A Study Trial of a Brief Psycho-educational Group Intervention for HIV/AIDS-Infected Adults Who are Non-Adherent With Their Medications

by

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Abstract

With the use of Highly Active Antiretroviral Therapy (HAART), the key to successful HIV/AIDS treatment is adherence to medications. Young adults, aged 18 to 30, are becoming infected with HIV at increasingly high rates and tend not to be adherent to their HAART regimens. The main contributing factors to HAART non-adherence in young adults are HIV disease stigma, mental health and substance use disorders, as well as beliefs/issues regarding medication. A needs assessment conducted in the Johns Hopkins Hospital outpatient infectious disease clinic in fall 2015 indicated that 50% of young adults infected with HIV/AIDS are non-adherent with their HAART regimen. In an effort to improve medication adherence in this population, an intervention was designed that included six psycho-educational groups utilizing the Information-Motivation-Behavioral Skills (IMB) model for young HIV/AIDS-infected adults. The study enrolled 21 participants, but it failed to be implemented due to poor participant attendance at the scheduled group sessions. Of the 21 participants, 76.19% reported a medication adherence of 95-100%. However, these participants had detectable HIV viral loads, indicating medication adherence below 95-100%. Additional research must be conducted to fully understand and address the barriers HIV/AIDS-infected young adults face before an effective intervention can be implemented.

Key Words: Acquired Immunodeficiency Syndrome (AIDS), Human Immunodeficiency Virus (HIV), Viral Load (VL), Young Adults, Stigma, Mental Health, Substance Use, Medication Adherence, Information-Motivation-Behavioral Skills (IMB) model
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Executive Summary

The first cases of Acquired Immunodeficiency Syndrome (AIDS) were diagnosed in the United States in 1981, and since then, over 600,000 people in the United States and over 30 million people globally have died as a result of AIDS. In 2014, the Centers for Disease Control and Prevention estimated that there were 37,600 new HIV infections in the United States. Thirty-seven percent of the new infections were among individuals between the ages of 15 and 30 (CDC, 2014).

In the 1980s, HIV/AIDS was considered a chronic illness that almost always resulted in a patient’s early death. Some treatments were made available for patients in 1987 beginning with the FDA’s approval of AZT. These early treatments, similar to chemotherapy for cancer, were often more devastating than the illness itself. These early medication regimens typically included up to 20 pills that needed to be taken three or four times a day. Common side-effects caused by these initial HIV/AIDS medication regimens included peripheral neuropathy (pain in the hands and toes), gastrointestinal issues, lipoatrophy (loss of fat in face, arms, legs, and buttocks), rashes, dizziness, vivid dreams, and fatigue.

The future of HIV/AIDS treatment shifted in June 1995 when the FDA approved the use of protease inhibitors to combat the virus. To increase their effectiveness, HIV/AIDS treatment providers began using medications in combination as Highly Active Antiretroviral Therapy (HAART). HAART is the combination of protease inhibitors with two other drugs in the class of reverse transcriptase inhibitors. Computer simulation modeling in 1996 found that patients on HAART consistently lived four to six years longer than patients did prior to the use of HAART. Holtgrave (2005) estimated that the
discovery and implementation of HAART delayed between 33,480 and 41,784 AIDS deaths in the United States between 1995 and 2002.

Currently, there are 12 combination drugs—two or more different HIV medications combined in one pill—approved for the treatment of HIV/AIDS and roughly 30 antiretroviral drugs that are classified by their mechanism of action. These include Entry and Fusion Inhibitors, Integrase Inhibitors, Non-nucleotide Reverse Transcriptase Inhibitors, Nucleotide Reverse Transcriptase Inhibitors, Pharmacokinetic Enhancers, and Protease Inhibitors (aidsinfo.nih.gov/drugs). The newer HAART regimens require fewer pills, can be taken less frequently, and have fewer side-effects compared to the older medications used to treat HIV/AIDS.

The utilization of HAART was paramount in the history of the AIDS epidemic in the United States. By 1997, the AIDS mortality rate in the United States dropped by 47%. The public’s perception of HIV/AIDS shifted from a terminal disease to a chronic, manageable illness. HIV/AIDS patients no longer needed to choose between the toxic effects of medication and decreasing immune function. Instead, the importance of adherence to medication regimens has become the focus in managing HIV.

Non-adherence or inconsistent adherence to HAART has been shown to lead to medication-resistant HIV, increased health issues, inability to achieve an undetectable viral load, and an increased likelihood of death. Inadequate adherence to a HAART regimen has also been shown to decrease a patient’s life expectancy due to the fact that uncontrolled HIV makes one more likely to develop other health conditions, like cardiovascular disease. The onset of other health conditions among non-adherent patients causes an increase in health costs. Rudy et al. (2009) reported that the most prevalent
factors for non-adherence to HIV medications fell into one of the following three categories: cognitive/behavioral factors related to antiretroviral medication regimens, mental health and substance use disorders, or structural barriers (homelessness, lack of insurance, transportation issues, etc.).

Young adults between the ages of 18 and 30, are becoming infected with HIV/AIDS at alarming rates. Additionally, this group exhibits high rates of non-adherence to their HIV medications. Many research articles focused on young adults infected with HIV/AIDS have concluded that the factors that drive non-adherence to HAART in this population are HIV disease stigma, mental health and substance use disorders, and beliefs/issues regarding medication. Other promising research demonstrates that the Information-Motivation-Behavioral Skills (IMB) model of medication adherence improves adherence to HAART among many populations of HIV/AIDS-infected patients.

With this in mind, the intervention proposed for this study consists of a series of psycho-educational groups for young adult, HIV/AIDS-infected patients of the outpatient infectious disease clinic at Johns Hopkins Hospital. The educational groups were designed to utilize the IMB model of medication adherence and to target the factors driving non-adherence in young adults including HIV disease stigma, mental health and substance use disorders, and beliefs/issues regarding medication.

From mid-September 2016 until February 1, 2017, 21 participants were enrolled from the Johns Hopkins Hospital outpatient infectious disease clinic. Ten participants were randomized into the control group and 11 participants were randomized into the intervention group. The intervention consisted of six, modular, psycho-educational
groups scheduled between February 15 and April 19. Participation in the six-group sessions was scarce, due to multiple barriers, and thus the intervention resulted in insufficient data. Information obtained from the medication adherence scale taken at the time of consent revealed that 76.19% of the 21 participants reported medication adherence of 95-100%. However, upon review of the medical record, these same participants all had detectable HIV viral loads, proving that they had not been maintaining a medication adherence of 95-100%.

In the future, it may be better to attempt the intervention as a six-session individual intervention that is scheduled, but also has the flexibility to accommodate the chaos that can be associated with the lives of HIV/AIDS-infected young adults. It is important to investigate the barriers preventing young adults from being adherent to their HIV/AIDS medications and, in general, their medical care. It may be interesting to study why young adults report a medication adherence rate that is not accurate.
Chapter 1 – Literature Review

Overview of the Problem of Practice

The first cases of Acquired Immunodeficiency Syndrome (AIDS) were diagnosed in the United States in 1981. Since then, over 600,000 people in the United States and over 30 million people globally have died as a result of AIDS. According to the Center for Disease Control (CDC), 47,352 new cases of Human Immunodeficiency Virus (HIV) infection were reported in the United States in 2013. The CDC (2013) estimates that in 2012, 13,712 individuals infected with HIV/AIDS died. Current estimates indicate that there are over 1.2 million people in the United States living with HIV/AIDS (CDC, 2013). In 2015, the number of new HIV diagnoses in the United States was 39,513 (CDC, 2015). Thirty-seven percent of these new infections were among individuals between the ages of 15 and 30.

HIV is the virus that can lead to AIDS, which is the most advanced stage of HIV infection. HIV is spread when mucous membranes located in the rectum, vagina, opening of the penis, or mouth come in contact with bodily fluids like blood, semen, pre-semen, rectal fluids, vaginal fluids, or breast milk. HIV is usually spread through sexual contact, the sharing of drug injection equipment (i.e., needles, syringes, and rinse water), and mother-to-child transmission. In terms of sexual transmission, the highest risk is anal intercourse (receptive anal intercourse being riskier than insertive anal intercourse) followed by vaginal intercourse (females are at higher risk than males). Oral sex rarely results in HIV transmission unless the person preforming oral sex has compromised mucous membranes in their mouth due to a cut or sore (Gallant, 2009).
In the 1980s, HIV/AIDS was considered a chronic illness that almost always resulted in a patient’s early death. Some treatments were made available for patients in 1987 beginning with the FDA’s approval of AZT. These early treatments, similar to chemotherapy for cancer, were often more devastating than the illness itself. Early medication regimens typically included up to 20 pills that needed to be taken three or four times a day. Some pills needed to be taken on an empty stomach while others needed to be taken with food to be effective. Common side-effects caused by these initial HIV/AIDS medication regimens included peripheral neuropathy (pain in the hands and toes), gastrointestinal issues, lipoatrophy (loss of fat in face, arms, legs, and buttocks), rashes, dizziness, vivid dreams, and fatigue.

The future of HIV/AIDS treatment shifted in June 1995 when the FDA approved the use of protease inhibitors to combat the virus. To increase their effectiveness, HIV/AIDS treatment providers began using medications in combination as Highly Active Antiretroviral Therapy (HAART). HAART is the combination of protease inhibitors with two other drugs in the class of reverse transcriptase inhibitors. Computer simulation modeling in 1996 found that patients on HAART consistently lived four to six years longer than patients did prior to the use of HAART. Holtgrave (2005) estimated that the discovery and implementation of HAART delayed between 33,480 and 41,784 AIDS deaths in the United States between 1995 and 2002.

Currently, there are 12 combination drugs—two or more HIV drugs formulated into one pill—approved for the treatment of HIV/AIDS and roughly 30 antiretroviral drugs that are classified by their mechanism of action. These include Entry and Fusion Inhibitors, Integrase Inhibitors, Non-nucleotide Reverse Transcriptase Inhibitors,
Nucleotide Reverse Transcriptase Inhibitors, Pharmacokinetic Enhancers, and Protease Inhibitors (aidsinfo.nih.gov/drugs). The newer HAART regimens require fewer pills, can be taken less frequently, and have fewer side-effects compared to the older medications used to treat HIV/AIDS. HAART regimens today typically consist of three pills taken once a day or two-to-three pills taken twice a day. Three pills taken twice daily might be considered a high pill count, especially considering the increasing availability of combination drugs that afford some patients the convenience of one pill taken once a day.

Some of the medications used today do require intake with food while others require intake on an empty stomach. The medications should be taken at the same time every day. A HAART regimen is taken indefinitely unless there is a medical reason to change the regimen. For example, an HIV/AIDS treatment provider may choose to switch or discontinue the current regimen if the patient’s viral load is no longer suppressed or if the medications cause adverse effects like renal issues, liver toxicity, or worsening neuropathy.

The utilization of HAART is paramount in the history of the AIDS epidemic in the United States. By 1997, the AIDS mortality rate in the United States dropped by 47%. The psychological effects of having the HIV/AIDS virus changed with the utilization of HAART regimens. The ability to effectively manage the virus had a profound effect on all individuals involved with the virus, from patients to health providers to researchers. The public’s perception HIV/AIDS has shifted from a terminal disease to a chronic, manageable illness. HIV/AIDS patients no longer needed to choose between the toxic effects of medication and decreasing immune function. Instead, the importance of adherence to medication regimens has become the focus in managing HIV.
An HIV-infected individual’s health is monitored by blood tests focusing on two measurements—the CD4 cell count and the HIV Viral Load. CD4 cells are white blood cells, often referred to as T Cells, which help one’s immune system function properly. A person with a healthy immune system has a CD4 count between 500 and 1,600 cells/mm3; a person is said to have AIDS when their CD4 count is below 200. The Viral Load (VL) blood test measures the amount of HIV particles present in one milliliter of blood and is the best indicator of the effectiveness of HAART. A person is said to have undetectable levels of HIV when their VL is less than 20 or 50 particles per milliliter. The CD4 count and HIV VL help predict the rate of the disease’s progression and therefore help medical providers manage their HIV-infected patients.

Non-adherence or inconsistent adherence to HAART has been shown to lead to medication-resistant HIV, increased health issues, inability to achieve an undetectable viral load, and an increased likelihood of death. Inadequate adherence to a HAART regimen has also been shown to decrease a patient’s life expectancy due to the fact that uncontrolled HIV makes one more likely to develop other health conditions, like cardiovascular disease. The onset of other health conditions among non-adherent patients causes an increase in health costs. Rudy et al. (2009) reported that the most prevalent factors for non-adherence to HIV medications fell into one of the following three categories: cognitive/behavioral factors related to antiretroviral medication regimens, mental health and substance use disorders, or structural barriers (homelessness, lack of insurance, transportation issues, etc.) These common non-adherence categories were noted in adults with no specific age range.
Young adults between the ages of 18 and 30 are becoming infected with HIV/AIDS at alarming rates. Additionally, this group exhibits high rates of non-adherence to their HIV medications. A brief psycho-educational intervention can be designed to target this problem of practice, and improve adherence to HIV medications among infected young adults.

**Theoretical Framework**

Prior to the development of an intervention to help alleviate or eliminate a problem, it is essential to fully understand all aspects of the problem. Studying a problem from multiple perspectives and utilizing a sound theoretical framework leads to a sound understanding of all aspects of the problem.

Reviewing the history of the HIV/AIDS epidemic in the United States leads to a thorough understanding of the treatment of the virus, the social stigma, public policy, and sexual practices surrounding the disease. The historical perspective also highlights the lessening side effects of the currently available treatments and the changing medical management of infected patients. Interestingly, public opinion and the societal stigma of having HIV/AIDS has shifted over the course of the epidemic as well. Research conducted in the mid-1990s focused on the implications of mental health disorders soon after HAART treatments were introduced (Lyketos et al., 1997).

Using a sociological perspective is an excellent way to examine the relationship between society and the HIV/AIDS public health crisis (Maticka-Tyndale, 2001). “Generally speaking, the outlook of sociology is that human behavior is largely determined by societal practices and societal organization” (Krishnan, 2009, p.26). Looking at the problem of practice from this view point can highlight factors in the
context of society, which could be overlooked if only evaluating the data or the individuals directly involved. Understanding why society was, and still is, such fertile ground for this epidemic and why certain groups are more vulnerable than others may illuminate the key to increased adherence and ultimately, decreased transmission and acquisition of HIV/AIDS (Maticka-Tyndale, 2001). For example, society’s opinions on sexual practices and health education (Francis, 2009) are related to homophobia (Ruel & Campbell, 2006) and other social stigmas surrounding HIV/AIDS and can directly affect treatment and prevention efforts (Lyon & Woodward, 2003).

When you focus on young adults infected with HIV/AIDS, a complete understanding of their daily lives, cultural influences, and psychosocial stressors can help illuminate causes for medication non-compliance (Asher, Miller, & Green, 2011). The best way for young adults to obtain undetectable viral loads, and therefore remain healthy with limited adverse effects on their life expectancy, is through compliance with their respected HAART regimen (Flynn et al., 2004). Numerous articles mentioned that interpersonal conflict between young patients and their treatment providers lead to medication non-adherence (Catz et al., 2000; Fernandez et al., 2011). Anthropological and ethnographic approaches are effective for getting very specific non-judgmental information about the research group as well. Utilizing an approach without bias, ensures that the data and information obtained through research is reliable (Krishnan, 2009)

**Review of Literature**

In 2006, Rangel et al. explored the epidemiology of HIV/AIDS among infected adolescents and young adults. In their study, Rangel et al. examined the diagnosis of individuals, ages 13 to 24, which had been reported to the national HIV/AIDS Reporting
Service from 1985 to 2003. The cases were from all 50 states, the District of Columbia, and U.S. trusts and territories. They discovered that, by the end of 2003, 7,074 individuals between the ages of 13 and 24 were HIV-infected and living in the United States (Rangel et al., 2006).

According to the CDC, in 2013 the estimated number of individuals living in the United States newly diagnosed with HIV was 47,352 and 33.5% of these newly infected individuals were between the ages of 20 and 30. Young adults are becoming infected with HIV at increasingly high rates. The CDC (2013) estimated that there was a 22% rise in infection rate from 2008 to 2010 among 13 to 24 year olds. Though the young adults who are being infected with HIV cannot be cured of their disease, their HIV/AIDS can be effectively managed. Flynn et al. looked at the current treatment for HIV/AIDS in individuals between the ages of 13 to 24 in a 2004 study. One hundred and twenty participants in this age group were followed between March 1999 and October 2001 while they were on a HAART regimen. The participants had their blood drawn and their CD4 count and viral load measured at baseline and then again at weeks 4, 8, 12, 16, and 24. Fifty-nine percent of the participants had an undetectable viral load by the end of the study, which was less than anticipated. The calculated adherence rate of 27% was only measured by self-report and most likely accounts for the lower than expected rate of undetectable viral load among the participant population.

Young adults infected with HIV/AIDS can live long lives and their disease can be effectively managed if they remain adherent to their HAART regimen. Dr. C. Everett Koop, former Surgeon General of the United States, was often quoted as saying, “Drugs don’t work in patients who don’t take them” (Bartlett, 2002). In accordance with recent
trends, young adults will continue to become infected with HIV/AIDS. Therefore, not only is adherence to HAART fundamental to the wellbeing of youth living with HIV, but adherence also has an impact on the broader scope of public health. Adherence to HAART has been shown to be the single most important factor in achieving undetectable viral loads in youth living with HIV (Flynn et al., 2004). Poor medication adherence has been implicated in the emergence of drug resistant strains of HIV (Mehta et al., 1997; Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez, 2007). Several studies have shown that patients who consistently took their antiretroviral medication regimen had much better health outcomes compared to patients who were not adherent to their HIV/AIDS medication (Magidson et al., 2014). The adherence rate needed to suppress HIV/AIDS to undetectable levels is 90-95%. Reisner et al. (2009) conducted a review of 21 studies published between 1999 and 2008 on HIV-infected adolescents and the rate of adherence to medication was from 28-69%. Adherence rate improvement has been shown to correlate with increased age (Murphy et al., 2004).

A large majority of the factors that negatively affect medication adherence in young adults fall into the categories of HIV/AIDS disease stigma, mental health and substance use disorders, and beliefs/issues regarding medication (Garvie, 2010).

**HIV/AIDS disease stigma.** Harper et al. (2014) conducted a behavioral experiment in young adults diagnosed with HIV/AIDS that looked at whether a group-based behavioral intervention could diminish the stigma of the disease experienced by the participants. In the study, the stigma of having HIV was categorized in four ways: personalized stigma, disclosure concerns, negative self-image, and concern with public opinion. The measurement tool utilized was the Berger HIV Stigma Scale. The
behavioral intervention ran for 12 weeks and consisted of HIV/AIDS education, acquisition of coping skills, and initiation of contact with other HIV/AIDS-infected youth for social support. The study included a sample of 50 young adults (28 males, 22 females, mean age = 19.24 years) from four geographically diverse clinics. The study had a pre-test/post-test design along with a three-month follow-up to assess the sustainability of any improvements made. The primary outcomes of the post-test were measured as reduction in stigma for personalized stigma, disclosure concerns, and negative self-image. At the three-month follow-up, sustained stigma reduction was present in negative self-image. Additionally, the three other types of stigma (personalized stigma, disclosure concerns, concern with public opinion) increased at each subsequent follow-up interval. When the data was analyzed by gender, it showed that personalized stigma was the only reduced stigma type for females who completed the intervention and it was not sustained at the three-month follow-up. The authors hypothesized that this gender discrepancy may exist because the decision to disclose is a more complicated, nuanced issue for young women due societal and cultural gender stereotypes.

One of the categories of stigma used by Harper et al. (2014), concern with public opinion, was best understood through a historical perspective of HIV/AIDS. In 1994, Trezza (1994) studied college undergraduates and psychologists in terms of their knowledge and feelings about HIV itself, as well as their knowledge and feelings about people infected with HIV. The participant sample included 660 undergraduates and 596 clinical and counseling psychologists. The study consisted of five survey tests: The Generalized AIDS Information Questionnaire, The Issues of AIDS Prevention Scale, The Attitudes About AIDS Scale, The Self-Perceptions About AIDS Scale, and the Index of
Homophobia. The undergraduates were given the survey questions in a class and the psychologists were mailed their surveys. Results of this study revealed that participants felt very low concern regarding real HIV risks (unprotected sex, IV drug use) in their own lives, but had a high level of concern about unreal risks (becoming infected with HIV due to casual contact with an infected individual). Also, sigma about the disease seemed to be closely tied to homophobia.

Rose Weitz’s article, “Living with the Stigma of AIDS,” is based on interviews she conducted with 23 AIDS patients between July 1986 and March 1987. Weitz gives us a glimpse into the very early days of the AIDS epidemic. It discusses how the stigma of being infected with HIV/AIDS affects the patients’ relationships with family, friends, lovers, healthcare workers, and fellow workers. The article examines how stigma gets reinforced by having people who the patients are close to adopt “extreme and medically unwarranted anti-contagion measures” (Weitz, 1990, p. 28). The article also touches on the patients’ struggles with obtaining health insurance, finding healthcare providers, and hiding signs of weight loss. These issues are not as relevant today as they were in the late 1980s. However, early barriers to medical care and the aspects of living with HIV/AIDS people experienced in the early days of the epidemic are still very important to consider since these are the elements from which the stigma was created. One aspect of stigma that Weitz discusses which is not as prevalent today as it once was, is the notion that HIV/AIDS is a divine punishment for sin. “While some people believe that herpes or leprosy are divine punishments for sin, far more people believe that AIDS is a divine punishment” (Weitz, 1990, p. 26). Currently, there are seemingly fewer references to “divine punishment” in the literature and it is unclear if this correlates to a better
understanding of the disease, a decrease in society’s religiosity, or a decrease in disapproval.

Rao et al. (2007) looked at information obtained from 25 HIV/AIDS-infected adolescents and young adults who participated in moderator-led focus groups. These focus groups discussed the stigma of being infected with HIV/AIDS and the participants’ individual efforts to conceal their HIV status. This study showed that the invulnerability of youth, commonly seen in studies involving adolescents and young adults, was not a factor in non-compliance to HAART. Ninety-two percent of the study participants reported that they knew that compliance with their medications was important to remain healthy (Rao, Kekwaletyswe, Hosek, Martinez, & Rodriguez, 2007). The results from the study identified barriers to medication adherence, which included dishonesty with health providers to avoid criticism, fear of discrimination from friends and family, interference of the disease with their life style, and the development of depressive symptoms (Rao, Kekwaletyswe, Hosek, Martinez, & Rodriguez, 2007). To help understand the results from this study, we can categorize the barriers identified (dishonesty with health providers to avoid criticism, fear of discrimination from friends and family, interference of the disease with their life style, and the development of depressive symptoms) into the four categories defined by Harper et al. (2014)—personalized stigma, disclosure concerns, negative self-image, and concern with public opinion. Dishonesty with health providers to avoid criticism would fit under the category of negative self-image and fear of discrimination from friends and family would fit under the category of disclosure concerns. Though stigma can cause a great deal of emotional distress, the third barrier,
the development of depressive symptoms, fits better under the general category of mental health and substance use disorders and not HIV/AIDS disease stigma.

Ruel et al. (2006) conducted a study looking at society’s view on homosexuals as a result of the AIDS epidemic. The purpose of the study was to determine if the early period of the AIDS epidemic caused a negative attitude towards homosexual males in the United States. The data used for analysis came from the General Social Survey (GSS) for the period from 1973 to 1998 and the Centers for Disease Control (CDC) for the period from 1981 until 2006. The GSS was not carried out in 1972, 1975, 1978, 1983, and 1986, causing a limitation in the study design. In the data sample, only 45 states and Washington DC were represented. For the years 1981 to 1987, the CDC did not distinguish how an individual became infected with HIV/AIDS. Data analysis revealed that there was a negative shift in the public’s attitude toward homosexual males, particularly during what this article refers to as the “diffusing period” of the AIDS epidemic from 1986 to 1991. After 1991, the AIDS epidemic seemed to become more mainstream. In turn, support for those affected by HIV/AIDS grew exponentially. The authors suggest that AIDS evokes stigma because it is contracted voluntarily through behaviors which are stigmatized by many individuals, it is contagious, it puts others at risk, and because it is incurable and can be fatal (Ruel et al., 2006).

The stigmatization of HIV/AIDS has remained a constant part of the epidemic and it may be the reason that some young adults do not want to take their medications. It is not uncommon for a provider to report that their young adult patient tells them that the medications are a constant, daily reminder that they have HIV/AIDS.
**Mental health and substance use disorders.** The diseases of addiction and mental illness are chronic health issues that are difficult to treat, meaning that patients often struggle for years to find effective treatment. The combination of one or both of these diseases with HIV/AIDS can be devastating to an individual or even a vulnerable population.

HIV/AIDS shifted from a terminal disease to a chronic, manageable disease with the advent of the HAART regimen in 1996. This realization had an effect on the psyche of HIV/AIDS patients and, ultimately, their psychiatric care (Lyketsos et al., 1997). Using a cohort-design study of 126 HIV/AIDS patients referred by their treatment providers, Lyketsos and et al. (1997) wanted to understand if psychiatric treatment had an effect on the success of HIV treatment. The study was conducted in a psychiatric clinic that functions as a specialty clinic within the primary HIV/AIDS treatment clinic. The purpose of the study was to determine if the psychiatric treatment of HIV/AIDS-infected patients would help reduce alcohol and drug use, as well as determine variables that are predictive of positive treatment outcomes. Results indicated that half of the patients showed decreased frequency and amount of drug and alcohol use. Ninety-five percent of the compliant patients showed at least small improvement, whereas 85% of the poorly compliant patients showed no improvement or worsening symptoms related to alcohol and drug use.

Compounding the negative effects of substance use on adherence to a HAART regimen is the existence of depression in HIV/AIDS patients. Gonzalez et al. (2011) showed that a patient’s level of depression was a significant indicator of non-adherence.
with their HAART regimen. Magidson et al. (2014) also found that the presence of depression was a consistent predictor of a patient’s non-adherence with HAART.

Rudy et al. (2009) conducted a study with 396 participants between the ages of 12 and 24 that examined the following personal barriers to HAART adherence: mental health barriers/substance use, high/low self-efficacy and outcome expectancy, and the presence of specific structural barriers (homelessness and lack of insurance). The study used a cross-sectional observational design. The participants had all been infected with HIV/AIDS after the age of nine, and were recruited either from the Adolescent Trials Network for HIV/AIDS Interventions or the Pediatric AIDS Clinical Trials Group. The most non-adherent patients were diagnosed with both a mental health disorder and an active substance use disorder. Cruess et al. (2003) reviewed numerous studies that looked at the prevalence of mental illness in HIV/ADIS-infected individuals and found the most prevalent mental health disorder among the study population was mood disorder. Furthermore, the data indicated that depression had a slightly higher rate of occurrence than the other mood disorders (Cruess et al., 2003). Bing et al. (2001) conducted a study of HIV/AIDS-infected patients from across the country where he screened 2,864 patients for the presence of mental health disorders and found that close to 50% of them did meet these criteria.

Hosek et al. (2005) conducted a study of 42 HIV/AIDS-infected young adults between the ages of 16 and 24 years old. Twenty-five of the participants were male and 17 were female. Seventy-six percent of the participants were African-American, 12% Latino, 10% Multi-racial, and 2% Caucasian. In terms of sexual orientation, 55% of the participants identified as heterosexual, 26% as homosexual, and 19% identified as
bisexual. All of the participants were taking antiretroviral medications. The purpose of the study was to determine if there was an effect on medication adherence based on mood instability, cognitive ability/formal reasoning, and substance use. The methodology of the study included several surveys: Time-Line Follow-Back, AIDS Clinical Trial Group Adherence Follow-Up Questionnaire, Arlin Test of Formal Reasoning, Vocabulary test (subtest from the Weschler Adult Scale of Intelligence-Third Edition), Center for Epidemiology Studies-Depression Scale, State-Trait Anxiety Inventory, Beck Hopelessness Scale, and the Addiction Severity Index. All questions were read aloud to the participants by the interviewer and the surveys were completed during a one-hour period. The results of the study substantiated other studies findings of poor medication adherence in adolescent and young adults infected with HIV/AIDS. Fifty-six percent of the participants were less adherent than the 95% adherence rate needed for viral suppression. Forty-two percent of the participants reported missing a dose of their medication regimen the day prior to their study interview. Thirty-five percent of the female participants and 40% of the male participants met the criteria for depression. Also of significance was the interrelationship between poor adherence to the HAART regimen and age of first-time marijuana use. This is important to consider since the rate of marijuana use among young adults infected with HIV/AIDS is high.

Peters et al. (2011) conducted an eight-week randomized clinical trial that tested 122 participants (mean age of 21.40) with the efficacy of placebo-controlled naltrexone plus brief individual counseling to reduce heavy drinking. The Daily Drinking Questionnaire-Revised, the Young Adult Alcohol Consequences Questionnaire, the Contemplative Ladder, the nine-item Drinking-Induced Disinhibition Scale, and the four-
item Medication Adherence Questionnaire were used as measures. Young adult heavy drinkers with co-occurring marijuana use reported higher rates of medication non-adherence and showed higher rates of non-planning impulsivity (Peters et al., 2011). Young adults who are HIV/AIDS-infected and suffer from an untreated mental illness are less adherent with their HAART regimen and, subsequently, have an increased mortality rate.

**Beliefs/issues regarding medications.** Prior to any health provider discussing medications with their patient, it would be wise to acknowledge existing ideas, beliefs, preconceived notions, and judgments about medications and what being on medications means in the patient’s mind.

MacDonell et al. (2011) conducted a study in HIV/AIDS-infected young adults to explore whether “situational temptation” (the presence of circumstances in the environment that influence an individual to deviate from his/her chosen course of action) played a role in treatment non-adherence and if assessing the patient’s perception of situational temptation could benefit medication adherence. The sample size included 186 participants, of whom 83% were African American. The study was conducted at multiple sites. The initial data found that participants felt that side effects of HIV/AIDS medication (nausea, stomach upset, and/or unpleasant taste) were the most common reason for non-adherence. However, the reasons that lead to the most significant non-adherence are lack of social support, need for a medication vacation, and failure to understand the need for medication. The authors concluded that there was a disconnect between perceived reasons for non-adherence and actual reasons for non-adherence.
Fernández et al. (2011) conducted a study that tested the HIV Treatment-Readiness Measure (HTRM) for infected adolescents prior to the initiation of a HAART regimen. The authors hypothesized that if a provider were able to accurately measure when a young HIV/AIDS-infected patient was ready to initiate HAART, adherence to the HAART regimen would be significantly higher than if the patient was not ready. The study was conducted in 15 adolescent clinics, with a sample size of 201 patients. The mean age of the sample population was 20.5 years old; 48% of the sample was identified as homosexual and 15% as bisexual. The findings of this study showed that HTRM seemed to be valid. The authors did note that larger studies conducted over longer periods of time are needed to fully test the reliability of the measurements used.

In their study of medication adherence among young adults, Hosek et al. (2005) found that the number one reason given for missed medication doses during the month leading up to the study was forgetfulness. This was reported by 73.8% of the participants, while 78.6% of the participants reported the number of pills they needed to take was important. However, the study results indicated that only 19% of the participants reported that they missed doses due to the number of pills. Dosing frequency was reported by 71.4% as an important factor in considering whether to take medications. Furthermore, 88.1% of the participants reported that medication side effects were an important consideration, but only 26% reported that side effects were the reason for missing a medication dose. This discrepancy between perceived reason for non-adherence and actual reason for non-adherence supports the 2011 study by MacDonell et al., where the participants reported that side effects were the most prominent reason to miss doses of medication, but the actual reason of medication non-adherence reported by the study
participants was lack of social support, need for a medication vacation, and failure to understand the need for medication.

Lee et al. (2014) researched the stability of specific barriers to medication adherence among HIV/AIDS positive adolescents and young adults. The barrier categories studied included Disease Frustration/Adolescent Issues, Regimen Adaptation/Cognitive Issues, Ingestion Issues, and Parent Reminders. They found that specific barriers to medication adherence tend to be stable over time. In other words, without some type of targeted obstacle-specific intervention, medication adherence is not going to improve. This study was conducted using a population sample of 51 young adults who were slated to receive organ transplants. Although not exactly the same, this population has a strong correlation to young adults with HIV/AIDS infection because of the increased potential of mortality. “Failure to follow prescribed medical recommendations can result in organ rejection, death, and decreased patient quality of life” (Lee et al., 2014, p. 667). Also, many of the reasons given for medication non-adherence were similar to what one would expect with HIV/AIDS patient non-adherence, including “cognitive factors (forgetting, poor planning), aversive medication properties, or difficulty ingesting medication” (Lee et al., 2014, p. 667). With respect to medication non-adherence in HIV/AIDS patients due to issues with medications, some side effects were found to be more strongly associated with non-adherence than others. In particular, “nausea, vision problems, anorexia, insomnia, and abnormal fat distribution” have been associated with non-adherence (Murphy et al., 2004). In terms of cognitive factors negatively affecting HIV/AIDS-infected young adults’ adherence to HAART, a recent
A multi-site study reported that for 73% of 498 non-adherent youth, “forgetting was the primary reason for non-adherence” (Beltzer et al., 2014, p. 687).

Regularly taking medications can be challenging for most people, but young adults seem to have more difficulty with medication adherence partly due to their feelings regarding medication.

**Conclusion**

Research has shown that young adults are becoming infected with HIV/AIDS at alarming rates when compared to other age groups. When these young adults enter into treatment, most are non-adherent with their HAART regimens. The public health implications for these HIV/AIDS-infected young adults include resistance to many of the medications used to combat it. Since this population is still sexually active, the transmission of multi-drug-resistant strains of HIV is becoming a more frequent concern (Gebo et al., 2003). HIV/AIDS is still an epidemic in this country, but on an individual basis the disease can be effectively managed if patients are adherent to their medication regimens. At this point in the fight against HIV/AIDS, adherence is the key to reducing transmission of the virus. With proper HAART adherence, a patient’s viral load will decrease. Thus, the chances of infecting a partner are greatly diminished and the risk of mortality is also diminished.
Chapter 2 - Needs Assessment

Context of Study

HIV/AIDS treatment providers began using medication regimens called Highly Active Antiretroviral Therapy, commonly referred to as HAART regimens, in 1996 to treat infected patients. The utilization of this new medication regimen was a pivotal event in the history of the AIDS epidemic. The psychological effects of having the HIV/AIDS virus changed with the utilization of HAART regimens, as HIV/AIDS went from being perceived as a terminal disease to a chronic disease that could be managed (Dray-Spira & Lert, 2003). The best way to obtain an undetectable viral load, and therefore remain healthy with limited adverse effect on their life expectancy is thorough compliance with their respected HAART regimen (Flynn et al., 2004).

Young adults, 18 to 30 years old, are becoming infected with HIV/AIDS at increasingly high rates. Young adults, in general, are reasonably healthy and therefore can be well managed with minimal side-effects with newer HAART regimens. The issue many clinics are facing now is how to treat these young adult patients who have difficulty coming to terms with their illness and accepting the fact that they have a chronic illness that needs daily management in order to prevent further illness. This is an individual issue, an HIV/AIDS provider issue, a clinic issue, and ultimately, a public health issue.

One of the biggest problems facing the HIV/AIDS epidemic today, is the high percentage of young adults (18 to 30 years old) who are becoming infected and are non-adherent with their medical treatment (Rao, Kekwaletyswe, Hosek, Martinez, & Rodriguez, 2007). This non-adherence to treatment presents mostly in the form of non-adherence to their HIV/AIDS medication regimens, which can be broken down into sub-
categories of readiness for treatment (Fernandez et al., 2011) and treatment compliance (Catz et al., 2000). Factors associated with these subcategories in HIV/AIDS-infected young adults include cognitive and developmental issues, educational issues (HIV/AIDS prevention and patient education), HIV/AIDS stigma (Lyon & Woodward, 2003), mental health and substance use disorders, high risk behaviors (mostly involving sexual behavior), economic factors including socioeconomic status or position, cultural issues, and medication side-effects. In considering all of these contributing factors, the most prominent concepts include economic (Catz et al., 2000), education, cognitive development (Chandwani et al., 2011), mental health (Lyketsos et al., 1997) and stigma (Curtis, 2008). The economic concept consists of costs to treat HIV/AIDS-infected individuals and individual characteristics of those receiving treatment. The education concept consists of preventative education (Valdiserri, 2011) and health education that newly infected HIV/AIDS patients receive. The concept of mental health includes mental health disorders, substance use disorders, and high-risk behaviors. Stigma encompasses the disease itself, sexuality and gender (Dodds et al., 2003), and cultural influences (Puccio et al., 2006; Rudy et al., 2009).

A needs assessment can be utilized to determine if HIV/AIDS-infected young adults, ages 18 to 30, who attend the Johns Hopkins Hospital outpatient infectious disease clinic exhibit medication non-adherence. If the needs assessment provides sufficient evidence of this phenomenon, then the aforementioned concept drivers will be explored in more detail and utilized to potentially develop an intervention for corrective action.

**Goals and objectives.** Although the national rates of non-adherence to HAART regimens among young adults is quite high, every infectious disease clinic operates a bit
differently. Therefore, it is important to determine as accurately as possible, what the rate of non-adherence is among the young adults who receive their HIV/AIDS treatment in the outpatient infectious disease clinic at Johns Hopkins Hospital. Participants will sign a consent form (see Appendix A) before data collection begins. Several key variables in this needs assessment that will be measured according to secondary data include HIV viral load, clinic attendance, and history of mental health and/or substance use disorders. Primary data will be obtained from the HIV/AIDS Medication Adherence Questionnaire (Appendix B) and the HIV/AIDS Basic Knowledge Questionnaire (Appendix C).

Fifty young adults between the ages of 18 and 30 who attended the outpatient infectious disease clinic at Johns Hopkins Hospital between January 1 and December 31, 2014 will be asked to complete the HIV/AIDS Medication Adherence Questionnaire and the HIV/AIDS Basic Knowledge Questionnaire. Additionally, the participants’ medical records will be reviewed for clinic attendance rate, and recent HIV viral load (within the past six months). The needs assessment will provide data to either support or discount the three primary drivers—HIV/AIDS disease stigma, mental health and substance use disorders, and beliefs/issues regarding medication—of medication non-adherence in HIV/AIDS-infected young adults (18 to 30 years old).

Hypothesis 1: The rate of medication non-adherence among the young adults (18 to 30 years old) infected with HIV/AIDS who receive their HIV/AIDS treatment at the Johns Hopkins Hospital outpatient infectious disease clinic will be around 75% noncompliant as evidenced by their detectable viral load.

- Dependent Variable: Medication Compliance
- Independent Variable: HIV Viral Load
• Determination: Hypothesis 1 can be determined by medical record review of participants’ HIV viral load levels (within six months of enrollment). Detectable HIV viral loads will indicate less than 95% adherence rate.

Hypothesis 2: A high percentage (>75%) of the young adults (18 to 30 years old) infected with HIV/AIDS who receive their HIV/AIDS treatment at the Johns Hopkins Hospital outpatient infectious disease clinic that demonstrate a non-adherence with their medications suffer from a mental health and/or a substance use disorder, struggle with HIV/AIDS disease stigma, and/or have conflicting beliefs/issues regarding medication.

• Dependent Variables: HIV/AIDS disease stigma, mental health and/or substance use, and beliefs/issues regarding medication

• Independent variable: Medication non-adherence

• Determination: Hypothesis 2 can be determined by medical record review of participants’ history of mental health and substance use disorders, HIV viral load (within six months of enrollment), and review of participants HIV/AIDS Medication Adherence Questionnaire responses.

Hypothesis 3: Poor understanding about their illness negatively impacts medication adherence among young adults (18 to 30 years old) infected with HIV/AIDS attending the Johns Hopkins Hospital outpatient infectious disease clinic.

• Dependent Variable: Understanding about HIV/AIDS

• Independent Variable: Medication compliance and clinic attendance

• Determination: Hypothesis 3 can be determined by review of participants’ HIV/AIDS Basic Knowledge Questionnaire responses and by medical record review of participants’ history of adherence to their medications.
review of participants’ HIV viral load within six months of enrollment; poor understanding of HIV/AIDS would correlate to a detectable HIV viral load.

Methods

Participants and study setting. The HIV/AIDS-infected young adults (18 to 30 years old) who receive their medical care at the Johns Hopkins Hospital outpatient infectious disease clinic seem to be non-adherent to their respective HAART regimens at unusually high rates. Non-adherence is the result of the patient completely stopping their medication or missing several doses of medication every week (less than 95% adherent). This non-adherence can lead to the development of viral resistance in response to the HAART regimen, resulting in the need to change the regimen to effectively suppress the HIV/AIDS virus.

The target population consists of young adults between the ages of 18 and 30 who are infected with HIV/AIDS and receive their HIV/AIDS care at the outpatient infectious disease clinic located in the Johns Hopkins Hospital in Baltimore, Maryland. Some participants will have been infected prenatally by an HIV/AIDS-infected mother and the rest of the participants will have acquired the virus behaviorally, either through unprotected vaginal or anal sexual intercourse or the sharing of needles via intravenous (IV) drug use. Based on the clinic population, the study sample should include 50 participants (25 males, 25 females). The sample should have a good mix of race (40 should be African American, seven to eight Caucasian, two to three other races) and sexual orientation (heterosexual, homosexual, transgendered) to be representative.

Instruments and data. The secondary data, including HIV viral load and associated mental health and/or substance use disorders, will be obtained from the main
database used by Johns Hopkins Division of Infectious Disease and includes the medical records of all patients treated in the outpatient infectious disease clinic. For the random sample of secondary data, a simple query of the aforementioned database will be run to include young adult patients who have been seen in the outpatient infectious disease clinic in 2014 and have had an HIV viral load checked within the last six months. Of those listed in the query, the first 50 young adults who come to the clinic and agree to sign an informed consent will be asked to complete the two questionnaires to provide primary data.

The 13-question HIV/AIDS Medication Adherence Questionnaire is based on factors and reasons for medication non-adherence among adolescent and young adults infected with HIV/AIDS. The factors and reasons for non-adherence were determined by a thorough review of previous research; several of the relevant articles are included in the reference section of this paper. The HIV/AIDS Basic Knowledge Questionnaire is based on the HIV-KQ-18 (Carey et al., 1997). Questionnaire data will be obtained, in person, from 50 young adults between the ages of 18 and 30, who receive their HIV/AIDS care at the outpatient infectious disease clinic at Johns Hopkins Hospital in April 2015. Newly diagnosed patients who have not been started on a medication regimen will not be eligible to complete the survey or questionnaire.

**Initial Summary of Results**

The patients from the query of the Johns Hopkins Division of Infectious Disease who were between the ages of 18 and 30 and had detectable viral loads within the past six months were eligible to complete the needs assessment. The medical records of 50 young adults from the query were analyzed for secondary data (see Tables D1-D6). Correlation
data analysis was possible comparing viral load and percentage of missed clinic appointments (see Table D2). The mean HIV viral load was calculated to be 50563.18 ±181883.162 (see Table D7) and the mean clinic appointment no show percentage was calculated to be .28220 ±.150622 (see Table D7). With n=50, Pearson’s correlation is .144, which shows that there is not a significant correlation between a detectable viral load and a high percentage of missed clinic appointments (see Table D8). Other correlational data is listed in Tables D8 and D9.

Due to some study limitations, only 13 participants agreed to complete the HIV/AIDS Medication Adherence Questionnaire and the HIV/AIDS Basic Knowledge Questionnaire. This discrepancy was due the short period of time allotted to collect primary data, the number of participants willing to participant, and the high rates of non-attendance to clinic appoints. Results of the HIV/AIDS Medication Adherence Questionnaire and HIV/AIDS Basic Knowledge Questionnaire are listed in Appendix E and Appendix F respectively.

Hypothesis 1: The rate of medication non-adherence among the young adults (18 to 30 years old) infected with HIV/AIDS who receive their HIV/AIDS treatment at the Johns Hopkins Hospital outpatient infectious disease clinic will be around 75% noncompliant as evidenced by their detectable viral load.

- **Dependent Variable: Medication Compliance**
- **Independent Variable: HIV Viral Load**

To test Hypothesis 1, a random sample of 50 participants was selected from the main patient database of the Division of Infectious Disease at the Johns Hopkins Hospital. The complete set of secondary data collected includes the participants’ most
recent viral load, the percentage of clinic appointments that they miss, their race, and their gender. The frequency of the viral loads of the participants in the sample population include 44% with an undetectable viral load and 56% with a detectable viral load at the time of enrollment, and thus were being non-adherent with their medications (see Table D5). I hypothesized the percentage of the population being non-adherent would be 75%, but is was calculated at 56%.

Hypothesis 2: A high percentage (>75%) of the young adults (18 to 30 years old) infected with HIV/AIDS who receive their HIV/AIDS treatment at the Johns Hopkins Hospital outpatient infectious disease clinic that demonstrate a non-adherence with their medications suffer from a mental health and/or a substance use disorder, struggle with HIV/AIDS disease stigma, and/or having conflicting beliefs/issues regarding medication.

- Dependent Variables: HIV/AIDS disease stigma, mental health and substance use, and beliefs/issues regarding medication
- Independent variable: Medication non-adherence

For Hypothesis 2, the dependent variables were going to be based on data collected from the survey data. Due to the limitations listed above, the population that participated in taking the survey was small (n=13). The results obtained from the HIV/AIDS Medication Adherence Questionnaire are summarized in Tables E1-E4. All 13 respondents chose the “Never” option when asked about alcohol and marijuana negatively affecting their medication adherence (see Table E1). In terms of mental health negatively affecting their adherence the “yes” option was chosen twice and the “no” option was chosen 11 times (see Table E2). Additionally, five of the 13 participants who took the survey reported some concern over people discovering their HIV/AIDS status by
observing them taking their medications (see Table E1). With only 13 respondents, the significance of these findings is of little value.

Hypothesis #3: Poor understanding of their illness negatively impacts medication adherence among young adults (18 to 30 years old) infected with HIV/AIDS attending the Johns Hopkins Hospital outpatient infectious disease clinic.

- Dependent Variable: Understanding of HIV/AIDS
- Independent Variable: Medication compliance and clinic attendance

The average score on the HIV/AIDS Basic Knowledge Questionnaire was 84.1538 ± 12.97335 (see Table F1). The frequency of the scores are listed in Table F3. Due to the small number of participants who took the two questionnaires, the only other data analysis option available was a one-sample t-test, which looked at the relationship between viral load and HIV/AIDS knowledge. The test value for the quiz score used was 80%, which indicates adequate knowledge of the subject matter being tested. The results of the test, with a 95% confidence rate, illustrate that there is not a significant relationship between HIV/AIDS knowledge and clinic attendance (see Table F2).

**Conclusion**

Fifty-six percent of the 50-patient random sample of HIV/AIDS-infected young adults who attend the outpatient infectious disease clinic at the Johns Hopkins Hospital in Baltimore, Maryland have a detectable viral load, and therefore, are non-adherent to their respective HIV medication regimen. Although this percentage is less than hypothesized, it is still significant and warrants an intervention to improve medication adherence. Due to the brief amount of time available to conduct the research, coupled with the fact that many of the non-adherent young adults do not show for their scheduled clinic
appointments, limitations exist in the sample. The 13 patients who did complete the survey and questionnaire regularly attend their clinic appointments and take their medications as directed. Therefore, the survey and questionnaire data creates a limitation in the needs assessment meaning the data does not perfectly represent the targeted population. A longer period of time is needed to collect data utilizing the survey and questionnaire instruments, which could supply valuable insight into the reasons young adults in the Johns Hopkins Hospital outpatient infectious disease clinic are non-adherent with their medications and help direct an appropriate intervention.
Chapter 3 - Intervention Literature Review

Problem Statement and Intervention Rational

Today, there still is no cure for HIV/AIDS, but beginning in the mid-1990s HIV treatment providers started using a combination of medications referred to as Highly Active Antiretroviral Drugs (HAART) to fight the virus. The utilization of this new medication regimen was an important event in the history of the AIDS epidemic because the once terminal disease, became a chronic, manageable condition (Dray-Spira & Lert, 2003). The psychological effects of having the HIV/AIDS virus changed with the utilization of HAART regimens. The ability to effectively manage the virus had a profound psychological effect on all individuals involved with the virus, from patients to health providers to researchers (Lyketsos, Fishman, Hutton, Cox, Hobbs, Spoler,…Treisman, 1997).

Young adults between 18 and 30 years old are becoming infected with HIV/AIDS at increasingly high rates (Flynn, Rudy, Douglas, Lathey, Spector, Martinez, Silio, Belzer, Friedman, D’Angelo, McNamara, Hughes, & Lindsey, 2004). Adolescents and young adults ages 13 to 24 are one of the fastest growing populations with HIV infection in the United States with about half of the new diagnoses occurring in this age range (Flynn et al., 2004). The CDC estimated that from 2006 to 2010, there was a 132% increase in the number of young people (ages 13 to 24) who were diagnosed with HIV/AIDS (Thurston, Bogart, Wachman, Closson, Skeer, & Mimiaga, 2013). From 2008 to 2010, HIV infections increased by 22% among 13 to 14 year old males who have sex with men (MSM) (Aliabadi, Carballo-Dieguez, Bakken, Rojas, Brown, Carry et al., 2015). The main issue facing individuals infected with HIV/AIDS is the lack of
adherence to medication regimens. The best way for young adults to obtain undetectable viral loads, and therefore remain healthy with limited adverse effects on their life expectancy, is through compliance with their respective HAART regimens (Flynn et al., 2004).

With the increase in the number of young adults who are becoming infected with HIV/AIDS and the high rate of medication non-adherence among those on treatment, a growing number of young adults are running out of treatment options. Therefore, their risk of mortality is dramatically increasing. Young adults, in general, are reasonably healthy and therefore can be well managed with minimal side-effects with newer HAART regimens. The issue many clinics are facing now, is how to treat these young adult patients who have difficulty coming to terms with their illness and cannot accept the fact that they have a chronic illness that needs daily management in order to prevent further illness. This is an individual issue, an HIV/AIDS provider issue, a clinic issue, and ultimately, a public health issue.

One consequence of these issues is that young adults who are not taking their medications properly, or not at all, are wasting large quantities of very expensive HIV/AIDS medications. As funding for HIV/AIDS medications is starting to diminish, an ethical quandary arises in determining when to give young adults medication to treat their HIV/AIDS infection. Using Thiel et al.’s (2012) ethical decision-making model and leader sense making strategies of emotion regulation, it seems that self-reflection, forecasting, and information integration would be very helpful in trying to weigh the ethical implications of decisions that can affect the mortality rate of young adults infected with HIV/AIDS. Any decision made in terms of an intervention should take into account
the project leader’s personal ethics. The current situation in the healthcare industry and the environmental constraints of working in a hospital clinic are some of the personal, situational, and environmental constraints that would be a part of the sense-making process.

In 2016, a young adult infected with HIV/AIDS should not have his/her life expectancy shortened by a chronic illness, especially when proper medications and experienced medical providers to properly control the disease are available. In the outpatient infectious disease clinic at Johns Hopkins Hospital, well-trained and experienced clinicians are available to treat young adults with HIV/AIDS. There are also social supports necessary to facilitate obtaining the needed medications in a timely fashion, along with the appropriate laboratory tests needed to monitor the virus.

**Theory of Treatment**

HIV/AIDS is a treatable, but not yet curable, chronic illness (Flynn et al., 2004). The targeted population for this intervention is HIV/AIDS-infected young adults between the ages of 18 and 30, who are non-adherent with their HIV/AIDS medications and therefore have detectable viral loads (Leviton & Lipsey, 2007). The theory of treatment for this intervention is to combat the social stigma of HIV/AIDS, the lack of effective coping skills, and the overall denial of being infected through psycho-educational groups. The intended outcome of the intervention will be participants’ undetectable viral loads, which is measureable through blood tests (Leviton & Lipsey, 2007). The intervention is depicted in the causal diagram of the theory of treatment (Figure K1).

The potential participants will be determined by reviewing the Johns Hopkins Hospital outpatient infectious disease clinic patient schedule on a daily basis for patients
between 18 and 30 years old and have a detectable viral load within the last six months. When those patients who meet the criteria present at the time of their scheduled clinic appointment, they will be asked to consent to the study and will be asked to fill out a medication adherence scale. After obtaining the consent of 30 participants, they will be randomized into an intervention group and a control group. The intervention group will be asked to attend six scheduled psycho-educational groups. The participants in the group sessions will receive gift card and bus token incentives for group attendance and will complete a medication adherence scale at the end of each group. The control group will be asked to attend a lunch with an educational component at the end of the study. For each participant in the study, his or her viral load at the time of consent will be recorded and the viral load at the end of the study will also be recorded.

**Review of Literature**

McNicholl (2008) found that some effective strategies in improving patient adherence were establishing readiness to start therapy, providing education on medication dosing, anticipating and treating adverse effects, using educational aids, and simplifying regimens. Zaric, Bayoumi, Brandeau, & Owens (2008) found that medication adherence counseling for HIV/AIDS-infected individuals was cost-effective, but it is unclear how advantageous this is for patients. In earlier research on adherence counseling, Golin, Smith, & Reif (2004) found that clinicians working with young adults infected with HIV/AIDS often reported not having enough training nor enough time to properly provide adherence counseling to HIV/AIDS-infected individuals. These elements are important points of reference to keep in mind when developing an effective intervention targeted at this population.
Young adults with HIV/AIDS can be effectively managed and can live long lives, but adherence to their HAART regimens is critical. Dr. C. Everett Koop, former Surgeon General of the United States was often quoted as saying, “Drugs don’t work in patients who don’t take them” (Gallant, 2009). Young adults with chronic illnesses have lower rates of medication compliance than older adults (Hinkin, 2004). Adherence to HAART has been shown to be the single most important factor in achieving undetectable viral loads in youth living with HIV (Flynn et al., 2004). Not only is adherence to HAART fundamental to the wellbeing of youth living with HIV, but adherence has a far-reaching impact on broader public health issues, as poor medication adherence has been implicated in the emergence of drug resistant strains of HIV (Mehta, Moore, & Graham, 1997; Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez, 2007). Several studies have shown that patients who consistently adhere to their antiretroviral medication regimen have much better health outcomes than patients who were not adherent to their HIV/AIDS medications (Magidson, Seitz-Brown, Safren, & Daughters, 2014). The adherence rate needed to suppress the viral load in an HIV/AIDS-infected patient is 90-95% (Bartlett, 2002). Treatment experiences (regimen complexity, side effects, etc.), support from providers and others, health care environment and material factors (access to care, financial concerns), informational resources (HIV general knowledge and knowledge about medications), cognitive and psychological function (cognitive impairment, literacy, forgetfulness, depression), use of drugs, alcohol, and tobacco, and health beliefs in the effectiveness and self-efficacy of taking medications are all factors that have great influence on adherence to HIV medications according to Reynolds (2004).
In an attempt to devise an intervention to help improve medication adherence among HIV/AIDS-infected adults, Diiorio, McCarty, Resnicow, Holstad, Soet, Yeager,…Lundberg (2008) conducted a randomized control trial of 247 HIV/AIDS-infected participants to determine if a Motivational Interviewing (MI) intervention (n=125) was more effective than a control group (n=122) in improving adherence to antiretroviral medication. The MI intervention consisted of five individual therapy sessions conducted by registered nurses over a three-month period. Some of the therapy sessions were conducted via the telephone for participants unable to get to the clinic. The participants in the intervention group were paid for attending therapy sessions and all study participants were paid for completing adherence interviews. For all participants, their medication adherence was followed through the utilization of the Medication Event Monitoring System (MEMS). Their findings were significant in the large participant sample it used. Also of importance were the post-intervention measures taken at four-week intervals up to 10 months after the intervention period. The benefits of the intervention were not initially significant, but three months after the intervention was completed, the intervention group’s adherence rate continued to improve while the control group’s adherence continued to decline.

Taking a different approach to improving medication non-adherence, Koenig, Pals, Bush, Pratt Palmore, Stratford, & Ellerbrock (2008) conducted a randomized controlled study to determine if a social support intervention (Project HEART) was more effective than treatment as usual, normal health counseling. The study’s sample population included 226 HIV/AIDS-infected participants recruited from the Infectious Disease Program (IDP) of Grady Health System in Atlanta, Georgia between 1999 and
2002. Of the 319 patients screened, 236 were randomized with 116 to the intervention group and 120 to the control group (treatment as usual). Ten patients did not complete baseline assessments and dropped out of the study. The study population’s mean age was 37 years. The population was 83% African American and 58% heterosexual. The intervention consisted of five individual adherence-counseling sessions with a nurse educator. The first two sessions took place prior to the initiation of medication and were spaced seven and 14 days apart. The remaining three sessions took place following the initiation of medication at weeks two, four, and eight. There was a follow-up session six months after the start of medication along with labs taken to assess viral loads. Labs were taken to test viral load levels at baseline, 12 weeks post-initiation of medications, and six months post-initiation of medication. Other measures used included face-to-face interviews, Center for Epidemiologic Studies-Depression Scale, and Medication Event Monitoring System (MEMS). The findings of the study showed that 38% of the participants were lost to follow-up by the six-month follow-up session. The number of participants who were adherent with their medications declined over time. Participants who were adherent to medications and attained an undetectable viral load included 40.15% of the intervention group verses 27.59% of the control group. The findings were confirmed at the six-month follow-up session. Good baseline assessments and six-month follow-up assessments make this a study with credible findings. This intervention consisted of five to six individual sessions to improve medication adherence among people infected with HIV/AIDS.

Chandwani, Abramowitz, Koenig, Barnes, & D'Angelo (2011) investigated another behavioral intervention called Adolescent Impact. The study tested the
effectiveness of the 12-step behavioral intervention to improve how HIV/AIDS-infected adolescents, ages 13 to 21, negotiated their respective medical treatment protocols. The age range of the participants was ages 18 to 30, slightly younger that the problem of practice’s (POPs) target population. The study was conducted at three separate sites in the northeastern United States. The study design was a randomized control trial with an intervention group (n=83) and a control group (n=83). The participants were 94% African American and 53% female, which is almost exactly the racial and gender demographic of the POPs target population. Also, due to the growing trend of the HIV/AIDS affecting increasingly larger numbers of females and African Americans (CDC, 1991, 2004), this study’s sample population is very significant. The study found that 83.3% of the participants attended at least half of the sessions, with the mean number of sessions attended being 9.4. The study did not compare pre- to post-intervention viral loads of the participants, nor were medication adherence rates compared. For purposes of this POP, the high attendance rate is positive, but the lack of quantitative data limits the usefulness of this study.

The stigmatization of the HIV/AIDS disease has remained a constant aspect in living with the disease. In the areas of HIV/AIDS treatment and research, the social stigmatization of HIV/AIDS is defined as a real or perceived fear of negative responses from others (Abel, Rew, Gortner, & Delville, 2004). Kalichman & Grebler (2010) found that participants in the study that had poor adherence reported more internalized HIV/AIDS stigma and symptoms of depression, along with higher incidence of illicit drug use. It is not uncommon for a provider to report that their young adult patient has told them that they feel the medications are a reminder that they have HIV/AIDS. Rose
Weitz’s article, “Living with the Stigma of AIDS,” is based on interviews she conducted with 23 AIDS patients between July 1986 and March 1987. This article gives a picture of the very early days of the AIDS epidemic. It discusses how the stigma of being infected with HIV/AIDS affects patients’ relationships with family, friends, lovers, healthcare workers, and fellow workers. The article explores how the people patients are close to, adopt, “extreme and medically unwarranted anti-contagion measures” (Weitz, 1990, p. 28) that reinforces stigma. Some examples of these measures include using separate dishware and sheets or excessive cleaning habits.

Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez (2007) looked at information obtained from 25 HIV/AIDS-infected adolescents and young adults who participated in moderator-led focus groups. The focus groups discussed the stigma of being infected with HIV/AIDS and the participants’ individual efforts to conceal their status. One of the results from this study was that the theme of the invulnerability of youth, commonly seen in studies involving adolescents and young adults, was not a factor in non-compliance to HAART. Ninety-two percent of the study participants reported that they knew that compliance with their medications was the way to remain healthy (Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez, 2007). The results from this study revealed that the barriers to medication adherence were dishonesty with health providers to avoid criticism, fear of discrimination from friends and family, interference of the disease with their life style, and the development of depressive symptoms (Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez, 2007).

Harper, Lemos, & Hosek (2014) conducted a behavioral experiment looking at whether a group-based behavioral intervention could diminish the stigma of being
diagnosed with HIV/AIDS in young people living with the disease. In the study, the stigma of having HIV was categorized in four ways: personalized stigma, disclosure concerns, negative self-image, and concern with public opinion. The measurement tool utilized for the study was the Berger HIV Stigma Scale. The behavioral intervention lasted for 12 weeks, and consisted of HIV/AIDS information, acquisition of coping skills, and initiation of contact with other HIV/AIDS-infected youth for social support. The study included a sample of 50 youths (28 males, 22 females, mean age = 19.24 years) from four geographically diverse clinics. The study had pre-test/post-test design in addition to a three-month follow-up to assess sustainability of any improvements in the any of the four categories of stigma. The post-test results showed a reduction in three of the four stigma categories—personalized stigma, disclosure concerns, and negative self-image. At the three-month follow-up, sustained stigma reduction was present in negative self-image. However, the other three stigma types—personalized stigma, disclosure concerns, and concern with public opinion—increased at each subsequent follow-up interval. When analyzed based on gender, personalized stigma was the only reduced stigma for females from the intervention, and it was not sustained at the three-month follow-up. The authors hypothesized that this gender difference may have been due to the fact that the decision to disclose is a more complicated and nuanced issue for young women, possibly due to societal and cultural gender stereotypes.

Some research insists that cognitive factors negatively affect adherence to HAART in HIV/AIDS-infected young adults. A recent multi-site study reported that for 73% of 498 non-adherent youth, “forgetting was the primary reason for non-adherence” (Belzer et al., 2014, p. 687). Beltzer et al. (2014) conducted a 48-week randomized
control study of 37 HIV/AIDS-infected participants, ages 15 to 24, to determine if receiving cell phone support would improve adherence to HAART. Eighteen participants were randomized to the control group and 19 were randomized to the intervention group. The participants in the intervention group received phone calls the same number of times each day that they took medication for 24 weeks. The adherence rates were compared between the groups at the 24-week mark and at 24-week post-intervention (48-week mark). The findings show that the intervention resulted in significantly lower viral load levels in the intervention group versus the control group. This study used a small sample, and the post-intervention measures were taken only 24 weeks later, making it difficult to determine if the benefits of the intervention were sustainable. The age range of the study is close to the age range of the POP’s target population of 18 to 30 year olds. The racial mix of the participants was 70% African American which is also very close to the POP’s target population of 85 to 90% African American. The manpower and training requirements of this study make it an unlikely potential solution to the POP, but the information and techniques utilized in the scripted phone conversations may be beneficial in designing a psycho-educational intervention.

Another study by Hosek, Brothers, & Lemos (2005) investigated the negative effects of cognitive factors on medication non-adherence among young adults. In their study of medication adherence rates among young adults, the number one reason given for missed medication doses was forgetfulness, which was reported by 73.8% of the participants. Approximately 78.6% of the participants reported that the number of pills needed was important, but the results of the study found that only 19% of the participants reported that they missed doses due to the number of pills. Furthermore, 71.4% of
participants reported that dosing frequency was an important factor in considering whether to take medications, 88.1% reported that medication side effects were an important consideration, but only 26% reported side effects were the reason for missing a medication dose. This discrepancy between perceived reason for non-adherence and actual reason for non-adherence supports the 2011 study by MacDonell, Naar-King, Murphy, Parsons, & Huszti, in which the participants reported that side effects were the most tempting reason to miss doses of medication. The findings concluded that the actual reason of medication non-adherence reported by the study participants was lack of social support, need for a medication vacation, and failure to understand the need for medication.

Depression is a consistent psychological predictor of medication non-adherence across medical conditions (Catz, Kelly, Bogart, Benotsch, & McAuliffe, 2000; Molassiotis, Lopez-Nahas, Chung, & Lam, 2003; Safren, Otto, Worth, Salomon, Johnson, Mayer et al., 2001; Wagner, Kanouse, Koegel, & Sullivan, 2003). The association between depression and non-adherence is particularly troubling given that between 25-40% of HIV patients are depressed (Rabkin, Mcelhiney, & Ferrando, 2004; Taso, Dobalian, Moreau, & Kobalian, 2004). Gonzalez, Psaros, Batchelder, Applebaum, Newville, & Safren (2011) showed that a patient’s level of depression was a significant indicator of non-adherence to their HAART regimen. Magidson, Seitz-Brown, Safren, & Daughters (2014) also found that the presence of depression was a consistent predictor of a patient’s non-adherence with HAART.

Rudy et al. (2009) conducted a cross-sectional observational study examining mental health barriers/substance use, high/low self-efficacy and outcome expectancy, and
the presence of specific structural barriers (homelessness and lack of insurance) as personal barriers to adherence to HAART in 396 participants between 12 and 24 years old. The participants had all been infected with HIV/AIDS after the age of nine and were recruited either from the Adolescent Trials Network for HIV/AIDS Interventions or the Pediatric AIDS Clinical Trials Group. The study found that two of the barriers that often coincided with poor medication adherence were the presence of a mental health disorder and active substance use. Cruess, Evans, Repetto, Gettes, Douglas, & Petitto (2003) reviewed numerous studies that looked at the prevalence of mental illness in HIV/AIDS-infected individuals and found the most prevalent mental health disorder among individuals infected with HIV/AIDS was mood disorders. He found that, within the mood disorders, depression had a slightly higher rate of occurrence (Cruess et al., 2003).

Fisher, Fisher, Amico, & Harman (2006) utilized the Information-Motivation-Behavioral Skills (IMB) model of adherence to HAART based on the IMB approach initially developed in 1992 (Fisher & Fisher, 1992) and validated in numerous studies since then (Fisher, 2011; Fisher, 2012; Fisher et al., 2012; Ferrer et al., 2010) to determine if the model could improve adherence among HIV-infected patients who were not adherent to their HAART. The study showed that by utilizing the IMB model, 31% participants who had been non-adherent at the start of the study had become adherent and stayed adherent at three months’ post-intervention check-in. Horvath et al. (2014) noted that the IMB model of adherence was beneficial to participants even if they were actively using drugs and/or alcohol and had active depression.

Horvath et al. (2014) used the Information-Motivation-Behavioral Skills (IMB) model of antiretroviral therapy (ART) adherence in HIV/AIDS-infected patients who
were receiving their medical treatments from an outpatient clinic. The aims of this study were to: (1) determine if implementing the IMB model helps with medications adherence and (2) determine if adherence gained from the IMB model persists in the presence of active depression and active substance use. The 312 participants had an average age of 43 years, had been living with HIV for nine or more years, and were mostly male (84.0%), Caucasian (68.8%), and gay-identified (74.8%). The results of the study determined that patients’ adherence improved with the use of the IMB model even in the presence of active drug use and depression.

Konkle-Parker, Erlen, Dubbert, & May (2012) also used the IMB model in a randomized controlled pilot study conducted in a large public health clinic in the southern United States. The intervention included HIV education, a peer video, motivational interviewing, and attention to behavioral skills including communication with providers and adherence-enhancing devices. Dependent variables included three-week adherence recall, medication refill rate, changes in IMB subscale scores, appointment attendance, and HIV-associated laboratory findings. Of individuals starting or restarting antiretroviral therapy, 73 were enrolled and 56 were randomized. The patients’ medication adherence improved, but the study was not powered to show statistical significance. Threats to power included a 51% attrition rate, resulting mostly from loss to clinical care or prolonged gaps in care.

Based on the literature reviewed, adherence to HAART remains a major health obstacle for young adults infected with HIV/AIDS. There has been some positive research in terms of the benefits of technology in adherence improvement and the importance of treating co-occurring illnesses that adversely affect adherence such as
ment health and substance use disorders. Some of the trials that used psycho-educational individual and group counseling targeting health education and compliance demonstrated a positive outcome. It seems that an intervention of a limited number of psycho-educational adherence groups, where viral loads could be collected at baseline, post-intervention, and several months post-intervention, would be important to study on a broader scale. The psycho-educational adherence groups would be best served by utilizing the IMB model in the curriculum to cover adherence-related information, ways to improve motivation to become adherent to treatment, and techniques to acquire behavioral skills to overcome environmental obstacles to treatment adherence (Ferrer et al., 2010; Fisher et al., 2006; Horvath et al., 2014, Konkle-Parker et al., 2012).

Beltzer et al. (2014) conducted a 48-week randomized control study of 37 HIV/AIDS-infected participants, ages 15 to 24, studying the use of mobile phones to deliver adherence counseling to aid in adherence improvement and diminished viral loads. This strategy proved effective, but required significant manpower and the sustainability of this approach has not been extensively proven. Puccio et al. (2006) demonstrated in a small pilot study that reminder calls to the mobile phones of young adults infected with HIV/AIDS and on HAART were effective in the improvement of adherence rates. Again, the sustainability of this approach has yet to be extensively proven. Using mobile phones for participant reminders to attend group sessions and the utilization of alarms for reminders to take medication could prove beneficial (Puccio et al., 2006).
Conclusion

Research has shown that young adults are becoming increasingly infected with HIV/AIDS and when they begin treatment, they are non-adherent with their HAART regimens at high rates. The public health implications of this non-adherence include growing viral resistance to many of the medications used to combat it and the continued spread of the disease. Since these infected young adults are still sexually active, the transmission of multi-drug-resistant strains of HIV is becoming more frequent (Gebo et al., 2003). HIV/AIDS is still an epidemic in this country, but on an individual basis the disease can be effectively managed if the patients can be adherent with their medication regimens. At this point in the fight against HIV/AIDS, adherence is the key to controlling the virus and therefore, ways to improve adherence must be implemented.

Educational and motivational interventions are effective in combating non-adherence (Bartlett, 2002; Gordon et al., 2005). Thurston et al. (2014) showed that a group psycho-educational therapy intervention model that targeted depression and medication adherence had promising results in treating both aims. Motivational Interviewing (MI) has shown some effectiveness in adherence rate improvement, but requires a significant investment in the training of staff (Diiorio et al., 2008). Dodds et al. (2003) discovered that support groups and developmental and educational services were some of the key elements needed to help improve adherence among young patients infected with HIV/AIDS. This study provides further support of the psycho-educational group model.

The IMB model has been shown to work well with HIV/AIDS-infected individuals in helping to produce improved health behaviors and, in many populations,
increase medication adherence. I believe that the young adult population who attend the Johns Hopkins Hospital outpatient infectious disease clinic would benefit greatly from a psycho-educational group intervention incorporating the IMB model. Some MI elements can be utilized for group exercises to help decrease behaviors that are obstacles for medication adherence and to decrease HIV/AIDS stigma. Based on prior research, each interventional group should end with a brief group therapy session that is facilitator led, but will mostly involve participation by the workshop participants. Mobile phone reminders can also be used to help improve attendance and retention throughout the intervention.
Chapter 4 - Intervention Procedure & Methodology

Introduction

Young adults who are 18 to 30 years old are becoming infected with HIV/AIDS at increasing rates and once infected, they have poor rates of adherence in terms of taking their Highly Active Antiretroviral Therapy (HAART) regimens. Many research articles on young adults infected with HIV/AIDS have concluded that the factors that drive this non-adherence to HAART are HIV disease stigma, mental health and substance use disorders, and beliefs/issues regarding medication. There has been promising research that demonstrates that the Information-Motivation-Behavioral Skills (IMB) model of medication adherence improves adherence to HAART among many populations of HIV/AIDS-infected patients. The intervention proposed for this study is a series of psycho-educational groups for HIV/AIDS-infected young adult patients of the outpatient infectious disease clinic at Johns Hopkins Hospital. The groups will be utilizing the IMB model of medication adherence and targeting the factors driving non-adherence—HIV disease stigma, mental health and substance use disorders, and beliefs/issues regarding medication.

Methods

Based on the needs assessment, at least 50% of the young adults, 18 to 30 years old, who are infected with HIV/AIDS and attend the outpatient infectious disease clinic at Johns Hopkins Hospital are non-adherent with their HIV medication regimen. In 2016, a young adult infected with HIV/AIDS should not have their life expectancy shortened by this chronic illness, especially with the availability of proper medications and experienced medical providers. In the infectious disease clinic at Johns Hopkins
Hospital, well-trained and experienced clinicians are available to treat young adults with HIV/AIDS. This clinic also provides the social supports necessary to facilitate obtaining the needed medications in a timely fashion and the appropriate laboratory tests needed to monitor the virus. A young adult only needs to take their medications as prescribed and follow up with necessary blood tests when ordered, but this is where the treatment obstacles seems to occur.

To improve HIV/AIDS medication adherence in young adults, I propose an intervention that consists of six, one-hour psycho-educational groups held in the clinic. The groups will be modular in design, will be interactive, and will incorporate multimedia elements as well as group discussion. Each group will contain all three elements of the IMB model focused on medication adherence. Topics covered in the modular psycho-educational groups will be basic HIV/AIDS education, techniques shown to improve medication adherence, mindfulness, cognitive behavioral therapeutic technique of thought disputing, HIV stigma reduction skills, alcohol and drug education/reduction, mental health education/treatment, and problem solving skills. The first three groups (groups 1, 2, and 3) will be held every week. The next two groups (groups 4 and 5) will be held at two-week intervals. The last group (group 6) will be held three weeks after group 5. To help increase attendance and follow-up, patients can sign-up for calls, texts, and/or emails reminding them of their scheduled group times. For substantiation of the effectiveness of the initial six-group intervention, baseline labs to quantify viral load values prior to staring the first group will be obtained, in addition to getting viral load lab values four weeks after the last psycho-educational group.
Thus, the groups will consist of a mindfulness exercise, an educational segment, and a group therapy segment. The educational components will cover HIV/AIDS stigma, motivation, mental health and substance use education, emotional regulation strategies and techniques, and mental beliefs and issues regarding HIV medications. Beginning at enrollment and at each group meeting, participants will complete an ART Adherence Questionnaire to rate how much of their current antiretroviral medication they have taken in the past seven days on a Visual Analog Scale (VAS).

Short-term results will include engagement and participation in groups, the increase in understanding about management of a chronic illness, and increase in awareness about HIV stigma. Medium-term results will hopefully include a decrease in viral load, a decrease in HIV/AIDS stigma (Abel et al., 2004), improved life expectancy, a decrease in medication aversion, and improved coping skills and/or strategies surrounding HIV (Dodds et al., 2003; Diiorio et al., 2008). The ultimate impact should be evidenced by sustained medication adherence, sustained viral load suppression, medication adherence improvement (McNicholl, 2008), and improved mortality rate (Magidson et al., 2014). The intervention will help with the participants’ adherence to their medications, but it is possible that other elements may affect the intended outcome of the intervention (Leviton & Lipsey, 2007).

**Participants and study setting.** The participants recruited for this study will be 30 HIV/AIDS-infected young adults, ages 18 to 30, who receive their outpatient HIV treatment in the outpatient infectious disease clinic at Johns Hopkins Hospital. The participants should be patients who have struggled with their medication adherence as evidenced by detectable HIV viral loads. Additionally, patients with active substance use
and mental health disorders will be accepted if they would possibly benefit from the intervention and it is congruent with their treatment. Patients who could be too disruptive and/or too ill to benefit from a psycho-educational group will be excluded. All patients will sign an informed consent before data collection begins.

**Procedures.** Factors to consider when implementing the proposed intervention include staff (mostly the author, but possibly clinic nurses and another clinic counselor), time (recruitment, preparation for groups, facilitation of groups, medical record review), space to conduct a group, medical record review of participants’ HIV viral loads at different time points, tracking of participants’ clinic attendance, and group materials (copies of exercises and examples of things discussed in group). The most integral part of the proposed intervention will be the development of the actual curriculum and how that curriculum is delivered to the study participants.

From September 2016 to February 2017, the outpatient infectious disease clinic schedule will be screened by age and viral load (within six months) to identify eligible participants. When these screened patients arrive in the clinic for their scheduled clinic appointments, they will be approached about the study. Potential participants will be told about the study. If they are interested in participating, they will sign an informed consent (Appendix G) and complete a baseline ART Adherence Questionnaire (Appendix H).

Once all 30 participants are enrolled, they will be assigned to either the control group, or the intervention group. Random assignment will not be used, but instead individual matching (Rossi, Lipsey, & Freeman, 2004) will be used so that the demographics of the two groups are fairly similar, particularly in terms of gender, race, and sexual orientation. To help decrease selection bias (Shadish, Cook, & Campbell,
a blinding protocol will be implemented directing a staff member to separate the recruited participants into two groups with similar demographics and then the principal investigator will randomly choose one of the groups to be the experimental group and other group will be the control group.

The schedule for the six psycho-educational groups will be set at the designated intervals and email or phone reminders will be sent to participants in the intervention group. Participants who join the study will receive a $5.00 gift card. At each group, participants who attend will receive a $5.00 gift card and bus tokens for travel.

**Data Analysis**

A simple t-test will show significant differences in medication adherence to their respective HAART regimen between the control group of HIV/AIDS-infected young adult, 18 to 30 years old, participants and the HIV/AIDS-infected young adult, 18 to 30 years old, participants in the psycho-educational group study as measured by their viral load.

For the psycho-educational group study, utilizing the proposed IMB medication adherence model, the intervention will utilize a quasi-experimental design with a control group and some form of a pre-test (Shadish, Cook, & Campbell, 2002). The control group will be compared to participants in the experimental group who go through the six psycho-educational group protocol. The pre-test will include the HIV viral loads of the participants when they are inducted into the study and the post-test will be the viral loads of the participants at several intervals after study intervention. The viral loads used for the pre-program measure will be viral loads determined from the participant’s medical record that has been taken within three months of the start of the intervention. The post-
program measures will be viral loads taken from participant’s medical records of the
control and experimental groups at intervals of one month and three months after
intervention. Since the same measure (viral load) is being used for the observed outcome
for both the control group and experimental group prior to study participation, a possible
way to estimate the study’s impact is through a basic value-added design: regression-
adjusted for a preprogram measure (Henry, 2010).

**Effect size.** In line with the study conducted by Konkle-Parker, Erlen, Dubbert, &
May (2012), the proposed psycho-educational group intervention should have a power of
0.8 to make the results significant (Shadish, Cook, & Campbell, 2002) and a mid-range
effect size of 0.5 (Ingersoll, Farrell-Carnahan, Cohen-Filipi, Heckman, Ceperich,
Hettema, & Marzani-Nissen, 2011; Carey, Braaten, Maisto, Gleason, Forsyth, Durant, &
Jaworski, 2000; Ferrer, Morrow, Fisher, & Fisher, 2010). For the study to have a power
of 0.8 and an effect size of 0.5, a minimum sample size of 128 participants with 64 in the
control group and 64 in the experimental group is needed. Using the G*Power 3.1
software, this generates an actual power of 0.8014596. The effect size of 0.5 seems
possible based on the number of participants and the probable change in viral load
between control and experimental groups (Brown, Carballo-Diéguez, John, & Schnall,
2016). Konkle-Parker, Amico, & McKinney (2014) used a sample population of 100
participants when they did a study based on the pilot study of Konkle-Parker, Erlen,
Dubbert, & May (2012). However, even with a sample population of 100, the study was
still underpowered. Zarani, Besharat, Sarami, & Sadeghian (2012) used a sample
population of 152 patients in a study assessing the effects of IMB on patient adherence
and achieved a significant effect of condition on information and motivation in a one-
month post-test determined by univariate ANCOVAs. While recruiting a sample size of 128 participants may seem feasible for this specific intervention, running psycho-educational groups for the 64 participants in the experimental condition may prove difficult due to space, staff, and time constraints within the clinic. Using fewer participants is possible if the results lead to a greater effect size closer to 0.8. The power would need to stay at least at .8 because in order for the study to have relevance, a Type 2 error cannot occur (Rossi, Lipsey, & Freeman, 2004). In considering time and space constraints, it is feasible to recruit 30 participants and then pick 15 participants for the intervention according to the matching process previously explained.

**Strengths and limitations of design.** Using the basic value-added design (Henry, 2010) helps with narrowing the possible difference between the individuals in the control and experimental groups. A limitation of this design is the omitted variable bias (Henry, 2010), which refers to other possible factors that could positively or negatively affect the control or treatment groups. All the participants in the control and the experimental groups are patients still receiving medical care from their respective providers in the Johns Hopkins Hospital outpatient infectious disease clinic, and the providers’ mission is to try and engage these patients in care and effectively treat their HIV/AIDS. Thus, a threat to the study’s validity is that a change in participants’ viral load may not be a result of the intervention, but due to something that occurs with the routine medical treatment the patient receives in the clinic (Shadish, Cook, & Campbell, 2002). Since random assignment of the participants is not going to be utilized, there will be some selection bias present, but the masking protocol, previously mentioned, along with the random selection of the group to the experimental condition should reduce this bias. At the conclusion of
the study, we aim to say that in the clinic in which the study was conducted, a significant number of participants having gone through the psycho-educational groups demonstrated improved medication adherence based on lower and/or undetectable HIV viral loads.

Fidelity of implementation. “The extent to which the project was implemented as originally planned” (Berman and McLaughlin, 1976) is the definition of fidelity that fits within the proposed intervention to help improve medication adherence among young adults who are HIV/AIDS-infected and are receiving treatment in the outpatient infectious disease clinic of Johns Hopkins Hospital. As noted in Nelson et al. (2012), it is important to specify the change model that will be used and then part of the fidelity of implementation is to make sure that the specified change model and its components are used. For the intervention proposed for this study, the change model will be the implementation of psycho-educational groups using the Information-Motivation-Behavioral Skills (IMB) model of adherence to HAART (Fisher & Fisher, 1992). An adaptation of the IMB model that will be utilized will employ Motivational Interviewing (MI) techniques for the motivation part of the IMB model of adherence (Diiorio et al., 2008).

For this study, it would be considered high fidelity if 100% of the participants meet the criteria for the study—participants are between the ages of 18 and 30 years old, are infected with HIV/AIDS, are prescribed HAART and are not adherent with their regimen resulting in a detectable viral load. The criteria for high fidelity would also include that the instructor precisely followed the lesson plan of each of the six psycho-educational groups. Another element of high fidelity would be that each study participant stayed for the duration of each group and attended all six of the groups. The final element
of high fidelity would be that baseline labs and post-intervention labs were collected on each study participant in order to determine if a change in viral load occurred as a result of participation in the study. Low fidelity for this study’s intervention would be represented by not following the groups lesson plans precisely, if group members missed too many groups and/or too much time out of any one group, participants being chosen who were not appropriate for the study (most likely due to being too psychiatrically and/or medically ill or being too cognitively impaired for psycho-educational group participation) and/or did not meet the inclusion criteria for the study.

For this study, indicators of fidelity of implementation will be measured in four of the five ways mentioned in Dusenbury et al. (2003): adherence, dose, participant responsiveness, and quality of delivery (see Table J1). Adherence is defined as “the extent to which implementation of particular activities and methods is consistent with the way the program is written” (Dusenbury et al., 2003, p.241). Dose: is “the amount of program content received by the participants” (Dusenbury et al., 2003, p. 241). Participant responsiveness is the “ratings of the extent to which participants are engaged by and involved in the activities and content of the program” (Dusenbury et al., 2003, p. 244). Quality of delivery is the “ratings of provider effectiveness which assesses the extent to which a provider approaches a theoretical ideal in terms of delivering program content” (Dusenbury et al., 2003, p. 244). It will be important, for the sake of fidelity of implementation, to make sure the actual implementation of the intervention matches the proposed program design, because without this type of adherence it will be difficult to determine if the results of the intervention are congruent with the program design or due to some adaptation made during implementation.
In terms of the fidelity indicator of adherence, the instructor must precisely follow the lesson plans. The elements of instruction, group therapy, and the utilization of technology must be incorporated as instructed. Adherence will be checked by reviewing the course schedule, the lesson plans, and the instructors log prior to and after each group. The principle investigator and the instructor will check adherence and the same individual may perform both roles. Also, baseline and follow-up labs must be drawn at predetermined times for each study participant and then reviewed by the principle investigator. As noted in Nelson et al. (2012), the intervention components of the psycho-educational groups and each group’s structure and curriculum constitute the representations of change and the participant’s medication adherence and subsequent viral load constitute the potential outcomes of the intervention.

In terms of dose, the participants must attend enough of the groups to meet the minimum requirement and must be present in the groups which they attend for at least 85% of the session in order to be exposed to the lesson plan based on the IMB adherence strategy initially developed by Fisher and Fisher (1992). Dose is determined by keeping attendance, documenting how many groups each participant attends, and if they stayed for the whole group. These measures will be important when analyzing results of the intervention. There may be a correlation between the amount of the program content that a participant was exposed to and the patient’s medication adherence and subsequently their HIV viral load. Also, there may be some topics covered in a group that lead to participant drop out. The instructor and the principle investigator will review dose for each participant after every group.
Quality of delivery as an indicator of fidelity is very important for the
effectiveness of this study. Quality of delivery involves the skill of the instructor in the
execution of the specific lesson plan for each group and the utilization of all the elements
that should be present in each and every group (Schulte et al., 2009). This will be
checked and determined after every group by the principle investigator based on the
instructor’s log and questionnaires completed by the participants.

Participant responsiveness will be measured after every group and reviewed by
the instructor and the principal investigator. Responsiveness is based on questionnaires
that each group participant completes which indicate their level of interest and
understanding.
Chapter 5 - Findings & Discussion

Process of Implementation

From mid-September 2016 until February 1, 2017, 21 participants were enrolled in the intervention study. The enrollment period was over four months long and was double the amount of time anticipated to enroll fewer patients that were originally planned for the study. Initially, the plan was to enroll 30 to 35 participants and attempt to obtain an intervention group of 15 participants. The patient schedule for the outpatient infectious disease clinic at Johns Hopkins Hospital was reviewed daily from mid-September 2016 until February 1, 2017 and between five and ten potential participants were selected every day for potential study participation. Unfortunately, the potential study participant candidates had a very high no-show rate for their clinic appointments, which resulted in taking over four months to ultimately obtain only 21 study participants.

An overview of the primary and secondary data collected, including self-calculated adherence, gender, sexual orientation, race and ethnicity, age, and viral load can be found in Table II.

The effect size for this study was always going to be small, and because it was designed to be a small feasibility study, it was not expected to show significance due to the low power. However, it was hoped that the intervention would generate feedback from the participants on how beneficial they found the various topics covered in the psycho-educational groups and about the value of the group reminders. At the time of consent, each of the 21 enrolled participants filled out a self-report visual analog scale (VAS) of their medication adherence to their Highly Active Antiretroviral Therapy (HAART) in the week prior to enrollment. Also at the time of their consent, their most
recent viral load was collected from the electronic medical records of each of the enrolled participants. Eleven of the enrolled participants were selected for the intervention group and the remaining 10 participants were designated to the control group. Study participants reflected the demographics of the clinic’s patient population, and more specifically, the clinic’s young adult patient population. The average age of the participants was 27 and 85.7% of the participants were African American, 9.5% were Caucasian, and 4.76% were Hispanic (see Table I1). The participants’ self-identified their sexual orientation, with 33.3% identified as gay, 61.9% identified as heterosexual, and 4.76% identified as bisexual (see Table I1). The intervention was started on February 15, 2017 with the first of the planned six sessions of the psycho-educational group. The six sessions were scheduled as follows: February 15, 2017: 1st Session, February 23, 2017: 2nd Session, March 1, 2017: 3rd Session, March 15, 2017: 4th Session, March 29, 2017: 5th Session, and April 19, 2017: 6th Session. The appreciation lunch for the control group was scheduled for April 26, 2017. The study was concluded on April 28, 2017 with no additional data being collected. Prior to each group session, each participant in the intervention group was emailed, texted, and telephoned with reminders. During the reminders, the participants would report that they wanted to come to the group and were generally very positive about the reminders.

Findings

Table I1 shows the HIV viral loads of the intervention participants at the beginning of the study and at the end of the study. Table I2 shows the viral loads of the control participants at the beginning of the study and at the end of the study. Due to the
aforementioned low enrollment and lack of attendance, no viable conclusions can be made from this data.

In terms of attendance at the groups, there was extremely limited participation. One participant showed up for the initial group session and another participant showed up for the fourth group session. For sessions 2, 3, 5, 6, and the control group appreciation lunch, where I had hoped to collect more self-report medication adherence data, there was no attendance. On three separate occasions, members of the intervention cohort showed up for the group session 3 to 4 hours late and were reportedly intoxicated on alcohol and marijuana.

In an effort to improve attendance for the group sessions, the incentive was adjusted based on participant feedback. The participants desired the $5.00 Walmart gift cards and were much less interested in receiving tokens for public transportation, so two $5.00 gift cards were offered, totaling $10.00. Starting with group 4, the incentive was increased to four $5.00 gift cards, totaling $20.00. However, this unfortunately did not seem to have a positive correlation in terms of attendance.

Conclusions

The intervention can best be described as a failed protocol based on the almost non-existent attendance at any of the group sessions by the recruited participants. Thus, the intervention could not be implemented and no usable data were collected. It seems that the barriers to medication adherence that have been researched extensively and described in this dissertation were often the very same barriers to the participants’ attendance, or lack thereof, for the group sessions.

As stated in earlier chapters, the stigmatization of the HIV/AIDS disease has
remained a constant part of living with the disease. It seems to be one of the main reasons that some young adults do not want to take their medications. Three of the 21 participants were hospitalized during the study for medical complications caused by their worsening health, secondary to their poor adherence to HAART. Some participants reported that they just could not cope with a daily reminder of their HIV/AIDS diagnosis and felt that the medications were a daily reminder. Young adults who are HIV/AIDS-infected and suffer from untreated mental illnesses are less adherent with their HAART regimen and subsequently have an increased mortality rate (Rao, Kekwaletyswe, Hosek, Martinez, & Rodriguez, 2007). In terms of these treatment barriers, two of the participants dropped out of medical treatment completely due to active drug use. Several of the participants showed up to group quite late and intoxicated, and one participant was dually enrolled in the clinic’s Suboxone program during the study period.

Furthermore, one of the participants had a 10-day inpatient stay on one of the psychiatric units in the hospital and two other participants had emergency room visits due to worsening psychiatric symptoms. One of the participants in the intervention group was unable to attend any of the sessions because her motorized wheelchair was broken and it took over four months for the chair to be properly repaired. The patient’s physical handicaps, due to being neonatally infected with HIV/AIDS, made her unable to utilize a non-motorized specialized wheelchair. Several of the participants had insurance difficulties during the study and, although this did not preclude them from attending a group session, it did cause them to become disillusioned with treatment in general and to disengage from active medical care. All of these participant anecdotes underline the various and myriad host of issues that affect participants in every facet of their lives, not
just to their medication adherence nor their attendance and participation is this study.

Prior to any interaction with a health provider about medications, there seems to already exist in the minds of most patient’s ideas, beliefs, preconceived notions, and judgments about medications and what being on medications means for a particular patient. During many of the interactions with the participants during the study, it was extremely common for the participants to report different beliefs and judgments they have made about HIV/AIDS medications.

I spoke at length one afternoon with one of the intervention group participants, a 28 year old heterosexual female who was infected at age 18 by her new boyfriend. The patient had not attended any of the group sessions due to a hospitalization a few days after the intervention began in order to treat her worsening renal disease and ocular issues both secondary health disorders caused by her 10 year history of medication non-adherence to her many different HAART regimens. She said, “I just can’t look at the medications every day; they’re a reminder that I have this disease and can never be rid of it.” These similar beliefs and judgments are rarely based in fact and/or science and it is unclear how these ideas form in the minds of the participants.

**Discussion**

The intervention was designed to be a clinic-based study requiring very modest resources, and thereby something which would be cost-effective and could be easily replicated. It was hoped that a low-cost, brief intervention requiring minimal staffing could improve medication adherence to some degree and could be easily duplicated across various clinical settings. Ideally, the intervention could be scaled-up in poorly
resourced clinic settings around the country where there is a significant epidemic of young adults infected with the HIV/AIDS virus.

The intervention period was from February 15 to April 19, 2017. As stated previously, during those nine weeks, three of the 11 participants in the intervention group were hospitalized at Johns Hopkins Hospital for medical problems caused by their non-adherence to HAART. Two of the 11 participants relapsed to active heroin and cocaine use, dropped out of treatment altogether, and are currently lost to follow-up in terms of their medical care. One of the participants was enrolled in the clinic’s Suboxone program and could not attend the group sessions due to the requirements of the program. Six of the participants spent several days in multiple hospital emergency rooms in the Baltimore metropolitan area. One of the participants spent several weeks on one of the inpatient psychiatric wards at Johns Hopkins Hospital for suicidal ideation and increasing destabilization of her bipolar disorder.

Limitations of this study initially included small sample size, but due to the poor attendance outlined above, the intervention could not be properly implemented as planned. Although it was never originally reported as a barrier, lack of transportation could be a much more significant environmental factor than was initially anticipated. It is possible that if transportation to and from the clinic in the form of a cab were provided, the attendance in group sessions might have improved significantly. It was also determined, upon further review, that the conclusion of no correlation between medication non-adherence and clinic attendance drawn during the needs assessment conducted in the clinic was not accurate. This was found to be the case because the attendance rate for scheduled appointments that is calculated in each patient’s medical
record is not completely accurate. This is due to the fact that some of the young adult clinic patients come into the clinic for an unscheduled appointment and are scheduled when they walk in for a same-day appointment. This improves their overall attendance rate for scheduled appointments when in actuality, they do not have very good attendance for clinic appointments that are not scheduled for same-day treatment.

In the future, it may be better to attempt the intervention as a six-session individual intervention that is scheduled but also has the flexibility to be administered when the patient comes into the clinic for other reasons, like a medical appointment, medication needs, lab work, and/or a research appointment. The individual intervention may be a more effective way to work with the patients as they struggle to navigate some of the emotional, environmental, and social barriers, mentioned in the preceding paragraphs, that these young adults must face due to their HIV/AIDS diagnosis. Also, the intervention could be administered to the patient when they are in the hospital for other reasons like an emergency room visit or inpatient hospital stays for medical, psychiatric, and/or substance abuse issues.

Interestingly, 76.19% of the 21 participants reported medication adherence of 95-100% at the time of consent into the study. Upon review of the medical record, these same participants all had a detectable HIV viral load, proving that they had not been maintaining a medication adherence of 95-100%. Further research can be done to study why young adults report a medication adherence rate that is not accurate. It is unclear if these participants were being actively deceptive, or simply were not aware of their poor adherence to HAART. Several of the studies regarding medication non-adherence among young HIV/AIDS-infected adults mentioned that the participants reported a desire to tell
the HIV/AIDS medical treatment provider what, the patient felt, the provider wanted to hear; which that they, the patient, were adherent to their medication regimen regardless of whether or not this was actually accurate (Catz, Kelly, Bogart, Benotsch, & McAuliffe, 2000).

In conclusion, as seen throughout the chapters of this dissertation, the combination of treatment and environmental barriers for young adults infected with HIV/AIDS are myriad and significant, and in order for an intervention to be successfully implemented, many of these barriers need to be accounted for. In the future, the intervention needs to have a protocol that is flexible enough to accommodate the chaos that can be associated with the lives of some of these HIV/AIDS-infected young adults.
References


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students' communication with dating partners about HIV and AIDS. *Health Communication, 16*(4), 427-449.


Appendix A

Study Participant Informed Consent, Needs Assessment

Protocol Number: ___________________________
Participant Study ID: ___________________________
Instructor Participant Code: ___________________________

Johns Hopkins University
Homewood Institutional Review Board (HIRB)

Study Participant Informed Consent

Title: Investigating reasons for treatment non-adherence among young adults, infected with HIV/AIDS, who receive their HIV treatment in the Johns Hopkins Infectious Disease Outpatient Clinic

Principal Investigator: Nicholas P. Schweizer MS, LCADC, LCPC
Johns Hopkins School of Education

Date: March 28, 2015

PURPOSE OF RESEARCH STUDY:
The purpose of this research study is to discover reasons for why patients are non-adherent with the medications and if there is a correlation between HIV/AIDS knowledge and clinic appointment attendance.

PROCEDURES:
The participants will be asked to complete one survey and one HIV/AIDS knowledge questionnaire. The questions from the survey and the questionnaire will be read out loud to the participant to help with any reading fluency difficulties.

Time required: The time to take the survey and then complete the questionnaire is estimated to take fifteen to twenty minutes.

RISKS/DISCOMFORTS:
There are no anticipated risks to study participants.

BENEFITS:
Potential benefits are increased understanding about HIV/AIDS and greater insight into the reasons that the participant may or may not be adherent with his/her medication regimen. Also possible reasons for missed clinic appointments may be discovered.

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW:
Your participation in this study is entirely voluntary. If you choose not to participate, there are no penalties, and you will not lose any benefits to which you would otherwise be entitled.
You can stop participation in the study at any time, without any penalty or loss of benefits. If you want to stop your participation in the study please contact Nicholas P. Schweizer via phone or email: 410-608-6767, nschwei1@jhmi.edu.

**CONFIDENTIALITY:**
Any study records that identify you will be kept confidential to the extent possible by law. People responsible for making sure that research is done properly, including members of the Johns Hopkins University Homewood Institutional Review Board and officials from government agencies such as the Office for Human Research Protections, may review the records from your participation. (All of these people are required to keep your identity confidential.) Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records.

The Principal Investigator will examine all measures and research affiliates only (including those entities described above). No identifiable information will be included in any reports of the research published or provided to school administration. A participant number will be assigned to all surveys and the student’s achievement scores.

Surveys will be collected in paper format. This data will not include identifiable information.

All research data including paper surveys will be kept in a locked office. All paper documents shredded, ten years after collection.

Only group data will be included in publication; no individual achievement data will ever be published.

**COMPENSATION:**
You will not receive any payment or other compensation for participating in this study.

**IF YOU HAVE QUESTIONS OR CONCERNS:**
You and your child can ask questions about this research study at any time during the study by contacting Nicholas P. Schweizer via phone or email: 410-608-6767, nschwei1@jhmi.edu.

If you have questions about your rights as a research participant or feel that you have been treated unfairly, please call the Homewood Institutional Review Board at Johns Hopkins University at (410) 516-6580.

**SIGNATURES**

**What your signature means:**
Your signature below means that you understand the information in this consent form. Your signature also means that you agree to allow your child to participate in the study.
By signing this consent form, you have not waived any legal rights you otherwise would have as a participant in a research study.

Participant’s Name

Participant’s Signature Date

Signature of Person Obtaining Consent (Investigator or HIRB-Approved Designee) Date
Appendix B

HIV/AIDS Medication Adherence Questionnaire

Thank you again for participating. Please remember that all of your responses will be kept confidential. Please answer each question as honestly as possible. The same questions will be asked of everyone in the study.

Participant Study ID  __________________________
Provider ID  __________________________
Interview Date  __________________________
What is your date of birth?  __________________________
What is your sex?  __________________________
What is your race?  __________________________

The following questions relate to reasons why you would or would not take your HIV medications as prescribed. Different people have different reasons for doing that, and we want to know how much you agree or disagree with the following questions:

How often per week do you forget to take your medications?
- 1 time
- 2-3 times
- 4-5 times
- Never miss a dose
- I do not take the medications

Is being reminded about your HIV diagnosis a reason that you are not compliant with your medications?
- 1-Never
- 2-Sometimes
- 3-Usually
- 4-Always
- 5-Refused/Don’t know

Does side effects or fear of side effects prevent you from taking your medications?
- 1-Never
- 2-Sometimes
- 3-Usually
- 4-Always
- 5-Refused/Don’t know
The following questions relate to reasons why you would or would not take your HIV medications as prescribed. Different people have different reasons for doing that, and we want to know how much you agree or disagree with the following questions:

Does difficulty swallowing pills keep you from taking your medicine?
- 1-Never
- 2-Sometimes
- 3-Usually
- 4-Always
- 5-Refused/Don’t know

Does fear of people seeing your medicines and discovering your diagnosis prevent you from taking your medicines?
- 1-Never
- 2-Sometimes
- 3-Usually
- 4-Always
- 5-Refused/Don’t know

Does the dosing schedule of the medications cause you to forget taking your medications?
- 1-Never
- 2-Sometimes
- 3-Usually
- 4-Always
- 5-Refused/Don’t know

Does alcohol and/or marijuana negatively affect your taking medicine?
- 1-Never
- 2-Sometimes
- 3-Usually
- 4-Always
- 5-Refused/Don’t know

Does lack of faith in the effectiveness of your medications keep you from being compliant with your medicine?
- 1-Never
- 2-Sometimes
- 3-Usually
- 4-Always
- 5-Refused/Don’t know
The following questions relate to reasons why you would or would not take your HIV medications as prescribed. Different people have different reasons for doing that, and we want to know how much you agree or disagree with the following questions: Does confusion about medication dosing keep you from taking your medicines?

- 1-Never
- 2-Sometimes
- 3-Usually
- 4-Always
- 5-Refused/Don’t know

Does running out of your medicine keep you from taking your medicine?

- Yes
- No
- Don’t know

Do mental health issues (Depression, Anxiety, Hearing Voices, Paranoia) keep you from taking your medicine?

- Yes
- No
- Don’t know

Do you miss taking 3-4 doses of your medicine each week?

- Yes
- No

If yes then answer the next question: Is your rate of missed clinic appointments greater than 50%?

- Greater than 50%
- Less than 50%

Thank you so much for completing the survey. Your answers will help us understand about why patients sometimes have difficulty taking their HIV medications.
## Appendix C
### HIV/AIDS Basic Knowledge Questionnaire

For each statement, please circle “True” (T), “False” (F), or “I don’t know” (DK). If you do not know, please do not guess; instead, please circle “DK”

<table>
<thead>
<tr>
<th>Statement</th>
<th>True</th>
<th>False</th>
<th>Don’t Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Coughing and sneezing <strong>DO NOT</strong> spread HIV.</td>
<td>T</td>
<td>F</td>
<td>DK</td>
</tr>
<tr>
<td>2. A person can get HIV by sharing a glass of water with someone who has HIV.</td>
<td>T</td>
<td>F</td>
<td>DK</td>
</tr>
<tr>
<td>3. Pulling out the penis before a man climaxes/cums keeps a woman from getting HIV during sex.</td>
<td>T</td>
<td>F</td>
<td>DK</td>
</tr>
<tr>
<td>4. A woman can get HIV if she has anal sex with a man.</td>
<td>T</td>
<td>F</td>
<td>DK</td>
</tr>
<tr>
<td>5. Showering, or washing one’s genitals/private parts, after sex keeps a person from getting HIV.</td>
<td>T</td>
<td>F</td>
<td>DK</td>
</tr>
<tr>
<td>6. All pregnant women infected with HIV will have babies born with AIDS.</td>
<td>T</td>
<td>F</td>
<td>DK</td>
</tr>
<tr>
<td>7. People who have been infected with HIV quickly show serious signs of being infected.</td>
<td>T</td>
<td>F</td>
<td>DK</td>
</tr>
<tr>
<td>8. There is a vaccine that can stop adults from getting HIV</td>
<td>T</td>
<td>F</td>
<td>DK</td>
</tr>
<tr>
<td>9. People are likely to get HIV by deep kissing, putting their tongue in their partner’s mouth, if their partner has HIV.</td>
<td>T</td>
<td>F</td>
<td>DK</td>
</tr>
<tr>
<td>10. A woman cannot get HIV if she has sex during her period.</td>
<td>T</td>
<td>F</td>
<td>DK</td>
</tr>
<tr>
<td>11. There is a female condom that can help decrease a woman’s chance of getting HIV.</td>
<td>T</td>
<td>F</td>
<td>DK</td>
</tr>
<tr>
<td>12. A natural skin condom works better against HIV than does a latex condom.</td>
<td>T</td>
<td>F</td>
<td>DK</td>
</tr>
<tr>
<td>13. A person will <strong>NOT</strong> get HIV if she/he is taking antibiotics.</td>
<td>T</td>
<td>F</td>
<td>DK</td>
</tr>
</tbody>
</table>
14. Having sex with more than one partner can increase a person’s chance of being infected with HIV.  
T  F  DK

15. Taking a test for HIV one week after having sex will tell a person if she or he has HIV.  
T  F  DK

16. A person can get HIV by sitting in a hot tub or a swimming pool with a person who has HIV.  
F  DK

17. A person can get HIV from oral sex.  
T  F  DK

18. Using Vaseline or baby oil with condoms lowers the chance of getting HIV.  
T  F  DK

Participant Study ID_________________  Date ___________________

*This HIV/AIDS knowledge questionnaire was adapted from the HIV-KQ-18: Carey MP, Morrison-Beedy D, Johnson BT. The HIV-Knowledge Questionnaire: Development and evaluation of a reliable, valid, and practical self-administered questionnaire. AIDS and Behavior. 1997; 1:61–74.
Appendix D

Needs Assessment Secondary Data Analysis

Table D1

50 Participant Random Sample Overview of Secondary Data

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<thead>
<tr>
<th>Participant</th>
<th>HIV Viral Load</th>
<th>No Show Percentage</th>
<th>Race</th>
<th>Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>UD</td>
<td>41%</td>
<td>AA</td>
<td>F</td>
</tr>
<tr>
<td>2</td>
<td>795</td>
<td>42%</td>
<td>AA</td>
<td>F</td>
</tr>
<tr>
<td>3</td>
<td>UD</td>
<td>22%</td>
<td>C</td>
<td>M</td>
</tr>
<tr>
<td>4</td>
<td>5290</td>
<td>37%</td>
<td>AA</td>
<td>F</td>
</tr>
<tr>
<td>5</td>
<td>41897</td>
<td>41%</td>
<td>C</td>
<td>F</td>
</tr>
<tr>
<td>6</td>
<td>85</td>
<td>29%</td>
<td>AA</td>
<td>M</td>
</tr>
<tr>
<td>7</td>
<td>36</td>
<td>21%</td>
<td>H</td>
<td>M</td>
</tr>
<tr>
<td>8</td>
<td>UD</td>
<td>20%</td>
<td>AA</td>
<td>M</td>
</tr>
<tr>
<td>9</td>
<td>4528</td>
<td>36%</td>
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<td>M</td>
</tr>
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<td>F</td>
</tr>
<tr>
<td>11</td>
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<td>F</td>
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<td>F</td>
</tr>
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<td>17%</td>
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<td>F</td>
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<td>No Show Percentage</td>
<td>Race</td>
<td>Gender</td>
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<td>M</td>
</tr>
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<td>10%</td>
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<td>F</td>
</tr>
<tr>
<td>43</td>
<td>UD</td>
<td>11%</td>
<td>C</td>
<td>M</td>
</tr>
<tr>
<td>44</td>
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<td>30%</td>
<td>AA</td>
<td>M</td>
</tr>
<tr>
<td>45</td>
<td>9841</td>
<td>64%</td>
<td>AA</td>
<td>M</td>
</tr>
<tr>
<td>46</td>
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<td>40%</td>
<td>AA</td>
<td>M</td>
</tr>
<tr>
<td>47</td>
<td>56</td>
<td>11%</td>
<td>AA</td>
<td>M</td>
</tr>
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<td>48</td>
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<td>30%</td>
<td>AA</td>
<td>F</td>
</tr>
<tr>
<td>49</td>
<td>44255</td>
<td>15%</td>
<td>AA</td>
<td>F</td>
</tr>
<tr>
<td>50</td>
<td>UD</td>
<td>40%</td>
<td>C</td>
<td>M</td>
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</table>

Note. N = 50. AA = African American; C = Caucasian; H = Hispanic

Table D2

50 Participant Random Sample Secondary Data Mean, Median, and Mode

<table>
<thead>
<tr>
<th>Statistics</th>
<th>Viral Load</th>
<th>No Show Percentage</th>
<th>Race</th>
<th>Gender</th>
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<tbody>
<tr>
<td>N Valid</td>
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<td>50</td>
<td>50</td>
<td>50</td>
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<td>50563.18</td>
<td>.28220</td>
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<td>Median</td>
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</table>

a. Multiple modes exist. The smallest value is shown
### Table D3

50 Participant Random Sample Race and Ethnicity Frequency

<table>
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<tr>
<th>Race</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
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<td>African American</td>
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</tr>
<tr>
<td>Latino/Hispanic</td>
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<tr>
<td>Other</td>
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### Table D4

50 Participant Random Sample Gender Frequency

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<th>Gender</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
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<tbody>
<tr>
<td>Valid</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
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<tr>
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Table D5

50 Participant Random Sample HIV Viral Load Frequency

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<th>Viral Load</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
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<tr>
<td>Undetectable</td>
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<td>50.0</td>
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<td>56</td>
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<td>2.0</td>
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</table>
Table D7

Mean HIV Viral Load and Clinic Appointment No Show Percentage

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<th>Std. Deviation</th>
<th>N</th>
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<td>Viral Load</td>
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<td>181883.162</td>
<td>50</td>
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<td>Clinic Appointment No Show Percentage</td>
<td>.28220</td>
<td>.150622</td>
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</tbody>
</table>

Table D8

Correlations of Viral Load and Clinic Appointment No Show Percentage

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<tr>
<th></th>
<th>Viral Load</th>
<th>Clinic Appointment No Show Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral Load</td>
<td>Pearson Correlation: .144</td>
<td>.320</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed): .320</td>
<td>.320</td>
</tr>
<tr>
<td></td>
<td>Sum of Squares and Cross-products: 1620992750319.381</td>
<td>192650.130</td>
</tr>
<tr>
<td></td>
<td>Covariance: 33081484700.396</td>
<td>3931.635</td>
</tr>
<tr>
<td></td>
<td>N: 50</td>
<td>50</td>
</tr>
<tr>
<td>Clinic Appointment No Show Percentage</td>
<td>Pearson Correlation: .144</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed): .320</td>
<td>.320</td>
</tr>
<tr>
<td></td>
<td>Sum of Squares and Cross-products: 192650.130</td>
<td>1.112</td>
</tr>
<tr>
<td></td>
<td>Covariance: 3931.635</td>
<td>.023</td>
</tr>
<tr>
<td></td>
<td>N: 50</td>
<td>50</td>
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Table D9

Nonparametric Correlations of Viral Load and Clinic Appointment No Show Percentage

<table>
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<th>Viral Load Correlation Coefficient</th>
<th>Clinic Appointment No Show Percentage Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Kendall's tau_b</strong></td>
<td>1.000</td>
<td>.237*</td>
</tr>
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<td>Viral Load</td>
<td>Sig. (2-tailed)</td>
<td>.024</td>
</tr>
<tr>
<td>N</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Clinic Appointment</td>
<td>Correlation Coefficient</td>
<td>1.000</td>
</tr>
<tr>
<td>No Show Percentage</td>
<td>Sig. (2-tailed)</td>
<td>.024</td>
</tr>
<tr>
<td>N</td>
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<td>50</td>
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<tr>
<td><strong>Spearman's rho</strong></td>
<td>1.000</td>
<td>.321*</td>
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<tr>
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<td>Sig. (2-tailed)</td>
<td>.023</td>
</tr>
<tr>
<td>N</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Clinic Appointment</td>
<td>Correlation Coefficient</td>
<td>.321*</td>
</tr>
<tr>
<td>No Show Percentage</td>
<td>Sig. (2-tailed)</td>
<td>1.000</td>
</tr>
<tr>
<td>N</td>
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<td>50</td>
</tr>
</tbody>
</table>

*. Correlation is significant at the 0.05 level (2-tailed).
Appendix E

HIV/AIDS Medication Adherence Questionnaire Results

Table E1

HIV/AIDS Medication Adherence Questionnaire Results, Part 1

<table>
<thead>
<tr>
<th>HIV Medication Adherence Survey Questions</th>
<th>Never</th>
<th>Sometimes</th>
<th>Usually</th>
<th>Always</th>
<th>Refused/Don’t Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is being reminded about your HIV diagnosis a reason that you are not compliant with your medications?</td>
<td>7</td>
<td>4</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Does side effects or fear of side effects prevent you from taking your medications?</td>
<td>9</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Does difficulty swallowing your pills keep you from taking your medicine?</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Does fear of people seeing your medicines and discovering your diagnosis prevent you from taking your medicines?</td>
<td>7</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Does alcohol and/or marijuana negatively affect your taking medicine?</td>
<td>13</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Does lack of faith in the effectiveness of your medicines keep you from being compliant with your medicine?</td>
<td>12</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Does confusion about medication dosing keep you from taking your medicines?</td>
<td>10</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
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Note. N = 13
Table E2

HIV/AIDS Medication Adherence Questionnaire Results, Part 2

<table>
<thead>
<tr>
<th>HIV Medication Adherence Survey Questions</th>
<th>Yes</th>
<th>No</th>
<th>Don’t Know</th>
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</thead>
<tbody>
<tr>
<td>Does running out of your medicine keep you from taking your medicine?</td>
<td>4</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>Do mental health issues (Depression, Anxiety, Hearing Voice, Paranoia) keep you from taking your medicine?</td>
<td>2</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>Do you miss taking 3-4 doses of your medicine each week?</td>
<td>3</td>
<td>9</td>
<td>0</td>
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</table>

Note. N = 13

Table E3

HIV/AIDS Medication Adherence Questionnaire Results, Part 3

<table>
<thead>
<tr>
<th>HIV Medication Adherence Survey Questions</th>
<th>1 time</th>
<th>2-3 times</th>
<th>4-5 times</th>
<th>Never miss a dose</th>
<th>I do not take the medication</th>
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</thead>
<tbody>
<tr>
<td>How often per week do you forget to take your medications?</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>7</td>
<td>1</td>
</tr>
</tbody>
</table>

Note. N = 13

Table E4

HIV/AIDS Medication Adherence Questionnaire Results, Part 4

<table>
<thead>
<tr>
<th>HIV Medication Adherence Survey Questions</th>
<th>Greater than 50 %</th>
<th>Less than 50 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes then answer the next question: Is your rate of missed clinic appointments greater than 50%?</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

Note. N = 13
Appendix F

HIV/AIDS Basic Knowledge Questionnaire Results

*Table F1*

Mean HIV Viral Load and HIV Knowledge Questionnaire Grade

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral Load</td>
<td>13</td>
<td>6560.3846</td>
<td>23329.51471</td>
<td>6470.44319</td>
</tr>
<tr>
<td>HIV Knowledge Quiz Grade</td>
<td>13</td>
<td>84.1538</td>
<td>12.97335</td>
<td>3.59816</td>
</tr>
</tbody>
</table>

*Table F2*

t-Test Results for HIV Viral Load and HIV Knowledge Questionnaire Grade

<table>
<thead>
<tr>
<th></th>
<th>t</th>
<th>df</th>
<th>Sig. (2-tailed)</th>
<th>Mean Difference</th>
<th>95% Confidence Interval of the Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral Load</td>
<td>1.002</td>
<td>12</td>
<td>.336</td>
<td>6480.38462</td>
<td>-7617.5000 - 20578.2693</td>
</tr>
<tr>
<td>HIV Knowledge Quiz</td>
<td>1.154</td>
<td>12</td>
<td>.271</td>
<td>4.15385</td>
<td>-3.6859 - 11.9936</td>
</tr>
</tbody>
</table>

*Table F3*

HIV/AIDS Basic Knowledge Questionnaire Grade Frequency

<table>
<thead>
<tr>
<th>Questionnaire Grade</th>
<th>Frequency of Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>2</td>
</tr>
<tr>
<td>94%</td>
<td>4</td>
</tr>
<tr>
<td>78%</td>
<td>5</td>
</tr>
<tr>
<td>72%</td>
<td>1</td>
</tr>
<tr>
<td>56%</td>
<td>1</td>
</tr>
</tbody>
</table>
Study Participant Informed Consent, Needs Assessment

Johns Hopkins University
Homewood Institutional Review Board (HIRB)

Study Participation Informed Consent Form

Title: Study to determine if psycho-educational groups could improve the medication adherence among young adults (18-30 years old) infected with HIV/AIDS who receive their HIV treatment in the Johns Hopkins Infectious Disease Outpatient Clinic

Principal Investigator: Nicholas P. Schweizer MS, LCADC, LCPC
Johns Hopkins School of Education

Date: April 1, 2016

PURPOSE OF RESEARCH STUDY:
The purpose of this research study is to discover if participation in psycho-educational groups would improve the medication adherence for patients who are non-adherent with the medications and lead to a decrease in viral load and improvement in overall health of the patient.

We anticipate that approximately 15 people will participate in this study.

PROCEDURES:
The study will consist of 5 psycho-educational groups 60 minutes each held in the clinic. The groups will be modular and the participant can attend any of the first 4 groups. The groups will be interactive and will incorporate multimedia elements as well as group discussion. Topics covered will be basic HIV/AIDS education, techniques shown to improve medication adherence, mindfulness, cognitive behavioral therapeutic technique of thought disputing, HIV stigma reduction skills, alcohol and drug education/reduction, mental health education/treatment, and problem solving skills. The first 4 groups will be held at 2-week intervals. The 5th group will be for any patient that attended any of the first 4 groups and it will be held 4 weeks after the 4th group. This will be a booster group and will incorporate Motivational Interviewing Techniques.

The entire study should take 10 weeks and if a participant attended all 5 groups the total amount of time the participant was in a group would be 5 hours.

RISKS/DISCOMFORTS:
There are no anticipated risks to study participants.
BENEFITS:
Potential benefits are increased understanding about HIV/AIDS and greater insight into the reasons that the participant may or may not be adherent with his/her medication regimen. Also it is possible that the patient’s viral load decreases and his/her overall health improves.

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW:
Your participation in this study is entirely voluntary. If you choose not to participate, there are no penalties, and you will not lose any benefits to which you would otherwise be entitled.

You can stop participation in the study at any time, without any penalty or loss of benefits. If you want to stop your participation in the study please contact Nicholas P. Schweizer via phone or email: 410-608-6767, nschweil@jhmi.edu.

CIRCUMSTANCES THAT COULD LEAD US TO END YOUR PARTICIPATION:
Under certain circumstances we may decide to end your participation before you have completed the study. Specifically, we may stop your participation if your behavior in group is disruptive to the group process and/or the participations of the other group members, if you are threatening to the group leader and/or any group members, and if you seem to be incapacitated and unable to focus and participate in the group. There may also be other circumstances that would lead us to end your participation.

ALTERNATIVES TO PARTICIPATION:
If you are unable to participate in the study, but would like to improve your adherence to your HIV medications then a referral to the psychiatry service and the pharmacy service will be made for you.

CONFIDENTIALITY:
Any study records that identify you will be kept confidential to the extent possible by law. The records from your participation may be reviewed by people responsible for making sure that research is done properly, including members of the Johns Hopkins University Homewood Institutional Review Board and officials from government agencies such as the National Institutes of Health and the Office for Human Research Protections. (All of these people are required to keep your identity confidential.) Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records.

The Principal Investigator will examine all measures and research affiliates only (including those entities described above). No identifiable information will be included in any reports of the research published or provided to school administration. A participant number will be assigned to all surveys and the student’s achievement scores.
Any questionnaires will be collected in paper format. This data will not include identifiable information. All research data including paper surveys will be kept in a locked office. All paper documents shredded, ten years after collection.

Only group data will be included in publication; no individual achievement data will ever be published.

**COMPENSATION:**
You will receive any payment or other compensation for participating in this study.

**IF YOU HAVE QUESTIONS OR CONCERNS:**
You and your child can ask questions about this research study at any time during the study by contacting Nicholas P. Schweizer via phone or email: 410-608-6767, nschwei1@jhmi.edu.

If you have questions about your rights as a research participant or feel that you have not been treated fairly, please call the Homewood Institutional Review Board at Johns Hopkins University at (410) 516-6580.

**SIGNATURES**

*What your signature means:*
Your signature below means that you understand the information in this consent form. Your signature also means that you agree to participate in the study. By signing this consent form, you have not waived any legal rights you otherwise would have as a participant in a research study.

<table>
<thead>
<tr>
<th>Participant's Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Signature of Person Obtaining Consent</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Investigator or HIRB Approved Designee)</td>
<td></td>
</tr>
</tbody>
</table>
Appendix H

ART Adherence Questionnaire

Please place an “X” on the line below at the point showing your best guess about how much of your current antiretroviral medication you have taken in the past 7 days.

0% means you have taken none of your current antiretroviral medication, 50% means you have taken half your current antiretroviral medication, 100% means that you have taken every single dose of your current antiretroviral medication in the past 7 days.
Appendix I

Intervention and Control Group Data Collection

*Table II*

Secondary Data for Intervention and Control Groups

<table>
<thead>
<tr>
<th>Participant</th>
<th>Gender</th>
<th>Sexual Orientation</th>
<th>Race</th>
<th>Age</th>
<th>HIV Viral Load</th>
<th>Adherence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>Heterosexual</td>
<td>AA</td>
<td>28</td>
<td>107,142</td>
<td>100%</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>Heterosexual</td>
<td>C</td>
<td>28</td>
<td>32,800</td>
<td>75%</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>Homosexual</td>
<td>AA</td>
<td>22</td>
<td>29</td>
<td>100%</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>Homosexual</td>
<td>AA</td>
<td>28</td>
<td>74,200</td>
<td>100%</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>Heterosexual</td>
<td>AA</td>
<td>29</td>
<td>62</td>
<td>100%</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>Heterosexual</td>
<td>AA</td>
<td>25</td>
<td>109</td>
<td>100%</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>Homosexual</td>
<td>AA</td>
<td>22</td>
<td>43</td>
<td>85%</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>Heterosexual</td>
<td>H</td>
<td>29</td>
<td>1,297</td>
<td>100%</td>
</tr>
<tr>
<td>9</td>
<td>M</td>
<td>Homosexual</td>
<td>AA</td>
<td>26</td>
<td>1,364</td>
<td>100%</td>
</tr>
<tr>
<td>10</td>
<td>M</td>
<td>Bisexual</td>
<td>AA</td>
<td>28</td>
<td>30,400</td>
<td>100%</td>
</tr>
<tr>
<td>11</td>
<td>M</td>
<td>Heterosexual</td>
<td>AA</td>
<td>28</td>
<td>43</td>
<td>100%</td>
</tr>
<tr>
<td>12</td>
<td>F</td>
<td>Heterosexual</td>
<td>AA</td>
<td>28</td>
<td>57</td>
<td>100%</td>
</tr>
<tr>
<td>13</td>
<td>F</td>
<td>Heterosexual</td>
<td>AA</td>
<td>28</td>
<td>74</td>
<td>100%</td>
</tr>
<tr>
<td>14</td>
<td>F</td>
<td>Heterosexual</td>
<td>AA</td>
<td>27</td>
<td>5,892</td>
<td>100%</td>
</tr>
<tr>
<td>15</td>
<td>F</td>
<td>Heterosexual</td>
<td>AA</td>
<td>29</td>
<td>38</td>
<td>90%</td>
</tr>
<tr>
<td>16</td>
<td>F</td>
<td>Heterosexual</td>
<td>AA</td>
<td>27</td>
<td>10,316</td>
<td>100%</td>
</tr>
<tr>
<td>17</td>
<td>M</td>
<td>Homosexual</td>
<td>C</td>
<td>25</td>
<td>144,000</td>
<td>100%</td>
</tr>
<tr>
<td>18</td>
<td>M</td>
<td>Homosexual</td>
<td>AA</td>
<td>29</td>
<td>94</td>
<td>75%</td>
</tr>
<tr>
<td>19</td>
<td>F</td>
<td>Heterosexual</td>
<td>AA</td>
<td>26</td>
<td>16,354</td>
<td>100%</td>
</tr>
<tr>
<td>20</td>
<td>M</td>
<td>Heterosexual</td>
<td>AA</td>
<td>25</td>
<td>1,370</td>
<td>0%</td>
</tr>
<tr>
<td>21</td>
<td>F</td>
<td>Homosexual</td>
<td>AA</td>
<td>27</td>
<td>23</td>
<td>95%</td>
</tr>
</tbody>
</table>

*Note.* N = 21. AA = African American; C = Caucasian; H = Hispanic
### Table I2

Viral Load at Consent and at Study Conclusion in Intervention Group

<table>
<thead>
<tr>
<th>Participant</th>
<th>Viral Load at Consent</th>
<th>Viral Load at Study Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>107,142</td>
<td>72</td>
</tr>
<tr>
<td>2</td>
<td>32,800</td>
<td>103,000</td>
</tr>
<tr>
<td>4</td>
<td>74,200</td>
<td>11,000</td>
</tr>
<tr>
<td>7</td>
<td>43</td>
<td>20,100</td>
</tr>
<tr>
<td>8</td>
<td>1,297</td>
<td>6,260</td>
</tr>
<tr>
<td>10</td>
<td>30,400</td>
<td>UD</td>
</tr>
<tr>
<td>15</td>
<td>38</td>
<td>288</td>
</tr>
<tr>
<td>17</td>
<td>144,000</td>
<td>37</td>
</tr>
<tr>
<td>18</td>
<td>94</td>
<td>3,270</td>
</tr>
<tr>
<td>20</td>
<td>1,370</td>
<td>No Lab; lost to follow-up</td>
</tr>
<tr>
<td>21</td>
<td>23</td>
<td>UD</td>
</tr>
</tbody>
</table>

*Note.* N = 11. Undetectable is defined as < 20 particles per mL. UD = undetectable

### Table I3

Viral Load at Consent and at Study Conclusion in Control Group

<table>
<thead>
<tr>
<th>Participant</th>
<th>Viral Load at Consent</th>
<th>Viral Load at Study Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>29</td>
<td>20</td>
</tr>
<tr>
<td>5</td>
<td>62</td>
<td>UD</td>
</tr>
<tr>
<td>6</td>
<td>109</td>
<td>UD</td>
</tr>
<tr>
<td>9</td>
<td>1,364</td>
<td>UD</td>
</tr>
<tr>
<td>11</td>
<td>43</td>
<td>No Lab, lost to follow-up</td>
</tr>
<tr>
<td>12</td>
<td>57</td>
<td>25</td>
</tr>
<tr>
<td>13</td>
<td>74</td>
<td>142,000</td>
</tr>
<tr>
<td>14</td>
<td>5,892</td>
<td>No Lab, lost to follow-up</td>
</tr>
<tr>
<td>16</td>
<td>10,316</td>
<td>UD</td>
</tr>
<tr>
<td>19</td>
<td>16,354</td>
<td>14,700</td>
</tr>
</tbody>
</table>

*Note.* N = 10. Undetectable is defined as < 20 particles per mL. UD = undetectable
Appendix J

Intervention Data Collection

Table J1

Intervention Data Collection Matrix

<table>
<thead>
<tr>
<th>Fidelity Indicator</th>
<th>Data Source</th>
<th>Data Collection Tool</th>
<th>Frequency</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adherence</strong></td>
<td>Course schedule</td>
<td>Instructor’s group check list</td>
<td>Every group</td>
<td>Instructor</td>
</tr>
<tr>
<td>1. Follow course schedule.</td>
<td>Instructor</td>
<td>Instructor’s log</td>
<td></td>
<td>PI</td>
</tr>
<tr>
<td>3. Incorporation of Motivational Interviewing Techniques.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>Instructor</td>
<td>Attendance sheets</td>
<td>Every group</td>
<td>Instructor</td>
</tr>
<tr>
<td>1. Participant’s group attendance</td>
<td>Participant</td>
<td>Instructor notes/log</td>
<td></td>
<td>PI</td>
</tr>
<tr>
<td>2. Participant’s time spent in group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Quality of Delivery</strong></td>
<td>Instructor</td>
<td>Questionnaire</td>
<td>Every group</td>
<td>Instructor</td>
</tr>
<tr>
<td>Participant</td>
<td>Participant</td>
<td>Instructor’s log</td>
<td></td>
<td>PI</td>
</tr>
<tr>
<td><strong>Participant Responsiveness</strong></td>
<td>Participant</td>
<td>Questionnaire</td>
<td>Every group</td>
<td>Participant</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Instructor</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PI</td>
</tr>
<tr>
<td>Indicator</td>
<td>Role of Indicator</td>
<td>Data Source(s)</td>
<td>Frequency</td>
<td>Responsibility</td>
</tr>
<tr>
<td>-----------</td>
<td>------------------</td>
<td>----------------</td>
<td>-----------</td>
<td>----------------</td>
</tr>
<tr>
<td>Gender</td>
<td>Moderating variable</td>
<td>Intake data</td>
<td>1 time at intake</td>
<td>PI</td>
</tr>
<tr>
<td>Knowledge about HIV/AIDS medications</td>
<td>Mediating variable</td>
<td>Classroom activities &amp; discussions</td>
<td>Every group</td>
<td>Instructor</td>
</tr>
<tr>
<td>Prior medication adherence intervention</td>
<td>Control variable</td>
<td>Participant</td>
<td>1 time at intake</td>
<td>PI</td>
</tr>
<tr>
<td>Viral load</td>
<td>Outcome measure</td>
<td>Blood work</td>
<td>Pretreatment; 1 month Post treatment; 3 month Post treatment</td>
<td>PI</td>
</tr>
</tbody>
</table>
Figure K1: Psycho-educational Group Intervention

**Situation:** Young adults (18-30 years old) infected with HIV/AIDS who are non-adherent to their treatment.

**Priorities:** Stigma, socio-economic issues, and environmental obstacles.

**Intended Outcomes:**
- Increased engagement and participation in groups.
- Increased understanding about management of a chronic illness.
- Increased awareness about HIV/AIDS stigma.

**Medium Term Results:**
- Decrease in viral load.
- Decrease in HIV/AIDS stigma.
- Improved life expectancy.
- Decrease in medication aversion.
- Improved coping skills and strategies.

**Ultimate Impact:**
- Sustained medication adherence.
- Sustained viral load suppression.
- Medication adherence improvement.
- Improved mortality rate.
- Avoidance of the development of drug resistance.

**Who we reach:**
- Young adults who attend the groups.
- Other healthcare providers who treat the participants and indirectly hear about the groups and see the results.
- Family and friends of the participants who see the results of the groups via the participants.

**What we do:**
- Five 60 minute modular groups.
- Multimedia elements: Videos, powerpoint presentations, computer based learning module.
- Utilization of Motivational Interviewing Techniques.
- Utilization of Information Motivation and Behavioral Therapy.

**What we invest:**
- Staff Time
- Money
- Materials
- Clinic space
- Technology
- Data base
- Lab time
- Pharmacy

**Priorities:**
- Stigma
- Socio-economic issues
- Environmental obstacles
- Pill aversion

**Intended Outcomes:**
- Decrease in viral load.
- Improved medication adherence.

**Situation:** Young adults (18-30 years old) infected with HIV/AIDS are non-adherent with their treatment.

**Priorities:**
- Stigma
- Socio-economic issues
- Environmental obstacles
- Pill aversion

**Intended Outcomes:**
- Decrease in viral load.
- Improved medication adherence.
Appendix L

Group Session Outlines

Session 1
- Mindfulness exercise & medication compliance training
- Social Stigma & HIV/AIDS
- **Goal:** this module is designed to help participants overcome barriers in thinking patterns around their HIV/AIDS diagnosis. Participants will discuss about HIV/AIDS stigma and will learn to identify and correct negative views that become barriers to health
- Brief group therapy

Session 2
- Mindfulness exercise & medication compliance training
- Motivation
- **Goal:** Develop concrete steps that help patients start to take action with regards to the management of their chronic health disorder.
- Brief group therapy (Discussion about control & power)

Session 3
- Mindfulness exercise & medication compliance training
- Mental Health Disorders & HIV/AIDS
- **Goal:** this module is designed to help participants overcome barriers in thinking patterns around their HIV/AIDS diagnosis. Participants will discuss about HIV/AIDS stigma and will learn to identify and correct negative views that become barriers to health
- Brief group therapy

Session 4
- Mindfulness exercise & medication compliance training
- Substance Abuse & HIV/AIDS
- **Goal:** this module is designed to help participants understand about the disease of addiction and about the possible health consequences of abuse
- Brief group therapy (Discussion to focus on marijuana & alcohol)

Session 5
- Mindfulness exercise & medication compliance training
- Emotional Regulation & HIV/AIDS
- **Goal:** this module is designed to help participants understand that feelings and emotions are not facts. Some coping techniques and strategies for managing one’s emotions presented & practiced
- Brief group therapy (Possibly processing about response control)
Session 6

- Mindfulness exercise & medication compliance training
- Beliefs & Issues with Medications
- Goal: this module is designed to help participants overcome faulty beliefs about medications, particularly about HIV/AIDS medications. Participants will review medication adherence strategies and ways to minimize side-effects.
- Brief group therapy (Possibly around pill fatigue and/or aversion)
Biographical Sketch

Name:

Nicholas P. Schweizer MS, LCADC, LCPC

Education/Training:

- Bachelor of Arts - English Literature, Loyola College, 12/93
- Master of Science Degree - Clinical Community Counseling, Johns Hopkins University, 5/00
- Certificate of Advanced Graduate Study - Substance Abuse Counseling, Johns Hopkins University, 5/00
- Licensed Clinical Professional Counselor, 8/02
- Licensed Clinical Alcohol and Drug Counselor, 3/03
- Part-time Faculty appointment at the Johns Hopkins University, Department of Psychiatry, (1/07–10/10)
- Licensed Approved Clinical Professional Counselor Supervisor, 8/15
- Doctoral candidate, Johns Hopkins University, School of Education, anticipated degree conferral, 8/17

A. Personal Statement

I am a licensed psychotherapist and a substance abuse specialist with over 15 years of clinical experience in mental health and substance abuse treatment in outpatient and inpatient treatment settings. I am an experience lecturer and mental health/substance abuse consultant that has conducted educational programs in treatment and educational settings. I am completing my doctoral work in education in the hope that I can become a better educator of mental health and substance abuse topics.

B. Positions and Honors

Program Manager, AIDS Psychiatry Service

Johns Hopkins University, Department of Psychiatry (1/14 – present)

Provides psychiatric and substance abuse services to HIV/AIDS-infected individuals at the Johns Hopkins Moore Clinic and at clinics in the surrounding counties including but not limited to:

- Provides clinical supervision to the individual counselor that works directly with the patients in the Suboxone program that operates within the Moore Clinic.
- Provides group supervision and clinical dual diagnosis expertise to the Suboxone treatment team that meets every week.
- Instructs and supervises the PGY3 resident that works in the AIDS Psychiatry Program at the Moore Clinic
- Supervises the psychotherapist(s) that works in the AIDS Psychiatry Program at the Moore Clinic.
• Works directly with the Director of the Program in the development and preparation of grants that help fund the AIDS Psychiatry Program. Also acts as a liaison between program staff and funding agency/Health Department.
• Manages the day to day clinical and operational issues of the AIDS Psychiatry Program in the Moore Clinic.

**Psychotherapist & Substance Abuse Specialist**  
*Johns Hopkins University, Department of Psychiatry (1/07 – 1/14)*

• Provides psychiatric and substance abuse services to HIV/AIDS-infected individuals at the Johns Hopkins Moore Clinic and at clinics in the surrounding counties including but not limited to:
• Initial evaluations of new clients in collaboration with staff psychiatrist
• Ongoing psychotherapy and continued monitoring of psychiatric and behavioral disorders
• Facilitates triage and care of acute cases and emergencies, as well as referral of clients to other health care providers or inpatient service as indicated
• Ongoing substance abuse counseling and evaluation of acute emergencies

**Psychotherapist & Substance Abuse Specialist**  
*Private Mental Health Practice (1/05 – 1/12)*

Conduct all aspects of private practice specializing in substance abuse and psychiatric issues including but not limited to:

• Individual psychotherapy for adults and adolescents
• Psycho-educational groups for adults and adolescents
• Interventions, consultations and diagnostic evaluations
• Lectures at schools and treatment centers on substance abuse and other mental health issues.

**Part-time School Counselor**  
*Harford Day School (9/08 – 6/10)*

Private Independent School (AIMS accredited) kindergarten prep. – 8th grade in Bel Air, Maryland

• Made assessments of identified students for possible referral for long-term counseling and/or diagnostic services.
• Coached middle school lacrosse team
• Worked closely with faculty and administration to better help the school better meet the needs of students.
• Helped coordinate and teach the 8th grade Passages (Health & Wellness) Class.

**Counseling Specialist**  
*Ashley Inc., Counseling Department (1/04 – 1/05)*

• Assisted Clinical Program Director in updating recovery workbook, which patients utilize during inpatient stays for substance abuse treatment.
• Authored/presented lectures to general patient population and to friends/families of patients as part of Family Educational Program.
- Wrote curriculum for/ran specialty groups with young adults and other individuals with mental health issues including chronic pain, grief and loss issues, eating disorders. Also worked with survivors of domestic violence and other types of abuse.

**Psychiatric Therapist**  
*Johns Hopkins Hospital, Department of Psychiatry, Community Psychiatry Program (7/01 - 1/04)*

- Provided individual therapy to patients who suffer from major mental illnesses including substance abuse.
- Conducted initial psychosocial evaluations and worked closely with psychiatrists to establish and maintain appropriate medication regime with patients.
- Established/ran dual-diagnosed therapy group for patients referred from within clinic.

**Psychiatric Therapist**  
*Johns Hopkins University, Department of Psychiatry, The Moore Clinic (1/01-7/01, part-time)*

- Facilitated substance abuse group.
- Worked with staff psychiatrists to assess and determine proper therapeutic course of treatment for patients.
- Conducted individual substance abuse counseling.

**Clinical Supervisor**  
*Johns Hopkins Bayview Medical Center-Center for Addiction and Pregnancy (5/00-11/00)*

- Provided supervision for three mental health counselors. Monitored development of patients’ treatment plans, individual sessions, and documentation.
- Monitored methadone protocols, withdrawal symptoms, and dosage adjustments for inpatient and ambulatory patients.
- Carried caseload involving more difficult dually diagnosed patients and in conjunction, provided individual, family, and couples counseling.

**Counseling Internship**  
*Johns Hopkins Bayview Medical Center-Center for Addiction and Pregnancy (9/99-5/00)*

- Developed/facilitated Supportive-Other psycho-educational group for patients needing stronger support network. Facilitated individual couples counseling sessions.
- Acted as primary liaison between Center for Addiction and Pregnancy and Labor and Delivery Department in Johns Hopkins Bayview Medical Center.
- Managed caseload of ten female patients in need of intensive individual therapy for issues including: physical, emotional, and sexual abuse; clinical depression anger management; substance abuse; and schizophrenia. Developed individual treatment plans for patients.
Mental Health Counselor
*Johns Hopkins Bayview Medical Center-Center for Addiction and Pregnancy* (8/98-8/99)
- Managed caseload of 20 plus clients for weekly sessions, developed treatment plans; created relapse prevention plan and provided crisis intervention.
- Acted as member of multidisciplinary treatment team and as liaison with the staff psychiatrist for dually diagnosed patients.
- Facilitated 5-7 psycho-educational groups per week on topics such as group therapy, relapse prevention, drug education, and 12-step work.

Research/Data Assistant
*Johns Hopkins Bayview Medical Center-Behavioral Pharmacology Research Unit* (9/97-7/98)
- Received training in administering structured and semi-structured clinical research tools including the Addiction Severity Index Interview (ASI)
- Coordinated clinic computer lab, collected and evaluated all data for large-scale double blind pharmacological clinical trials.
- Tracked discharged participants who had completed studies to ensure successful completion of follow-up studies.

C. **Contributions to Science**