smith, & Steinhart, 2005).

Frequently women are not diagnosed with HIV until they require hospitalization or become pregnant (Abercrombie, 1996; Burpo, 2000; Hader et al., 2001; Hudson et al., 2004; Levine et al., 2001; Sowell, Moneyham, & Aranda-Naranjo, 1999). The importance of diagnosing HIV in pregnant women became evident when in November 2001 the CDC made the following recommendations (CDC, 2001b, 2001c; 2002):

- Provide HIV testing as a routine part of prenatal care for all pregnant women
- Simplify the testing process so that pretest counseling is not a barrier to testing
- Increase the flexibility of the consent process including oral and written informed consent
- Explore and address reasons for refusal of testing
- Emphasize HIV testing and treatment at the time of labor and delivery for women who have not received prenatal testing and prophylaxis (CDC, 2001b, 2001c).

A 1999 CDC study examining the HIV testing practices of pregnant women in 14 states found the state-specific proportion of mothers who recalled discussing HIV testing with their prenatal health care provider ranged from 63.4% to 86.7%. The proportion of mothers who recalled being tested ranged from 58.0% to 80.7% (CDC, 1999a, 1999b). In all 14 states Black women were significantly more likely than white or Latina expectant mothers to report that their provider discussed testing. In addition, in several states women with less than a high school education, less than 25 years of age, and receiving public health assistance (Medicaid) were more likely to have received some form of counseling for HIV testing during pregnancy (CDC,

1999b). While the issue of pregnancy and prenatal HIV disease management and care is beyond the scope of this study, the above information highlights some of the issues of sub-optimal medical management for women at risk for or diagnosed with HIV.

Health care providers are aware of the factors causing lymphocyte depletion and HIV. Providers also are aware of the risk factors associated with disease exposure and the fact that the disease has no limitations or boundaries for men and women who are at risk. There are treatment regimens to manage and control disease; however, to enhance the effectiveness and efficacy of these regimens requires that treatment guidelines be followed (Yeni et al., 2004). Understanding the efficacy of the regimen requires monitoring individuals' adherence to antiretroviral medications. The focus on adherence to antiretrovirals centers around the fact that 1) the virus has the potential to mutate and to change its genetic structure, 2) persons on antiretroviral medications may become resistant to current treatments due to viral mutation, and 3) less than near perfect adherence increases the likelihood of both mutation and resistance. Although issues that may affect or predict medication adherence have been investigated for men with HIV, women, for the most part, have not been the focus in similar investigations. Findings from studies of antiretroviral medication adherence are providing some information about what issues contribute to non-adherence for men with HIV. Therefore, it is timely and important to investigate the issues that may influence antiretroviral adherence for women with HIV and to design interventions to address the identified predictors.

1.2 BACKGROUND OF THE PROBLEM

Two significant changes in the course of HIV/AIDS since the 1990's are the development of antiretroviral medications and the decrease in the rate of deaths from disease. There has been a 14% decline in deaths from 1998 to 2002 and an 8% decline from 2000 to 2004 (CDC, 2004). There have been approximately 550,000 deaths of men, women, and children in the United States (US); 83,000 of those deaths have been women (CDC, 2004). HIV/AIDS is the fifth.

With the introduction of highly active antiretroviral therapy in 1995 there has been a marked decrease in morbidity and mortality related to HIV and AIDS disease. Contrary to some beliefs, antiretroviral therapy does not promise a cure for HIV. However, therapy does have the potential to reduce the plasma concentration of HIV RNA (or viral load) and increase the immune response as demonstrated by an improved CD 4 lymphocyte count (Yeni et al., 2002, 2004). The result of less HIV virus and an improved immune response decreases the individual's risk of opportunistic infections and offers the hope and potential for disease survival (Liu et al., 2006).

While the overall number of new cases of HIV/AIDS decreased in the US from 2001 to 2003, there has been an increase of approximately 1% per year in new cases of HIV since that time (CDC, 2004). Women, especially Black (African American) and Latina (white Hispanic) continue to demonstrate a sizeable increase in number of newly diagnosed cases per year; 46% of all new cases of disease were among Black women (CDC, 2006). The HIV surveillance report, which is now two years old, suggests that over one million people in the USA have been diagnosed with HIV and approximately 880,000 have been diagnosed with AIDS (CDC, 2004). This same report estimates that approximately 41,000 new cases of HIV will be diagnosed annually in the USA with half of these newly diagnosed cases of disease being

persons (both males and females) under 25 years of age and from minority groups: Latinos, Blacks, and women (CDC, 2004).

In 1999, the leading cause of death for men and women ages 25 to 44 was AIDS (CDC, 1999b). For Black women AIDS was the most frequent cause of death for persons 25 to 34 years of age. Also, for Black women 21 to 24 and 35 to 44 years of age, AIDS is the fourth leading cause of death (CDC, 2006) and it is also the fourth leading cause of death for Latinas ages 35 to 44 (CDC, 2006). Overall, AIDS is the most frequent cause of deaths in women (25 to 34 years of age).

Of particular concern is the age of risk exposure of these women. Females who are 13 to 39 years of age continue to demonstrate the most significant increases of newly diagnosed cases of HIV (CDC, 2001a, 2006; Graham, 1997; Hader et al., 2001; Wortley & Fleming, 1997). Although white women remain in the majority of the female population in the USA, Black and Latina women account for approximately 80% of all cases of HIV/AIDS (CDC, 2006; Hader et al., 2001). A diagnosis of HIV/AIDS is 25 times more likely to occur in Black women than in their white peers and 4 times more likely for Latina women than white women (CDC, 2006).

In addition, women constitute over 9,000 new cases of HIV annually (CDC, 2004). Estimates are that approximately 100,000 women are currently living with the disease (CDC, 2000, 2001a, 2004). The number of women with HIV has increased such that in 1987 only 12.5% of all reported cases of HIV/AIDS were women (CDC, 1989). However, in 2000 women accounted for 22% of all new cases of disease (CDC, 2001a) and 27% of all cases by 2004 (CDC, 2004).

Summary of Medication Adherence. There is a paucity of research addressing adherence to antiretroviral medications among women with HIV especially in non-urban areas of the US.

The documented information regarding adherence to antiretroviral medications in women with HIV often has been generalized from previous research of men with disease and their medication adherence.

In light of the potential for virus mutation, newly infected persons first need to have a virus resistance test prior to initiating an antiretroviral regimen (Little et al., 2002; Tapper et al., 2005). Tapper and colleagues (2005) recommend careful screening of the individual for life issues that may interfere with adherence. Screening should include assessment of the individual's readiness to begin a life-long treatment plan, as well as the potential for side effects, the presence of co-morbidities such as diabetes, and consistent evaluation and monitoring of medication adherence.

The measurement of one's adherence to medications and/or treatment modalities, including lifestyle change is often subjectively approached using a variety of descriptive self-report measures. Although these self-report instruments are suggestive of one's adherence, these measures are often subject to human error when reporting adherence. Other more invasive methods of assessing adherence such as collecting blood samples increases the cost of the research and decreases subject participation (Paterson, Pitoski, & Capitano, 2002). Another method of evaluating medication adherence is through the use of electronic event monitors. However, these devices continue to have the potential for bias due to subject manipulation of their medications and/or the electronic equipment.

Because HIV medication is pivotal to successful disease management there is a need for the individual to strive toward complete medication adherence. HIV medication regimens are continually being improved. These improvements are due to ongoing experimental research, introduction of new medications, patient use, side effects of medication use, the ability to

decrease dosing frequencies and the combination of medications into a single pill rather than multiple pills, and changes in disease management (Tapper et al., 2005). Designing appropriate interventions that will increase medication adherence in women with HIV requires an understanding of which factors influence adherence in this group of persons.

1.3 PROBLEM STATEMENT

The overall purpose of this research was to examine selected psychological factors (depressive symptomatology, social support, and perceived stigma) and selected physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) that may be predictors of self-reported adherence among women with HIV who were prescribed antiretroviral medications. The second purpose of this study was to examine the mediating effect of self-efficacy on the relationships between the selected psychological factors (depressive symptomatology, social support, and perceived stigma) and selected physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) and self-reported adherence to antiretroviral medications. Therefore, the specific aims and hypotheses of this study were to:

1. Describe overall patterns of self-reported adherence among women with HIV/AIDS prescribed antiretroviral medications.
2. Describe the relationship between patterns of self-reported adherence and sociodemographic factors (age, education, race/ethnicity, marital status, and exposure risk category) among women with HIV/AIDS who were prescribed antiretroviral medications.

H2A: There is an association between patterns of self-reported adherence and sociodemographic factors (age, education, race/ethnicity, marital status, and exposure risk category) among women with HIV/AIDS who were prescribed antiretroviral medications.

3. Examine the relationship between selected psychological factors (depressive symptomatology, social support, and perceived stigma) and self-reported adherence among women with HIV/AIDS who were prescribed antiretroviral medications.

   H3A: Women who report less depressive symptomatology will have better self-reported adherence to antiretroviral medications.

   H3B: Women who report strong social support will have better self-reported adherence to antiretroviral medications.

   H3C: Women who report less perceived stigma will have better self-reported adherence to antiretroviral medications.

4. Examine the relationship between selected physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) and self-reported adherence among women with HIV/AIDS who were prescribed antiretroviral medications.

   H4A: Women who report higher CD 4s and lower disease viral load will have better self-reported adherence to antiretroviral medications.

   H4B: Women who report fewer HIV disease symptoms will have better self-reported adherence to antiretroviral medications.

   H4C: Women who report better physical well-being will have better self-reported adherence to antiretroviral medications.

5. Examine the mediating effect of self-efficacy on the relationships between selected psychological factors (depressive symptomatology, social support, and perceived stigma) and selected physiological factors (CD4, viral load, HIV disease symptoms, and physical well-being) and self-reported adherence among women with HIV/AIDS who were prescribed antiretroviral medications.

   H5A: Self-efficacy will mediate the relationship between selected psychological factors (depressive symptomatology, social support, and perceived stigma) and self-reported adherence to antiretroviral medications among women with HIV/AIDS.

   H5B: Self-efficacy will mediate the relationship between selected physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) and self-reported adherence to antiretroviral medications among women with HIV/AIDS.

6. Describe patterns of adherence in a subsample of women with HIV/AIDS who were prescribed antiretroviral medications as assessed by a self-reported instrument of adherence and as measured by the Medication Event Monitoring System (MEMS).

1.4 DEFINITION OF TERMS

1.4.1 Independent variables

1.4.1.1 Depressive Symptomatology

Depressive Symptomatology was the individual's subjective perceptions of guilt and worthlessness, loss of appetite, sad mood, low energy, and sleep disturbances (Radloff, 1977).

The Center for Epidemiologic Studies-Depression Scale (CES-D) was used to measure depressive symptomatology (Radloff, 1977).

1.4.1.2 Social Support

Social Support was the resources that individuals have available to them through interpersonal relationships (Cohen & Syme, 1985). Social support was measured by using the Interpersonal Support Evaluation List (ISEL) that assesses the individual's perceived available overall resources for social support (Cohen, Mermelstein, Kamarck, & Hoberman, 1995).

1.4.1.3 Perceived Stigma

Perceived Stigma was defined as the perceived interaction with and from others that makes the individual feel undesirable, tainted, flawed, and/or morally degenerated (Goffman, 1963). Perceived stigma was measured using the HIV Social and Emotional Aspects Questionnaire (Berger, Ferrans, & Lashley, 2001). The measure examines the overall emotional and social issues relevant to living with HIV.

1.4.1.4 CD 4

CD 4 was defined as a lymphocyte that has circulated through the thymus gland and has differentiated to become thymocytes. The presence of CD 4 cells suggests the individual's immune response is functioning and the potential to resist disease (Malarkey & McMorrow, 1996).

1.4.1.5 Viral Load

Viral Load was the plasma concentration of HIV RNA in the blood that suggests the presence of HIV disease. These data (CD 4 and viral load) were self-reported on the sociodemographic measure.

1.4.1.6 HIV Disease Symptoms

HIV Disease Symptoms were defined as the subjective changes in how one feels related to their HIV disease in the last 5-days. HIV disease symptoms were measured by using The Revised Sign and Symptom Check-List for HIV (SSC-HIV rev) (Holzemer, Hudson, Kirksey, Hamilton, & Bakken, 2001).

1.4.1.7 Physical Well being

Physical Well-being was defined as one's current appraisal and satisfaction with their physical abilities and social functioning with others. Physical well-being was measured using the overall physical well-being score of the Medical Outcomes Study-HIV (MOS-HIV) that includes the subscales of physical functioning, bodily pain, general health, vitality/energy and fatigue, and social functioning (Wu et al., 1991).

1.4.2 Dependent Variable

1.4.2.1 Adherence

Adherence was defined as the degree to which one follows a prescribed regimen. The AIDS Clinical Trial Group Assessment (ACTG) (Chesney et al., 2000) was used to assess

overall rates of self-reported adherence to antiretroviral medications. In addition, for a sub-sample of women in the study the Medication Event Monitoring System (MEMS) cap was used to assess adherence rates over a 29-day period.

1.4.3 Mediating Variable

1.4.3.1 Perceived Self-efficacy Beliefs

Perceived Self-efficacy was defined as the individual's perceived ability to successfully manage their antiretroviral medications (Bandura, 1977, 1986, 1997). Perceived self-efficacy was measured using the HIV Medication Taking Self-efficacy Scale (Erlen, Cha, Sereika, Caruthers, unpublished manuscript).

2.0 SECOND CHAPTER

INTRODUCTION

Improved understanding of medication taking adherence and issues that affect one's adherence are important topics to address among persons with HIV/AIDS. Although there is considerable research literature focusing on medication adherence issues for men with HIV/AIDS, there remains a gap in the literature about medication adherence for women with this disease. Thus, women with HIV/AIDS and their adherence to antiretroviral medications are a timely and significant topic. Non-adherence to antiretroviral medications can lead to genetic changes in the virus and the altered viral RNA may become resistant to current medications. Thus, persons using antiretroviral medications may potentially exhaust their options for medications to manage their disease. The resistant genetically changed virus can also create a potential threat to public health as the resistant viral genome is passed on to others.

2.1 OVERVIEW OF THEORETICAL FRAMEWORK

This research examined selected psychological factors (depressive symptomatology, social support, and perceived stigma) and selected physiological factors (CD 4, viral load, HIV disease related symptoms, and physical well-being) as potential predictors of adherence among women with HIV prescribed and taking antiretroviral medications. Following an extensive investigation

of cognitive and social learning models: Theory of Reasoned Action (Fishbein & Ajzen, 1975), Health Belief Model (Becker, 1974; Rosenstock, 1966), Health Promotion Model (Pender, 1982), and Social Cognitive Theory (Bandura, 1977), Self-efficacy Theory (Bandura, 1986, 1997) was selected as the conceptual framework for this study.

Self-efficacy Theory is rooted in Bandura's Social Learning Theory (SLT) (1977), a framework for examining motivation, human thought, and action. Social Learning Theory is based on the premise that behavior is influenced by environmental events, personal factors, and the interaction of these multiple dimensions. Bandura modified SLT resulting in Social Cognitive Theory (SCT). Social Cognitive Theory considers how patterns of behavior are learned and the cognitive process in learning. Once these patterns are learned, SCT considers how and why the behavior continues, changes, or ceases. Both SLT and SCT are based on the premise that behaviors are learned by modeling the actions (behaviors) of others. Learned behaviors begin at an early age through what Bandura refers to as observational modeling (1977). Thus, the individual learns and perceives behaviors that will result in a favorable outcome or avoids behaviors that produce a negative result.

A concept of SCT is self-reinforcement composed of efficacy expectation and outcome expectancies. Briefly, efficacy expectation is the conviction that one can successfully execute a behavior that produces the desired outcome (Bandura, 1977). Outcome expectation is one's estimate that a given behavior will lead to the identified outcome (result). Efficacy expectation became the basis of perceived self-efficacy, which addresses one's fear in attempting or not attempting a given behavior and forecasts the potential for eventual success in a behavior. Thus, self-efficacy is a cognitive process that is influenced by past behaviors, the successes and failures

of those behaviors, and the environment where the behaviors are attempted and performed, as well as the recognition for achieving the desired outcome.

Bandura (1986) asserted that one's perceived self-efficacy is a powerful predictor of the individual's resulting behavior. Self-efficacy theory can be used to predict and explain an individual's health behavior. The premise is that one's expectation of personal mastery and success in a behavior determines whether an individual will engage in a select behavior(Bandura, 1986). Self-efficacy is the individual's expectation or perception of confidence in one's ability to perform a specific task/behavior (Bandura, 1977). Self-efficacy is not static; it changes from one behavior expectation to another. Self-efficacy evolves from previously learned positive and negative experiences (Bandura, 1977). Thus, perceived self-efficacy, an indicator of the individual's potential for success and expectations of self-efficacy, can affect one's behavior (Bandura, 1986, 1997).

Three principles underscore an individual's efficacy expectation: 1) magnitude or degree of task difficulty, 2) generality or the degree to which the expectation can be implied to other situations, and 3) strength of the mastery of the expectation. Persons who feel strongly that they can be successful with a task or behavior such as adherence to medication taking, even under complicated and stressful conditions, are more likely to adhere to the recommended regimes (Bandura, 1986).

The importance of self-efficacy theory is becoming recognized within nursing literature. Washington (1999) reported that increased self-efficacy was important for chemically dependent women to be successful when re-entering the work force. Educational interventions were noted as increasing self-efficacy for men to request prostate screening (Boehm et al., 1995). Kehoe and Katz (1998) reported self-efficacy to be a key component in adherence to pharmacotherapy,

as well as diet and exercise programs. Poor self-efficacy was associated with worker's resistance to engage in use of protective hearing equipment (Lusk, Ronis, Kerr, & Atwood, 1994). Finally, in a comprehensive review of the literature, Fitzgerald (1991) reported that self-efficacy was a predictor of an individual's motivation for attempting, achieving, and maintaining behaviors to overcome unhealthy lifestyles.

In this model using self-efficacy theory (Figure 1), the demographic variables (identified as age, race/ethnicity, education, marital status, and exposure risk category) are characteristics within the person/individual. As identified in the model, demographic variables and exposure risk categories are believed to be characteristics of the person/individual. There is a direct link between the person and self-reported adherence to antiretroviral medications. However, perceived self-efficacy may have a possible mediating effect on the relationship between person and self-reported adherence to antiretroviral medications. Perceived self-efficacy may influence the relationship between the psychological factors (depressive symptomatology, social support, and perceived stigma) and/or physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being,) and adherence to antiretroviral medication. These psychological and/or physiological factors may moderate or mediate one's perceived self-efficacy.

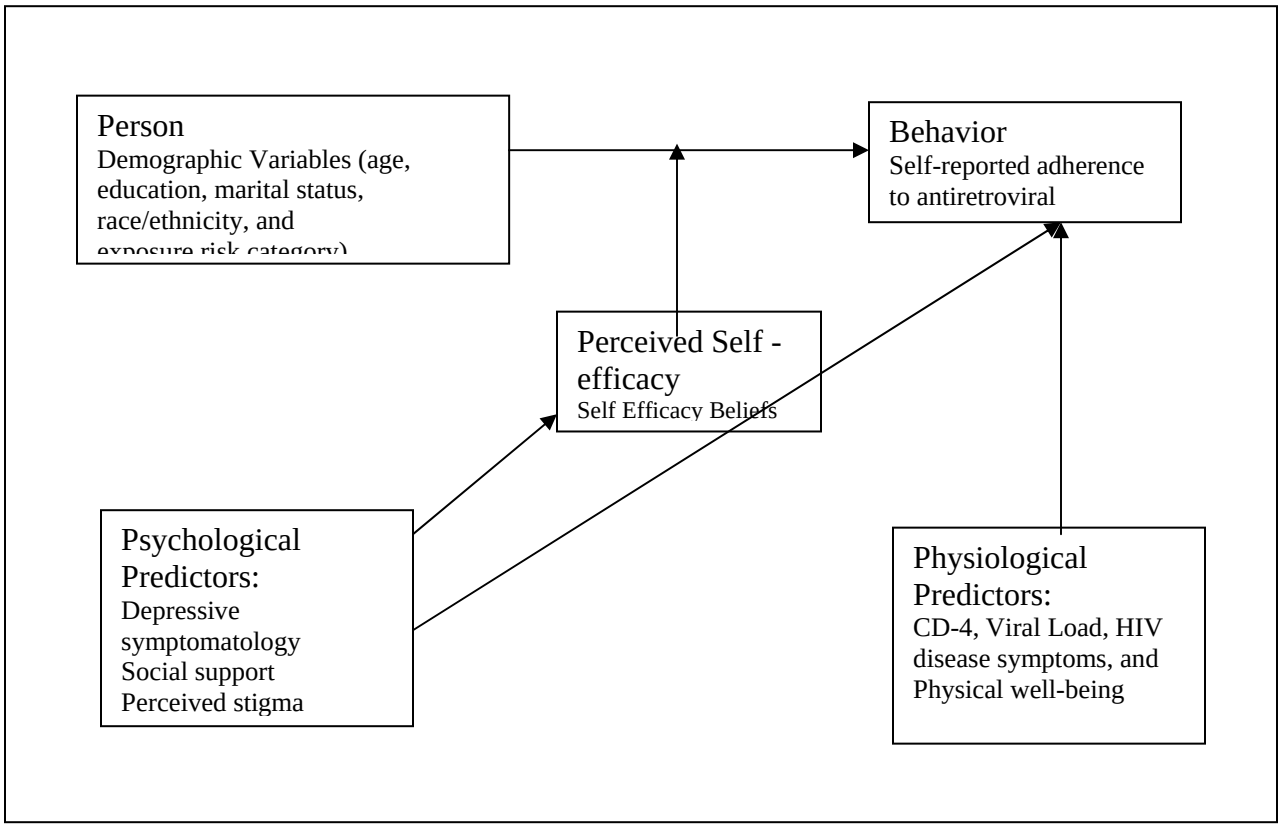

Figure 1 Theoretical Framework using a Modified Social Cognitive Theory.

2.2 REVIEW OF SCIENTIFIC LITERATURE

2.2.1 Adherence.

There is extensive research on adherence and chronic disorders such as diabetes, hypertension, and heart disease (MacLean, & Lo, 1998; Metz et al., 1997; Wagner, Schnoll, & Gipson, 1998). Overall, the research suggests approximately 30 to 60% of persons with chronic disorders/diseases are non-adherent to their prescribed medication regimens (Berg, Dunbar-

Jacob, & Rohay, 1998; Blackwell, 1992; Dunbar-Jacob & Mortimer-Stephens, 2001; Morisky, Green, & Levine, 1986; Sackett, Haynes, Gibson, Taylor, Roberts, & Johnson, 1978). Early studies of hypertension and adherence showed marked decreases in systolic and/or diastolic readings after adherence reached 80% or better (Blackwell; Morisky et al.; Sackett et al.). Sackett and colleagues (1978) in their early research noted patients were less adherent as their regimen became more complex; over time adherence continued to falter. In addition, researchers have found that when cueing and supportive strategies were curtailed, adherence decreased, and eventually ceased for many people (Blackwell; Burke & Dunbar-Jacob, 1995; Dunbar-Jacob & Mortimer-Stephens; Morisky et al.).

Adherence is evident when patient behaviors are congruent with medical advice, including prescription management and lifestyle changes such as diet and exercise (Morisky et al., 1986). The goal of adherence is to produce the desired control and ultimately reduce the complications and risks associated with chronic disorders (Berg, Dunbar-Jacob, & Rohay, 1998), for example, increased morbidity and mortality (Hoffman, Rice, & Sung, 1997). Successful adherence is a function of positive attitudes (Blackwell, 1992), an acceptance of the challenges of illness (Erlen & Mellors, 1999), the capacity to incorporate others for support (Erlen & Mellors), and positive self-esteem (MacLean & Lo, 1998).

2.2.1.1 Adherence and Antiretroviral Medications for Women with HIV.

The concept of adherence to medications has a different meaning for each individual. However, for persons with HIV the key to their disease management frequently revolves around their pill-taking regimen. The ability of persons with HIV to achieve adherence to antiretroviral medications thus results in their potential for survival with disease, as well as preventing opportunistic infections such as tuberculosis and preventing treatment failure. Bangsberg

(2006a) stated that the goal of adherence assessment to antiretroviral medications for persons with HIV is to "detect specific levels and specific patterns of adherence that put a patient's particular regimen at risk for resistance" (p. 250).

Medication management of HIV has changed over the last several years. Initially, medications were prescribed early in the diagnosis of the disease (Bova, 2000; Hogg et al., 1998; Mellors et al., 1998; Valenti, 2004). However, this practice was believed to be a contributing factor to increased reports of medication resistance. Medication resistance was also attributed to non-adherence. Poor adherence was often due to the complexity of the regimen, taking medications at inappropriate times or combining medications incorrectly, or patient initiated drug-holidays (planned break) in taking one's medication (Aversa & Kimberlin, 1996), and numerous side effects (Catz, Kelly, Bogart, Benotsch, & McAuliffe, 2000; Hader et al., 2001; Ickovics et al., 2001; de Olalla et al., 2002).

The recent change in antiretroviral medication use that may have the potential for improvement is the change in the dosing regimen, which includes combining of two or three different medications into one pill. These changes have decreased the patient's pill burden but not necessarily the medication side effects (Hawkins, 2004; Portsmouth, Osorio, McCormick, Gazzard, & Moyle, 2005; Yeni et al., 2004). Portsmouth and colleagues (2005) reported an increase in adherence for subjects when their combination-medication regimen was changed from twice daily to once daily (97.7% vs. 99.4% adherence); however, this finding was not clinically significant ($p = 0.2327$). Nor was there a change in control of viremia or CD 4 levels (Portsmouth et al.).

Hawkins (2004) in his review of clinical trials for once vs. twice daily dosing suggested that both a decrease in dosing of antiretroviral medications and a decrease a pill burden resulted

in improved medication adherence. In most studies reviewed in this meta-analysis (Hawkins, 2004), the use of a once-daily regimen did not produce an increase in viremia or medication failure. However, Hawkins (2004) stressed the necessity of individualizing the antiretroviral regimen to best fit the patient's lifestyle and personal needs, and identifying a regimen that fits the experienced patient's preference for medication use.

The guidelines for use of antiretroviral medication were revised in 2002 (Yeni et al., 2002). Following these recommendations, three new medications emerged from clinical trials. This has resulted in further revisions to the guidelines. The revisions take into consideration new information regarding side effects of all antiretrovirals, new information about medication resistance, and suggestions for improved therapeutic strategies for antiretroviral maintenance. The guidelines now focus on four major areas for overall improved antiretroviral medications use, which includes: when to initiate therapy, what antiretroviral medications to use when beginning therapy, when it is appropriate to make changes in therapy, and what changes in the therapeutic regimen best fit the patient's specific needs (Yeni et al., 2004).

Current recommendations for beginning pharmacological treatment are designed to reduce the plasma HIV RNA (viral load) and enhance the recovery potential for CD 4 cells. For patients with advanced disease or those symptomatic with opportunistic illness, therapy is recommended immediately, unless co-administration of medications to treat another illness such as with tuberculosis could potentially be toxic for the patient. This therapy has had an increased success in person's naïve to previous antiretroviral therapy (Yeni et al., 2002, 2004). Antiretroviral medications should begin before the individual has a CD 4 (lymphocyte) below 200 cell/ul (Yeni et al., 2002; 2004). However, research is inconclusive as to what specific parameters for a CD 4 above 200cell/ul will result in success (Yeni et al., 2002; 2004). Also, for

those individuals with a CD 4 greater than 200cell/ul but less than 350 cell/ul beginning antiretroviral medication is based on the patient's symptoms of disease and potential for medication adherence. Individuals with a a CD 4 greater than 350cell/ul but less than 500 cells/ul and a viral load above 100,000 copies should be closely monitored because the CD 4 has been noted to rapidly decrease in the presence of increased viral loads (Yeni et al., 2002, 2004). Research also suggests that women with disease require close observation of their viral load. Even though women may have a CD 4 greater than the 250 to 350 cell/ul, their viral load may be elevated and they may quickly develop disease-related symptoms (Farzadegan et al., 1998; Fletcher et al., 2005; Junghans et al., 1999). In addition, some antiretroviral medications, although effective, are not recommended for women contemplating pregnancy or those who are already pregnant due to the teratogenic effects of the drugs (Yeni et al., 2004).

Prior to beginning any regimen patient centered issues such as other illnesses need to be carefully considered. The provider also needs to be mindful of the potential for issues of patient convenience, their knowledge of the importance of medication adherence, possible food/drug interactions, the potential for tolerability, the individual's possible lifestyle, and their desire to commit to the HIV regimen (Yeni et al., 2004). HIV disease management continues to include a combination of medications. The standard treatment recommendations for initial therapy are: a non-nucleoside reverse transcriptase inhibitor (NNRTI); a protease inhibitor (PI) with Ritonavir; and two-nucleoside reverse transcriptase inhibitors (NRTI). The use of three NRTI is no longer recommended due to ineffective response of the CD 4 and viral load. Likewise, a regimen of four drugs with the addition of a PI is no longer recommended (Yeni et al., 2004).

The patient needs to be monitored carefully for side effects during the first months of therapy and changes to the regimen are often made to produce the best results, decreased viral

load and improved CD 4 with the greatest comfort to the patient. If the patient fails to demonstrate improved CD 4s and a decrease in viral load using the above recommendations, the care provider must carefully evaluate adherence and testing for medication resistance. When resistance testing confirms viral sensitivity to the current therapy then the issue of non-adherence may be the cause of treatment failure. If the issue is resistance, the care providers may consider an alternate regimen (Yeni et al., 2004).

A regimen of antiretroviral medications will be life long and has the potential to result in non-adherence over time (Bova, 2001; Cochran & Wilson, 1999; Mellors et al., 1998; Paterson et al., 2000). Even 5% non-adherence can quickly lead to viral mutation, resistance to current medications, and development of medication resistant strains of the virus (Mellors et al.; Paterson et al.).

Unfortunately, antiretroviral medications have numerous side effects such as chronic diarrhea, hyperlipidemia, abnormal fat distribution and type-2 diabetes, weight changes, fatigue, anemia, and peripheral neuropathy (Bova, 2000, 2001; Cochran & Wilson, 1999). Although some medication combinations have changed to once or twice daily dosing, increasing the potential for adherence, the side effects of these toxic drugs remain a salient concern for the health care provider and the person with HIV disease. Despite the introduction of combination-therapy, patients may continue to take many different medications daily, including antiretrovirals and medications to manage depression, anxiety, diabetes, high blood pressure, hyperlipidemia, and HIV related diseases, such as tuberculosis and Hepatitis C, as well as other opportunistic diseases (Murphy et al., 2000; Yeni et al., 2004). In addition, a regimen may require timing of each medication with and without food for maximum effectiveness (Bova, 2000, 2001; Yeni et al., 2002, 2004.).

The importance of adherence cannot be understated. Lack of knowledge about one's medications may also be a contributing factor to non-adherence. Catz et al. (2000) found that in their study of 72 HIV positive individuals, 18% could not correctly name all of their antiretroviral medications. In addition, 30% of participants could not recall the regimen requirements without cueing (Catz et al.). When patients experience side effects from the medications this can lead to non-adherence. And as the viral load decreases and CD 4 increases, the individual may feel better and adherence may decline (Aversa, Kimberlin, & Segal, 1998; Mellors et al., 1998).

Paterson et al. (2000) found a significant relationship between virologic failure and decreased adherence to participant's antiretroviral regimen. Nieuwkert et al. (2001) in their investigation of antiretroviral medications adherence suggested a significant difference in viral load when patients achieved greater adherence; fully adherent (OR = 1.07; 95% CI, 0.64 - 1.35) and not fully adherent (OR = 0.81; 95% CI, 0.48 - 1.10) (Nieuwkert et al.).

More recent studies suggest treatment failure and increased viremia are not only related to poor adherence but also to drug resistance (Bangsberg et al., 2006b; Bangsberg et al., 2004; Bangsberg et al., 2003, King, Burns, & Kempt 2004; Lange, Perriens, Kuretzher, & Zewdie, 2004; Yeni et al., 2004). In addition, when compared with adherence rates of greater than 90% (Sethi, Celentano, Gange, Moore, & Gallant, 2003) reported that increased viremia (viral rebound) and medication resistance were significantly associated with adherence rates of 70 to 89% (95% CI 1.61-7.20; $p = 0.01$) or less than 70% adherence.

2.2.1.2 Overview Measurement of Adherence.

The assessment of adherence to medications has been approached by both direct and indirect methods. Direct methods include objective assessments, such as the clinician dispensing

the medications and visually observing the individual taking each prescribed medications, and clinical or biological markers and assays, i.e., blood levels of specific medications. Indirect methods include subjective assessments such as self-report via questionnaires or diaries, pill counts, prescription refills, pill identification, clinical outcomes (i.e., CD 4 and viral load), and the use of electronic event monitors (Morse et al., 1991; Paterson et al, 2002; Samet, Sullivan, Traphagen, & Ickovics, 2001).

Patient self-reports are the most frequently used method for assessing medication adherence. Advantages of self-report are that it costs less to administer and requires a shorter time necessary for administration. However, self-report measures can be biased. Regardless of the medication or treatment being measured, patients and study participants are prone to over-or-under report their adherence. Diary data are also biased, with patients and research participants often having difficulty recalling their regimens and activities for longer than 24 hours (Erlen, Sereika, Cook, & Hunt, 2002). The pill count method does not clearly document when or if individuals took their medications, only the number of pills missing from the prescription bottle (Liu et al., 2001; Paterson et al., 2002). There may also be an over-reporting of medications taken. Bangsberg and colleagues (2001) reported 73% adherence using pill count with HIV infected patients. In their investigation of multiple measures of adherence, Liu and colleagues (2001) reported inconsistencies in adherence to antiretroviral medication when subjects used self-report, pill count, and use of the Medication Events Monitoring System (MEMS) cap. Fletcher and colleagues (2005) reported that their self-report measure, the ACTG, reflected a more accurate assessment of subject's antiretroviral use than the daily diary, pill counts, or an electronic measure (MEMS). Simoni and colleagues (2006) suggested self-report measures

especially those in longitudinal studies are a good predictor of subject's adherence, changes in viral load, and the potential need for a medication treatment adjustment.

In a longitudinal cohort study of women, Stone and colleagues (2001) reported an association between adherence and comprehension of correct medication dosing instruction. Adherence was measured using an interview format questionnaire. The questionnaire questioned the type of antiretroviral medication use, how it was prescribed, dosing frequency, and timing with food or beverages. There was a relationship between dose frequency with three or more daily doses and non-adherence (OR = 1.4; 95% CI, 0.9-2.3) and food/empty stomach requirements (OR = 1.5; 95% CI, 0.9-2.6) and three or more daily doses (OR = 1.4, 95% CI, 0.4-4.3). In addition, participants with increased understanding of both medication use instructions and food restrictions had better adherence over the previous 3-day period (OR = 0.6; 95% CI, 0.4-1.0) (Stone et al.).

Erlen and colleagues (2002) refer to the absence of a "gold standard" in the measurement of adherence. However, there has been a movement toward use of electronic measures such as the MEMS. This device has a computer chip embedded in the cap of the medication bottle that records each time the cap is opened; thereby monitoring, in theory, the timing of pill removal. The limitations of the MEMS cap include the lack of quality control to assure that the medication has been taken, the patient requiring specific instructions on the use of the cap, the cost of the cap, the cost of the scanning device for cap data, and the time needed to evaluate patterns of adherence. In addition, it is important that an individual remain in the study and return the MEMS cap for evaluation. The importance placed on returning the MEMS cap cannot be devalued (Paterson et al., 2002).

The use of the MEMS cap had been considered to approach a standardized assessment of adherence (Paterson et al., 2002). However, Samet and associates (2001) suggested when assessing adherence to antiretroviral medications, patient use of the MEMS may not be the "magic bullet" (p. 28) as previously envisioned by researchers. Investigations by others (Bova et al., 2005; Fletcher et al., 2005; Levine et al., 2006) suggest flaws with use of the MEMS cap. Liu and colleagues (2001) reported that the MEMS underestimated subject's adherence to antiretroviral medications. Two additional studies suggested use of the MEMS may not be more accurate in assessing adherence to antiretroviral medications than self-report measures (Fletcher et al., 2005; Samet et al., 2001). Bova and colleagues (2005) in their investigation of adherence and use of the MEMS cap reported numerous pitfalls in using the device. These obstacles included problems with some medications such as use of liquid medication requiring refrigeration and individual issues including delays in refilling the bottle, failure to use the bottle vs. a pill box device, pocket dosing (removal of multiple doses at one time), patient incarceration and hospitalization, and frequent changes in available housing (Bova et al.). The failure of the MEMS to accurately evaluate adherence in Bova and colleagues study was also due to need for multiple medications to be used for control and management of subject's HIV disease as well as personal, social, and environmental dynamics unique to persons with HIV.

Another indirect method of adherence is through pharmacy records. Laine et al., 2000) in their investigation from pharmacy records of 549 HIV-positive women reported that the presence of other chronic diseases in this sample of women was predictive of antiretroviral medication adherence (OR = 0.67; 95% CI, 0.44-1.0).

2.2.1.3 Adherence to Antiretroviral Medications

Successful disease management requires a conscious commitment from the individual being treated as well as a supportive collaborative relationship with family, significant others, and care providers. As stated by Sorenson and colleagues (1998) “adherence reflects an attitude that a patient is empowered by a medication regimen, rather than simply complying with the wishes of medical staff” (p. 297). This section on adherence to antiretroviral medications addresses studies that have examined samples of men only or men and women.

In a sample of 224 (201 men and 23 women) HIV-positive persons taking antiretroviral medications, Nieuwkert and colleagues (2001) reported a significant relationship between taking all medications as directed (correct timing of doses and food/beverage restrictions) and improved viral load (median concentration ratio, 0.81 vs. 1.07; $p = 0.001$). This study used a researcher developed self-report measure of adherence. Participants were divided into fully adherent, taking all medications as required and not fully adherent, not taking all medications on time including with food requirements (Nieuwkert et al., 2001).

Two investigations used the AIDS Clinical Trail Group Assessment (ACTG) self-report measure of adherence. Chesney et al. (2000) reported non-adherence was associated with working outside the home, forgetting to take medications, and pill burden (X^2 [1] = 4.99, $p = 0.03$). Murphy and colleagues (2002) reported improved adherence after 3 months with the intervention group more likely to follow their antiretroviral regimen than controls, $p = 0.06$ (Murphy et al.). A study of 133 HIV-positive persons which was largely male (86%) and white (62%) used a modified self-report measured of adherence to antiretroviral medications from the HCSUS study (Gifford et al. 2000). The researchers reported an association between non-

adherence and one's antiretroviral medication regimen (adjusted OR = 5.3; 95% CI, 2.4-11.8). Adherence for women with disease was not analyzed separately (Gifford et al.).

2.2.1.4 Women with HIV and Adherence to Antiretroviral Medications.

Adherence to antiretroviral therapy in women began to be addressed later than men. Initially when pregnant women tested positive for HIV, the standard recommendation of physicians was to terminate the pregnancy, causing some women to postpone prenatal care until after 24-weeks gestation (Marlink, Kao, & Hsieh, 2001). The 1994 Pediatric AIDS Clinical Trails Group (PACTG) Protocol 076 served to significantly advance the treatment and prevention procedures for women with HIV. By July 1995, the PACTG 076 findings generated U. S. Public Health Service recommendations for universal prenatal HIV-1 counseling; HIV testing for all consenting pregnant women; and the use of a monotherapy (Zidovudine, ZVD) for reduction in perinatal transmission. The tide turned for inclusion of women in clinical trials following a 1997 Food and Drug Administration (FDA) ruling. The ruling revoked previous guidelines that placed restrictions on women of reproductive age from being included in any clinical trials (Marlink et al.). Subsequent epidemiological studies in the USA and France demonstrated a sharp decline in maternal to child, vertical transmission and opened the doors for inclusion of non-pregnant women in clinic trials (Marlink et al.; Shapiro et al., 1999, 2000).

An early study of Zidovudine (ZVD), found women's beliefs about treatment for HIV were influenced by their perceptions that health care is substandard for women in general and for socioeconomically disadvantaged non-white women in particular (Misener & Sowell, 1998). The failure to include minorities and women in clinical trials and related studies can adversely affect health promotion, health intervention strategies, and adherence to antiretroviral medication regimens (Hader et al., 2001).

Besides the failure to include women in clinical trials, research has identified several reasons for the lack of understanding among health care providers regarding women with HIV such as lack of funding and numerous psychosocial, psychological, physiological, and sociodemographic problems, including poverty (Bova, 2001, 2000; Catz, Gore-Felton, & McClure, 2002; Catz et al., 2000; Gardner et al., 2002; Greene et al., 2002; Hudson, Lee, Miramontes, & Portillo, 2001; Lehman-Trzynka & Erlen, 2004; Simoni & Ortiz, 2003).

2.2.1.5 Summary of Women with HIV and Adherence to Antiretroviral Medications.

There is little doubt that adherence to one's medication regimen is important. There remains a gap in the research regarding adherence to antiretroviral medications in women with HIV and AIDS. There is also a gap in studies that investigate factors that may affect antiretroviral medication adherence such as stigma or social support in a sample of women with disease. And, there is limited research that explores adherence among HIV infected women in rural areas of the Northeastern United States. In addition, there are inconsistencies in the measurement of adherence. This investigation used two measures in an attempt to bridge this gap. The study used the self-report ACTG measure for all study participants and the "gold standard" MEMS for a select subsample.

2.2.2 Self-Efficacy

Self-efficacy has been identified as the theoretical framework, as well as a potential mediator of the relationship between the person (a woman with HIV) and her adherence to antiretroviral medications. According to Bandura (1986), perceived self-efficacy affects the individual's current and future behaviors. There is continual change throughout one's life course and in one's

perceived self-efficacy. Success or failure in one's health behaviors is highly influenced by perceived self-efficacy and previous experiences (Bandura, 1997).

2.2.2.1 Self-efficacy and Adherence to Antiretroviral Medications.

An extensive review of computerized databases (CINAHL, Medline, and PsychInfo) identified few research studies focused on self-efficacy and adherence to antiretroviral medications for men and/or for women with HIV.

Catz et al. (2000) examined 63 men and 9 women and their adherence self-efficacy to their antiretroviral treatment. Approximately 82% (59) of the participants were identified as adherent using an adapted 8-item instrument to measure treatment adherence self-efficacy. A paired t-test of adherent versus non-adherent participants suggested increased treatment adherence self-efficacy among adherent individuals [t (70) = 3.32, p = 0.001]. In addition long-term treatment adherence was a significantly related to adherence self-efficacy, X^2 = (5, N = 72) = 15.2, $p < 0.01$ (Catz et al., 2000).

Chesney and colleagues (2000) in a cross-sectional study of 60 men and 15 women reported a significant relationship between adherence and self-efficacy. This study used the AIDS Clinical Trials Group Assessment (ACTG) instrument with items to measure self-efficacy. In this sample, approximately 26 persons (36%) were identified as adherent to their antiretroviral medications. Non-adherent participants were less confident of their ability to take most or all of their medications (Mann-Whitney Z = 2.77, p = 0.006) (Chesney et al.).

Murphy and colleagues (2002) used an investigator-modified measure of self-efficacy from the ACTG measure and investigated adherence at baseline, 7 weeks post intervention, and 3 months following the intervention. Study participants included 29 men and 4 women. Those

subjects randomized to the intervention group demonstrated improved adherence from baseline to the 3-month follow-up period, t (31) = 2.13, p = 0.04. Subjects that demonstrated improved self-efficacy were more willing to continue antiretroviral medications despite negative responses from family and friends, t (31) = -2.10, p = .04, and reported the ability to better communicate problems with their medications to clinic personnel, t (31) =-2.13, p = 0.04 (Murphy et al.).

A study of 133 HIV-positive persons, 86% male and 62% white, reported an association between non-adherence and one's antiretroviral medication regimen (adjusted OR = 5.3; 95% CI, 2.4-11.8) and between non-adherence and self-efficacy for use of HIV medications (adjusted OR = 9.0; 95% CI, 1.8-45.3). The study used a modified self-report measure of adherence to antiretroviral medications from the HCSUS study (Gifford et al., 2000). Reynolds and colleagues (2004) also reported that improved confidence in one's ability to take their antiretroviral medications was related to more adherent behaviors. In this investigation of adherence self-efficacy for 325 men and women adherence was reported at 89% (Reynolds et al.).

A study of 136 Chinese men investigated self-efficacy as a predictor of adherence (Molassiotis et al., 2002). Using a stepwise regression for the overall model, self-efficacy was a significant predictor of adherence (Beta = 0.47, p = 0.002). This study used a translated version of the ACTG self-efficacy measure. Gifford et al. (2000) reported in their study of 133 subjects a significant relationship between non-adherence and self-efficacy for use of HIV medications (adjusted OR = 9.0; 95% CI, 1.8 - 45.3).

2.2.2.2 Women with HIV: Self-efficacy and Adherence to Antiretroviral Medications.

Kalichman et al. (2001) in their investigation of 72 HIV-positive women reported that increased antiretroviral medication adherence was significantly related to increased self-efficacy,

t (70) = 2.4, $p < 0.02$. Gifford and colleagues (1996) investigated behavioral skills self-efficacy using a 7-item instrument. The 39 women identified as "good adherers" also had significant differences in four of the seven self-efficacy items: medication schedule (t [70] = 2.8, $p < 0.01$), following one's medications schedule when changes occur in their daily routine, (t [70] = 2.3, $p < 0.02$), following their medication schedule when not feeling well (t [70] = 2.6, $p < 0.01$), and taking medications even if it interfered with one's day (t [70] = 2.1, $p = 0.01$) (Kalichman et al.). A study of 56 minority women reported a significant relationship between adherence and self-efficacy and a decrease in viral load ($r = -0.275$, $p < 0.05$) (Ironson et al., 2005).

2.2.2.3 Summary of Self-Efficacy and Adherence to Antiretroviral Medications.

Despite the limited research focusing on self-efficacy and self-reported adherence to antiretroviral medications, there is some emerging recognition of this relationship. Bandura (1986) acknowledges that perceived self-efficacy influences one's successes and failures when attempting new behaviors. The research focusing on studies of HIV/AIDS patients suggests that perceived self-efficacy affects one's confidence and ability to achieve adherence to antiretroviral medications. Few of the studies reviewed exclusively focused on women with disease. Therefore, at this juncture in HIV and AIDS research investigating the potential relationship between perceived self-efficacy and antiretroviral medications for women with this disease is important.

2.3 PREDICTORS OF ADHERENCE AMONG WOMEN WITH HIV/AIDS

2.3.1 Socioeconomic Factors

Socioeconomic status, poverty, and limited education have been identified as having an influence on adherence to antiretroviral medications for persons with HIV. Leenarts (1998) addresses these issues for white women. Moneyham and colleagues (2000), and Catz, Gore-Felton, and McClure (2002) discuss these issues for minority Black women. Simoni and Ortiz (2003) highlight these issues as well as the cultural dynamics for Latina women living in urban areas. These researchers and others (Bova, 2001; Gardner et al., 2002; Hudson et al., 2001) have found poverty (lower socioeconomic status) to be associated with receiving care or not receiving care, with care providers believing poor women are unable to maintain self-care, and unable to follow HIV medications adherence guidelines (Catz et al., 2000; Greene et al., 2002; Marlink et al., 2001). In addition, Hudson and colleagues (2001) found that limited economic resources contributed to women's psychological distress and ability to manage disease or medication related symptoms.

Simoni and Ortiz (2003) in their qualitative study discussed the issues of Puerto Rican women relocating to the USA mainland and the socioeconomic difficulties they may experience due to language barrier issues, discrimination, and poverty. Likewise, Gardner et al. (2002) reported the disparity of care for impoverished women with HIV. These researchers found a relationship between having insurance (OR= 0.14; 95% CI, 0.04-0.5), less than an eighth-grade education (OR = 0.3, 95% CI, 0.1- 1.1), history or present illegal drug use (OR = 0.4; 95% CI, 0.1–0.95), and depressive symptoms (OR = 2.8, 95% CI, 1.3-6.2). Women having Medicaid were more likely to receive care from an HIV specialist (OR = 2.1; 95% CI, 0.7- 6.5). Women without insurance or those having private insurance that did not reimburse for a specialist did not

receive care from a HIV specialist. Those women not receiving HIV specialist care were also less likely to be receiving antiretroviral therapy and to have abnormal clinical markers; increased viral load and decreased CD 4 ($p = 0.009$) (Gardner et al.).

Greene and colleagues (2002) in their essay address various sociocultural, interpersonal, temporal, and situational contexts that influence HIV-positive women's relationships and abilities to manage their disease. The authors reported that cultural and gender norms, social roles and sexual issues, life-stage development, and the impact of one's environment contributed to the socioeconomic struggles of women with HIV (Greene et al.).

2.3.1.1 Socioeconomic Factors and Adherence to Antiretroviral Medications.

In a study of 85 men and 53 women, Kalichman et al. (1999) reported that low-literacy, less than 12 years of education (49% of the subjects) was associated with decreased adherence (X^2. 1,138; 4.99; $p = 0.05$). Another study of 52 men and 20 women found disease severity ($F = 7.72$, $p = 0.007$), lack of appropriate education on medication use (i.e., doctor's instructions) (Beta = - 0.33, $t = -2.69$, $p = 0.009$), insurance benefits and belief in the effectiveness of the medications (medication efficacy) (Beta = 0.36; $t = 2.92$, $p < 0.01$) were associated with decreased adherence (Gao, Nau, Rosenbluth, Scott, & Woodward, 2000). For this study, the final regression model showed that insurance benefits, medication efficacy, and education on medication use were significant predictors of HIV antiretroviral non-adherence, ($F = 8.00$, $p < 0.001$) (Gao et al.). Reynolds et al. (2004) in their study of 325 men and women with HIV reported that improved adherence to antiretroviral medications were associated with achieving a better education ($p = <. 007$) and being older ($p < .0001$).

Murphy and colleagues (2004) reported that older subjects were also more adherent to their antiretroviral medications. In this culturally diverse sample of 115 men and women using a

modified version of the ACTG for a 3-day recall of antiretroviral medication use, increased age was significantly associated with improved adherence (Wald Chi-sq. = 8.32; OR = 1.12 (95% CI, 1.04 -1.22) (Murphy et al.). Other studies reported that improved adherence was related to being younger in age (O.R. = 2.47 (1.46-4.16, 95% C.I.; p = .001) (Ammassari et al., 2001; Stone et al., 2001). Kleebeerger and colleagues (2001) in their multi-centered study of 5,622 men with HIV reported a significant relationship between non-adherence and an income of less than $50,000 (OR = 2.6; 95% C.I.; p = .001) and African-American ethnicity (OR = 2.2; 95% C.I.; p = .005). Gifford and colleagues (2000) reported an association between non-adherence and ethnicity (African-American) (adjusted OR = 0.4; 95% CI, 0.2 – 1.0, $p < 0.05$). The Ammassari et al. (2001) study of 358 Italian men and women also reported that non-adherence was significantly associated with unemployment (O.R. 3.29 (1.92-5.65, 95% C.I.; $p < .001$).

Using an interview format, Wilson and colleagues (2002) reported a significant relationship between adherence and age, drug use, viral load, and health perception ($X^2 = 55.4$; $p < .01$). However, they did not have a sufficient number of women to analyze those data separately. The regression model showed that less than 9% adherence was associated with a participant being younger (OR = 1.60; 95% CI, 1.30- 2.17, $p < 0.01$) and having a viral load at detectable levels (OR = 2.00; 95% CI, 1.37 –2.94, $p < 0.01$) (Wilson et al.)

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Murphy and colleagues (2004) reported that older subjects were also more adherent to their antiretroviral medications. In this culturally diverse sample of 115 men and women using a modified version of the ACTG for a 3-day recall of antiretroviral medication use, increased age was significantly associated with improved adherence (Wald Chi-sq. = 8.32; OR = 1.12 (95% CI, 1.04 -1.22) (Murphy et al.). Other studies reported that improved adherence was related to being younger in age (O.R. = 2.47 (1.46-4.16, 95% C.I.; $p = .001$) (Ammassari et al., 2001; Stone et al., 2001). Kleebeerger and colleagues (2001) in their multi-centered study of 5,622 men with HIV reported a significant relationship between non-adherence and an income of less than $50,000 (OR = 2.6; 95% C.I.; $p = .001$) and African-American ethnicity (OR = 2.2; 95% C.I.; $p = .005$). Gifford and colleagues (2000) reported an association between non-adherence and ethnicity

(African-American) (adjusted OR = 0.4; 95% CI, 0.2 – 1.0, $p < 0.05$). The Ammassari et al. (2001) study of 358 Italian men and women also reported that non-adherence was significantly associated with unemployment (O.R. 3.29 (1.92-5.65, 95% C.I.; $p < .001$).

Using an interview format, Wilson and colleagues (2002) reported a significant relationship between adherence and age, drug use, viral load, and health perception ($X^2 = 55.4$; $p < .01$). However, they did not have a sufficient number of women to analyze those data separately. The regression model showed that less than 9% adherence was associated with a participant being younger (OR = 1.60; 95% CI, 1.30- 2.17, $p < 0.01$) and having a viral load at detectable levels (OR = 2.00; 95% CI, 1.37 –2.94, $p < 0.01$) (Wilson et al.).

2.3.1.3 Summary of Socioeconomic Factors and Adherence to Antiretroviral Medications.

The burden of chronic disease can contribute to a decrease in one's financial resources. Also one's socioeconomic status may contribute to poor disease management and living with HIV (Ammassari et al., 2001; Kleebeerger et al., 2001; Stone et al., 2001). Poverty, less educational opportunities, and dissatisfaction with one's life may be contributing factors in risk taking behaviors. Age has also been identified in some investigations as being a factor contributing to one's non-adherence but the results are inconclusive as to whether the younger or the older person is more likely be adherent. Perhaps the Greene et al. (2000) article best summarizes the plight of marginalized women and their risk for, as well as their struggle with HIV disease. HIV disease knows no boundaries. It, unlike sickle cell disease, is not restricted to a specific racial/ethnic group. However, the proportion of Black and Latino men and women diagnosed with HIV is higher than the proportion among white men and women (CDC, 2000, 2006). Research suggests one's environment: lack of education, poverty, and gender may make

living with HIV disease more complex. However, those findings cannot be generalized as to the degree these factors affect one's adherence to antiretroviral medications (Bova, 2000, 2001; Catz et al., 2002; Catz et al., 2000; Gao et al., 2000; Greene et al., 2002; Hudson et al., 2001; Kalichman et al., 1999; Simoni & Ortiz, 2003).

Transportation, prejudice, limited employment opportunities and workplace discrimination, low wages, and poor working conditions may contribute to financial issues for women with HIV living in rural areas (Lehman-Trzynka & Erlen, 2004). In addition, all of the above may be issues that limit women's resources to health care (Lehman-Trzynka & Erlen, 2004). Heckman and colleagues (1998) reported that lack of knowledge about HIV among health care providers, inaccessibility to appropriate services, and late diagnosis and delayed entry into treatment were more common among rural women with HIV. The above studies suggest that the result of the impact of various socioeconomic variables on adherence to antiretroviral medications among women is inconclusive.

2.4 PSYCHOLOGICAL PREDICTORS OF ADHERENCE AMONG WOMEN WITH HIV

2.4.1 Depressive Symptomatology

The advent and introduction of antiretroviral medications has placed HIV in the category of a chronic disorder. However, this chronic disease has multiple dynamic issues that perhaps makes living with the HIV more burdensome than living with many other chronic disorders (Greene et al., 2002; Jones, Beach, Forehand, & group, 2001). HIV is frequently accompanied with the co-

morbid condition of depression, which has an impact on the individual's behavior, mood, and ability to address and manage life expectations and navigate medication use (National Institute of Mental Health [NIMH], 1999).

Depression is often a manifestation associated with ineffective coping from life situations, other diseases, and/or poor adaptation in living with chronic disease (Cabaj, 1996; Katon, 2000; NIMH, 1999). The NIMH has identified the diagnosis of depression as a primary co-morbid disorder and as the number one disease management problem in the USA (NIMH). Estimates are that approximately 19 million people in the USA suffer from some form of depression (NIMH). Depression is diagnosed correctly only 50% of the time; less than half of those persons receive appropriate medication and only 10% receive psychotherapy (Katon, 2000). There are however no estimates of the percentage of persons with HIV who have the co-morbidity of depression.

Depression is a psychological entity that is treatable if diagnosed and properly managed with psychotherapy, counseling, medications, and often lifestyle changes. The symptoms associated with depression are often confused with other disease pathology and left untreated (Cabaj, 1996; Katon, 2000; NIMH, 1999). This investigation used depressive symptomatology over the previous two weeks as defined by The Center for Epidemiological Studies-Depression Scale (CES-D) (Radloff, 1977). The Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) classification of depression (APA, 1994) includes the presence of a "depressed mood" for the majority of the day over a period of two years with a report of at least two of the following symptoms: feelings of hopelessness, inability to concentrate or make decisions, poor self-esteem, decreased energy or fatigue, sleep disorders, and appetite changes (APA, 1994). The

reader is referred to the DSM-IV for additional information of the classifications of depression and its various disorders in specific domains (APA, 1994).

2.4.1.1 Depressive Symptomatology and Adherence to Antiretroviral Medications.

HIV research has established associations between the individual being diagnosed with HIV and depressive symptomatology (Ickovics et al., 2001) and adherence to medications (Catz et al., 2000; Singh et al., 1996). Several investigations have addressed depressive symptomatology among men and women with HIV (Nott et al., 1995; Singh et al., 1996; Ickovics et al., 2001; Jones, Beach, Forehand, & Group, 2001; Laine et al. 2000; Morrison et al., 2002; Simoni and Ortiz, 2003). Morrison and colleagues (2002) discussed the co-morbidity of depressive symptoms in women with disease and failure to take antiretroviral medications; however, adherence was not assessed in this study. Tostes, Chalub, and Botega (2004) reported that of the 76 HIV-positive women in their investigation almost all study participants had symptoms of psychiatric problems and/or mental health issues and were not receiving any health care to address this co-mobility.

Singh and colleagues (1996) used the Profile of Mood States (POMS) in an early investigation of men with HIV and found an association between adherence and increased depression (M = 14.2 vs. M = 22.1, p = 0.04), decline in CD 4 (59% vs.41%, $p < 0.25$), and increased mortality (18% vs. 50%, p = 0.12). Simoni and Ortiz (2003) reported that in a sample of 12 Latina women depressive symptomatology was highly correlated with low self-esteem, cultural influences, education, and mastery of one's life; the mean CES-D score was 22.75 (SD = 12.34) approximately four times greater than community dwelling adults.

Catz and colleagues (2000) in their research of HIV positive men and women compared CES-D scores between adherent and non-adherent participants (M = 17.39, SD = 12.48 vs. M = 27.38, SD = 16.31; t [70] = 2.47, p = .016). Kalichman et al. (1999) also used the CES-D in a study of men and women and found that depressive symptomatology was significantly related to nonadherence (OR = 4.1; 95% CI, 1.6 -10.5). The participants' CES-D depression score were not analyzed according to gender.

Reynolds et al. (2004) used a modified 7-item CES-D measure to assess depressive symptomatology and the ACTG as the measure of adherence in their study of 325 subjects, 181 women. Approximately one-half of the subjects had a "fairly high prevalence of depressive symptomatology" (p. 144). A standard mean for this measure was not available due to the author's modification of items on the CES-D and changes in scoring. In this study depressive symptomatology was a statistically significant predictor for nonadherence (r = .33, p < .001) (Reynolds et al.). Mannheim and colleagues (2005) did not assess the relationship of depressive symptoms and adherence but reported in their study of 412 men and 102 women an improved mental health score (using the SF-12) for 100% adherent vs. non-adherent subjects (45.8 vs. 42.0; p < 0.005) over the 12 months of their investigation.

2.4.1.2 Depressive Symptomatology and Adherence to Antiretroviral Medications for Women with HIV.

A retrospective chart audit of 549 pregnant HIV-positive women found 22% of study participants were treated for depression (Laine et al., 2000). Research also suggests a connection between increased depressive symptomatology and use of protease inhibitor medications (Morrison et al., 2002). Seropositive women had significantly more depressive symptomatology,

as compared to the seronegative study participants (47% vs. 38.7%, $p = 0.05$). For women taking protease inhibitors their mean Hamilton Depression Scale scores were $M = 10.6$, $SD = 9.1$, while women taking other antiretroviral medications had lower scores ($M = 7.8$, $SD = 7.3$). However, this difference was not statistically significant (t (91) = 1.6, $p = 0.10$; Beta = 2.8, 95% CI, 0.6-6.2). Adherence to the antiretroviral medication as a co-variate for increased depression was not explored in this study (Morrison et al.).

Using the CES-D as a measure of depressive symptomatology in a large cohort study of 765 women with HIV, Ickovics and colleagues (2001) suggested that the higher classification of depression [chronic ($M = -0.35$, $SD = 0.54$), intermittent ($M = -0.27$, SD = 0.60), or limited without symptoms ($M = -0.13$, $SD = 0.60$)] was related to changes in clinical indicators and disease progression. Based on levels of depression (Standardized Beta = -0.14, $p < 0.001$), the results suggested an association between declines in CD 4 (Beta = -0.12, $p < 0.001$) and increased mortality for participants with viral loads greater than 10,000 copies (48%, 31%, and 21%) respectively by depression classifications. In the final model, women with CD 4s less than 200ml/ul and increased viral loads were significantly related to increased mortality F (2, 111) = 5.0; $p = 0.009$). The authors did not assess adherence to antiretroviral medications; however, 375 (49%) of the women were prescribed and taking antiretroviral mediations. For this study, adherence to antiretroviral medications was documented through improved clinical markers (Ickovics et al.).

Catz and colleagues (2002) in a study of 100 HIV-positive minority and low- income women assessed depressive symptoms, physiological distress, coping styles, stressors, and perceived social support. When fit into the multivariate regression model less social support, avoidance coping, less problem solving, and increased stressors contributed to increased

depressive symptoms (R^2 = .46, F [7,89] = 10.04, p < 0.001) (Catz et al.). The CES-D mean score was extremely high (M = 24.9, SD = 12.5) with 75% of the women scoring in the range of mild to severe depression; half (n = 56) of the women had scores suggestive of major depression.

A study that investigated 118 women with HIV reported only 29% were adherent o their antiretroviral regimen (Murphy et al., 2000). The researchers found that, depressed subjects were less likely to be adherent, X^2= 11.8; OR = 0.3, p < 0.03 (Murphy et al.). Phillips and colleagues (2005a) investigated sleep disturbance, depressive symptomatology, and adherence to antiretroviral medications in 173 women with HIV. Adherence was measured by the ACTG and depressive symptomatology by the CES-D. The mean CES-D score for this sample was 24.1. In the last 3 months, 70% (121) of the women reported being nonadherent to their antiretroviral medications; 35% (61) reported missing at least one of their medications in the last 30-days. Women with severe depression (M = 1.8 $\pm$ 3.9) were less adherent than those women with moderate depression (M = 6.1 $\pm$ 10.1; (t, = 123) = df -3.8, p = 0.0002). Women with severe depression were also more likely to miss medications due to falling asleep, reported difficulty taking medications as prescribed such as with meals or on an empty stomach, and reported feeling ill from taking the medications. The authors predicted the mediating effect of sleep quality on depressive symptoms and reported that sleep quality significantly predicted depressive symptoms (p < 0.0001) and adherence, (p < 0. 0001). Depressive symptoms were the most significant predictor of women's adherence (p = .032) (Phillips et al., 2005a).

2.4.1.3 Summary of Depressive Symptomatology and Adherence to Antiretroviral Medications.

Research suggests depressive symptomatology and one's mental health influences an individual's ability to cope with disease and focus on managing one's life, as well as adherence to antiretroviral medications. This issue of depressive symptomatology and antiretroviral medication adherence for women with HIV has not been fully explored. Therefore, it is important that research continues to investigate the potential relationship between depressive symptomatology and adherence to antiretroviral medications in all persons with disease. Research is needed to clarify how depressive symptomatology affects women with HIV because they often must manage the lives of others, including children.

2.4.2 Social Support and HIV

Social support can come from many sources such as the provider-patient relationship, family, significant others, peers, and networks within one's community. All of these sources may be instrumental in a person's ability to continue with a new and/or complicated long-term treatment (Erlen & Mellors, 1999; Mellors, Riley, & Erlen, 1997; Misener & Sowell, 1998). Almost from the beginning of this disease, there was a tendency to blame the victim. In the early 1980s before HIV was identified, there was discrimination against men with gay related immunodeficiency disorder (GRID) and/or the related diseases (Shilts, 1987). Historical research on HIV underscores the importance of social support for gay males with HIV. These men networked and formed strong social and political organizations such as ACT UP (AIDS Coalition to Unleash Power; www.actupny.org) to study every aspect of the disease (Shilts.). ACT UP and other social support networks were largely responsible for changing the direction of HIV/AIDS research

leading to improved HIV disease management (Greene et al., 2002; Oppenheimer, 1988; Patton, 1987; Shilts.). These same networks also allowed gay males to have the types of relationships needed to sustain the difficult times in managing and living with HIV/AIDS. Unfortunately, women lack these types of social networks. Thus, women must negotiate personal issues such as social support, stigma, and other psychological issues alone or with minimal social support (Greene et al.; Patton; Treichler, 1988.).

There are investigations, many with men or men and women that address the importance of social support from many sources and the individual's physical well-being, depression, coping ability, and improved health. Nott, Vedhara, and Power (1995) reported that social support from others outside the family including male-partner support and best friend support was important. However, for this sample of gay men, family members were more important than friend support; fathers were the poorest source of support (Nott, Vedhara, & Power). Other researchers have also reported the importance of friend and family support, which played a key role in managing the disease (Serovich, Brucker, & Kimberly, 2000; Derlega, Winisead, Oldfield, & Barbee, 2002). Murphy and colleague's study (2002) also found that family, friends and children were the greatest sources of social support; medication cueing (38%) was shown to be the most frequent type of support. This study included 560 men and 44 women with disease.

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Participants in the Erlen and Mellors (1999) study of men and women described a supportive relationship with care providers as important in their decision to begin antiretroviral medications. Likewise, mistrust of one's physician (OR = 0.21, 95% CI 0.074 –0.57) and feeling socially isolated (OR = 1.92, 95% CI 1.14-3.24) were predictors of subjects' not taking antiretroviral medications (Schroeder et al., 2001).

Eleven (73%) of the 15 HIV-positive Black women in a qualitative study identified their physician as being the most influential factor in their decision to take antiretroviral medications as prescribed (Sankar, Luborsky, Schuman,& Roberts, 2002). Women in another qualitative investigation identified the continued support of their health care providers as important (Metcalfe et al., 1998). However, these women felt a greater need for peer support from other women with disease (Metcalfe et al.). The women also identified a greater need for more social support from community agencies to cope with the unique struggles they had in managing their children, their lives, and their HIV disease. Yet women in another study reported their greatest and most important form of support from informal family (kin) networks; parents, spouses or significant other, and children (Ciamborone, 2002).

Research on impoverished inner-city women with HIV showed that a lack of social support and social isolation contributed to participants' psychological distress (Hudson et al., 2001). In this study, perceived tangible social support was significantly associated with HIV-

positive women's emotional and disease related distress (F [7, 61]; p = 042) and explained 14% of the variance in the regression model (Hudson et al.).

Misener and Sowell (1998) found that woman's negative attitudes regarding medications for HIV were influenced by lack of information from providers, mistrust in the medical and social service agencies, and poor reinforcement from family and friends. Martinez et al. (2000) also found that poor social support from providers and others (family and/or peers) influenced adherence in inner city young adults and adolescent males and females. Ciambrone (2002) also addressed poor (negative) social support from family, friends, and children "invalidating the illness" (p. 888).

Bova's (2001) study of 101 HIV-positive Black, Latina, and white women showed that social support did not influence disease adjustment or symptoms; however, appraisal of illness appeared to act as a mediator of social support, disease adjustment, and symptom experience. African American women reported better perceived social support (F = 5.35, df = 2, p < 0.01) and fewer HIV symptoms (F = 5.02, df = 2, p < .01), including less pain (F = 3.66, df = 2, p < .05) and a more positive appraisal (F = 7.13, df = 2, p < .01) than did their white and Latina cohorts (Bova).

Likewise, women participating in a qualitative study felt they lacked social support due to their failure to disclose their disease status (Johnston-Roberts & Mann, 2000). For the women in this study limited access to friend networks was due to other responsibilities, particularly childcare (Johnston-Robert & Mann, 2000). One participant in the research described the absence of social support resources as "being placed in an emotional prison" (p. 380). Black and Miles (2002) in their qualitative investigation of women with HIV reported that it was the desire

for social support from family and friends that led some of the women to disclose their HIV status despite the perceived stigma of HIV disease.

Simoni and Cooperman (2000) investigated social support among 373 ethnically diverse inner-city women. The researchers found improved social support had a buffering effect on depressive symptomatology (R^2 = -0.17, $p < 0.001$) and physical well-being (R^2 = .11, $p < 0.05$). In addition, there was a difference between perceived social support among the women. In this study, lesbian women reported greater perceived social support than their heterosexual cohorts (R^2 = 0.11, $p < 0.05$).

2.4.2.1 Social Support and Adherence to Antiretroviral Medications.

A study of 63 men and 9 women showed that there was a significant relationship between adherence and decreased perceived social support (t [70] = 2.63; p = 0.011), increased depressive symptomatology (t [70] = 2.47; p = 0.16), less adherence self-efficacy (t [70] = 3.32; p = 0.001), and more medication side effects (t [70] = 2.15; p = .035) (Catz et al., 2000). The most significant independent predictors of adherence were social support and adherence self-efficacy. For each decrease in the standard deviation for perceived social support, participants were more than twice as likely to have reported missed doses of antiretroviral medication (OR = 2.27; 95% CI, 1.04 - 4.96) (Catz et al.).

Power et al. (2003) reported 74% of 39 men and 34 women were 100% adherent to their antiretroviral medications. And having a satisfactory relationship or support from one's partner was statistically significant with improved adherence to antiretroviral medications (Beta = 0.113, p = 0.040) (Power et al., 2003). Support from friends and family was not statistically related to improved adherence.

A study of 39 female and 19 male urban inner-city Blacks and Latinos, demonstrated that poor social support was significantly associated with non-adherence (Beta = 0.24, p = 0.04) (Simoni, Frick, Lockhart, & Liebovitz, (2002). However, in the final regression model, social support was not statistically significant when integrated with social support and self-efficacy (Beta = -.32, p = 0.04) and self-efficacy and poor adherence (Beta = -0.49, p < 0.01). The authors identified social support as having a mediating effect on adherence (Simoni et al.).

Simoni, Frick and Haung (2006) recently explored the potential mediating effect of social support on adherence to antiretroviral medications. They followed 75 men and 61 women were for a period of 6 months. Using modified structure equation modeling there were statistically significant paths for social support, negative affect, greater spirituality, self-efficacy to adhere, adherence at 3 months, and viral load at 6 months [X^2 (113, N = 136) = 152.78, p = .008, CFI = .95, TLI = .94, RMSEA = .05 (.03, .07)]. There was no direct relationship between social support and adherence. There was an indirect relationship for adherence and social support through negativity (Beta = -.422, p <. 001), spirituality (Beta = .53, p < .01), self-efficacy (Beta = .40, p < .001), and negative affect (Beta = -.26, p < .01). In addition, using this model explained the 8% of the variance for adherence after 3 months and 8% of the variance in the viral load (Simoni Et al.). The authors suggest that interventions to increase and maintain social support for persons with HIV and taking medications might improve their self-efficacy to adhere, spirituality, decrease their negativity, and thus, result in better adherence (Simoni et al., 2006).

2.4.2.2 Social Support and Adherence to Antiretroviral Medications fo Women with HIV.

Gardner et al. (2002) reported a relationship between increased support from HIV specialist care providers and more education about medication use and better medication

adherence (relative risk [RR] = 2.4; 95% CI, 1.3 - 4.6). The relationship did not exist for women in the study receiving care from a generalist. In another study, the support and positive reinforcement of an HIV specialist contributed to women accepting antiretroviral treatment (OR = 2.8; 95% CI, 1.0 - 7.5) and improved clinical indictors, specifically an improved CD 4 and lower viral load (OR = 1.4; 95% CI, 0.5 - 4.0) (Mostashari, Riley, Selwyn, & Altice, 1998). Findings from a qualitative study with 20 ethnically diverse women showed a relationship between positive social support and improved adherence to antiretroviral medications in women with HIV (Johnston-Roberts & Mann, 2000).

The type of social support received and from whom also appears to impact women's decisions to take antiretroviral medications and their adherence to the regimen (Misener & Sowell, 1998). Results from a study of 24 HIV-positive women demonstrated a relationship between perceived family support and fewer depressive symptoms (r = -0.560; $p < 0.01$), anxiety (r = -0.455; $p < 0.05$), stress (r = -0.731; $p < 0.01$), and feelings of loneliness (r = -0.748; $p < 0.001$) (Serovich, Kimberly, Mosack & Lewis, 2001). Although support from friends was important, it was the perception of the sustaining support from family members that had a greater impact on mental health for this sample of women with HIV (Serovich et al.). However, other researchers failed to find a relationship between social support and/or social networks and adherence to antiretroviral medications for adolescent females with HIV (Murphy et al., 2000). The authors explained that these phenomena might be related to the increased sociability during this time in adolescent development and/or other adherence behaviors.

2.4.2.3 Summary of Social Support and Adherence to Antiretroviral Medications.

Research suggests that positive as well as negative social support and interaction influences one's perception of their disease and consequent life stressors such as depressive symptomatology. In addition, some research suggests from whom the social support comes (i.e., family, friends, or physician) and the amount of social support provided may affect one's adherence to their antiretroviral regimen.

There is little research that has specifically reported a relationship between social support and adherence to antiretroviral medications for women with HIV. There is anecdotal evidence, such as in the Misener and Sowell (1998) study, to suggest social support has an affect on the use of antiretroviral medications. Therefore, there is a need to examine the potential affect social support may have on women taking antiretroviral medications and achieving optimal, 95% adherence to these medications.

2.4.3 Perceived Stigma and HIV

Stigma comes from the Greek language and is associated with the tattoo and mark of shame or disgrace (Goffman, 1996). Social interaction occurs between persons who perceive themselves as normal (the unstigmatized) and the non-normal (the stigmatized). The stigmatized are labeled and/or identified as flawed, undesirable, and morally corrupt. Thus, a diagnosis of HIV is potentially stigmatizing, as it often labels the woman as unworthy, prejudges her moral values and lifestyle, and devalues her as a mother, sister, and wife (Leenarts, 1998). Disclosure of one's disease to others is often regulated by the perceived stigma attached to a diagnosis of HIV (Greene et al., 2002). In fact, Greene and colleagues suggested that the perceived stigma

associated with HIV might play a pivotal role in delayed testing for disease and seeking health care.

Perceived stigma occurs because of how the disease was acquired through sexual contact or IDU and by being diagnosed as HIV-positive. There is no doubt that from the time the new gay related immune disease (GRID) was recognized, there was a stigma attached to how the disease was acquired and who were affected; gay males and drug users (Crandall & Coleman, 1992; Oppenheimer, 1988; Shilts, 1987). Crandall and Coleman address the perceived and actual stigma and discrimination associated with GRID and/or HIV. This early study of 40 men and 8 women reported perceived stigma was highly correlated with depression, negative affect, distrust of others, and anxiety about their disease. In addition, the study reported an association between loss of social support due to the associated perceived stigma of the HIV diagnosis; however, the researchers did not analyze the variable separately for women.

Bunting (1996) acknowledged that women with HIV are often stigmatized because of their sexuality, gender, minority status, poor socioeconomic status, and the diagnosis of their disease. Women with HIV are blamed for their disease, which enables those without disease to place themselves on a higher moral plain (Bunting.). Women with HIV fear prejudice and discrimination and perceive a risk that includes losing custody of one's children if their disease status is known (Simoni & Ortiz, 2003).

Black and Miles (2002) in their qualitative research of perceived stigma identified three patterns of disclosers of women with HIV: secretive, selective, and full-disclosers. Each category presented the women with both risks and benefits of revealing their HIV-positive status. Secretive-disclosers usually concealed their HIV status from all but one or two trusted individuals, usually a partner/husband or mother like-figure. For this category, the fear of

shunning and the resulting consequence often resulted in feelings of anger, isolation, and loss of social relationships. Selective-disclosers expanded their network of others aware of their diagnosis on a "needs to know basis" (p. 693). Women in this category closely linked their disclosure choice to their need for increased social support (child-care or transportations to health care service) versus a willingness to risk the perceived stigma associated with HIV. Only three of the 48 women in the study were identified as full-disclosers. Each of these women identified a different reason for fully disclosing their disease status but all withheld the information from their children. This latter group appeared able to withstand the perceived stigma associated with the disease for themselves but did not want the effects of stigma transferred to their children (Black & Miles).

A qualitative study of eight HIV-positive women reported that aside from the trauma of learning their diagnosis, all participants expressed unknown fear of societal reactions to women with HIV (Metcalfe et al., 1998). However, the greatest fear for these women did not focus around their diagnosis of disease but the uncertain implications their disease would have for their children and the resulting stigmatization associated with their HIV disease.

Berger and colleagues (2001) used the HIV Stigma Scale with a sample of 310 men (80.6%) and women (19.4%) and reported Pearson r correlations between stigma and low self-esteem (r = -.60, p < .001), depressive symptomatology using the CES-D (r = .63, p < .001), social support (r = .54, p < .001), and social conflict (r = .59, p < .001). In addition, stigma as related to negative self image was negatively correlated with low self esteem (r = -.68), depressive symptomatology (r = - .66), and subjective social interaction (r = -.62) (Berger, Ferrans, & Lashley).

2.4.3.1 Perceived Stigma and Adherence to Antiretroviral Medications.

There were no investigations assessing perceived stigma or stigma and any direct relationship of stigma on one's self-reported adherence to antiretroviral medications for either men or women with disease following an extensive search of Medline, Pub Med, CINAHL, and Psych Info. There were several publications that addressed stigma such as: disclosure and antiretroviral medication use (Klitzman et al., 2004), coping, disclosure and women's use of antiretroviral medications (Siegel & Schrimshaw, 2005), stigma and depression(Abel, Rew, Gortner, & Delville, 2003), disease associated stigma and use of medications and reports of non-adherence related to stigma (Schrimshaw & Siegel, 2003).

2.4.3.2 Summary of Perceived Stigma and Adherence to Antiretroviral Medications.

The above articles briefly review the importance of perceived stigma in living with and managing one's HIV disease. The stigmatizing impact of HIV is not in question. There is sufficient research that addresses the perceived stigma of a diagnosis of HIV. For many persons with HIV, particularly women, they must also struggle with the perceived stigma of poverty, race, poor education, single parenting, and limited opportunities for themselves and their children. Most research that addresses the perceived stigma attached with HIV has been of a qualitative nature. The Berger et al. study (2001), although extensive and diverse, does not explore the issue for a large sample of women. Moreover, there is little research investigating the relationship between perceived stigma and adherence to antiretroviral medications in women with HIV.

2.5 PSYCHOLOGCIAL PREDICTORS OF ADHERENCE TO ANTIRETROVIRAL MEDICATONS

As shown in the framework for this study, four concepts of physiological predictors will be examined. The first two, CD 4s and viral load and their significance and relationship to disease progression and adherence have been addressed in earlier sections of this and the previous chapter. Although an increase in one's viral load and a decrease in CD 4 is often suggestive of non-adherence, there may be other reasons for a change in the CD 4 and viral load. HIV disease symptoms will be reviewed within the context of the various symptoms that may have an affect on women's adherence to antiretroviral medications. Physical well-being as it is reviewed is a function of one's abilities for social and role functioning, general perception of health, and one's quality of life.

2.5.1 CD 4 and Viral Load and HIV

Catz et al. (2000) in their study of 63 men and 9 women used self-reported medication adherence to assess their antiretroviral medications, complete a calendar of activities, and report the total number of medications missed over the previous 5 days. Thirteen participants (18%) were identified as non-adherent. There was a significant relationship between number of missed doses and increased viral loads, Mantel-Hanszel X^2 (1, N = 72) = 5.3, $p < 0.05$ (Catz et al.).

2.5.1.1 Summary of CD 4 and Viral Load and Adherence to Antiretroviral Medications.

CD 4 and viral load is no longer considered a method of assessing one's adherence to antiretroviral medications. An individual may be 100% adherent but yet there may be changes in

their CD 4 and viral load; suggesting the possibility of medication resistance. Or, an individual be less than 95% adherent and yet reflect adequate CD 4 and viral load laboratory values. Therefore, CD 4 and viral load, if known, are no longer appropriate for assessment of adherence.

2.5.2 HIV Disease Symptoms and HIV

Nurses and health care providers often group the physical manifestations of disease, signs and symptoms together as one. Dodd et al. (2001)using the University of California, San Francisco (SCSF) School of Nursing Center for Symptom Management model defines symptoms as " a subjective experience reflecting changes in the biophysical functioning, sensation, or cognition of an individual" (p. 669). A sign is a part of the physical assessment process for evaluating "disease status and to evaluate and verify the effectiveness of management strategies" (p. 669). Dodd et al. (2001) reported that both signs and symptoms are important and both can be significant indicators of abnormal health and possible pathology associated with illness. For example, fever (a symptom) reflects a temperature (a sign) either of which is not an expected clinical finding during a physical assessment or which may prompt a person call to their health care provider. An elevated temperature is suggestive of an infection, dehydration, or many illnesses; viral or bacterial. On the other hand, the lack of a symptom or sign does not suggest an individual is in optimal health, nor does it suggest they do not require the interventions of a health care provider.

Persons with HIV may or may not have symptoms. The presence of symptoms may be suggestive of disease progress; a change in the CD 4 or viral load (Holzemer, 2002). To further complicate the assessment of symptoms, it is sometimes difficult to separate the symptoms associated with HIV from those symptoms associated with the use of antiretroviral medications.

In fact, the use of antiretroviral medications may exacerbate the symptoms already associated with the presence of HIV disease (Chesney et al., 1999; Gifford et al., 2000; Hudson et al., 2004; Johnson, Stallworth, & Neilands, 2003). As Mannheimer and colleagues (2005) suggest, these symptoms can and often do interfere with one's quality of life (QoL) for persons with HIV and limit their abilities to care for themselves and others (Hudson et al., 2004; Holzemer et al., 1999; Holzemer et al., 2001; Holzemer, 2002; Johnson et al.; Justice et al., 2001; Spirig, Moody, Battegay, & DeGeest, 2005; Reynolds et al., 2004).

2.5.2.1 Symptoms and HIV.

Dodd and colleagues report it is not only the presence of the symptoms that are important but how the individual responds to the symptoms. Researchers address the complexity of the symptom experience, the behavioral implications, physical and psychological, which may further affect one's social relationships. For example, for women with HIV the presence of fatigue may result in the inability to work outside their home. The inability to financially provide for their children and themselves may contribute to feelings of sadness, depressive symptomatology, fear, and anxiety, and may result in social isolation from family, friends, and peers (Holzemer, et al., 1999; Hudson et al., 2004; Reynolds et al., 2004).

Holzemer (2002) explains it is not just the presence or absence of symptoms but how the person responds to their array of symptoms that may ultimately affect their adherence to medication, social and role function, and overall ability to live with and manage their HIV disease. In fact, the presence of an increased number of symptoms, especially depressive symptomatology, was associated with non-adherence (Holzemer et al., 1999). Other research suggests that increased symptoms result in a change in health behaviors such as increased use of alcohol and poor quality of life (Hudson et al., 2004; Johnson et al., 2003; Mannheimer et al.,

2005; Phillips et al., 2004; Phillips et al., 2005a; Phillips et al., 2005b; Spirig et al., 2005; Valenti, 2004).

Numerous symptoms have been associated with HIV disease. Justice et al. (2001) and Holzemer (1999, 2001, 2002) have done extensive research to identify the following symptoms: shortness of breathe, fever, fatigue, night sweats, gastrointestinal complaints (diarrhea, nausea, vomiting, and constipation), weight loss, tender and swollen lymph glands, decreased strength, anxiety, fear, and depression. Holzemer et al. (2001) revised the self-reported symptoms list to include changes in body fat distribution (lipodystrophy) and women's unique gynecological related symptoms: vaginal discharge, itching, odor, irregular or heavy menstrual cycles, break-through bleeding (between menstrual cycles), and pelvic pain. The symptoms or side effects of antiretroviral medication include abdominal complaints (gas and bloating, upset stomach, nausea, vomiting, diarrhea, and constipation), fatigue/malaise, headache, muscle and joint pain, dry mouth, changes in taste, anemia, hair loss, and physical changes to one's body fat distribution (Johnson et al., 2002).

A multi-site study of 336 men and 84 women used a modified 4-item self-report measure to assess adherence to antiretroviral medications (Holzemer et al., 1999). The participants also completed additional measures for depression (CES-D), functional status (13 items from the MOS-SF 36), quality of life (7 items from the MOS-SF 36), living with disease, and environmental/interpersonal resources. Using hierarchical multiple regression analysis to identify predictors of non-adherence, the researchers found that symptoms of disease was the strongest predictor of adherence (R^2 = 0. a predictor of adherence, X^2 (420) = 38.521; *df* 10, $p <$ 0.00. In this model, nausea and vomiting (OR = 0.68; p = 0.06) and depression (OR = 1.05; p = 0.01) were significant predictors of adherence. In addition, environmental/interpersonal factors

and poor social support were the strongest predictors of subjects' non-adherence to their antiretroviral medications (OR = 0.46; p = 0.00) (Holzemer et al.).

Hudson and colleagues (2001) reported issues of symptom control for women; however, did not assess adherence. In another study, 420 men and women reported that the presence of symptoms explained 11% of the variance in their multi-factor model with subjects reporting greater symptoms also reporting being less adherent to their medications (Holzemer et al., 2001). 111, p = 0.004). Logistic regression analysis of the nine symptom predictors also supported symptoms as

2.5.2.2 Summary of HIV Disease Symptoms and Adherence to Antiretroviral Medications.

There is anecdotal evidence to suggest that symptoms impact adherence. There is also some connection between the presence and absence of symptoms and changes in the patient's CD 4 and viral load. Numerous studies address the effect of HIV disease related symptoms on one's quality of life, role and social function as cited above (Dodd et al., 2001; Holzemer, 2002; Hudson et al., 2004). However, there remains a gap in the literature for HIV disease symptoms and the possible relationship they may have on one's self-reported adherence to antiretroviral medications. This gap is true for literature relating to men and women living with and trying to manage their HIV disease.

2.5.3 Physical Well being and HIV

The perception of one's quality of life is often centered on one's abilities to be physically well and engage in multiple physical and social activities. An individual who is acutely ill often has

limited capacity and desire to engage in physical activity. However, once the acute phase has past and their illness becomes chronic, one's physical and social activities may continue to be adversely influenced.

As discussed in the section on depressive symptomatology, one's mental well-being interacts with one's physical wellness and influences one's overall quality of life. The HIV disease related symptoms are often manifested as one or more physical signs and/or symptoms of disease. However, for persons with HIV it is often difficult to discern disease related symptoms from antiretroviral medication related symptoms and both appear to influence one's physical, role, and social functioning (Holzemer et al., 1999, 2001; Hudson et al., 2004; Johnson et al., 2003; Justice et al., 2001).

2.5.3.1 Physical Well-being and Adherence to Antiretroviral Medications.

Liu and colleagues (2006) reported that despite the use of antiretroviral medications to manage disease, women reported negative feelings, which interfered with their social, role and physical functioning. In their research, van Servellen and colleagues (2002) investigated the gender differences in physical well-being as a function of health related physical well-being. This study of 44 women and 82 men reported that regardless of ethnicity, women had more HIV-related symptoms and impaired physical function than men. Women had more HIV-related symptoms (women, M = 2.4, SD = 1.1; men, M = 1.7, SD 1.3, $p < 0.01$), more functional limitations (women, M = 10.4, SD 2.2; men, M = 11.8, SD = 2.6, $p < 0.01$), and decreased physical well being (women, M = 1.5, SD = 0.6; men M = 0.9, SD = 0.7, $p < 0.001$) (van Servellen et al.).

Tate and colleagues (2003) reported a relationship between mood and decreased physical functioning (r = - 0.355, $p < 0.05$), mental health (r = - 0.613, $p < 0.01$), social functioning (r = -

0.556, $p < 0.01$), emotional role functioning ($r = -0.411$, $p < 0.01$), vitality ($r = - 0.443$, $p < 0.01$), pain ($r = - 0.481$, $p < 0.01$), and general health perception ($r = - 0.468$, $p < 0.01$. There was also a trend toward lower scores for all components of physical function for the MOS-HIV (F [1, 61] = 3 .9, $p = 0.051$) (Tate et al.). Likewise, Mrus et al. (2005) in their comparison study of 976 men and 202 women with HIV reported that women had lower physical functioning scores than their male cohort (women 6.7 points lower; $p < 0.001$). The authors used the ACTG Quality of Life Health Survey, which is a modified version of the MOS SF-20.

Mannheimer and associates (2005) investigated the relationship between physical and mental well being and adherence to antiretroviral medications in a study of 412 men and 102 women with HIV over a period of 1 year. The SF-12 Health Survey instrument was used for this study, a version of the MOS-HIV (Wu et al., 1991); scores were categorized into physical and mental component summary scores. Adherence was self-reported using a 7-day recall measure with subjects' adherence rates identified as 100%, 99-80%, and less than 80% adherent. Over the 1-year, adherent vs. non-adherent subjects had better physical scores (49.20 vs. 46.15, $p <0.001$). Subjects identified as 100% adherent had significantly better physical scores (48.7 vs. 43.9, $p < 0.001$) than subjects with 80% adherence. In addition, as subjects' adherence improved over the 12-month period their physical component score increased; those with < 80% adherence had a decrease in their physical component score (Mannheimer et al.).

In a clinical trial of antiretroviral medications, 967 men and 189 women reported improved physical and mental well-being as the CD 4 values increased and viral load decreased (Weinfurt, Wilke, Glick, Freimuth, & Schulman, 2000). These changes in physical health (PH) and mental health (MH) were more noticeable 12 weeks into the study for viral load (PH, $R^2 = 0.23$, $p < 0.05$; MH, $R^2 = 0.23$, $p < 0.05$) than changes in the CD 4 (PH, $R^2 = 0.32$, $p < 0.05$; MH,

R^2 = 0.38; p < 0.05). The CD 4 and viral load were used as indicators of adherence to antiretroviral medications

An investigation of 114 men and 28 women hospitalized with AIDS explored the relationship between functional status, symptoms, and clinical indicators (Sousa, Holzemer, Henry, & Slaughter, 1999). Findings from the four-tiered multiple linear regression analysis suggested statistical significance for general health perception (R^2 = .107, p < 0.001), functional status (R^2 = 0.158, p < 0.001), symptom status (R^2 = 0.202, p < 0.001), and clinical markers (R^2 = 0.201, p < 0.05) (Sousa et al.). Antiretroviral medications were not measured.

Reynolds et al. (2004) in their study of men and women reported significant relationships between non-adherence and role function (r = 0.16; p = 0.005), non-adherence and health perception (r = 0.19; p = 0.001), and non-adherence and social emotional-cognitive functioning (r = 0.25; p = 0.001).

Although adherence to antiretroviral medications was not assessed, another large investigation explored health related quality of life (HRQoL) for 2,864 persons with HIV, 49% men (Hays et al., 2000). Men and women with HIV/AIDS had more disease-related symptoms, less functional ability, and poorer physical well-being than was demonstrated in studies of persons with other chronic disorders (difference [USA population] = HIV disease of 14 points; 95% CI, 11-18; p <0.001). In addition, for persons with AIDS the differences were more pronounced than for people with other chronic disorders (difference, 32 points; 95% CI, 28-35; p < 0.001) (Hays et al.).

2.5.3.2 Physical well-being and adherence to antiretroviral medications for women with HIV.

Liu and colleagues (2006)) in their longitudinal study investigated women naïve to antiretroviral treatment and women using antiretroviral medications. For this sample of 458 matched pairs of women, the use of antiretroviral medications demonstrated significant improvements in four-domains; role function (mean change: 5.08; $p = 0.01$), social function (4.33; $p = 0.01$), pain (4.53; $p = 0.01$), and perceived health index (4.53, $p = 0.01$). Over time, there was only a small decline in these domains; role function (2.17; $p < 0.01$), social function (0.11; $p < 0.02$), pain (1.57; $p < 0.01$), and perceived health index (0.24, $p < 0.01$). Simoni and Cooperman (2000) in their research of inner city women with HIV reported a relationship between three domains: general health ($r = 0.15$; $p < 0.01$), physical symptoms ($r = -.25$; $p < .001$), and CD 4 ($r = .11$; $p < .05$).

An adherence investigation of 766 women with HIV reported statistically significant relationships between participants with greater than 95% adherence (585) and women with less than 95% adherence (181) using the MOS-HIV (Wilson et al., 2002). Differences between non-adherent and adherent women for the domains specific to the physical well-being subscore were: physical functioning ($M = 64.5$, $SD = 29.4$ vs. $M = 69.2$, $SD = 28.3$; $p < .05$), pain ($M = 66.4$, $SD = 26.9$ vs. $M = 72.9$, $SD = 27.3$; $p < .01$), energy/fatigue ($M = 51.1$, $SD = 24.2$ vs. $M = 57.3$, $SD = 24.6$; $p < .01$), and health perception ($M = 48.5$, $SD = 23.1$ vs. $M = 56.9$, $SD = 24.3$; $p < .01$), social function and role function were not statistically significant (Wilson et al.).

Cowdery and Pesa (2002) in their investigation of 82 HIV-positive women reported statistically significant relationships between independent variables, demographics (age, ethnicity, education, and employment), social support, and time since HIV diagnosis, CD 4,

symptoms and Karnofsky performance score (KPS). Based on six multiple regression models there were predictors for each of the six domains of the MOS-SF-20. Age and KPS was correlated with physical functioning (R^2 = 0.442, p = 0.009). Employment status was correlated with role function (R^2 = 0.394, p = 0.005). Age, employment status, and KPS were correlated with social functioning (R^2 = 0.391, p = 0.005). Social support was correlated with mental health (R^2 = 0.389, p = 0.005). KPS and social support were correlated with health perception (R^2 = 0.348, p = 0.020), and KPS, social support, and discrimination were correlated with pain (R^2 = 0.413, p = 0.002) (Cowdery & Pesa).

2.5.3.3 Summary of Physical Well-being and Adherence to Antiretroviral Medications.

Research would suggest that one's physical functioning has a relationship with social and role function and overall ability to interact with others. Research would suggest that one's physical functioning has a relationship with social and role function and overall ability to interact with others. There is limited research that has investigated the relationship between physical well-being and adherence to antiretroviral medications. Although researchers reported poor physical function greatly affected women with HIV (Remplle, Hilton, Ratner, & Burdge, 2004; Tostes et al., 2004; Weaver et al., 2004), there is a gap for how this relates to their adherence to antiretroviral medications.

2.6 SUMMARY

HIV as a chronic disease is an open field for nursing research due to the recent advances in disease management and late entry of women with disease into clinical trials.

The course has been set for pursuing such research with the suggestion of potential psychological and physiological variables, as findings suggest from previous research. This investigation of psychological and physiological factors may influence future research for adherence to antiretroviral medications in women with HIV disease. For research to contribute to the body of knowledge regarding women with HIV, it must focus on specific variables/factors that affect adherence to antiretroviral medications. The factors that were explored for this study were selected psychological factors (depressive symptomatology, social support, and perceived stigma) and selected physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) and if or how these factors predicted self-reported adherence to antiretroviral medications use in women with HIV. In addition, selected sociodemographic variables (age, education, race/ethnicity, marital status, and exposure risk category) were examined for their potential relationships on self-reported adherence to antiretroviral medication use in women with HIV.

Guided by theory, self-efficacy was examined for its potential mediating effect on the relationships between the selected psychological factors, selected physiological factors, and demographic variables and self-reported adherence to antiretroviral medication use in women with HIV. Because women with HIV often have less education, poor financial resources, and are from minority groups, their perceived self-efficacy may already be less than others. It was important that research of perceived self-efficacy for women with HIV be investigated. Addressing the identified gaps in the literature is needed prior to designing adherence strategies for optimal success with HIV antiretroviral medication management in the future.

3.0 CHAPTER THREE

3.1 METHODOLOGY

Conducting research, similar to conducting a literature review of the concepts of interest, can be approached from many perspectives. However, both processes require a plan, albeit a method. Polit and Hungler (1994) refer to the research design as an "overall plan for obtaining answers to research questions and testing the research hypothesis" (p. 225). The method selected for one's inquiry is the "formal, systematic, and rigorous process" that Fawcett describes in her work (1998, p. 8). The design of the research lays out strategies for the researcher to implement and conduct the study. Indeed, if the theoretical or conceptual framework drives one's study, the methodology provides the mechanics and components of the engine.

3.2 DESIGN

This descriptive cross-sectional study was conducted to examine selected psychological factors (depressive symptomatology, social support, and perceived stigma) and selected physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) that were considered to be potential predictors of self-reported adherence among women with HIV who were prescribed antiretroviral medications. In addition, this study examined the mediating effect of

self-efficacy on the relationships of the selected psychological factors (depressive symptomatology, social support, and perceived stigma) and selected physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) and self-reported adherence to antiretroviral medications among women with HIV who were prescribed antiretroviral medications. Standardized research measures were used to collect data on each of the study variables in a convenience sample of women with HIV living in the tri-state area of western Pennsylvania (Ohio and Pennsylvania, and West Virginia). No women were recruited from West Virginia.

3.3 POPULATION AND SAMPLE

The population of interest was English speaking women who were 18 years of age or older and diagnosed with HIV or AIDS. Specifically, the sample was recruited from an urban university primary care clinic, a community-based center, and rural clinics only in Western Pennsylvania.

3.3.1 Setting

Women who received HIV care at a university primary care clinic, community-based center, and rural clinics in the tri-state areas of western Pennsylvania were asked to participate in the study. The multiple sites for recruitment and data collection were selected to increase the diversity of the sample. However, as data collection progressed there was limited diversity as western Pennsylvania has primarily white, non-Hispanic and African American populations. The projected sample from the university and rural clinics consisted of white and Black participants.

The original plan was to include women from a clinic in Lancaster County, Pennsylvania. This site was selected because of the HIV health care provided to Latina women, primarily women who had migrated from Puerto Rico. However, this site became unavailable. The western Pennsylvania university-based clinic had approximately 900 clients with an estimated 25% being women. The rural clinics of northwestern PA had approximately 200 clients with an estimated 35% being women.

3.3.2 Eligibility Criteria

Women who were 18 years or older, diagnosed with HIV/AIDS for a period of at least six months or longer, and prescribed antiretroviral medications were invited to participate in the study. Participants needed to be free of neurocognitive impairment and mental health disorder based on self-report. Participants were required to read and write English. The inclusion criteria, speaking English, did not discriminate in any way toward a non-English speaking person. Health care agencies in the tri-state area of western Pennsylvania serve primarily Black and white patients with less than 1% of the population being non-English speaking. Females of childbearing age and pregnant women were not excluded from the study provided they met the other inclusion criteria. Participants were required to have access to a telephone for the researcher to contact them to schedule an appointment to obtain informed consent, screen, and collect data.

3.3.3 Sampling Procedure

The study was originally projected to include a convenience sample of 75 women. At that time, the sample size was configured by considering the feasibility of recruiting the desired sample and having adequate power (.90) when evaluating the primary aims of the study. A secondary analysis of baseline data from an intervention study (R01NR04749, J. Erlen, Principal Investigator) at the University of Pittsburgh, School of Nursing, assisted in estimating the number of subjects needed for the greatest power. Multiple linear regression analysis of depressive symptoms, social support, perceived stigma, and physical well-being on self-reported adherence, explained 44.7% of the variance in adherence. Given this finding, a sample size of 75 women would have had at least .90 power to detect an R-squared of .447 based on eight predictor variables (using total scale scores) when using multiple linear regression analysis with an alpha of .05, two-tailed test (PASS, version 2002, Kaysville, UT). With 0.80 power this study would have be able to detect R-squared as small as .183 based on eight predictor variables with an alpha of .05, two-tailed test (PASS, version 2002, Kaysville, UT).

Table 1. Multiple Regression Power Analysis

Power	N	Alpha	Beta	Count	Ind. Variables Tested R^2	Count	Ind. Variables Controlled R^2
0.9999	75	0.0500	0.0000	8	0.447	0	0.0000
0.9000	75	0.0500	0.1000	8	0.222	0	0.0000
0.8000	75	0.0500	0.2000	8	0.183	0	0.0000

Because of problems with recruitment the sample size was re-calculated using the above-described procedures. A more complete discussion of the changes in the power analysis and sample recruitment will be addressed later in this chapter under the heading, Difficulties and Limitations.

3.4 PROCEDURES

3.4.1 Recruitment

Following approval from the Institutional Review Board at the University of Pittsburgh, the researcher began to recruit, enroll, and screen participants, and collect data. Women who met the inclusion criteria were invited to participate in the research study. Nurses, physicians, social workers, and case managers at the recruitment locations assisted the researcher in identifying potential participants by informing the women about the study. In addition, self-referral materials (a bi-fold handout and "pull-off" posters) were available for staff at all recruitment sites to distribute to interested and potential participants. The "pull-off" was a standard 8 by 10 colored piece of paper, which included a brief description of the study and had pre-cut sections at the bottom of the sheet with the study contact number. Potential participants were able to self-refer by contacting the researcher at a toll-free telephone number or an email address. Both the telephone number and email address were included on the self-referral handout and "pull-off poster". The researcher made telephone contact with each potential participant to screen for appropriateness, query for permission to ask personal information, determine if the potential participant was interested, and arrange an appointment to obtain informed consent and collect data. Recruitment for the study occurred at multiple sites including the rural clinics and public areas of convenience for the potential participants from the rural areas and the university clinic.

A brief description of the study was provided to each potential participant during initial contact. In addition, the researcher assured the potential participant of her confidentiality and discussed the need for written informed consent. The researcher screened for inclusion criteria during the initial telephone call or personal contact. At that time, the researcher made an

appointment with the participant at a mutually agreed upon time and place. Numerous subjects at the rural clinics elected to meet immediately and continued with the informed consent and data collection. When potential participants made appointments through telephone contact, they received a telephone reminder call the day of the scheduled appointment. If contact was not established, a second reminder call was made; a message was left on an answering machine, if possible and the researcher continued to the recruitment site at the designated time. Use of a mobile telephone made it possible for potential participants to contact the researcher while traveling to the recruitment site to cancel and/or reschedule the appointment.

The preferred location for data collection at recruitment sites was a private conference room. However, due to issues of convenience for potential subjects, recruitment occurred in their home or at a designated location near their home. This strategy greatly increased recruitment for women who received health care from the rural clinics. Most of these rural dwelling women lived 30 to 60 miles or more from their respective clinic. The dates and times for their next clinic appointment occurred on a rotating or variable monthly schedule meaning they did not attend a clinic again for 1 to 3 months. Regardless of recruitment site, following discussion of the informed consent and summary of the key points of study participation, the potential participant was asked to sign the informed consent document. Each participant received a signed copy of the informed consent. The researcher kept a copy of the informed consent in a locked file in her office that was separate from the data files.

3.4.2 Data Collection

Following informed consent and using an interview format, the researcher screened the participant. Two screening measures were used. The Rapid Estimate of Adult Literacy in

Medicine (REALM) was used to briefly assess the ability of the participant to read and understand medical terminology (Davis et al., 1993). Possible neurocognitive impairment was assessed using the 4-item HIV Dementia Scale [HDS] (Powers, Selnes, Grim, & McArthur, 1995). These measures took approximately 10 minutes to complete. If any subject stated that she was unable to read or the researcher suspected a reading or mental handicap that limited the participant's ability to read and understand the informed consent process, she was informed she was ineligible for the study at this time.

The AIDS Clinical Trial Group Assessment (ACTG) measure of self-reported adherence (Chesney et al., 2000) required a brief interview to identify the prescribed antiretroviral medications and the regimen, frequency of dosing, and number of pills taken at each time interval. The remainder of the ACTG and all other instruments were self-administered. The participants answered all questionnaires only one time. Completing the questionnaires took approximately 45-60 minutes. The researcher reviewed each questionnaire for completeness prior to the participant's leaving the site. A token of appreciation ($15.00) was provided to assist with the recruitment of subjects and was given to women immediately after completing the questionnaires.

Subjects who had not previously used the electronic Medication Event Monitor system (MEMS) cap or had not used the MEMS cap in a previous study for at least a period of 90 days, and were agreeable, were asked to use the MEMS cap for one antiretroviral medication for a 29-day-period. A convenience subsample of 12 women was recruited to use the MEMS cap. Participants were instructed in the purpose of the MEMS for the selected antiretroviral medication during the next 29 days. When a participant took more than one antiretroviral medication, the researcher assigned a number to each medication. Each number (for example 1,

2, 3, 4) was written on a small piece of paper and placed in an envelope. The subject then selected one number from the envelope and the number corresponding to a specific medication was identified as the medication for use with the MEMS cap. The identified medication, dosing, and frequency were recorded in the participant's adherence and research record and written on the label of the pill bottle. Each subject was provided an instruction sheet for using the cap, refilling the bottle, beginning date for using the cap/pill bottle, date to return the cap, and a self-addressed stamped envelop to return the cap and bottle to the researcher. Dosage of the identified medication was verified using the instructions as written on the subject's medication-prescription bottle**.** Subjects began using the cap and pill bottle the day following enrollment in the study for the 29-day period.

The use of the MEMS cap began the day after enrollment into the study. Participants were instructed to return the MEMS cap 30 days from enrollment in the researcher-addressed mailing envelope. As a reminder, each participant using the MEMS cap received a telephone call from the researcher at least two days before the scheduled MEMS cap return date. If a subject no longer had a working telephone number, a note and an additional envelope were mailed to the participant. When the MEMS cap was not returned within 10 days after the end date, the researcher made an additional reminder telephone call or sent a note and envelope, if telephone service had been discontinued. All MEMS caps were distributed with an anticipation attrition of 20% (loss of two subjects). Once the cap was returned, the subject received a $5.00 gift card to a store of her choice such as a regional grocer or a discount store. A thank you note was included with the gift card. A record was maintained for caps returned and those not returned.

3.5 INSTRUMENTATION

As diagrammed in the theoretical framework, the following psychological variables (depressive symptomatology, social support, and perceived stigma) and physiological variables (CD 4, viral load, HIV disease symptoms, and physical well-being) were identified for this investigation. In addition, demographic attributes (age, education, race/ethnicity, marital status, and exposure risk category) of the woman were identified as possible covariates within the model.

3.5.1 Psychological Variables

3.5.1.1 Depressive Symptomatology

Depressive symptomatology was defined as the individual's subjective perceptions of guilt and worthlessness, loss of appetite, sad mood, low energy, and sleep disturbances (Radloff, 1977). The Center for Epidemiological Studies - Depression Scale (CES-D) was used to assess depressive symptomatology. This 20-item self-report measure uses a Likert-response format from 0 (rarely or none) to 3 (most or all of the time). The CES-D measures depressive symptoms over the previous week for community dwelling adults and adolescents (Radloff, 1977; Radloff & Lock, 1986) with summary scores that range from 0 to 60. The CES-D has been used widely in samples of persons with HIV and has acceptable internal consistency reliability, test-retest reliability, and discriminate validity (Catz et al., 2000; Chesney et al., 2000; Ickovics el al., 2001; Lyon & Munro, 2001; Murphy et al., 2000). Chesney and colleagues (2000) reported a coefficient alpha of .85 in their study of 75 (60 men and 15 women) HIV patients. Numerous studies using the CES-D in community dwelling persons with HIV were addressed in the

literature review. In addition, the measure has been used in HIV adherence clinical trials and in conjunction with studies within the AIDS Clinical Trials Group.

For this study, the total score on the Center for Epidemiological Studies -Depression Scale (CES-D) was used to measure depressive symptomatology (Radloff, 1977). A score of 16 or greater is suggestive of depressive symptomatology; a score of 25 or greater indicates severe mental distress (Radloff, 1977).

3.5.1.2 Social Support.

Social support was defined as the resources individuals have available to them through interpersonal relationships (Cohen & Syme, 1985) including family, friends, peers within the community, and health care providers. Social support was assessed by the Interpersonal Support Evaluation List (ISEL) a 40-item Likert scale with responses from 0 “definitely false” to 3 “definitely true”. Negative items are reverse coded. This measure appraises the individual’s perceived available resources for social support using four-domains: tangible support, appraisal support, self-esteem support, and belonging support. The total scores range from 0 to 120 with higher overall scores suggestive of greater perceived potential availability of social support. The ISEL has been used to assess social support as a buffer or mediator of distress and disease in numerous samples (Cohen & Herbert, 1996) including cancer (Helgeson & Cohen, 1996), women’s immunity and depression (Miller, Cohen, & Herbert, 1999), infectious disease (Glaser, Rabin, Chesney, Cohen, & Natelson, 1999), smoking cessation (Mermelstein, Cohen, & Lichtenstein, 1983) and HIV (Catz, Gore-Felton, & McClure, 2002). The measure has shown a total score internal consistency reliability coefficient alpha from .88 to .90 (Cohen, Mermelstein, Kamarch, & Hoberman, 1995).

There is limited research with HIV patients reported using the ISEL. Catz and colleagues

(2002) in their study of 100 minority and low-income HIV-positive women reported a total mean score of 106.8 (*SD* = 27.4) indicating a moderate degree of perceived social support. Findings from this study (Catz et al.) showed that less social support contributed independently to increased depressive symptoms (R^2 = .46, *p* = <.001). Psychometric properties for the ISEL were not reported. Although the ISEL has the potential for four subscores within the measure, for purposes of this investigation only the total support score was used for analysis.

3.5.1.3 Perceived Stigma

Perceived stigma was defined as the perceived interaction with and from others that makes the individual feel undesirable, tainted, flawed, and/or morally degenerated (Goffman, 1963). The total score of the HIV Social and Emotional Aspects Questionnaire was used to access the overall emotional and social issues relevant to living with HIV (Berger, Ferrans, & Lashley, 2001). The measure is composed of 40-items. The measure uses a 4-point Likert-type format with responses from strongly disagree (1) to strongly agree (4) with higher values indicating more item agreement. Using exploratory and confirmatory factor analysis, the authors of the measure identified a four-factor model for stigma. Each of the four factors addresses aspects of perceived stigma for persons with HIV: personalized stigma, disclosure concerns, negative self-image, and public attitudes. Total scores on the measure can range from 40 to 160. Two items were reverse coded and raw scores for each subscore are then totaled. Sixteen items are associated with more than one subscore reflecting the intercorrelation of the factors.

Construct validity of the subscales and total measure are excellent. Pearson r correlations for the total HIV Stigma Scale and other measures are: Rosenburg self-esteem (-.60), CES-D depressive symptoms (.63), social support availability (-.54), social support validation (-.54), subjective social integration (-.65), and social conflict (.59), p = < .001 for all correlations

(Berger, Ferrans, & Lashley, 2001). Internal consistency reliability of the total measure (*N* = 318) is reported as 0.96. Internal consistency reliability of the subscores ranged from 0.90 to 0.96. Test-retest reliability (*N* =139) has been reported as 0.87 to 0.92 for the subscales and 0.92 for the overall score (Berger et al.)The total score of the measure was used in the data analysis. Higher scores suggest greater item agreement and less perceived stigma (Berger et al.).

3.5.2 Physiological Variables

3.5.2.1 Clinical Indicators.

The two clinical indictors for evaluation of HIV disease progression were the CD 4 and viral load. *C*D 4 is the lymphocyte count and measures the individual's immune response and ability to resist disease. Viral load refers to the amount of HIV-RNA copy present in the HIV-infected individual. As a part of the sociodemographic measure, participates self-reported, if known, their CD 4 and viral load.

3.5.2.2 HIV Disease Symptoms.

HIV disease symptoms were defined as the subjective changes in how one feels related to their HIV disease in the last 5 day period. HIV disease symptoms were measured by using The Revised Sign and Symptom Check-List for HIV (SSC-HIV rev) (Holzemer, Hudson, Kirksey, Hamilton, & Bakken, 2001). Eleven factors explained 73.3% of the variance in this sample of women with HIV disease related symptoms (Hudson, Kirksey, & Holzemer, 2004) Each of the symptoms is scored based upon intensity for the present day. Items are scored from 0 not present today, mild (1), moderate (2), or severe (3). The mean score for HIV disease symptoms present the day data were collected was 20.82 (*SD* = 16.50). HIV symptoms ranged from 0 (none present

today) to 56. Hudson and colleagues (2004) reported a Cronbach's alpha coefficient of .97 in a sample of 118 women.

3.5.2.3 Physical Well being

Physical well-being was defined as one's current appraisal and satisfaction with their physical abilities and social functioning with others (Wu et al., 1991). Physical well-being was operationalized using the overall physical well-being score of the Medical Outcomes Study-HIV (MOS-HIV) (Wu et al., 1991). The SF-20 measure assessed general health perceptions, physical function, role function, social function, mental health, and cognitive function. The MOS-HIV includes domains specific to persons with HIV that have the potential to impact their quality of life (QOL), pain, energy/vitality, health distress, and health transition. The MOS-HIV appraises the individual's physical and mental health through their perceived well-being; functional behaviors, disability, and overall perception of health. The measure has excellent reliability and validity with coefficient alpha for all subscales ranging from .62 to .96 (McHorney, Ware, Lu, & Sherbourne, 1994). The MOS-HIV health survey has been given to more than 15,000 men and women with HIV (Wu, Hays, Kelly, Malitz, & Bozzette, 1997a). The measure has two summary scores: physical well-being and mental well-being. Exploratory and confirmatory factor analysis identified physical function, pain, and role function with the physical well-being summary score (Revicki, Sorenson, & Wu, 1998).

The mental well-being summary score includes mental health distress, QOL, and cognitive function. The domains of general health, energy/vitality, and social function contribute to both factors. The internal consistency for the physical health summary score has shown Cronbach's alpha coefficients ranging from 0.90 to 0.92. The Cronbach's alpha for mental health score ranged from 0.91 to 0.94 (Wu et al., 1997b). Wu and colleagues (1997a, 1997b) reported

good construct validity of the total measure, as well as the physical and mental health summary scores.

There is some suggestion of a potential for a ceiling effect for subscores of role, social, and physical functioning for persons with less severe disease and a floor effect for role function in persons with more disease related symptoms (Wu, Hays, Kelly, Malitz, & Bozzette, 1997a; Wu, Revicki, Jacobson, & Malitz, 1997b). In addition, Badia et al. (2000) found that the MOS-HIV had improved test-retest treatment change of 86.4% when compared to the Multidimensional Quality of Life.

3.5.3 Sociodemographic Data

Demographic data were collected on the subjects using an investigator-modified version of a demographic measure currently used by the University of Pittsburgh, School of Nursing, Center for Research in Chronic Disorders. Questions on the self-report sociodemographic form included race/ethnicity, education, age, martial status, employment, income, number of children and children living at home, living arrangements, number of persons living in the home, exposure risk category, drug and alcohol use, health care coverage, CD 4, and viral load. Five of these attributes (race/ethnicity, age, education, marital status, and exposure risk category) were considered possible covariates of adherence.

3.5.4 Adherence to Antiretroviral Medications

Adherence was defined as the degree to which one follows a prescribed regimen.

3.5.4.1 Self-reported Adherence.

Overall rates of self-reported adherence to antiretroviral medications were assessed using the AIDS Clinical Trial Group Assessment (ACTG) measure (Chesney et al., 2000). The ACTG is composed of three subsections with a total of 40 items. *Section A* of the measure requires the researcher to interview the subject and list all antiretroviral medications, dosing frequency, and number of pills per dose. *Section B* is a daily diary to summarize missed "pills" for the previous 4 days. S*ection C* is composed of single to multiple questions with Likert-type responses, graded from low (0) to high (4) (Chesney et al.). This section explores possible reasons for not taking one's medications as per the required regimen. The ACTG has been used in clinical trials (Chesney et al.; Ickovics et al., 2001; Murphy et al., 2000); however, reports of the psychometric properties have not been included. The measure does distinguish adherent from non-adherent participants in independent *t*-test and Mann-Whitney statistical analysis (Chesney et al.; Ickovics et al.).

3.5.4.2 MEMS Cap.

A subsample of 12 participants agreed to use the MEMS cap (AARDEX Corp, Aug, Switzerland) for a period of 29 days. This electronic device is designed to record each time the subject opens the bottle cap. This device consists of a standard plastic medication bottle and a cap containing a microchip circuit that records the time and date when the cap is removed. The cap is sealed and is water proof. The subject uses the cap in the same manner as any screw-type

medication bottle cap. The cap has sufficient memory capacity to record and store information far beyond the required 29 day period. The battery within the cap has a 2-year life capacity. The MEMS cap can be used with any dosing schedule.

Three adherence rates were calculated in the following manner: First, dividing the actual number of cap openings by the prescribed number of openings during a designated 29 day period and multiplying by 100 for percent of adherence. Second, rates of adherence were calculated computing the percent of days in which the subject opened the MEMS cap and third removed the medication at the correct time of day. A subject was identified as adherent if she scored a 95% or greater adherence rate and patterns. A subject was identified as moderately adherent with a score of 80 to 94% for both rate and patterns of adherence. A subject was identified as non-adherent if she scored less than 95% in her adherence rate and patterns. Data housed in the microchip of the cap were retrieved using a communicator and software package and downloaded into a Windows-based computer.

3.5.5 Potential Mediator of Adherence

3.5.5.1 Perceived Self Efficacy Beliefs.

Perceived self-efficacy was defined as the individual's perceived ability to successfully manage their antiretroviral medications (Bandura, 1977, 1986, 1997). Perceived self-efficacy was measured using the total score of the HIV Medication Taking Self-Efficacy Scale (Erlen et al., unpublished manuscript). Erlen and colleagues developed this 26-item measure. A total score and two subscales scores can be calculated. The subscores are self-efficacy beliefs with 17 items and outcome expectancies with 9 items. The instrument uses a Likert-type response format to appraise the individual's perceived confidence in the management of their HIV/AIDS

medications. The measure is scaled from 1 (not at all confident) to 10 (totally confident). Pilot data with 26 subjects reported a Cronbach's alpha of .96 for the total scale with a test-retest correlation (r = .45, p = .02) (Erlen et al, 2001). The subscales also show good reliability with a Cronbach's alpha of .96 for self-efficacy beliefs with a test-retest correlation (r = .47, p = .01) and a Cronbach's alpha of .95 for outcome expectancies with a test-retest value (r = .42, p = .03) (Erlen et al., 2001). Additional examination of the psychometric properties of the measure is currently underway (personal communication, J. Erlen, September, August, 2006).

3.6 PILOT STUDY

The pilot study was undertaken for two reasons: 1) to develop and implement a data analyses plan and 2) to assist the researcher in identifying possible measures that would be appropriate for the dissertation. The data set used for the secondary analysis was part of a larger on going study (R01 NR04749, J. Erlen, Principal Investigator). The larger study enrolled both men and women; however, the data used included only women enrolled into the study at the time the pilot study was conducted in spring of 2003.

The pilot study instruments differed from this dissertation in respect to the use of the subscale of the MOS-HIV, mental well-being for assessment of depressive symptomatology, the Modified Morisky Self-Report Measure (Morisky et al., 1986) for measurement of self-reported adherence, Berger's earlier measure to assess perceived stigma (Berger, Cohen, Ferrans, & Patel, 1995), and the Revised Sign and Symptom Check-List for HIV (SSC-HIV rev) (Holzemer, Hudson, Kirksey, Hamilton, & Bakken, 2001). In addition, only the demographic attributes of

age, race (Black and white), highest level of education, and marital status were included in the secondary analysis. The exposure risk category was not included in the secondary analysis.

3.6.1 Discussion of Pilot Specific Aims.

Five specific aims were explored in the pilot study. The specific aims of the dissertation were expanded and the reader is referred to Chapter One for more detailed information.

3.6.1.1 Specific Aims 1.

Describe rates of self-reported adherence among women with HIV who were taking antiretroviral medications.

3.6.1.2 Specific Aims 2.

Describe the associations between rates of self-reported adherence and sociodemographic factors (age, highest level of education, race/ethnicity, and marital status) among women with HIV who were taking antiretroviral medications.

3.6.1.3 Specific Aims 3.

Examine selected psychological factors (social support, mental well-being, and perceived stigma) and a selected physiological factor (physical well-being) that may be predictors of self-reported adherence among women with HIV who were taking antiretroviral medications.

3.6.1.4 Specific Aims 4.

Examine the relationships among selected demographic variables (age, education, race/ethnicity, and marital status) and selected psychological predictors (social support, mental well-being, and perceived stigma) and a physiological predictor (physical well-being) and self-reported adherence to antiretroviral among women with HIV/AIDS who were taking antiretroviral medications.

3.6.1.5 Specific Aim 5.

Examine the mediating effect of self-efficacy on the relationship of selected psychological factors (social support, mental well-being, and perceived stigma) and a selected physiological factor (physical well-being) that may be predictors of self-reported adherence among women with HIV who were taking antiretroviral medications.

3.6.2 Data Analysis of the Pilot Study.

A detailed descriptive analysis of all data was done, involving the summarization and the use of exploratory analytic techniques. The information obtained from this preliminary analysis was used to describe the univariate and bivariate sample distributions of the data, ascertain the interrelationships between and among the variables, and check for violations of assumptions necessary for statistical techniques. Means, percentiles, dispersions, and standard deviations of each variable were computed. The distributions of important covariates at baseline (e.g., race and age) were compared among the levels of key predictors of interest to ascertain possible confounding. From these preliminary investigations, the level of significance was established at 0.05 (two-tailed). When strong relationships existed, the variables were treated as covariates in

the preliminary analysis. Initially, the bivariate relationships were investigated for the specific aims using simple linear regression to obtained crude (unadjusted) estimates of the effect of each predictor variable. Stepwise linear regression was then used to further define the selection of variables into the predictive model. Lastly, higher order effects and interactions of the predictor variables were considered for possible inclusion in the predictive model.

3.6.3 Description of the Pilot Sample

There were 71 women in the pilot study. The mean age was 39.38 (*SD* = 7.713) with ages ranging from 24 to 55 years. Three categories for highest level of education were created (*N* = 69): less than high school education (*N* =18, 25.4%), high school education (*N* = 26, 36.6%), and greater than a high school education (*N* = 27, 38%). Marital status (*N* = 71) was grouped into never married (*N* = 22, 31%), currently married/living with partner (*N* = 22, 31%), no longer married (*N* = 25, 35.2%), and other (*N* = 2, 2%). Race included 36 (51%) subjects identified as white and 35 (49%) subjects identified as Black (*N* = 71).

3.6.4 Discussion of the Findings

3.6.4.1 Specific Aims 1

Describe rates of self-reported adherence among women with HIV who were taking antiretroviral medications. Using the Modified Morisky Self-report Measure of Adherence (Morisky et al., 1986), most women reported being adherent to their antiretroviral medications (*M* = 9.24, S*D* = 2.192). However, there was considerable variability in self-

reported adherence (Var. = 4.806). The skewness of the data was -.255 and kurtosis was -.515. Two subjects had missing data (n = 69).

3.6.4.2 Specific Aims 2

Describe the associations between rates of self-reported adherence and sociodemographic factors (age, highest level of education, race, and marital status) among women with HIV who were taking antiretroviral medications. There was no significant relationship between age and adherence using a bivariate correlation, Pearson r. There was no significant relationship between adherence to antiretroviral medications and age, educational group, racial group, or martial status using a nonparametric approach, Kendall's Tau (Table 2).

Table 2. Sociodemographic Associations with Adherence

	Age	Highest Level of Education	Race	Marital Status
Adherence	r =.180, p =.139	r = .106, p = .286	r = -.073, p =.486 (white) r = .041, p = .694 (Black)	r = -0.19, p = .851

3.6.4.3 Specific Aims 3

Examine selected psychological factors (social support, mental well-being, and perceived stigma) and a selected physiological factor (physical well-being) that may be predictors of self-reported adherence among women with HIV who were taking antiretroviral medications. Using the Pearson r to examine the possible associations between selected variables and adherence, a significant relationship between social support and adherence to antiretroviral medications was

found (r = .262, p = .029). There was no relationship between the subscales of perceived stigma and self-reported adherence for this sample of HIV positive women. The findings for each subscale included: personalized stigma (r = -.220, p = .072), disclosure stigma (r = -.018, p = .885), negative self-image (r = - .208, p = .086), and perceptions of public attitudes (r = -.090, p = .463). Using the mental well-being sub-score of the MOS-HIV, women who reported a better state of mental well-being had improved adherence to antiretroviral medications (r = .332, p = .005). Using the physical well-being subscale from the MOS-HIV, women who reported better physical well-being also had improved adherence to antiretroviral medications (r = .256, p = .033) (*Table 3*).

As described, due to the strong relationships between social support, mental well-being, and physical well-being and self-reported adherence these variables were fit into a multiple regression model. Although significant relationships were found between these variables and self-reported adherence to antiretroviral medications (R^2 = .112, p = 0.036), additional stepwise regression entering social support, mental well-being, and physical well-being in one of three blocks suggested only social support contributed to the model (R^2 = .069, p = .029).

Table 3. Relationships between predictor variables and adherence to antiretroviral medications.

	Social Support	Mental well-being	Stigma	Physical well-being
Adherence	r = .262, p = .029	r = .332, p = .005	personalized stigma (r = -.220, p = .072) disclosure stigma (r = -.018, p = .885), negative self-image (r = - .208, p = .086), and perceptions of public attitudes (r = -.090, p = .463)	r = .256, p = .033

3.6.4.4 Specific Aims 4

Examine the relationships between selected demographic variables (age, education, race, and marital status) and selected psychological predictors (social support, mental well-being, and perceived stigma) and a physiological predictor (physical well-being) and self-reported adherence to antiretroviral medications) among women with HIV/AIDS who were taking antiretroviral medications. Using a Kendall Tau association for all analyses, a significant negative relationship was found between one's race and personalized stigma: white subjects (r = -.240, p = .018) and Black subjects (r =. 257, p = 0.11). There was a significant relationship found between race and social support: white subjects (r = .229, p = .020) and Black subjects (r = .229, p = 0.19). Likewise, there was a significant negative relationship between race and physical well-being for Black subjects (r = -.230, p = .020). There was also a significant relationship between highest level of education and negative self-image (r = .205, p = .030). The variables of race (white and Black), personalized stigma, social support, physical well-being, highest level of education, negative self-image, and self-reported adherence were fit into a multiple regression model to further test the relationships. No relationship was found between these variables and self-reported adherence to antiretroviral medications (R^2 = .174, p = .104).

3.6.4.5 Specific Aims 5

Examine the mediating effect of self-efficacy on the relationship of selected psychological factors (social support, mental well-being, and perceived stigma) and a selected physiological factor (physical well-being) that may be predictors of self-reported adherence among women with HIV who were taking antiretroviral medications. Bivariate correlations of self-efficacy and the demographic variables did not demonstrate a relationship among any of the attributes. Pearson r correlations showed a significant relationship between self-efficacy and social support

(r = .473, p = .000). There were significant negative relationships between self-efficacy and personalized stigma (r = -.316, p = .008) and between self-efficacy and negative self-image (r = -.393, p = .001). There were significant relationships between self-efficacy and physical well-being (r = .380, p = .001) and between self-efficacy and mental well- being (r = .545, p =.000). Fitting a multiple regression model suggested self-efficacy had a significant direct effect on adherence (Beta coefficient = .620, p = .0001; R^2 = .38) and self- Efficacy mediated mental well being and self-reported adherence (Beta coefficient = .601, p = .000; R^2 = .299 (See Figure 2).

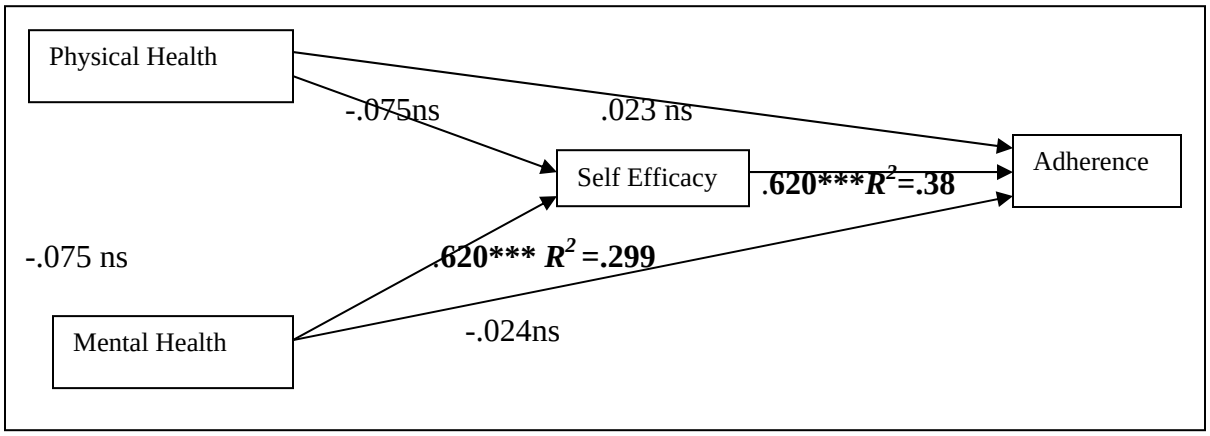

Figure 2. Path Analysis of the Mediating Effect of Self-efficacy and Adherence to Antiretroviral Medications using Subscales of the MOS HIV.

Furthermore, fitting a model for all variables (social support, mental well-being, physical well-being, personalized stigma, disclosure stigma, negative self-image, perceptions of public attributes, and self-efficacy resulted in self-efficacy significantly mediating social support (R^2 = .223) and mental health (R^2 = .392). No other significant relationships were found within the model.

Additional stepwise regression analysis for all variables was conducted. This consisted of seven variables within the model, each was entered as a block: 1) self-reported adherence, 2) all demographic variables (age, race-white, race-Black, highest level of education, and marital status), 3) social support, 4) all stigma sub-scores (personalized stigma, disclosure stigma, negative self-image, and public attitudes), 5) self-efficacy, 6) physical well-being, and 7) mental well-being. Only two models, the second and the fourth, demonstrated significant findings (See Table 4).

Table 4. Regression Model Summary

Model	*Variables*	*R Square*	*Beta Coefficient*	*Significance*
1	Demographic Variables (Marital status, race-white, race-Black, age, highest level of education)	.097	2.171	.260
2	Demographic Variables Social Support	.176	2.091	**.019***
3	Demographic Variables Social Support Perceived Stigma Subscales (Personalized Stigma, Disclosure Stigma, Negative Self-Image, & Public Attitudes)	.235	2.084	.360
4	Demographic Variables Social Support Perceived Stigma Subscales Self-efficacy	.444	1.792	.000**
5	Demographic Variables Social Support Perceived Stigma Subscales Self-efficacy Physical Well-being	.447	1.805	.628
6	Demographic Variables Social Support Perceived Stigma Subscales Self-efficacy Physical Well-being Mental Well-being	.447	1.821	.854

Findings from the second model suggested that social support contributed to adherence (R^2 = .176, p = .019). Model four suggested that self-efficacy contributed the most to adherence (R^2 =

.444, p = .0001). Fitting all variables (self-reported adherence, demographic factors, social support, perceived stigma subscales, self-efficacy, physical well-being, and mental well-being) into the final sixth model, suggested that only self-efficacy significantly contributed to self-reported medication adherence for women with HIV (Beta coefficient = .580, p = .0001).

3.6.5 Summary of the Pilot Study

For this sample of women (N = 71) there was little covariance within the model for demographic attributes (age, highest level of education, race, or marital status). Improved social support and physical well-being influenced adherence to antiretroviral medications. Increased mental well-being had a positive relationship with adherence to medications among women with HIV. These findings are important for designing interventions to improve adherence. Including interventions that may improve social support, physical well-being, and mental well-being may potentially lead to better adherence.

This pilot study was used to subsequently guide the dissertation study. A review of these pilot study data suggested self-efficacy had a mediating effect on self-reported adherence to medications among women with HIV/AIDS who were taking antiretroviral medications. There was a significant relationship between self-efficacy and mental well-being and self-efficacy and social support. This pilot study did not use the same measure of self-reported adherence as the dissertation study. The dissertation used the CES-D as the measure of depressive symptomatology. Several additional measures were also used for assessment of variables in the dissertations study. The HIV Social and Emotional Aspects Questionnaire (Berger, Ferrans, & Lashley, 2001) for assessed of perceived stigma, CD 4 and viral load were self-reported, and HIV disease symptoms was assessed using the revised Sign and Symptoms Check-list for HIV

(SSC-HIV rev (Holzemer et al., 2001). The MEMS cap adherence was also included to assess adherence in the dissertation study for a subsample of women.

3.7 DATA MANAGEMENT AND ANALYSIS

3.7.1 Data Screening

Before data entry, all forms were checked for completeness as described in the procedure section. If categorical data were missing an asterisk was substituted. Some personal information, such as income is sensitive and subjects may have chosen not to include this information. Data were screened for the type of missingness. If the data were missing at random and were continuous, the mean value was substituted for the missing value. If data were missing at random for a categorical value, these data were retained for analysis. If data were not missing at random for a subject's questionnaire and more than 20% of the data were missing for a given measure, that subject's data set was removed from the study.

3.7.2 Data Entry

Instrument forms were created using the Teleform™ Designer. All forms were scanned using Teleform™ optical reader and converted into a data file for each instrument. In addition, all forms were pre-coded to help minimize errors when processing data. Once the format (i.e., layout, naming and coding of variables, settings of valid ranges, verification standards, etc.) was finalized, the form was activated for use in data collection. Data entry and verification were

conducted using Teleform Windows-based software for automated data entry/verification. SPSS for Windows was used for data management (SPSS, 2006, Version 13, SPSS UK LTD, Surrey, Great Britain). A data dictionary was generated and the associated database table was initialized and readied for data entry. Database tables were formatted for use in SPSS for Windows. Data were backed up on a continual basis as they were entered in the data base, archived on compact-disc (CD) for future use, and stored in the researcher's office.

Preliminary Data Analysis

A detailed descriptive analysis of all data was done involving the summarization and the use of exploratory analytic techniques. The information obtained from this preliminary data analysis was used to: 1) describe univariate and bivariate sample distributions of the data, 2) ascertain the interrelationships between and among variables, and 3) check for violations of assumptions necessary for statistical techniques. Statistics describing the means, percentiles, dispersions, and standard deviations of each variable were computed. The distribution of important covariates at baseline (e.g., ethnicity, age) was compared among the levels of key predictors of interest to check for possible confounding. For these preliminary analyses, the level of significance was established at 0.05 (two-tailed). When strong relationships existed, these variables were treated as covariates in the primary analysis.

3.7.3 Primary Data Analysis

Bivariate relationships were investigated for the aims using simple linear regression to obtain crude (unadjusted) estimates of the effect of each predictor variable. Stepwise linear regression was then used to further define the selection of variables into the predictive model. Lastly, higher

order effects and interactions of the predictor variables were considered for possible inclusion in the predictive model. The level of significance was set at 0.05.

3.7.4 Procedure for the Protection of Human Subjects

3.7.4.1 Confidentiality

The proposal was submitted to the University of Pittsburgh Institutional Review Board (IRB) and approval was received. Each participant was assigned a three-digit code number. A master list of participants' names, addresses, and telephone numbers was kept in the event that further contact was required. All personal identification and completed instruments were filed separately from the assigned codes to protect anonymity. This confidential identifying information was kept under double lock accessible only by the researcher and will be destroyed upon completion of the study, or as per University policy, at 5 years following study completion, whichever occurs last. A computerized tracking system was developed, which captured information regarding participant eligibility and study completion.

3.7.4.2 Risk and Benefits Ratio

Participants were assured there was minimal risk if they agreed to participate in the research study. One possible risk was that women might become embarrassed when asked to report personal matters. There was also a risk that participants may become fatigued during the data collection session. No subject reported fatigue; however, if fatigue had occurred, the researcher would have allowed time for rest or rescheduled the data collection at another agreed

upon time. Participants were assured there was no retribution if they decided not to participate in the study or withdraw from the research study at any time. If a participant decided not to take part in this research study, she continued to receive her usual care from her health care provider. Participation in the study did not replace the usual treatment from the subject's health care provider.

3.7.4.3 Potential Benefits to Patient

There were no benefits to the participant from taking part in this research study. For future subjects, there is the possibility that the results of this study may benefit women as more investigations are undertaken that explore issues of adherence to medications for women with HIV. This study may also guide a future study to improve adherence to antiretroviral medications for women with HIV.

3.7.4.4 Competency to Consent to Research

Adult participants (i.e., women 18 years and older) diagnosed with HIV/AIDS for at least a period of six months or more and prescribed antiretroviral medications, and receiving health care for their HIV infection in a hospital or university affiliated primary care clinic or rural clinic were recruited for this study. All persons involved in the study were required to be able to read and write English, as well as to vocalize their feelings and acknowledge an understanding of their disease and medication use. The clinic and hospital liaisons were instructed to provide brochures about the study to potential subjects. Women who were able to read and discuss and sign the consent form were assumed mentally competent to participate in this study.

3.7.4.5 Cost and Payments

Neither the participant nor her insurance provider was charged for costs of any procedures performed for the purpose of this study. In the unlikely event that an injury would occur as a result of the research procedures the participant was informed to contact the Principal Investigator on the first page of the Informed Consent Form (Medication Management for Women). No injuries were reported.

3.7.5 Difficulties and Limitations

As with any research investigation there were potential difficulties identified prior to the initiation of a study; the researcher had planned for many of these problems in advance. There was considerable difficulty in recruiting the original sample of 75 HIV-positive women. The researcher had planned for this possibility by establishing relationships with three HIV care centers (see Setting) and commitment of key personnel at the facilities to assist in the identification of potential participants. This plan, although well designed, was not successful. Many obstacles occurred including inability to secure support from the HIV clinic in Lancaster County, PA; this site would have increased the potential for recruiting minority Latina women. Other obstacles were a long delay in receiving a physician letter of support and slow recruitment at all rural and urban sites. These limitations are further addressed in Chapter 5 of this report. Anticipating difficulties with recruitment and as an incentive, a token of appreciation ($15.00) was provided to enhance recruitment of potential participants.

Due to the difficulty in recruitment the power analysis for the study was recalculated for the potential of 35 and 45 subjects recruited into the study. Using the same power analysis technique as described previously the following demonstrates the changes in power.

Power	N	Alpha	Beta	Count	Ind.Variables Tested R^2	Count	Ind. Variables Controlled R^2
0.9999	45	0.05	0.0001	8	0.57413	0	0.0000
0.9500	45	0.05	0.05	8	0.38362	0	0.0000
0.9000	45	0.05	0.1	8	0.34276	0	0.0000
0.8000	45	0.05	0.2	8	0.29072	0	0.0000

Power	N	Alpha	Beta	Count	Ind. Variables Tested R^2	Count	Ind. Variables Controlled R^2
0.9999	35	0.05	0.0001	8	0.65307	0	0.0000
0.9500	35	0.05	0.05	8	0.46352	0	0.0000
0.9000	35	0.05	0.1	8	0.41969	0	0.0000
0.8000	35	0.05	0.2	8	0.36212	0	0.0000

Original Power Analysis

Power	N	Alpha	Beta	Count	Ind. Variables Tested R^2	Count	Ind. Variables Controlled R^2
0.9999	75	0.0500	0.0000	8	0.447	0	0.0000
0.9000	75	0.0500	0.1000	8	0.222	0	0.0000
0.8000	75	0.0500	0.2000	8	0.183	0	0.0000

It was anticipated that women in the subsample using the MEMS cap might misplace or lose the MEMS cap and/or the return-mailing envelope and/or forget to forward the MEMS cap. Therefore, the researcher contacted each participant using the MEMS cap as described. In addition, participants who completed use of the MEMS cap for 29 days were provided with an additional token of a $5.00 gift card following return of the MEMS cap.

It was also anticipated that childcare might be an issue and deter some women from participating in the study. To assist women accompanied by children to participate in the study, the researcher was present and available to assist with childcare as needed. There were only two recruitment situations that required supervision of children.

4.0 CHAPTER FOUR

4.1 RESULTS

Two identified overall purposes guided this descriptive cross-sectional study. The first purpose was to examine the psychological factors (depressive symptomatology, social support, and perceived stigma) and physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) that may be predictors of adherence among women with HIV/AIDS who were prescribed antiretroviral medications. The second purpose was to examine the potential mediating effect of self-efficacy on the relationships between the psychological factors (depressive symptomatology, social support, and perceived stigma) and physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) and self-reported adherence to antiretroviral medications for women with HIV.

The specific aims were to: (*1)* describe overall patterns of self-reported adherence among women with HIV/AIDS prescribed antiretroviral medications, (*2*) describe the relationships between patterns of self-reported adherence and age, education, race/ethnicity, marital status, and exposure risk category among women with HIV/AIDS prescribed antiretroviral medications, (*3)* examine the relationships between the selected psychological factors (depressive symptomatology, social support, and perceived stigma) and self-reported adherence among women with HIV/AIDS prescribed antiretroviral medications, (*4)* examine the relationships

between the selected physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) and self-reported adherence among women with HIV/AIDS prescribed antiretroviral medications, (*5)* examine the mediating effect of self-efficacy on the relationships between selected psychological factors (depressive symptomatology, social support, and perceived stigma) and selected physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) and self-reported adherence among women with HIV/AIDS prescribed antiretroviral medications, and (*6)* describe patterns of adherence in a subsample of women with HIV/AIDS who were prescribed antiretroviral medications using a self-reported measure of adherence and the Medication Event Monitoring System (MEMS).

4.1.1 Screening

Forty-five women were recruited into the study. Following informed consent each subject was screened for inclusion through the use of standardized tests and one self-report questionnaire. Two standardized screening measures were used. The Rapid Estimate of Adult Literacy in Medicine (REALM) was used to briefly assess the ability of the participant to read and understand medical terminology (Davis et al., 1993). One subject was excluded due to her inability to read and understand medical terminology. The remaining subjects (N = 44) had acceptable scores on the REALM and were included in the sample. Possible neurocognitive impairment was assessed using the 4-item HIV Dementia Scale [HDS] (Powers, Selnes, Grim, & McArthur, 1995). No subject was excluded based upon her HDS score (<10). No potential subject self-reported a history of mental illness; therefore, this criterion did not exclude anyone from participation.

4.1.2 Data Analysis of the Study

A detailed descriptive analysis of all data was done, involving the summarization and the use of exploratory analytic techniques. Scatter plots were run for each of the five socio-demographic variables and independent variables. There were no outliers for any of the variables. Using a scatter plot and/or stem and leaf graphs for each of the ACTG adherence items and each socio-demographic variable showed that there were no outliers. In addition, using a scatter plot and stem and leaf graphs for each of the ACTG adherence items and the independent variables showed no outliers. The possibilities of indirect effects of the independent variables on the dependent variable for the ACTG items were explored; no indirect effects were identified.

The information obtained from this preliminary analysis was used to: 1) describe the univariate and bivariate sample distributions of the data and 2) ascertain the interrelationships between and among the variables and check for violations of assumptions necessary for statistical techniques. The means, percentiles, dispersions, and standard deviations of each variable were computed. The distributions of important covariates at baseline (e.g., race and age) were compared among the levels of key predictors of interest to ascertain possible confounding. When strong relationships existed, the variables were treated as covariates in the preliminary analysis. Initially, the bivariate relationships were examined relevant to the specific aims using simple linear regression to obtained crude (unadjusted) estimates of the effect of each predictor variable. Stepwise linear regression was then used to further define the selection of variables to be entered into the predictive model. Lastly, higher order effects and interactions of the predictor variables were considered for possible inclusion in the predictive model.

4.2 SAMPLE

After cleaning the data, descriptive statistics were used to describe the sample. The 44 women in this convenience sample ranged in age from 29 to 60 years with a mean age of 42.89 (*SD* = 7.97) years. Of this sample 28 (64%) were women over 40 years of age. In addition, nine of these 28 women were 50 years of age or older and one women 60 years of age, which equals 20% of the total sample. More than half of the sample was white or non-Hispanic (*n* = 23, 55%). Thirty-six percent (*n* = 18) of the women were Black/African American. Three (7%) of the women identified themselves as Latina, specifically Puerto Rican. Three women indicated that their race/ethnicity was biracial. These latter three groups were classified as non-white for data analysis purposes.

Years of education reflected a range from 6 through 18 years of education. The mean number of years of education was 12.34 (*SD* = 2.07). Twenty-seven (62%) of the women had either a high school education or general education degree (GED). Eleven women (25%) reported to have never been married; thirteen (30%) were currently either married or living with a partner/significant other. Twenty women (46%) were divorced, separated, or widowed.

The women were recruited from western Pennsylvania and eastern Ohio. Using mailing zip codes as indicators of area of residence, 18 women (41%) resided in small towns/rural areas throughout Western PA. An additional eleven women (25%) resided in a large urban city and 15 women (34%) resided in suburban areas or moderately sized towns in western PA and eastern Ohio. Other demographic information is included in Table 5 below.

Twenty-eight (64%) of the women did not respond to the question on income. However, all 44 responded to the question regarding income meeting their basic needs; 27 (61%) reported that their income met their basic needs. The majority of subjects (75%) reported that their main

source of income came from social security, supplemental security or retirement/survivor benefits. Only five women reported being employed 35 hours per week or more. Forty women (91%) reported their exposure risk as being through heterosexual sex with a man who was HIV positive. Other socio-demographic information is included in Table 5.

In addition, for the subsample of women who participated in the monitored adherence substudy (n =10) the socio-demographic and variable data were compared with the total sample (N = 44). The ten women were equally divided with five white and five non-white participants. Five women had a high school education or general education degree (GED). One woman had less than a high school education and four women had more than a high school education. Six women were between ages 29 and 39. Three women were between the ages of 40 and 49 and one woman was age 50 or older. All ten women reported their HIV exposure risk as being through heterosexual contact.

Table 5 Socio-demographic Characteristics (N =44).

Variable	Frequency	Percent
Age		
Less than 30	1	2
30 – 39	15	34
40 – 49	19	43
50 – 59	8	18
60 and over	1	2
Race		
White	23	52
Black/African American	16	36
Latina/Hispanic	3	7
Biracial	2	5
Education		
< High School	9	20
GED	10	23
High School	17	39
> High School	8	18

Table 5 (continued)

Martial Status		
Never married	11	25
Married	5	11
Living with partner	8	18
Widowed	4	9
Separated/divorced	16	37
Area of Residence		
Urban	11	25
Suburban	15	34
Rural/Small towns	18	41
Income		
< 10,000	8	18
10,000 – 14,999	3	7
15,000 – 19,999	1	2
20,000 – 29,999	3	7
30,000 – 39,999	1	2
Not reported	28	59
Employment		
Employed full-time	5	11
Employed part-time	3	7
Retired/laid-off	2	4.5
Disabled	28	64
Homemaker full-time	5	11
Seasonal worker	1	2
Exposure Risk Category		
Multiple Selections possible		
Heterosexual Contact	40	91
Intravenous drug use	2	4.5
Blood	2	4.5
Children		
Yes	35	80
No	9	20
Insurance		
Private Insurance	9	20
Medicare	16	36
Medicaid/SSI	19	44

Table 5 (continued)

Insurance to Cover Meds		
Yes, all	25	57
Yes, some	15	34
No	3	7
Unknown	1	2

4.3 DESCRIPTION OF THE MEASURES

The psychological variables included depressive symptomatology, social support, and perceived stigma. The Center for Epidemiological Studies - Depression Scale (CES-D) was used to assess *depressive symptomatology* (Radloff, 1977). A score of 16 or greater suggests depressive symptomatology; a score of 25 or greater is suggestive of severe depressive symptomatology. The mean CES-D score was 22.4 (*SD* = 8.80). CES-D scores ranged from 8 to 41. *Social support* was measured by the Interpersonal Support Evaluation List (ISEL) (Cohen & Syme, 1985). Scores on this measure can range from 0 to 120 with higher overall scores suggestive of greater perceived potential availability of social support (Cohen & Syme.). The mean score for this sample was 79.33 (*SD* = 19.07). Social support scores ranged from 45 to 115. *Perceived stigma* was measured using the total score of the HIV Social and Emotional Aspects Questionnaire (Berger et al., 2001). The scores on this measure can range from 40 to 160. For the women in this study, the mean score for perceived stigma was 100.43 (*SD* = 21.14); scores ranged from 56 to 155. Higher scores suggest greater item agreement and less perceived social support (Berger et al.)

The physiological variables included self-reported *CD 4* and *viral load, HIV disease symptoms,* and *physical well-being*. CD 4 and viral load were self-reported by the subjects as a part of the socio-demographic measure. Eighteen (41%) subjects did not know their CD 4. Twenty-six (59%) reported their CD 4; the range for CD 4 was 0 to 1400 (*M* = 338.45, *SD* = 429.91). Thirty-two women (75%) did not know their viral load.

The Revised Sign and Symptom Check-list measured *HIV Disease Symptoms for HIV (SSC-HIV rev)* (Holzemer et al., 2001). This measure assesses symptoms associated with HIV disease, treatments, and medications. The revised measure includes eight gynecological symptoms for women with HIV disease. The total score reflects a sum of 72 items. The mean score for HIV disease symptoms present the day of data collection was 20.82 (*SD* = 16.50). HIV symptoms ranged from 0 (none present today) to 56. The higher the score the more symptoms present and the greater the intensity of the symptoms. The most frequently reported symptoms (present today) were: fatigue, fear/worries, joint pain, weight gain, muscle aches, shortness of breath, abdominal complaints (gas, bloating, diarrhea, nausea) headache, dizziness, and night sweats.

Physical well-being was measured using the subscale of the Medical Outcomes Study-HIV (MOS-HIV) measure (Wu et al., 1991). The subscale includes the domains of physical function, pain, role function, overall health, energy/vitality, and social function. The mean score was 44.24 (*SD* = 12.33) with scores ranging from 22.34 to 63.95**.** Scores are summated from 0 to 100 with higerh scores suggestive of better health (Wu et al.).

The mediating variable, *perceived self-efficacy,* was assessed using the HIV Medication Taking Self-efficacy Scale (Erlen, 1999). This 26-item measure includes an overall score for self-efficacy and two subscales, self-efficacy beliefs and outcome expectancies. The overall

score ranges from 26 to 260 with higher scores suggestive of greater perceived confidence in management of their HIV/AIDS medications. The *self-efficacy beliefs subscale* was used for data analysis. The mean score was 151.43 (*SD* = 21.51) with scores ranging from 17 to 170.

The dependent variable, self-reported adherence, was assessed for all 44 women in the study using the *AIDS Clinical Trial Group Assessment (ACTG)* measure (Chesney et al., 2000). The ACTG is composed of three subsections with a total of 40 items. In addition, a subsample of 10 women used an electronic event medication system (MEMS). This electronic device is designed to record each time the subject opens the bottle cap and can be used with any dosing schedule. Following selection of the medication to be monitored (see Chapter Three for further descriptions of medication selection) each subject was instructed on the filling and use of the pill bottle. The mean, standard deviation, range of scores, and Cronbach's alpha for the measures are presented in Table 6.

Table 6. Psychometric properties of the measures (*N* = 42).

Measure	Mean Score	Standard Deviation	Range	Cronbach's Alpha
CES-D	22.42	8.80	8 - 41	.79
ISEL	79.33	19.07	45 - 115	.94
Perceived Stigma	100.43	21.14	56 - 155	.95
Self-efficacy Belief	151.43	21.51	17 - 170	.93
HIV symptoms	20.82	16.59	0 - 88	.93
MOS-HIV Physical Well-being	44.24	12.33	22.34 - 63.95	.90

There were differences in the mean score for two measures for the women who used the MEMS cap and those that did not use the MEMS cap in regard to HIV disease symptoms and physical

well-being, neither of the differences were significant. The women using the MEMS cap had better physical well being, yet more HIV disease symptoms. (See Table 7).

Table 7 Comparison of measures for the total sample and subsample using the MEMS cap.

Measure	Sample (N = 42)		Cap Subsample (n = 10)	
	Mean	SD	Mean	SD
CES-D	22.42	8.80	20.40	7.29
ISEL	79.33	19.07	81.80	21.07
Perceived stigma	100.43	21.14	99.00	19.22
HIV symptoms	20.82	16.59	27.64	24.12
MOS-HIV Physical well-being	44.24	12.33	40.74	18.25
Self-efficacy Beliefs	231.39	27.51	233.20	26.85

4.4 SPECIFIC AIMS

4.4.1 Specific Aims 1

Describe the overall patterns of self-reported adherence among women with HIV/AIDS prescribed antiretroviral medications. The ACTG measure of adherence (Chesney et al., 2000) contains six questions. Each question/item was examined separately. (See Table 8). For this sample of 44 women with HIV/AIDS who were prescribed antiretroviral medications, 34 women (77%) reported they never missed taking their medications on any of the last 4 days. However, the ten (23%) remaining women reported missing doses of medications at least one to four days over that last 4-day period. When responding to a question regarding following a specific schedule for their medications, such as 2 to 3 times a day, 28 women reported that they follow

this regime all of the time; six women followed the regimen some to half of the time. Approximately 59% of the women (*n* =26) reported taking their medications according to the special instructions, such as with or without food or on an empty stomach; ten women (22.7%) reported following these special instructions all of the time. Most of the women (82%) reported that they were not forgetful about taking their medications on the weekends. Nine women (21%) reported that they "never skip medications", 13 (30%) reported skipping their medications more than 3 months ago, 15 (34%) missed their medication during the last 3 months, and 7 (16%) missed medications within the last week. (Table 8).

The most frequently identified reasons for missing medications were: being away from home (*n* =16), busy with other things (*n* =15), simply forgot (*n* = 12), feeling sick (*n* = 11), change in routine (*n* = 9), falling asleep or slept through the dosing time (*n* = 9), and not wanting others to notice taking medications (*n* = 6). Only two women reported missing medications due to running out of their medication.

4.4.2 Specific Aims 2

Describe the relationships between patterns of self-reported adherence and socio-demographic factors (age, education, race/ethnicity, marital status, and exposure risk category) among women with HIV/AIDS who were prescribed antiretroviral medications.

H2A: There is an association between self-reported adherence and socio-demographic factors (age, education, race/ethnicity, marital status, and exposure risk category) among women with HIV/AIDS who are prescribed antiretroviral medications.

The ACTG self-report adherence questionnaire does not use a composite score, rather there are five separate items/questions addressing aspects of medication adherence. For these

analyses, items 1 and 6 were considered as continuous variables. Items 2, 4, and 5 were either categorical or dichotomous variables. Item 3 does not assess adherence, rather it inquires about special instruction (medications have special instructions, i.e., with food).

Table 8 Self-reported medication adherence as assessed using the ACTG (*N* = 44).

	Possible Responses	Frequency	Percentage
Missed taking all of your doses in the last 4 days	0 None	34	77.3
	1 One day	5	11.4
	2 Two days	3	6.8
	3 Three days	0	0.0
	4 Four days	2	4.5
Following dose instructions (i.e., 2 to 3 times a day).	0 Never	0	0.0
	1 Some of the time	2	4.5
	2 About half the time		
	3 Most of the time	4	9.1
	4 All of the time	10	22.7
		28	63.5
Medications have special instructions (i.e., with food).	Yes	26	59
	No	18	41
Follow special instructions *N* = 26	0 Never	0	0.0
	1 Some of the time	3	6.8
	2 About half of the time		
	3 Most of the time	1	2.3
	4 All of the time	12	27.3
		10	22.7
Missed pills on the weekend	Yes	36	81.8
	No	8	18.2
Last time you missed medications.	Within past week	7	15.9
	Between1-2 weeks ago	4	9.1
	Between 2-4 weeks ago	4	9.1
	Between 1-3 months ago	7	15.9
	More than 3 months ago	13	29.5
	Never	9	20.5

Age was treated as a continuous variable in the analyses. The Pearson r correlation was used to examine the associations between age (range was 29 to 60 years) and self-reported adherence questions (1 and 6). There were no significant relationships between these items and the subject's age. Kendall's Tau correlation was used for the other three questions (2, 4, and 5). There were no significant relationships between these self-reported adherence items and the subject's age. (See Table 9).

Three categories for highest level of education were created: less than high school education (n = 9), high school education or GED (n = 27), and greater than a high school education (n = 8). Marital status was grouped as follows: never married (n = 11), married or in a relationship (n = 13), and no longer married, divorced, separated, or widowed (n = 20). Race was grouped into two categories: white (n = 23) and non-white (n = 21). The latter group included those women who self-reported their race as Black/African-American, Hispanic, and biracial.

Significant relationships were identified when using Kendall's Tau to examine race/ethnicity groups, education, and marital status (Table 9). There was a moderately significant relationship between race/ethnicity and "missed taking any of your doses in the last 4 days" (r = .340, p = .021). There was a significant moderate relationship between education and "following dose instructions (i.e., 2 to 3 times a day)" (r = .346, p = .013) and a significant moderate relationship between education and "follow special instructions" (r = .420, p = .025). There was a significant moderate negative relationship between marital status and "following dose instructions (i.e., 2 to 3 times a day)" (r = -.333, p =. 017). There were no associations between exposure risk category and the five items of self-reported adherence. Therefore, hypothesis 2A was partially supported.

Table 9 Associations between socio-demographic variables and self-reported adherence (*N* =44)

Self-reported Adherence	Age	Education	Race	Marital Status	Exposure Risk
1. Missed taking all of your doses in the last 4 days.	*r* = .003, *p* =.982	*r* = -.257, *p* = .069	*r* = .340, *p* = .021*****	*r* = .112, *p* =.426	*r* = -.045, *p* = .759
2. Following dose instructions (i.e. 2 to 3 times a day).	*r* = -.077, *p* = .528	*r* = .346, *p* = .013*****	*r* = .160, *p* = .271	*r* = -.333, *p* =.017*****	*r* = .110, *p* = .445
4. Follow special instructions. *n* = 26	*r* = -.157, *p* = .346	*r* = .420, *p* = .025*****	*r* = .206, *p* = .290	*r* = .000, *p* = .100	*r* = .162, *p* = .400
5. Missed pills on the weekend.	*r* = .037, *p* = .772	*r* = .188, *p* = .200	*r* = -.257, *p* = .091	*r* = -.276, *p* = .058	*r* = .263, *p* = .082
6. Last time you missed meds.	*r* = .194, *p* = .208	*r* = -.111, *p* = .395	*r* = .024, *p* = .857	*r* = .133, *p* = .304	*r* = - 191, *p* = .156

4.4.3 Specific Aim 3

Examine the relationship between selected psychological factors (depressive symptomatology, social support, and perceived stigma) and self-reported adherence among women with HIV/AIDS who were prescribed antiretroviral medications.

H3A: Women who report less depressive symptomatology will have better self-reported adherence to antiretroviral medications. A Pearson r correlation for assessing self-reported adherence "missed taking any of your doses in the last 4 days" and depressive symptomatology showed a weak significant association between these two variables (*r* = .315, *p* =. 040). There were no associations between the other self-reported adherence items using either the Pearson r correlation or Kendall's Tau non-parametric procedure. Thus, this hypothesis was partially supported.

H3B: Women who report strong social support will have better self-reported adherence

to antiretroviral medications. There were no significant associations between adherence and social support using either the Pearson r or Kendall's Tau. This hypothesis was not supported.

H3C: Women who report less perceived stigma will have better self-reported adherence to antiretroviral medications. The Pearson r correlation for self-reported adherence (questions1 and 6) and perceived stigma demonstrated no significant relationships. Using Kendall's Tau to examine self-reported adherence to questions 2, 4, and 5 and perceived stigma, resulted in one significant association was shown. Perceived stigma was significantly negatively associated with "following dose instructions" (r = -.275, p = .023). There were no other significant associations between self-reported adherence and perceived stigma. Therefore, this hypothesis was partially supported.

4.4.4 Specific Aim 4

Examine the relationship between selected physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) and self-reported adherence among women with HIV/AIDS who were prescribed antiretroviral medications.

H4A: Women who report higher CD 4s and lower disease viral load will have better self reported adherence to antiretroviral medications. Only 26 women were aware of their CD 4. Self-reported adherence assessing "last time you missed meds" and CD 4 was significantly negatively associated (r = -.256, p = .031) using the Pearson r procedure. Self-reported adherence "following dose instructions (i.e., 2 to 3 times a day)" was significantly associated with CD 4 (r = .317, p = 0.12) using Kendall's Tau. Of the 44 women, fifteen (34%) self-reported their viral load and three (6%) self-reported their viral load as undetectable. There were

no significant correlations between self-reported viral load and self-reported adherence using the Pearson r or Kendall's Tau. Thus, this hypothesis was partially supported.

H4B: Women who report fewer HIV disease symptoms will have better self-reported adherence to antiretroviral medications. Using a Pearson r correlation for self-reported adherence and HIV disease symptoms there were no significant associations. There was a strong significant negative association between HIV symptoms and "following dose instructions (i.e., 2 to 3 times a day)" (r = -.427, p = .009), using a Kendall's Tau non-parametric procedure. Therefore, this hypothesis was partially supported.

H4C: Women who report better physical well-being will have better self-reported adherence to antiretroviral medications. Using Pearson r and Kendall's Tau there were no significant associations between physical well being and self-reported adherence. Therefore, this hypothesis was not supported.

The Pearson r correlation was used to explore the possible relationships between the selected psychological factors or physiological factors. There were significant associations between depressive symptomatology and two variables, perceived stigma (r =. 482, p = .001), HIV disease symptoms r = .585, p = .000), and a trend for a negative relationship with CD 4 (r = -.294, p =.056). Social support was significantly negatively associated with perceived stigma (r = -.497, p = .001) and HIV disease symptoms (r = -.316, p = .036). Perceived stigma was significantly negatively associated with CD 4 (r -.310, p = .041) and physical well being (r = -.358, p = .018) with a trend for a relationship with HIV disease symptoms (r = .291, p = .055). In addition, there was a significant negative relationship between HIV disease symptoms and physical well-being (r = -.358, p = .018). These associations are represented in Table 10.

Table 10 Associations between variables (*N* =42)

Variable	Depressive Symptom-atology	Social Support	Perceived Stigma	CD 4	Viral load	HIV Disease Symptom	Physical Well - Being
Depressive Symptomatology	1	*r* = -.272, *p* = .078	*r* =. 482, *p* = .001	*r* = -.294, *p* =.056	*r* = -.075, *p* = .632	*r* = .585, *p* = .000	*r* = .002, *p* = .990
Social Support		1	*r* = -.497, *p* = .001	*r* =. 267, *p* = .080	*r* = -.119, *p* = .440	*r* = -.316, *p* = .036	*r* = .199, *p* = .201
Perceived Stigma			1	*r* -.310, *p* = .041	*r* = .090, *p* = .561	*r* = .291, *p* = .055	*r* = -.358, *p* = .018
CD 4				1	*r* = -.014, *p* = .928	*r* = -.78, *p* = .617	*r* = -.212, *p* = .172
Viral load					1	*r* = .117, *p* = .448	*r* = -.261, *p* = .091
HIV Symptoms						1	*r* = -.358, *p* = .018
Physical Well – Being							1

4.4.5 Specific Aim 5

Examine the mediating effect of self-efficacy on the relationship between selected psychological factors (depressive symptomatology, social support, and perceived stigma) and selected physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) and self-reported adherence among women with HIV/AIDS who were prescribed antiretroviral medications.

H5A*: Self-efficacy will mediate the relationship between selected psychological factors (depressive symptomatology, social support, and perceived stigma) and self-reported adherence to antiretroviral among women with HIV/AIDS.*

H5B*: Self-efficacy will mediate the relationship between selected physiological factors (CD 4, viral load, HIV disease symptoms, and physical well-being) and self-reported adherence to antiretroviral medications among women with HIV/AIDS.*

The self-efficacy measure includes a total score and two subscales scores: self-efficacy beliefs and outcome expectancies. The relationships between self-efficacy beliefs and self-reported adherence for the five ACTG items were investigated prior to examining the possible mediating effect of self-efficacy.

Using the Pearson r, there was a significant negative association between the self-efficacy beliefs and self-reported adherence "last time you missed meds" (r = -.310, p = .041). Using Kendall's Tau, there was a significant association between the self-efficacy beliefs subscale score and self-reported adherence "missed pills on the weekend" (r = .257, p = .047).

The Pearson r was used to examine possible associations between self-efficacy beliefs and the psychological predictor variables (depressive symptomatology, social support, and perceived stigma). The self-efficacy beliefs subscale was significantly associated with social support (r = .394, p = .008). The Pearson r was used to examine possible associations between self-efficacy beliefs and the physiological predictor variables (CD 4, viral load, HIV disease symptoms, and physical well-being). There were no significant associations between self-efficacy beliefs and the physiological predictor variables. Associations are presented in Table 11 for self-efficacy beliefs subscale score and psychological and physiological predictor variables.

The potential mediating effects of self-efficacy beliefs the variables were examined using the regression analyses techniques as identified by Baron and Kenny (1986). In this article, the authors describe a mediating variable as influencing the relationship between the independent variables and the dependent variables. Thus, the mediating variable, self-efficacy beliefs, has the

Table 11 Correlations between Self-efficacy Beliefs and Predictor Variables (*N* = 42)

Variable	Depressive Symptomatology	Social Support	Perceived Stigma	CD 4	Viral Load	HIV Symptoms	Physical Well-Being
Self - efficacy beliefs subscale	r = -.045, p = .776	r = .394, p = .008*	r = -.243, p = .112	r = .208, p = .175	r = -.054, p = .727	r = -.159, p = .301	r = .164, p = .292

potential to provide additional insight about the relationships between the independent variables (depressive symptomatology, social support, perceived stigma, CD 4, viral load, HIV disease symptoms, and physical well-being) and the dependent variables of the ACTG self-reported adherence measure.

The tests for mediation include the following steps (Baron & Kenny, 1986): Step 1, regress the mediator on the independent variables, Step 2, regress the dependent variables on the independent variables, which includes the five dependent variables of the ACTG and the seven independent variables, and Step 3, regress the dependent variables (ACTG items) on both the mediator (self-efficacy beliefs) and the seven independent variables. These analyses included linear regression with continuous dependent variables, items 1, 2, 4, and 6 and logistic regression with dichotomous dependent variables, items 3 and 5. Item 3, is concerned with the medications having special instruction, such as taking the medication with food. Twenty-six women responded yes to this answer; therefore, this item was explored in the logistic regression as this approach is used for dichotomous variables, such as a yes and no response.

Step 1. The possible relationships between self-efficacy beliefs and depressive symptomatology, social support, perceived stigma, CD 4, viral load, HIV disease symptoms, and physical well-being were fit into a linear regression model using the SPSS default of enter (*N*= 42). There were no significant relationships. However, using a step-wise approach yielded

significant results for a relationship between self-efficacy beliefs and social support (*Unstandardized Beta* = .431, R^2 = .145, *p* = .013).

Step 2. To explore the possible relationships between the ACTG continuous dependent variables, items 1,2 ,4, and 6 and seven independent variable each were fit into separate linear regression models (*N*= 42). There were significant associations as follows: a significant positive association between self-reported adherence (item 1) "missed taking any of your doses in the last 4 days" and depressive symptomatology (*Unstandardized Beta* .035; R^2 = .095, *p* = .047), a significant positive association between self-reported adherence (item 2) "following dose instructions, i.e., 2 to 3 times a day" and CD 4 (*Unstandardized Beta* .001; R^2 = .138, *p* = .015), a significant negative association between self-report adherence "last time you missed meds" and CD 4 (*Unstandardized Beta* = - .001; R^2 = .358, *p* = .020). The logistic model for items 3 and 5 of the ACTG and the independent variables did not yield significant results.

Step 3. The possible relationships between the dependent variables, self-reported adherence items 1, 2, 4, and 6 and self-efficacy beliefs, depressive symptomatology, social support, perceived stigma, CD 4, viral load, HIV disease symptoms, and physical well-being were further tested by fitting these variables into a linear regression model (*N*= 42). The enter default mode was used for the analyses. There were significant associations between item 2 "follow special instructions, i.e., taking medications 2 or 3 times a day" and CD 4 (*Unstandardized Beta* = .001, *t* = 2.181, *p* = .036) and item 4 "following special instructions, i.e., taking with food" and perceived stigma (*Unstandardized Beta* = -.038, *t* = -2.360, *p* = .032.

Using a step-wise linear approach yielded the following results: a significant positive association between self-reported adherence (item 1) "missed taking any of your doses in the last 4 days" and CD 4 (*Unstandardized Beta* .035; R^2 = .095, *t* = 2.046, *p* = .047), a significant

positive association between self-reported adherence (item 2) “following dose instructions, i.e., 2 to 3 times a day” and CD 4 (*Unstandardized Beta* .001; R^2 = .138, t = 2.530, p = .015), and a significant negative association between self-reported adherence “last time you missed meds” and CD 4 (*Unstandardized Beta* = - .001; R^2 = .358, t = -2.423, p = .020). These data are the same as above with self-efficacy beliefs entered into the regression model with all of the independent variables in step two.

Due to the limited responses from the subjects for their CD 4 and viral load these independent variables were removed from the model and the data again explored. As in the previous analyses, there was a significant positive association between self-reported adherence (for item 1) “missed taking any of your doses in the last 4 days” and depressive symptomatology with the results the same as step two (*Unstandardized Beta* .035; R^2 = .095, p = .047). However, with CD 4 and viral load removed from the linear regression there was a significant negative association between self-reported adherence “last time you missed meds” and self-efficacy beliefs (*Unstandardized Beta* = - .026; R^2 = .102, p = .040). Using a logistic regression approach for categorical data of the self-report measure of adherence (ACTG) items 3 and 5 did not yield significant results.

Additional regression analysis for all variables was conducted. This consisted of eight variables within the model, each variable was entered one at a time into the block in the following sequence: each self-reported adherence item as the dependent variable and 1) self-efficacy beliefs, 2) depressive symptomatology, 3) social support, 4) perceived stigma, 5) CD 4, 6) viral load, 7) HIV disease symptoms, and 8) physical well-being. There was a significant association between self-reported adherence “missed taking any of your doses in the last 4 days” and depressive symptomatology. (See Table 12).

Table 12 Regression Model Summary (Missed taking any of your doses in the last 4 days).

Model	Variables	R Square	Unstandardized Beta Coefficient	Significance
1	Self-efficacy Beliefs	.073	-.012	.083
2	Self-efficacy Beliefs Depressive Symptomatology	.165	.034	**.046**
3	Self-efficacy Beliefs Depressive Symptomatology Social Support	.165	.001	.927
4	Self-efficacy Beliefs Depressive Symptomatology Social Support Perceived Stigma	.169	-.004	.667
5	Self-efficacy Beliefs Depressive Symptomatology Social Support Perceived Stigma CD 4	.194	.000	.299
6	Self-efficacy Beliefs Depressive Symptomatology Social Support Perceived Stigma CD 4 Viral load	.201	.000	.581
7	Self-efficacy Beliefs Depressive Symptomatology Social Support Perceived Stigma CD 4 Viral load HIV Disease Symptoms	.211	.009	.567
8	Self-efficacy Beliefs Depressive Symptomatology Social Support Perceived Stigma CD 4 Viral load HIV Disease Symptoms Physical Well-being	.222	.010	.429

There was a significant association for self-reported adherence “last time you missed meds” and self-efficacy beliefs. (See Table 13). In fact, self-efficacy beliefs remained significant for several blocks in the overall model. Figure 3 represents the mediating effect of self-efficacy beliefs and the independent variable, depressive symptomatology and one ACTG adherence item “missed taking any of your doses in the last four days”.

There were no other significant associations in the models using linear or logistic regression. Using a logistic regression approach for categorical data responses of the self-report measure of adherence (ACTG) items 3 and 5 did not yield significant results. Therefore, hypothesis 5A was partially supported. Hypothesis 5B was not supported; however, there is a strong trend for self-efficacy beliefs to mediate HIV disease symptoms and physical well-being.

Table 13 Regression Model Summary (Last time you missed your medications).

Model	Variables	R Square	Unstandardized Beta Coefficient	Significance
1	Self-efficacy Beliefs	.102	-.026	**.040**
2	Self-efficacy Beliefs		-.025	**.039**
	Depressive Symptomatology	.046	.046	.128
3	Self-efficacy Beliefs		-.027	**.046**
	Depressive Symptomatology			
	Social Support	.156	.005	.750
4	Self-efficacy Beliefs		-.027	**.049**
	Depressive Symptomatology			
	Social Support			
	Perceived Stigma	.156	-.001	.939
5	Self-efficacy Beliefs		-.024	.070
	Depressive Symptomatology			
	Social Support			
	Perceived Stigma			
	CD 4	.225	-.001	.083
6	Self-efficacy Beliefs		-.024	.074
	Depressive Symptomatology			
	Social Support			
	Perceived Stigma			
	CD 4			
	Viral load	.225	-000	.936
7	Self-efficacy Beliefs		-.026	.055
	Depressive Symptomatology			
	Social Support			
	Perceived Stigma			
	CD 4			
	Viral load			
	HIV Disease Symptoms	.260	-.029	.212
	Table 13 (continued)			
8	Self-efficacy Beliefs		-.026	.059
	Depressive Symptomatology			
	Social Support			
	Perceived Stigma			
	CD 4			
	Viral load			
	HIV Disease Symptoms			
	Physical Well-being	.260	.000	.993

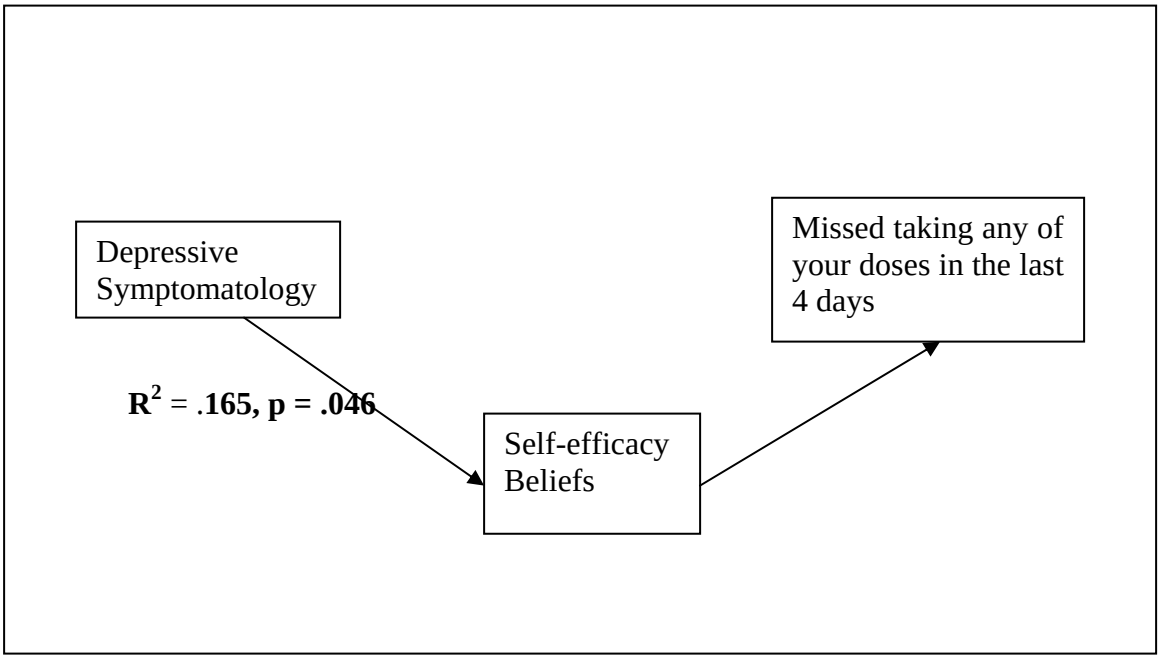

Figure 3 Path analysis of the mediating effect of self-efficacy beliefs on adherence

4.4.6 Specific Aim 6

Describe patterns of adherence in a subsample of women with HIV/AIDS who were prescribed antiretroviral medications using self-reported adherence and the Medication Event Monitoring System (MEMS).

Using the ACTG, subject's medications and self-reported adherence were assessed for the 4 days prior to the data collection. Subjects took from 2 to 5 different antiretroviral medications. Six subjects reported having special instructions for taking their medications (i.e., taken with food or on an empty stomach); two reported not following these instruction all of the time. One subject reported missing medications on the weekend (last Saturday or Sunday). Two of the ten subjects reported having missed their medications in the last one to two weeks. One subject missed all of

one prescription for the last 4-day period. See Table 14 for antiretroviral medications information and self-reported adherence responses. Subjects are listed according to their specific medication, dosing regimen, and response to the ACTG items for the medication used with the cap.

MEMS caps were distributed to a convenience sample of twelve women (23%). One cap was not returned. Eleven caps were returned and downloaded. One cap could not be read and the data were lost. Data were retrieved from 10 caps. Data were computed for 29 days for the ten subjects.

Using the cap data, a subject was identified as adherent if she attained a 95% or greater adherence rate. A subject was identified as non-adherent if she attained a rate less than 95%. The three adherence rates were calculated in the following manner: First, dividing the actual number of cap openings by the prescribed number of opening during a designated 29-day period and multiplying by 100 for doses adherent. Second, days adherent was calculated computing the percent of days in which the subject opened the MEMS cap as prescribed. Third, a dose taken on schedule was calculated by computing the percent of days when the cap indicated removal of the medication at the correct time of day. For the ten women using the cap the following data were collected: doses adherent (*M* = 63.39%, *SD* = 27.60%, *Range* 6.60 to 90.00%), days adherent (*M* = 52.31%, *SD* = 28.85%. *Range* 2.70 – 90.00%), and doses taken on schedule (*M* = 42.63%, *SD* = 27.21%, *Range* 2.70 – 89.30%).

Table 14 Antiretroviral Medications and Self-reported adherence (*n* = 10).

Medications prescribed and taken per day	Schedule pill and doses per day	Missed taking any in the last 4 days	Following dose instructions (i.e., 2 to 3 times a day)	Follow special instruction	Missed pills on the weekend	Last time you missed meds
Sustiva Combivar	1 pill x 1 1 pill x 2	0 0	All the time	No instructions	No	1-3 months
Kaletra Zerit Epivir	3 x 2 2 x 2 1 x 2	0 4 0	Most of the time	No instructions	Yes	1-2 weeks
Combivar Viramune	1 x 2 1 x 2	0 0	All of the time	No instructions	No	> 3 months
Reyataz Norvir Truvada	2 x 1 1 x 1 1 x 1	0 0 0	All the time	Yes - All the time	No	1 to 3 months
Epivir Viracept Ziagen	2 x 2 2 x 2 1 x 2	0 0 0	All the time	Yes - All the time	No	1-2 weeks
Sustiva Combivar	1 x 1 1 x 2	0 1	All the time	Yes - Some of the time	Yes	Within the past week
Truvada Zerit Kaletra	1 x 1 1 x 2 2 x 2	0 0 0	All the time	Yes - All the time	No	Never skip
Trizivir Reyataz Norvir	1 x 2 2 x 1 1 x 1	0 0 0	All the time	Yes - All the time	No	> 3 months
Invirase Kaletra ZVD Viread Epivir	5 x 2 4 x 2 1 x 2 1 x 1 1 x 1	0 0 0 0 0	All the time	Yes - Some of the time	No	> 3 months
Zerit Epzicon Reyataz Norvir	1 x 1 1 x 1 2 x 1 1 x 1	0 0 0 0	All the time	Yes- most of the time	No	> 3 months

Table 15 Cap Data for 29 Days (*n* = 10)

Medication Information		Cap Data		
Randomized Medication	Frequency (dosing) of identified med	Percent of doses adherent	Percent of days adherent	Percent of days doses taken on schedule
Sustiva	1 pill Once daily	100%	93.1%	89.3%
Zerit	2 pills Twice daily	62.1%	44.8%	38.6%
Viramune	1 pill Twice daily	100%	100%	31.6%
Truvada	2 pills Once daily	83.0%	75.9%	82.1%
Ziagen	1 pill Twice daily	84.5%	72.4%	63.2%
Combivar	1 pill Twice daily	7.2%%	6.1%	4.7%
Truvada	1 pill Once daily	82.8%	82.8%	71.4%
Norvir	1 pill Once daily	86.2%	79.3%	57.1%
ZVD	1 pill Twice daily	39.7%	3.4%	1.8%
Zerit	1 pill Once daily	89.7%	89.7%	78.6%

The ten women were equally divided between those that took a medication from the MEMS cap once or twice daily. When exploring the difference in means between taking a pill once vs. two times daily for percent of doses adherent, the women who took only one pill per day had a mean of 88.34% (*SD* = 7.1, *Range* = 82.80 – 100.00) vs. two pills per day with a mean of 58.7% (*SD* = 36.7, *Range* = 7.20 – 100.00). The wide dispersion in standard deviation is reflected in the wide range of percentages adherent to one's daily dose. Likewise for subjects taking a once daily drug verses those taking a twice daily drug there was a difference in percent of days adherent (*M* = 84.16 *SD* = 7.1, *Range* 75.90 - 93.10 vs. *M* = 45.4, *SD* = 41.96, *Range*

3.40 - 100.00) and percent of days following dosing schedule (*M* = 75.7, *SD* = 12.23, *Range* = 57.10 - 89.30 vs. *M* = 27.98, *SD* = 25.46, *Range* = 1.80 - 63.20).

Three women took only two medications with two of the women reporting perfect adherence in relation to doses for the last 4 days. One subject who took two medications daily was less than 10% adherent based on cap data. She also self-reported that she (1) missed medications in the last four-day period, (2) missed her medications over the past week, (3) had difficulty taking her medications on the weekend, and (4) followed the special instructions for her medications "some of the time". One subject who took five different antiretroviral medications reported perfect adherence, which was not reflected in the cap data. For this subject cap data reflect percent of doses adherent at 39.7%, percent of days adherent at 3.4% and percent of days doses taken on schedule at 1.8 percent. Five subjects who took three different antiretroviral medications all reported "perfect adherence" for the last 4 days on the ACTG self-report measure; however, various percentages of doses adherent, number of days adherent, and on-time dosing of medications were reflected in the cap recording.

The assessment of self-reported adherence is a retrospective recall of self-reported adherence 4 days prior to starting to use the MEMS cap. These self-report data included the adherence patterns for all of the subject's medications not just the medication included and used in the MEMS cap. Using the cap was prospective for the next 29 days. Using paired t-tests for doses adherent, days adherent, and doses taken on schedule and self-reported adherence suggested significant associations between the two measures. The self-reported adherence question "missed taking any of your doses in the last 4 days" was significantly associated with cap data: doses adherent (t = 6.89, (df 9) 95% CI; p = .000), days adherent (t = 5.498, (df 9) 95% CI; p = .000), and doses taken on schedule (t = 4.652, (df 9) 95% CI; p = .001). The self-report

adherence question “last time you missed meds.” was significantly associated with cap data: doses adherent (t = 7.134, (df 9) 95% CI; p = .000), days adherent (t = 5.363, (df 9), 95% CI; p = .000), and doses taken on schedule (t = 4.847, (df 9) 95% CI; p = .001). Using a chi-square procedure for the remaining self-report adherence items (2, 4, and 5) did not result in any significant associations.

5.0 CHAPTER FIVE

5.1 SUMMARY OF FINDINGS

This descriptive cross-sectional study had two overall purposes. The primary purpose was to describe the self-reported adherence patterns to antiretroviral medications for a sample of women with HIV/AIDS and factors that affected their self-reported adherence. In addition, the study examined the potential mediating effects of self-efficacy and the relationship this factor had on self-reported adherence for these women. The hypotheses were partially supported.

Forty-four women were recruited as a convenience sample from western Pennsylvania and eastern Ohio. Seventy-five percent of the women lived in rural areas, small towns, or suburban areas. The mean age was 42.89 years. The women were almost equally divided between whites and non-whites; the latter group included three women of Latin descent. Approximately 80% of the women had a high school education or its equivalent; 18% had an education beyond high school. Seventy percent of the women were single, divorced, widowed, or separated. Only five women were employed full-time; three were employed part-time. Twenty-eight women were identified as disabled. Twenty-eight women did not report their income with 12 women reporting an income of less than $20,000 annually. Thirty-five women reported their insurance as coming from Medicare or Medicaid. Nearly all identified their exposure to HIV as being through heterosexual contact.

The findings showed that there was a significant relationship between race/ethnicity, marital status, and education and one's self-reported adherence to antiretroviral medications. There were significant relationships between depressive symptomatology, perceived stigma, CD 4, and HIV disease symptoms and self-reported adherence to antiretroviral medications. Social support and physical well-being failed to show a significant relationship with one's self-reported adherence. The data suggested interrelationships among variables including social support; however, only two variables, depressive symptomatology and CD 4 contributed to one's self-reported adherence in the regression model. In addition, self-efficacy had a mediating effect between depressive symptomatology and self-reported adherence.

Within the larger study, a small group of twelve women agreed to use an electronic event monitor (MEMS) cap for a period of 29 days. However, data were available for analysis for only ten subjects MEMS caps. One subject failed to return her MEMS cap despite attempts to contact her by telephone and mailing her an additional return envelope. Data were irretrievable from one cap and could not be downloaded into the file. Data from the caps were examined for rates of adherence. These data were compared to the self-reported adherence data. Based on the MEMS cap data, seven (70%) of the women achieved a dose adherence rate of 80% or better. Two of these seven women achieved a dose adherence rate of 95% or better in terms of dose adherence. Three women were less than 80% adherent; one subject achieved only 7% adherence. For percent of days adherent, two women were adherent 93% or more of the days they used the MEMS cap. However, these two women only followed their dosing schedule 82% and 89% of the time respectively. Thus, 80% of the this subsample of women with HIV using the MEMS cap did not achieve the recommended 95% level of adherence for taking their medications as prescribed daily or taking their medications at the appropriate time intervals. Another woman

with a dose adherence and percent of days adherent was only achieved percent of doses taken on schedule 32% of the time.

5.2 DISCUSSION OF THE FINDINGS

The sample of 44 women was approaching middle age with 9 (20%) of the women age 50 years or older. The white subjects represented HIV positive women in rural areas and small towns in western PA and eastern Ohio. These women obtained their HIV health care from rural clinics in their area. The majority of the non-white subjects were from a large urban inner city and receiving their HIV health care from a university-affiliated clinic.

Although small towns have non-whites with HIV disease living in their communities, these women did not participate in the study or may have received their HIV care from the larger metropolitan area or local health care provider. The rural areas of western PA are predominately white, whereas the metropolitan/inner city area has a larger non-white population. There is very little racial/ethnic diversity throughout this section of western PA and eastern Ohio with less than 1% of the population being of Asian or Latin ethnicity. Thus, this sample reflected the populations of the respective areas.

Neither the subject's age nor exposure risk category was significantly associated with self-reported adherence. Non-white subjects were less adherent over the last 4 days then their white peers (r = .340, p = .021) with white subjects achieving 91% adherence. Increased education was associated with better adherence; women with greater than a high school education reported adherence at 87.5% vs. women with less than a high school education who reported adherence of approximately 11% (r = .420, p = .025). In addition, women who were no

longer married were adherent 48% of the time in following special medication instructions; their single or married peers were less adherent.

The above findings reflect the variability of the effects of socio-demographic factors on self-reported adherence to antiretroviral medications as reported in the literature. Kalichman et al. (1999) reported that low literacy (education) was associated with decreased adherence, while Kleebeerger and colleagues (2001) reported African-Americans were less adherent to their antiretroviral medications than white subjects. There is a gap in the literature regarding the impact of marital status on adherence to antiretroviral medications. However, it may be that women no longer in a relationship strive for better adherence because if they become ill there may be limited availability of another person to care for them. Or, these women may be more focused on meeting their personal needs.

Although Wilson et al. (2002) reported younger participants in their study were less adherent to antiretroviral medications, Murphy and colleagues (2004) reported the opposite with older subjects being less adherent. For this study, age did not influence self-reported adherence to antiretroviral medications. The mean age of the women in this study were approximately 43 years old.

Self-reported adherence did not attain the desired 95% rate recommended in the literature (Paterson et al., 2002; Yeni et al., 2002; 2004). However, 34 (77%) of the women reported they had not missed taking any of their antiretroviral medications during the previous four-day period. It may be that these women were truly adherent to their medications, they were unable to adequately recall their patterns of medication taking for the previous four-day period, or there may have been some degree of subject bias to over-or-under reportiing their adherence. In the subsample of ten women who used the electronic cap (MEMS) dose adherence was 80% or

better for seven out of the ten subjects. These data may reflect an accurate account of adherence for this sample of women with HIV/AIDS. That said, when the sample of 10 women were divided between those taking medications once vs. twice daily, the once daily group (n = 5) was more adherent in the taking of medications daily, doses taken daily, and following their prescribed schedule. These data may suggest, at least for this small sample of five women that pill burden influenced adherence.

Among the 34 women who reported missing their medications "last time you missed medications", seven (20.6%) of these women, reported that they missed taking their medications during the last week and 28 (82.4%) reported that they missed taking their medications more than one week ago. Being involved with the day-to-day activities in their lives represented the most frequently identified reasons for missing antiretroviral medications. Weekend activities were not identified as a frequent reason for missing medications with only eight women reporting weekend activities as a problem.

Adherence to one's antiretroviral medications remains a pivotal issue for persons with HIV. The fact that there are medications to suppress the replication of the HIV virus is a blessing; however, taking these medications has been shown to be a burden for some people (Erlen & Mellors, 1999). The proactive status of pharmaceutical companies in continuing research on HIV medications and combining, simplifying, and decreasing the "pill burden" has the potential to increase adherence (Portsmouth et al., 2005; Yeni et al., 2004). In fact, in the last few months a new medication has been introduced that combines three antiretroviral medications into one pill with once daily dosing. However, these advances in management of HIV do not negate the importance of HIV education and prevention; nor, is there a cure for HIV on the horizon. Likewise, reinforcement of patient adherence to antiretroviral medications must be an

ongoing intervention strategy used by health care providers (Paterson et al., 2002; Yeni et al., 2002; 2004).

Using The Center for Epidemiologic Studies-Depression Scale (CES-D), the level of depressive symptomatology approached a moderately high level in this sample of women (M = 22.42) (Radloff, 1977). Although the score for depressive symptomatology was well beyond the cut-point of 16, there was only a weak association with depressive symptomatology and self-reported adherence to antiretroviral medications and that was for "missed taking any of one's medications" in the last four-day period.

Depressive symptomatology was associated with perceived stigma and the presence of HIV disease symptoms. Perhaps, the perception of increased stigma contributed to depressive symptomatology. Likewise, more HIV disease related symptoms and/or medication related physical symptoms may have contributed to depressive symptomatology. That said, it was surprising there was no significant association between depressive symptomatology and physical well-being.

Catz et al. (2002) reported a mean CES-D score of 24.9 for the 100 women in their study with over 50% of the women having scores suggestive of severe depressive symptomatology. In their earlier study of men and women with HIV/AIDS, Catz and colleagues (2000) reported that subjects who were adherent to their antiretroviral therapy had a mean CES-D score of 17.39 while non-adherent subjects had a mean score of 27.38. Phillips and colleagues (2005) reported a mean CES-D score of 24.1. Ickovics and colleagues (2001) reported that increased depressive symptomatology was also associated with decreased adherence. Thus, the finding of a high level of depressive symptomatology in this sample of 44 women with HIV reflects the work of other researchers, which may suggest that one's depressive state may influence one's ability to achieve

adherence. In addition, in the regression model, the relationship between self-reported adherence and depressive symptomatology was mediated by self-efficacy beliefs.

Considering that the mean score for depressive symptomatology was high, it may have been important to assess who was or was not taking antidepressant medications. These data were not assessed for the first 18 subjects. The remaining 26 women were questioned during the telephone screening process about the use of all medications, including any medications that may have affected their mood or any medications for depression. Three women reported taking antidepressant medications; however, these data did not change the depressive symptomatology mean for the sample as a whole or the latter 26 women. This finding may suggest that depressive symptomatology may not be appropriately assessed during a primary care visit. It is also possible that some women did not report a change in mood state to their health care providers and/or some of the women in the study did not accurately report their use of antidepressant medications to the researcher. Perhaps some women taking antidepressant medications were embarrassed to admit they were experiencing a change or problem in their mood, sleep patterns, appetite, or other symptoms often associated with depressive symptomatology. Katon (2000) addressed the failure of health care providers to diagnose and effectively treat depressive symptomatology in more that 50% of persons in the USA. Thus, depression is a hidden health problem for many people, not only persons with HIV/AIDS.

The finding that the regression model suggested self-efficacy beliefs mediated the relationship between depressive symptomatology and self-reported adherence is important. This finding suggests that people's beliefs or level of confidence that they can be successful with their medication regimen does indeed affect their behaviors. These findings also fit with the theoretical framework as noted in Chapter Two. As Bandura (1977) explained, when individuals

learn and perceive that their behaviors will result in a favorable outcome, they will strive for that desired outcome. For this study, the desired outcome, improved self-reported adherence to antiretroviral medications, was attainable despite a moderately high self-reported appraisal of depressive symptomatology. In addition, these women may have been mindful that non-adherence could have produced a negative result; an increase in HIV disease related symptoms, opportunistic diseases, medication failure, and/or "being sick". The level of adherence education provided by their health care providers was not assessed.

The literature review demonstrated the importance of social support for women with HIV (Bova, 2001; Hudson et al., 2001; Misener & Sowell, 1998; Simoni & Cooperman, 2000). Responses to the measure of social support, the Interpersonal Support Evaluation List (ISEL) (Cohen & Syme, 1985) suggested that these women had a limited amount of social support (M = 79.33). However, despite the significant negative relationships with stigma and HIV disease symptoms, social support was not identified as contributing to self-reported adherence in the bivariate correlations with the self-reported adherence items or in the regression models.

Catz and colleagues (2002) used the ISEL for their study, reporting a mean of 106.80. Thus, the women in this study had less social support than those in the study by Catz et al. This was the only identified study that used the ISEL for men or women with HIV. Like adherence, there are numerous measures for the assessment of social support. The ISEL does not include specific subscale sores for family, friends, or health care provider support. Perhaps, being able to assess these factors would have better captured the issue of social support for these women. Erlen and Mellors (1999) addressed the importance of a supportive relationship with one's health care provider. The women in this study receiving care from the rural clinics appeared to have a close working and friendship type relationship with the nurses and case managers. Because some

of the women often traveled a great distance (i.e., 30 miles or more) to their clinic appointments, they may have viewed this as a social outing. Some women that may have desired to participate in the study felt they could not because they had other family members with them or had made "other plans" after their appointment. A similar relationship may have existed at the university clinic; however, that was not observed. Given these observations, it is possible that the rural clinic and university setting met the need of this sample for understanding and social support.

The hypothesis that perceived stigma influences self-reported adherence was supported in part; although, there was not a relationship with self-efficacy beliefs. Despite these limited results, perceived stigma was significantly associated with depressive symptomatology and social support, and significantly negatively associated with CD 4 and physical well being.

Most of the research reported on perceived stigma is qualitative. Anecdotally, many women in this study remarked how difficult it was to live with HIV and how people treat you; however, if a woman provided an example of being stigmatized this was shared in confidence. Several women, as in Black and Miles (2002) study concealed their HIV status from their children, as well as from younger family members, i.e., nieces, nephews, and grandchildren. All of the rural women who met in public areas near their homes were very guarded about seeing someone they may have known. Rural women who met at their clinic were open, friendly, and very eager to share their negative HIV experiences. One woman, who lived approximately 150 miles from Pittsburgh, was not concerned about other people knowing her HIV status. She had the attitude that it was other peoples' ignorance that was the problem, not her having HIV disease. Another woman described living with HIV as being like a cancer survivor but no one wants to celebrate your living with the disease, your survival, or your success – people just want to judge you for getting the disease. Yet another woman made reference to that fact "no one

knows you are sick with HIV, I don't look sick, I look like all the other women in this place" (meaning the researcher and the female health care providers at the rural clinic).

When exploring the subscale scores for perceived stigma there were several significant relationships among other variables, including social support. It may be that the measure of perceived stigma failed to capture the type of perceived stigma most prevalent for these women with HIV. There was no literature to support the relationship of perceived stigma and self-reported adherence. Therefore, this may be the first study to examine the possible relationships of these variables for women with HIV and also the potential mediating effect of self-efficacy.

CD 4 data were available for only 26 of the women and was significantly negatively associated with self-reported adherence defined as "last time you missed your medications" and significantly associated with "following dose instructions". CD 4 was negatively associated with perceived stigma and physical well-being. There was a strong trend for a relationship between CD 4 with HIV disease symptoms. These relationships are interesting, given that self-efficacy had a mediating effect for depressive symptomatology and self-reported adherence in the regression models but not CD 4 and HIV disease symptoms, or physical well-being. Although there was not a significant relationship between CD 4 and self-efficacy, it may be that awareness of one's CD 4 increases one's self-efficacy beliefs; thus, improving one's self-reported adherence to antiretroviral medications. The caveat to these CD 4 data is their lack of completeness. Eighteen of the women did not know their CD 4. Fifteen (34%) of the women were aware of their viral load; these data were not associated with self-reported adherence. In addition, viral load was not associated with any other factor; there were no strong trends in the data.

CD 4 and viral load data were incomplete for several subjects. This may have occurred because the women were only aware of their status as "undetectable" for viral load, that laboratory values were not collected on a monthly basis, or that they did not want to report less than favorable data for the study. In light of this absence of data, if CD 4 and viral load are used in future studies, a medical record review would be recommended for gathering these data. However, this would not have been possible for this study given that many rural subjects were not enrolled and recruited from the clinic setting. That said, subjects or their health care providers may not have consented to a medical record review; thus, adding an obstacle to recruitment and enrollment. Also, at the time the proposal was written for this study, CD 4 and viral load were suggestive of one's adherence. The issue of medication failure and resistance was just beginning to emerge in the literature. At the present time, these clinical markers are not always suggestive of the individual's adherence, especially in the absence of symptoms (Yeni et al., 2004). A future study would not include these data for analysis unless a medical record review was completed. However, including a response item for knowing one's CD 4 or viral load might be an example of how well the women were aware of their disease status and self-management of their disease.

Although, HIV disease symptoms did not contribute to the regression analyses as affecting one's adherence to antiretroviral medications, there were several significant associations between variables. There was a significant association between HIV disease symptoms and depressive symptomatology and a negative association with social support. There was a strong trend for a relationship with perceived stigma. There was also a negative association with the self-efficacy beliefs. Considering these trends it may be fruitful to continue exploration

of the effect of HIV disease symptoms on one's adherence to antiretroviral medications in future studies of women with HIV.

Holzemer and colleagues (1999, 2001, 2004) have done extensive research on the effects of HIV disease and medication related symptoms. These authors have explored HIV disease symptoms in relation to depressive symptomatology (Holzemer et al., 1999), one's quality of life (Hudson, Kirksey, & Holzemer, 2004), and self-care (Holzemer et al., 1999; 2001). Likewise, the presence of HIV disease symptoms has been associated with lower CD 4 and increased viral loads and poor adherence (Fletcher et al., 2004). As identified, these data may or may not currently reflect the individual's adherence due to long-term use of antiretroviral medications and disease resistance and/or viral mutation (Yeni et al., 2004).

The possibility exists the wording on the HIV disease symptoms measure was confusing to subjects. One subject did not understand the wording "not present today". Three subjects reported they did not have any HIV disease or medication related symptoms. It is interesting that these three women also had scores of less than 16 for depressive symptomatology. This instrument was selected because including gynecological symptoms and addressing symptoms that may be bothersome to women with disease. However, few women reported the presence of gynecological symptoms. The most frequently reported symptoms were fatigue, fear, joint pain, muscle aches, and gastrointestinal problems, such as gas, bloating, diarrhea, and nausea. Given the age of these women, it is possible that they had learned to function and live with the HIV disease related symptoms and symptoms no longer were an issue for them. It is also possible that since the measure only assessed the presence of the symptoms "today" that the true nature of their symptoms, if present in the past, were not captured. Perhaps, the measure needs to be

revised to follow the self-reported adherence measure and assess the presence of symptoms for the previous 4-day period.

There were no associations for physical well-being and self-reported adherence with bivariate correlations or in the regression models. In addition, physical well-being was significantly negatively associated with perceived stigma, which has been addressed. The fact that the physical well-being subscale score of the MOS-HIV failed to demonstrate a relationship with self-reported adherence in this sample was surprising.

The research by Liu and colleagues (2006) demonstrated extensive improvement in one's physical well-being when adherent to medications. Simoni and Cooperman (2002) also reported improved physical well-being with better adherence. However, there remains limited research on the relationship of self-reported adherence and one's physical well-being. It may be that since the women in this study had lived with this disease for several years, they had adapted to changes in their physical well-being and no longer felt it affected their lives. It is also possible that the MOS-HIV subscale of physical well-being failed to capture the essence of issues of physical well-being for these women. Another measure may have been a better choice or use of selected items for the measure may have provided a better assessment.

The MOS-HIV has been used extensively and is well documented as a valuable measure. In the future, using this measure to assess the overall health related quality of life for women with HIV may prove to be more reflective of their lives. Exploring their quality of life may also add valuable insight for increasing self-reported adherence.

The theoretical framework, self-efficacy theory, is partially supported. The person, identified through the socio-demographic variables (age, education, race/ethnicity, marital status, and exposure risk category) had a direct relationship to one's behavior, self-reported adherence

to antiretroviral medications. The subscale of self-efficacy beliefs demonstrated significant relationships with two of the self-reported adherence items; “last time you missed your medications”, and “missed pills on the weekend”. Using bivariate correlations, there was a significant relationship between self-efficacy beliefs and social support. There was not a direct relationship between the physiological variables (CD 4, HIV symptoms, and physical well-being). However, based upon the definition of self-efficacy, the subscales score for self-efficacy beliefs was used to further explore the potential mediating effect.

Self-efficacy beliefs were fit into the step-wise regression model suggested by Barron and Kenny (1986). Regression of the mediator (self-efficacy beliefs) on the independent variables using a step-wise approach contributed to the model with a relationship between social support and self-reported adherence. Regression of the dependent variables, the five items of the ACTG, and seven independent variables resulted in significant associations being demonstrated when using a separate linear regression for each ACTG item “missed taking your doses in the last four days” and depressive symptomatology, and “following doses instructions” and “last time you missed your meds” and CD 4. And finally in the last approach, “following dose instructions” and “last time you missed your meds” resulted in significant relationships with CD 4 and perceived stigma.

As noted previously, there were a limited number of responses for CD 4 and viral load. Therefore, the last approach was repeated with these variables removed from the analysis. This resulted in the identification of self-efficacy beliefs mediating the relationship between self-reported adherence “missed taking any of your doses in the last four days” and one’s depressive symptomatology. In addition, self-efficacy beliefs had a significant affect on the model with self-reported adherence item “last time you missed your medications” and depressive

symptomatology as well as for social support. These findings suggest that self-efficacy beliefs greatly affect one's adherence to antiretroviral medications. The contribution of strong self-efficacy beliefs also had a mediating effect on self-reported adherence despite the moderately high scores for depressive symptomatology.

The significance of self-efficacy beliefs mediating depressive symptomatology has been discussed. The fact that the model was supported, at least in part, has also been addressed. These findings suggest an implication that reinforcement of one's self-efficacy beliefs may be pivotal in increasing adherence. This is not to say, thorough patient education regarding the importance of 95% adherence or better to antiretroviral medications can be overlooked and not re-evaluated on an ongoing basis. Perhaps, when poor adherence is identified the health care provider and patient should discuss their "belief in their ability to be adherent", which could identify barriers to adherence. Perhaps, designing an intervention program that will sustain and/or increase one's self-efficacy beliefs may be a key for future research. For the women in this study, self-efficacy beliefs for their use of antiretroviral medications appear to assist in the management of their HIV disease and medication adherence.

Only two of the 10 women in this study who used the MEMS cap achieved the recommended level of adherence. There was a "super adherer" with 117% adherence; however, subtracting 17 from 100 resulted in an adherence rate of 83%, far less than desired. Also, one woman had less than 10% adherence, which possibly skewed the finding for doses adherent (M = 63.39), days adherent (M = 52.31), and doses taken on schedule (M = 42.63). However, examining the individual data for each of the 10 women, five women had an adherence rate of 83% or better; two women had an adherence rate of 100%. One subject self-reported near perfect adherence; however, her cap data reflected adherence at less than 10 percent. There w was no

association between percentage of adherence and the number of different antiretroviral medications a subject took daily. In addition, most subjects accurately self-reported their adherence when this finding was compared to the MEMS data.

Bova et al. (2005) reported numerous obstacles when using an electronic measure including cap failure for refrigerated medications. Researchers suggest use of a self-report measure of adherence may be as successful as using an electronic device such as the MEMS cap for assessment of adherence (Bova et al; Levine et al., 2006). The use of the MEMS cap or any electronic measure also increases the cost of assessment, measurement, and data analysis.

Eleven women agreed to use the electronic measure with 10 caps available for data analysis. One cap was "frozen" and data were irretrievable. The instructions for use of the cap took approximately 10 additional minutes to explain to these subjects. None of the subjects required additional information for use. Two subjects required additional phone calls to return the cap following the 29-day period. It may have been beneficial to have the subjects make an appointment to return the caps and re-evaluate their self-reported adherence. This may have captured their adherence patterns more accurately.

5.3 LIMITATIONS OF THE STUDY

5.3.1 Sample and Recruitment

The most notable limitations in this study were the small sample size and the lack of diversity; three Latina women were recruited and enrolled in the study. Western PA and eastern Ohio lack cultural diversity. Unique to the study is the percentage of women that resided in rural areas and

small towns of western PA. People in this area of the state, as a whole, have limited access to merchandise, food supplies, home materials, and public transportation, as well as health care, medications, and other social service. Obstacles in recruitment contributed to the size of the sample size.

Each subject was provided a stipend of $15.00 for completing the study. There were no blatant attempts to complete the study quickly. However, the clinic staff may have used the stipend as an inducement for subjects to consider participation. Thus, the sample may have been biased due to the needs of the potential participant and/or a desire to please the clinic staff. The staff, case managers, and nurses approached potential subjects at the rural clinics and university setting. Although this was advantageous in providing the study literature and introducing the study, this literature may have been distributed to those women who had established patterns of appointment keeping adherence, could use the stipend, and/or those that had participated in other studies. To increase recruitment and enrollment the researcher was present at the clinics on as many specific HIV clinic days as possible. This had the benefit of increasing recruitment and enrollment but may also have contributed to bias in the selection of potential participants.

The cross-sectional nature of the study may have increased subject participation but may not have reflected the true nature of the participant's self-reported medication adherence or factors for women as a whole in the area of recruitment. It is also possible that the snapshot assessment of self-reported adherence did not truly reflect the individual's self-reported adherence. Therefore, collecting data over a period of weeks may have more accurately captured the selected factors as well as self-reported adherence.

5.3.2 Measures

Women in this study completed multiple measures requiring on average 60 minutes. Several women completed the instruments in the 60 minutes or less. However, after completing and submitting the measures, two women wanted to chat or visit with someone interested in women with HIV. Many of the women freely contributed personal information about themselves, their families, their living situations, and their experiences of living with HIV. This would have been an excellent opportunity to collect qualitative data.

The neuro-cognitive measure could probably have been eliminated because it was another measure for the subjects to complete. Including a self-reported history of severe mental illness as an exclusion criterion was probably adequate. Although the clinic staff expected literacy to be an issue and recommended a measure be included, this was only a problem for one subject. All of the instruments were organized in a random order except the measure of self-reported adherence, which required the interview format. Nevertheless, the randomization of the measures may not have been adequate to reduce subject bias for the multiple measures. Subjects may also have decided to complete the measures differently than presented possibly contributing to some response bias.

Perhaps the measure that was most difficult for participants was the self-report measure of adherence. Some women were unclear regarding what was meant by 4 days ago. It may have been helpful to have had a calendar present for subjects while completing this measure. In addition, using fewer items of the measure may have been less confusing for subjects.

The fact that the measures were self-report was in and of itself a limitation, as subjects may over-or-under-report not only their adherence but other issues, such as perceived stigma or their sense of physical well-being. However, there is no other way to collect these subjective data

than through self-report. Adherence can only be accurately measured when the medication is directly observed as the subject swallows each and every pill. This is not feasible for community dwelling persons. This approach would not only be costly but also extremely time consuming and potentially limit the recruitment of subjects into any study.

The analysis of the self-report measure of adherence was problematic. Only two items could be considered continuous data. One item was not a measure of adherence. Each question required separate analyses for bivariate correlations and regression analysis. The use of the two continuous items or another measure of adherence may have better captured the overall patterns of self-reported adherence. The questions regarding the types of medications taken and rationale for missing one's medication were interesting but did not factor into the data analyses.

Many measures have been used to assess social support. Perhaps it may be worthwhile to re-evaluate the relationship of social support and self-reported adherence by adding a qualitative aspect to this study. Including a taped dialogue recording may have suggested areas for social support interventions. These recordings may also have provided themes for addressing the perceived stigma of living with HIV. As mentioned, the inability of all subjects to report their CD 4 and viral load was problematic. In addition, as addressed previously assessing the presence of HIV symptoms over the previous 4 days may have captured the problematic nature of symptoms. And, using only select items from the MOS-HIV, such as role and social function rather than a composite score would have been beneficial. Finally, using a cross sectional research design did not allow for true cause and effect it merely suggests the potential for a relationship between variables of interest.

5.4 CONCLUSIONS

The study, although limited in the total number of subjects recruited, may be the first to explore the relationship between perceived stigma and self-reported adherence to antiretroviral medications. There has been limited quantitative research addressing the relationship between social support and self-reported adherence for women with HIV. Although, social support was not related to self-reported adherence for these women, and did not contribute to the model overall, further investigation is warranted. Certainly, depressive symptomatology remains a major issue for women with HIV and interventions to address their depressive symptomatology may be a key factor in the future. This study identified the significance of one's self-efficacy beliefs in mediating self-reported adherence to antiretroviral medications, especially for women with depressive symptomatology. Furthermore, the study contributed to the body of knowledge regarding psychological and physiological variables that may affect self-reported adherence. The sub-study of women that used the MEMS cap suggested that women with HIV may accurately report their adherence to antiretroviral medications.

5.5 IMPLICATIONS FOR THE FUTURE

There continues to be a gap in the literature regarding issues that affect self-reported adherence to antiretroviral medications for women with HIV. This study is unique in that it examines these phenomena for rural dwelling white women in the north central part of the United States. This study is however, just the beginning and should be expanded. In the future it may be worthwhile to pursue the relationship of marital status on one's self-reported adherence to antiretroviral

medications. In addition, it may be important to investigate the issue of aging and self-reported adherence behaviors in a larger sample of older women, particularly women over the age of 50.

Since depressive symptomatology was so prevalent in this sample of women future research may need to explore the use of antidepressant medications and a psychotherapy intervention to decrease depressive symptomatology. Increasing the overall sense of mental well-being, may ultimately increase one's self-reported adherence to antiretroviral medications.

This sample size of the study was small. However, this study began to explore and explain multiple factors and their potential relationships on self reported adherence to antiretroviral medications for women with HIV. It may be well served for persons with HIV to continue this research with a larger more diverse sample of women. Future research might explore the relationship between years taking antiretroviral medications and living with the HIV disease as a possible covariate to self-reported adherence. Because of the maturity of this sample it may be salient to limit enrollment to women older than 40 years of age. This study is not an end but a step toward better understanding of these phenomena for women with HIV residing in western PA and eastern Ohio. It is also a beginning of a research program for women with chronic disease, particularly for women with HIV.

APPENDICIES

APPENDIX A

ADDITONAL FINDINGS

Possible relationships between the psychological (depressive symptomatology, social support, and perceived stigma) and physiological variables (CD 4, viral load, HIV disease symptoms, and physical well being) of interest were examined using Pearson r correlations. Depressive symptomatology was significantly associated with perceived stigma (r =. 482, p = .001) and HIV disease symptoms (r = .607, p = .000). Social support was significantly negatively associated with perceived stigma (r = -.497, p = .001) and HIV disease symptoms (r = -.310, p = .040). Perceived stigma was also significantly negatively associated with CD 4 (r = -.310, p = .041). HIV disease symptoms was significantly negatively associated with physical well-being (r = -.350, p = .022).

The measures of social support and stigma each have four subscale scores that were not considered as separate factors for these analyses. However, due to the relationships between these variables and depressive symptomatology the subscale scores were investigated. The social support measure consists of subscales for appraisal support, belonging support, tangible support, and self-esteem support (Cohen & Syme, 1985). The perceived stigma measure consists of subscales for personalized stigma, disclosure, negative self-image, and public attitudes

(Berger et al., 2001). The Pearson r was used to examine the possible association between depressive symptomatology and social support subscales and perceived stigma subscales. There was a significant negative relationship between depressive symptomatology and social support subscale, self-esteem (r = -.306, p = .046). There were significant associations between depressive symptomatology and personalized stigma (r = .512, p = .000), negative self-image (r = .482, p = .001), and public attitudes (r = .484, p = .001).

The Pearson r was used to examine possible associations between social support subscales and perceived stigma subscales. Personalized stigma was negatively associated with appraisal support (r = -.392, p =. 008), belonging support (r = -.553, p = .000), tangible support (r = -.458, p = .002), and self-esteem (r = -.386, p = .014). Negative self-image was significantly negatively associated with appraisal support (r = -.345, p =. 022), belonging support (r = -.445, p = .002), tangible support (r = -.471, p = .001), and self-esteem (r = -.480, p = .001). Public attitudes were significantly negatively associated with appraisal support (r = -.359, p = .017), belonging support (r = -.470, p = .001), tangible support (r = -.445, p = .003), and self-esteem (r = -.392, p = .008).

HIV disease symptoms were significantly negatively associated with appraisal support (r = -.304, p =. 044) and belonging support (r = -.363, p = .016). HIV disease symptoms were significantly associated with personalized stigma (r = .394, p = .008).

APPENDIX B

CAP DATA ANAYLSES

AARDEX Ltd.

PowerView Compliance Report

Patient number:	7	Patient initials:	
Patient name:		Monitor number:	219386
Investigator:		Drug name:	.
Regimen:	Once a day		

Results:	21/july/2005 3:00: to 19/aug/2005 2:59: (1)	Number of monitored days:	29
Number of doses taken:	29	Shortest interval (hrs):	7.6
Longest interval (hrs):	39.9	% Prescribed number of doses taken:	100.0%
% Days correct nbr of doses taken:	93.1%	% Prescribed doses taken on schedule:	89.3%
Therapeutic coverage:	99.4%	Drug duration of action (in hours):	36.0
Number of prescribed doses:	29		

July 2005

Mon	Tue	Wed	Thr	Fri	Sat	Sun
			21 1	22 1	23 1	24 1
25 1	26 1	27 1	28 1	29 1	30 1	31 1

August 2005

Mon	Tue	Wed	Thr	Fri	Sat	Sun
1 1	2 1	3 1	4 1	5 1	6 1	7 1
8 1	9 1	10 1	11 1	12 1	13 1	14 0
15 2	16 1	17 1	18 1			

AARDEX Ltd. **PowerView** **Compliance Report**

Patient number:	11	Patient initials:	
Patient name:		Monitor number:	217616
Investigator:		Drug name:	
Regimen:	Twice a day		
Results:	26/aug/2005 3:00: to 24/sept/2005 2:59: (1)	Number of monitored days:	29
Number of doses taken:	36	Shortest interval (hrs):	4.0
Longest interval (hrs):	96.1	% Prescribed number of doses taken:	62.1%
% Days correct nbr of doses taken:	44.8%	% Prescribed doses taken on schedule:	38.6%
Therapeutic coverage:	69.8%	Drug duration of action (in hours):	18.0
Number of prescribed doses:	58		

August 2005

Mon	Tue	Wed	Thr	Fri	Sat	Sun
				26 2	27 2	28 2
29 2	30 2	31 2				

September 2005

Mon	Tue	Wed	Thr	Fri	Sat	Sun
			1 0	2 0	3 0	4 1
5 2	6 1	7 2	8 1	9 0	10 2	11 1
12 2	13 0	14 0	15 1	16 1	17 1	18 2
19 1	20 1	21 2	22 2	23 1		

AARDEX Ltd. **PowerView** **Compliance Report**

Patient number:	12	Patient initials:	
Patient name:		Monitor number:	217619
Investigator:		Drug name:	
Regimen:	Twice a day		
Results:	15/sept/2005 3:00: to 14/oct/2005 2:59: (1)	Number of monitored days:	29
Number of doses taken:	58	Shortest interval (hrs):	6.9
Longest interval (hrs):	17.7	% Prescribed number of doses taken:	100.0%
% Days correct nbr of doses taken:	100.0%	% Prescribed doses taken on schedule:	31.6%
Therapeutic coverage:	100.0%	Drug duration of action (in hours):	18.0
Number of prescribed doses:	58		

September 2005

Mon	Tue	Wed	Thr	Fri	Sat	Sun
			15 2	16 2	17 2	18 2
19 2	20 2	21 2	22 2	23 2	24 2	25 2
26 2	27 2	28 2	29 2	30 2		

October 2005

Mon	Tue	Wed	Thr	Fri	Sat	Sun
					1 2	2 2
3 2	4 2	5 2	6 2	7 2	8 2	9 2
10 2	11 2	12 2	13 2			

AARDEX Ltd. **PowerView** **Compliance Report**

Patient number:	15	Patient initials:	
Patient name:		Monitor number:	219390
Investigator:		Drug name:	.
Regimen:	Once a day		
Results:	28/sept/2005 3:00: to 27/oct/2005 2:59: (1)	Number of monitored days:	29
Number of doses taken:	34	Shortest interval (hrs):	1.2
Longest interval (hrs):	47.0	% Prescribed number of doses taken:	117.2%
% Days correct nbr of doses taken:	75.9%	% Prescribed doses taken on schedule:	82.1%
Therapeutic coverage:	98.4%	Drug duration of action (in hours):	36.0
Number of prescribed doses:	29		

September 2005

Mon	Tue	Wed	Thr	Fri	Sat	Sun
		28 2	29 1	30 1		

October 2005

Mon	Tue	Wed	Thr	Fri	Sat	Sun
					1 1	2 1
3 0	4 1	5 1	6 1	7 1	8 1	9 1
10 1	11 1	12 1	13 2	14 1	15 1	16 2
17 1	18 1	19 2	20 1	21 1	22 2	23 1
24 2	25 1	26 1				

AARDEX Ltd. **PowerView** **Compliance Report**

Patient number:	19	Patient initials:	
Patient name:		Monitor number:	217620
Investigator:		Drug name:	.
Regimen:	Twice a day		
Results:	25/jan/2006 3:00: to 23/feb/2006 2:59: (1)	Number of monitored days:	29
Number of doses taken:	49	Shortest interval (hrs):	5.4
Longest interval (hrs):	60.8	% Prescribed number of doses taken:	84.5%
% Days correct nbr of doses taken:	72.4%	% Prescribed doses taken on schedule:	63.2%
Therapeutic coverage:	88.1%	Drug duration of action (in hours):	18.0
Number of prescribed doses:	58		

January 2006

Mon	Tue	Wed	Thr	Fri	Sat	Sun
		25 2	26 2	27 0	28 0	29 2
30 2	31 2					

February 2006

Mon	Tue	Wed	Thr	Fri	Sat	Sun
		1 2	2 1	3 2	4 3	5 2
6 2	7 2	8 2	9 2	10 2	11 1	12 2
13 2	14 2	15 2	16 2	17 1	18 2	19 0
20 2	21 2	22 1				

AARDEX Ltd. **PowerView** **Compliance Report**

Patient number:	21	Patient initials:	
Patient name:		Monitor number:	217617
Investigator:		Drug name:	.
Regimen:	Twice a day		
Results:	07/feb/2005 3:00: to 08/mar/2006 2:59: (1)	Number of monitored days:	394
Number of doses taken:	57	Shortest interval (hrs):	3.9
Longest interval (hrs):	7324.1	% Prescribed number of doses taken:	7.2%
% Days correct nbr of doses taken:	6.1%	% Prescribed doses taken on schedule:	4.7%
Therapeutic coverage:	7.6%	Drug duration of action (in hours):	18.0
Number of prescribed doses:	788		

February 2005

Mon	Tue	Wed	Thr	Fri	Sat	Sun
7 0	8 0	9 0	10 0	11 0	12 0	13 0
14 0	15 0	16 0	17 0	18 0	19 0	20 0
21 0	22 0	23 0	24 0	25 0	26 0	27 0
28 0						

March 2005

Mon	Tue	Wed	Thr	Fri	Sat	Sun
	1 0	2 0	3 0	4 0	5 0	6 0
7 0	8 0	9 0	10 0	11 0	12 0	13 0
14 0	15 0	16 0	17 0	18 0	19 0	20 0
21 0	22 0	23 0	24 0	25 0	26 0	27 0
28 0	29 0	30 0	31 0			

April 2005

Mon	Tue	Wed	Thr	Fri	Sat	Sun
				1 0	2 0	3 0
4 0	5 0	6 1	7 0	8 1	9 0	10 0
11 0	12 0	13 0	14 0	15 0	16 0	17 0
18 0	19 0	20 0	21 0	22 0	23 0	24 0
25 0	26 0	27 0	28 0	29 0	30 0	

AARDEX Ltd. **PowerView** **Compliance Report**

Patient number:	23	Patient initials:	
Patient name:		Monitor number:	219402
Investigator:		Drug name:	.
Regimen:	Once a day		
Results:	23/feb/2006 3:00: to 24/mar/2006 2:59: (1)	Number of monitored days:	29
Number of doses taken:	24	Shortest interval (hrs):	23.2
Longest interval (hrs):	49.8	% Prescribed number of doses taken:	82.8%
% Days correct nbr of doses taken:	82.8%	% Prescribed doses taken on schedule:	71.4%
Therapeutic coverage:	92.5%	Drug duration of action (in hours):	36.0
Number of prescribed doses:	29		

February 2006

Mon	Tue	Wed	Thr	Fri	Sat	Sun
			23 1	24 1	25 1	26 1
27 1	28 1					

March 2006

Mon	Tue	Wed	Thr	Fri	Sat	Sun
		1 1	2 1	3 1	4 1	5 1
6 1	7 1	8 1	9 1	10 1	11 1	12 1
13 0	14 1	15 0	16 1	17 1	18 1	19 0
20 1	21 1	22 0	23 0			

AARDEX Ltd.

PowerView Compliance Report

Patient number:	34	Patient initials:	
Patient name:		Monitor number:	219391
Investigator:		Drug name:	.
Regimen:	Once a day		

Results:	23/mar/2006 3:00: to 21/apr/2006 2:59: (1)	Number of monitored days:	29
Number of doses taken:	26	Shortest interval (hrs):	22.4
Longest interval (hrs):	48.3	% Prescribed number of doses taken:	89.7%
% Days correct nbr of doses taken:	89.7%	% Prescribed doses taken on schedule:	78.6%
Therapeutic coverage:	95.1%	Drug duration of action (in hours):	36.0
Number of prescribed doses:	29		

March 2006

Mon	Tue	Wed	Thr	Fri	Sat	Sun
			23 1	24 1	25 1	26 1
27 1	28 1	29 1	30 1	31 1		

April 2006

Mon	Tue	Wed	Thr	Fri	Sat	Sun
					1 1	2 1
3 1	4 1	5 1	6 1	7 1	8 1	9 0
10 1	11 1	12 1	13 1	14 1	15 0	16 1
17 0	18 1	19 1	20 1			

Days adherent (%)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2.70	1	2.3	10.0	10.0
	5.60	1	2.3	10.0	20.0
	43.30	1	2.3	10.0	30.0
	48.00	1	2.3	10.0	40.0
	61.40	1	2.3	10.0	50.0
	61.80	1	2.3	10.0	60.0
	63.20	1	2.3	10.0	70.0
	69.00	1	2.3	10.0	80.0
	75.00	1	2.3	10.0	90.0
	93.10	1	2.3	10.0	100.0
	Total	10	22.7	100.0	
Missing	System	34	77.3		
Total		44	100.0		

Doses taken on schedule (%)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2.70	1	2.3	10.0	10.0
	4.30	1	2.3	10.0	20.0
	24.10	1	2.3	10.0	30.0
	37.30	1	2.3	10.0	40.0
	40.80	1	2.3	10.0	50.0
	46.50	1	2.3	10.0	60.0
	55.20	1	2.3	10.0	70.0
	58.50	1	2.3	10.0	80.0
	67.60	1	2.3	10.0	90.0
	89.30	1	2.3	10.0	100.0
	Total	10	22.7	100.0	
Missing	System	34	77.3		
Total		44	100.0		

Frequencies

Statistics

		Doses adherent (%)	Days adherent (%)	Doses taken on schedule (%)
N	Valid	10	10	10
	Missing	34	34	34
Mean		63.3900	52.3100	42.6300
Std. Deviation		27.59414	28.85063	27.21344
Skewness		-.810	-.797	-.022
Std. Error of Skewness		.687	.687	.687
Kurtosis		.850	.090	-.344
Std. Error of Kurtosis		1.334	1.334	1.334

Frequency Table

Doses adherent (%)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	6.60	1	2.3	10.0	10.0
	36.50	1	2.3	10.0	20.0
	48.00	1	2.3	10.0	30.0
	61.70	1	2.3	10.0	40.0
	65.90	1	2.3	10.0	50.0
	69.00	1	2.3	10.0	60.0
	75.00	1	2.3	10.0	70.0
	76.50	1	2.3	10.0	80.0
	94.70	1	2.3	10.0	90.0
	100.00	1	2.3	10.0	100.0
	Total	10	22.7	100.0	
Missing	System	34	77.3		
Total		44	100.0		

APPENDIX C

Instrument Number:

2 4 4

(For internal use only)

HIV DEMENTIA SCALE

Scoring Sheet

Center for Research in Chronic Disorders

ID Number: ☐☐☐☐☐☐☐☐☐☐

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

Test Time: 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○

Administration Time: ☐☐ : ☐☐ (hr) (min)

1. Attention (Anti-saccadic eye movements)

○ 0 ○ 1 ○ 2 ○ 3 ○ 4

2. Psychomotor Speed (Alphabet)

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6

3. Memory Recall (Words)

Dog ○ 0 ○ .5 ○ 1

Hat ○ 0 ○ .5 ○ 1

Green ○ 0 ○ .5 ○ 1

Peach ○ 0 ○ .5 ○ 1

4. Constructional (Cube)

○ 0 ○ 1 ○ 2

Total Score: ☐☐

30812

RAPID ESTIMATE OF ADULT LITERACY IN MEDICINE (REALM)©

Terry Davis, PhD • Michael Crouch, MD • Sandy Long, PhD

Patient Name/
Subject # _____ Date of Birth _____

Reading Level _____

Grade Completed _____

Date _____ Clinic _____ Examiner _____

List 1		List 2		List 3	
fat	____	fatigue	____	allergic	____
flu	____	pelvic	____	menstrual	____
pill	____	jaundice	____	testicle	____
dose	____	infection	____	colitis	____
eye	____	exercise	____	emergency	____
stress	____	behavior	____	medication	____
smear	____	prescription	____	occupation	____
nerves	____	notify	____	sexually	____
germs	____	gallbladder	____	alcoholism	____
meals	____	calories	____	irritation	____
disease	____	depression	____	constipation	____
cancer	____	miscarriage	____	gonorrhea	____
caffeine	____	pregnancy	____	inflammatory	____
attack	____	arthritis	____	diabetes	____
kidney	____	nutrition	____	hepatitis	____
hormones	____	menopause	____	antibiotics	____
herpes	____	appendix	____	diagnosis	____
seizure	____	abnormal	____	potassium	____
bowel	____	syphilis	____	anemia	____
asthma	____	hemorrhoids	____	obesity	____
rectal	____	nausea	____	osteoporosis	____
incest	____	directed	____	impetigo	____

SCORE

List 1 _____

List 2 _____

List 3 _____

Raw Score _____

Instrument Number: 181
(For internal use only)

Study ID: 223

ADHERENCE FOLLOW-UP QUESTIONNAIRE

Center for Research in Chronic Disorders

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

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

(FOR STAFF USE ONLY)

Please use the following example to answer all questions:

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

THIS PAGE IS TO BE COMPLETED BY THE PATIENT AND STUDY PERSONNEL TOGETHER.

Section A

INSTRUCTIONS: Complete this worksheet with the study participant. Please list only antiretroviral medications.

Medication	# of Pills Each Time (**Pills** Each Dose)	# of Times Per Day (**Doses** Per Day)
(a) (for office use only)	(b)	(c)
(1.) _____		
(2.) _____		
(3.) _____		
(4.) _____		
(5.) _____		

20259

PATIENT ONLY CONTINUES HERE.

Section B

We need to understand how people with HIV are really doing with their pills. Please tell us what you are actually doing. Don't worry about telling us that you don't take all of your pills. We need to know what is really happening, not what you think we want to hear.

This section asks about HIV medications you may have MISSED over the last four days. Please complete the table below, using one line for each HIV medication that you are taking. If you did not miss any doses, write zeros ("00") in the box. Note that the table asks about **DOSES**, not pills.

IF YOU TOOK ONLY A PORTION OF A DOSE ON ONE OR MORE OF THESE DAYS, PLEASE REPORT THE DOSE(S) AS BEING MISSED.

Step 1 **Medication**	(a) (for office use only)	HOW MANY DOSES DID YOU MISS			
		Step 2 **Yesterday** **# of doses:**	*Step 3* **Day before yesterday (2 days ago)** **# of doses:**	*Step 4* **3 days ago** **# of doses:**	*Step 5* **4 days ago** **# of doses:**
(1.) _____	(for office use only)	(b)	(c)	(d)	(e)
(2.) _____	(for office use only)				
(3.) _____	(for office use only)				
(4.) _____	(for office use only)				

The following questions pertain to the medications listed on the previous pages.

If you took only a portion of a dose on one or more of these days, please report the dose(s) as being missed.

1. **During the past 4 days, on how many days have you missed taking all of your doses?**
   Choose ONE response only . . . .

   ○ 0 None
   ○ 1 One day
   ○ 2 Two days
   ○ 3 Three days
   ○ 4 Four days

2. **Most HIV medications need to be taken on a schedule, such as "2 times a day" or "3 times a day" or "every 8 hours." How closely did you follow your specific schedule over the last four days?**
   Choose ONE response only . . . .

   ○ 0 Never
   ○ 1 Some of the time
   ○ 2 About half of the time
   ○ 3 Most of the time
   ○ 4 All of the time

3. **Do any of your HIV medications have special instructions, such as "take with food" or "on an empty stomach" or "with plenty of fluids?"**

   ○ 1 Yes ----> a. How often did you follow these special instructions?
   Choose ONE response only . . . .
   ○ 0 Never
   ○ 1 Some of the time
   ○ 2 About half of the time
   ○ 3 Most of the time
   ○ 4 All of the time

   ○ 2 No

4. **Some people find that they forget to take their pills on the weekend. Did you miss any of your HIV medications last weekend - last Saturday *or* Sunday?**

   ○ 1 Yes
   ○ 2 No

5. **When was the last time you missed any of your medications?**
   Choose ONE response only . . . .

   ○ (5) Within the past week
   ○ (4) 1 - 2 weeks ago
   ○ (3) 2 - 4 weeks ago
   ○ (2) 1 - 3 months ago
   ○ (1) More than 3 months ago
   ○ (0) Never skip medications ------> **If you NEVER miss your medications, you are now finished with this questionnaire!**

Otherwise, please continue by answering the next set of questions.

20259

6. **People may miss taking their medications for various reasons. Here is a list of possible reasons why YOU may miss taking your medications.**

How often have YOU missed taking your HIV medications because you . . . .

Choose only ONE response for each question . . . .

	Never	Rarely	Sometimes	Often
	0	1	2	3
a. were away from home?	○	○	○	○
b. were busy with other things?	○	○	○	○
c. simply forgot?	○	○	○	○
d. had too many pills to take?	○	○	○	○
e. wanted to avoid side effects?	○	○	○	○
f. did not want others to notice you taking medication?	○	○	○	○
g. had a change in daily routine?	○	○	○	○
h. felt like the drug was toxic/harmful?	○	○	○	○
i. fell asleep/ slept through dose time?	○	○	○	○
j. felt sick or ill?	○	○	○	○
k. felt depressed/overwhelmed?	○	○	○	○
l. had problem taking pills at specified times (with meals, on empty stomach, etc)?	○	○	○	○
m. ran out of pills?	○	○	○	○
n. felt good?	○	○	○	○

Thank you very much for completing these questions!

20259

Instrument Number: 220
(For internal use only)

Study ID: 223

QUESTIONNAIRE (CES-D)

Center for Research in Chronic Disorders

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

(FOR STAFF USE ONLY)

Please use the following example to answer all questions:

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

INSTRUCTIONS: Below is a list of some of the ways you may have felt or behaved. Please indicate how often you have felt this way **during the past week.**

	Rarely or None of the Time (Less than 1 Day) 0	Some or a Little of the Time (1-2 Days) 1	Occasionally or a Moderate Amount of Time (3-4 Days) 2	Most or All of the Time (5-7 Days) 3
1. I was bothered by things that usually do not bother me.	○	○	○	○
2. I did not feel like eating; my appetite was poor.	○	○	○	○
3. I felt that I could not shake off the blues, even with help from my family or friends.	○	○	○	○
4. I felt that I was just as good as other people.	○	○	○	○
5. I had trouble keeping my mind on what I was doing.	○	○	○	○
6. I felt depressed.	○	○	○	○
7. I felt that everything I did was an effort.	○	○	○	○
8. I felt hopeful about the future.	○	○	○	○

(continued on next page)

42279

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

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

Study ID: 2 2 3

	Rarely or None of the Time (Less than 1 Day) 0	Some or a Little of the Time (1-2 Days) 1	Occasionally or a Moderate Amount of Time (3-4 Days) 2	Most or All of the Time (5-7 Days) 3
9. I thought my life had been a failure.	○	○	○	○
10. I felt fearful.	○	○	○	○
11. My sleep was restless.	○	○	○	○
12. I was happy.	○	○	○	○
13. I talked less than usual.	○	○	○	○
14. I felt lonely.	○	○	○	○
15. People were unfriendly.	○	○	○	○
16. I enjoyed life.	○	○	○	○
17. I had crying spells.	○	○	○	○
18. I felt sad.	○	○	○	○
19. I felt that people disliked me.	○	○	○	○
20. I could not get going.	○	○	○	○

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

42279

Instrument Number: 259
(For internal use only)

Study ID: 223

ISEL

Center for Research in Chronic Disorders

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

(FOR STAFF USE ONLY)

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

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

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

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

(continued on next page)

18429

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

(continued on next page)

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

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

Study ID: 2 2 3

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

(continued on next page)

18429

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

Instrument Number: 7 1 1
(For internal use only)

Study ID: 2 2 3

PERCEIVED STIGMA SCALE

Center for Research in Chronic Disorders

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

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

(FOR STAFF USE ONLY)

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

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

This study asks about some of the social and emotional aspects of having HIV. For each of the following statements, fill in the one circle that corresponds to how strongly you agree or disagree to that statement. There are no right or wrong answers. Feel free to write in comments as you go through the statements.

The first set of statements asks about some of your experiences, feelings, and opinions as to how people with HIV feel and how they are treated. Please do your best to answer each question. *(Fill in only ONE circle for each statement.)*

Use the following scale as a basis for your answers:

[1] = Strongly Disagree
[2] = Disagree
[3] = Agree
[4] = Strongly Agree

	Strongly Disagree 1	Disagree 2	Agree 3	Strongly Agree 4
1. In many areas of my life, no one knows that I have HIV.	○	○	○	○
2. I feel guilty because I have HIV.	○	○	○	○
3. People's attitudes about HIV make me feel worse about myself.	○	○	○	○
4. Telling someone I have HIV is risky.	○	○	○	○
5. People with HIV lose their jobs when their employers find out.	○	○	○	○
6. I work hard to keep my HIV a secret.	○	○	○	○

9872

	Strongly Disagree 1	Disagree 2	Agree 3	Strongly Agree 4
7. I feel I am not as good a person as others because I have HIV.	○	○	○	○
8. I never feel ashamed of having HIV.	○	○	○	○
9. People with HIV are treated like outcasts.	○	○	○	○
10. Most people believe that a person who has HIV is dirty.	○	○	○	○
11. It is easier to avoid new friendships than worry about telling someone that I have HIV.	○	○	○	○
12. Having HIV makes me feel unclean.	○	○	○	○
13. Since learning I have HIV, I feel set apart and isolated from the rest of the world.	○	○	○	○
14. Most people think that a person with HIV is disgusting.	○	○	○	○
15. Having HIV makes me feel that I'm a bad person.	○	○	○	○
16. Most people with HIV are rejected when others find out.	○	○	○	○
17. I am very careful who I tell that I have HIV.	○	○	○	○
18. Some people who know I have HIV have grown more distant.	○	○	○	○
19. Since learning I have HIV, I worry about people discriminating against me.	○	○	○	○
20. Most people are uncomfortable around someone with HIV.	○	○	○	○
21. I never feel the need to hide the fact that I have HIV.	○	○	○	○
22. I worry that people may judge me when they learn I have HIV.	○	○	○	○
23. Having HIV in my body is disgusting to me.	○	○	○	○

Many of the items in this section assume that you have told other people that you have HIV, or that others know. This may not be true for you. If the item refers to something that has not actually happened to you, please imagine yourself in that situation. Then give your answer based on how strongly you think you would feel or how you think others would react to you. Please fill in only ONE circle for each statement.

As in the previous section, use the following scale as a basis for your answers:

[1] = Strongly Disagree
[2] = Disagree
[3] = Agree
[4] = Strongly Agree

	Strongly Disagree 1	Disagree 2	Agree 3	Strongly Agree 4
24. I have been hurt by how people reacted to learning I have HIV.	○	○	○	○
25. I worry that people who know I have HIV will tell others.	○	○	○	○
26. I regret having told some people that I have HIV.	○	○	○	○
27. As a rule, telling others that I have HIV has been a mistake.	○	○	○	○
28. Some people avoid touching me once they know I have HIV.	○	○	○	○
29. People I care about stopped calling after learning I have HIV.	○	○	○	○
30. People have told me that getting HIV is what I deserve for how I lived my life.	○	○	○	○
31. Some people close to me are afraid others will reject them if it becomes known that I have HIV.	○	○	○	○
32. People don't want me around their children once they know I have HIV.	○	○	○	○
33. People have physically backed away from me when they learn I have HIV.	○	○	○	○
34. Some people act as though it's my fault I have HIV.	○	○	○	○
35. I have stopped socializing with some people because of their reactions to my having HIV.	○	○	○	○

	Strongly Disagree 1	Disagree 2	Agree 3	Strongly Agree 4
36. I have lost friends by telling them I have HIV.	○	○	○	○
37. I have told people close to me to keep the fact that I have HIV a secret.	○	○	○	○
38. People who know I have HIV tend to ignore my good points.	○	○	○	○
39. People seem afraid of me once they learn I have HIV.	○	○	○	○
40. When people learn you have HIV, they look for flaws in your character.	○	○	○	○

Instrument Number: 722
(For internal use only)

Study ID: 223

SELF-EFFICACY SCALE

Center for Research in Chronic Disorders

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

(FOR STAFF USE ONLY)

Part A:

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

How confident are you	Not at all confident 1	2	3	4	5	6	7	8	9	Totally confident 10	
1. that you can keep your clinic appointment?	○	○	○	○	○	○	○	○	○	○	
2. that you can follow your overall treatment regimen?	○	○	○	○	○	○	○	○	○	○	
3. that you can follow the plan of care for taking your HIV medication?	○	○	○	○	○	○	○	○	○	○	
4. that you can take your HIV medication the same time each day?	○	○	○	○	○	○	○	○	○	○	
5. that you can take the correct dose of your HIV medication each day?	○	○	○	○	○	○	○	○	○	○	1
6. that you can follow the plan for taking your HIV medication											
a. at work?	○	○	○	○	○	○	○	○	○	○	1
b. on a weekday?	○	○	○	○	○	○	○	○	○	○	2
c. on a weekend?	○	○	○	○	○	○	○	○	○	○	3
d. at a social outing?	○	○	○	○	○	○	○	○	○	○	4
e. at a party?	○	○	○	○	○	○	○	○	○	○	5
f. at a planned event?	○	○	○	○	○	○	○	○	○	○	6
g. at an unplanned event?	○	○	○	○	○	○	○	○	○	○	7
h. when you travel?	○	○	○	○	○	○	○	○	○	○	8
i. when you feel well?	○	○	○	○	○	○	○	○	○	○	9
j. when you feel ill?	○	○	○	○	○	○	○	○	○	○	10
k. when you have side effects from your medications?	○	○	○	○	○	○	○	○	○	○	11
l. when you are experiencing a crisis?	○	○	○	○	○	○	○	○	○	○	12

52384

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

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

Study ID: 2 2 3

Part B:

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

How confident are you	Not at all confident									Totally confident	
	1	2	3	4	5	6	7	8	9	10	
7. that HIV medication will											
a. improve your health?	○	○	○	○	○	○	○	○	○	○	13
b. improve your quality of life?	○	○	○	○	○	○	○	○	○	○	14
c. improve your ability to function?	○	○	○	○	○	○	○	○	○	○	15
d. allow you to live a long life?	○	○	○	○	○	○	○	○	○	○	16
e. enable you to lead a near normal life?	○	○	○	○	○	○	○	○	○	○	17
f. decrease the likelihood of developing HIV-related symptoms?	○	○	○	○	○	○	○	○	○	○	18
g. decrease your viral load?	○	○	○	○	○	○	○	○	○	○	19
h. increase your T-cell count?	○	○	○	○	○	○	○	○	○	○	20
i. prevent you from requiring hospitalization?	○	○	○	○	○	○	○	○	○	○	21

52384

Instrument Number: 302
(For internal use only)

(staple here)

Study ID: 223

Sociodemographic Questionnaire

Center for Research in Chronic Disorders
University of Pittsburgh

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

(FOR STAFF USE ONLY)

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

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

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

1. What is your sex?

○ (1) Male
○ (2) Female

2. What is your date of birth?

___ / ___ / _____
(month) (day) (year)

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

___ (years)

44080

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

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

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

(years)

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

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

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

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

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

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

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

(for office use only)

44080

9. Where do you live?

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

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

○ **N/A**
(No Secondary Residence)

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

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

(for office use only)

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

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

(years)

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

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

13. What is your current employment status?

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

44080

. Are you currently employed?

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

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

○ (2) No

○ (3) I have NEVER been employed

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

○ (1) Yes

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

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

d.) Did you change occupations to accomodate your illness?

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

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

V

_____

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

f.) When you were employed, what was your primary occupation?

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

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

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

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

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

V

_____

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

44080

15. Do you have any children?

- ○ (1) Yes ----> a.) Please specify the number of children: [ ]
- ○ (2) No

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

a. [ ] (adults)

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

17. Do you have a religious background or preference?

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

  (for office use only) [ ]

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

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

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

44080

19. Do you have health care insurance?

○ (1) Yes ---> a.) What type(s) of insurance do you have? (Choose all that apply.)

○ (2) No

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

_____

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

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

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

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

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

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

(a.) Wages, salaries, commisions, bonuses, or tips from all jobs ○ (1) Yes

(b.) Self-employment income from farm or non-farm business ○ (1) Yes

(c.) Interest, dividend, net rental income, royalty income, or income from estates or trusts ○ (1) Yes

(d.) Social security or railroad retirement ○ (1) Yes

(e.) Supplemental security income or other public assistance income ○ (1) Yes

(f.) Retirement, survivor, or disability pensions ○ (1) Yes

(g.) Other (specify): _____ ○ (1) Yes

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

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

○ **N/A (Not Employed)**

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

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

○ N/A (Never Employed)

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

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

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

- ○ (1) Yes
- ○ (2) No

Instrument Number: 303
(For internal use only)

(staple here)

Study ID: 223

Sociodemographic Questionnaire (continued)

Center for Research in Chronic Disorders
University of Pittsburgh

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

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

(FOR STAFF USE ONLY)

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

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

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

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

62520

Instrument Number: 804
(For internal use only)

(staple here)

Study ID: 223

Sociodemographic Questionnaire (continued)

Center for Research in Chronic Disorders
University of Pittsburgh

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

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

(FOR STAFF USE ONLY)

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

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

26. What is (are) the most likely way(s) that you became infected with HIV?
(Choose either "Yes" or "No" for each question.)

(a.)	Sex with a man who was HIV +	○ (1) Yes ○ (2) No
(b.)	Sex with a woman who was HIV +	○ (1) Yes ○ (2) No
(c.)	Shared needles with a person who was HIV +	○ (1) Yes ○ (2) No
(d.)	Blood transfusion or other medical procedure	○ (1) Yes ○ (2) No
(e.)	Don't know	○ (1) Yes ○ (2) No
(f.)	Other (needle stick at work, etc.)	○ (1) Yes ○ (2) No

Please specify: _____

(for office use only)

27. What is your CD-4 count: | | | | | |

(1) ○ Unknown

28. What is your viral load: | | | | | | | |

(1) ○ Unknown

2434

29. Have you ever used marijuana?

- ○ (1) Yes ----> a.) Have you used it within the last 6 months?
  - ○ (1) Yes
  - ○ (2) No
- ○ (2) No

30. Have you ever used cocaine (powder, crack, or freebase)?

- ○ (1) Yes ----> a.) Have you used it within the last 6 months?
  - ○ (1) Yes
  - ○ (2) No
- ○ (2) No

31. Have you ever used heroin?

- ○ (1) Yes ----> a.) Have you used it within the last 6 months?
  - ○ (1) Yes
  - ○ (2) No
- ○ (2) No

32. Have you ever used amphetamines (speed)?

- ○ (1) Yes ----> a.) Have you used it within the last 6 months?
  - ○ (1) Yes
  - ○ (2) No
- ○ (2) No

33. Have you ever used Ecstacy?

- ○ (1) Yes ----> a.) Have you used it within the last 6 months?
  - ○ (1) Yes
  - ○ (2) No
- ○ (2) No

34. Are you currently in methadone treatment?

- ○ (1) Yes
- ○ (2) No

35. How often have you had a drink containing alcohol (a glass of beer, wine, a mixed drink, or any kind of alcoholic beverage) *in the last 30 days*?

(Choose ONE response only.)

- ○ (1) Daily
- ○ (2) Nearly every day
- ○ (3) 3 - 4 times a week
- ○ (4) Once or twice a week
- ○ (5) Once a month
- ○ (6) Never

36. *In the last 30 days*, on days when you drank any alcoholic beverages, how many drinks did you usually have altogether? (By a "drink" we mean a can or glass of beer, a 4-ounce glass of wine, a wine cooler, a 1-1/2 ounce shot of liquor, or a mixed drink with 1-1/2 ounces of liquor.)

(Choose ONE response only.)

- ○ (1) Daily
- ○ (2) Nearly every day
- ○ (3) 3 - 4 times a week
- ○ (4) Once or twice a week
- ○ (5) Once a month
- ○ (6) Never

37. *During the last 30 days*, how often have you had 5 or more drinks of alcohol in a row, that is, within a couple of hours? (e.g., 2 - 4 hours)

(Choose ONE response only.)

- ○ (1) Daily
- ○ (2) Nearly every day
- ○ (3) 3 - 4 times a week
- ○ (4) Once or twice a week
- ○ (5) Once a month
- ○ (6) Never

Instrument Number: 7 1 2 (For internal use only)

Study ID: 2 2 3

HIV DISEASE SYMPTOMS CHECKLIST

Center for Research in Chronic Disorders

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

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

(FOR STAFF USE ONLY)

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

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

Below is a list of potential problems that <u>you may be experiencing today</u>. If you have the problem, rate the degree of *INTENSITY* that best describes the extent of the problem.

If you do not have the problem <u>today</u>, fill in the circle that corresponds to "Not Present Today."

1. FATIGUE

Problem:	*INTENSITY*			
	Mild 1	Moderate 2	Severe 3	Not Present Today 0
a.) Muscle aches	○	○	○	○
b.) Weakness	○	○	○	○
c.) Painful joints	○	○	○	○
d.) Fatigue	○	○	○	○

2. FEAR

Problem:	INTENSITY			
	Mild 1	Moderate 2	Severe 3	Not Present Today 0
a.) Difficulty concentrating	○	○	○	○
b.) Depression	○	○	○	○
c.) Memory loss	○	○	○	○
d.) Fear/worries	○	○	○	○

3. FEVER

Problem:	INTENSITY			
	Mild 1	Moderate 2	Severe 3	Not Present Today 0
a.) Fever	○	○	○	○
b.) Chills	○	○	○	○
c.) Day sweats	○	○	○	○
d.) Night sweats	○	○	○	○

4. STOMACH / BOWEL UPSET

Problem:	INTENSITY			
	Mild 1	Moderate 2	Severe 3	Not Present Today 0
a.) Loose stools	○	○	○	○
b.) Diarrhea	○	○	○	○
c.) Gas/bloating	○	○	○	○
d.) Abdominal pain	○	○	○	○
e.) Nausea	○	○	○	○
f.) Vomiting	○	○	○	○

5. SHORTNESS OF BREATH

Problem:	INTENSITY			
	Mild 1	Moderate 2	Severe 3	Not Present Today 0
a.) Shortness of breath at rest	○	○	○	○
b.) Wheezing	○	○	○	○
c.) Shortness of breath with activity	○	○	○	○

6. SORE THROAT

Problem:	INTENSITY			
	Mild 1	Moderate 2	Severe 3	Not Present Today 0
a.) Sore throat	○	○	○	○
b.) Painful swallowing	○	○	○	○
c.) Mouth ulcers	○	○	○	○
d.) White spots in mouth/thrush	○	○	○	○

7. NUMBNESS

Problem:	INTENSITY			
	Mild 1	Moderate 2	Severe 3	Not Present Today 0
a.) Numbness/tingling of arms	○	○	○	○
b.) Numbness/tingling of hands/fingers	○	○	○	○
c.) Numbness/tingling of legs	○	○	○	○
d.) Numbness/tingling of feet/toes	○	○	○	○

8. HEADACHE

Problem:	INTENSITY			
	Mild 1	Moderate 2	Severe 3	Not Present Today 0
a.) Dizziness	○	○	○	○
b.) Headaches	○	○	○	○
c.) Heart racing	○	○	○	○
d.) Chest pain	○	○	○	○

9. RECTAL ITCH

Problem:	INTENSITY			
	Mild 1	Moderate 2	Severe 3	Not Present Today 0
a.) Rectal itching	○	○	○	○
b.) Rectal bleeding	○	○	○	○
c.) Rectal discharge	○	○	○	○

10. BRUISING / BLEEDING

Problem:	INTENSITY			
	Mild 1	Moderate 2	Severe 3	Not Present Today 0
a.) Sore/bleeding gums	○	○	○	○
b.) Nose bleeds	○	○	○	○
c.) Easy bruising	○	○	○	○
d.) Blood in spit/sputum	○	○	○	○

11. BODY CHANGES

Problem:	INTENSITY			
	Mild 1	Moderate 2	Severe 3	Not Present Today 0
a.) Weight gain in stomach area	○	○	○	○
b.) Concern over weight gain	○	○	○	○
c.) Hump on back of neck/shoulders	○	○	○	○
d.) Skinny arms and legs	○	○	○	○
e.) Prominent leg veins	○	○	○	○

****The following question is FOR WOMEN ONLY****

(1)

If you are MALE, please fill in this circle ----------> ○
then skip to Question 13 on the next page.

12. GYN-RELATED PROBLEMS

Problem:	INTENSITY			
	Mild 1	Moderate 2	Severe 3	Not Present Today 0
a.) Vaginal discharge	○	○	○	○
b.) Irregular period	○	○	○	○
c.) Heavy period	○	○	○	○
d.) Bad cramps	○	○	○	○
e.) Vaginal itching	○	○	○	○
f.) Vaginal odor	○	○	○	○
g.) Bleeding between periods	○	○	○	○
h.) Pelvic pain	○	○	○	○

13. OTHER SYMPTOMS / COMPLAINTS . . . .

Problem:	INTENSITY			
	Mild 1	Moderate 2	Severe 3	Not Present Today 0
a.) Swollen glands	○	○	○	○
b.) Swollen feet	○	○	○	○
c.) Dry mouth	○	○	○	○
d.) Thirst	○	○	○	○
e.) Coughing	○	○	○	○
f.) Lack of appetite	○	○	○	○
g.) Constipation	○	○	○	○
h.) Concern over weight loss	○	○	○	○
i.) Flushing	○	○	○	○
j.) Rash	○	○	○	○
k.) Itchy skin	○	○	○	○
l.) Insomnia/can't sleep	○	○	○	○
m.) Anxious	○	○	○	○
n.) Blurred vision	○	○	○	○
o.) Seizures/tremors	○	○	○	○
p.) Nipple discharge	○	○	○	○
q.) Breast pain/changes	○	○	○	○
r.) Sores or lumps on genitals	○	○	○	○
s.) Burning with urination	○	○	○	○

Instrument Number: 7 5 3
(For internal use only)

Study ID: 2 2 3

MEDICAL OUTCOMES STUDY

Center for Research in Chronic Disorders

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

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

(FOR STAFF USE ONLY)

Please use the following example to answer all questions:

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

***INSTRUCTIONS*: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.**

1. In general, would you say your health is: (choose one response only...)

   ○ 1 Excellent
   ○ 2 Very good
   ○ 3 Good
   ○ 4 Fair
   ○ 5 Poor

2. How much bodily pain have you generally had <u>during the past 4 weeks</u>: (choose one response only...)

   ○ 1 None
   ○ 2 Very mild
   ○ 3 Mild
   ○ 4 Moderate
   ○ 5 Severe
   ○ 6 Very severe

3. For how long (if at all) has your health limited you in each of the following activities?

	Limited for more than 3 Months	Limited for the last 3 Months	Not Limited at all
	1	2	3
a. The kinds or amounts of **vigorous activities** you can do, like lifting heavy objects, running, or participating in strenuous sports	○	○	○
b. The kinds or amounts of **moderate activities** you can do, like moving a table, carrying groceries, or bowling	○	○	○
c. Walking uphill or climbing (a few flights of stairs)	○	○	○
d. Bending, lifting, or stooping	○	○	○
e. Walking **one block**	○	○	○
f. Eating, dressing, bathing, or using the toilet	○	○	○

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

○ 1 Yes, for more than 3 months
○ 2 Yes, for 3 months or less
○ 3 No

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

○ 1 Yes, for more than 3 months
○ 2 Yes, for 3 months or less
○ 3 No

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

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

Study ID: 2 2 3

For *each* of the following questions, please fill in the circle that corresponds to the *one* answer that comes *closest* to the way you have been feeling ***during the past month:*** (choose one response on each line...)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
	1	2	3	4	5	6
6. How much of the time, during the past month, has your *health limited your social activities* (like visiting with friends or close relatives)?	○	○	○	○	○	○
7. How much of the time, during the past month, have you been a *very nervous person?*	○	○	○	○	○	○
8. During the past month, how much of the time have you felt *calm and peaceful?*	○	○	○	○	○	○
9. How much of the time, during the past month, have you felt *downhearted and blue?*	○	○	○	○	○	○
10. During the past month, how much of the time have you been a *happy person?*	○	○	○	○	○	○
11. How often, during the past month, have you felt *so down in the dumps that nothing could cheer you up?*	○	○	○	○	○	○
12. How often ***during the last four weeks***						
a. did you feel full of pep?	○	○	○	○	○	○
b. did you feel worn out?	○	○	○	○	○	○
c. did you feel tired?	○	○	○	○	○	○
d. did you have enough energy to do the things you wanted to do?	○	○	○	○	○	○
e. did you feel weighed down by your health problems?	○	○	○	○	○	○
f. were you discouraged by your health problems?	○	○	○	○	○	○
g. did you feel despair over your health problems?	○	○	○	○	○	○
h. were you afraid because of your health?	○	○	○	○	○	○

57761

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
	1	2	3	4	5	6
13. How much of the time, during the *past month*, did you have difficulty reasoning and solving problems (for example: making plans, making decisions, learning new things)?	○	○	○	○	○	○
14. During the *past month*, how much of the time did you forget things that happened recently (for example: where you put things, appointments)?	○	○	○	○	○	○
15. How much of the time, during the *past month*, did you have trouble keeping your attention on any activity for long?	○	○	○	○	○	○
16. During the *past month*, how much of the time did you have difficulty doing activities involving concentration and thinking?	○	○	○	○	○	○

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

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

18. How would you rate your physical health and emotional condition *now* compared to *4 weeks ago?* (choose one response only...)

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

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