

DISSERTATION

**UNDERSTANDING THE NATURE OF MEDICATION ADHERENCE ISSUES WITH
THE HIV INFECTED PATIENT IN THE FAMILY PRACTICE SETTING**

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WE HEREBY RECOMMEND THAT THE DISSERTATION PREPARED UNDER OUR SUPERVISION BY PETER THOMAS PRUTCH ENTITLED UNDERSTANDING THE NATURE OF MEDICATION ADHERENCE ISSUES WITH THE HIV INFECTED PATIENT IN THE FAMILY PRACTICE SETTING BE ACCEPTED AS FULFILLING IN PART REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY.

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ABSTRACT OF DISSERTATION

UNDERSTANDING THE NATURE OF MEDICATION ADHERENCE ISSUES WITH THE HIV INFECTED PATIENT IN THE FAMILY PRACTICE SETTING

One of the greatest challenges in managing the medication therapy in any chronic disease is how to influence human behavior, such as adherence to antiretroviral therapy in the Human Immune Virus (HIV) positive patient. Although data demonstrate significant viral suppression and immunologic benefits of therapy when taking antiretroviral medication at a 95% adherence, non-adherence remains a problem in the HIV or Acquired Immune Deficiency Syndrome (AIDS) population. Past literature indicates it may relate to the quality of information given, the impact of the regimen on daily life, the physical or the incapacity of patients, or their social isolation.

This is a basic qualitative research study. The purpose of this study is to have a basic interpretive qualitative understanding of the nature of non-adherence to medication in the HIV infected patient in a family practice setting. During interviewing, each participant had their own personal story about being HIV positive and why they adhere or do not adhere to their medication regimen. It appears that adherence to any highly active antiretroviral therapy (HAART) revolves around the well being and the understanding of lifelong commitment of the HIV patient. A hypothetical model has been constructed relating the Health Belief Model to HIV medication adherence as found in this study. The educational opportunities for the HIV infected person have improved over the past 10 years. Many private and government organizations provide training and learning

materials and the healthcare providers are more aware of the needs of the HIV positive person. The lifestyles of HIV positive people are no different than the non-infected person. However, the side effects of the HAART have been shown to affect the adherence. Seeing HIV in a more positive light contributes to the well being of the infected person. Patients find it easier to cope with their disease if they see it as an opportunity for personal growth or can attach some other positive meaning to it. The outlook on HIV disease has gone from a death sentence to one of guarded optimism. It is viewed as a life long commitment.

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CHAPTER 1: INTRODUCTION

“It is more important to know what type of patient has a disease than what type of disease a patient has” (Sir William Osler, as cited in World Health CME, 2003). Highly active antiretroviral therapy (HAART) for the treatment of Human Immune Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) can be incredibly complicated, with three to four different medications, many doses per day and a myriad of additional dosing rules and restrictions. Yet, despite the complex nature of these regimens, it is essential that patients take them consistently, and exactly as prescribed. Failure to maintain the necessary “adherence” to the prescribed regimen leads to therapeutic failure of the treatment regimen. Given this pivotal role that adherence plays in the success of HIV treatment, HIV/AIDS treating healthcare providers need to be knowledgeable regarding key strategies for enhancing their patients’ adherence to HAART and comfortable utilizing these strategies in a family practice clinic.

Before one can understand the nature of non-adherence and adherence to HIV medication, one must understand the disease itself, and its history. Where did HIV originate? HIV is very closely related to Simian Immune Virus (SIV) found in chimpanzees. Apes can be infected with HIV, and they can also suffer from a version of SIV (Randerson, 2002). During the 1999 Sixth Annual American Conference on Retroviruses and Opportunistic Infections the keynote address, delivered by Beatrice Hahn, stated HIV is likely to have originated in West African chimpanzees. HIV could have been transferred from monkeys to humans; mainly because, when hunting monkeys,

it is not unusual for both the hunter and the hunted to exchange blood during the capture (Uhavax, 2003).

Some scientists believe HIV spread from monkeys to humans sometime between 1926 and 1946. The earliest fully documented case of HIV dates back to 1959. A man died in the Congo in what researchers now say was the first proven AIDS death. A frozen blood sample from the medical study was preserved, found, and then analyzed in 1998. It was verified that he had been HIV positive. It has also been claimed that the disease originated from African green monkey kidneys. The kidneys were used to cultivate poliovirus in the late 1950s and early 1960s. According to Uhavax (2003), this theory has a low probability.

The first recorded cases in the United States occurred in New York City in 1952, 1959, and 1979. By 1978, gay men in the U.S. and Sweden and heterosexuals in Tanzania and Haiti began showing signs of what would later be called AIDS (AEGIS, 2001). The term AIDS was not introduced until 1982. The Food and Drug Administration (FDA) approved the first HIV antibody test in 1985. All blood products in the U.S. and Japan began to be tested for HIV. President Ronald Regan refused to mention the word "AIDS" in any public speech, so in 1986 the U.S. Surgeon General Everett Koop published a report on AIDS and made the first public speech on the subject. By then, the HIV/AIDS epidemic was in full force. Koop announced the importance of sex education and "safe sex." It was not until 1987 that President Reagan would use the word AIDS in public (Uhavax, 2003).

In 1987, zidovudine (AZT) became the first anti-HIV drug approved by the FDA. HIV drugs are designed to fight the disease process. The recommended dose was one 100mg capsule every four hours around the clock. Between 1987 and 2003, there were 22

additional FDA approved anti-retroviral drugs added to the course of treatment for HIV (Bayer, 2000). Unfortunately, all these medications have side effects such as nausea/vomiting, severe fatigue, and nightmares. Combination drug therapy was introduced in the early 1990s and continues today. Most HIV infected patients receive a combination of three or more anti-retroviral medications, hence the name “drug cocktails.” Although the regimes or cocktails have simplified over the years, it is still not unusual for an HIV infected person to take 8 to 10 medications, two to three times a day. With the large pill burdens and toxic adverse effects of the antiretroviral prescriptions, it is difficult to convince the patient to adhere to their medications. Research needs to be done regarding medication adherence, especially in the family practice clinic.

A family practice clinic is a medical specialty in which general medical care, counseling and problem solving is provided to an individual or family, without regard to age or as to whether the patient is male or female. Family practice is a broad area and ranges from work with infants to caring for people who are dying (Evergreen Health Care, 2005).

Need for the Study

Adherence to antiretroviral therapy is a crucial determinant of treatment success. John Bartlett, from the University of San Francisco, has unequivocally demonstrated the close association between adherence and plasma HIV ribonucleic acid (RNA) levels, CD4 cell counts, and mortality in-patients with HIV infection and disease. Adherence levels of greater than 95% are required to maintain virologic suppression. Nevertheless, actual adherence rates are often far lower. Studies have shown that 40% to 60% of patients are less than 90% adherent (Chesney, 2000). Adherence also tends to decrease over time. Patients offer a range of reasons for non-adherence, but the most frequently

cited one is simply that they forget. Other reasons include being away from home, being busy, or experiencing a change in daily routine. Additional barriers to adherence include psychiatric disorders, such as depression or substance use; uncertainty about the effectiveness of treatment and the consequences of poor adherence, regimen complexity, and treatment side effects. There is a need for this study due to the lack of HIV research in the family practice clinic setting, particularly regarding HIV medication adherence.

Statement of Research Problem

The lack of adherence to HIV medications have lead to further complications regarding the disease process. Estimates of average rates of non-adherence to an antiretroviral therapy range from 50% to 70%. Adherence rates of 80% are associated with detectable virus in patients (Bartlet, 2002). The purpose of this basic interpretive qualitative research study will be to explore the nature of non-adherence to medication in the HIV infected patient in a family practice clinic setting.

Research Questions

Grand tour question: What issues need to be addressed in order for the HIV positive person to adhere to their medication regimen in a family practice setting?

1. What educational opportunities were available to the participants concerning their drug therapy?
2. What is the participant's day-to-day lifestyle, including routine schedule?
3. What side effects of HAART most concern the participants?

Definition of Terms

Adherence. Routinely taking a prescribed medication at least 95% of the time.

Antiretroviral medication. Medications that help control HIV/AIDS.

Educational opportunities. Any learning tool or tools needed by the participant to help understand their disease and potential complications.

Family practice setting. Medical clinic that cares for all ages. The primary healthcare provider in this setting is the primary person who gives the medical care to the patient. This could be a doctor, physician's assistant or nurse practitioner.

Highly active antiretroviral therapy (HAART). Taking three or more antiretroviral medications. These medications can be administered one to four times a day and include between 3 to 14 pills at a time.

HIV positive person. Any person who is infected with the Human Immune Virus.

Medication regime. Taking a prescribed medication on a routine base, basically at the same time daily.

Protease Inhibitors (PI). These Medications prevent the enzyme protease from cleaving or cutting up the newly formed viral precursor proteins into viral structural proteins and enzymes.

Side effects of medication. Any adverse reaction to the prescribed medication.

Significance of the Study

In a survey of the literature, no studies were found that took place in a Family Practice Clinic setting. This study takes place in the family practice setting where the participants have their healthcare needs met by the same healthcare provider. Because most of the healthcare needs of the participants are met in this setting, the healthcare provider has the benefit of understanding what other issues may be impeding the adherence to their medication regimen. Additionally, this study comes at a time where several new antiretroviral medications are being approved by the Food and Drug

Administration (FDA). Some of these newer medications have few side effects, and the daily dosing of medication can be less frequent (Bartlett, 2003).

This study will aid future and possibly present research in other family practice clinics or other small health care clinics that are interested in HIV care.

Investigator's Perspective

This researcher has been a registered nurse for 24 years and a nurse practitioner since 1996. This researcher has been working with HIV positive patients for many years. I have observed many patients successfully adhere to their strict medication regimen and live healthy lives. However, I have also observed HIV positive patients who do not adhere to their medication regime and suffer the consequences. I feel the healthcare provider in a family practice clinic has a better understanding of the HIV positive person's healthcare needs because they not only work with the healthcare issues of HIV, but all healthcare issues. I believe patient education is the most important aspect to anyone's good health. Adherence to medication is an essential part of life for HIV positive people and essential to prevent disease progression.

CHAPTER 2: LITERATURE REVIEW

Medication adherence is the degree of correspondence between the patient's actual dosing history and the prescribed regimen. The concept of adherence denotes a collaborative, interactive, patient-clinician relationship (Meredith, 1999). According to Lisabeth Hall (1999) in the United States medication non-adherence causes an estimated 125,000 deaths annually, a loss of 20 million workdays and \$1.5 billion in earnings. Non-adherence is the cause of 10% of hospital admissions, and \$8.5 billion in excess hospitalization costs. In addition, about 39% of all adverse drug reactions necessitating hospitalization are a consequence of the improper use of medication (Hall, 1999). When the medication the healthcare provider prescribes fails to produce the benefit he expects he often responds by changing the medication. Thus, the healthcare provider puts the blame on the medication rather than the patient. Although it is known that about half of the medicines prescribed for patients with long-term conditions are not taken as prescribed, the concerns of health professionals have focused almost exclusively on improving the quality of their own prescribing choices. Yet non-adherence continues to represent a serious therapeutic deficit at the core of medical practice, with consequent massive personal, societal, and economic cost (Marinker, 2003).

Patients may not comply with a medication regimen for many reasons. Non-adherence may be intentional or involuntary. According to Haynes (1996), adherence may relate to the quality of information given, and the impact of the regimen on daily life, the physical or the mental incapacity of patients, or their social isolation. Many

interventions to overcome these impediments have been tried, but evidence of sustained success is scant.

Medication adherence is an integral part of healthcare for patients with chronic conditions. Non-adherence not only causes negative clinical outcomes, but it can also be costly for patients and healthcare organizations (Col, 1990). Unnecessary hospitalization and emergency department visits related to poor adherence cost as much as \$100 billion, annually (Lewis, 1997). Overdosing is uncommon, but delayed doses, missing a single dose, and missing more than one dose are the most common adherence problems.

Another common adherence problem is when a patient misses doses for an extended period, then resumes taking the medication at full dose. This behavior can cause toxicity and adverse effects (Urquhart, 1999).

Characteristics of Adherence and Non-adherence

Medication adherence is measured by the number of doses taken and the impact on the medical diagnosis (Elder, 2000). Non-adherence to medication regimens is common, especially with long-term therapy. It is a serious, but potentially correctable cause of treatment failure and adverse drug-related complications resulting in hospitalization and even death among older adults. Reasons for non-adherence among the elderly are incompletely understood but include complex medication regimens, age-related disease and disability, frank or subtle cognitive impairment, poor understanding of medication use, and inadequate patient-provider communication (Durson, 2001).

In 1990, Dr. Nathan Col demonstrated only a vague relationship between medication non-adherence and socioeconomic status, gender, or marital status, however, people with financial constraints or lack of insurance may not fill prescriptions or return for follow-up office visits.

During the first few months, treatment for a chronic condition has a high discontinuation rate; consequently, the early treatment period is an opportune time to identify adherence problems. Failure to begin a regimen and early discontinuation may be linked to patient perceptions that the treatment has limited benefits or did not help them. Patients who experience adverse effects are more likely to discontinue treatment, however, advising patients of potential adverse effects neither increases the complaints of adverse effects nor prevents medication adherence (Park, 1999).

To some extent, patients and physicians work at cross-purposes when it comes to medications, states Dr. Steven Goldfinger (as cited in Park, 1999) at a meeting on mental health sponsored by the University of Virginia.

Don't be surprised when patients don't take their medicines. Pills don't work if you don't take them. Often, physicians are busy trying to titrate the dose of medication to improve symptoms, only to find out from blood analysis that patients aren't taking any of them. The core of the matter is that we care about effects and our patients care about side effects. Physicians only ask about side effects that they care about. They don't ask about sexual side effects, weight gain, or other side effects that are important to the patients. In fact, medications do not have effects and side effects. They only have effects. Diphenhydramine is the perfect example. If you take it because you have a runny nose, the fact that it makes you drowsy is a side effect. If you take it because you can't sleep, the fact that makes you dry is a side effect. (p. 350)

From the patient's perspective, there is a spectrum of acceptability of therapy. Medications that have an immediate desired effect without side effects are medications that patients want to take. Medications that have little perceived effect and few side effects are less likely to be taken by patients. Medications that have delayed or unwanted side effects and that, in the patient's perspective, treat symptoms that patients don't think they have are very unlikely to be taken by patients (Wachter, 2003).

Although knowledge of disease processes does not aid adherence, patients who understand the purpose of a drug and how the drug is to be taken are more likely to take it

as prescribed. A patient's belief in the efficacy of the medication and faith in his ability to take the medication as prescribed is also critical. Patients are more likely to adhere to a regimen when the relationship with their healthcare provider allows them to express concerns about a condition or treatment, when treatment goals are shared, and when plans are made to over-come identified barriers (Schaffer, 2001).

According to Cohen (2003), at least half of all people stop taking their blood pressure medications because of the side effects that typically include fatigue, lethargy, dizziness, and sexual dysfunction. Cohen states he knows why people do not adhere to blood pressure medication, "The dose is set too high" (p. 5). He takes issue with the prevailing belief among doctors and drug manufacturers that side effects are inevitable and unavoidable. In his book, *Over Dose: The Case Against Drug Companies*, Dr. Cohen says that the drug companies set the dosage for all prescription drugs at a high level because it is more convenient for doctors and not the patient. Thus, drug side effects occur, causing poor adherence to the medication regimen in the hypertensive patient (Cohen, 2003).

To determine medication adherence and predictors of sub-optimal adherence in a community cohort of patients with diabetes and to test the hypothesis that adherence decreases with increased number of medicines prescribed, Richard W. Grant and associates conducted a 30 day study using 128 diabetic patients, with the average patient taking a mean of 4.1 diabetes-related medicines daily. In Grant's (2003) sample, patients reported very high medication adherence rates regardless of the number of medicines prescribed. Moreover, a higher number of prescribed medicines were not associated with poorer per-medicine adherence. Rather, patients with suboptimal overall adherence tended to have problems with one specific medicine out of their overall medical regimen.

Among patients on three or more diabetes-related medicines, Grant found the majority of those patients with less than perfect adherence did take at least one medicine faithfully. Correlates of poor adherence included problems with side effects and a lack of conviction on the patient's part that the medicine was helping either current symptoms or future health.

New research presented at the annual meeting of the College of Psychiatric and Neurological Pharmacists demonstrates that failure to consistently take medication increases the risk of hospitalization in patients with schizophrenia, with a direct relationship between days missed and risks (Manisses Communication Group, 2003). The 12-month study examined prescription records for 4,325 patients with schizophrenia who were enrolled in the California Medicaid system. The main reasons given for poor adherence to medications were the side effects of the drugs and inconvenient regimes (2003).

According to a national survey of 661 patients, even epilepsy patients miss medication doses Kirn (2003). The survey found that 71% of the epilepsy patients acknowledged missing at least one dose of medication in the last month. Perhaps the most relevant finding of the study was that 45% of the patients overall reported that they experienced a seizure related to missed medication at some time in the past. Analysis of the data revealed that the longer a patient had taken epilepsy medication, the more likely he or she was to have missed a dose at some time. It also found that the greater numbers of different medications taken, and the more frequently the epilepsy medication had to be taken, were closely related to missed doses. The odds of missing a dose increased by 27% for each increase in the number of times a patient had to take medication in a day. The number of pills a patient had to take in a day was not found to be related to missed doses.

Patients who do not adhere to a regimen for antidepressants have several defining characteristics. The preliminary results of a survey of 102 outpatients from the practices of 20 Northwest Ohio primary care physicians showed that non-adherent patients appear to be younger, unmarried, and less educated than those patients who adhere to an antidepressant regimen. Of the 102 patients who were in the study, 86% were adherent, which meant that they had been compliant all or most of the time during the previous four weeks with their antidepressant regimen (Evans, 2003).

Asthma is the most common chronic disease in childhood, and it continues to be associated with high rates of morbidity and mortality despite improved treatment protocols. Lack of adherence to individual treatment plans has been implicated in these poor outcomes. Divertie (2002) conducted a study to identify obstacles that might limit adherence to asthma treatment and offer practical suggestions for promoting adherence in pediatric patients. The reasons children fail to adhere to individual treatment plans include financial barriers, misconception about asthma, cultural influences, and mistaken health beliefs. In addition, family education about asthma management can be inadequate without an efficiently run asthma program, which includes telephone access to the provider. By eliminating barriers to adherence, maintaining open communication, and consistent positive support children with asthma can maintain the highest quality of life.

Reviewing all five chronic diseases: hypertension, diabetes, epilepsy, mental health and asthma it is clear that adherence to the medication regimen is critical, yet studies show non-adherence is common. Serum drug levels help measure non-adherence but not for all drugs. The medications taken for the treatment of all four chronic diseases have side effects and are inconvenient to take, and do not fit into the day-to-day lifestyles of many patients.

Psychological Theoretical Framework of Adherence

Golin's (Golin, et al., 2001) meta-analysis focused on understanding the immensely complex phenomenon of patient's adherence to medical treatment. Empirical studies since the late 1960s have raised many questions, some of which remain unanswered in spite of decades of research and a variety of study designs, including Meta analytic methods and multidimensional models. Both of these methods have contributed important results and usually they tell the same story. It is important to recognize that fully understanding the role of adherence in treatment outcomes requires further analysis of the conceptual and methodological factors that affect this relationship, and future research on adherence would do well to provide quantitative data to further this examination. Evidence from the present study complements findings from intervention research to suggest that patient adherence is linked to more positive outcomes than is non-adherence, and thus, adherence may be a valuable goal of intervention.

Angela Hausman (2001) studied the impact on patients' compliance with physicians' instructions of (1) open communication between the patient and physicians; (2) impersonal communication through prescription drug advertising; (3) participation of patients in determining treatment options; and (4) the interactions of these constructs. A convenience sample of 239 patient-respondents was obtained.

The importance of communication, both as a form of information exchange and social support, and of participative decision making, improves patient compliance. These results, based on structural equation modeling, also support the interaction of communication and participative decision-making positively affecting compliance. Frequency analysis shows that drug advertising is highly effective in increasing awareness of the product, but few patients surveyed discussed the advertised drug with

their physician (2001). It is concluded that one-way communication from physician to patient and patient education will not solve adherence problems by themselves. Instead the solution revolves around open, bi-directional information exchange, active listening by both parties, and truly informed consent on the part of patients.

Doctors DiMatteo, Giordani, Lepper, and Croghan (2002) conducted a study that reviewed three decades of research on patient adherence and the outcomes of treatment using the techniques of meta-analysis to combine effects from more than 19,000 patients in 63 studies. On average, 26% more patients experienced a good outcome by adhering than by not adhering to prescribed treatment regimens, a slightly stronger effect than in a study of the outcomes of adherence-enhancing interventions and similar to a recent focused review on adherence and heart disease outcomes. The strength of these effects suggests that the behavioral phenomenon of adherence may be as important to outcomes as many well established medical interventions.

Factors, such as the efficacy of recommendations and treatment, genetic variations in response rates, and limitations in current understanding of disease can affect outcomes. In some cases, such as when misdiagnosis, adverse drug reactions, or prescribing errors occur, adherence to recommended treatment could be harmful. The conceptualization and operationalization of measurement appears to be critical to understanding the adherence-outcome relationship. Reverse causality may also play a role, so that a good outcome may promote subsequent adherence. It is also important to consider the perspectives of patients, many of who may view non-adherence as a rational choice (Donovan, 1992).

Factors that modify the adherence-outcome relationship, particularly those involving the nature of diseases and of patients, appear to be extraordinarily complex. For

example, the adherence-outcome relationship is higher in studies of chronic diseases than in studies of acute conditions. One possible explanation is the illness might be more self-limiting, making adherence less important than in long term care, although several of the moderators were intercorrelated. Chronic conditions involved more non-medication regimens, were less serious, and were more likely to use continuous measures of adherence, all factors associated with higher adherence-outcome correlations. The adherence-outcome relationship was also higher for pediatric patients compared with adults, possibly because of the less serious medical conditions represented in the pediatric samples or because parental adherence behavior may have been accompanied by additional care-taking that promotes better health outcomes. Conversely, the achievement of good outcomes might be more difficult in adults because of co-morbid conditions or long standing poor health habits. This result could also be an artifact of differences between the two groups in their outcome measures. The adherence-outcome relationship was lower in studies of more serious conditions, a finding that could be explained by this variable's correlation with other moderators, or by the possibility that patient adherence behavior makes a greater difference under less extreme medical circumstances (DiMatteo, 2002).

Overall, the outcome difference between high and low adherence is 26% (Golin, 2001). According to stringent random effect models, adherence is most strongly related to outcomes in studies of non-medication regimens, where measures of adherence are continuous, and where the disease is chronic. Inter-correlations among moderator variables in multiple regression show that the best predictor of adherence-outcome relationship is methodological, the sensitivity/quality of the adherence assessment (Golin et al., 2001).

HIV Medication Non-Adherence and Adherence Issues

Taking medication as prescribed is particularly critical for AIDS patients, and the ramifications of not taking medications as prescribed have serious consequences.

Jones (2002) conducted a qualitative study of nine HIV positive patients to explore the experience of daily life of taking combination drug therapy, or HARRT. The purpose of the study was to gain a better understanding of factors relating to HIV medication adherence and non-adherence. Implementation of the study and analysis of the data were done using an integrated method for conducting phenomenological research. Face-to-face in-depth interviews were conducted using three women and six men who were HIV positive. The participants acquired HIV thru occupational exposure, sexual transmission, and contaminated blood products. All nine were taking HIV antiretroviral medications in various combinations. Analysis of all nine interviews revealed six major themes that described the day-to-day experiences in taking their HIV medications. The six themes were: becoming a patient, managing and being managed by the medications, coping with the medications, feeling lousy, negotiating the hassles and the cost, and living under a dark cloud (Jones, 2002).

Flaherty (2003), in a small Chicago study, suggested that attitudes about HIV and AIDS among HIV-infected people can be broken down into types that are predictive of how well the patients will adhere to their medication regimens. If the study's findings are confirmed in a larger cohort, then it will soon be possible for HIV clinicians to predict which HIV patients will have the most difficulty taking their medications based on their presenting attitudes about HIV disease.

It's pretty clear to me that adherence is the key, at least in affluent societies like ours that have access to antiretroviral medication. The people who do well over the long haul are different from those who don't do well, principally on the basis

of being able to take their medications. I think we spend most of our time in the clinic on that issue with patients (p. 38).

What HIV clinicians might sense from their experience with HIV patients is that some patient personalities and attitudes appear to do much better in adhering to antiretroviral regimes. Rachel Power (et al., 2003) examined the relationship of adherence to antiretroviral treatment with three types of social support (partner, friends, and family) and use of two coping strategies (denial and substance use). Seventy-three men and women with HIV infection were drawn from a larger sample of 186 clinical trial patients. Based on inclusion criteria, patient trial participants taking antiretroviral therapies and those with complete data on self-reported measures of adherence were considered eligible for the study. Overall, 26% of participants were found to be non-adherent, which were defined as one or more missed doses of treatment in the prior 4-day period. Logistic regression analysis was conducted to determine the association of social demographic and psychosocial variables with adherence to antiretroviral regimens. Results indicated that heterosexual participants and participants of Latino ethnicity were significantly more likely to report missed medications. Perceived satisfaction with support from a partner was associated with taking antiretroviral therapy as prescribed, whereas satisfaction with support from friends and from family was not significantly related to adherence. Examination of coping strategies showed that participants reporting drug and alcohol use to cope with HIV-related stress were more likely to be non-adherent. These findings call for adherence interventions designed to address barriers and strengths, such as community norms or traditional cultural values, specific to certain populations. Furthermore, couple-based approaches enlisting the partner's support may help persons living with HIV to adhere to antiretroviral regimens (Power et al., 2003).

Social support was also found to play a small but potentially important role in helping HIV-positive people adhere to the complicated schedules for taking their drug “cocktails.” Simoni (2003) conducted a pilot study of primarily indigent Black and Puerto Rican men and women at an HIV clinic in New York City. The study suggested that individuals who had the social support they needed were more likely to take their medications. The pilot project was part of a larger study to assess the efficacy of peer support to enhance people’s adherence to their cocktail or HARRT. “Social support can be as simple as having someone ask if you took your pills today,” said Jane Simoni. In the study, patients were asked specifically about their need in the past month for other people (including friends, professionals or those they live with) to bolster their self-efficacy and to provide information, advice and suggestions about their medications. “Highly active antiretroviral therapy was first touted as a cure for AIDS, but it is difficult to take the medications and to take them at the rate needed to control the virus. But this is not the first time in history people haven’t taken their medicine. Even if we did the perfect vaccine or pill, or magic bullet, people still would have to take it. So adherence would still be a problem” (p.2). Jane Simoni’s pilot study, self-reported data from 50 people, indicated that they took 85% of their medications over the previous 3 days. However, the rates of compliance dropped off sharply when they were questioned more closely about taking the correct number of pills, following dosing schedules and other special instructions. The study showed as many as 60% of people taking the antiretroviral cocktails adhere to their medication less than 90% of the time. Dose effect studies indicate HIV positive people need to take their medicine at least 95% of the time.

Simoni (2003) stated that the daily regimen for the cocktail is not quite as complicated today as it was when the therapy was first introduced. However, the side

effects of the medications remain, and people may experience vivid nightmares, headaches, nausea, diarrhea, rashes, altered liver functions, change in their body's fat distribution and elevated cholesterol levels. Simoni also states the most common reasons given for not taking medications were "I just forgot" by 50% of the patients and "I felt worse when I took the pills" by 46%.

Another group of clinical investigators conducted a similar study that evaluated adherence and rates of virologic failure/success in 886 antiretroviral-treatment-naïve patients beginning triple combination therapy (Low-Beer, 2000). Adherence was estimated by monthly prescription refill data. As with Paterson, they found a significant linear trend of improved virologic suppression across adherence categories, with at least 95% adherence associated with high rates of virologic success. In this observational study, 84% of patients who were 95% adherence had HIV RNA less than 500 copies per milliliter, whereas only 64% of patients who were between 90 – 94% adherent had HIV RNA less than 500 copies/per milliliter (Low-Beer, 2000).

Gifford (2002) also reported on the relationship between self-reported adherence and plasma HIV-1 RNA concentrations among 133 HIV infected adults receiving antiretroviral therapy. While the method of adherence measurement and the examination of virologic response differ from those used in Paterson and Low-Beer, this study also reported a significant relationship between adherence and the level of viral suppression. He also reported that adherence was poor (less than 80%) 28%, fair (80% - 99%) in 23%, and excellent (100%) in 50% of study subjects. Mean decreases in Plasma HIV- RNA from highest ever levels were 1.3, 1.6, and 2.0 in the three groups, respectively ($p < 0.02$).

The study known as the Trilege study (as cited in Descamps, 2000), an analysis of pill counts, resistance assays, and drug plasma levels, suggested that non-adherence was the cause of viral rebound rather than lack of antiretroviral potency or development of resistance mutations. The Trilege study was an induction-maintenance study that evaluated the efficacy of three maintenance regimens that followed an initial induction therapy of three drugs. Patients were randomized to continue their initial induction therapy, or receive dual therapy with one additional drug. All but two patients failing the triple regimen had undetectable drug plasma levels. This study suggests that non-adherence, rather than lack of potency of HAART, can often explain early treatment failures.

HIV/AIDS is a chronic life threatening disease. Like other chronic diseases the treatment requires long-term medication therapy. Also, like other chronic diseases, people are not always adherent to their medication regimens. Several well-known infectious disease specialists have studied this problem. Yet non-adherence remains a problem.

Strategies for Adherence for HIV Positive Patients

Several strategies can be employed in the effort to support patients' adherence, and all members of the multidisciplinary team should, ideally, employ these strategies in combination. Efforts should be made to educate and motivate the patient, simplify treatment regimens and tailor them to individual lifestyles, prepare for and manage side effects, and address the concrete issues that may be a barrier to adherence. Recruiting an adherence monitor, providing memory aids for medication taking, and anticipating course corrections can also help patients achieve the adherence rates needed for successful treatment of HIV infection and disease (Bartlett, 2002).

Measurement of adherence may be important in determining why patients fail antiretroviral therapy. Although patient self-reports are by far the most frequently used means of assessing adherence, self-reporting overestimates adherence. However, patients who state they are non-adherent almost always are. The pill identification test is a recently described tool that may be useful in clinical practice. The best methods of adherence measurement are pill counts and electronic monitoring. Pill counts suffer from an inability to record the time of consumption of therapy. Electronic monitoring enables timing of pill consumption and is the closest to a gold standard for measuring adherence. However, this is only the case if patients are carefully instructed in how to use the device, e.g., not to remove extra doses from their pill bottle (Paterson, 2002).

Cederfjall (2002) studied the relation between self-reporting adherence to antiretroviral treatment and degree of sense of coherence in a group of HIV positive patients. Ninety-nine patients were from an outpatient clinic, all undergoing antiretroviral therapy. Questionnaires were answered twice at a 12-month interval. The 29-item Sense of Coherence (SOC) scale was used for measuring the ability to cope with stressful life situations. Medication adherence was assessed with self-reported measurements. Clinical characteristics and background variables were collected from the medical records. Results from variables measured with the 12-month intervals show a significant concordance with disease stage and in HIV 1 RNA copies per milliliter and an increase in CD4 cell count. The analysis showed significant differences between non-adherent patients and adherent patients at the last measurement, (i.e., the non-adherent group had lower CD4 cell counts and higher HIV1 RNA levels than the adherent group). Finally, multiple regression analyses showed that at measurement 2 the SOC predicted non-adherence, the lower the SOC the more missed doses. Because SOC seems to play an

important role in this group of patients managing their disease, a caring patient-provider relationship should be developed to minimize non-adherent behavior. For this reason, Cederfjall (2002) suggests the SOC scale might be of great clinical value to identify patients needing the most support for successful treatment.

Kathleen Johnston Roberts and Paul Volberding (1999) conducted a study in which they explored how HIV/AIDS care physicians communicated with HIV positive patient about the need for adherence to antiretroviral treatment regimens. The study was a face-to-face interview, qualitative research method with fifteen physicians, and most of which were board certified in internal medicine and / or infectious diseases, all were involved in HIV continuity care.

Roberts and Volberding's (1999) research results concluded that most physicians engaged in both pre- and post- prescription phases of adherence communication with their patients. During the pre-prescription phase, physicians made decisions about offering prescriptions to patients, often based on their beliefs about the patient's likelihood of adhering to therapy. During the post- prescription phase, physicians asked patients how they were adhering to the regimens. Physicians' practices, such as the length of time spent in the pre-prescription phase, the timing of the check-ins in the post prescription phase, and the overall content of both phases varied significantly.

Physicians have diverse ways of communicating with patients regarding adherence to antiretroviral medications. The effect of such communication on treatment outcome needs to be assessed; however, the potential benefit suggests that training programs should be developed to improve physicians' skill in this area.

Physicians estimate their patients' adherence to medications, and base decisions about treatment on these estimates. In HIV, misjudgment of patient adherence can have

adverse consequences, including withholding of therapy, unnecessary changes in therapy, or unnecessary laboratory testing. A review of the literature demonstrates physicians are often inaccurate in estimating patient adherence with antiretroviral therapy. These findings have implications for practice. Standardized methods for adherence assessment are currently available that can be used to enhance physicians' ability to understand adherence behavior and barriers. The patient-physician relationship presents a unique setting for improving adherence. Improved communication, including discussion about patient lifestyle and preferences, can facilitate a frank exchange of information, negotiation, and a spirit of cooperation. Active patient participation in the decision-making process is crucial (Murri, 2002).

Rapid advances in biomedical science, such as pharmaceutical developments for HIV disease, must be integrated with advances in behavioral science to further our understanding of medication adherence. Adherence is a complex dynamic behavior influenced by characteristics of the patient, treatment regimens, disease, patient-provider relationship, and clinical setting. Therefore, the most promising interventions are multifaceted and target different locations in this matrix simultaneously. Unfortunately, non-adherence remains a formidable barrier in the management of HIV, resulting in the development of the transmission of HIV, in general, and transmission of drug-resistant strains of HIV specifically. Despite substantial attention to adherence in recent years, much more remains to be done to better understand and promote adherence to antiretroviral therapy (Ickovics & Meade, 2002).

Paterson (2002) assessed protease inhibitor adherence with Medication Events Monitoring System (MEMS) in 99 subjects in a Veterans Affairs medical center and a university medical center. He found a highly significant relationship between adherence

and viral suppression at three months and noted that failure rates increased sharply with decreasing levels of adherence below 95%. Paterson also reported that physicians and nurses poorly predicted adherence for 41% and 30% of patients respectively.

Several strategies may prove useful in fostering adherence to HAART in adolescent patients. Pugatch, Bennet, and Patterson (2002) conducted a pilot study to qualitatively identify major factors which may correlate with HIV positive adolescent adherence to drug regimens. Six HIV positive adolescents ranging in age from 16 to 24 were interviewed. For each patient data were collected by medical chart review, a brief questionnaire and a semi-structured interview. The major factors found to negatively influence adherence were: strong fear of social stigma relating to HIV disclosure, familial over-involvement in the regimen, a complex drug regimen, medication side effects, poor general knowledge about the HIV infection, and the quality of the doctor-patient relationship (Pugatch, Bennett, Paterson, 2002).

There is no gold standard for monitoring adherence that can easily be implemented in clinical practice. A variety of methods have been used to measure adherence including serum blood levels, medication events monitoring systems (MEMS) that record pill-bottle opening to gauge adherence, and self-reporting questionnaires. Clearly, non-adherence is a problem with patients who are required to take HAART.

The Family Practice Clinic

Family Practice physicians, physician-assistants, and nurse practitioners have as their primary commitment the provision of patient-centered care, which is biopsychosocial-spiritual in nature. Family physicians receive 4 years of medical school training and three years of residency training in Family Practice, physician-assistants receive 4-5 years of bachelor level training in accredited PA programs in colleges or

universities, and nurse practitioners receive two to three years of master's level training in FP nursing. All of these providers also must pass a certifying examination and licensing examinations before they can practice medicine. After their training is completed, these provider can provide the full spectrum of care to their patients, including family centered prenatal and delivery care, GYN services, adult and child preventive serves, managing current and chronic illnesses, and teaching patients how to prevent or reduce the likelihood of further illness. In other words, family practice providers can provide continuity of care and preventive services to patients of all ages, both sexes, inclusive of medical, surgical, obstetric, pediatric, and geriatric addressing the needs of the whole person, biologic, psychological, social and spiritual concerns. In providing continuity of care, the family practice provider may provide the service directly or coordinate and co-manage the care with an appropriate specialist, with another partner in the group, counselor, or another community resource (University of Michigan, 2005).

The family practice clinic is unique in the sense it is a specialty in which general medical care is provided to all age groups. The internal medicine practice or clinic specializes in the study of organs inside the body and diseases of these organs. The pediatric clinic cares for the development of children, usually from birth to 18 years of age. Psychiatry is the study and treatment of emotional, mental, and behavioral disorders. Gynecology is the study of the health care of women, including diseases and normal physical care of the female reproductive system. Obstetrics is the care of women and their fetuses during pregnancy and childbirth, and during he events that come before and soon after birth (Evergreen Health Care, 2005).

Conclusion

Several authors have researched medication adherence in all chronic disease states. Non-adherence to medication is the cause of many reported deaths, also non-adherence is ultimately expensive in the United States because of the loss of workdays and earnings. The number of doses taken and the impact of the medical diagnosis measure medication adherence. Reasons for non-adherence range from simply forgetting, too many pills, and intolerance of side effects caused by the medication.

HIV positive patients who are on medication have been studied extensively. Most studies were conducted in large medical clinics or infectious disease clinics. Simoni (2003) study like many of the others, showed as many as 60% of people taking antiretroviral cocktails adhere to their medications less than 90% of the time. Dose effect studies indicate HIV positive people need to take their medicine at least 95% of the time. No study was uncovered that involved a small family practice clinic. The family practice clinic is a medical specialty in which general medical care is given to all ages and all disease states. HIV positive patients often seek all their health care at the family practice clinic.

The literature review uncovered several issues needed to address the HIV positive person's medication adherence regimens, but not in the family practice setting. The educational opportunities, the patient's life styles and the drug side effects were also addressed in the literature review. However, they were all quantitative research. The method of this study is qualitative.

CHAPTER 3: METHOD

One of the most challenging aspects of treating patients who have HIV/AIDS is finding ways to increase adherence to the often-complicated medication regimen. Many studies have been conducted regarding medication adherence and particularly adherence to HIV related drugs. The literature review revealed that the HIV related adherence studies were conducted in large clinics, i.e.: University, VA Hospitals, and Infectious Disease HIV/AIDS Clinics. However, not all people who are infected with HIV seek medical attention at this type of clinic. Family practice clinics also care for the HIV infected patient. These clinics offer more than HIV/AIDS care. The family practice healthcare providers care for the patient's entire healthcare needs. This includes everything from the common cold to major chronic healthcare issues. There is a need to study the HIV patient and their medication adherence within the family practice clinic.

It is not uncommon for the family practice healthcare provider to have longer patient-provider time. Because multiple healthcare issues are being cared for in the family practice setting, the healthcare provider may have more in-depth knowledge of the HIV/AIDS patient's and personal well being. This may make a difference in understanding the adherence problems noted in the literature review.

The research question can be addressed; What issues need to be addressed in order for the HIV positive person to adhere to their medication regimen in the family practice setting. Along with answering this research question three sub-questions will be addressed: What educational opportunities were available to the participants concerning

their drug therapy, What is the participant's day to day lifestyle, including routine schedule, and What side effects of HARRT most concern the participants?

Research Design and Rationale

I explored the meaning of adherence and non-adherence to HIV medication. This study was a basic interpretive qualitative research design (Merriam, 2002). A central characteristic of qualitative research is that individuals construct reality in interaction with their social worlds. Constructivism thus underlies what is called a basic interpretive qualitative study. Here the researcher is interested in understanding the meaning a phenomenon has for those involved. Meaning however "is not discovered but constructed. Meaning does not appear in the object, merely waiting for someone to come upon it...Meanings are constructed by human beings as they engage with the world they are interpreting" (Crotty, 1998, p. 42-43).

Phenomenology and symbolic interactionism also informs interpretive qualitative research. From phenomenology comes the idea that people interpret everyday experiences from the perspective of the meaning it has for them. Thus, drawing from phenomenology and symbolic interaction in particular, qualitative researchers conducting a basic interpretive study would be interested in (1) how people interpret their experiences, (2) how they construct their worlds, and (3) what meaning they attribute to their experiences. The overall purpose is to understand how people make sense of their lives and their experiences (Merriam, 2002).

This basic interpretive study showed how HIV positive people interpret their experiences of taking their antiretroviral medications and what meaning they attributed to their experiences. The purpose was to understand the nature or identify the issues of

medication adherence issues with the HIV infected patient in the family practice setting. The data was collected from face-to-face interviews conducted over 30 to 60 minutes.

Participants and Site

The informants were purposively selected (Gliner & Morgan, 2000). This procedure was used to select a sample from the participants, or groups of participants that were judged to be appropriate or especially informative for the purpose of this research. The participants were handpicked from the accessible population using specific criteria.

The participants were located through my professional, academic network. A letter of agreement from the organization, (family practice clinic) on letterhead was obtained. None of the participants were my family members, personal friends, or actual patients of mine. The formal setting of the interviews was on site at the family practice clinic on a scheduled date and time. All interviews took place in a private room. The participants all spoke English as their first language.

The healthcare providers handed out an information flyer (see Appendix A) to prospective participants asking for their participation. The participants included were HIV positive patients who receive their total healthcare at a selected family practice clinic in a western state. They all have been HIV positive for ten years or greater and have been on Highly Active Antiretroviral Therapy (HAART) drug regimen for 5 years or more. All participants work full time in a variety of jobs and are not considered critically ill.

After 15 participants were interviewed, I felt the information I was receiving from them became repetitive, and saturation had been reached. After I began to code the conversations I found saturation and repetitive themes began after the 12th interview and complete saturation occurred by the 15th interview.

The family practice clinic is located in an upper class, urban neighborhood in a mid-western state. The clinic is considered to be gay friendly and advertises in the local gay newspaper as a well-established diverse medical clinic, and HIV knowledgeable. The clinic cares for all age groups and all general healthcare issues. The clinic has a total of four healthcare providers. Three out the four providers are openly gay. Two of the providers are family practice physicians and two providers are mid-level providers (physician assistant and nurse practitioner). The clinic gives healthcare to nearly 3,000 patients and approximately 1,200 of those patients are HIV infected.

Data Collection

The Colorado State University Human Research Committee application to use human subjects was completed and reviewed by the committee and principal investigator. The primary means of data collection was a semi-structured interview with open-ended questions that lasted approximately one hour and was audiotaped. Three of the participants refused to be audiotaped, so only handwritten notes were taken by me. Prior to the interview the participants were advised of the informed consent to participate in a research project and were required to sign the consent (see Appendix B). Participants were asked open-ended questions. The participants had the opportunity to elaborate as much as they would like on each question and to give the best answer they felt was appropriate. The following are the questions I asked each participant.

1. What HIV educational opportunities are available to you?
2. Explain the HIV medication opportunities available to you in the past 5 years.
3. Where did you get the most HIV information regarding your medication regimen?
4. How much Internet access do you have regarding HIV and HIV medication?
5. What learning material is most useful to you?

6. Explain your day-to-day lifestyle, including your routine schedule.
7. Explain the ease or difficulty of remembering to take your pills on a timely manner?
8. What concerns do you have while you are on HAART?
9. Are meals routinely skipped during the day?
10. What do you consider a meal?
11. How much travel do you have, vacation or work?
12. How does health insurance or the cost of your medication affect you and your lifestyle?
13. What type of dietary restrictions are you presently on?
14. What side effects have you experienced while on Highly Active Antiretroviral Therapy?
15. Which drug side effects are the most difficult to control or concern you the most?
16. How many pills do you take daily and how often?
17. Are you on other medications that are not related to HIV?
18. If you were able to make changes to your medication regimen, what would they be?

All participants were interviewed at the family practice setting during their routine three-month HIV/AIDS examination. Data was analyzed throughout the study. The data was coded according to the constant comparative method until themes began to emerge.

After the interviews were conducted a copy of the participant's transcripts were given back to them for review. A new consent form was signed because the first consent did not give me permission to re-interview. The second consent allowed a re-interview

which helped me to uncover further research information, and it allowed the participants to determine whether they thought the information was accurate.

Data Analysis

From the principals of grounded theory, I attempted to derive themes by using multiple stages of data collection and the refinement and interrelationship of categories of information. Two primary characteristics of this design are the constant comparison of data with emerging categories, and theoretical sampling of different groups to maximize the similarities and the difference of information (Strauss & Corbin, 1990).

Some design types in qualitative research have detailed protocols for data analysis. For example, Strauss and Corbin (1990) provided a series of data analysis steps that consist of open coding, axial coding, selective coding, and the generation of a conditional matrix. In this process, the researcher attempts to saturate categories by “constantly comparing” incidents with incidents until categories emerge and through the sampling of informants that will lead to the development of categories.

The constant comparative method of qualitative analysis worked well to help analysis the collected data from the face-to-face interview of all participants. After I reviewed each interview, I started with a simple coding process of each transcript. This step starts by coding each incident into as many categories of analysis as possible, as categories emerge or as data emerge that fit into an existing category. Which meant I coded important comments from each answer that was given to me. The codes related to adherence. This step started to generate theoretical properties of the category. The analysts gave a full range of the types of categories and the dimensions. I then found the common themes. I re-coded the themes into three groups. This process started to change from comparison of incident with incident to comparison of incident with properties of

the category. This was the start of answering which the research questions. The three categories were educational opportunities, lifestyle and side effects. The third coding process was more specific to my research questions. This step of coding began to delimit two major categories. These categories were what shapes the nature of adherence and what motivates adherence or does not. The purpose of constant comparison method of joint coding and analysis is to generate themes more systematically. Two themes emerged. The first theme was welling being and the second theme was life long commitment. This method of comparative analysis is to be used jointly with the sampling, whether for collective new data or on previously collected or complied qualitative data. The constant comparative method is designed to aid the analyst in generating themes that are integrated, consistent, and plausible. Still dependent on the skills and sensitivities of the analyst, the constant comparative method is not designed to guarantee that two analysts working independently with the same data will achieve the same results: it is designed to allow, with discipline, for some of the vagueness and flexibility that aid the creative generation of theory (Glaser, 1967).

Trustworthiness

The trustworthiness refers to trusting the data and not the participant trusting the researcher. Trustworthiness of this study is very important and refers to the believability of the findings. The trustworthiness increases the study's validity and verification. This was established through member checking, researcher's biases, the confidence of safety, and deserving credibility (Merriam, 1998).

Member checking was conducted by taking data and tentative interpretations back to the participants interviewed and asking them if they agreed with the results. This was done through out the study. While the researcher may have used different words,

participants should be able to recognize their experience I the interpretation or suggest some fine-tuning to better capture their perspectives (Merriam, 2002).

The researcher's biases clarified any assumptions that were made prior to the onset of the study. Such as, directing the participants towards a particular course or answer. This allowed an open and honest narrative. Merriam (2002) states by identifying bias and monitoring them it sharpen the collection and interpretation of data.

Safety is the state of being safe. This study exempts all participants from loss or the state of not being liable from danger or injury. The participants were not considered to have passed or failed in regards to their answers. This was made clear to everyone involved in this research. Psychotherapy was available to the participants if needed prior to and after the interview.

More over the federal government has established regulations to protect human subjects in biomedical behavioral, and social research. Professional codes and federal regulation deal with issues common to all social science research, the protection of subjects from harm, the right to privacy, the notion of informed consent, and the issue of deception (Merriam, 1998).

Credibility commands belief and was established through a personal journal that was kept during the process for personal reflections of each interview. This journal allowed the researcher to reflect on what questions or responses seemed comfortable/uncomfortable to both researcher and participant. Each participant was allowed to review his or her response to each question and make changes in their answer. No participant made any type of change to the transcription. Also a copy of the final report will be available to each participant. Each participant was given a fictitious name. The name is related to correct gender only.

CHAPTER 4: FINDINGS

Through a basic interpretive qualitative research design (Merriam, 2002) research was conducted to investigate the issues that need to be addressed in order for the HIV positive person to adhere to their medication regimen in a family practice setting. A central characteristic of qualitative research is that individuals construct reality in interaction with their social worlds. Constructivism thus underlies what Merriam (2002) is calling a basic interpretive qualitative study. Here the researcher is interested in understanding the meaning a phenomenon has for those involved.

Meaning, however, “is not discovered but constructed. Meaning does not inhere in the object, merely waiting for someone to come upon it... Meanings are constructed by human beings as they engage with the world they are interpreting” (Cotty, 1998). Each participant was given an opportunity to voice his opinion and tell his personal story regarding the difficulty of adherence to an HIV medication regimen. Also, several questions were asked of each participant. It should be noted that each participant gave unique answers and each story was profoundly interesting and interestingly there was a common set of findings.

Participant Adherence Stories

Sam is a male in his late forties who was diagnosed with being HIV positive for greater than 10 years. He is self-employed and owns and operates a very successful business. He states he was in denial of his disease for the first year. He refused to take medications and was not willing to follow up with his doctor. He said he was angry at the world due to his diagnosis. It was not until he became very ill that he decided it was time

to start medications. He feels the HIV medications have saved his life but he has had many complications with his drug side effects. He is presently on a simple drug regimen that consists of two pills in the morning with breakfast and two pills in the evening with dinner. He rates himself as being “about 95%” adherent to his medication regimen. He sometimes forgets the evening dose due to his busy work schedule.

James is in his early thirties and states he has worked for the U.S. Post Office for 10 years. He enjoys being a mail carrier because he loves the outdoors and the independence of his job. He was diagnosed being HIV positive when he was 25. He said it was a complete shock to him. He only had a few sexual partners prior to his diagnosis and he thought his sexual practice was safe. He said the worst part of being told you are HIV positive is telling your family the news. He has been on several different HIV medication regimens. He claims that he became resistant to the drugs because he did not take the disease seriously and had very poor adherence. He stated, “I only took the drugs when I felt like it.” He now says he has a better understanding of the disease process and only misses a few pills a month.

Patrick is a male in his late thirties who recently moved from California to Colorado because of a job transfer. He was diagnosed with HIV seven years ago. He said he remembers the date, time, and place well. It was a major lifetime change. Prior to his diagnosis he called himself a “carefree type of guy.” He had several sexual partners but never thought he would contract HIV. He started HARRT five years ago and states he tries to be as adherent to his medications as possible, but due to his business travel he either forgets to pack his medications or does not have time to take them. He hopes now that he has moved to Colorado his traveling will decrease and he will be better about taking his drugs.

Joe states he is a landscape architect. He said he could only have a job that gives him the freedom of being outside. In his words, "If I had to be indoors all day and wear a tie, I would die." He was diagnosed being HIV positive when he was 30 years old. However, he has only been on HARRT for 5 years. He said he did not start medications early in his diagnosis because he knew it would be a lifelong commitment and he was not prepared for that type of commitment. He feels he is very adherent to his medications," I never leave home without them." He did have issues with side effects when he first started to take the drugs. He once again experienced the side effects when his regimen was recently changed. He claims the side effects lasted about two months.

Fred is a restaurant owner. He works 12 hours a day and usually does not get too much time for anything else. He said he was 45 years old and has been HIV positive for 12 years. He has been off and on HARRT for several years. His lifetime partner is also HIV positive. He can recall days when he was very ill due to his illness and he can recall many days that he was ill due to his medications. Because he has a very busy work schedule he has told his doctor that he would only take HIV medications that were easy to take and only once a day. He has told his doctor that he refuses to take any medication that would cause severe fatigue or nausea. He states he is about 95% adherent to his present HARRT regimen. Because he deals with the public so much he also refuses to be on any medication that could cause body changes. He once was on a medication that caused severe diarrhea, which made his workday difficult. Presently he is having problems with his weight. He is 6'2" and only weighs 145. His doctor has told him that he may have to start on growth hormone therapy, which may interfere with his daily lifestyle. He stated he understands that HIV is a lifelong commitment, but feels it is more of a punishment.

Gerald claims he can tell you the exact day he was infected with HIV. He has been infected with HIV for 10 years. His lifetime partner is also HIV positive. He met his partner at a support group. Prior to meeting his partner he felt since he had contracted the disease, he would always be alone. His medication regimen is somewhat complicated since he has to take some of them on an empty stomach and some of them with food. Also, his medications are taken three times a day. Presently he remodels homes for a living and can set his own hours of work.

Paul is the lifetime partner of another participant. He said he agreed to participate in the research study because his partner encouraged him to. This participant is a CPA. He has five very busy months out of the year and then in his words, “relaxes and gets ready for the next tax season.” Like his partner, he is 43 years old and has been HIV positive for 10 years. He is very conscious of any body changes and his well being. He takes several types of vitamins and mineral supplements. He said he works out at the gym up to five times a week. He is also very interested in his blood counts each visit. He reported that he keeps a book of all his records and past and present medication regimens. He loves to travel on his free time. However, he does not like to travel with his medications. He was once stopped at the airport and his luggage was searched. He was taken into a private room until proper medical authorities could identify his medications. He hates to miss his medications because he usually has the side effect of nausea if he is not consistent. He said he has seen several doctors because of his disease and has finally found the healthcare provider he can trust.

“Finding out” is what Jess said he is always worried about. He is in his late forties and states he always worries that someone at his workplace will find out he is HIV positive. He works at a bank and has been with the same banking service for over 20

years. He repeatedly complains about the inconvenience of his HIV medications. If he is not worrying about someone finding out at work he is worrying about getting sick. His health and well being are very important to him. He has been HIV positive for at least 12 years. He states he does not smoke or drink alcohol because he does not want his immune system to get weak. His HIV medication regimen is twice a day. On his business trips he hides his drugs to avoid anyone asking him questions. He states he is very proud of his accomplishment and wants to be around for a long time. He claims to be 100% adherent to his medications.

Thomas was very eager to be interviewed. He is a very thin athletic guy. He usually has his bicycle helmet with him because he prefers to ride a bike than drive a car. This participant is 43 years old, but gets compliments all the time about how young he looks. He has been HIV positive for 8 years and on medications for at least 5 years. He states he had a very rough time with the medications when he first started taking them. He suffered from severe fatigue and nausea. His lifetime partner died of complications due to AIDS five years ago. He says he has seen what HIV/AIDS can do to a body and he will try anything and everything to prevent the tragedy of AIDS. He still has problems with remembering to take his medications everyday.

Joshua is the oldest participant in this study. He frequently stated his age during the interview as 58. He says he cannot remember not being HIV positive. In reality, he has been positive for 19 years. He contributes his long HIV life to his constant awareness of well being. He is moderately overweight, does not exercise; however, he does not drink alcohol or smoke. He claims the only thing he does correctly and on a regular basis is take his medications. He can recall the days when there were not a lot of choices in regards to HIV medications. He said during his interview that when he was first

diagnosed with HIV 19 years ago, he was told to go home and prepare to die. He knew immediately he would not let the disease or any doctors tell him how to live his life. "I am 100% adherent to my HIV medications. Always have been and always will be." He also takes several daily dietary supplements. He sold his dry cleaning business three years ago and has started to travel. During his HIV history he has had difficulty with different medication regimens. He is presently on a twice a day regimen, but also takes medications to control his blood pressure and elevated cholesterol. He said his medicine cabinet looks like a pharmacy.

The youngest participant is Zachary. He stated he was only 30 years old and has only been HIV positive for 10 years, but feels much older and feels like he has been HIV positive most of his life. He has been working as a flight attendant for the past six years. He started HARRT immediately after being diagnosed. He was shocked to find out he was HIV positive. At 25 years old, he thought he was too young to contract such a deadly disease. He had a good job, his family was well respected in the small community where he grew up, and HIV was only seen in the poor minority population. He has experienced many different side effects of the HIV medication, which have interfered with his work performance. He feels he has his medications under control and his side effects.

Andrew is in his early fifties. He said he has been working for an advertising agency for many years. His job takes him to various parts of the country. He has been HIV positive for 10 years. This participant likes to lift weights as part as his exercise regimen. His face is thin, most likely due to the HIV medication he is on. He is well aware that he has had body changes since being diagnosed as HIV positive. He is not happy with current HIV regimen and plans to switch drug plans on his next office visit. He said he is simply on too many pills. He has friends who only take one or two pills a

day and he wants an easier regimen and one with fewer pills. This participant said he feels HIV and his HIV medications run his life for him.

Casey is 39 years old and travels from the western slope of Colorado for the HIV care. He does not feel comfortable with the healthcare providers in his town. He works from his home and does computer consulting. He states he likes computers more than he likes humans. He has been HIV positive for 7 years. His former significant partner was HIV positive also. He is presently single and says it is difficult to date when you have HIV hanging over your head. He started HIV medications immediately after finding out he was positive, but two years later he stopped all medications to try an alternative holistic approach. Within two years his viral load had tripled and his immune system began to fail. He realized he had to make a lifelong commitment to the therapy and started up on a new and easier drug regimen. He claims to be at least 95% adherent to his therapy.

“I was 21 and dumb when I contracted HIV,” stated Kevin. He is now 41 years old and feels he is doing very well physically and mentally. “I have been HIV positive for 20 years and it has not been easy.” He was diagnosed with AIDS when he was 30 years old. He states he refused to take his medications because of side effects. He states the drugs interfered with his social life. He had returned to college and felt the medications caused him to be too fatigued to study. He took no medication for several years before he developed a pneumonia that was related to AIDS. He is now on his fourth HARRT regimen. He said he has graduated from college and works as a store manager for a home improvement company.

Austin stated he was a travel agent. He loves to travel but hates to take his medications with him. He has been HIV positive for 10 years. He found out he was

positive when he went to a Sexual Transmitted Disease (STD) clinic. He said he did not tell anyone for two years. He finally went to his primary healthcare provider and began therapy. “I was concerned about my future and well being so I thought it was time to let someone else in on my secret.” He states he never felt sick until he started the HIV medication. Eventually the drug side effects lessened. He started a support group for other HIV infected persons and an HIV newsletter that has a mailing list of over 900. He feels the more informed a person is in regards to HIV the more adherent and safe their lives will be.

All 15 participants have a different story regarding their HIV disease and the antiretroviral medications they’re presently on. An issue they all have in common is they all have had problems adhering to the drug regimens. They agree that the educational opportunities have greatly increased regarding the medications, but still find they battle problems such as drug side effects, frequency of taking the medications, and the amount of pills they have to take. These HIV infected participants have very active lifestyles. Their adherence issues center on their well being and the acceptance of HIV as being a lifelong commitment.

Two Broad Contextual Themes

Two themes appear to capture the meaning of adherence and non-adherence. Adherence is important to the well being of the HIV infected person and adherence is a lifelong commitment. These are driven by lifestyle and drug side effects.

Well being

Several of the participants stated they wanted to improve their lives. Joshua stated he never thought he would have to commit to taking medication for the rest of his life.

His lifestyle had completely changed once he started HAART. He felt as though he has to plan his day around taking his medications.

I take my medication everyday because I don't want to get sick. I want to lead as normal a life as I can. My well being is not only important to me but also to my lifelong partner. (Joshua)

My family depends on me to be healthy, because I am the primary financial provider for them. Without my income we would be on welfare. (Sam)

It is not socially acceptable to be sick all the time. So I take my medications and adjust my lifestyle to accommodate my medications. (Fred)

Seeing HIV in a more positive light contributes to the well being of the infected person. Sam stated he describes being HIV positive as a challenge rather than a threat. For instance, he associates it with a greater psychological well being which results in a lower level of depression. Other factors such as his social support and the ability to cope with his disease contribute to his good overall mental health.

I was in a down hill lifestyle. I partied every night. Some times waking up in places I had know idea how I got there or where I was. Once I found out that I was HIV positive, my well being completely changed. It was a major wake up call to me. I began to eat healthier, I started to exercise and I paid more attention to my job and family. I am now on HARRT and try to be adherent to the medication. (Zachary)

It was not until I was diagnosed being HIV positive that I started to take care of my self both physically and mentally. (Fred)

Living with HIV does not mean you can't enjoy your life. (Austin)

Living healthily and finding a balance can helps the HIV infected person to enjoy each day to the fullest. (Andrew)

Many participants in this research project voiced their concerns about medication adherence and how it is related to mainly other well being factors such as exercise, nutrition, and the reduction of stress in their life. They agree that basic exercise is important for everyone, no matter what your physical condition. In addition to toning

muscles and improving strength, exercise can greatly improve the immune system and help you feel better about yourself, which is especially beneficial for those living with HIV.

It seems that when I exercise regularly, I also take my medications on a regular basis. I just feel better about myself and want to continue to look and feel good. So I guess that makes me want to be more adherent to my HIV medications. (Andrew)

I have chosen an exercise program that I enjoy and incorporate into my regular routine. It is as simple as walking, lifting weights, and swimming. It makes me feel good about myself and in return I am more adherent to my HIV medication regimen. (Thomas)

While some stress is actually necessary for you to function at your best, too much takes a mental and physical toll. Several participants said they have learned to manage stress levels to prevent anxiety, depression and other mental health issues.

There are times I am so stressed out because of work or personal reasons; I simply forget to take my medications. That is when I know I need to get more focused. Stressing about work has gotten me trouble more than once regarding my HIV medications. (Paul)

I am seeing a psychotherapist right now to help me with my stress and other mental health issues. He too realizes how important it is for me to adhere to my medications. When I am overwhelmed or slipping into a depression, I am less likely to take my medications. (James)

I am hopeless in remembering to take my HIV drugs if I start to have anxiety attacks due to stress. I have learned to seek help when this happens. Also I have learned to set a time frame, then block out when I will accomplish certain tasks. (Fred)

Part of well being is good nutrition. The participants were concerned about eating well balanced diets and taking their medications. Joshua said he was always confused about which pill he was supposed to take on an empty stomach and which pill he was suppose to eat something first.

I have begun to work closely with a dietitian and personal trainer. I want to be in the best health as possible. That means eating right, exercising and being adherent to my medication. (Thomas)

Another part of well being that emerged during the interviewing process was the necessity of planning. While it may sound obvious, many participants said they find themselves running short of one or another drug for a variety of reasons. This was often because of poor planning.

I get my medications mailed to me through a mail order pharmacy in a different State. I just take it for granted that the warehouse will mail my drugs on time. There have been times when I have ran out of medications before the new shipment has arrived. (Fred)

I live in a small town and sometimes the local pharmacy does not have my HIV available when I need them. So I have to wait for the pharmacist to reorder the drugs. That could take up to three days. (Casey)

Some drugs have different storage requirements than others, so the participant's planning must also address the storage needs. Fred said he puts aside a full week's supply of medications in an accessible place right after getting his drugs, and then starts using the rest of the his supply. This creates an emergency stash should unforeseen circumstances cause his basic supply to run short.

A few participants expressed their general well being as changing for the better since they were diagnosed with HIV and having started HARRT. They felt they took their general good health for granted, and did not give it much thought. A few exercised daily and tried to eat the right foods, but never thought about the consequences of contracting a chronic and possibly fatal disease such as HIV. Since being diagnosed with HIV and having to take handfuls of pills they find themselves being more conscious about what they eat, where they travel, and other medication they may have to take. They no longer consider a simple cold a simple cold. They realize that since their immune

system is compromised they have to increase their healthcare awareness. A simple head cold can now lead into serious respiratory complication.

Paul explained how his well being and HIV medications are related. He stated the main thing to understand is what the treatment options are and how to strike a balance between controlling HIV and maintaining a good day-to-day quality of life. By preserving the health of the immune system so it can fight disease HIV treatments can keep people well and active both now and in the future

Lifelong Commitment

The outlook on HIV disease has gone from a death sentence to one of guarded optimism. HAART has produced substantial improvements in viral blood levels, illness episodes, quality of life, and death rates. This all comes from being committed to taking medications for the rest of your life. As Paul stated, “I take my medications to live to see another day.”

The participants are well aware that missing just two drug doses can result in increased levels of virus in the body or resistance to the drug, derailing their effectiveness. They state the healthcare providers constantly remind them that maintaining HIV control requires a near perfect score in drug adherence. But some drug regimens for HIV are hard to stick to. The drugs can be difficult to tolerate. In addition, some regimens require upwards of 20 pills per day, pills that must be refrigerated or taken at particular times during the day or pills that must be taken with or without food. The participants want to have the “perfect score,” but find the level of difficulty is high, and the risk of failing is even higher.

The participants voiced their concerns about having to take medications on a daily basis. However, they realize that once they start the medications, it is a commitment for life.

Once I accepted the fact that I was HIV positive, I had to work on the fact that I would eventually have to take medications for the rest of my life. It is a commitment you hate to accept. I delayed starting medications as long as I could. I knew it would possibly slow down my busy lifestyle. (Jess)

I have been on HIV medication for a long time and everyday I wish I did not have to take the drugs but it is my disease and it is not going away very soon. (Joshua)

The participants agreed that managing HIV was a lifelong commitment; meaning the disease was not curable and it needs to be handled like any chronic disease. As one participant stated, his routine health exams were essential and preventive medicine was more important than ever.

I am HIV positive and will be that way for the rest of my life. It is up to me to stay well, follow the advice of my doctor, take my medications, and prevent further damage to my body. (Jim)

It frustrates me to think that I will have to take some type of medication for the rest of my life. This is the result of my past reckless lifestyle. I am now committed to stay healthy. It is my disease. I will not allow it to control me. (Zachary)

Sam is a healthcare professional. He states he looks back at his entire HIV experience as being educational. He has had several therapy changes and has dealt with his own issues of how many times a day he has to take his medication and whether he needed to take it with food or not. However, he also deals with other HIV infected patients every day and he feels he can relate to what they are going through. It helps him realize that being HIV positive is a lifelong commitment to taking pills and staying healthy.

Adherence is the key to a successful drug regimen. If a person is willing to take their medications as prescribed every day, then they're more likely to keep the

viral levels down in their body and have a more successful therapy. Any time anybody slips up, and people do slip up. There have been times where I've missed a dose myself, and sometimes things happen where you just can't help it. I've had several patients come into my workplace that have had various and sundry issues with taking the medications that have been prescribed for them. They need to try the medication first if they haven't ever been on it before. They need to try it first to see if it'll work. Not everybody will experience the same side effects from the same medication. Not everybody will experience side effects at all. I always end up telling them that this is a lifelong commitment, and you don't always get it right on the first try. (Sam)

Most of the participants stated they refused to start a HIV medication regimen until they absolutely had to. They knew it would be difficult and once they started they were committed to the therapy. Typically the medications will be dosed two or three times a day. When the medication has been prescribed to be taken twice a day the patient should try to take it every 12 hours. If their instructions are to take it three times a day, they should take it every eight hours.

I feel if the doctor is going to prescribe a medication for me and he wants me to take it for the rest of my life, then he better make sure that the drug only has to be taken once a day. Any more than that and I'll forget taking it. (Fred)

Setting up a good relationship with the healthcare provider is critical for maintaining adherence and plays a role in the lifelong commitment of HIV therapy. Healthcare provider variables that affect adherence include whether the provider developed trust with the patient. Many of the participants voiced appreciation toward the healthcare provider who takes the time to develop a tailored treatment plan to fit their lifestyle. They want a provider who has a good treatment alliance with them, one who telephones the patient at critical times, and who helps develop the patient's belief in the medication regimen effectiveness. Patrick said his first doctor did not seem committed to taking care of the HIV infected patient and that made him feel less willing to commit to

the treatment of HIV. Once he found a doctor whom he felt was committed to the treatment he then felt committed to take the medications as instructed.

I have been told several times by my doctor not to miss any doses of my HIV medication regimen. However, that is not as easy as he thinks. I always tell him if he took these drugs as long as I have he would skip a dose once in a while too. (Joshua)

I know the importance of taking my medications daily and not missing a dose, but after a while you just want to take a break from the drugs. (Joe)

I stopped taking my medication last summer because I was going to be out of the country. I figured it is my disease and I will have it the rest of my life so I'll take breaks when I want to. (Kevin)

The HIV positive person who missed or stopped taking their medications did not feel sick immediately. They stated they felt fine without taking their medications.

However, many patients stated they learned the hard way about stopping or missing doses.

I stopped taking my medications. I did fine for over a year, and then I began to lose weight and developed a cough that would not go away. My HIV blood work was drawn and my viral levels had drastically increased and my immune system had crashed. I ended up in the hospital with a life-threatening pneumonia. I learned the hard way. I now know HIV is a lifelong commitment and my goal is to stay healthy. (Patrick)

Stopping and starting my HIV drug regimen did not mean anything to me until I discovered that I had developed resistance to many of the drugs. The virus had mutated, which caused many of the drugs to become ineffective to the HIV. I am now on a multiple drug regimen, which is not easy to take, but it is my fault for not being adherent to the simpler regimens. (Kevin)

The participants seem to have a good understanding about their future and the importance of taking their medications on a daily basis. They want to improve their lives by better understanding the disease and being proactive with their health.

Issues Related to Well being and Lifelong Commitment

Despite the grave consequences of non-adherence to HAART, control of HIV is only maintained effectively if treatment is not interrupted, respecting not only the number of pills, but dosage conditions. A treatment regimen can be complex and several areas need to be considered with regards to adherence failure. Description of the patient's HIV educational opportunities, their day-to-day lifestyle, and the medication side effect emerged from the participant's stories.

HIV Educational Opportunities

Participants in this research study have been infected with HIV for several years. They have been on some type of antiretroviral drug therapy for at least five years. The participants agreed that the opportunities have improved over the past five years. Several of the participants believed the community and the healthcare professionals have become more educated regarding HIV because the disease has been around for a while. Some of the participants stated that they believe people want to know more about HIV/AIDS and are not afraid to ask questions about it. The private organizations such as Colorado AIDS Project have spent more money along with the government to educate the general public, the infected patient, and the healthcare workers.

Several opportunities are available now. Unlike ten years ago when I had no place to turn to. The AIDS educational centers were hidden in back alleys and no one spoke of them. (Kevin)

There are several AIDS Service Organizations available now. Even small towns have support groups you can attend to receive HIV information. (Gerald)

It is wonderful the way time has changed the stigma of HIV/AIDS. You can even find AIDS in the local newspaper regarding support groups and information regarding HIV medication. (Austin)

Most of the participants have computer access and utilized the Internet almost daily to retrieve information about their medications or other HIV information. As Jess said, "Who doesn't have a computer these days?" The Internet allows anyone the freedom of being anonymous. It gives the person the right to research any subject at anytime. James said he does not use the computer very much because he finds computers to be confusing; however, he does own one and uses it only for emailing and entertainment. The other participants utilize the Internet on a regular basis.

I depend on the Internet for most of my HIV information. I don't always believe what I read, but at least it is easy to find the information. (Paul)

I work in front of the computer all day, so it is easy for me to access information through the Internet. I even bring information to my doctors that I have found on the Internet. (Paul)

Another common thread that was noted is the participants depend on their healthcare providers for information about their disease and the medications they are placed on. There are several other levels of the healthcare profession that have primary care of the HIV infected patient. In addition to doctors, these other healthcare providers often include Registered Nurses, Nurse Practitioners, Physician Assistants, public healthcare workers, and psychotherapists. James stated he depended on his doctor to keep up on all the latest HIV drug regimens and educational literature and then pass it on to him. Although this is an ideal concept, he said he realizes it is not always possible for the doctor to collect all the latest information and pass it along to his/her patients. The majority of the participants felt their healthcare provider gave them a good start in regards to the educational opportunities and information, but lacked with continuation of information or they had poor follow-up. Participants felt they need to stay up-to-date with the latest information regarding drugs, immunization, and general well being.

My doctor is wonderful and very up-to-date on HIV/AIDS. However he does not always pass along important information about my disease. I have to be very specific with my questions to him or I'll leave the office without new information. (Jess)

In the beginning, my doctor(s) gave me a lot of information and pointed out the educational opportunities that were available to me. I depended on them to give me the most up-dated data. Although I still depend on them for this information, I now do my own data research. (Gerald)

Support groups are another opportunity for the HIV positive person to get information about their disease and about the medications available to them. Several local and national groups advertise in the various newspapers and magazines. Austin stated he felt the support groups were more beneficial early in his disease process. They gave him the opportunity to meet other HIV positive people and to help him understand the importance of adhering to his medication regimen. There are many support groups available. Friends and family are just as important. Outside support is very important to an HIV infected person.

Colorado AIDS Project has been a major part of my life since I found out I was HIV positive. (Fred)

I try to attend as much community based AIDS/HIV workshops as possible. (Joe)

The majority of participants felt the pharmaceutical information was biased and over glamorized the particular product they produced; however, there were certain educational items that all participants appreciated, such as pill charts that showed the various HIV medications and the dosing regimens. Also the various adherence reminders such as the pillboxes.

The majority of educational material that is given out by the pharmaceutical companies has a heavy emphasis on their product, and usually one-sided. (Thomas)

The pharmaceutical companies have been very helpful in regards to sponsoring various AIDS awareness classes or workshops. (Sam)

It is nice to know that the drug companies are involved with HIV education and helping with drug adherence issues. (Gerald)

I like to attend the pharmaceutical company educational programs because they usually provide a meal along with the lecture and the program is free. (Fred)

Lifestyles

Everyone has a different lifestyle and the HIV infected patient seems to be no different. To put this section in context, early in the history of the HIV disease process the infected person felt as though they were given a death sentence. Many gave up their jobs and careers and prepared for death. Several of the participants stated they were happy with all the HIV research with Highly Active Antiretroviral Therapy (HAART), because patients continue to function in society without difficulty and, more importantly, live long productive lives. Many of the research participants work jobs that require greater than 40 hours per week. A few participants stated they work two jobs primarily for financial gain. The participants felt it was important to remind me that being HIV positive does not mean you have to stay home all the time. It does not mean the person is always sick or even looks sick. The HIV person is on the go more now than ever. Many stated that being active has caused a problem with adherence because they simply forget to take their medications because they are too busy. Also the participants complained about the problems of storing the medications. Many medications require refrigeration, which hinders travel.

My lifetime partner and I live a very active life. We both work greater than 40 hours a week. We don't have time to be sick, yet sometimes we don't have time to take our medicine either. (Thomas)

Travel is a major part of my life. I understand that treatment interruption can cause long-term problems, but I don't like to travel with my medications. (Austin)

I don't get home until late and I travel a lot. Traveling with HIV medications is not always simple, and taking these medications on vacation is annoying. (Zachary)

Sometimes I am just too tired to remember to take my medication. (Joshua)

Most of the participants take more than ten pills daily. The complexity of the regimen served to be a barrier to adherence partly when the participant's understanding of the dosing requirements was too complex for them. The participants stated they preferred a once a day regimen or no more than a twice a day regimen. The number of pills taken daily did not seem to be a major factor to the decision of taking the medication. As Joe said, "One pill or a handful, it really does not matter, it's the frequency that is more important." Missing a dose or the daily regimen is not uncommon among the participants. The reason for missing a dose or interrupting HAART varied from simply "I forget" to "sometimes I just don't want to take my medication." It was not uncommon to hear the below statements.

I wish I did not have to take so many pills. (Kevin)

A once a day regimen would be very helpful. (Joe)

I am constantly forgetting to take my evening pills. I wish I could just take them all in the morning. (Joshua)

Food restriction played an important role in their lifestyles and adherence. Many HIV medications have to be taken with food and a few should be taken on an empty stomach. Because of the food restrictions several participants reported that they missed a dose of medication because they missed eating or they had already eaten something. Many participants stated missing a meal was not unusual because of their busy lifestyle. Breakfast was the most commonly skipped meal.

I get so confused sometimes. One pill I am suppose to take with food and one I am suppose to take on an empty stomach. That means I am taking the medication at different times, which really means I am not really on a once a day regimen. (Kevin)

I asked my doctor to put me on a regimen that did not require any food restrictions. (Thomas)

I will sometimes skip my morning dose because I don't always eat breakfast. If I take the medication without food or breakfast, I became very nauseated. (Casey)

Because HIV medications are extremely expensive, it is important to have health insurance. Many participants take additional non-prescription medications such as vitamins and dietary supplements. The non-prescription type medications are usually not covered by the traditional health insurance. These are considered "out of pocket" expenses. The participants in this research study work full-time and voiced the importance of good health insurance.

Without health insurance, HIV prescriptions could cost a person \$2000 to \$3000 per month. (Paul)

Insurance is an important aspect of a good lifestyle. (Andrew)

My out of pocket expenses for my HIV medication is \$200 a month, and that is with insurance. I have no idea how much I would be paying if I did not have good health insurance. (Casey)

Side Effects

Both short-term and long-term side effects and toxicities were shown to be associated with HAART adherence. Short-term side effects included skin rash, nightmares, fatigue, and gastrointestinal effects such as nausea, and vomiting.

Many participants reported having a skin rash the first month of starting a new regimen. The participants who were on the non-nucleoside reverse transcriptase inhibitors reported skin rashes. They were worried these skin rashes indicated an allergic

or hypersensitivity reaction. Not all patients experience rash but as one participant said, “It’s simply embarrassing,” other comments include:

It is bad enough to experience toxic side effects of these medications, but to have a visually noticeable side effect such as a skin rash. You find yourself having to explain to other people what is wrong with you. (Sam)

There are some medications I refuse to be placed on because I do not want to risk the chance of developing a severe rash. (Patrick)

Certain antiretroviral medications have been known to cause strange dreams or even nightmares. Not all participants complained about this side effect. Many said they did not consider their dreaming to be nightmares, but very vivid, and colorful. Never the less, they did not feel they had restful nights.

I remember not wanting to go to bed at night because I never know what to expect with my dreaming. I lay awake at night fearful of having some type of bizarre nightmare. (Sam)

I was given fair warning from my doctor that I might experience strange dreams the first few weeks of my new HIV medication regimen, and he was correct. I still have very vivid dreams. (Sam)

Fatigue was also included in the long-term side effects. Most of the participants complained about the continuous problem of fatigue. One participant said his friends always know if he stops taking his medication because his energy level increases and he is more social.

It has never been clear to me why I am always so tired. My doctor said it is one of the major side effects of being on HIV medication. It is one I could do without. (Thomas)

I worry that if I am this tired now, what will it be like when I am much older? Maybe by then they will develop a new drug that will not cause as much fatigue. (Gerald)

Nausea and vomiting or gastrointestinal problems are the most talked about side effect and usually occurs when the participants first start a HAART regimen. Some HIV

drugs cause nausea when taken on an empty stomach. Thomas stated he would skip a dose of his medication if he did not eat something just to avoid being nauseated.

I still get nauseated during the day even after being on HAART for 5 years. However, it is more controllable now. (Sam)

Supportive medication has been prescribed to me just in case I get nauseated or I start to vomit. That just means another drug I have to take. It is never ending story. (Jim)

Other long term side effects or toxicity's the participants voiced a concern about were elevated cholesterol, and body changes. Some of the participants stated they never had a blood cholesterol problem until they started an HIV regimen that contained a protease inhibitor. They were not made aware of this possible side effect until they started to get reports back for their healthcare provider reporting the elevations. A few of the participants were aware of the possibility and asked for a regimen that had less potential impact on cholesterol.

I went from normal total cholesterol of 150 to a cholesterol level of 250 with in 6 months. This scared me so I stopped taking my HIV drugs for a few months. (Jess)

I had read something about the possibility of my triglyceride blood levels elevating due to the HIV regimen I was on. This was a big concern to me since I already have a strong family history of cholesterol problems. (Joshua)

I was not happy to find out my HIV medication that was suppose to save me from dying of AIDS could cause me to die of a heart attack because it elevated my cholesterol. (Kevin)

The most talked about side effect attributed HAART is body fat redistribution or lipodystrophy. These body changes were given several nicknames, including "crix belly", "protease paunch", and "buffalo hump." The participants reported that fat is lost from the thighs, limbs and face, and accumulates in the trunk or at the base of the neck.

Interestingly, no one reported an increase of overall body weight or at least did not blame their HIV regimen on an increase of body weight.

I have asked my doctor not to put me on any medication that would make me look like a freak. I would simply not take the drug if I developed a buffalo hump on my back. (Zachary)

You can always tell if someone is on an HIV regimen that causes body changes. They usually have sunken cheeks and big round crix bellies. (Austin)

I'll stop taking my medications if I ever start to notice body changes. (Kevin)

The participants gave many reasons for their adherence or lack of adherence to their HAART regimens. They agreed that the educational opportunities are readily available from the Internet, their healthcare providers, and the pharmaceutical companies. The participants stated their lifestyles are no different then the non-infected person with the exception of having to take anti-HIV drugs and dealing with the drug side effects.

Summary

This basic interpretive qualitative research study addressed the issues regarding HIV medication adherence. This study took place in a family practice setting. Each participant interviewed was given the opportunity to voice opinions and give their story regarding being HIV positive and the HIV regimens they have experienced. Throughout the interviewing process two major themes were captured regarding adherence and non-adherence to HIV medications. This included the importance of well being of the HIV infected person and the acceptance of the lifelong commitment. These two themes are driven by lifestyles and social acceptance.

Regarding well being, the participants voiced their concerns and desire to remain as healthy as possible. Being HIV positive was viewed more as a challenge then a threat. If well being meant staying healthy, that meant basic daily exercise, decreasing stress in

life, and maintaining proper nutrition and diet. Another aspect of well being that helped enhance medication adherence was planning. Since many of the HIV medication are taken at various times of the day and quantities vary, planning the day, week or month is essential. Also planning for storage of the medication is important since some the medications require refrigeration.

HIV is no longer a death sentence. Until a cure is developed, it is treated like a chronic disease. Therefore acceptance of a lifelong commitment is essential along with understanding issues about the disease and the medications prescribed for treatment. The Internet access and other educational opportunities to learn about HIV and the medications have drastically increased in the past 10 years. The HIV positive person wants to know as much as possible about their disease and expects to have a healthcare provider who they can trust and who is very knowledgeable in regards to HIV and the various medication regimens.

The HIV infected persons lifestyle is no different than the non-infected person. They travel, work and enjoy life the same. The HIV medication regimens can be complicated, but need to fit into their lifestyles too. These regimens need to have as low side effect as possible. These side effects include rash, nightmares, fatigue, nausea/vomiting, and elevated cholesterol and body changes. The healthcare provider in the family practice setting can address all these issues.

CHAPTER 5: DISCUSSION

The first case of HIV was reported as early as 1952. At that time, virtually nothing was known about the virus that causes the disease, and there was little that clinicians could do to slow its inevitable progression to AIDS, then death. There have been several changes since then, and though there is still no cure for HIV, the virus can often be controlled now with medications. These medications are known as HAART, or Highly Active Antiretroviral Therapy (Heilman, 2003).

Despite the undoubted benefits of antiretrovirals, control of the HIV is only maintained effectively if treatment is taken without interruptions, respecting not only the number of doses and pills, but also the dosage regimen. Proper adherence is a key element in optimizing the efficacy of the drugs prescribed. Missing just two drug doses can result in increased levels of virus in the body or resistance to the drug, stopping their effectiveness. Maintaining HIV control requires a near perfect score in drug adherence. However, some drug regimens are difficult to tolerate. Some require upwards of 20 pills per day. Some of the medications require refrigeration; some must be taken with food, and some on an empty stomach (Chesney, 2000).

Adherence levels of greater than 95% are required to maintain virologic suppression. Nevertheless, actual adherence rates are often far lower; most studies show that 40% to 60% of patients are less than 90% adherent (Chesney, 2000). Adherence tends to decrease over time. Reasons for non-adherence range from simply “I forgot” to “intolerable side effects,” to “they just don’t fit into their lifestyle.”

The purpose of this basic interpretive qualitative study was to explore the nature of non-adherence to HIV medications in the family practice clinic setting. It is not uncommon for the family practice healthcare provider to have longer patient-provider time. Because multiple healthcare issues are being cared for in the family practice setting, the healthcare provider may have more in-depth knowledge of the HIV/AIDS patient's well being.

The literature review found authors predicting and analyzing reasons people in general do not adhere to their medication regimens. According to Robert Haynes (1996), patients may not comply with a medication regimen for several reasons. Non-adherence may be intentional or involuntary. Adherence may relate to the quality of information given, the impact of the regimen on daily life, the physical or the incapacity of patients, or their social isolation. Many interventions to overcome these impediments have been tried, but evidence of sustained success is scant.

Simoni (2003) stated that the daily regimen for the cocktail or HAART is not quite as complicated today as it was when the therapy was first introduced. However, the side effects of the medications remain, and people may experience vivid nightmares, headaches, nausea, diarrhea, rashes, altered liver function, change in their body's fat distribution and elevated cholesterol levels. Simoni also states the most common reasons given for not taking medications was, "I just forgot."

The Health Belief Model

The Health Belief Model (Rosenstock, 1966) grew out of a set of independent, applied research problems with which a group of investigators in the Public Health Services were confronted between 1950 and 1960. Becker (1974) indicates that the theory and development of the Model grew simultaneously with the solution of practical

problems. Two classes of circumstance should be described which were largely responsible for the type of model that ultimately emerged. These concern the setting in which research was required and the training and background experiences of those who participated in the development of the Model.

The Health Belief Model (HBM) extends the use of socio-psychological variables to the explanation of preventive health behavior. The model analyzes an individual's motivation to act as a function of the expectancy of goal attainment in the area of health behavior, (Rosenstock, 1966). Rosenstock stated that the HBH is derived from the social-psychological theory of researcher's K. Lewin, and Marshall Becker who have suggested that the Model can be categorized as an "expectancy x value" theory, attempting to describe behavior or decision-making under conditions of uncertainty. The HBM, which is concerned with the subjective world of the acting individual, proposes the following theoretical conditions and components. Becker (1974) indicated that the first individual's psychological readiness to take action (adherence) is determined by both the person's perceived susceptibility or vulnerability to the particular condition awareness of well being issues, and by his perceptions of the severity of the consequences of contracting the condition (lifetime commitment). Second, the individual's evaluation of the efficaciousness (education regarding value of drugs) weighted against this perception of psychological (life style issues) and other barriers or costs side (effects). Finally, a stimulus or "cue to action" is needed as a trigger (education).

The "cue to action," held as necessary for activating the readiness variables, appears to serve to make the individual consciously aware of this feeling, thus enabling him to bring them to bear upon the particular problem.

The HBM assumes that motivation is a necessary condition for action and that motives selectively determine an individual's perceptions of the environment. The concept of motivations is operationalized in the model's dual dimensions. The HBM assumes that motivation is a necessary condition for action and that motives selectively determine and individual's perception of the environment. The concept of motivation is operationalized in the model's dual dimensions (Rosenstock, 1966).

It has been suggested by Becker (1974) that the HBM should be expanded to include a separate motivational variable representing the need or desire for achieving health-related goals by employing the concept of "General health motivation". According to his modification, motives are viewed as dispositions within the individual to approach certain classes of positive incentives, and it is postulated that the desire of attain or maintain a positive state of health and to avoid a state of illness is dimension of health motivation.

Glanz (2002) states the HBM is based on the understanding that a person will take a health-related action (ie., use condoms) if that person:

1. Feels that a negative health condition can be avoided.
2. Has a positive expectation that by taking a recommended action, he/she will avoid a negative health condition.
3. Believes that he/she can successfully take a recommended health action.

A recent addition to the HBM is the concept of self-efficiency, or one's confidence I the ability to successfully perform an action.

Evelyn B. Winfield and Arthur L. Whaley (2002) in their study tested an expanded version of the HBM in the prediction of condom use during vaginal intercourse among African American college students. Results from regression analyses indicated that only

the core HBM explained significant amount of variance in condom use. Perceived barriers and gender were the only significant predictors of condom use. Consistent with past research finding, high levels of HIV/AIDS risk knowledge was not significantly correlated with condom use.

The Health Belief Model and Behavior Related to HIV Medication Adherence

In comparing and contrasting the HBM to HIV and HIV medication adherence, this study found that two themes or elements need to be focused on and what drives the two themes/elements. The first theme was well being, driven by side effects of the medications. This is representing differences in degree of concern for the individual health matters. The second theme is the acceptance of lifelong commitment of the disease. This is driven by lifestyle. All are tied to educational awareness.

A hypothetical model has been constructed relating the HBM to HIV medication adherence as found in this study, seen in Figure 1. This model can be useful as a rubric for further research on HIV positive patient related aspects of delivery of care, and avoid expenditure of large amounts of time and effort on additional examination of variables found in most instances to be related to adherence behavior.

The Meaning of Adherence

According to Sharan Merriam (2002), all qualitative research is interested in how meaning is constructed, how people make sense of their lives and their worlds. Here the researcher is interested in understanding the meaning a phenomenon has for those involved. The primary goal of a basic qualitative study is to uncover and interpret these meanings. Some disciplinary-based concept, model, or theory always frames the inquiry. Two themes capture the meaning of adherence and non-adherence. Adherence is

important to the well being of the HIV infected person and adherence is a lifelong commitment. These are driven by lifestyle.

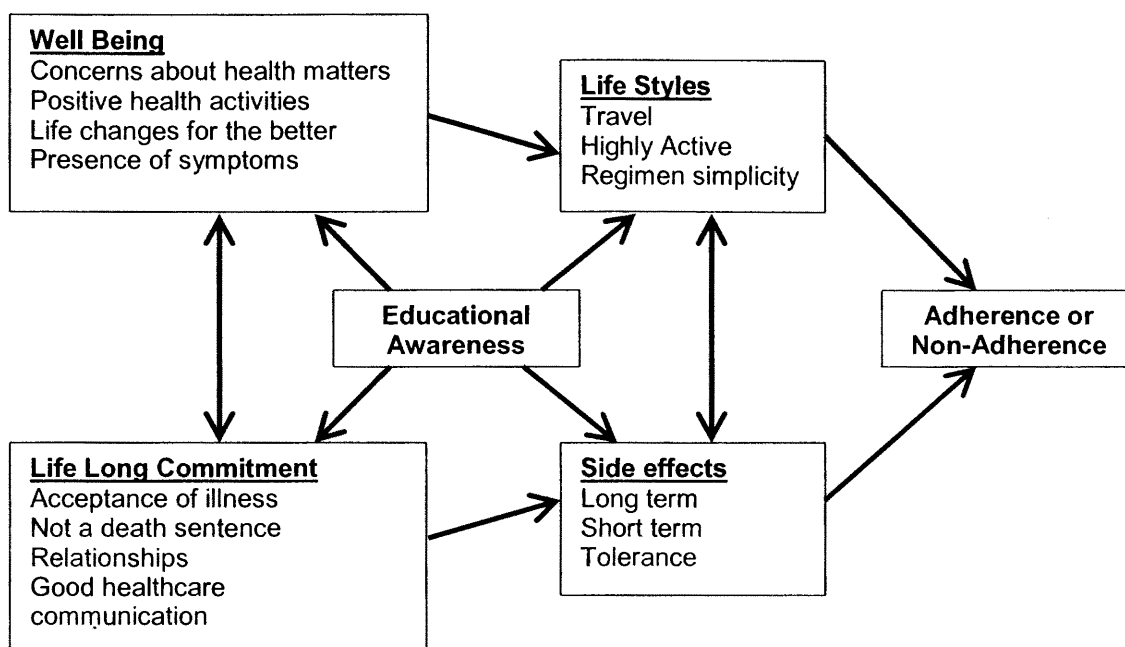


Figure 1. The Meaning of Adherence/Non-Adherence.

HIV medications have only been available since 1987. Since 1987, many pharmaceutical companies have researched and developed several new drugs. The goal for all HIV medication or antiretrovirals is to lower the HIV viral concentration in the blood. Consequently, by lowering the viral load the HIV infected patient can live a longer and healthier life. Unfortunately many of the participants are not 100% adherent to their medication regimen, (Bayer, 2002).

Similar to what Bayer (2002) has reported, a few of the participants in this study have been taking HIV medications since they were first discovered to be useful in the treatment of HIV in 1987. They admit they have not been 100% adherent with their medications and the final outcome was poor viral suppression.

John Bartlet (2003) stated improving length and quality of life is the ultimate objective in treating people with HIV/AIDS. Without treatment, eventually the HIV infected person becomes seriously ill and death occurs. In my research, all the participants had a goal to improve the length and quality of their lives. They voiced their concerns and understanding that without medication treatment the end result for them would be death.

According to Chesney (2000), patients find it easier to cope with their disease if they see it as an opportunity for personal growth or can attach some other positive meaning to it. Their perception of their disease might affect how well they stick to a medication schedule or avoid risky behaviors related to HIV infection. I found that the more information and the better understanding they had about their disease, the better the medication adherence.

Basic exercise is important for everyone, no matter what your physical condition. In addition to toning muscles and improving strength, exercise can greatly improve the immune system and help you feel better about yourself, which is especially beneficial for those living with HIV (Williams, 2001). Two years later Flaheery (2003) stated that by decreasing stress and focusing on staying mentally healthy, adherence to the HIV medications improved. Also, good nutrition aids the immune system in fighting disease and strengthens the body in preparation for those medications that will help the HIV infected person to stay healthy. I agree with both researchers. The participants in this study explained to me that they try to be proactive in their healthcare by exercising on a regular basis and by having a healthy nutritional intake. They claim to have a better adherence to their medication when they feel good about themselves.

My study agrees with Hausman's (2002) observation that a stable access to drugs is critical for the participants to adhere to their medication regimen. People cannot stay on their medication if they don't have access to their medications. Many of the participants in my study are frequent travelers, either due to frequent vacations or work related. They stated they have a very difficult time remembering to take their medication while traveling or if they get too busy at work. I also found that the patients who have to refrigerate their medications are more likely to not to take the drugs with them if they are traveling. It was also uncovered that the patient who lives in a rural community has less access to the HIV medications and is more likely to miss doses due to simply running out of drugs and not having nearby access.

My study agrees with Bartlet (2002) that adhering to an HIV drug regimen can pose tremendous challenges. Missing any two doses can result in increased levels of virus in the body or resistance to the drugs. No one can be sure how well clients follow their prescribed drug regimens. An adherence rate of 95% is considered necessary for viral suppression, but actual adherence rates are often far lower; most studies show that 40% to 60% of patients do not take their medications as ordered 90% of the time. I did not uncover information regarding the length of time a patient becomes non-adherent to the time they are adherent again to their medications. This area of research needs to be better understood and researched. What my research does reveal is the HIV infected person can be just as active as the non-infected person and because of their active lifestyles the more non-adherent they become.

Johnson and Volberding (1999) studied healthcare providers of HIV patients. Their research showed non-adherence could be frustrating for the healthcare provider and the patient. Some patients just can't seem to do it. They just cannot take their medication

or they won't, so their viral load gets worse. As a healthcare professional/provider who cares for the HIV infected patient, I find it very frustrating and alarming to find out the patient is not taking their HIV medications as directed or has stopped taking them entirely. I have asked other providers how the non-adherence of their patients makes them feel and they too indicate they became very frustrated. Often the provider is not aware of the non-adherence until blood work is performed and the viral load has increased and the immune system begins to fail. I feel more research can be done with various HIV healthcare providers on how they cope with the frustration of the non-adherent patient.

Today's effective treatment means that people with HIV are living longer, healthier lives than ever before. To live longer and healthier means to accept the lifelong commitment of the disease and medication adherence. But adhering to an HIV regimen can pose tremendous challenges. Some drug regimens for HIV are hard to stick to. The drugs can be difficult to tolerate. Missing doses of HIV medications is a big issue. The drugs are carefully dosed to maintain blood levels that will suppress the virus. The virus will be unable to replicate because of the drugs' actions. But if a person does not take the prescribed dosage, the drug level can fall and there will not be enough concentrate of the drug to inhibit the virus. Even if this information is given to the patient they still forget to take their medications or just stop taking them after a period of time (Paterson, 2002). As Paterson's (2002) research suggests, there are not immediate physical signs related to missed doses or someone stopping their medications. When a patient skips a dose it's not like a cold and their symptoms become worse or their health returns. There is not the immediate physical illness to remind them to take their medication. However, many patients stated they learned the hard way about stopping or missing doses. They

eventually became sick and were restarted on a more difficult drug regimen. The participants in this study have been HIV positive for 10 year or more which gives proof that the HIV infected patient can live long healthy lives. This could be due to better HIV medications, and I believe because the patients are now accepting HIV as a lifelong commitment.

I believe that Jones (2002) research compared the closes to my research. His participants experienced six essential themes. The experience of “Becoming a Patient”, dealt with the physical and psychological shift form being well to taking HIV medications, which caused the participants to feel ill. Becoming a Patient occurred for the study participants with the decision to start on HIV combination drug therapy. After the initial agreement to initiate HIV medication therapy, the participants had to deal with taking their medications. The experience of “Managing and Being Managed by the Medications”, incorporated the tremendous change in lifestyle that occurred because of necessary medication-taking behaviors and activities. “Coping With the Medications” involved strategies to facilitate long-term adherence to the HIV medication regimen. “Feeling Lousy”, described experiencing side effects of the medications. “Negotiating the Hassles and the Cost”, involved battling the system, including insurance companies and managed care. The attitude of a health maintenance organization (HMO) was perceived as an uncaring feeling of no emergencies. “Living Under a Dark Cloud”, described the ever present fear of development of drug resistance, worry about the future, and the uncertainty of how long the mediation regimen would stay effective and keep the individual healthy.

Similar to Jones, my research uncovers the initial agreement to initiate HIV medications and then facing the life long commitment and life style changes. The drug

side effects were addressed as they were in my study. However, Jones study was conducted in a large medical setting and total patient care was not provided to each patient. My study takes place in the family practice clinic where the patients total health care issues are addressed. I believe this is important since I have noticed an increase in HIV positive patients seeking their care at family practice clinic.

In conclusion, the literature review and this study suggest that HIV patients sometimes simply forget to take their medications. My literature review uncovers very little information on the new lifestyles of the HIV infected patient. Bayer, (2000) does review the history of HIV including “The Dark Years, Fear, Impotence and Rejection” of the HIV positive patient. He address the life style changes from once know as a domed life style to one of active and well educated. My study also revealed the HIV infected patient is just as active in the community as the non-infected person. They travel and work the same jobs. The uniqueness of this study is how the lifestyles and acceptance of the lifelong commitment was researched in a small family practice clinic and these two themes influence adherence or non-adherence to the HIV regimens.

Research Questions Answered

This research project asks the question, “What issues need to be addressed in order for the HIV positive person to adhere to their medication regimen in a family practice setting.” In order to answer the question, three other questions had to be answered.

1. What educational opportunities were available to the participants concerning their drug therapy?

The participants felt there were adequate educational opportunities. They believed the opportunities have increased over the past 5 to 10 years. Many stated they could remember having hunted for information regarding HIV, and particularly HIV

medications. Now, public classes and community forums are held on a weekly basis. Even popular magazines give some type of educational information. The participants are thankful for the educational opportunities the pharmaceutical companies provide. Also, the healthcare providers in the family practice setting are better educated on HIV and have up-to-date patient literature/books/fliers, which are readily available. Because most of the participants have computer access, the Internet has greatly improved the awareness and education of HIV.

The previous literature poorly addresses the question of educational opportunities. Although the several authors (e.g., Bartlet, 2003; Chesney, 2000; Johnston, 1999) addressed HIV/AIDS very well, including the history and patho-physiology of the disease, the patient opportunities were not covered very well. Schaffer (2001) stated that if the patient understands the purpose of a drug and how the drug is to be taken, they are more likely to take it as prescribed. He states also that the patient is more likely to adhere to a regimen when the relationship with the healthcare provider is good. Researchers such as John Bartlet and Paul Volberding work in large infectious disease clinics. No research was uncovered regarding the patient in a family practice setting. Chesney (2002) has addressed the importance of various support groups and journal/magazines that address the HIV infected patient. She states support groups and journals such as *POZ* have become increasingly available in general stores and newsstands. Also, there has been an increase in advertising in the newspapers for public support group meetings.

2. What is the participant's day-to-day lifestyle, including routine schedule?

It is clear that the HIV infected patients can and do live normal lives. Just like the non-infected patient they work all types of jobs and are very active in the community. Being HIV positive does not stop the HIV patient from traveling/vacationing. The

participants stated it was a major problem traveling with their medications. Many times it was due to the simple problem of quantity or volume of medications they have to pack. It was stated several times during the interviewing process that they would rather stop taking their medications while traveling or vacationing because of the inconvenience and embarrassment of being stopped in the airport by the security guards. Traveling can be a problem because some of the medications require refrigeration.

Jones (2002) did address the life style of his research participants. The nine participants were active full-time employed nurses. The nurses describes being HIV positive as being a life-changing experience. They improved their over-all well-being and remained active in the community.

Bayer (2000) has addressed the issue of day-to-day lifestyle of the HIV patient in his research. He stated the HIV infected patient today could live a normal lifestyle. In the past he would talk to his patients about death and illness. Now he talks about life. He talks about managing side effects and continuing a "normal life." He states the HIV infected patient is now going back to school, traveling, exercising, and preparing for retirement. This is a drastic change from living in the 80s.

3. What side effects of HAART most concern the participants?

Many different side effects are associated with the use of anti-HIV drugs. The occurrence of side effects plays a large role in adherence to drug regiments, which in turn can impact the development of drug resistance. Short-term side effects that most participants complained about were skin rash, nightmares, fatigue, and gastrointestinal effects such as nausea and vomiting. Long term side effects that the participants voiced the most concern about was elevated cholesterol and body changes. Some of the

participants stated they would not take their medications because they feared heart complications or they feared unpleasant body changes.

Medication side effects were well represented in the literature review. According to Cohen (2003), at least half of all people stop taking their medications because of side effects that typically include fatigue. During this research project an article by Liza Highleyman (1998) was uncovered about side effects associated with anti-HIV drugs. Her comments about side effects and drug adherence relate well to this research project.

Many different side effects are associated with the use of anti-HIV drugs. The occurrence of side effects plays a large role in adherence to drug regimens, which in turn can impact the development of drug resistance. Side effects such as nausea and diarrhea, which affect drug absorption, can also contribute to drug resistance. The frequency and severity of side effects vary greatly from person to person. In some cases, side effects are worse when a drug is first started and may lessen over time. Side effects are often more frequent and more severe in people with advanced HIV disease who are more immunocompromised. However, people with HIV are often able to manage side effects so that they can benefit from potent anti-HIV treatment while maintaining a good quality of life. (p. 40)

The issues that need to be addressed in order for the HIV positive person to adhere to their medication regimen in a family practice setting are complex. However, this study addressed the question well. The lifestyle of the HIV infected patient is no different than the non-infected person. The HIV infected person now lives long and healthy lives due to Highly Active Antiretroviral Therapy (HAART). This regimen of medication has become well accepted by the HIV positive person through the wide range of educational opportunities presently available to them. The more education provided to this patient, the greater the chance of medication adherence. When side effects of these medications are addressed along with possible prevention issues, adherence has improved.

In conclusion, the issues that need to be addressed in order for the HIV positive person to adhere to their medications in a family practice setting is a combination of understanding the educational opportunities, the patients lifestyle and the side effects that most commonly affect the patient. Since total patient care is given in the family practice setting, a pamphlet could be developed to address the two themes. 1.) The well being of the patient and, 2.) The life long commitment. This pamphlet could be in question and answer form, addressing the most common responses this research uncovered. This pamphlet can start an open dialog with the family practice provider and continue to address non-adherence issues.

Implication for Practice

The results of this study indicated that educational opportunity for the HIV infected person has greatly improved in the past 5 to 10 years. The healthcare providers in the family practice clinic need to be abreast of what these opportunities are and encourage the patient to continue their HIV/AIDS education and understanding. Also, everyone has a different lifestyle and the HIV infected patient seems to be no different. As long as the disease itself is controlled, it should not handicap a person from living a healthy fulfilled life. Both short-term and long-term side effects can hinder the adherence of HIV medications; however, with the proper patient education the side effects can be reduced. The healthcare provider needs to be aware of the potential drug side effects of the anti-HIV medications and when ever possible, choose a drug regimen that fits into the patient's lifestyle.

Two themes capture adherence and non-adherence. Adherence is important to the well being of the HIV infected person and is a lifelong commitment. This is driven by the life style of the participants and medication side effects. Improving length and quality of

life is the ultimate objective in treating people with HIV/AIDS. This disease is not a death sentence. HIV infected people live long and healthy lives. HIV is considered a chronic disease and the infected patient must make a lifelong commitment to control the disease and not let the disease control them. To do this the patient must make a commitment to adhere to their medications and be proactive with other healthcare issues.

Other healthcare providers in the family practice settings who care for HIV infected patients should learn from this study that HIV medication adherence issues are more complicated than just pill burden and frequency. The HIV infected person does not sit around the house waiting to die. They travel and work and function in today's society just like the non-infected person/patient. Since the family practice provider is caring for the entire healthcare of the HIV positive person, more time needs to be spent on discussing the lifestyle of each patient. When this issue was addressed with a healthcare provider, he stated he sometimes forgets to look at the whole picture. Because of this study he will begin taking more time getting to know his HIV patients, and "find out what makes them click." The family practice provider should learn from this study that the patient wants and needs to become more actively involved with choosing their treatment regimens. As one provider said, "It makes sense to me. It is their disease and they will more likely take the medication if they buy into it too." Since the family practice provider is taking care of the HIV infected person's entire healthcare, it is essential they keep up-to-date with all HIV regimens and help educate the patient.

Recommendations for Future Research

As a result of this study, a few recommendations can be made. This study should be replicated at much larger level. More than one family practice clinic can be involved and women should be included. Multiple case sampling adds confidence to findings. By

looking at a range of similar and contrasting cases, we can understand a single case finding, grounding it by specifying how and where and, if possible, why it carries on as it does. We can strengthen the precision, the validity, and the stability of the findings by following a replication strategy. If a finding holds in one setting and given its profile also holds in a comparable setting but does not in a contrasting case, the finding is more robust. The "multiple comparison groups" used in a grounded theory work play a similar role (Miles, 1994).

Although this study was designed as a basic interpretive qualitative research, a future design could be conducted as a grounded theory study. A grounded theory study is when the researcher attempts to derive a theory by using multiple stages of data collection and the refinement and interrelationship of categories of information (Strauss, 1990). The grounded theory approach, particularly the way Strauss develops it, consists of a set of steps whose careful execution is thought to "guarantee" a good theory as the outcome. Strauss would say that the quality of a theory can be evaluated by the process by which a theory is constructed. Although not part of the grounded theory rhetoric, but because of the topic of this study, HIV, it is apparent that grounded theorists are concerned with or largely influenced by true meaning the world and, in this case HIV medication adherence. The researcher will use categories drawn from respondents themselves and which can focus on making implicit belief explicit.

Two primary characteristics of this design are the constant comparison of data with emerging categories, and theoretical sampling of different groups to maximize the similarities and the difference of information (Creswell, 1994).

Finally, this study can be narrowed down to a biographical study. A biographical study would look at an individual HIV positive person and his or her experiences before

their diagnosis of HIV and after. If an individual's history and lifestyle was followed, it may help explain why other HIV infected people are adherent or non-adherent to an HIV medication regimen. In a biographical study the life story of an individual is written by someone other than the individual being studied using archival documents and records. Subjects of biographies may be living or deceased (Denzin, 1989).

Conclusion

Adherence issues regarding HIV medications in the family practice setting is a complicated subject. There are many reasons why HIV infected patients on medications stop or skip doses of medications. Several researchers have studied adherence issues for several years. The majority of studies uncovered in the literature review concluded that the drug side effects, pill burden (too many pills to take), and frequency of pill taking were the most causes of non-adherence.

However, none of these studies were conducted in the family practice setting. This study revealed the HIV infected person is just as active with and within the community as the non-infected person, and HIV is treated as chronic disease and not as a death sentence. Both the family practice healthcare provider and the patient are better educated regarding HIV and the medications used for treatment. This study suggests adherence is under the influence of well being and the acceptance of being a lifelong commitment. The lifestyles of the patients need to be addressed with any HIV medication treatment, along with the potential side effects of these drugs.

REFERENCES

- AEGiS. (n.d.). *So Little time...An AIDS History*. Retrieved June 29, 2003, from <http://www.aegis.com/topics/timeline/default.asp>
- Bangsberg, D. R., Hecht, F. M., Chesney, M., & Moss, A. (2001). Comparing objective measures of adherence to HIV antiretroviral therapy: Electronic medication monitors and unannounced pill counts. *AIDS and Behavior, 5*(3), 275-281.
- Bartlet, J. G., & Gallant, J. E. (2003). *Medical management of HIV infection* (2nd ed.). Baltimore: Library of Congress Catalog Card Number 95-070888.
- Bartlett, J. A. (2002). Addressing the challenges of adherence. *Journal of Acquired Immune Deficiency Syndromes, 29*, S2-S10.
- Bayer, R., & Oppenheimer, M. (2000). *AIDS Doctors, Voices from the Epidemic*. Oxford: Oxford University Press.
- Becker, M. H. (1974). *The Health Belief Model and Personal Health Behavior*. Charles B. Slack, Inc., Thorofare, New Jersey.
- Cederfjall, C., Langius-Eklof, A., Lidman, K., & Wredling, R. (2002). Self-reporting adherence to antiretroviral treatment and degree of sense of coherence in a group of HIV infected patients. *AIDS Patient Care and STDs, 16*, 609-616.
- Chesney, M. A. (2002). Factors Affecting Adherence to Antiretroviral Therapy. *AIDS*.
- Chesney, M. A., Morin, M., & Sherr, L. (2000). Adherence to HIV combination therapy. *Social Science and Medicine, 50*, 1599-1605.
- Chesney, M. A. (2003). Adherence to HAART regimens. *AIDS Patient Care and STDs, 17*(4), 169.
- Cohen, J. S. (2003). Many people stop taking anti-hypertensive drugs because the dose is too high. *Health Facts, 28*(8), 5.
- Col, N., Fanale, J. E., & Kronholm, P. (1990). The role of medication noncompliance and adverse drug reactions in hospitalization of the elderly. *Arch Internal Medicine, 150*, 841-845.
- Creswell, J. W. (1994). *Research design: Qualitative and quantitative approaches*. Thousand Oaks, CA: Sage Publications.

- Creswell, J. W. (1998). *Qualitative Inquiry and Research Design: Choosing Among Five Traditions*. Thousand Oaks, CA: Sage Publications.
- Crotty, M. (1998). *The foundations of social research: Meaning and perspective in the research process*. Thousand Oaks, CA: Sage.
- Denzin, N. K. (1989). *Interpretive biography*. Newbury Park, CA: Sage.
- Descamps, D., Flandre, P., & Calvez, V., et al. (2000). Mechanisms of virologic failure in previously untreated HIV infected patients from a trial of induction-maintenance therapy. *JAMA*, 283, 205-211.
- DiMatteo, R. M., Giordani, P. J., Lepper, H. S., & Croghan, T. W. (2002). Patient adherence and medical treatment outcomes: A meta-analysis. *Medical Care*, 40, 794-811.
- Divertie, V. (2002). Strategies to promote medication adherence in children with asthma. *MCN, The American Journal of Maternal/Child Nursing*, 27(1), 10-18.
- Donovan, J. I., & Blake, D. R. (1992). Patient non-compliance: Deviance or reasoned decision-making? *Social Science Medicine*, 34, 507-513.
- Durso, S. C. (2001). Technological advances for improving medication adherence in the elderly. *Annals of Long Term Care*, 9(4), 43-48.
- Evans, J. (2003). Non-adherent patients tend to be younger, unmarried, less educated. *Clinical Psychiatry News*, 31(7), 35.
- Evergreen Health Care. (n.d.) *The Family Practice*. Retrieved May 27, 2005, from <http://www.evergreenhealthcare.org/showpage.asp>
- Flaheery, J. P. (2003). Attitude is the key part of treatment adherence. *AIDS Alert*, 18, 38.
- Forman, L. (1993). Medication: Reason and interventions for noncompliance. *Journal of Psychosocial Nursing and Mental Health Services*, 31(10), 36-37.
- Gifford, A. L., Bormann, J. E., Shively, M. J., Wright, B. C., Richman, D. D., & Bozette, S. A. (2002). Predictors of self-reported adherence and plasma HIV concentrations in patients on multi-drug antiretroviral regimens. *Journal of Acquired Immune Deficiency Syndrome*, 23, 386-395.
- Glanz, K., Rimer, B.K. & Lewis, F.M. (2002). *Health Behavior and Health Education. Theory, Research and Practice*. San Francisco: Wiley & Sons.
- Glaser, B. G., & Strauss, A. L. (1967). *The discovery of grounded theory*. New York: Aldine De Gruyter.
- Gliner, J. A., & Morgan, G. A. (2000). *Research methods in applied settings*. Mahwah, NJ: Lawrence Erlbaum Associates, Inc.

- Godin, G., Gagen, C., & Naccache, H., (2003). Validation of a self-reported questionnaire assessing adherence to antiretroviral medication. *AIDS Patients Care and STDs*, 17(7), 325-328.
- Golin, C. E., DiMatteo, M. R., & Leake, B., et al. (2001). A disease-specific measure of diabetic patients' desire to participate in medical decision-making. *Diabetes Education*, 27, 875-886.
- Golin, C. E., DiMatteo, M. R., & Leake, B., et al. (2001). A disease-specific measure of diabetic patients. *Diabetes Education*, 27, 875-886.
- Grant, R. W., Devita, N. G., & Singer, D. E. (2003). Polypharmacy and medication adherence in patients with type 2 diabetes. *American Diabetes Association*, 26, 1408.
- Hall, L. (1999). Medication compliance. *American Journal of Nursing*, 99(7), 14.
- Hausman, A. (2002). Taking your medication: Relational steps to improving patient compliance. *Health Marketing Quarterly*, 19(2), 49-71.
- Haynes, R. B., McKibbon, A., & Kanani, R. (1996). Systematic review of randomized trials of interventions to assist patients to follow prescriptions for medications. *Lancet*, 348, 383-386.
- Heilman, E. (2003). Managing HIV: A life-long commitment. *Daily News Health*, 5(26) 15-30.
- Highleyman, L. (1998). Side effects associated with anti-HIV drugs. *Bulletin of Experimental Treatments for AIDS*, April, p.35-45.
- Hinkin, C. H., Cassstellon, S. A., Hardy, D. J., Lam, M. N., Mason, K. I., Thrasher, D., et al. (2002). Medication adherence among HIV+ adults: Effects of cognitive dysfunction and regimen complexity. *Neurology*, 59, 1944-1950.
- Ickovics, J. R., & Meade, C. S. (2002). Adherence to antiretroviral therapy among patients with HIV: A critical link between behavioral and biomedical sciences. *Journal of Acquired Immune Deficiency Syndromes*, S98-S102.
- Johnston Roberts, K., & Volberding, P. (1999). Adherence communication: A qualitative analysis of physician-patient dialogue. *AIDS*, 13(13), 1771-1778.
- Jones, S. G. (2002). The other side of the pill bottle: The lived experience of HIV-positive nurses on HIV combination drug therapy. *Journal of the Association of Nurses in AIDS Care*, 13(3), 22-36.
- Kirn, T. F. (2003). Epilepsy patients miss doses fairly regularly. *Internal Medicine News*, 36(5), 25.

- Low-Bear, S., Yip, B., O'Shaughnessy, M. V., Hogg, R. S., & Montaner, J. S. (2000). Adherence to triple therapy and viral load response. *Journal of Acquired Immune Deficiency Syndrome*, 23, 360-361.
- Lewis, A. (1997). A \$100 billion problem. *Remington Report*, 5, 14-15.
- Manisses Communications Group (2003). *Skipped doses increase risk of hospitalization*. Retrieved September 18, 2003, from Psychopharmacology Update Web Site: <http://hwrc@galegroup.com>
- Mannheimer, S., Friedland, G., Matts, J., Child, C., & Chesney, M. (2002). The consistency of adherence to antiretroviral therapy predicts biologic outcomes for human immunodeficiency virus-infected persons in clinical trials. *Clinical Infectious Diseases*, 34, 1115-1121.
- Marinker, M., & Shaw, J. (2003). Not to be taken as directed: Putting concordance for taking medicines into practice. *British Medical Journal*, 326, 348-349.
- Mellors, R. C. (n.d.). *Natural History of HIV Infection*. Retrieved, July 30, 2003, from Well Medical College of Cornell University Web Site: http://edcenter.med.cornell.edu/CUMC_PathNotes/HIV_Infection/HIV_Infection_03.htm
- Meredith, P. A. (1999). *Drug regimen compliance: Issues in clinical trials and patient management*. New York: John Wiley & Sons.
- Merriam, S. B. (1998). *Qualitative Research and Case Study Applications in Education*. San Francisco, CA: Jossey-Bass Publications.
- Merriam, S. B. (2002). *Qualitative research in practice*. San Francisco, CA: Jossey-Bass Publications.
- Miles, M. B., & Huberman, A. M. (1994). *Qualitative data analysis*. Thousand Oaks, CA: SAGE Publications.
- Murri, R., Antinori, A., Ammassari, A., Nappa, S., Orofino, G., Abbrrescia, N., et al. (2002). Physician estimates of adherence and the patient-physician relationship as a setting to improve adherence to antiretroviral therapy. *Journal of Acquired Immune Deficiency Syndromes*, 31, S158-S162.
- Nebraska AIDS Education and Training Center (2002). *The history of HIV: A timeline* (1st ed.) [Brochure]. Nebraska.
- Park, D.C., Hertzog, C., Leventhal, H., et al. (1999). Medication adherence in rheumatoid arthritis patients. *Journal of American Geriatric Society*, 47, 172-183.
- Paterson, D. L., Potoski, B., & Capitano, B. (2002). Measurement of adherence to antiretroviral medications. *Journal of Acquired Immune Deficiency Syndromes*, 31, S103-S106.

- Pezzotti, P., Pappagallo, M., Phillips, A., Boros, S., Valdarchi, C., & Sinicco, A. (2001). Response to highly active antiretroviral therapy according to duration of HIV infection. *Journal of Acquired Immune Deficiency Syndromes*, 26, 473-479.
- Power, R., Koopman, C., Volk, J., Israelski, D. M., Stone, L., Chesney, M. A., et al. (2003). Social support, substance use, and denial in relationships to antiretroviral. *AIDS Patient Care and STDS*, 17, 245.
- Powsner, S., & Spitzer, R. (2003). Sex, lies, and medical compliance. *The Lancet*, 361, 937.
- Pugatch, D., Bennett, L., & Patterson, D. (2002). HIV medication adherence in adolescents: A qualitative study. *Journal of HIV/AIDS Prevention and Education for Adolescents and Children*, 5, 9-29.
- Randerson, J. (2002). HIV's complex family history unraveled. *Science*, 300, 1713.
- Roberts, K. J., & Volberding, P. (1999). Adherence communication: A qualitative analysis of physician-patient dialogue. *AIDS*, 13, 1771-1778.
- Rosenstock, I. M. (1966). Why people use health services. *Milbank Memorial Fund Quarterly*, 44, 94-124.
- Rosenthal, R. (1995). Progress in clinical psychology: Is there any? *Clinical Psychology Science Practice*, 2, 133-2150.
- Schaffer, S. D., & Yoon, S. L. (2001). Evidence-based methods to enhance medication adherence. *The Nurse Practitioner*, 26(12), 44,50,52,54.
- Simoni, J. (2003). Need for social support deters HIV patients from taking their drug cocktails. *Virus Weekly*, January 28, 2.
- Strauss, A. & Corbin, J. (1990). Basics of qualitative research: Grounded theory procedures and techniques. Newbury Park: Sage
- Turner, B. J. (n.d.). In *Adherence to Antiretroviral Therapy by Human Immunodeficiency Virus-Infected Patients* (2000). Retrieved April 16, 2003, from University Chicago Web Site:
<http://www.journals.uchicago.edu/JID/journal/issues/v185nS2/010690.text.html>
- Uhavax. (n.d.). *The Rise of HIV/AIDS*. Retrieved June 29, 2003, from Hartford Web Site:
<http://uhavax.hartford.edu/begl/rise.htm>
- University of Michigan (n.d) *What is Family Practice?* Retrieved May 11, 2005 from University of Michigan Web Site. <http://www.healthteam.msu.edu/clinics.family.practice.htm>
- Urquhart, J. (1999). Pharmacoeconomic impact of variable compliance. *Drug Regimen Compliance: Issues in Clinical Trial and Patient Management*. (p. 119-145): New York: John Wiley & Sons.

- Wachter, K. (2003). Work with patients to improve their medication compliance. (Consider why medications aren't taken). *Skin and Allergy News*, 34(7), 40.
- Wagner, G. J., & Rabkin, J. G. (2001). Measuring medication adherence: Are missed doses reported more accurately than perfect adherence? *AIDS Care*, 12, 405-408.
- White, J. (2003, July 25). Prescription solutions develop predictive modeling technique to improve medication compliance. *Drug Cost Management Report*, 4, 3.
- Williams, A. B. (2001). Adherence to HIV regimens: 10 vital lessons. *American Journal of Nursing*, 101(6), 37-43. \
- Winfield, E. B. & Whaley, A. L. (2002). A Comprehensive Test of the Health Belief Model in the Prediction of Condom Use among African American College Students. *Journal of Black Psychology*, 28(4), 330-346.
- Winland-Brown, J. E., & Valiante, J. (2000). Effectiveness of different medication management approaches on elders' medication adherence. In *Outcome Management for Nursing Practice* (4th ed., pp. 172-176). Lippincott Williams and Wilkin, Inc.
- World Health CME (2003). *Adherence issues in challenging populations* [Brochure]. New York: Author.

APPENDIX A: HAART ADHERENCE STUDY FLIER

**ATTENTION PATIENTS WHO ARE ON
HIGHLY ACTIVE ANTIRETROVIRAL
THERPY**

A study will be conducted at Apex Family Medicine regarding medication adherence. We are looking for several patients who have been on HIV medications for five years or greater and are willing to discuss important issues regarding their medications.

The study will consist of a 30 to 60 minute private interview.

The information will be used as part of a research project being conducted by Peter Prutch, NP-C in partial fulfillment of his requirements for the Degree of Doctor of Philosophy at Colorado State University.

Under the supervision of Don Quick PhD. Professor of Education at Colorado State University

Confidentially will be honored.

If you are interested in participating in this study, please contact Peter Prutch at (303) 321-0222 by March 20, 2004.