

**Factors Affecting Antiretroviral Drug Adherence among HIV
Adult Patients Attending HIV Clinic at the University Teaching
Hospital in Lusaka**

A dissertation submitted in partial fulfilment of the requirements for the degree of Masters of
Science in Epidemiology

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Declaration

I UCHIZI CHIRWA hereby declare that the research document being presented for the Degree of Masters in Epidemiology has never been submitted either partly or wholly for another degree at this or any other university or institution of higher learning.

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Approval

This dissertation by Uchizi Chirwa is approved in partial fulfilment of the requirements for the award of a Master of Science in Epidemiology (MSc. Epi) by the University of Zambia.

Examiner 1

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Dedication

To God Almighty

A dedication to my husband Katai Chola and children Nathan and Kutemwa.

Acknowledgments

I would like to acknowledge the help and guidance of my supervisors Professor C. Michelo, Ms R. Dambe and Mrs C. Jacobs to ensure a successful completion of my dissertation.

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Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ARV	Antiretroviral
ATC	Advanced Treatment Centre
ACOE	Adult Centre of Excellence
EHR	Electronic Health Record
HAART	Highly Active Antiretroviral Therapy
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
MTM	medication therapy management
NNRTI	Non-nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Reverse Transcriptase Inhibitor
PI	Protease Inhibitor
PLWH	People Living with HIV and AIDS
UNAIDS	United Nations Programme on HIV/AIDS
UNZABREC	University of Zambia Biomedical Research Ethics Committee
UTH	University Teaching Hospital
WHO	World Health Organisation

CHAPTER ONE

1.0 Abstract

Introduction

The effectiveness of anti-retroviral therapy (ART) relies on a strict adherence to it. To achieve optimum therapeutic levels and reduce drug resistance requires levels $\geq 95\%$ adherence. As such, identifying factors to adherence is essential. We sought to determine factors associated with ART adherence within the context of patient demographics and factors, and factors and to explore care treatment and support strategies used by patients and health workers.

Method

A Mixed Method Sequential Explanatory Design (MMSED) was employed to study adult patients receiving ART from the Adult Centre of Excellence (ACOE), UTH, Lusaka. Adherence was measured by missed clinic appointments and pharmacy collections over the last six months. The quantitative method involved assessing 715 complete medical and pharmacy records. We developed a logistic model for both bivariate and multivariate logistic regression analysis. Qualitative research involved participants' self-reports of missed doses in the past four days. Research questions were drawn up from the quantitative findings and in-depth interviews were conducted with 2 key informants and 5 participants. Thematic analysis was used.

Results

The mean age in years was 38 (± 10.5). Results showed 79.4 % of the patients were adherent to clinical appointments while 46.3 % were adherent to pharmacy refills. Multivariate analysis showed lower adherence amongst the widowed on clinical appointments (OR = 0.3; 95% CI: 0.1–0.9). The stepwise regression analysis revealed significant factors for adherence on clinical appointment and pharmacy refills for widowed, co-habiting and no education, ($p = 0.008$, $p = 0.044$, and $p = 0.018$), respectively. About 80 % of patients interviewed were adherent to ART.

Conclusion

The results show moderate ART adherence (80%). However, in view of the identified factors affecting adherence, concerted and collaborative efforts through effective counselling and social support are needed to improve the adherence levels to at least $\geq 95\%$.

CHAPTER TWO

2.0 Background

Globally, about 35 million people are living with HIV. According to 2012 WHO Global Health Observatory Data Repository, Sub-Saharan Africa is the most affected region, with 25.8 million people living with HIV (UNAIDS, 2012). It accounts for almost 70% of the global total of new HIV infections. Zambia has been one of the most severely hit with this disease. The United Nations Programme on HIV/AIDS (UNAIDS) 2013, estimates that the number of people living with HIV (PLWH) in Zambia are 1,100,000 [1,100,000 - 1,200,000] with a prevalence rate of 12.5% [11.9% - 13.3%] in adults aged 15 to 49.

In the early 90's people were dying from the disease and so the National HIV/AIDS/STD/TB Council (NAC) in Zambia became operational in 2002 to look into this developing problem. One of its main concerns is to provide care, treatment and support to PLWH (WHO, 2012). In 2004, the Ministry of Health (MOH) in Zambia provided antiretroviral therapy (ART) at four clinics in Lusaka, Zambia (Lewis, 2005). The objective of the government was to provide HIV care and treatment and free ART service package to the public sector (Stringer et al., 2006).

Antiretroviral therapy (ART) consists of the combination of antiretroviral (ARV) drugs to maximally suppress the HIV virus, stop the progression of HIV disease and prevent HIV transmission (UNAIDS, 2013). The use of potent ARV regimens in the early stages of the disease has dramatically improved the prognosis and quality of life for HIV/AIDS patients [(Gifford et al., 2000); (Bangsberg, 2006); (Wang and Wu, 2007)]. Antiretroviral therapy (ART) reduces the amount of virus in the body to very low levels, allowing the immune system to recover its strength. Highly active antiretroviral treatment (HAART) reduces the morbidity and mortality associated with HIV infection by suppressing viral replication, restoration and preservation of immune function, and prevention of drug resistance (Simoni et al., 2006). The 3 main classes of antiretroviral drugs include nucleotide reverse transcriptase inhibitors (NRTI) non-nucleoside reverse transcriptase inhibitors (NNRTI), protease inhibitors (PI), fusion inhibitors. Achieving optimal therapeutic outcomes, such as reduce viral load, reduction of drug resistance, and improved survival, requires strict adherence to ART regimens (Wood et al., 2003)

Adherence to ART, however, is very important for successful treatment of HIV/AIDS. Previous studies have suggested that $\geq 95\%$ adherence results in virologic success of $> 80\%$, while the success rate drops to 60% in patients with 80–94% adherence [(Sethi et al., 2003); (Paterson et al., 2000); (Chesney, 2000); (UNAIDS, 2012)]. However, according to two studies, a moderate adherence (80-90%) should lead to an enhanced viral suppression under more effective regimen [(Maggiolo et al., 2005); (Bangsberg, 2006)]. The commonly identified factors for non-adherence are forgetfulness, being away from home, side effects of drugs, poor understanding of the relationship between non-adherence and disease progression, alcohol and drug abuse, poor social support, poor health provider-patient relationships, stigma, educational level, and others (Chesney, 2000). Even when the consequences of poor adherence to medication are known, adherence rates remain quite low. According to WHO report of 2013, retaining people receiving ART in care and ensuring good treatment adherence are critical determinants of successful ART outcomes.

Adherence levels differ from person to person and over time. This study aims at determining the factors affecting drug adherence among adult HIV patients on antiretroviral treatment by using timing of ARV doses and keeping to clinic appointments and pharmacy refills as key indicators. This study will help identify factors that are associated with antiretroviral drug adherence among adult HIV patients at the Adult Centre of Excellence and hence improve the quality of life and reduce mortality rates.

2.1 Factors that affect adherence

Highly active antiretroviral therapy (HAART) has led to increasingly complex drug regimens (Simoni et al., 2006). These regimens present significant challenges to both patients and health-care providers with respect to adherence. The effectiveness of ART depends on a strict adherence to it. Therefore if one is not adherent to ART it could result in insufficient viral suppression, immunologic failure, rapid disease progression, and the development of drug resistance (Mitiku et al., 2013). Therefore, recognizing and overcoming the factors that reduce adherence to antiretroviral agents is important for continued viral load suppression.

Chesney (2000) notes important issues in the study of adherence to antiretroviral drugs such as defined measurement of adherence, assessment of the impact of adherence on viral load and clinical effect, determination of the factors that affect adherence, and the development of interventions. This study will only focus on determining the factors that affect adherence.

Major factors related with non-adherence seem to be patient-related, including substance and alcohol abuse (Chesney, 2000). Other factors may also have a bearing on adherence, such as

untimely dosing frequency, dietary restrictions, pill burden, and side effects; patient–health-care provider relationships; and the system of care (Chesney, 2000). A relationship worth noting between improved ART adherence and reduced viral load has been demonstrated for patients with HIV/AIDS in several studies. For example, a study by Grossberg et al. (2004) undertook in a Veterans Affairs Medical Centre found that each adherence rate increase of 10% was associated with a viral load decrease of 0.12 log₁₀ (95% CI = 0.01 log₁₀-0.23 log₁₀) copies per millilitre (mL).

Service related factors

Pharmacists can better improve adherence of medication in patients by providing Medication therapy management (MTM) services (Miller and Gilmer, 2009). This service involves an assessment of patients' ability to adhere to medication, identifying and managing adverse drug reactions, tailoring ART regimens to meet special lifestyle needs, counselling when medication overuse or underuse was detected, refill reminder services, referral to other medical services as needed (Pellegrino et al., 2009). Miller and Gilmer (2009) reported positive outcomes associated with patient attendance at pharmacist-led clinic and found a reduction in viral load at 6 to 12 months and improved medication adherence. March et al. (2007) reported significant improvement from baseline in CD4 + T-lymphocyte counts and viral loads, and a significant decrease in the severity of ART-related toxicity in patients attending a pharmacist-managed drug optimization clinic. MTM studies are hardly being provided at the HIV clinic in Lusaka due to lack of pharmacy staff. While this study is not about the provision of MTM services and how it can improve adherence levels, the role of MTM in improving drug adherence can be seen clearly. A good patient–health-care provider relationship may be an important motivating factor for taking and adhering to complex combination drug therapies (Stone et al., 1998). Nozaki et al. (2011) conducted a study in rural Zambia found that health care workers need to provide instructions to patients on how to take medication as they had limited ways of knowing the exact time and ways to remember how to take ARVs. A qualitative study of homosexual youths showed that primary-care providers exhibited judgmental behaviour, stereotyping, homophobia, and failure to address cultural issues when administering care (Schilder et al., 1998). This type of patient-health-care provider relationship can turn people away from the facility and hence lead to adherence issues. However, Zambia has not experienced homosexuality publicly. If a homosexual patient comes to seek medical attention and has not made it known to the health-care provider his sexual preference, it is likely to lead to stigmatisation as cultural issues would be a factor.

It could also be a possible a reason for non-adherence as the health-care provider would not be able to fully dispense his/her duties. Possibly exploring this area will help provide solutions to providing better service delivery and hence reduce non-adherence to same sex couples.

Age

Shah et al. (2007) conducted a cross-sectional study in 279 (98.6%) patients on ART adherence and its correlates;found that adherence was positively associated with people aged more than 50 years (adjusted odds ratio [aOR], 3.90) and medication self-efficacy (aOR, 4.01). However, a study conducted in Zambia to determine social factors affecting ART adherence in rural setting (Nozaki et al., 2011) found that age was an independent factor for being classified in the non-adherent group. Preliminary data from a number of studies of adherence to antiretroviral agents have been presented in abstract form [(Paterson et al., 1998); (Gifford et al., 1998)]. Specific findings vary from study to study, due at least in part to the different sample sizes and measures used.

Patient Related Factors

Generally, it appears that the most important factors that affect adherence are patient-related. A study conducted in rural Zambia(Birbeck et al., 2009) suggested that psychosocial factors surrounding stigma fears resulted into concealing HIV status are key determinants of adherence among rural Zambians. Most common reasons for non-adherence given by patients were: forgot or busy, away from home, change in daily routine, side effects, depression or illness, lack of interest or drug “holidays” [(Potchoo et al., 2010); (Oyugi et al., 2007); (Curioso et al., 2010)] The major reasons were that they forgot or were busy. These factors will be investigated further.

Side effects of ARV drugs may have an effect on adherence levels. Commonly experienced side effects are neurologic adverse events, skin rash, nausea and vomiting and diarrhoea. A study conducted in Zambia to view patients’ perceptions on factors that facilitate and challenge access and adherence found that even with barriers such as side effects, produced good adherence (Grant et al., 2008).Patients that report experiencing “severe” side effects tend to stop taking their medication saying that it interferes with their social lives (Dahab et al., 2008). However, this may not be so with others as they want to get better.

Social drinking is widely accepted and has been incorporated into many important ceremonies. Alcohol consumption significantly lowers the likelihood that patients will be adherent to highly active antiretroviral therapies (HAART) [(Arnsten et al., 2002); (Hendershot et al., 2009); (Lucas et al., 2002); (Parsons et al., 2008)]. Additionally, alcohol

use has been shown to be the most significant predictor of non-adherence to HAART (Samet et al., 2003). On days on which patients consume alcohol, odds of medication non-adherence are nine times higher, compared to non-drinking days, and each additional drink consumed increases the odds of skipped or delayed medication doses by an additional 20% (Parsons et al., 2008). Studies done in South Africa and Botswana revealed suboptimal ART adherence due to alcohol consumption was quite significant [(Bhat et al., 2010); (Do et al., 2010)].

Another study documented mental illness at baseline with alcohol and substance abuse increased non-adherence to ART medication (Mellins et al., 2009). HIV-positive patients who drink any alcohol, irrespective of frequency or quantity of drinking, are only 50–60% as likely to be adherent as avoiders (Hendershot et al., 2009).

A common finding in studies of adherence to treatment of diabetes, hypertension, asthma, and HIV infection is that adherence decreases with greater dosing frequency (Dezii et al., 2002); (Golin et al., 2002). Another study found that a higher dosing frequency of three times daily dosing regimen compared with once or twice daily regimens decreases adherence levels to treatment. (Gardner et al., 2005)

2.2 Conceptual Framework

To answer the research question and address the specific objectives, the conceptual framework was developed based on the proximate determinants (Figure 1). The model used in this study is an adaptation of the works of Irunde et al.,(2006) in a study on anti-retroviral adherence in Tanzania: a pre-intervention perspective, 2005.

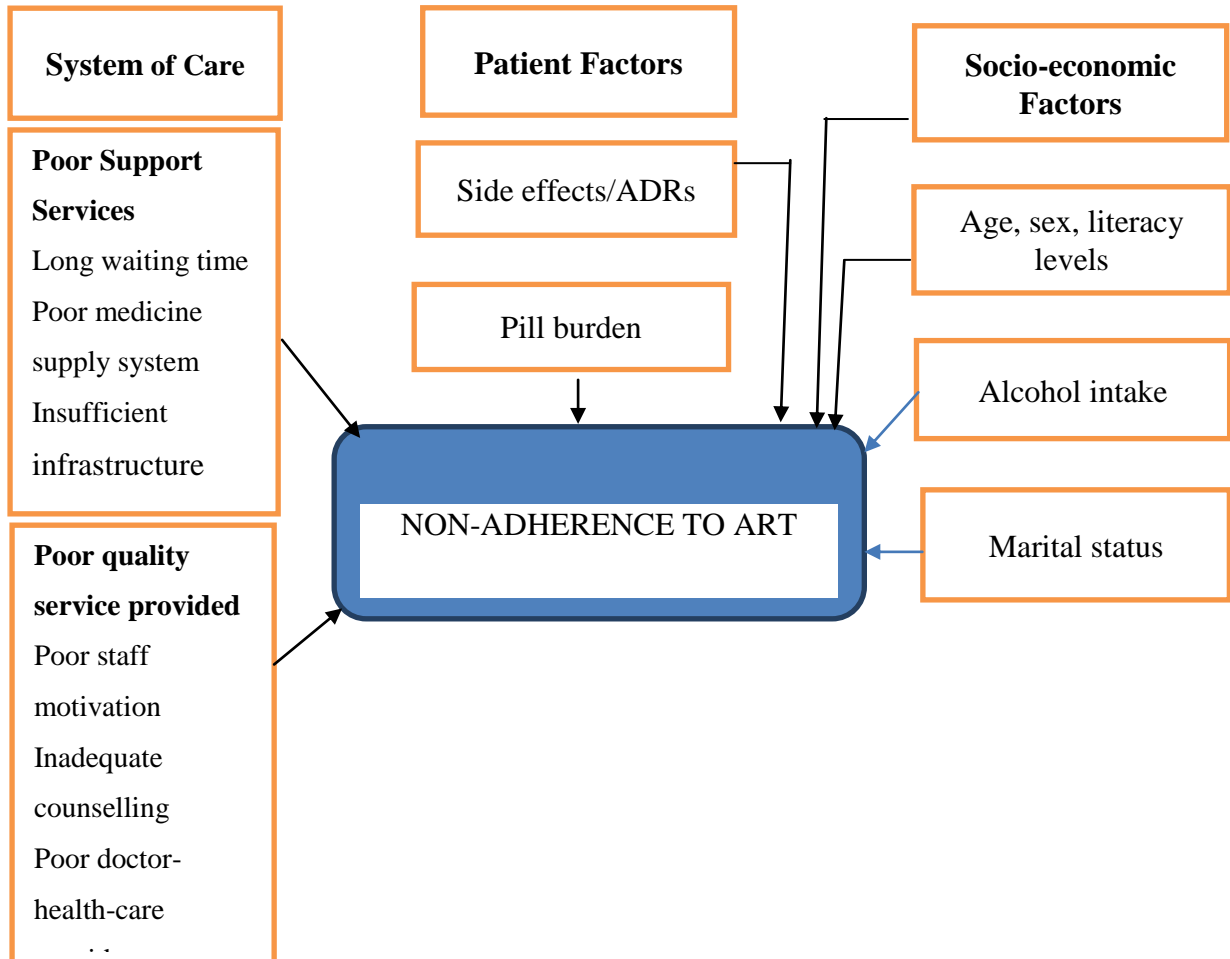


Figure 1: Conceptual Framework: Adapted from WHO, 2012

The model has been modified to suit this research. Other studies have described a range of factors affecting ARV treatment adherence at various levels including individual, community and health facility levels(Weiser et al., 2003); (Nozaki et al., 2011); (Potchoo et al., 2010)This model identifies service factors, patient factors and socioeconomic and cultural factors leading directly and indirectly to sub-optimal adherence to ARVs.This framework forms the basis for the variables used in the research as it shows the factors that are affecting ART drug adherence.

CHAPTER THREE

3.0 Study Focus

3.1 Problem Statement

Non-adherence to ART could result in insufficient viral suppression, immunologic failure, rapid disease progression, and the development of drug resistance (Mitiku et al., 2013). The exact burden of adherence to ART is limited at the ACOE. Adherence remains the single most important strategy for long term success and sustainability of patients on ART (UNAIDS, 2013). Antiretroviral treatment failure generally results from a failure with adherence and efforts to ensure good adherence from the onset of ART initiation must be mandatory. Good adherence means drugs should be taken at the same time of the day to maintain constant drug blood level; taking all the medications at the right time, in correct doses; not skipping doses; not stopping and restarting therapy without medical advice; adopting health seeking behaviour (Health, 2010).

The Adult Centre of Excellence (ACOE) in Lusaka was set up in 2008 to provide specialised ART services and help improve lives of PLWH by reducing resistance through drug adherence. Drug adherence is promoted by one on one session as well as group discussions and once weekly seminars. Despite such interventions there are low levels of adherence (estimated at 70%). Therefore this study seeks to identify factors leading to low levels of adherence at the ACOE, UTH.

3.2. Justification for this study

Adherence to medication improves drug levels in patients taking ART medication and thus reduce viral load which will in turn reduce resistance and improve patients' survival levels (Wood et al., 2003). Despite this fact, there is a lack or little follow-up studies to identify the various factors altering the medication adherence to ART in adult patients of Lusaka at the ACOE. The Ministry of Health national guidelines provided on ART adherence does not give the percentage of adherence that one needs to attain. The ACOE in Lusaka was chosen because it is the largest referral HIV clinic in Zambia where the best quality care is provided, with well-trained medical staff in HIV. Chesney (2000) notes important issues in the study of adherence to antiretroviral drugs such as defined measurement of adherence, assessment of the impact of adherence on viral load and clinical effect, determination of the factors that affect adherence, and the development of interventions. However, this study will only focus on determining the factors that affect adherence. It is hoped that by determining the level and

factors of adherence in patients at ACOE in Lusaka will inform management at which level of adherence the facility is so that effective and efficient interventions are made to improve on the referral centre as well as those clinics that refer patients.

3.3. Research Question

What proportion of adult patients above 18 years attending the HIV/AIDS clinic at UTH in Lusaka are adherent to ART and their associated factors?

3.4 Objectives

General objective

To determine ART adherence and associated factors among adult HIV/AIDS patients on antiretroviral treatment at UTH, Lusaka

Specific Objectives

1. To determine ART adherence.
2. To identify socio-demographic and patient factors associated with ART adherence.
3. To explore ART care treatment and support strategies used by patients and health care workers.

CHAPTER FOUR

4.0 Methods

4.1 Study Setting

The study was conducted at the, Adult Centre of Excellence (ACOE), University Teaching Hospital (UTH) in Lusaka. The University Teaching Hospital is the biggest hospital in Zambia, with 1655 beds. It is located in the capital city Lusaka approximately 4Km east of the city centre. The ACOE was set up in 2008 for the treatment of patients with HIV.

4.2 Study Population

The study was conducted at the ART clinic at the University Teaching Hospital, Lusaka. The study population consisted of 715 patients aged 18 years or above attending the ART clinic receiving 1st line ART and 2nd line ART and 2 health workers at the ART clinic, UTH in Lusaka.

4.3 Study Design

A Mixed Method Sequential Explanatory Design was employed. This method consists of two distinct phases: quantitative and qualitative (Creswell et al., 2003). This design calls for the collection and analysis of the quantitative data (numeric) first, thereafter the qualitative data (text) is collected and analysed, sequentially.

4.4 Phase One: Quantitative Design

4.4.1 Eligibility Criteria

Inclusion Criteria

- All HIV patients that attend the clinic who were above the age of 18 years.
- Participants that were on ART for at least three months

Exclusion Criteria

- All incomplete records that had missing data such as marital status, age
- Patients on 3rd line ART regimen

4.4.2 Sample size determination

The sample size formula employed was

$$n = \frac{z^2 P(1-P)}{d^2} \text{ where } p=\text{proportion, } d=\text{precision, } z=1.96$$

50% proportion estimated

95% CI, 5% significance level

80% power

0.04 precision

80% response rate

Sample size = 715

Files were selected by simple random sampling to ensure that participants have an equal chance of participating in the study.

4.4.3 Study Variables

Dependent Variables

ART adherence (dichotomous variable), was measured by missed clinic appointments and pharmacy refills over the last six months. Adherence on clinical appointment meant that a patient attended at least 2 clinical appointments in the six months period of data collected. This was because some people had been on ART for a few months to few years and doctors' appointments were given either every three months or on a six monthly basis. Adherence on pharmacy refills meant that a patient should have refilled on medication more than three times at the pharmacy in the six months of data collection. This is because medication is given on a three monthly basis for those that are experienced. Those that just start treatment are given monthly for the next three months and thereafter given every three months.

Background Variables

- Age
- Sex
- Education level
- Marital status
- Medication regimen
- Alcohol intake

Table 1: Measurement of Variables

Types of Variables	Variable	Indicator	Scale of Measurement
Dependent variable	ART adherence (Dichotomous)	<ul style="list-style-type: none"> • Pharmacy records (number of drugs dispensed over last 6 months) • Clinic appointment logs • Number of doses missed in last 4 days 	Adherence >95% or adherence <95%
Background variables	Alcohol intake	Yes No	Percentage (%)
	Age		Categorical Percentage (%)
	Sex	Male Female	Percentage (%)
	Education level	Primary Secondary Tertiary Never	Percentage (%)
	Marital Status	Never married Married Divorced	Percentage (%)
	Medication regimen	Dosing complexity (pill burden)	1-2 tabs/day (%) >2 tabs/day (%) >4 tabs/day (%)
	Patient-healthcare provider	Availability	Poor Good Average Excellent
	System of care	Availability	Weak Average Strong

4.4.4 Data Management

Data was extracted from the pharmacy dispensing tool and Smartcare at the ACOE from patient files with the use of a checklist as a tool guide. Smartcare is the MoH designated national standard for electronic health record (EHR). Smartcare is the EHR tool that collects, stores, reports on and aggregates data from a large patient population. Permission was requested from management to access this data for the purpose of the study upon receipt of approval from Ethics committee. Information such as socio-demographic characteristics,

medication regimen, other drugs and other diseases was obtained. The data was exported from excel spreadsheet to Stata software version 12 where it was then cleaned ready for analysis.

4.4.5 Data Analysis

Using Stata Version 12 statistical software, we conducted preliminary descriptive statistics using univariate analysis to explore each individual variable in the data set, separately, to assist in describing significant independent linear patterns and association with adherence as the outcome variable. We developed a logistic model for both bivariate and multivariate logistic regression analysis. The precision of estimates was measured at 95% Confidence Interval with the probability (p-value) of ≤ 0.05 . Only variables with significant results were kept for the final model.

4.5 Phase Two: Qualitative Design

4.5.1 Eligibility Criteria

Inclusion Criteria

- All patients that attend the clinic above the age of 18 years.
- Participants that were on ART for at least three months
- Health care workers

Exclusion Criteria

- Hospitalized HIV patients
- Participants (patients and health care workers) not willing to participate in the study.

4.5.2 Sampling

As a follow up to the quantitative data collection and analysis, purposive sampling was employed to get a clear understanding of the perceptions of health workers and patients where in-depth interviews were conducted with 2 key informants (i.e. one doctor and one nurse) and 5 patients.

4.5.3 Data Collection

Upon quantitative data collection and analysis, research questions were drawn up from the findings and in-depth interviews were conducted with the 2 key informants and 5 participants. Data on perceptions of adherence issues, quality of care and challenges faced

were collected from the participants. Patients that reported having missed doses for the past four days were classified in the non-adherent group.

4.5.4 Qualitative analysis

After the results of the quantitative analysis, research questions were drawn up for qualitative research interviews to take place. We recorded interviews conducted with the patients and health workers. Analysis was manually done and later transcribed verbatim. Thematic analysis of the interviews was used where common themes were identified from the interviews. Thematic analysis was used because it provides accessible and theoretically flexible approach to analyzing qualitative data (Braun and Clarke, 2006). Thematic analysis looked at the following stages:

1. Familiarization: the researcher listened to the recordings as transcribing was taking place. This process was repeated several times to get a clear understanding of the responses from the conversations.
2. Generation of codes: this stage involved identifying and highlighting the relevant key words/phrases in each of the sentences or paragraphs. In this way, descriptive words were assigned to them. During this process, emphasis was placed to retain the original meaning of the context.
3. Next, we searched for themes. This involves piecing together components of the conversations/experiences of the informants to form a more comprehensive picture of their collative experiences. This was done to reduce the number of different pieces of data in the analysis. Similar codes were grouped together to form categories.
4. Reviewing themes: this involved assessing categories to see if they could be generalized. Major themes were developed by interpreting the categories for their underlying meaning.

4.6 Dissemination

Data from this study will be shared with the Department of Public Health under the School of Medicine at the University of Zambia, the Ministry of Health, Centre of Excellence Management Team by conducting a one day workshop, and Research Ethics Committee. Other copies of the research report will be sent to relevant authorities for journal publications of research findings as opportunities arise.

4.7 Ethical Considerations

Prior to conducting this research, the Research and Ethics Committee of the University of Zambia reviewed and approved the protocol (Ref. No. 024-06-15). Further permission was sought from the Head of Internal Medicine to collect data from the Centre of Excellence where access to their data set was permitted. Access and review to the patients' records was done by the principle investigator and kept only by the principle investigator.

Interviews were conducted in the shortest possible time without compromising on quality. The participants were not under any physical risks. There were no direct benefits to the participants, only that they are contributing to the body of knowledge regarding ART adherence. With regards to risk and confidentiality, there was no serious risk as the names of the patients were not used.

4.8 Data Integration

The results of the quantitative and the qualitative designs were then integrated into the discussion. The qualitative results of this study helped to explain the initial results of the quantitative design.

CHAPTER FIVE

5.0 Results

5.1.0 Quantitative Component

5.1.1 Description of characters

Of the 715 patients that were eligible in the study, 53% were female and 36.7% were male. The mean age in years was 38 (± 10.5) with the age range of (18-75). The majority of the participants were in the age range of 35-44 years 268 (37%) followed by the age range 25-34 years 198 (28%). Distribution by sex showed that 53% were women and 37% were men. The majority of the respondents 407 (56.9%) had reached secondary level followed by primary 124(17.3%), 70.8% were married while 6.6% were never married.

Table 2: Demographic and health related characteristics of ART patients at AIDC UTH, Lusaka

Characteristics	Frequency (N=715)	Percent (%)
Age in years		
18-24	63	8.8
25-34	198	27.7
35-44	268	37.5
45-75	186	26.0
Sex		
Female	381	53.3
Male	334	36.7
Education		
Primary	124	17.3
Secondary	407	56.4
Tertiary	95	13.7
None	86	12.0
Marital status		
Never married	47	6.6
Married	506	70.8
Divorced	34	4.8
Widowed	35	4.9

Co-habiting	93	13.0
Other diseases		
TB	668	93.4
Renal failure	5	0.7
Hypertension	19	2.7
Other	23	3.2
Drug regimen		
1 st line	601	84.1
Co-trimoxazole	5	0.7
2 nd line	109	15.2
Other drugs		
Co-trimoxazole	615	86
ATT	71	9.9
Other	29	4.1

* TB= tuberculosis, ATT= anti-tuberculous drugs

5.1.2. Antiretroviral Adherence

Using clinical appointments 568 patients (79.4%) were $\geq 95\%$ adherent. Results taken from pharmacy refills found that 53.7% were non-adherent. Pearson correlation among the two adherence outcomes (clinical appointment and pharmacy refills) indicated no significant level of association ($\chi^2(1) = 2.8820$, $Pr = 0.093$). The proportion of those that were adherent to pharmacy refills to those that were adherent to clinical appointments (47.9%) compared to those that were not adherent to clinical appointment (40.1%) were not different. From those found non-adherent on clinical appointments (20.6%), 59.9% were also non-adherent on pharmacy refills.

Table 3: Anti-retroviral Therapy Adherence

Variable	Status	n	%
Clinical Appointment	Adherent*	568	79.4
	Non-adherent **	147	20.6
Pharmacy refills	Adherent*	331	46.3
	Non-adherent**	384	53.7

*adherence of $\geq 95\%$, **adherence of $< 95\%$

5.1.3. Factors associated with ART adherence

Table 3 shows the association between background factors and ART adherence. We found that demographic characteristics had no relationship with drug adherence. The presence of another disease besides HIV and taking other drugs besides antiretroviral drugs was not associated to drug adherence. However, we found that there was association between the ART drug regimen that a person was on and adherence to pharmacy refills (P=0.037) but not to a clinical appointment.

Table 4: Factors associated with adherence – Results of Pearson’s Chi-squared test

	Pharmacy refills			Clinical appointments		
	No (n(%))	Yes	P	No (n(%))	Yes (n(%))	P
Age in years			0.857			0.381
18-24	36(9.4)	27(8.2)		17(11.6)	46(8.1)	
25-34	107(27.9)	91(27.5)		38(25.9)	160(28.2)	
35-44	139(36.2)	129(39.0)		59(40.1)	209(36.8)	
45-75	102(26.6)	84(25.4)		33(22.5)	153(26.9)	
Sex			0.694			0.901
Female	202(52.6)	179(54.1)		79(53.1)	302(53.2)	
Male	182(47.4)	152(45.9)		68(46.3)	266(46.8)	
Education			0.244			0.350
Primary	67(17.5)	57(17.2)		25(17.0)	99(17.4)	
Secondary	225(58.6)	182(54.9)		86(58.5)	321(56.5)	
Tertiary	50(13.0)	48(14.5)		16(10.9)	82(14.4)	
None	42(11.0)	44(13.6)		20(13.6)	66(11.6)	
Marital Status			0.554			0.161
Never Married	24(6.3)	23(6.9)		8(5.4)	39(6.9)	
Married	269(70.1)	237(71.6)		102(69.4)	404(71.1)	
Divorced	16(4.2)	18(5.4)		6(4.1)	28(4.9)	
Widowed	18(4.7)	17(5.1)		13(8.8)	22(3.9)	
Co-habiting	51(14.8)	36(10.9)		18(12.2)	75(13.2)	
Other diseases			0.751			0.251
TB	358(93.2)	310(93.7)		138(93.9)	530(93.3)	
Renal failure	4(1.04)	1(0.3)		1(0.4)	4(0.7)	
Hypertension	10(2.6)	9(2.7)		1(0.7)	18(3.2)	
Other	12(3.1)	11(3.3)		7(4.8)	16(2.8)	
Drug Regimen			0.037			0.548
1 st line	328(85.4)	273(82.5)		122(82.9)	479(84.3)	
Co-trimoxazole	5(1.3)	0(0.0)		2(1.4)	3(0.5)	
2 nd line	51(13.2)	58(17.5)		23(15.7)	86(15.1)	

Other Drugs			0.125			
Co-trimoxazole	338(88.0)	277(83.7)		125(85.0)	490(86.3)	0.400
ATT	30(7.8)	41(12.4)		18(12.2)	53(9.3)	
Other drugs	16(4.2)	13(3.9)		4(2.7)	25(4.4)	

* TB= tuberculosis, ATT= anti-tuberculous drugs

5.1.4. Determinants of ART adherence

Table 4 is a summary on univariate analysis of factors that might potentially affect adherence to ART. We found that demographic characteristics had no relationship with drug adherence. However, on clinical appointment, we see lower adherence amongst the widowed than those that had never been married (P= 0.043). Other diseases and drug regimen were found not to be associated with drug adherence. Those on anti-tuberculous drugs had greater odds of adherence than those on Co-trimoxazole on pharmacy refills (OR, 1.7; 95%CI, 1.0-2.7).

Table 5: Association between Demographics/patient factors and ART adherence - Results of Univariate logistic regression

	Pharmacy refills			Clinical appointments		
	OR	95%CI	P	OR	95%CI	P
Age in years						
18-24	Ref.					
25-34	1.1	0.6-2.0	0.667	1.6	0.8-3.0	0.189
35-44	1.2	0.7-2.2	0.457	1.0	0.7-2.5	0.400
45-75	1.1	0.6-1.9	0.751	1.7	0.9-3.4	0.116
Sex						
Female	Ref.					
Male	0.9	0.7-1.3	0.694	1.0	0.7-1.5	0.901
Education						
Primary	Ref.					
Secondary	0.951	0.6-1.4	0.806	0.91	0.6-1.6	0.816
Tertiary	1.128	0.7-1.9	0.655	1.3	0.6-2.6	0.465
None	2.015	0.9-4.3	0.066	0.5	0.2-1.2	0.146
Marital Status						
Never Married	Ref.					
Married	0.919	0.5-1.7	0.783	0.8	0.4-1.8	0.607
Divorced	1.174	0.5-2.8	0.722	0.9	0.3-3.1	0.941
Widowed	0.986	0.4-2.4	0.974	0.3	0.1-0.9	0.043
Co-habiting	0.659	0.3-1.3	0.248	0.9	0.3-2.1	0.738
Other diseases						
TB	Ref.					
Renal failure	0.289	0.0-2.6	0.268	1.0	0.1-9.4	0.979
Hypertension	1.039	0.4-2.6	0.934	4.7	0.6-36.4	0.134

Other	1.059	0.5-2.4	0.893	0.6	0.2-1.4	0.262
Drug Regimen						
1 st line	Ref.					
Co-trimoxazole	Empty			0.4	0.1-2.3	0.295
2 nd line	1.366	0.9-2.1	0.135	0.9	0.6-1.6	0.849
Other Drugs						
Co-trimoxazole	Ref.					
ATT	1.7	1.0-2.7	0.044	0.8	0.4-1.3	0.325
Other drugs	0.9	0.5-2.1	0.982	1.6	0.5-4.7	0.394

* TB= tuberculosis, ATT= anti-tuberculous drugs

Table 5 shows that pharmacy refills adherence was higher among those that were taking anti-tuberculous drugs compared to those taking Co-trimoxazole (P = 0.036). On clinical appointment adherence it was found that adherence was lower in the widowed than those that were never married (P = 0.035)

Table 6: Association between demographics/patient factors and ART adherence - Results of Multivariate logistic regression

	Pharmacy refills			Clinical appointments		
	OR	95%CI	P	OR	95%CI	P
Age in years	1.0	0.9-1.2	0.760	1.0	0.9-1.0	0.236
Sex						
Female	Ref.					
Male	0.9	0.7-1.3	0.695	0.9	0.7-1.5	0.982
Education						
Primary	Ref.					
Secondary	0.9	0.6-1.4	0.682	0.9	0.5-1.6	0.753
Tertiary	1.2	0.7-2.0	0.557	1.3	0.6-2.6	0.468
None	2.3	1.1-4.9	0.066	0.6	0.2-1.3	0.184
Marital Status						
Never Married	Ref.					
Married	1.0	0.5-1.9	0.970	0.9	0.4-1.9	0.699
Divorced	1.3	0.5-3.2	0.599	1.0	0.3-3.3	0.990
Widowed	0.9	0.4-2.2	0.838	0.3	0.1-0.9	0.035
Co-habiting	0.6	0.3-1.2	0.169	0.8	0.3-2.2	0.719
Other diseases						
TB	Ref.					
Renal failure	0.3	0.6-2.6	0.262	0.9	0.1-9.0	0.976
Hypertension	1.2	0.4-3.6	0.763	2.8	0.3-2.4	0.349
Other	1.1	0.5-2.8	0.788	0.4	0.2-1.2	0.111

Drug Regimen						
1 st line	Ref.					
Co-trimoxazole	Empty			0.4	0.1-2.2	0.260
2 nd line	1.4	0.9-2.1	0.122	1.0	0.6-1.7	0.992
Other Drugs						
Co-trimoxazole	Ref.					
ATT	1.7	1.0-2.9	0.036	0.8	0.4-1.4	0.444
Other drugs		0.4-2.5	0.980	1.5	0.4-5.6	0.514

* TB= tuberculosis, ATT= anti-tuberculous drugs

5.1.5 Predictors of ART adherence

Table 6 shows the results of multivariate analysis of the independence of these factors after the stepwise regression analysis. Three of the factors remained significant: marital status - widowed on clinical appointment (adjusted OR, 0.4; 95% CI, 0.2–0.8), Co-habiting (adjusted OR, 0.6; 95% CI, 0.4-0.9); no education (OR, 2.3; 95% CI, 1.1-4.6).

Table 7: Predictors of ART adherence for pharmacy refills and clinical appointments

	Pharmacy refills			Clinical appointments		
	Adjusted OR	95%CI	P	Adjusted OR	95%CI	P
Marital status						
Never Married	Ref.					
Widowed				0.4	0.2-0.8	0.008
Co-habiting	0.6	0.4-0.9	0.044			
Education						
Primary	Ref.					
None	2.3	1.1-4.6	0.018			

5.2.0. Qualitative Component

5.2.1. Description of Participants

Five participants above the age of 18 were interviewed. All of them were above the age of 25 years and the oldest was above 45 years and most of them were female. Two key informants were interviewed; one female nurse and one male doctor.

Table 8: Participants and Key Informants

Number	Gender	Type
AP01	Female	Patient
AP02	Female	Patient
AP03	Male	Patient
AP04	Female	Patient
AP05	Female	Patient
KI01	Male	Key Informant (Doctor)
KI02	Female	Key Informant (Nurse)

5.2.2. Presentation of findings – Themes

This section describes the major issues that emerged from the interviews with the participants and the key informants at the Adult Treatment Centre regarding their perceptions on ART adherence. The findings were categorised into two broad themes as follows:

- a) Care and Treatment
- b) Support strategies

Care and Treatment

- a) Knowledge

Interviews with patients revealed that they knew and understood why they were taking ART, the drugs that they were taking and the importance of taking the drugs at the same time every day. They were of the view that taking the drugs would keep them healthy and live longer. They however, disclosed that they had difficulty in naming/pronouncing the drugs but knew their doses and frequencies.

“...Yes I know but the problem is the names, but I know Atazanavir. I take 1 tablet at night then the other ones its 1 in the morning and one at night...if found positive its good you are put on drugs coz it helps your health at least lifespan will be good” AP03

The interviews also revealed that people knew and understood the consequences of not adhering to their drugs. Some of them felt that if they did not adhere to the regimen they would fall sick and die. Others said that there would be complications in their management and that they would acquire other diseases such as tuberculosis and pneumonia, and organ damage leading to death.

“I would die because those medicines go straight to the liver so once when I stop then I’ll die. I’ll destroy my liver then I’ll die” AP04

Interviews with the key informants revealed that when a patient comes to the clinic for an appointment, they are counselled on the disease, procedures, tests and medication to be taken. They mentioned that they provide all the necessary information that a patients needs to adhere to their medication, hence the revelation that patients are knowledgeable about their disease and the advantages and disadvantages of adhering and not adhering to their medication.

“...I have been practising for more than seven years and have been trained to handle HIV patients and have undergone numerous HIV trainings. In this clinic we use the Zambia Consolidated HIV Guidelines to manage out patients. We provide the necessary counselling and give them information about the disease, its setbacks and successes.” KI01

b) Adherence

Patients were asked about the importance of taking the drugs at the same time every day and all of them shared that they would live healthier longer lives. When they were asked if they had missed any doses in the last four days prior to the interview, all but one said they had not missed any doses. When that one person was further asked as to why she had missed a dose, she said that she was busy and forgot to take her drugs. However they all had a view that if one did not adhere to their medication, their immunity would be lowered, get sick and eventually die.

“Yes I missed a dose. Maybe its old age taking meds.... Morning is ok because u wake up and you’re fresh. I take my drugs twice so you have a busy day to run; by the time you get home you even forget that the other time is waiting for you. Most of the time I’m being reminded by my husband...There’s somebody to remind me. I’m trying to improve. Maybe memory that’s my weakness. Mostly forgetfulness of taking the drugs” AP02

Patients are well aware of the consequences of not adhering to their medication. They revealed that some of the consequences of non-adherence would be falling sick, having

complications, diseases, and organ damage leading to death. One of them also brought out the aspect of not sustaining a job because if you get sick it means you are too weak to go to work and if you are too weak to go to work and are off for a long time you might lose the job.

“Yes of course. We know that the HIV comes with all sorts of complications if you don’t take them regularly such as TB and pneumonia. Its means you can get to become weak and not be able to eat or walk or do the things or got to work and these days its hard if you don’t have a job.” AP02

When asked if they had a challenge with taking more than one drug, hence taking quite a number of tablets, some of the patients revealed that it was not a challenge as they were only taking the ARV drugs. Others mentioned that even though they were taking a number of drugs besides the ARVs they got used to it and would not miss a dose. One of them did however mention that she was at times exasperated because of the number of tablets that she had to take in a day.

“...Fortunately or unfortunately it’s like one who is diabetic on insulin or taking tablets you get , like I have to give myself a jab. It’s the same with swallowing pills/tablets. Yah there’s that thing but you get used to it. It’s a daily thing and its part of your life and you live with it so the thing with adherence is admit who you are, what you are and what is deserving of you. So what happens, you don’t see the number of years or the number of tablets that you drink...” AP02

When asked if having any form of education affects their adherence to ART, the patients mentioned that it was not likely to be a factor. However the problem that would arise is if they did not understand the instructions given to them.

“...they say ignorance is not a defence. There are so many things to remind us. But I’m happy because I have a partner who reminds me...” AP02

The key informants disclosed that generally, patients do not always keep their clinical appointments but will have their drugs refilled at the pharmacy. They estimated that adherence of HIV patients to ART was about 60-70% [... I would say that 60-70% of patients are “sufficiently adherent” to ART...KI01] They attributed this finding to not complying to clinical appointments, self-reports and occasional pill counts. They stated that adherence among the men and women was the same and that among the young was poor. Asked why this was so, he stated that younger adults had issues with stigma, disclosure and pill burden.

c) Quality of care

Patients revealed in the interviews that they were very happy with the services they were receiving at the ATC. [*...The service has been excellent! I've no challenges with the services... AP02*]. The patients stated that they are attended to promptly and that procedure is followed. They however, were not happy of late with the laboratory service as there were no reagents to test their blood.

“...Ok here the only problems I face is when you go for bleeding the results take time for them to be out. Sometimes when you go there they are lost again so you get your CD4 results after 8 months instead of 6 months. That's where the problem is. So that side they should be taking care of the results...” AP04

The patients revealed that they were satisfied with the drug supply as drugs were always in stock whenever they came to collect. The key informants agreed that they had no challenges with drug supply but had challenges with laboratory service in terms of providing their clients with laboratory results. The laboratory has had no reagents in the past few months and so would ask patients to find alternative laboratory service to carry out tests for them if they were needed urgently to decide a way forward on their management.

“Before reviewing a patient, we need to see their laboratory test results so that a decision is made about their continued management and treatment. Now you find that sometimes that patient cannot be reviewed at the time that you have requested him to come because you do not have lab results from which you need to make a rational decision about his treatment...” KI01

The patients were happy with treatment from the staff. They mentioned how polite and respectful the staffs were towards them and how well they were looked after when they came to the clinic. They mentioned that there was good patient-health worker relationship at the treatment centre. One of the patient said that there was better service at the ATC than from the clinic he had come from and the difference was evident in the way the staff treated him with respect. However, one of the patients was not very happy with the attitude of the staff at the reception.

“...I think the services here are very good. The nurses and doctors take care of us although the reception staffs are not very welcoming...” AP03

Support strategies

The key informants conduct adherence counselling at each clinical visit where self-reported adherence and pill counts are done. They mentioned weekly adherence seminars are held to improve adherence.

“...So the first time that a patient comes to the clinic and is put on ARV’s for the first time, we first of all do adherence counselling on ARV’s, treatment preparation including side effects of the drugs. We also do adherence counselling on patients that are switched on medication. At each clinical visit we conduct adherence counselling...”KI02

To improve upon the service provision and support to the patients, one of the patients in the interview stated that it would be good if the staff would communicate to them about any challenges the institution was facing in regard to treating and managing their disease condition. This was in regard to the instance of the unavailability of reagents. She also mentioned that pharmacy staff should give talks to the patients on the effects of the drugs and health as a whole.

“...When things like this are not there [reagents], convey the correct information to patients. You can walk to the patients and give them a short talk on health and even on pharmacy. Share something 2-3mins is not too much to say “oh please bear with us, we’ll correct it” ...” AP02

One of the key informants mentioned that the patient-doctor ratio was too big and so they do not spend as much time counselling the patient as they should. He mentioned that at the end of the day he was stressed out from the high volume of patients that he sees. He added that most of the patients came to the clinic with a lot of other issues besides the HIV that were contributing factors to them not adhering to either clinical appointments or pharmacy refills. He recommended that psychiatric support be provided at the clinic for such patients.

“The workload at this facility is overwhelming since this is a third level hospital all referrals come to this facility which also provides third line regimen. I feel that there should be more psychiatric support as most of these patients have more issues than meets the eye...” AP01

CHAPTER SIX

6.0 Discussion

The objective of this study was to determine the factors affecting drug adherence among adult HIV/AIDS patients on antiretroviral treatment and to identify socio-demographic factors associated with adherence. To explore further the care, treatment and support strategies used by patients and health workers we did a qualitative research. It was revealed that more than half of the patients were adherent to clinical appointments while less than half of them were adherent on pharmacy refills. The stepwise regression analysis revealed significant factors for adherence on clinical appointment and pharmacy refills for widowed, co-habiting and no education. About 80 % were adherent to ART.

Achieving good adherence to antiretroviral therapy can never be overstated as it is of utmost importance. A $\geq 95\%$ adherence rate results in a virologic suppression of $> 80\%$, while average rates of non-adherence to antiretroviral therapy have been approximated to range from 50% to 70%. (Sethi et al., 2003); (Chesney, 2000). What, then, are the factors that are influencing the level of drug adherence? It has been reported that a complex drug regimen compromises adherence. A greater number of antiretroviral medications, higher pill burden were found to be associated with lower adherence rates and worse virologic suppression (Chesney, 2000); (Nachega et al., 2014). Interestingly, the demographic variables under this study i.e. other diseases and other drugs were not statistically significant for association to ART adherence save antiretroviral regimen which was a factor associated to affect adherence upon pharmacy refill using the Pearson Chi-square ($P=0.037$). When the ART regimen variable was fed for univariate analysis, it was not significantly associated to ART drug adherence. This could mean that it could be a confounding factor associated to drug adherence. This is interesting because you would think that taking more than one tablet in a day would be a factor for non-adherence to treatment as the second line ART regimen warrants. However, multivariate analysis revealed that taking other drugs besides the antiretroviral drugs was significantly associated with pharmacy refills ($P= 0.036$). However, the stepwise regression analysis revealed that it was not significantly associated to ART adherence. Also, it would be expected that having another disease besides HIV and hence taking drugs for these diseases leading to pill burden would have an independent association with drug adherence. In the qualitative study, interviews conducted with the participants

revealed that to them taking other drugs for other disease conditions was not an issue as you get used to taking the drugs and taking them would prevent diseases and live longer. Counselling programmes that have been set up to prepare patients for HAART initiation and follow up help support patients maximise their adherence to the drugs. This could have contributed to such an observation. There is need to continue strengthening counselling points by the health-care providers on pill burden when patients are taking other drugs besides antiretroviral drugs. It would also be prudent to sit as a multidisciplinary team to see to it that patients are put on combination therapies for treating other diseases. It is also worth noting that even though having another disease besides HIV (though not statistically significant in this study) could have an effect on adherence both positively and negatively as there would also be a reduction in immune suppression and increase in pill burden.

In some studies, adherence to antiretroviral therapy has been found to be related to demographic characteristics such as age (Gordillo et al., 1999); (Kleeberger et al., 2001). However, other studies did not find an association between such a demographic and drug adherence. (Safren et al., 2005); (Chesney et al., 2000); (Fong et al., 2003). We also failed to find such an association in our study. Nevertheless, the lack of association could not be related to power of the study as it had a power of 80% and allowed by the moderate sample size.

Amongst the factors that we analysed in this study, two of them were significantly associated with adherence on univariate analysis –being a widow associated to clinical appointments and taking anti-tuberculosis drugs on pharmacy appointment. Furthermore, they were the only two that were found to be independent factors upon multivariate analysis. In the stepwise regression analysis, findings of the quantitative study have revealed that marital status (widow and co-habiting) and no education were factors associated to ART adherence. Being a widow is significantly associated to adherence in clinical appointments after adjusting for other variables ($P=0.008$) with the reduced odds of being adherent to ART on clinical appointment (OR, 0.4; 95% CI, 0.2-0.8). The odds of those that were co-habiting were 0.6 times that of those who were never married. This was statistically significant ($P=0.018$). Death of a spouse calls for the surviving spouse to fend for the family and spend hours/days looking for money to feed and/or educate the children. Weiser noted that food insecurity is a common and important barrier to accessing medical care and ART adherence (Weiser et al., 2010). Long hours of hard work and feeling tired at the end of the day would lead to forgetfulness and missing clinical appointments. In the self-reported cases, one of the patients

acknowledged missing a dose because she was busy and forgot but was however in most cases being reminded by her husband to take her medication. More social support from healthcare personnel is needed to facilitate adherence to ART as these people are less likely to get family support than those that are married.

It has been shown that a higher education is associated to ART adherence (Reynolds et al., 2004). On the contrary, our study found that those with no form of education have two times greater odds of being associated to ART adherence (OR, 2.3; 95% CI, 1.1-4.6) with a significance level of $P=0.018$. This finding was consistent with a qualitative study conducted in South Africa where providers believed that illiterate people had more difficulty in adhering to treatment (Dahab et al., 2008). However, patients interviewed in our study did not have the same views. They felt that one did not need to go to school to know how to adhere to medication. Effective counselling and good communication skills as well as support from family friends greatly affects drug adherence to ART to those that are not literate.

The improvement and quality of patients' lives and the drive for adhering to ART treatment, lies in both the patients' and clinicians' behaviour. This was explored in our study and was associated with better adherence outcomes to treatment. Patients felt that they trusted the health workers and that they received satisfactory service from the centre. We found that a high proportion of adult HIV infected patients attending the clinic had good adherence to their ART regimen based on self-reported adherence method (80%). This was favourably comparative with the situation in studies conducted in China (Fong et al., 2003) and Ethiopia (Tadios and Davey, 2006) though slightly higher than in most developed countries where rates ranged from 50-70% (Gordillo et al., 1999); (Gifford et al., 2000). Self-reporting may, however, overestimate the rate of adherence to medication (Bartlett, 2002). Even though this type of approach is not as objective as counting of pills, it provides useful additional information

The health workers felt that at least 70% of the patients adhered to their medication. However, patients felt that there was a need to improve laboratory services so that the full package of medical services is provided. Since there is need for long term adherence to antiretroviral treatment, and the objective is to prolong life, prevent disease progression and improve the quality of life, it is critical that patients are provided with as much education about the disease therapy and care as possible. It is of course imperative that the patients play their role in safety measures, lifestyle, motivation and resources necessary to adhere to treatment.

Knowledge about the illness and satisfaction with the health workers were high in the qualitative study and were associated with 80% compliance to treatment. This was contrary to a study conducted in Spain (Gordillo et al., 1999) where knowledge about illness, belief in treatment and satisfaction with clinicians were not associated with compliance. One of the sub-themes that emerged was that if they did not adhere (non-adherence) they would get diseases/complications and eventually die. A qualitative study conducted in Zambia on urban women (Murray et al., 2009) identified that they were unfamiliar with having a chronic potentially deadly disease.

Patients complained that the laboratory services were appalling. They complained that there were no laboratory reagents each time they went to have their blood drawn so that the results can be reviewed at the next clinical appointment. This could be a challenge for both the patients and the clinicians to help decide on the best management for them as they would be basing their treatment on clinical outcomes and not evidence based. Some of the patients also complained that counselling was not adequately done by the pharmacists.

There are several limitations to the study. Owing to its retrospective nature, the data in this study were not collected prospectively using a predefined tool. This study only sought to determine the factors that affect adherence while it could have also looked at defining measurement of adherence, as well as assess the impact of adherence on viral load and clinical effect. Secondly, secondary data was used to determine ART adherence and determine the demographic and patient factors affecting adherence. This posed a serious limitation as most of the data needed to be used as variables were missing and this caused a lot of time wasted as the investigator had to do a lot of data cleaning. One of the most critical variables with missing data that was thought to be a major determinant of adherence was alcohol. (Samet et al., 2003); (Bhat et al., 2010); (Hendershot et al., 2009) Information on this variable was not recorded at all. Thirdly, the study was not set out to determine either barriers or factors promoting better drug adherence. The relatively high level of drug adherence in our patients actually permits research into these factors. Identification of such factors may serve as reference for promoting adherence in patients who have suboptimal adherence to HAART. Fourthly, a pill count was not conducted to determine the number of pills taken till the time of the study as this is a one-time point study. Fifthly, the characteristic weakness of self-report in reflecting the actual drug taken, especially that of recall bias and over-estimate is likely to exist in our study.

6.1 Recommendations

There is need to find ways in helping the widowed and those co-habiting to ensure that they adhere to their medication therapy. It would be prudent that multidisciplinary efforts and counselling by trained psychologists are made necessary in this context since these are professionals and can provide guidance and be able to offer some assistance to treat some of these underlying factors and ultimately improve adherence. Administrative efforts need to be made to improve on collecting more patient data on data, albeit in this case alcohol. The challenges in the services that the clinic is facing should be communicated to so as not to pose an extra strain on the patients' time and finances.

The Adult Centre of Excellence is the “mother” of all ART government owned centres and seeks to achieve at least $\geq 95\%$ adherence. Further research is needed to study the characteristics between patients and their health-care providers and hence assess the impact of adherence on viral load and clinical effect based on the factors that have been identified in this research. Outreach programmes to the widowed need to be strengthened to improve the adherence levels and hence reduce incidences of treatment failure.

6.2 Conclusion

We found that the level of adherence was moderate (80%). Effective counselling practices have been established at the ATC. As a result patients are well informed about their disease and the consequences of not adhering to their medication. However, in view of the identified factors affecting adherence at the ATC, concerted and collaborative efforts through effective and efficient interventions are needed to improve the adherence levels to at least $\geq 95\%$. There is need for social support strategies for widows who are not likely to adhere to their medication due to their vulnerable state. Social support to the widows on ART could facilitate their adherence to ART. This is likely to require attention by ART services in the future, focusing on different social influences on the widows. Further research is needed to study the characteristics between patients and their health-care providers and hence assess the impact of adherence on viral load and clinical effect based on the factors that have been identified in this research.

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APPENDICES

APPENDIX I: INFORMATION SHEET

TOPIC:

FACTORS AFFECTING ANTIRETROVIRAL DRUG ADHERENCE AMONG HIV/AIDS ADULT PATIENTS ATTENDING HIV/AIDS CLINIC AT THE UNIVERSITY TEACHING HOSPITAL IN LUSAKA

INTRODUCTION

I, Uchizi Chirwa, a student of Masters of Science in Epidemiology from the University of Zambia is kindly requesting for your participation in the research study mentioned above.

PURPOSE OF THE STUDY

You are being asked to take part in a study which is aimed at determining the factors that affect drug adherence among adult HIV patients on antiretroviral treatment.

PROCEDURE

The study will involve collecting data from patient files and recording them. The study will also involve asking you a number of questions that will help us establish the factors that affect drug adherence to antiretroviral treatment. The questions on the questionnaire will be read to you and your responses will be recorded on the questionnaire. The interview will take approximately 10 minutes.

VOLUNTARY PARTICIPATION

Your participation in this study is purely voluntary. This means that you are free to decline to participate in the study without consequences. Furthermore, if you wish to discontinue, you are free to do so without facing any penalties.

RISKS AND DISCOMFORT

The probable risks that the study may present are disclosure of information and safe keeping of records. I will use my professional and ethical integrity to uphold confidentiality, privacy and safe keeping of the records; your name will not be disclosed.

BENEFITS

There are no monetary benefits for participating in this study. You will benefit by knowing the factors that affect drug adherence among HIV patients on antiretroviral treatment. Another benefit from knowing these factors is that it may improve patient management and improve drug availability.

CONFIDENTIALITY

I would like to reassure you that any personal information that you will reveal to me will not be disclosed to any other third party unless legally required to do so and with your consent. Your identity will also be kept anonymous.

INFORMATION AND CLARIFICATION

Please be informed that if you at any time need some clarification over the research study, you can direct your concerns to:

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APPENDIX II: CONSENT FORM

I agree that the purpose of the study has been explained to me. The risk and benefits have been clarified to me and I understand that participation or not will not affect my job security or health care that may be needed for me. I freely and voluntarily choose to participate. I also understand that my rights and privacy will be maintained.

I _____ (Names/thumbprint),
agree to take part in the study designed to find out factors that affect drug adherence in HIV/AIDS patients to antiretroviral drugs.

Signed (Finger print)Date.....(Participant)

Signed.....Date.....(Witness)

Signed.....Date.....(Researcher)

APPENDIX III: SEMI-STRUCTURED INTERVIEW WITH PATIENT

Patient Initials_____

Age of patient_____

Sex_____

Employment Status_____

Educational Level_____

1. Would you mind telling me about why you are taking ARVs, the names of the drugs and the dosage?

2. Please tell me more about the importance of taking the drugs at a particular time as guided by the pharmacist.

3. Do you think having an education or alcohol or other diseases and taking other drugs will have an effect on adhering to meds?

4. Do you think missing a dose would cause problems to your health? What sort of problems? What would make someone miss doses?

5. If you have missed any doses in the last 3 days, would you mind explaining why you missed the doses? What did you do when you missed the doses?

6. Give an overview of the services that you receive at this clinic. (The staff services, privacy, environment, time management)

7. What do you think is the biggest problem regarding taking ARV treatment?

8. In accessing ART, what areas of clinical care do you think have challenges and what would need improvement for all patients on ART?

APPENDIX IV: SEMI-STRUCTURED INTERVIEW WITH HEALTH WORKERS

Name of facility: _____

Name interviewer: _____

Interview number: _____

Date: _____

Background information on informant (health worker)

- a) Sex M/F

- b) Age _____ years

- c) Profession

- e) Role in ARV programme

- f) Involved in programme since....

Tasks and training

- a) What specific training have you received for this job in relation to ARV programme? Tell me about the training (Details)

- b) Do you think this training has been sufficient? (Details)

Drugs, treatment and procedures

- a) Which treatment guidelines for HIV/AIDS management do you use at this facility? (Give details if necessary, e.g. national guidelines etc)

- b) Are the drugs you prescribe always available? (If not, give details - how often, reason, what do you do about it)

- c) Are the drugs in the guidelines you use to dispense always available? (Give details - how often, reason, what do you do about it)

d) Have you had periods where your patients have not been able to get their medications because they were not available in stock?

e) How reliable are your lab and diagnostic support services? Do results come in on time? Details.

f) What is your procedure when a patient is put on ARV drugs for the first time?

g) What is your procedure when a patient switches regimens?

h) In what ways are ARV-users informed about and prepared for ARV treatment?

i) What kind of information do they receive? Please describe it to me:

- The disease process (i.e. HIV and AIDS)
- How the disease affects the body
- How ARVs work
- How to use them
- The need to continue treatment
- What to do if a pill is forgotten
- Possible interactions with other drugs
(including traditional medicines)
- Which side effects can occur & what to do if they occur
- (Breast) feeding requirements
- When and where to get re-supply

Adherence issues

- a) Generally speaking, do your patients keep their appointments?
- b) How do you think your patients do, generally speaking, in terms of adherence to ART?
- c) Could you estimate the percentage of your patients who you think are "sufficiently adherent" to ART? (Respondent gives their definition of 'sufficiently adherent' what level is that?) **
- d) What do you use to determine adherence (probe: appointments, refills?)
- e) I would like to get your views on the following (probe): From your experience
- How would you compare adherence between women and men?
 - How would you compare adherence between older patients and younger patients?
 - How does a patient's educational level affect adherence?
- f) How do you think the distance to the health facility affects adherence?
- g) From your experience how do you think the following affect adherence?
- Having or not having a treatment-support partner?
 - Duration of treatment?
 - Side effects?
 - Lack of food?
 - Knowledge about ART?
- h) What strategies are in place to monitor adherence?
- i) What strategies are in place to support adherence? (probe: family/community involvement).
- j) What are the main challenges you face in supporting your patients to adhere to ARV drugs (especially for longer term users)?

Challenges and staff support

- a) What are the main challenges you and your colleagues face more generally in your work?
(if necessary, prompt re workload, stress, burnout)

- b) Have you ever been afraid of being infected with HIV through your work? What were you specifically afraid about? How do you feel now about the HIV- infection risks? Do you take any extra precautions when working with them?

- c) Have these challenges changed in any way since you started working at the ARV clinic?

- d) Is any special support made available for staff engaged in management of HIV/AIDS at this facility? If no, do you think there is a need to have such support?

- e) Is there anything you would like to see done differently in this facility? If yes, what?

Is there anything else you would like to tell us or ask us?

Thank you very much for your participation in this interview.

APPENDIX V: CHECKLIST

Data Collection Instrument

Site: Adult Infectious Disease Center of Excellence, University Teaching Hospital, Lusaka

Data Extractor: (1) Principal Investigator (2) Research Assistant

- 1) Study ID #: _____ Date/Month/Year/ of Enrolment in the study: _____
- 2) Age: _____ years
- 3) Gender: (1) female (2) male
- 4) Years since HIV diagnosis: _____ years
- 5) Number of ART drugs dispensed consecutively over last 6 months (a) Yes (b) No
- 6) Number of clinic appointments kept in last 1 year
 - (a) At 6 months appointment
 - (b) Every 3 months out of 12
 - (c) Every month for 3 months
- 7) Alcohol intake: (a) Yes (b) No
- 8) Marital status _____
- 9) Medication Regimen _____
- 10) Any other disease conditions apart from HIV (a) Yes (b) No
- 11) Months out of stock of drugs at time of refill _____
- 12) Any other medications being taken apart from ART (a) Yes (b) No
- 13) Change of drugs due to side effects (a) Yes (b) No
- 14) Duration on ART since commencement _____

The University of Zambia
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31st August, 2015.

The Senior Medical Superintendent,
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Private Bag RX1,
LUSAKA.

U.F.S.: The Head, Department of Public Health

Dear Sir,

RE: REQUEST FOR CONDITIONAL PERMISSION TO GRANT ME A LETTER OF AUTHORITY

I am hereby requesting for a letter of authority for ethical review for my research proposal. I am a student undertaking a Master of Science in Epidemiology at the University of Zambia. My proposed title is “**Factors Affecting Drug Adherence among Adult HIV/AIDS Patients on Antiretroviral Treatment**”.

One of the conditions to review my research proposal by the Ethics Committee is to attach a letter of authority from the study site which I need to be given by your able office. Once the approval is availed to me by the Ethics Committee, I will then avail the letter to your office for formal request to carry out data collection at the study site from the School.

Attached is the protocol for the proposed research.

Your consideration will be highly appreciated.

Yours faithfully,

Uchizi Chirwa

