A CASE CONTROL STUDY TO IDENTIFY FACTORS THAT MAY INFLUENCE ANTI-RETROVIRAL TREATMENT ADHERENCE.

By

Fredrick Mulenga Chitangala

A dissertation submitted in partial fulfilment of the requirements for the degree of
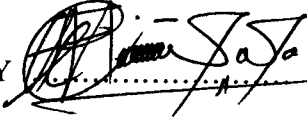
Master of Public Health (MPH)

The University of Zambia, School of Medicine

Department of Community Medicine

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DECLARATION

I, the immediate undersigned, do hereby dully declare that the work presented in this dissertation for the Degree of Master of Public Health has not been presented either wholly or in part for a diploma or a degree in any other university and is not currently being presented for any other degree.

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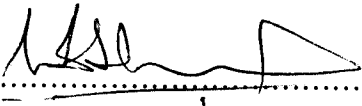
CERTFICATE OF APPROVAL

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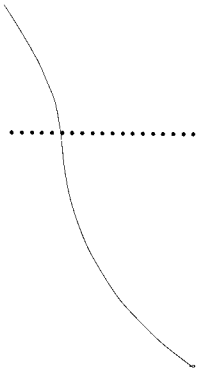
ABSTRACT

This study was carried out in order to determine factors that may influence anti-retroviral therapy (ART) adherence. The main objective was to identify factors that can be used to predict adherence in patients taking ARVs. Specific objectives were to identify associations between patients' knowledge, beliefs, socio-economic status and disclosure and adherence. This was a case-control study carried out at Chreso Ministries ART and VCT Centre in Lusaka, Zambia. A total of 304 respondents who had been on ART for not less than 6 months were studied between may 2006 and September 2006. Tests of associations using the Chi-squared test or the Fisher's Exact test were done using Epi Info. SPSS's logistic regression was used to determine predictability.
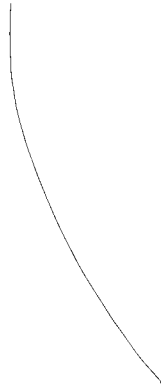
Age and education yielded insignificant differences of adherence among different age groups (X^2 1.27; p value 0.259) and among different education levels (X^2 4.51; p value 0.211). Results on knowledge showed that there was no association between knowledge and adherence (p value 0.817). Respondents who believed in both ARVs and God were 1.96 times (95% CI 1.06 to 3.69) more likely to adhere to treatment than those that believed in God alone. The association between beliefs regarding whether ARVs have potency to restore life or not and adherence was not statistically significant (P value of 1.000). We also wanted to determine whether an association existed between disclosure of one's HIV status and adherence. The results of the test of significance were X^2 0.93 and p value of 0.335 indicating that there was no significant association between disclosure and adherence. Most of the respondents disclosed their status in both groups (92.3% among persons among the cases [adherent clients] and 95.8% among the controls [non adherent clients).

The association between income and adherence was not statistically significant (p value = 0.905). Employment status yielded no significant results (p value=0.161). However, there was a significant association between presence of another chronic illness (that demands for more pills per day) and adherence (X^2=3.9; p value=0.048). Respondents with a chronic illness were 43% (OR=0.57, 95% CI 0.33 to 1.00) less likely to adhere compared to respondents who had no chronic illness. Then we found no significant association between those that had taken alcohol in the last 3 months and adherence (OR=0.82; P value=0.617; and at 95% CI 0.34 to 1.56)

Most importantly in this research, we were interested in predicting adherence using the record captured variables of employment status at enrolment, income level at enrolment, disclosure status at enrolment and timing of treatment inception. The probabilities of predicting adherence were employment status 0.375; income 0.383, disclosure 0.369 and timing of treatment inception 0.292. The probabilities of predicting adherence using any of these variables were found to be too small to be used for prediction and therefore we concluded that there is need to continue researching for good predictors of adherence.

DEDICATIONS

I dedicate this study with deepest love, gratitude and affection to the pie of my heart, my wife, Mwangala Mbindawina Chitangala for showing understanding even when I could go home very late from the library. My first borne son, Mulenga Chitangala gave the strongest motivation because his future lied between my books. I also pay gratitude to my late uncle, Hon. Musa Kunda Chitangala, who, together with his wife (mum), made sure that I had university education amidst tough economic battles. He would have been the happiest man if he was alive to see me complete the MPH program. May you rest in peace daddy.

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CHAPTER 1

BACKGROUND INFORMATION

1.0 Problem Identification

In the past four (4) centuries, the world has experienced wars, natural disasters, civil unrest and epidemics. But the threat that HIV/AIDS (Human Immuno-deficiency Virus/Acquired Immune Deficient Syndrome) has posed on the human face is incomparable. According to AVERT.ORG (2006), more than 25 million people worldwide have died of AIDS from 1981 and since then Africa has had 12 million AIDS orphans with women accounting for 46% of all adults living with HIV worldwide, and for 57% in Sub-Saharan Africa while young people (15-24 years old) accounted for half of all new HIV infections worldwide - more than 6,000 become infected with HIV every day by December 2005. However of the 6.5 million people in developing and transitional countries who need life-saving AIDS drugs, only 1 million were receiving them (AVERT.ORG, 2006)

The Sub-Saharan Africa accounts for more than 64% of the global HIV infections. According to the joint report by the UNAIDS and WHO in 2004, currently one in every six adults in Zambia is living with HIV and the life expectancy at birth has fallen below 40 years. The same report indicate that the impact of AIDS has gone far beyond the individual level; all areas of the public sector and the economy have been weakened, and national development has been stifled.

Responses to HIV/AIDS in Zambia have for many years aimed to prevent HIV transmission; to care for those who are infected and affected; and to reduce the

personal, social and economic impact of AIDS. Since late 2002, the state has been engaged in an ambitious antiretroviral (ARV) treatment programme (AVERT.ORG, 2006).

The WHO estimates that at the end of 2004, 149,000 people living with HIV in Zambia were in immediate need of ARV therapy (UNAIDS/WHO, 2004). By tackling the virus itself, this treatment can revive a person's immune system and give him/her years of more healthy life. However, until recently drugs could only be bought through the private sector and, at prices between $200 and $800 per month (France-Presse, 2002) and very few could afford them.

The provision of ARV therapy by the Government of Zambia began at two hospitals in Lusaka and Ndola in 2002. Just a year later, the President of the Republic of Zambia, President Levy Mwanawasa announced that his government planned to have 100,000 people accessing treatment by the end of 2005, as part of the World Health Organisation's (WHO) 3 by 5 initiative. However, on the 1st of December, 2005, during the commemorations marking the World AIDS Day, the National AIDS Council announced that Zambia had failed to reach its target of putting 100,000 people living with HIV/AIDS on ARV drugs by the end of December 2005 instead only 40,000 had so far been put on ARVs (www.znbc.co.zm, 1st Dec. 2005).

Zambia's treatment programme has only been made possible by an unprecedented amount of funding from the Global Fund, PEPFAR (Presidential Emergency Plan Fund for AIDS Relief in developing countries, USA) and other sources. The WHO's 3 by 5 initiative and PEPFAR had set their own targets for the end of 2005 and were

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determined to achieve them. The delivery of the programme relied on the involvement of many NGOs, churches and communities.

After a sluggish start, the programme made swift progress in the second half of 2004. By the end of that year, it had expanded to 53 centres, so that a third of Zambia's 72 districts had at least one site. According to Central Board of Health, 13,555 people were receiving ARV therapy through the public sector by September 2004; and at the end of the year, an estimated 18,000-22,000 Zambians (13% of those in need) were receiving treatment (including those who paid privately) (UNAIDS/WHO, 2004). Such a level of coverage was above the African average.

Many are now wondering whether such a rapid rate of expansion can be maintained, and whether all groups will ever have equal access. Shortage of health workers has dominated discussions of Zambia's ARV treatment programme. Until recently, ARVs were very expensive to the average Zambian. Even now, despite having free ARVs, laboratory tests and transport costs just add to the already overstretched budget of the patient (WHO/UNAIDS, 2004; Kombe and Smith, 2003; Lewis, 2005). Apart from the cost involved, there is another hidden challenge of the ARV therapy programs. This is treatment adherence.

Chishimba and Zulu (2004) reported that we had not recorded meaningful results in TB (Tuberculosis) treatment adherence and therefore we were likely to face more challenges in HIV/AIDS treatment.

In their classic study, Kazembe et al (2002), state the risk factors for non-adherence evaluated for a study 1201 HIV-infected Zambian individuals assigned to preventive therapy for TB. In this study only 23.5% adhered to therapy and the multivariate analysis showed that nondisclosure of HIV status and lack of belief in the effect of preventive therapy were significant impediments to adherence. The results further showed that those who scored highly on the health belief model were more likely to adhere. Those referred by family or friends were also more likely to adhere, underlining the point about disclosure.

There is no doubt that adherence is a challenge in our effort to scale up ARV therapy programs across the country. Worse, there is a paucity of data on the adherence rates for the people we have put on ARV therapy since 2002. This study, carried out at a PEPFAR funded Faith Based Organisation (Chreso Ministries) providing ARVs to about 2,000 people by the end of September 2006, aimed to find out whether or not we can be able to predict who is likely to adhere and who is not. It is believed that certain factors once predisposed to, can influence adherence. The factors that were studied are presented in the framework diagram below.

FIGURE 1: Problem Analysis

Patient Related Factors
• Lack of Social support
• *Late inception of Treatment*
• Presence of Psychological problems (depression, anxiety, dementia)
• Lack of Education
• Unhealthy Life styles-beer drinking, smoking
• Personal beliefs regarding potency of drugs
Service Related Variables
• Long waiting time
• Limited space
• Inconsistency drug supply
• Unqualified staff
• Unmotivated staff
• Inadequate patient follow-up
• Inadequate counselling
Regimen/Drug related factors
• Too many pills
• Enslaving Dosage routine
• Severe Side effects
• Restrictive drug food interaction

NON-ADHERENCE

1.1 Justification of The Study

Since the late 1990s, when certain people could afford to buy their own ARVs and indeed since 2002, when the Zambian Government started its own ARV therapy program, there have been few studies on factors associated with ARV therapy adherence.

In this study, we aimed to identify factors that health institutions, clinics and hospitals providing ARVs can use to predict who is likely to adhere to ART and who is not. This would help service providers to identify those who need more adherence

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counselling and those who need more follow-ups in their initial stages of ARV therapy program.

The results of this study are expected to influence policy especially on ART adherence. The findings will also help in planning counselling with emphasis on those most likely to default. In addition, it was hoped that these findings would assist the Ministry of Health in efforts to develop a scheme for rational use of ARVs, and also serve as a resource for research teams developing new protocols. Some of the burning issues covered in this study may be incorporated immediately to address urgent problems that may not require scientific inquiry at the study site.

FIGURE 2: Justification in Summary

CLINICAL RELEVANCE	RESEARCH RELEVANCE	ACADEMIC RELEANCE
• Enhance quality of life • Determine treatment efficacy • Assess treatment acceptability • Assess clinical effects on disease progression • Improve cost savings	• Evaluate new treatment • Monitor side effects • Determine treatment safety • Determine treatment acceptability • Improve study results	• In partial fulfillment of the requirements of degree of public health of the University Of Zambia

1.2 Operational Definitions of Key concepts

1. ADHERENCE: Taking medicines exactly as recommended, mostly at least 95% of the recommended times. This includes taking in exact dosages, going for appointments on exact dates and not delaying taking drugs.

2. *95% ADHERENCE Twice a day regimen = 2 pills per day. If a patient misses 1 pill in a week, that is less than 95% adherence. To achieve 96% adherence in a month, a patient should not miss more than 2 pills per month.*

3. ANTIRETROVIRALS (ARVs): Drugs designed to suppress the progression of HIV/AIDS, consisting of a double or a triple combination of ARV drugs.

4. CD4 T-CELL: Cells that recognize and help destroy bacteria in the body. The count determines the stage of AIDS.

5. CLIENTS: Persons who use the ARV therapy services

6. VIRAL LOAD: Levels of virus found in the blood per 10mls

7. SERVICE RELATED VARIABLES/FACTORS: Factors/variables that are as a result of the hospital/clinic way of operations that are affecting patient ARV adherence. Examples of these are waiting time, quality of staff, number of staff, quality of counselling, patient follow-ups, availability of treatment guidelines, drug supply, infrastructure, and distance to the health facility

8. PATIENT RELATED FACTORS/VARIABLES: Factors/variables that are as a result of the patient's demographic and historical features that are affecting patient ARV adherence. Examples of these are patient's beliefs, patient knowledge, onset of treatment, demographic factors, social support, disclosure of sero-status, occupation

9. DRUG RELATED FACTORS/VARIABLES: Factors/variables that are as a result of the drugs being taken and are affecting patient ARV adherence. Examples of these are Pill burden, Side effects, Dosage routine, Anxiety, Depression, AIDS dementia

CHAPTER 2

LITERATURE RELATED TO THE STUDY

Since 1996, an overwhelming amount of evidence from clinical trials has been published validating the use of ARVs for the treatment of HIV infection. Suppression of HIV replication, immune reconstitution, a halt in disease progression, increased survival; reduced morbidity and a better quality of life have been defined as the biological and clinical goals of treatment. In countries where access to this standard of care is available, AIDS related mortality and morbidity have significantly declined (Pallela, et al., 1998).

Maximum and durable suppression of HIV viral replication to below the level of detection is necessary to achieve the biological and clinical goals. To achieve success requires near-perfect adherence to combination regimens. Failure to suppress viral replication inevitably leads to the selection of drug resistant variants limiting the effectiveness of therapy (Perrin & Telenti, 1998). Non-adherence in patients on anti-HIV therapy is the strongest predictor of failure to achieve viral suppression below the level of detection and faulty adherence to anti-HIV drugs most often underlies treatment failure. It would appear that more than 95% percent adherence may be necessary to adequately suppress viral replication, produce a durable response and halt disease progression. This means that missing more than one dose of a regimen per week may be enough to cause treatment failure (Paterson, et al., 1999).

The challenge of adherence in the face of potential viral resistance, treatment failure and disease progression is worrying. Patients on long-term ARV therapy with undetectable HIV in plasma still harbour replication-competent virus (Shrager &

D'Souza, 1998). It would mean that with current medications, ARV therapy, at best, would be a life-long process. Conscientious treatment adherence is difficult under any circumstances; the unforgiving nature of HIV replication, the complexity of the ARV therapy regimens, and associated short and long-term toxicity all pose particularly difficult challenges for patients.

It needs to be recognized that adherence to ARV therapy is a central issue of concern and it is clear from the literature that the factors that influence a patient's ability to adhere are multiple and complex. A multitude of variables have been shown to affect adherence to ARV therapy (McAllister, 2000). In addition to that, small studies of antiretroviral therapy in developing countries show that there is already resistance circulating among patients who are starting their first "official" course of therapy (Mugyenyi, 2002). The following patient related, service related and drug related factors have been observed elsewhere as having a strong influence on one's ability to adhere or not to:

1. Patient Related Factors

Age

Age may influence adherence. Studies have found that apart from the most elderly, adherence increases with age. In two studies associated with ARV therapy, adherence showed a positive correlation with younger age (Klosinski & Brooks, 1998; Jones, et al., 1999).

Level of Education

A Lower level of general education and poorer literacy may impact negatively on patient's ability to adhere (Moralez, et al 1999) whilst a higher level of education has a positive impact (Schilder, et al., 1998).

Financial concerns

Literature reveals that patients on higher incomes have less difficulty with adherence (Marques, et al., 1998). To make matters worse, poverty is an increasing feature of the face of HIV especially in the third world where many people are living below the poverty line (Grierson, et al., 2000). In the Futures II study, which surveyed 924 Australian HIV positive people, more than half of the respondents reported experiencing some difficulty in meeting the cost of daily living (Grierson, et al., 2000). Medications and clinic visits cost money and may stress an already stretched budget. In the developing countries, there is no medical insurance or disability pension for people living with HIV (Katabira, 2002).

Social support

Living alone and a lack of support have been associated with an increase in non-adherence and social isolation is predictive of non-adherence (Besch, 1995). Not living alone, having a partner, social or family support, peer interaction, and better physical interactions and relationships are characteristics of adherent patients (Holzemer & Nokes, 1998).

Physical state and disease stage

Prior opportunistic infection, symptom severity and low CD4 counts (Erlon & Mellors, 1999) can predict adherence. Seeing an improvement in the immune and virologic indices used to monitor highly active anti-retroviral therapy (HAART) (T-cells and HIV viral load) may be a powerful incentive to maintain adherence. Lack of symptoms (despite laboratory evidence of the need for HAART) may affect adherence (Jones, et al., 1999). Most patients with untreated HIV infection have a median AIDS-free time of 11 years, and HAART is often commenced when patients have laboratory evidence of disease progression but are essentially asymptomatic and feeling well. According to Mugyenyi (2002), one can initiate treatment if he/she has a documented HIV infection and:

- World Health Organization (WHO) stage IV disease irrespective of CD4 cell count

- Advanced WHO stage III disease including persistent or recurrent oral thrush and invasive bacterial infections irrespective of CD4 cell count or total lymphocyte count.

- CD4 count of 200/mm^3 or less for patients in WHO stage I, II or III

- Tuberculosis with a CD4 cell count between 200-350/ mm^3

Depression and severe anxiety

Depression and severe anxiety are variables that predict non-adherence. Most people with HIV, at some time in the course of their illness, experience a psychiatric disorder and depression and/or anxiety are reported in up to 70% of patients with symptomatic HIV-disease. Adherent patients demonstrate significantly less depression or other psychiatric disturbances. HIV involvement of the central nervous system can affect memory. AIDS related dementia (AIDS Dementia Complex –

ADC) is a common finding in patients with advanced HIV disease and is characterized by abnormalities in cognitive as well as motor function (Wright, et al., 1997). Although studies describing adherence and ADC were not found, cognitive deficits do impact negatively on adherence to a HAART regimen (Meisler, et al., 1993). Even when cognition is unimpaired, it is difficult to remember to take medications.

Beliefs and knowledge

A patient's beliefs about his/her illness and the effectiveness of medication are predictive of adherence. A patient's level of knowledge about HIV disease, a belief that HAART is effective and prolongs life, and recognition that poor adherence may result in viral resistance and treatment all impact favourably upon a patient's ability to adhere. Conversely, a lack of interest in becoming knowledgeable about HIV and a belief that HAART may in fact cause harm adversely affect adherence (Horne, et al., 1999).

Beer drinking

A study carried out to associate beer drinking and ARV therapy adherence surveyed among over 200 individuals with HIV assessed how often they missed medication doses or took doses off schedule in relation to their drinking habits. The researchers categorized problem drinkers in three ways: women who had five and men who had six alcoholic drinks at one sitting at least once a month, women who had more than 12 and men who had more than 16 drinks weekly; and women and men with high scores on a test called the Alcohol Use Disorders Identification Test. The findings were that problem drinkers were more likely to take their HIV medications off

schedule. Nearly half of the problem drinkers reported taking medication off schedule during the previous week, compared to 26 percent of those without problem drinking behaviours. Some problem drinkers forgot to take their medications on time because they were drunk or distracted by social functions at bars or parties. Underlying personality traits, or conditions like depression, may lead to both problem drinking and difficulty with medication adherence (Uhl, 2001).

Substance Abuse

Researchers from the Montefiore Medical Center in New York City measured adherence to antiretroviral drug regimens in 85 HIV-infected current and former cocaine users. The study reported that active cocaine use was the strongest predictor of poor adherence and, in turn, failure to maintain viral suppression. Overall adherence among cocaine users was 27 percent, compared with 68 percent among subjects who reported no cocaine use during the 6-month study period. Thirteen percent of active cocaine users maintained viral suppression, compared with 46 percent of nonusers (Person, 2002).

2. Drug/Regimen Related Factors

The drug regimen

Almost all people living with HIV and AIDS (PLWHA) who are currently using anti-HIV drugs are on a regimen of 3 or more drugs (HAART). The likelihood of a patient's adherence to a given regimen declines with polypharmacy, the frequency of dosing, the frequency and severity of side effects, and the complexity of the regimen (Williams & Friedland, 1997).

A typical HAART combination commonly consists of three agents or drugs (Stavudine, Lamivudine and Nevirapine or Effavirenz) and usually plus other medication for prophylaxis of opportunistic infections. This can result into a high pill load, thrice-daily dosing, dietary and dosing idiosyncrasies, large capsules or tablets, and specific storage instructions. This regimen complexity significantly impacts upon a patient's ability to adhere (Ickovics & Meisler, 1997). Additional medications taken for symptomatic relief like analgesics, cough remedies and others common in patients with advanced HIV disease, further add to the pill burden and toxicity. In Zambia, the regimen requires Lamivudine, Stavudine and Nevirapine or Effavirenz as first line and Stavudine, Didanosine and Kaletra or Zidovudine, Didanosine and Kaletra as second line.

Side effects of ARVs

Drug hypersensitivity is far more common in patients with HIV and regimen associated toxicity is a common predictor of, and reason for, non-adherence across many studies (Murri, et al., 1999). Side effects associated with each individual antiretroviral drug are well described, and whilst not universal for every patient, can be predicted. Usually they defect after the first few weeks of therapy but for some, they persist. Anticipation and fear of side effects also impacts upon adherence (Broers, et al., 1994). Poor adherence has been associated with patients' desire to avoid embarrassing side effects in certain situations, for example, whilst on a date or attending a job interview (Burgos, et al., 1998).

Dietary restrictions attached to a drug

Dietary conditions add to the complexity and often require adjustments in lifestyle. Patients can find their meal schedule compromised by anti-HIV drugs that require dosing on a fasted stomach. This can be particularly difficult if work-mates, family or friends are unaware of the patient's HIV status (Grierson, et al., 2000). Complicated regimens with rigid dosing intervals may also interrupt sleep. The physical aspects of a particular medication (for example taste, size and formulation) may also impact on a patient's ability to be adherent (Crespo-Fierro, 1997).

3. Service Related Factors

In Uganda, issues like long waiting time, insufficient personnel, inadequate room, poor supply of drugs, insufficient counselling and inadequate home visits have been reported as having a negative effect on adherence (Nakiyemba, et al., 2004). In his study, McAllister (2000) said other service related factors that can affect adherence are: unmotivated staff, long distance to the health center, opening and closing times, lack of extra services such as health care, privacy, confidentiality, and unsympathetic/unempathetic and inconsistent staff (Kammann, et al., 1999). Physicians, counsellors, pharmacists and home visitors are supposed to be retained for some time to develop a lasting and trusting relationship with patients and this encourages adherence.

Difficulties with HAART re -supply

Obtaining a prescription before a clinic visit is reported as an obstacle to adherence. For just over half of PLWHA, a prescription for HAART lasts for 3 months in developed countries; however, 40% receive a prescription for one month and 12%

for 2 months (Grierson, et al., 2000). In addition, some dispensing pharmacies will only dispense one month's medication at a time. Not all pharmacies are able to dispense anti-HIV drugs, as a result, some PLWHA attend their local pharmacy for most prescription medicine and a specific pharmacy for their anti-HIV therapy. In developing countries the story is very worrying as PLWHA wait for long hours before they are attended and this factor may also impede adherence (Grierson, et al., 2000).

This study took two angles. The first one and of course the core of this study is that we attempted to determine factors that can be used to predict ARV therapy adherence using a multi-disciplinary perspective, with the probability of predicting found using a logistic regression model. However others have used psychological models like the health belief model to predict health behaviour. One example is a study by Toepell (2004) which found that the health belief model was effective in predicting condo use specific to partner type among the sampled prison population. However the current study will use a retrospective case control study and use a logistic regression model to predict adherence.

The second angle looked at the current status of the study sample. This was a cross sectional study type that attempted to determine if associations existed between adherence and disclosure; beliefs; socio-economic status and knowledge on the use of ARVs.

CHAPTER 3

RESEARCH OBJECTIVES AND HYPOTHESES

3.0 General Objective

To identify factors that can be used to predict adherence in patients taking ARVs at Chreso Ministries VCT and ARV therapy Centre in Lusaka, Zambia.

3.1 Specific Objectives

1. To identify associations between patient's knowledge on the use of ARVs and adherence to ARV therapy.

2. To determine whether there is an association between beliefs and one's adherence to ARV therapy.

3. To identify associations between disclosure of one's HIV serostatus and their ARV therapy adherence.

4. To identify associations between one's socio-economic status and ARV therapy adherence.

5. To determine the probability of predicting adherence to ARV therapy.

6. To make recommendations to the Government of Zambia's Ministry of Health and health centres currently providing ARVs (and those intending to provide) on how to ensure adherence in patients and issues to concentrate on during treatment coaching so as to avoid non-adherence.

3.2 Hypotheses

Null/or Research hypotheses

Anti-retroviral Therapy (ART) adherence cannot be predicted using income; employment status; disclosure of HIV status and timing of treatment inception.

Alternate Hypothesis

Anti-retroviral Therapy (ART) adherence can be predicted using income; employment status; disclosure of HIV status and timing of treatment inception.

CHAPTER 4

RESEARCH METHODOLOGY

FIGURE 3: Conceptual Framework of Variables
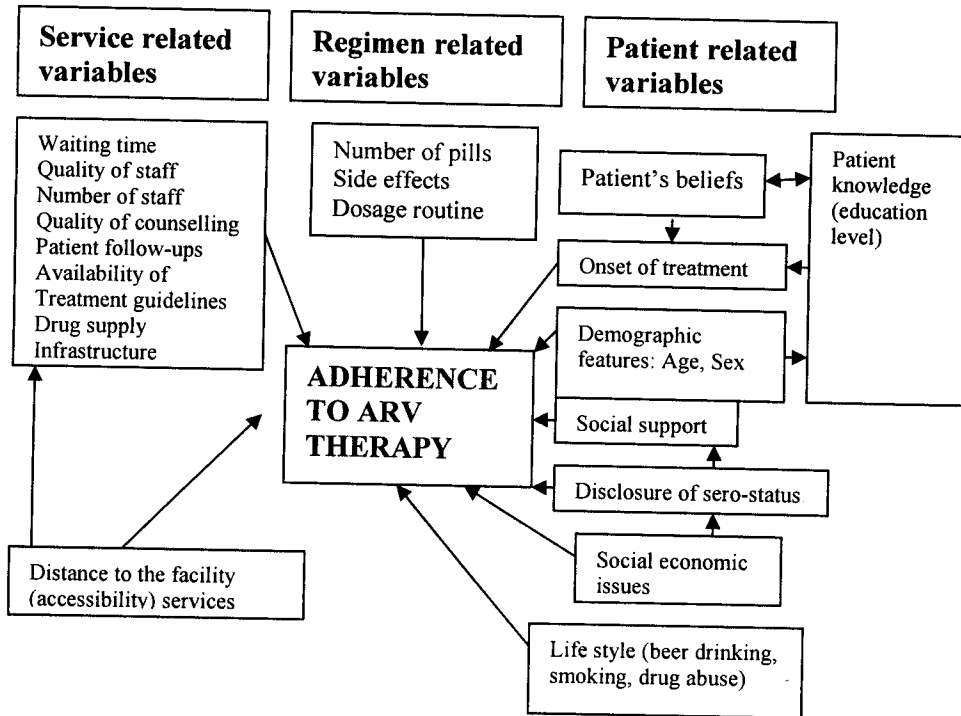
4.1 Study Design and Setting

This was a case control study that compared exposure levels to certain identified factors/variables in non-adherent and adherent respondents. The cases were those who were adherent and the controls were those who were not adherent to ARV therapy. There was also a component of a cross sectional study that attempted to determine associations of identified variables with adherence.

FIGURE 4: Diagrammatical representation of a case-control study
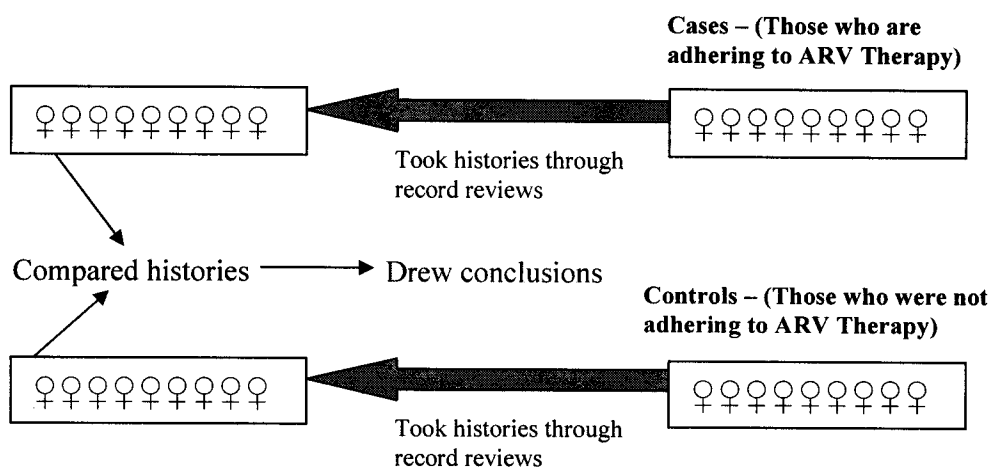
The study was conducted between May 2006 and September 2006 at Chreso Ministries Centre for ARVs and VCT. This is a privately owned Faith Based Organisation, funded through President Bush's PEPFAR initiative. The centre provides free ARVs, VCT and general clinic to people of Lusaka. The centre has laboratory services, equipped enough to do baseline laboratory services including CD4 counts, liver function, kidney function and all necessary tests needed to put one on ARV therapy. At the time when the study was beginning, the centre had 1,100 clients. At the end of data collection, the centre had 2,000 clients.

4.2 Data Collection Tools

The study used only quantitative methods. The quantitative methods used included structured interviews (questionnaires) and retrospective review of patient medical records to extract baseline data. This information was also necessary to describe and profile the patients under study.

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4.3 Sample Size Determination

The difference in the factors to explain adherence rates between those who have been adhering and those who have not been was determined. We needed to evaluate the influence of the factors mentioned in Chapter 3 on one's ability to adhere, and assuming that they would improve adherence from 90% to 95%, and considering power of 50% and a one tailed test at a significance level of 5%. The required size was therefore calculated from the following formula

$$n = \frac{(P1Q1 + P2Q2)}{(P1 - P2)^2} \times f(\alpha, \beta)$$

where P1Q1 is the expected proportion in the control group; P2Q2 is the expected proportion in the intervention group; α is the significance level and β is the power of the study

$$n = \frac{(90x10) + (95x5)}{(90-95)^2} \times 2.71$$

$$\frac{900 + 475}{25} \times 2.71$$

$$n = 149.05 = 150$$

Considering an average response rate of 90%, then the required number in each group became

$$n = \quad 150/.9 = 170 \text{ respondents in each group, giving us } 340$$

4.4 Sampling

The pharmacists helped us in identifying those they suspected not to be adhering and we confirmed this by the use of a list of questions that identified those that were

taking drugs in the right doses, went for appointments on exact days and were not delaying taking their medications. Then we used simple random sampling technique to draw a sample 150 clients who did not adhere to ARV therapy out of 700 non-adherent clients on the register. We also used the same procedure to come up with a sample of 150 clients who adhered to ARV therapy out of 301 adherent clients on the register.

4.5 Enrolment Procedure

By the time this research was beginning, there were 1,100 clients actively receiving ARVs at Chreso (By the time the research was finishing, they were 2,000). To be included in the study, clients

- Must have accepted to be included in the study by signing the consent form
- Must have been on ARVs for six months and above at Chreso Ministries
- Must have been resident in Lusaka by the time of the study
- Must have been either defined as adhering or not adhering

4.6 Target Population

The target population consisted of people living with HIV and were also on ARVs at Chreso Ministries ARV therapy and VCT Centre. The study population consisted of people receiving ARVs from Chreso Ministries ARV therapy and VCT Centre in Lusaka.

4.7 Testing of the Data collection tool/Pre-test

The data collection tool was pre-tested at Circle of Hope ARV therapy centre in Makeni on 50 clients. This clinic was conveniently sampled having considered the time limit. This was done two weeks before the actual study. The objectives were (1)

to appraise the potential of the data collection tool to yield reliable and valid data, (2) to see if study participants understood the phrasing and sequencing of the questions (3) to determine the length of time it would take to interview one client and (4) to identify and fill any gaps in the content of the tool. The results of this pre-test were that some questions needed to be rephrased, removed and more added. It was also found out that it took 30 minutes on average to interview one respondent. For this reason, questions were reduced from 78 to 66.

4.8 Data Entry and Analysis

Data was entered using Epi Info and exported to SPSS where the analysis was done. The Chi-squared test was used to determine associations. The cut-off point for statistical significance was set at the 5% level. In order to determine the probability of predicting adherence using employment status, the following formula was used

$$P = \frac{e^{a+bX}}{1 + e^{a+bX}}$$

Which is the logistic regression formula where the logarithms of the odds (probability divided by one minus the probability with both the dividend and the divisor raised to the exponent values of the sums of their constants.

CHAPTER 5

PRESENTATION OF DATA AND ANALYSIS

5.0 Introduction

With the use of structured interviews (questionnaires) and retrospective review of patient medical records to extract baseline data, 340 respondents were interviewed. After going through the questionnaires, 38 (18 from those who adhered and 20 from the non adherent group) questionnaires were rejected, leaving us with 302. The reasons for the rejection of these questionnaires were that some were incomplete and others had some pages missing while others had respondents withdrawing from the interview voluntarily. The mean age for the respondents at the time they were enrolling for ARV therapy was 35.5 years (standard deviation of 8.3). Out of the 302 respondents, 128 (42%) were male. The average age for males at ARV therapy enrolment was 35.8 years (standard deviation of 8.3) years and for females it was 35.2 years (standard deviation of 8.4).

Table 1: Age and adherence

	ADHERENT?		TOTAL
	Yes	No	
30 years and below	63 (34.6%)	33 (27.7%)	96
31 years and above	119 (65.4%)	86 (72.3%)	205
TOTAL	182 (100.0)	119 (100.0)	301

The observed differences in adherence for those aged 30 years and below of 34.7% among the respondents that adhered compared to 27.7% among the respondents that did not adhere in table 1 could have been due to chance (X^2 1.27; p value 0.259).

5.1 Knowledge on the use of ARVS and adherence

Knowledge levels regarding the use of ARVs and HIV were measured by how much one scored out of the 6 allocated questions (questions 21, 22, 23, 24, 27 and 28b). Anyone who scored 3 and below was classified as having low knowledge and those that scored 4 and above were classified as having high knowledge.

Table 2: Associations between knowledge on the use of ARVS and adherence

Knowledge Levels	ADHERED	
	Yes	No
High knowledge	64 (35.0%)	44 (37.0%)
Low knowledge	119 (65.0%)	75 (63.0%)
	183 (100%)	119 (100%)

The observed proportions of high knowledge of 35.0% among the respondents that adhered compared to 37.0% among the respondents that did not adhere in table 2 were not significantly different (X^2 0.05; p value 0.817).

5.2 Beliefs and adherence to ARV therapy.

A test of association between beliefs and adherence was made. To our interest were beliefs regarding attribution of recovery (whether God or ARVs or both) and also beliefs on whether ARVs have potency to restore one's life.

Table 3: Associations between beliefs regarding attribution of recovery and adherence

Where do you attribute your recovery?	ADHERED	
	Yes	No
Both God and ARVs	100 (75.2%)	51(60.7%)
God	33 (24.8%)	33 (39.3%)

Table 3 shows results of an association between beliefs regarding attribution of recovery and adherence. Respondents who believed in both ARVs and God were 1.96 times (95% CI 1.06 to 3.69) more likely to adhere to treatment than those that believe in God alone (X^2 4.44; p value 0.004).

Table 4: Associations between beliefs regarding whether ARVS have potency to restore life or not and adherence.

Do ARVs have potency to restore your life	ADHERED	
	Yes	No
Yes	176 (96.2%)	115(96.6%)
No	7 (3.8%)	4 (3.4%)
	183 (100)	119 9100)

Beliefs regarding whether ARVs have potency to restore one's life were also analysed to determine whether they were associated with adherence. Almost all of the respondents who adhered (96.2%) and those who did not adhere (96.6%) knew that ARVs have potency to restore life (table 4). These proportions were not significantly different (p value 1.000).

5.3 Disclosure of one's HIV serostatus and ARV adherence

Table 5: Associations between disclosure and adherence

Disclosed	ADHERED	
	Yes	No
Yes	169 (92.3%)	114 (95.8%)
No	14 (7.7%)	5 (4.2%)
	183	119

We also wanted to determine whether an association existed between disclosure of one's HIV status and adherence. The results of the test of significance were X^2 0.93 and p value of 0.335 indicating that there was no significant association between

disclosure and adherence. Most of the respondents disclosed their status in both groups (92.3% among persons who adhered and 95.8% among those who did not adhere) as shown in table 5.

5.4 Socio-Economic Status and ART Adherence

In order for us to identify associations between socio-economic status and adherence, we identified 2 variables (income and employment status).

Table 6: Associations between income and adherence

Income levels	ADHERED	
	Yes	No
<K200,000	104 (57.1%)	68 (57.1%)
>K200,000	78 (42.9%)	51 (42.9%)
	182 (100%)	119 (100%)

The association between income and adherence was not statistically significant as indicated by the results of X^2 0.001 and p value 0.905. About half of the respondents (57.1%) in either group earned less than K200,000 per month (table 6).

Table 7: Associations between employment status and adherence

Formal Employment status	ADHERED	
	Yes	No
Employed	96(52.5%)	73 (61.3%)
Unemployed	87 (47.5%)	46 (39.7%)
	183 (100%)	119 (100%)

About half (52.5%) of the respondents who adhered were employed compared with 61.3% among the respondents who did not adhere (table 7). However there was no

significant association between employment status and adherence (X^2 1.96; p value 0.161).

5.5 Presence of Chronic Illness and Adherence

We were also interested in determining whether there was an association between presence of another chronic illness (other than AIDS) that demands for more physician visits and more drugs taken per day and adherence.

Table 8: Associations between the presence of another chronic illness and adherence

Chronic illness	ADHERED	
	Yes	No
Yes	40 (21.9%)	39 (32.8%)
No	143 (78.1%)	80 (68.2%)
	183 (100%)	119 (100%)

A test of significance (X^2 3.9; p value 0.048) indicated that the observed proportion of respondents with a chronic illness among those who adhered (21.9%) is statistically different to that of the respondents who did not adhere (32.8%) as shown in table 8. Respondents with a chronic illness were 43% (OR=0.57, 95% CI 0.33 to 1.00) less likely to adhere compared to respondents who had no chronic illness.

5.6 Having taken alcohol in the last 3 months and adherence

Table 9: Associations between having taken alcohol and adherence

Have taken alcohol in the last 3 months	ADHERED	
	Yes	No
Yes	30 (16.4%)	23(19.3%)
No	153 (83.6%)	96 (80.7%)
	183 (100%)	119 9100%)

Though we have less people from the category of those that adhered and took alcohol (16.4%) than those that did not adhere and took alcohol (32.8%), the observation could as well have been due to chance as this was not significantly different (p value 0.617; X^2 0.25) (table 9).

5.7 Education and adherence

Table 10: Associations between education levels and adherence

Education levels	ADHERED		
	Yes	No	Total
No education to Grade 7	51 (27.9%)	33 (27.7%)	84
Grade 8 to Grade 9	53 (29.0%)	47 (39.5%)	100
Grade 10 to Grade 12	42 (23%)	22 (18.5%)	64
College/University	37 (20.2%)	17 (14.3%)	54
	183 (100%)	119 (100%)	302

The observed differences of adherence among the four educational categories ranging from no education to university are not significant (X^2 4.51; p value 0.211)

5.6 Record Reviews to Determine the Probability of Predicting Adherence to ART

Table 11: Probability of predicting adherence using logistic regression model

FACTOR	A	B	PROBABILITY OF PREDICTION
Employment status	-0.454	0.64	0.375
Income	-0.304	-0.174	0.382
Disclosure	-0.111	-0.423	0.369
Timing of Treatment inception	-0.343	-0.544	0.292

The probability of predicting adherence for employment status, income, disclosure and timing of treatment inception were between 0.2 and 0.4 with the income having the highest probability of predicting adherence of 0.382

CHAPTER 6

DISCUSSION OF RESULTS

6.0 Introduction

In this study, associations between employment status, income, disclosure, beliefs, having taken alcohol, presence of a chronic illness, and knowledge on one hand and adherence on another were examined. Also in this study, we tried to determine the probability of predicting adherence using income, employment status, disclosure and timing of treatment inception, the variables captured at commencement of ARV therapy six months or more before this study.

6.1 Limitations of the study

The following were the limitations of this study

1. Definitions of adherence: We had problems to define adherence. Because there was no universally accepted definition of adherence, we found it very difficult to find cases and controls. It is possible that some of the respondents we classified as cases could as well have been wrongly classified.

2. Limited number of variables captured during patient enrolment. In order for us to determine probabilities of predicting adherence, we needed to identify some variables that were found in the records of the respondents, captured during commencement of ARV therapy. The problem was that we had very few variables found in the records and this limited us to determine probabilities of predicting only by using income, employment, disclosure and timing of treatment inception.

3. Reliability of self-reported adherence: We relied mostly on self-reported adherence by respondents. Some times it is very difficult to rely on such reports as some people tend to over-report their adherence while others tend to

underreport in order to get more attention from both physicians and pharmacists. This was also observed in the report by Simon, et al (2003).

4. Sample size: The sample size was too small. A study on a bigger sample size is recommended to have at least a power of 80%.

6.2 Discussions on knowledge on the use of ARVS and adherence.

Literature indicates that patients' knowledge on the use of ARVs and HIV impact favourably on a patient's ability to adhere. Conversely, a lack of interest in becoming knowledgeable about HIV and a belief that HAART may in fact cause harm adversely affect adherence. This was reported in a study by Horne et al (1999). However, in the current study it was found that the observed difference of high knowledge of 35.0% among the respondents that adhered compared to 37.0% among the respondents that did not adhere could have been due to chance. This could be explained by the fact that a mere possession of knowledge on the use of ARVs does not necessary mean possession of knowledge on the benefits of ARVs. However, the insignificant association could be due to the small number of cases and also because there could have been cases among controls

6.3 Discussion on beliefs and adherence to ARV therapy

In this study, there was no association found between beliefs in the potency of ARVs and adherence. This was contrary to the study by Horne et al (1999) who reported that a patient's beliefs about their illness and the effectiveness of medication are predictive of adherence. Nevertheless, this could be explained by the fact that believing in the potency of ARVs alone may not necessarily mean understanding the exact and correct way of taking ARVs.

However, a significant association was observed between beliefs regarding attribution of recovery (God and ARVs or God alone) and adherence. It was found that believing in both ARVs and God doubled the chances of adhering to ARV therapy. This could be explained by the fact that attributing recovery to God alone could make someone non-adherent to ART while attributing recovery to ARVs alone may not give someone all the hope of recovery they need. Theologians have reported that believing in God opens doors for unconditional love. In his book, Dixon (2004) said Jesus came for all people especially sinners so that they can have forgiveness and healing. The same author goes on to say that if God made the whole world and he has all power, then he can heal, just like he can make a kettle boil without fire. It is therefore expected that people with strong beliefs in God and in ARVS made by God, are more likely to adhere than those who just believe in ARVs alone.

6.4 Discussion on disclosure of HIV status and adherence

In their classic study in Zambia, Kazembe et al (2002) state that nondisclosure of HIV status was one of the impediments to adherence. Those referred by family or friends were also more likely to adhere, underlining the point about disclosure. However, in this study, it was found that there was no significant association between disclosure and adherence. Most of the respondents disclosed their status in both groups (92.3% among persons who adhered and 95.8% among those who did not adhere). This could be explained by the fact that disclosure alone may actually not be enough especially that if the people disclosed to do not offer any support to the patient. It can also be explained that before ARVs, disclosure was a big thing because of fear of discrimination. But with the coming of ARVs, it is almost impossible to go on for a long time before someone else knows about it. It could as

well be that people do not mind disclosing to anybody because they do not expect to be stigmatized.

A Study by Michael (2006) in the USA indicates that HAART interacts with and shapes HIV disclosure issues in several ways. Medications may 'out' people living with HIV. Thus, in different settings (e.g. work, prisons, drug rehabilitations and public situations), some try to hide medications or modify dosing schedules, which can contribute to non-adherence, and affect sexual behaviours. Disclosure of HIV and/or HAART may also result in antagonism from others who hold negative attitudes and beliefs about HAART, potentially impeding adherence. In other ways, and because of different ways that HAART interacts and shapes HIV disclosure, there seems to be limited benefits of disclosure. This could be another explanation why there was no significant association between disclosure and adherence in the current study.

Observable side effects of medications can also 'out' individuals. Conversely, medications may improve appearance thereby making medications as impediments to disclosure. Some wait until they are on HAART and look 'well' before disclosing; some who look healthy as a result of medication deny being HIV-positive. Alternatively, HIV disclosure can lead to support that facilitates initiation of, and adherence to, treatment. But if there is no support expected from the person being disclosed to, then adherence becomes independent of disclosure. However it may as well be true that HIV disclosure and adherence can shape one another in critical ways. Yet these interactions have been under-studied and need to be further examined. Interventions and studies concerning each of these domains have

generally been separate, but need to be integrated, and the importance of relationships between these two areas needs to be recognized.

6.5 Discussion on income and ART adherence

According to separate reports by WHO/UNAIDS; Kombe & Smith; and Lewis in 2004, 2003 and 2003 respectively, ARVs have been very expensive until recently when they were made free but still laboratory tests and transport costs just add to the already overstretched budget of the patient. Other studies indicate that patients on higher incomes have less difficulty with adherence (Marques, et al, 1998). In the Futures II study, which surveyed 924 Australian HIV positive people, more than half of the respondents reported experiencing some difficulty in meeting the cost of daily living (Grierson, et al., 2000). This literature does not tally with the findings of this study in which it was found that there was no association between income and adherence as indicated by the results of about half of the respondents (57.1%) in either group (adherent and non adherent) earning less than K200,000 per month.

Most of the cited studies were done when ARVs used to cost money. Although the costs of transportation and other laboratory tests should not be ignored, it is worth mentioning that the current study was done among people receiving ARVs at no cost. Therefore, it is possible there may not be a significant association between income and adherence because no one is paying for the drugs and therefore the influence of income is diminished in this case.

6.6 Discussion on employment status and ART adherence

This study found no association between one's employment status and adherence. This calls for more studies as most publications indicate that those in good formal employment have less difficulty with adherence. This finding could be explained by the fact that the employed could be worrying about taking medication at work and fearing intimidation at work while the unemployed could be worrying about having the right food needed for medication to work well. Both groups may end up not adhering to therapy. ARVs in Zambia are free now and one does not need to be in employment of any kind to access the drugs.

Both income and employment status are not associated with adherence in the current study. Another reason is adherence support appears to work best when offered in the clinical setting. And this is why it is not necessary where somebody lives or where adherence counselling is offered from: home vs. clinic. A study by the New York AIDS Institute found that adherence support was most successful when offered in a clinical care setting through the clinical care team. In fact, the study determined that the single strongest and most consistent variable affecting adherence was the setting in which support is offered (Finkelstein, R 2004).

The fact that clinic settings are more suitable to deliver adherence support than social settings could be explained by the fact that a medical care setting helps staff identify and address patient problems with adherence quickly and effectively, because it allows easy contact and case sharing with other members of the clinical care team. Above all, clinical care settings are more equipped with tools and means of handling side effects than homes.

6.7 Discussion on presence of chronic illness and adherence

In this study we were also interested in determining whether there was an association between presence of another chronic illness (other than AIDS) that demands for more physician visits and more drugs (apart from ARVs) taken per day and adherence. Our results indicated that there was a significant association between the two. The results showed that those people with other chronic illnesses that call for more physician visits and more drugs per day other than ARVs are more likely to default on adherence than those without any other illness. This agrees well with other studies carried elsewhere. For example Ickovics & Meisler (1997) reported that the nature of HAART, plus drugs taken for other illnesses common in HIV can result into a high pill load, thrice-daily dosing, dietary and dosing idiosyncrasies, large capsules or tablets, and specific storage instructions. This regimen complexity significantly impacts upon a patient's ability to adhere. Additional medications taken for symptomatic relief like analgesics, cough remedies and others common in patients with advanced HIV disease, further add to the pill burden and toxicity.

6.8 Discussion on having taken alcohol in the last 3 months and adherence

In the current study, there was no significant association between adherence and alcohol. But in a study by Uhl (2001), problem drinkers were more likely to take their HIV medications off-schedule. Nearly half of the problem drinkers reported taking medication off schedule during the previous week, compared to 26 percent of those without problem drinking behaviors.

Although many factors have been identified as barriers to adherence (including unstable housing, current active substance use of time-distorting binge drugs, depression, severe side effects, and a past history of non-adherence to an

antiretroviral drug regimen or even to a TB regimen), research so far reveals a few surprises for anyone who tries to confidently predict adherence (Poppa, et al., 2003). For example, substance abuse with drugs such as heroin (which must be taken at regular intervals) is not associated with poor adherence.

Those that drink too much may forget to take their medications on time because they are drunk or carried away by social functions. Likewise, in a study by Mugavero et al (2006), results of a multivariate logistic regression analysis indicated that alcohol use was one of the variables associated with non-adherence (Mugavero, 2006).

6.9 Probabilities of predicting adherence.

The probability of predicting adherence using employment status at enrolment was only 0.375. This means that a clinician would be 37.5% certain that one would adhere to treatment if they were in formal employment. Using income at enrolment would give a probability of predicting adherence of 0.382. Disclosure would only give 0.369 while timing of treatment inception would give a probability of predicting adherence of 0.292. From these findings, it is not possible to predict adherence using employment, income, disclosure and timing of treatment inception. We therefore fail to reject the null hypothesis that anti-retroviral therapy (ART) adherence cannot be predicted using income; employment status; disclosure of HIV status and timing of treatment inception. These findings agree very well with other findings from another study (Poppa, et al., (2003).

Many HIV/AIDS service organizations are putting substantial resources to supporting adherence. Yet, their efforts are hindered for the reason that some pieces from the adherence puzzle are still missing. The bottom-line is that we often know

what can inhibit or support adherence, but we may not always know what will. It may be tempting to believe that we can predict who will adhere to a HAART regimen and who will not. This research just proves the contrary and other studies show that clinicians' ability to predict adherence is by chance. In fact, preliminary data noted in the British HIV Association's guidelines on provision of adherence support indicate that doctors overestimate adherence to HIV medications of patients currently on drug regimens. Sometimes this becomes even worse when patients deliberately want to impress their clinicians (Simoni, et al., 2003)

·Literature from other studies also confirms that it is impossible to predict adherence based on one's age, gender, ethnicity or socioeconomic status. In this study, we did not find any association between demographic characteristics and adherence. Although many factors have been identified as barriers to adherence (including unstable housing, current active substance use of time-distorting binge drugs, depression, severe side effects, and a past history of non-adherence to an antiretroviral drug regimen or even to TB drug regimen), research so far reveals that its not possible to predict adherence. Not even substance abuse has been associated with poor adherence (Hsu, 2005; Bangsberg, et al., 2005; Simoni, et al., 2003).

Because of the foregoing, it is important to mention that adherence support should be on-going. It may not even be wise to assume that currently adherence patients will remain adherent forever as clinical experience and research indicate that adherence is a "moving target": The longer a patient has been on a anti-retroviral therapy, the poorer his or her adherence is likely to be especially after 6 months and 1 year on treatment. This is why adherence counselling should be an on-going process (Simoni, et al., 2003).

CHAPTER 7

CONCLUSION

The key concluding remarks are as follows:

1. There was no association between ARV therapy adherence and one's socio-economic status.

2. From the variables captured on enrolment (employment, income, disclosure and timing of treatment inception), it was found that it is not possible to predict adherence.

3. There was no association between disclosure of one's HIV serostatus and ARV therapy adherence.

4. There was no association between patient's knowledge on the use of ARVs and adherence to ARV therapy.

5. There was no association between having used alcohol in the last 3 months and adherence.

6. There was no association between belief in the potency of ARVs to restore life and adherence.

7. There was an association between beliefs regarding attribution of recovery to both God and ARVs and adherence.

8. There was an association between presence of another chronic illness (other than AIDS) that demands for more pills take per day and adherence.

Despite the above findings, much work remains to be done. Because the study of adherence to HIV medications is still in its early days, it often raises more questions than answers. It is hereby suggested that further studies are needed in this area.

CHAPTER 8

RECOMMENDATIONS

1. All patients must receive adherence counselling and coaching, including those who look likely to benefit less from the sessions. We need to offer all patients at least some level of adherence support services on a regular basis (Poppa, et al., 2003). By the end of each year, each patient must have at least had not less than 17 times of adherence contact with clinic staff. Therefore, it is critical to monitor adherence for all clients—and to periodically assess whether adherence support is needed. Even though there was no association between having taken alcohol and adherence, we must ensure that all clients are exposed to continuous counselling in order to avoid too much alcohol.

2. Despite the fact that no association was found between social economic status and adherence, we need to pay particular attention to clients coming from impoverished homes. It should be noted that the costs of transportation to the clinic could actual negatively impede on adherence. Where possible, clients should be assisted with transportation. Therefore, a further study to compare adherence levels on clients using different types of transportation is recommended.

3. This study found a significant association between believing in both God and ARVs as reasons for recovery. In our daily contacts with patients, it is important to encourage patients to start going for church services and start developing a strong belief in God as a source of healing at the same time, continue to believe

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that ARVs can "heal" if taken while believing in God's power. The danger here lies in the fact that some people may be so radical that they may believe that only God can heal. When this happens, most people give up taking ARVs. But those that believe in both God and ARVs end up adhering more to therapy.

4. A study to focus on the respondents' knowledge on the benefits of ARVs can bring more answers to questions regarding knowledge and adherence. So many studies have been done on the respondents' knowledge on the use of ARVs and knowledge on HIV but none so far has been done on the benefits of ARVs.

5. It may as well be true that HIV disclosure and adherence can shape one another in critical ways. Disclosure was an issue when ARVs were just new on the "market". But now, with stigma and discrimination slowly dwindling, disclosure seems to be losing its importance in adherence. Therefore, more research on a bigger study sample is recommended here.

6. Continuous monitoring of patients starting ARV therapy is crucial. With the finding that patients with other chronic illnesses are more likely to default on adherence, we must ensure that clients starting ARV therapy and those already on treatment must be given prophylaxis and treatment for opportunistic infections.

CHAPTER 9

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CHAPTER 10

APPENDICES

APPENDIX 1: QUESTIONNAIRE ON FACTORS THAT MAY INFLUENCE ART ADHERENCE

INTRODUCTION

Dear Respondent,

We thank you for accepting to answer this questionnaire on factors that may influence ART adherence. There are eight (8) sections in this questionnaire. Make sure that you understand each question before you answer. Ask where you are not clear. Otherwise instructions are very straight forward. Thank you once again.

SECTION A: PERSONAL INFORMATION

1.	Id Number :		
2.	Date:		
3.	Age:		
4.	Gender:		
5.	Marital Status:	5a	[ ] Married
		5b	[ ] Single
		5c	[ ] Widowed
		5d	[ ] Divorced

6.	Number of children:		
7.	Race/Tribe:		
8.	Religion:		
9.	Occupational status	9a	[ ] Employed
		9b	[ ] Self employed
		9c	[ ] Unemployed
		9d	[ ] Student/at school
10	What is your average monthly income?	10a	[ ] Less than K100,000
		10b	[ ] Between K100,000 and K200,000
		10c	[ ] Between K200,000 and K500,000
		10d	[ ] Above K500,000

SECTION B: DISCLOSURE

11. Have you told anyone that you are HIV positive?

[ ] YES

[ ] NO

12. If yes to the above question, who have you told?

[ ] Friend

[ ] Close relative

[ ] Church member

13. What help do you get from the person you have told about your HIV status

[ ] Encourages me

[ ] Reminds me to take drugs

[ ] Financial and material support

14. Who do you stay with?

[ ] Friend

[ ] Close relative

[ ] Spouse

[ ] Church member

[ ] Alone

15. For how long have you stayed with the person you have mentioned?

[ ] Less than 6 months

[ ] Between 6 months and 1 year

[ ] Between 1 year and 2 years

[ ] Above 2 years

16. Does he/she know you are HIV positive?

[ ] NO

[ ] YES

17. Is she/he aware that you are on ARVS?

[ ] NO

[ ] YES

18. How would you describe this person's role in your condition and road to

recovery? If the answer to the above question was NO, then the answer to this

question is no buddy.

[ ] Dedicated buddy

[ ] Has buddy sometimes

[ ] Has no buddy.

19. In whose house do you stay?

[ ] mine (I RENT)

[ ] My relative

[ ] My friend

SECTION C: KNOWLEDGE (Educational level, literacy level, baseline knowledge regarding HIV, viral load, CD4 count, medications and significance of adherence)

20. How far have you gone in your education?

[ ] Not been to school

[ ] Primary school

[ ] Stopped Grade 9

[ ] Finished secondary school

[ ] College

21. What is HIV?

[ ] Is a virus that causes AIDS

[ ] Don't know

[ ] Other, specify---

22. Is there a cure for HIV?

[ ] YES

[ ] NO

23. What are ARVs?

[ ] Drugs used to treat PLWHA

[ ] I don't know

[ ] Other, specify---

24. Why do you take ARVs? ---

25. Do you think ARVs have helped you

   [ ] YES

   [ ] NO

26. How have they helped you? --

27. What do you think might happen if one misses too many doses? -------------------

28. Ask the respondent to tell you or show you the name of one of the drugs they

   take. Then ask them the following questions

   a. How many times a day are you to take this medicine?-----------------

   b. What is the name of this drug?---

   c. How do you take this drug?

      [ ] With food

      [ ] Before food

      [ ] After food

      [ ] Anytime

SECTION D: ACCEPTANCE AND EFFICACY OF DRUGS

29. Do you think the test was correct when it showed that you had HIV?

   [ ] YES

   [ ] NO

   [ ] I had doubts at first

30. Where do you attribute your recovery?

   [ ] My God

   [ ] My ARVs

   [ ] Other ----------------------------

31. Do you believe that the doctors that see you know what they are doing?

    [ ] YES

    [ ] NO

    [ ] Sometimes

32. Do you believe that ARVs have the potency to restore your life?

    [ ] YES

    [ ] NO

    [ ] Sometimes

33. Describe the effects of not taking ARVS correctly ------------------------------------

SECTION E: SOCIAL ECONOMIC STATUS

34. How many times do you eat a day?

    [ ] Once a day

    [ ] Twice a day

    [ ] More than twice a day

35. What type of foods do you eat at lunch/or super? -------------------------------------

36. What type of transport do you use when going to the clinic or anywhere you want to go?

    [ ] Walking

    [ ] Bicycle

    [ ] Public transport

    [ ] Own vehicle

37. Does your family have all the care and support they need

    [ ] YES

    [ ] NO

    [ ] Sometimes

SECTION F: CO-MORBIDITIES/INTERFERENCES

38. Do you think you could have a mild mental health problem that needs more than just basic counselling?

[ ] YES

[ ] NO

[ ] Sometimes

39. Do you think you could have a moderate mental illness that affects activities of daily living to a significant degree?

[ ] YES

[ ] NO

[ ] Sometimes

40. Do you think you also have another chronic physical disease that causes more physician's visits or medications?

[ ] YES

[ ] NO

[ ] Sometimes

41. Have you taken chemical substances (like drugs e.g. cocaine, marihuana, etc) in the last 3 months.

[ ] YES

[ ] NO

[ ] Sometimes

42. Have you taken alcohol in the last 3 months?

[ ] YES

[ ] NO

[ ] Sometimes

43. Have you had had blood transfusion in the past six months

  [ ] YES

  [ ] NO

44. Have you had sex without a condom in the past six months

  [ ] YES

  [ ] NO

SECTION G: DRUG RELATED QUESTIONS

45. How many times a day are you to take the medicine? ------------------------

46. Are those times suitable for you?

  [ ] YES

  [ ] NO

  [ ] Sometimes

47. Why are you taking pills at these times?

  [ ] Doctor/counsellor advised

  [ ] It's the time I prefer

48. How many pills are you to take each time? ----------------------------------

49. Do you think the number of pills you take are too many and inconveniencing?

  [ ] YES

  [ ] NO

  [ ] Sometimes

50. Does the way you take the drugs inconvenience your daily activities?

  [ ] YES

  [ ] NO

  [ ] Sometimes

51. Did you experience any side effects due to the ARVS?

[ ] YES

[ ] NO

[ ] Sometimes

52. If yes above, did these side effects at one time force you to miss a dose?

[ ] YES

[ ] NO

[ ] Sometimes

53. Is it all right to take it with food?

[ ] YES

[ ] NO

[ ] Sometimes

54. How many doses did you miss in April 06?

[ ] 0   [ ] 1

[ ] 2   [ ] 3

[ ] >3

55. How many doses did you miss in March 06

[ ] 0   [ ] 1

[ ] 2   [ ] 3

[ ] >3

56. How many doses did you miss in February 06

[ ] 0   [ ] 1

[ ] 2   [ ] 3

[ ] >3

57. How often do you miss your appointment?

[ ] Don't miss

[ ] Once a month

[ ] Twice a month

[ ] Thrice a month

[ ] More than 3 times a month

58. Have you ever delayed taking your medication?

[ ] Yes

[ ] No

59. If yes above, when was the longest period?

[ ] 1 hour

[ ] 2 hours

[ ] > 3 hours

60. How often has this been?-----------------------------

61. Get all self monitored calendars, at the end of the interview indicate how many times in each month doses were missed. Just count the number of times they did not tick

MONTH	Number of doses missed
Month 1	
Month 2	
Month 3	
Month 4	
Month 5	
Month 6	

SECTION H: SERVICE RELATED

62. Was there at one time at the clinic when you were told that they had run out of

    drugs you should come next time?

    [ ] YES

    [ ] NO

63. How would you describe the staff attitude towards you at Chreso?

    [ ] Very good

    [ ] Good

    [ ] Average

    [ ] Bad

    [ ] Very bad

64. Describe, in your own opinion, what you don't like about the way Chreso handles

    its clients like you --

65. Are some people from the clinic visiting you at home some times in the month?

    [ ] YES

    [ ] NO

    [ ] Sometimes

66. Do you think the staff that provide care to you at the clinic are qualified to do

    what they do?

    [ ] YES

    [ ] NO

    [ ] Sometimes

THANK YOU VERY MUCH FOR TAKING PART

APPENDIX 2: RESEARCH CONSENT FORM

TITLE OF STUDY:

A CASE CONTROL STUDY TO IDENTIFY FACTORS THAT MAY

INFLUENCE ANTI-RETROVIRAL TREATMENT ADHERENCE.

Researcher   *Supervisor*

Fredrick Mulenga Chitangala Principal investigator School of Medicine UNZA	Prof. S. Siziya, Department of Community Medicine School of medicine UNZA

Purpose

I am a student doing my masters degree in public health at the University of Zambia, School of Medicine. This course requires us to gain applied experience in designing and conducting research. As such, I have designed a research project to study the factors that may influence anti-retroviral treatment adherence.

Description

During this study, you will be asked to complete a questionnaire concerning your personal experiences with factors such as perceived social support, financial situations, problems with the ARVs, and problems with your service provider. You will also be asked for some demographic information (gender, age, etc). Your participation will require approximately 30 minutes of your time. The answers you provide will help us to devise ways and means of helping other patients to adhere to treatment as prescribed.

Potential harm

There are no known harms associated with your participation in this research.

Confidentiality

All records of participation will be kept strictly confidential, such that only I and the people that have been treating you and my supervisor will have access to the information. The results from this study will be reported in a written research report and an oral report during a class presentation. Information about the project will not be made public in any way that identifies individual participants.

Participation

Participation is completely voluntary. It may be discontinued at any time for any reason without explanation and without penalty.

Consent

I have read the above form and understand the information read. I also understand that I can ask questions or withdraw at any time. I consent to participate in today's research study.

Participant's signature/or thumb print: _____ or

| Thumb Print |

Investigator's signature: _____

Date: _____