

**PATIENT'S PSYCHO-SOCIAL, TREATMENT AND HEALTH SERVICE FACTORS
AFFECTING ART ADHERENCE IN CHOMA (ZAMBIA)**

By

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ABSTRACT

Research relating to factors responsible for adherence in Zambia has been limited. Clinic records at Choma show that the defaulter rate is at 9.9% (CIDRZ, 2007). This cross sectional study looked at common adherence problems like: level of adherence, patient factors, treatment factors, substance and alcohol, dietary restrictions, side effects and other factors that may be specific to poor settings.

Respondents were drawn from; (i) patients on ARVs with a history of defaulting from the defaulter patient's register or (ii) a member in a household with an adult taking ARVs (care giver). Data was collected using patient medical records and one to one interviews.

Tests of associations using the Chi-square test or the Fisher's exact test were done. SPSS logistic regression was used to determine predictability. Results showed that the majority of the respondents were from the 26-35 age group (35.2%) and women tended to be younger than males (26-53 age group). Most had never been to school or had only gone up to primary school (58.9%), were unemployed (34.6%), divorced or single (3%) and had no social support (52.4%). From treatment and service factors, 79.5% of dents were not keen to take drugs, 63% experienced side effects and 61% said clinic waiting times were long. There was significant association between non-adherence to ART and some known social factors; social support $P = 0.001$, marital status $p < 0.001$ and one's responsibility to take drugs $p = 0.001$. No significant association was found between non-adherence to ART and treatment factors; side effects $p = 0.960$ and discomforts $p = 0.960$. Service factors also had no association; patient education $p = 0.066$, availability of drugs $p = 0.732$, follow-ups $p = 0.301$ and long clinic waiting time $p = 0.187$.

Married respondents were 48% (AOR = 0.52, 95% CI [0.31, 0.87]) less likely to miss clinic appointments, compared to respondents who were single.

Respondents who had social support were 47% (AOR = 0.5 95% CI [0.32, 0.90]) less likely to miss clinic appointments, compared to those who did not have social support.

Respondents who were not keen to take medication were 72% (AOR = 1.72, 95% CI [1.03, 2.86]) more likely to miss clinic appointments, compared to those who were keen to take medication.

To enhance ART adherence, the study recommends that, all patients should be encouraged to receive adherence counseling. Ministry of Health should promote Health education campaigns.

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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TABLE OF CONTENTS

ABSTRACT	I
DECLARATION.....	II
CERTIFICATE OF APPROVAL.....	III
ACKNOWLEDGEMENTS.....	VII
TABLE OF CONTENTS.....	V
LIST OF TABLES	VIII
LIST OF FIGURES	VIII
ACRONYMS	IX
CHAPTER ONE - INTRODUCTION.....	1
1.0 BACKGROUND	1
1.1 Defaulters	3
1.2 Adherence	3
1.3 Global problem of HIV/AIDS	5
1.4 Zambia's Profile of HIV/AIDS and ARV Roll Out	6
1.5 Choma's Profile of HIV/AIDS	8
1.6 ARV Therapy in Resource Limited Settings	8
1.7 Benefits of ART.....	9
1.8 Statement of the Problem	11
1.9 Justification of this Study.....	11
CHAPTER TWO – LITERATURE REVIEW	13
2.0 CONSEQUENCES OF LACK OF ADHERENCE	13
2.1 Patterns of adherence	13
2.2 Challenges Inhibiting Access	13
2.3 Social Economic Factors influencing non adherence	14
2.4 Economic Cost.....	15
2.5 Health care factors	16
2.6 Treatment factors	17
2.7 Service Related Factors.....	19
2.8 Patient Psycho-Social Factors.....	20
2.9 Ways of responding (Interventions) to adherence problems	23
2.10 Methods Used in Measuring Adherence	25
2.11 Adherence Theory	27
2.12 Biomedical Factors.....	27
2.13 Social Factors.....	28

CHAPTER THREE- RESEARCH OBJECTIVES	29
3.0 RESEARCH OBJECTIVES.....	29
3.1 Research Hypotheses.....	29
CHAPTER FOUR-RESEARCH METHODOLOGY	30
4.0 RESEARCH DESIGN	30
4.1 Research setting	30
4.2 Sample Size and Sampling.....	30
4.3 Data collection Tools	32
4.4 Operationalisation of variables	33
CHAPTER 5: RESULTS	35
5.0 RESULTS.....	35
CHAPTER 6- DISCUSSION OF RESULTS AND CONCLUSION	48
6.0 INTRODUCTION	48
6.1 Limitations of the study	48
6.2 Discussion on Patient/psycho- social factors.....	48
6.2.1 Sex, age distribution	48
6.3 Treatment factors	49
6.4 Service factors	50
6.5 Factors independently associated with missed clinic appointments.....	51
6.6 CONCLUSION:	51
CHAPTER 7- RECOMMENDATIONS	52
APPENDICES	53
APPENDIX I: REFERENCES	53
APPENDIX II; PERCEPTIONS OF ARV MEDICATION SCALE (PAMS)	57
APPENDIX III BUDGET	62
APPENDIX IV: CONSENT FORMS AND INFORMATION SHEET	63
Ethical matters	65
Informed Consent	65
Risks	65
Benefits:.....	66
Confidentiality:	66
Rights and complaints:	66

LIST OF TABLES

TABLE 1: ADHERENCE FACTORS FOR ANTIRETROVIRAL THERAPY	22
TABLE 2: AGE GROUP OF THE RESPONDENTS BY MISSED CLINIC APPOINTMENT	35
TABLE 3: EDUCATION LEVEL OF THE RESPONDENTS BY MISSED CLINIC APPOINTMENT	36
TABLE 4: MARITAL STATUS OF THE RESPONDENTS BY MISSED CLINIC APPOINTMENT	37
TABLE 5: OCCUPATION OF THE RESPONDENTS BY MISSED CLINIC APPOINTMENT	37
TABLE 6: EXPLORED FACTORS THAT AFFECT NON-ADHERENCE	38
TABLE 7: THE RESPONSIBILITY FOR TAKING MEDICATION BY MISSED CLINIC APPOINTMENT	39
TABLE 8: SOCIAL SUPPORT BY MISSED CLINIC APPOINTMENT	39
TABLE 9: DRUG FACTORS AFFECTING NON ADHERENCE	400
TABLE 10: NOT KEEN TO TAKE DRUGS BY MISSED CLINIC APPOINTMENT;	411
TABLE 11: SIDE EFFECTS CAUSED ME REDUCED COMPLIANCE BY MISSED CLINIC APPOINTMENT..	422
TABLE 12: DISCOMFORTS CAUSE ME TO DEFAULT BY MISSED CLINIC APPOINTMENT	433
TABLE 13: SERVICE FACTORS THAT AFFECT DRUG INTAKE	433
TABLE 14: STAFF EDUCATED ME TO UNDERSTAND BY MISSED CLINIC APPOINTMENT	444
TABLE 15: DRUGS RAN OUT AT THE CLINIC BY MISSED CLINIC APPOINTMENTS	455
TABLE 16: CLINIC WAITING TIMES BY MISSED CLINIC APPOINTMENTS	466
TABLE 17: STAFF FOLLOW-UP EFFORT BY MISSED CLINIC APPOINTMENTS	477

LIST OF TABLE OF FIGURES

FIGURE 1: PROBLEM ANALYSIS DIAGRAM.....	12
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ACRONYMS

AIDS;	Acquired immune deficiency syndrome
ART;	Anti Retroviral Therapy
ARV;	Anti Retroviral Drugs
CRS;	Catholic Relief Services
CSO;	Central Statistical Office
CHAZ;	Churches Health Association of Zambia
CIDRZ;	Center for Infectious Disease Research in Zambia
DF;	Degrees of freedom
FHI;	Family Health International
HAART;	Highly Active Anti Retroviral Treatment
HIV;	Human Immunodeficiency Virus
ICAP;	International Center for Aids Care and Treatment Programmes
MOH;	Ministry of Health
MPH;	Master of Public Health
NAC;	National Aids Council
NAPCP;	National Aids Prevention Control Programme
PAMS;	Perceptions of ARV Modification Scale
PEPFAR;	Presidents Emergency Plan for Aids Relief
Sig;	Significance
SPSS;	Statistical package for social scientists
UNAIDS;	Joint United Nations Programme on HIV/AIDS
WHO;	World Health Organization

CHAPTER ONE - INTRODUCTION

1.0 Background

Since the launch of WHO's 3 by 5 initiatives in 2003, many countries in sub-Saharan Africa have established national antiretroviral treatment (ART) programmes. Although the WHO target of providing access to ART for 3 million people by 2005 was not achieved, by end of 2005, an estimated 1.3 million people in low and middle income countries had access to treatment, estimated at about 20% of those in need (WHO/ UNAIDS, 2006). By mid 2005, the WHO target had already been overtaken by a more ambitious aim. In July 2005, the G8 group of industrialized countries committed themselves to the goal of achieving as close as possible to universal access to treatment for all those who need it by 2010 (UNAIDS; G8 Gleneagles Summit, 2005).

Nonetheless, the challenges in the region remain great. Health systems are weak, and the target orientation of ART programmes risks an emphasis on initiating people on ART at the expense of ensuring effective use of medicines. Extremely high levels of adherence (at least 95%) are needed to ensure positive treatment outcomes and prevent the development of drug resistance (Paterson *et al.*, 2000). UNAIDS estimates that 40.3 million people globally were living with HIV in 2005 (UNAIDS/ WHO, 2005). The Comprehensive HIV and AIDS Care, Management Prevention and Treatment programme in Zambia is one of the largest and most comprehensive programmes in Sub Saharan Africa to address the epidemic. This programme has continued to place an important focus on the provision of ART. Monitoring of the ART adherence trends has not been an important component of the national strategy even though this is the means by which ART intake trends could be reviewed (UNAIDS, 2005).

In July 2004 the international community convened in Bangkok, Thailand, for the 15th international AIDS conference. The gathering occurred at an opportune time in global health as just months earlier, the World Health Organization and UNAIDS launched the "3 by 5" programme—a global initiative to provide antiretroviral therapy to 3 million patients with HIV/AIDS in developing countries by the end of 2005 (WHO, 2005). Additionally in the past

few years the Global Fund to Fight AIDS, Tuberculosis, and Malaria was created, to finance a scaling up of resources for interventions against all three diseases. These initiatives are augmented by increases in funding from private, national, and international sources. Together these efforts represent one of the most important trends in global health over the past five years. The movement for increased funding for ART in developing countries has brought attention to the issue and initiated a process of responding to it with special emphasis on adherence to all those accessing therapy.

Many global initiatives such as the “3 by 5” initiative from the World Health Organization, UNAIDS, and the US President’s Emergency Relief Plan for HIV/AIDS Relief (PEPFAR) – along with national government and bi-lateral efforts, have helped expand access to ART for people in developing countries. Although still short of targets set by WHO in 2003, at the end of June 2005, over one million people in developing countries were taking ART (WHO, 2005). In July 2005, at the Gleneagles summit, the Group of 8 leading industrialized countries endorsed universal access to ART by 2010 (G8 Communiqué, 2005).

Low compliance to prescribed medical interventions is ever present and complex problem, especially for patients with a chronic illness. With increasing numbers of medications shown to do more good than harm when taken as prescribed, low compliance is a major problem in health care (Haynes *et al.*, 2002)

Not taking medication as prescribed – taking either too little, or too much, for too short, too long a period, at the wrong time or in an ineffective way, can have negative consequences for patients, healthcare and the economy. This non-adherence (defaulting) problem grows even more important as the burden of chronic diseases is growing worldwide (World Health Organization, 2003)

Due to the scale of the problem it has been claimed that studies examining the effectiveness of adherence interventions should have priority over studies on new medical treatments. Numerous interventions have been developed and implemented but the problem of non-adherence appears difficult to solve (Sabaté, 2003). Given the weak theoretical underpinning of many adherence

interventions, a fruitful step might be to find the most promising mainstreams, which inhibit non-adherence to ARVs within the free treatment package.

1.1 Defaulters

These are patients who have missed 2 or more consecutive clinic appointments or those who have not been seen at the clinic for more than 3 months (WHO, 2007).

In Zambia, the national defaulter rate to ART is estimated at 30% (CIDRZ, 2007).

1.2 Adherence

Adherence in medical practice has been defined as: “the extent to which a person’s behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice” (Haynes, 1979). This definition delineates a range of patient behaviors (taking medications consistently, keeping clinic appointments, following special diets, making lifestyle changes) and suggests that patients’ choice of behaviors may or may not align with medical recommendations (Heather *et al.*, 2002)

McDonald *et al.*, 2002, also labored to define adherence. They submit adherence may be defined as the extent to which a patient’s behavior (in terms of taking medication, following a diet, modifying habits or attending clinics) coincides with medical or health advice. If a patient is prescribed an antibiotic for an infection to be taken as 1 tablet 4 times a day for a week but takes only 2 tablets a day for 5 days, the adherence would be 36% (10/28).

This simple definition of adherence belies the difficulties that many medical regimens present for patients. For example, the regimen described for type 2 diabetes mellitus includes a special diet, increased exercise, smoking cessation, oral hypoglycemic drugs, and risk factor management, usually involving additional drugs. Such regimens fulfill theoretical, physiological, and empirical considerations about optimal care, while ignoring practical patient-centered concerns, such as the nature, nurture, culture, and stereotyping of the patient, and the inconvenience, cost, and adverse

effects of the treatment. Indeed, low adherence with prescribed treatments is very common. Typical adherence rates for prescribed medications are about 50% with a range of 0% - 100%.

KITSO Manual (2004) considered adherence as the use of ARVs at the right frequency of dosing. They also checked the number of pills (correct dose) and the time patients were taking them, using a sun and moon chart. Ability to keep to this pattern of utilization is defined as 100% adherence, while adherence of $\geq 95\%$ is accepted as optimal adherence. Levels of adherence below 95% are considered to be sub-optimal.

In a study in Botswana, 54% of patients reported optimal adherence (defined as completing greater than or equal to 95% of prescribed doses) and 56% were seen as achieving optimal adherence on the basis of provider assessment (Weiser *et al.*, 2003). In a study in Tanzania, “*Near perfect adherence*” was defined as 95% and above adherence. The ability to consistently take the medicines at exactly or approximately the same times each day depends on the individual’s frame of mind as well as the support of family members, the people around them, and the community at large. Administration of ARVs imposes constraints on the daily schedule and lifestyle and it can be difficult for individuals to adapt to these demands, especially on a long-term basis.

Evidence suggests that greater than 95% adherence may be necessary to adequately suppress viral replication, produce a durable response and halt disease progression (Paterson *et al.*, 1999). This means that missing more than one dose of a regimen per week may be enough to cause treatment failure. In addition to leading to disease progression this may result in the development and transmission of drug - resistant viruses which cannot be treated with first - line (lower cost) medicines. This will require treatment with second and/or third line medicines, which are more expensive, associated with many side effects and are complex to manage.

Finally, adherence decreases as the complexity, cost, and duration of the regimen increase. While this may be the general case, there have been attempts to define adherence for HIV in using ART. While this has been so, there is no gold standard by which to measure adherence to ARV medication. Many studies employ a number of methods, either alone or in combination to

measure adherence. The most common include: electronic drug monitoring (EDM) devices, pill counts, biochemical markers, pharmacy refill records and various self reporting tools such as questionnaires and visual analogue (Haynes, 1991).

1.3 Global problem of HIV/AIDS

AIDS is the leading cause of death in sub-Saharan Africa. According to 2001 estimates, there are 28.5 million people living with AIDS in Africa, comprising >70% of the world's HIV-infected population. Since 1981, when the first AIDS cases were identified in the United States followed by Africa the next year, there has been a growing understanding of the HIV/AIDS epidemic's trajectory and the toll it has taken across the globe. Over time, refinements in methodology, increased data availability, and growing knowledge about the natural history of HIV disease necessitate revisions in HIV estimates. Last year, there was another major revision in the data compared to prior published figures. Better data provide a clearer picture of trends over time. The latest estimates from UNAIDS and the WHO indicate that (UNAIDS/WHO, 2008):

§ The number of people living with HIV/AIDS globally rose from 29.5 million in 2001 to 33 million in 2007 due to continuing new infections, people living longer with HIV, and general population growth;

§ The global prevalence rate (the percent of the population aged 15–49 with HIV), 0.8% in 2007, has leveled off since 2000;

§ Annual deaths increased from 1.7 million in 2001 to 2.0 million in 2007, but have declined in the last couple of years due in part to antiretroviral treatment scale up;

§ New HIV infections are believed to have peaked in the 1990s and declined between 2001 and 2007 from 3.0 million to 2.7 million. This decline is attributable to natural trends in the epidemic itself and to prevention efforts. Still, there were more than 7,000 new HIV infections each day in 2007 (UNAIDS/WHO, Core Slides: Global Summary of the HIV and AIDS Epidemic)

§ Women represent half of all people living with HIV/AIDS, as they have in recent years;

§ HIV is among the leading causes of death worldwide and the number one cause of death in sub-Saharan Africa;

§ Most people with HIV are unaware that they are infected. These most recent trends, and the snapshot provided below, represent significant revisions by UNAIDS/WHO based largely on improved methodology and better data availability from countries over time. Importantly, methodological changes have led to revisions in earlier published estimates including significant reductions between 2006 and 2007. For example, the current estimate of the number of people living with HIV/AIDS is a reduction of about 6 million from the 2006 published estimate. Most of the reduction (70%) is explained by revisions to prevalence estimates in India and five sub-Saharan African countries. Both incidence and mortality estimates are impacted by these changes and also reflect an increase in the estimated survival time for a person living with HIV, increasing from 9 to 11 years.

1.4 Zambia's Profile of HIV/AIDS and ARV Roll Out

Zambia's population is estimated at 10.4 million of which it is estimated that 14% are HIV positive (CSO, 2007). Zambia, in southern Africa, has one of the world's most devastating HIV and AIDS epidemics. One in every six adults in Zambia is living with HIV and life expectancy at birth has fallen below 40 years (WHO, 2005). This has compounded Zambia's existing economic problems. In four decades of independence, Zambia has found peace but not prosperity and today it is one of the poorest and least developed nations on earth.

Zambia's first AIDS case was reported in 1984. Only one year later 17.5% of hospital patients in the capital Lusaka were found to be HIV-positive. Within two years of the first report of AIDS in the country the National AIDS Surveillance Committee (NASC) and National AIDS Prevention and Control Programme (NAPCP) were established to coordinate HIV/AIDS-related activities. In the early stages of the epidemic much of what was known about HIV prevalence was kept secret by the authorities under President Kaunda. Senior politicians were reluctant to speak out about the growing epidemic (the President's announcement in 1987 that his son had died of AIDS (Bureau of Hygiene and Tropical Diseases, 'AIDS Newsletter', Issue 16, October, 1987) was a notable exception), and the press did not mention AIDS.

By the early nineties it was estimated that as many as 1 in 5 adults had been infected with HIV, leading the World Health Organization to call for the establishment of a National AIDS Advisory

Council in Zambia. The Health Minister did not favor this idea; it was felt that the government was preoccupied with reconstructing the bankrupt economy and paying down the country's debt (Does Zambia need a national AIDS council, Uganda-style or is that 'tunnel vision'?" (AIDS , 1992).

According to Stephen Lewis, the UN's Special Envoy for HIV/AIDS in Africa, throughout the 1990s the government was 'disavowing the reality of AIDS' and doing 'nothing' to combat the problem. Now, the National prevalence rate is estimated at 14%. The prevalence rates for males and females aged between 15-49 was estimated at 13% and 18% respectively (CSO, 2007). 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 reports indicate that the impact of AIDS has gone far beyond the individual level; all areas of the public sector and the economy have been affected.

Unlike in some countries, HIV in Zambia is not primarily a disease of the most underprivileged; infection rates are very high among wealthier people and the better educated. However, it is the poorest that are least able to protect themselves from HIV or to cope with the impact of AIDS. HIV has spread throughout Zambia and to all parts of society. However, some groups are especially vulnerable - most notably young women and girls. At the end of 2006, UNAIDS/WHO estimates that 17% of people aged 15-49 years old were living with HIV or AIDS. Of these million adults, 57% were women (UNAIDS/WHO, 'Report on the global AIDS epidemic'). AIDS has worst hit those in their most productive years, and, as families have disintegrated, thousands have been left destitute. Desperate people will inevitably turn to risky occupations - such as sex work - or migration. There is a saying among women in Zambia: "AIDS may kill me in months or years, but hunger will kill me and my family tomorrow".

The new millennium signaled a marked change in political attitude and, according to Stephen Lewis, 'an entirely new level of determination to confront the epidemic (Nussbaum *et al*, 1990). The National HIV/AIDS/STD/TB Council (NAC) became operational in 2002 when parliament passed a national AIDS bill that made the NAC a legally-established body able to apply for funding (the prospect of a large World Bank grant provided much of the necessary motivation).

At the passing of this bill, the NAC became the single high-level institution responsible for coordinating the actions of all segments of government and society in the fight against HIV and AIDS.

In 2002, the Government established a goal of making anti retroviral drugs accessible to all those in need at a subsidized fee. In 2004, the drugs were provided free of charge in the public sector. In June 2005, it was announced that a comprehensive package (labs, O.I drugs, consultations) would be provided at no cost. In 2004, the late President Mwanawasa declared HIV/AIDS a national emergency and promised to provide ARVs to 10,000 people by the end of the year; having exceeded this target, he set another to provide free treatment for 100,000 by the end of 2005. Additionally, government ministers and officials at all levels are now much more willing and able to talk about the epidemic. Even former president Kaunda has changed – he is now one of the most vocal and committed AIDS activists in the country.

Working through the Ministry of Health and NGO's, the decided to expand the free ART service to include all District Hospitals and some rural health centers. The target was to have as many as 100,000 patients on ARV's by the end of 2006. By end of December 2005, 40,000 patients had been placed on ART (UNAIDS/WHO, 2006).

1.5 Choma's Profile of HIV/AIDS

The 2001-2002 ZDHS was the first nationally representative population based survey to estimate the prevalence of HIV in Zambia, rather than relying on ante natal sentinel surveillance sites (CSO, 2003). CSO estimates the HIV prevalence in Choma overtime as lows; 1990; (16.3%); 1995; (21.3); 2000; 21%; and 2004; (19.2%).

1.6 ARV Therapy in Resource Limited Settings

The treatment and care of HIV-infected people requires comprehensive integration of patient-centered medical and social services. Essential elements of this approach include the provision of clinical care, nursing care, nutritional care and support, psychosocial support, health information and counseling, legal protection, and economic sufficiency. Notable components of successful

clinical care include early diagnosis, access to care, antiretroviral therapy, symptom control, prophylaxis against opportunistic infections, treatment of opportunistic infections and malignancies. The achievement of these objectives requires multi-sectoral and multi-disciplinary teams that are cross-linked to provide a continuum of care that involves patients, their families, healthcare providers, governmental and nongovernmental organizations, and society at large.

Prevention of new infections should be integrated into HIV/AIDS treatment and care programs as HIV infection remains incurable despite advances in antiretroviral treatment. Toward this end, “social immunization”—such as through community mobilization, widespread education, counseling and testing, sexual abstinence until marriage, monogamy, condom use, and female empowerment must be strengthened, as we await the perfection of vaginal microbicides, HIV vaccines, and other currently investigational prevention strategies. Even if HIV transmission were to cease completely, the existing burden of HIV/AIDS would continue to task all stakeholders into the foreseeable future.

Antiretroviral therapy (ART) has significantly reduced morbidity and mortality, prolonged life expectancy, and improved quality of life among people with HIV infection (Palella *et al.*, 1999) ART has also been effective in the prevention of mother-to-child transmission of HIV (PMTCT; Ioannidis *et al.*, 2001). Comprehensive Care including antiretroviral (ARVs), treatment of opportunistic infections, and the use of prophylactic agents benefits the individual, the community, and the country.

1.7 Benefits of ART

The biological and clinical goals of treatment with ARVs have focused on the suppression of viral replication, restoration of the immune response, a halt in the progression of disease, increased survival rates, reduced morbidity and a better quality of life. In countries where access to this level of care is available, AIDS related mortality and morbidity have significantly declined (Palella *et al.*, 1998; Perrin *et al.*, 1998). Numerous clinical trials as well as observational data (i.e. studies from clinical practice) have demonstrated beyond reasonable doubt that the benefits of antiretroviral treatment for people with HIV/AIDS far outweigh their risks. Antiretroviral are an extremely well tested class of medicines.

AIDS denialists say that the risks of antiretroviral outweigh their benefits. If this is the case, then why do people do better when they take more antiretroviral? The denialists cannot rationally explain this. A cursory look at continuous treatment versus structured treatment breaks by NIH, 2006 (International HIV/AIDS Trial Finds Continuous Anti-retroviral Therapy Superior to Episodic Therapy, 2006) in a randomized trial compared patients who took HAART continuously to patients who took structured treatment breaks. The rate of progression to AIDS or death in the continuous treatment arm was half the treatment break arm. AIDS denialists say that the risks of antiretroviral outweigh their benefits. If this is the case, then why do people who take antiretroviral all the time do better than people who take them occasionally? The denialists cannot rationally explain this. A selection from the many studies from clinical practice that have shown HAART substantially reduces death and illness. Besides the studies shown here, HAART has been shown to reduce death and illness in Zambia, Hong Kong and Brazil (Palella *et al.*, 2006).

1.8 Statement of the Problem

Up until now, limited research has been carried out to identify adherence problems in resource - poor settings and to strengthen adherence support (Jaffar *et al.*, 2005). Previous studies on adherence to ART in Africa have provided quantitative estimates of adherence and data on clinical outcomes, mainly from experimental settings (Ivers *et al.*, 2005). Recent studies in resource-limited setting show adherence levels of between 68% & 95% (Ak leswaran *et al.*, 2003). The methodological quality of these studies is variable as there is no gold standard for the measurement of adherence to use at the moment.

Clinic records at Choma show that there is a defaulter rate of 10% to ART (CIDRZ, 2007). This data however, cannot account for the current problems experienced by health workers in Choma in monitoring adherence of ART. No attempts have been made in the context of patient practices and culture to encourage patient adherence or do a study on factors affecting adherence. Given this scenario, we are not in position to make any empirical assertions on common adherence problems like: level of adherence, patient factors, treatment factors, substance and alcohol abuse, complexity of dosing regimen, pill burden, dietary restrictions and side - effects (WHO, 2004) and other factors that may be specific in poor settings (Hardon *et al.*, 2004).

1.9 Justification of this Study

This study is justifiable for the following reasons: We know that less than 95% adherence to a regimen can lead to viral resistance and ultimately treatment failure (Paterson et al., 2000). It has been estimated that every 10% decrease in adherence leads to a corresponding 16% increase in mortality (Friedland *et al.*, 1999). It is thus imperative that adherence levels above 95% are maintained at all times (KITSO Manual, 2004), which is not the case at Choma.

This is a pioneering study of factors affecting adherence to ART in this part of Zambia, and as such, the methodology will inform future researchers who may wish to do a much wider study. In addition, the results may be useful in developing simple interventions workable and feasible in (busy) clinical practice" that could be simple not only for the professional but for the patient as

well. It is envisaged that the study may bring into the fore a framework to for Choma' health system to address adherence.

Figure 1: Problem analysis diagram

Adopted from, Chesney *et al.*, 2000

CHAPTER TWO – LITERATURE REVIEW

2.0 Consequences of Lack of Adherence

Studies have shown that poor adherence results in increased morbidity and mortality, over use of health care services, and distorted results of medication trials. There has also been an association between antiretroviral adherence and viral suppression (Bangsberg *et al.*, 2000; Paterson *et al.*, 2000).

In separate studies (Walsh *et al.*, 2002; Howard *et al.*, 2002) demonstrated linear and direct associations between adherence and the number of drug resistance mutations (Gallego *et al.*, 2001). Subsequent studies with more extensive, concurrently obtained longitudinal adherence and resistance measures have confirmed the early findings (Bangsberg *et al.*, 2004; Miller *et al.*, 2003) found that, increasing adherence independently predicts the rate of accumulation of drug resistance mutations among patients with persistent detectable viraemia.

2.1 Patterns of adherence

In a study done in 18 ART facilities in Africa, Latin America and Asia (WHO, 2007), 15% of patients were lost to follow up. In Malawi, between 5- 25% are lost, while Botswana loses around 26% of patients (JAIDS, 2003). Zambia has a defaulter rate of 30% (CIDRZ, 2007).

2.2 Challenges Inhibiting Access

Obtaining a prescription during a clinic visit is reported as an obstacle to adherence. In some developing countries, just over 50% of ARV users are given a prescription which lasts for three months, 40% receive a prescription for one month and 12% for two months (Burgos *et al.*, 1998). In addition, some dispensing pharmacies will only dispense one month's medication at a time (often on a single designated clinic day) and not all pharmacies are able to dispense ARVs. As a result of such difficulties in prescription procedures, some patients attend their local pharmacy for most prescription medicine and another separate pharmacy for their ARVs. This is a barrier

to optimum adherence in that there are problems in obtaining or taking medicines have to wait until the designated clinic day, by which time patients may already be defaulting on their dose (Grierson *et al.*, 2000). Several studies in resource limited settings have previously reported that requiring patients to pay for ART is a major barrier to adherence and access to care that is associated with a high rate of losses to follow-up and poorer clinical outcomes. And in one Ugandan study presented at the Retrovirus Conference, 13.7% of almost 700 patients receiving ART at two clinics in Kampala discontinued treatment for at least one month — and the commonest reason for discontinuation, reported by 43%, was drug cost (AIDS MAP, 2007).

Data presented by Jembia Mosoko of the CDC in Cameroon suggest that even when fees are dramatically reduced; it can still be difficult to keep patients in care and on treatment. Cameroon's ART programme began in 2002 at the Limbe Provincial Hospital in the Southwest Province. Mosoko and colleagues performed a retrospective analysis of the clinical and pharmacy payment records for 2920 patients who enrolled in the programme between February 2002 and December of 2005 (AIDS MAP, 2007).

2.3 Social Economic Factors influencing non adherence

It should be recognized that adherence to ART is a critical issue, 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 such as gender, income, education and marital status have all been shown to affect adherence to ART, to differing degrees. For instance, literature reveals 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). Social support is one variable that has been observed to have an effect. Living alone and a lack of support have been associated with an increase in defaulting, (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 *et al.*, 1998).

Horne *et al.*,1990, identified beliefs and knowledge as predictors of adherence. Conversely, a lack of interest in becoming knowledgeable about HIV and a belief that HAART may in fact cause harm adversely affect adherence. A patient's beliefs about their illness and the effectiveness of medication are predictive of adherence. A good level of understanding about HIV by the patient, a belief that ART is effective and prolongs life, and recognition that poor adherence may result in viral resistance and treatment failure (Wenger *et al.*, 1999) all impact favorably upon a patient's ability to adhere. Conversely, a lack of interest in becoming knowledgeable about HIV and a belief that ART may in fact cause harm adversely affect adherence.

2.4 Economic Cost

This includes expenses for travel to the clinic, meals and user fees. And in one Ugandan study presented at the Retrovirus Conference, 13.7% of almost 700 patients receiving ART at two clinics in Kampala discontinued treatment for at least one month — and the commonest reason for discontinuation, reported by 43%, was drug cost (AIDSMAP, 2007).

Distance to Clinic;

Research in Uganda, Tanzania Botswana and elsewhere has shown that distance is factor in ARV adherence. Qualitative data elucidated on Universal access by 2010 challenges on the way by Anita Hardon and Colleen Daniels of Health Action International below, attests to this;

“I came from very far, over 50 kilometers from here. Before I come to the hospital I have to plan the money for a journey fare to the clinic. In fact my extra drugs got finished yesterday.” (Male ARV user, Uganda).

“I once missed my appointment for refill because there were no vehicles coming here. I was in the stop from early morning and by noon I went back home. Fortunately I still had some medications.” (Male ARV user, Botswana)

“I was registered to start ART in Kilimanjaro Christian Medical Centre (KCMC) in Moshi a year ago. At that time there was no ART clinic near my village. Now there is a clinic near

home but I am denied transfer from KCMC to my home clinic. KCMC is very far from here, about 170 km away. Some times I do not have the fare to travel to KCMC, hence I miss my doses.” (Male ARV user, Tanzania).

Although participants in all three studies received medicines free of charge, transport costs are an important reason why ARV users fail to visit the health facility for follow-up and refill. An article in IRIN Plus News loss-to-follow-up is an emerging problem in Namibia, where “concern has been growing over possible treatment interruptions for rural dwellers who start taking anti-retrovirals and are then unable to make follow-up visits. ‘It is not unheard of for patients to walk up to 20 kilometers to Eenhana Hospital because they are short of cash to pay for a ride. Sometimes they come to the clinic and sometimes they don’t,’” said one staff member at the clinic (www.plusnews.org).

2.5 Health care factors

The predominant work process is characterized by: fragmentation of teamwork, assistance centered on medical work, poor professional-patient communication due a lack of listening skills. On the other hand, the professionals feel themselves short of institutional support to deal with the suffering that results from working daily with young patients who carry a serious disease, and whose lifestyle often conflicts with the moral beliefs of the professionals who treat them. There is also a noticeable dispersion of responsibility as regards guidance in the use of ARV, as well as a lack of mechanisms for controlling and attracting non-adhering patients.

Patient adherence to treatment is largely the responsibility of the healthcare service. It is necessary that such services face up to this responsibility and develop creative ways for superseding traditional routines and for improving communication between professionals and patients. Identification of the mechanisms whereby healthcare services affect the level of adherence to treatment might help change the nature of care provided with regard to both the organization of actions taken and the content and mechanisms used to tackle the issue (Castanheira, 2000).

Research has shown that health care staff fail to make follow-ups. Gregory Bisson of the University of Pennsylvania and colleagues in Botswana performed a retrospective study among 410 patients who went onto ART during the first year of the Botswana programme at the Infectious Disease Care Clinic (IDCC) in Gaborone. Twenty nine (7%) individuals were classified as dead, by passive follow-up, and 68 (17%) were lost to follow-up. Then, after tracking down the lost patients, 69 (17% of the entire cohort) were found to be dead and 22 (5%) remained lost. Thus passive follow-up missed 40 patients (59%) who had died (AIDS MAP, 2007).

Three studies in Uganda, Tanzania and Botswana (Hardon *et al.*, 2005) showed that the problem of long waiting times was cited as a major challenge to adherence. In Tanzania, the mean time spent at the clinic was six hours. About half (12/28) of the health workers interviewed in Tanzania identified long waiting times as a problem. In Botswana, most respondents reported that they spent around four hours at the clinic. Nearly half of the respondents spent even more than that, with the longest wait being 12 hours. Inaccessible service, long traveling distance and lack of transport was also reported that expenses incurred attending hospital, unfriendly staff, inadequate confidentiality, seeing different health workers each time, poor communication style (use of jargon, patronizing language, lack of information, no opportunity for questions and lack of participation in interview) seemed to make patients de-motivated to take ARVs.

2.6 Treatment factors

Toxicities are the most common reasons for poor adherence to medications (Mellors *et al.*, 1996). Therapy discontinuation or modification is consistently identified as occurring in a significant minority of patients, especially in the first 3 months, with intolerance or toxicity rather than virological failure being given as the major reason for the change (Le Moing *et al.*, 2002). Almost all of those who are currently on ART are on a regimen of three or more ARVs and experience some side effects (Grierson *et al.*, 2000). Since different drugs have different food interactions, patients taking more than one drug at the same time need to consider the interactions and requirements of each drug. For those on multiple ARVs (combination therapy), sometimes one ARV needs to be taken with food and one without food, requiring the

drugs to be taken at separate times. Drug and food timetables need to be set to meet these requirements (Cadman *et al.*, 2001).

A typical HAART combination commonly consists of three agents or drugs (Stavudine, Lamivudine and Nevirapine or Effavirenz) and usually plus other medicine for prophylaxis of opportunistic infections. This can result into a high pill load. A study in Senegal reveals that a high pill burden is associated with poor adherence among patients who have to take a large number of ARV pills (Dansburg *et al.*, 2003).

Large capsules or tablets, and specific storage instructions impacts negatively upon a patient's ability to adhere (Ickovics *et al.*, 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. Anticipation and fear of side effects also impacts upon adherence. Poor adherence has been associated with patients' desire to avoid embarrassing side effects in certain situations, for example, whilst on date or attending a job interview (Burgos *et al.*, 1998).

Other than these factors, there are moments that complicated regimens with rigid dosing intervals may also interrupt sleep. The physical aspects of a particular medication (for example, taste, size or formulation) may also affect a patient's ability to adhere (Haynes *et al.*, 2002). One of the ways of mitigating poor adherence is Adherence and Treatment Support.

Success with any medication depends not only on the intrinsic properties of the drugs, but also on the ability of the patient to take the medications. HIV infection is one of the most difficult chronic diseases to treat optimally. Multiple drugs must be administered, the pill burden may be high, the regimen may be complicated, toxicities are common, drug interactions may occur, food restrictions may be required, and medications are expensive, the regimen carries an enormous social and psychological burden for many, and therapy is lifelong. HAART is lifesaving, yet it is anything but easy and it is very unforgiving. Less than 95% adherence to a regimen can lead to viral resistance and ultimately treatment failure (Paterson *et al.*, 2000). It has been estimated that every 10% decrease in adherence leads to a corresponding 16% increase in mortality (Friedland *et al.*, 1999).

Hunger and dietary restrictions attached to a drug

ARV users have complained about hunger during the initial stages of treatment, as the body needs extra nutrition as it regains strength and weight. They say they could not afford the amount of food needed to satisfy their increased appetites. The following quotes by Hardon and Daniels (2005) illustrate this.

“The problem I have with ARVs is related to food. I have no money and ARVs increase appetite. I am not capable of buying food.” (Male ARV user, Tanzania)

“I want to eat all the time and fear the hunger will eat into my stomach, since I have ulcers already. Sometimes I wake up in the night to eat food. This is a difficult situation for me.” (Male ARV user, Uganda)

“Majority of people say the ARV treatment makes them to eat a lot. They go to an extent of begging for old age pension from their grandparents. Others quit the treatment because they complain about the lack of food.” (FGD participant, Botswana)

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).

2.7 Service Related Factors

Long waiting time, insufficient personnel, inadequate income, poor supply of drugs, insufficient counseling and inadequate home visits have been reported as having a negative effect on adherence (Nakiyemb *et al.*, 2004). McAllister (2000) too in his study observed that 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/un empathetic and inconsistent staff. In developing countries, long waiting hours leads to poor adherence (Grierson *et al.*, 2000).

Staffing is one factor that seems to affect ARV adherence. In order to improve follow-up, Cutsem and colleagues from their study recommended that: “appropriate systems need to be created to accommodate the ever-increasing patient load. This includes capacitating all levels of health care workers (in the South African settings especially nurses) to deliver and monitor ART and ensuring additional adherence support by non-medical staff (www.aidsmap.com)

2.8 Patient Psycho-Social Factors

There are quite a number of patient variables that are related to adherence. Patient variables include socio-demographic factors (age, gender, race, income, education, literacy, housing status, HIV risk factors) and psychosocial factors (mental health, substance abuse, sociocultural issues and support, knowledge and attitude about HIV and its treatment) (Carrieri et al., 2002; Nemes et al., 2003; Murphy et al., 2004; Machtinger *et al.*, 2005).

Socio-demographic and psychological issues have great potential to impact on adherence. For instance, family support and religious beliefs about illness and medication may influence motivation and adherence (Haynes, et al., 1996). The issue of disclosure has also been found to have serious implications for adherence (Zea et al., 2005). For example, the use of medication may inadvertently reveal a person’s HIV status; poverty may prevent individuals from following treatment - related dietary advice; drug and alcohol abuse may impair judgment and the ability to adopt and maintain routine medication use; and family obligations may require adults to place the health care needs of others before their own. Some patients experience life stressors (lack of resources, unemployment, and life events) and these tend to affect their whole self. Age may influence adherence. Studies have found that, with the exception of the most elderly, adherence increases with age. In two studies associated with ART adherence, suboptimal adherence showed a positive correlation with being younger (Jones *et al.*, 1999). A lower level of general education and poorer literacy may impact negatively on some patients’ ability to adhere, while a higher level of education has a positive impact (Catz *et al.*, 1999).

Psychological factors, including mental health problems such as depression, have been associated with low adherence in HIV infected adults and adolescents, as have other psychological variables (Singh *et al.*, 1996). Depression and severe anxiety are both predictors of sub - optimal adherence (Hirschorn *et al.*, 1998). As the disease progresses, HIV may have an impact on the central nervous system and affect memory. AIDS - related dementia (AIDS Dementia Complex) is a common finding in patients with advanced disease and is characterized by abnormalities in cognitive and motor functions. Cognitive deficits have a negative impact on adherence to ART (Meisler *et al.*, 1993). Even when cognition is unimpaired, it is difficult to remember when to take medications (see Table 1).

Table 1: Adherence Factors for Antiretroviral Therapy

Factors Associated with Improved Adherence	Factors Associated with Poor Adherence
§ Patient knowledge of disease and drugs	§ Drug toxicity
§ Patient belief systems about HIV and modes of treatment	§ Heavy pill burden and frequent dosing schedule
§ Clinician knowledge of disease and drugs	§ Active illicit drug and/or alcohol use
§ Low pill burden	§ Untreated/uncontrolled psychiatric illness
§ Infrequent dosing schedule	§ Expense of drugs, monitoring, and travel
§ No food effect on drugs	§ Inconvenient appointments with clinic
§ Continuous availability of drugs	§ Lack of adequate transportation
§ Tracking treatment defaulters	§ Lack of food, clothing, and shelter
§ Treatment support (directly observed therapy, family member, community and support group)	§ Poor nutritional support
§ Develop linkage with local community-based organizations on adherence education and strategies	§ Young age

Active use of injected drugs or alcohol, psychiatric d and depression are also Studies among HIV-infected patients have indicated a strong preference for once-daily dosing and compact regimens (Claxton *et al.*, 2001). An improvement in the immune and virologic indices used to monitor highly active anti-retroviral therapy (HAART) may be a good indicator of adherence (Erlon *et al.*, 1999).

2.9 Ways of responding (Interventions) to adherence problems

Directly observed therapy

Directly observed therapy (DOT), in which a health-care provider observes the ingestion of medication, has been successful in tuberculosis management, specifically among patients whose adherence has been suboptimal. DOT, however, is labor-intensive, expensive, intrusive, and programmatically complex to initiate and complete; and unlike tuberculosis, HIV requires lifelong therapy. Pilot programs have studied DOT among HIV patients with preliminary success. These programs have studied once-daily regimens among prison inmates, methadone program participants, and other patient cohorts with a record of repeated suboptimal adherence. Modified DOT programs have also been studied in which morning dose is observed and evening and weekend doses were self-administered. The goal of these programs is to improve patient education and medication self-administration during a limited period (e.g., 3–6 months); however, the outcome of these programs, including long-term adherence after DOT completion, has not been determined (www.gwhealthpolicy.org)

Regimen-related strategies

Regimens should be simplified as much as possible by reducing the number of pills and therapy frequency and by minimizing drug interactions and side effects. For certain patients, problems with complex regimens are of lesser importance, but evidence supports simplified regimens with reduced pill numbers and dose frequencies (Bartlett *et al.*, 2001).

Volunteer Workers

ICAP is conducting cross-programme surveys trying to learn from one site to another, to assess just what sort of staffing might be needed (how many staff members of every different category, whether they are doctors, nurses, lay-professional staff or volunteers) to run a site well, terms of enrolment, and the proportion of various staff members needed per patient to keep them in care or on ART (www.aidsmap.com)

ICAAP discovered that the higher loss to follow-up rates was associated with inadequate staff resources for defaulter tracing together with inadequate community sensitization about the need for adherence. Stigma and lack of disclosure also played a part. The other big barrier was

transport to the clinic. In order to improve retention in care and adherence to treatment, ICAAP's clinics took the following steps:

- They encouraged family-based counseling in order to promote HIV testing and disclosure
- They began to provide transport from rural health centers to ARV clinics with high loss to follow-up rates, and established satellite clinics at local health centers too.
- Patients with an excellent record of adherence were permitted to take three months supply of drugs rather than having to return each month.
- Local awareness campaigns about the importance of adherence to ART were mounted.
-

Systems of care

There may be need to consider the incorporation of adherence interventions into convenient primary care settings; training and deployment of peer educators, pharmacists, nurses, and other health-care personnel in adherence interventions; and monitoring of clinician and patient performance regarding adherence are beneficial adherence (Bangsberg *et al.*, 2000). In the absence of data, a reasonable response is to address and monitor adherence during all HIV primary care encounters and incorporates adherence goals in all patient treatment plans and interventions.

Discussing possible treatment choices with the patient the logic behind them

The first principle of patient-related strategies is to negotiate a treatment plan that the patient understands and to which he or she commits (Friedland, 1997). Before writing the first prescription, clinicians should assess the patient's readiness to take medication, which might take two or three office visits and patience. Patient education should include the goals of therapy, including a review of expected outcomes that are based on baseline viral load and CD4 T cell counts, the reason for adherence, and the plan for and mechanics of adherence. Patients must understand that the first HAART regimen has the best chance for long-term success. Clinicians and health teams should develop a plan for the specific regimen, including how medication timing relates to meals and daily routines.

Temporary postponement of HAART initiation has been proposed for patients with identified risks for suboptimal adherence (Shere, 1998). For example, a patient with active substance abuse or mental illness might benefit from psychiatric treatment or treatment for chemical dependency

before initiating HAART. During the 1–2 months needed for treatment of these conditions, appropriate HIV therapy might be limited to OI prophylaxis, if indicated, and therapy for drug withdrawal, detoxification, or the underlying mental illness. In addition, readiness for HAART can be assessed and adherence education can be initiated during this period. Other sources of patient instability (e.g. homelessness) can be addressed during this time.

2.10 Methods Used in Measuring Adherence

There are several different methods of assessing adherence behaviors: (a) self-report questionnaires and structured interviews, (b) diary measures, (c) electronic monitors, (d) prescription refill histories, and (e) biochemical assays (Drotar, 2000; Quittner *et al.*, 2000) We did not include biological assays because their measurement properties seemed beyond the scope of this review and we did not include pharmacy refill accessed through pharmacy databases, which are not currently standardized. Each method has different strengths and weaknesses in terms of reliability, validity, and cost.

Self-report Questionnaires and Structured Interviews

The use of patient or parent self-report is the most common method of assessing adherence. Both self-report measures and structured interviews have been developed to measure adherence for a variety of pediatric chronic conditions, including asthma, diabetes and HIV-AIDS. Self-report measures have a number of strengths. They are inexpensive, comprehensive, and available for multiple informants (patients, parents, healthcare providers).

Structured interviews

Structured interviews also allow for follow-up questions which can provide important information about patient perceptions of the regimen and specific barriers. However, weaknesses include the tendency to overestimate adherence, problems with accurate recall, assessment of global perceptions rather than frequencies of behavior (e.g., “did you eat more calories today?” vs. “How many snacks did you eat today?”), and the difficulty of using them with younger children (8 years and below).

Daily Diary Methods

Diary measures can take several forms, including written logs, hand-held computers (PDAs) with time-sensitive prompts, and phone diaries completed directly with the respondent. Prior studies indicate that compliance with written logs is extremely poor and they are often completed just prior to their return, rather than on a daily basis (Johnson, 1993). Given that patients have difficulty adhering to their medical regimens, it is not surprising that they also have difficulty tracking their behaviors on diary cards. In contrast, modern diary methods, such as ecological momentary assessment (Csikszentmihalyi *et al.*, 1987) and day reconstruction methods (Kahnema, 2004) which assess daily activity patterns, hold considerable promise for measuring adherence because they obviate the most serious weaknesses of questionnaire/interview data problems with memory and recall (Modi *et al.*, 2006).

Electronic Monitors

Technological advances in microprocessors have led to the development of automated measures of adherence. These monitors are now available to record and store information on the date and time of tablet or liquid medication removal from standard vials, removal of pills from blister packages, actuation of metered-dose inhalers, blood glucose test results, and patient diary notations on adherence or other clinical events, such as pain levels. These monitors can store information in real-time from several months to 3 years and can be downloaded into data files for analysis. This is one of the most exciting developments in adherence measurement, with some even calling electronic monitors the "new gold standard" (Cramer, 1995; Rapoff, 1999).

Unfortunately, our set up cannot afford this equipment on a large scale.

2.11 Adherence Theory

Many scholars have written about the concept of “compliance” as we had stated in the earlier part of the definitions section. Compliance is meant to reflect the actions of a person to follow the provisions of a particular prescription. One indeed may be said to be complying with a prescription if it is acting in accordance with the obligations established in that particular source of treatment contract. But a patient’s participation in a treatment regimen is actually more complex. There may be contract that is binding or a voluntary one without any sanctions. Adherence can be taken to be binary concept. Patients may sign a contract and fulfill the provisions in varying degrees, and demonstrate varying degrees of commitment to the regimen based in part on their personal or family investment. Patients may also not sign but agree in principle as an expression of commitment, but not effect real changes in their behavior. Patients may even not agree yet exhibit some level of adherence to provisions of an expected conduct. Any patient on ARVs, at a given point in time, will fall somewhere along the spectrum of adherence.

2.12 Biomedical Factors

The most common biomedical predictor of non-adherence is the development of side effects from the prescribed medication (Bordenave-Gabriel *et al.*, 2003; Loffler *et al.*, 2003). Four other predictors are related to medications. A patient receiving inadequate or a sub-therapeutic dose is at greater risk for non-adherence. This is specifically relevant with individuals with major mood disorders (Ramana *et al.*, 1999). Two, patients that receive oral medications instead of depot are at an increased risk of non-adherence (Sullivan *et al.*, 1995). Patients on newer medications tend to have higher adherence rates (Ramana *et al.*, 1999), while those on older medications have lower adherence rates (Olfson *et al.*, 2000). Others suggest that adherence may be promoted by more simplified dosing schedules (Keller, 2004). Another biomedical factor is that patients with co-morbid conditions are more likely to be noncompliant with recommended medical and clinical treatment (Brent, 2002). The single largest co-morbidity associated with treatment non-adherence and hospital readmission is substance abuse; others include behavior problems and depression. Severity of symptoms, harder to treat symptoms, and chronic symptoms are also likely to increase risk of treatment non-adherence (Robinson *et al.*, 2002).

2.13 Social Factors

The single largest social factor impacting treatment adherence with patients is their family. Family adhesiveness, family members' support, and shared values have been found to have inordinate influence on patients and their adherence to treatment (Robinson *et al.*, 2002). Negative attitude of relatives, family rejection, or high levels of criticism and expressed emotion are powerful predictors of non-adherence and relapse (Sullivan *et al.*, 1995). Opposition of family or friends to medication treatment has a negative influence on treatment adherence (Bordenave-Gabriel *et al.*, 2003). For instance, in a study conducted by Favre and associates (1997), only 20% of the relatives of first episode patients with schizophrenia consider medication necessary. Also, patients have lower adherence if family members do not want to be involved in treatment or aftercare (Olfson *et al.*, 1998). Conversely, treatment adherence is increased if both parents of younger patients are involved (Robinson *et al.*, 2002).

General social support is another well studied social factor with higher support correlating with higher adherence, and decreased or poor social support a predictor on non-adherence (Robinson *et al.*, 2002). Patients discharged with appropriate and available clinical follow-up is another factor associated with treatment adherence (Svedberg *et al.*, 2001). Also, patients with a positive and well formed therapeutic alliance are more likely to remain compliant, while patients that feel professionals do not listen to them or experience relationship discord are at higher risk for non-adherence (Bordenave-Gabriel *et al.*, 2003).

A final important social factor associated with treatment non-adherence is the negative reaction to hospitalization (Sayre, 2000). Further, past hospitalization is a strong predictor of future hospitalizations (Sullivan *et al.*, 1995).

CHAPTER THREE- RESEARCH OBJECTIVES

3.0 Research Objectives

General; to explore known factors responsible for ART non-adherence in Choma. Specifically the study intended to:

1. Describe the level of ART non-adherence prevalent in Choma.
2. Identify patient/psycho-social related factors responsible for ART non-adherence in Choma.
3. Identify treatment factors related to non-adherence
4. Identify Health service factors associated with non-adherence at Choma hospital.

3.1 Research Hypotheses

H_{O1} ; There is no association between known patient/psycho-social, treatment, service factors and ART non-adherence.

H_{A1} ; There is an association between known patient/psycho-social, treatment, service factors and ART non-adherence.

CHAPTER FOUR-RESEARCH METHODOLOGY

4.0 Research Design

This was a cross-sectional, non-interventional study. This is one of the common and well-known study designs amenable to epidemiologists when either the entire population or a subset thereof is selected, and from these, data are collected to help answer research questions of interest. The study is cross-sectional because, the information about non-adherence and factors responsible for it that have been gathered represent what is going on in Choma at the time.

4.1 Research setting

The study was conducted in Choma, located in the southern province of Zambia, midway between Victoria Falls, Livingstone and the capital Lusaka. To create an understanding to the reader concerning the typicality of our respondents, we present a brief profile of Choma. Choma town covers an area of around 43,700 square kilometers, with a population of approximately 60,000 (210,000, taking all the local villages into account). The main industries are tourism and traditional crafts, including pottery and basket making. The town centre consists of traditionally built buildings mainly of one or two storey's, with a sprawling, tightly packed market area. Houses in the town are predominately brick built with metal sheet roofs and most have electricity and running water. In the villages, houses are smaller and usually built from handmade bricks with thatched roofs. These homes do not have electricity and water is obtained from standpipes fed from bore holes or dams.

4.2 Sample Size and Sampling

This study drew respondents from; (i) patient's on ARVs with a history of defaulting from the defaulter patient's register or (ii) a member in a household with an adult taking ARVs (care giver). The sampling decision to include these study elements made to triangulate the sources of information to answer the research questions. Simple random sampling was used to select patients from the ART defaulter patients register. The following formulae were used for sample size;

1. Initial sample size(n_1)

$$n_1 = \frac{z^2 pq}{d^2}$$

Where: $z = 1.96$ for 95% CI

p = estimate of the proportion with poor adherence

$q = 1 - p$

d = margin of error (10%)

$$\begin{aligned} &= 1.96^2 \times 0.075 (1 - 0.075) / (0.1)^2 \\ &= 3.84 \times 0.075 - 0.056 / 0.01 \\ n_1 &= 26.65 \end{aligned}$$

2. Modified sample size (n_2) to account for population size

$$n_2 = n_1 \times \frac{N}{N + n_1}$$

Where N is the number of patients with characteristic under study

$$\begin{aligned} &= 26.65 \times \frac{2800}{2800 + 26.65} \\ n_2 &= 26.3 \end{aligned}$$

3. Adjust for the design effect (n_3)

$$n_3 = B n_2$$

Where = Design effect inflation factor

$B = 1$ for simple random designs

$$n_3 = 1 \times 26.3$$

$$= 26.3$$

4. Adjust for non response to determine final sample size (n)

$$n = n_3 / r_1$$

Where r_1 = the expected response rate (25%; www.fhi.org 2000)

Sample size $n = 26.3/0.25$
= **105 patients**

Inclusion criteria

Only persons or relatives of person who were on ART, aged 16 and above and had a history or actually missed 2 or more consecutive clinic appointments were eligible to enroll into the study. Patients who appeared on ART registers for treatment as far back as one month to more than one year not documented as deceased, were targeted.

Exclusion criteria

Those patients documented as having transferred care to another facility or were lost to clinic follow-up or dead were not eligible for enrollment. Each patient had received a numerical identifier to preserve anonymity.

4.3 Data collection Tools

The study employed: Documentary retrospective review of patient medical records to extract baseline data. **Perceptions of ARV Medication Scale (PAMS)** questionnaires and one to one interviews were employed. Patients and relatives were questioned on the medications in their current regime. Adherence was measured by asking patients to recall the number of ART doses taken over the previous three days to the interview. Inhibitors and influencers were measured using three variables (patient/psycho-social, treatment and Health service factors).

The Perceptions of ARV Medication Scale (PAMS) assessed perceptions of the benefits and drawbacks of ARV medication. The scale measure uses numeric, nominal and a point Likert-type response scale. Likert-type scales were used with responses ranging from *never* to *always* or *almost every day*. The scales measured subjective response to medication use and inhibitors or influencers in an effort to obtain a more complete understanding of factors influencing medication compliance.

4.4 Operationalisation of variables

This study was set to examine an association between non-adherence to ART (missed clinic appointments for prescription refills) being the **dependent** variable with potential influencers being, patient/psycho-social factors, health service factors and treatment factors (**independent variables**).

1. Age was operationalized as a measure of maturity and was measured on a numeric scale.
2. Education was operationalized as a measure of literacy and was measured on nominal scale using the values: never been to school, lower primary upper primary, junior secondary, senior secondary, college, university
3. Substance abuse was operationalized as use of hashish and was measured on a nominal scale using the label Yes or No,
4. Beer drinking was operationalized as intake of locally brewed or commercial beer and was measured on an ordinal scale using the labels very much, much, just about okay, not much, not at all.
5. Hunger was operationalized as reduced intake of food and was measured on an ordinal scale using the labels always, frequently, occasionally, seldom, rarely, not at all
6. Social support was operationalized as help received from a partner, relatives, peers or lacking support and was measured on an ordinal scale using the vales, not at all to very much.
7. Non-adherence was operationalized as missing two or more consecutive clinic visits for prescription refills.
8. Barriers being a difficulty faced by a patient or relative supporting a patient who is on ART was operationalized in three ways as difficulties arising on account of;
 - Patient/psycho-social
 - treatment and
 - Health service factors.

Patient/psycho-social factors being bothers inherent of a patient to comply with the regimen were measured on a numeric scale to indicate the extent one followed the instructions about taking ARVs as follows;

- a. Education
- b. Substance abuse,
- c. Beer drinking
- d. Hunger
- e. Dietary restrictions attached to a drug
- f. Receive social support
- g. live alone
- h. Responsibility for taking your medication
- i. Distance to clinic is not a factor to get refills.
- j. Forgetting to take your medication

Treatment factors being bothers inherent of medication influencing a patient to fail to comply with the regimen were measured on a numeric scale to indicate the extent one followed the instructions about taking ARVs as follows:

- a. Experiencing discomforts due to side effects of drugs
- b. Drug and food timetables clash and create difficulties
- c. Side effects cause changes to my body.
- d. Side effects make me not to take the medication

Health service factors being bothers inherent of the health system influencing a patient to fail to comply with the regimen was measured on a numeric scale to indicate the extent one followed the instructions about taking ARVs as follows:

- a. Medicines run out at the clinic
- b. Health care staff fail to make follow-ups.
- c. The waiting times are long
- d. Doctors have made me understand about taking my medication and I do not miss.

CHAPTER 5: RESULTS

5.0 Results

Hospital records showed that out of 4000 patients on enrolled at Choma clinic, 400 (10%) were recorded as defaulters. Analysis on the variables was performed to show if there were associations between non-adherence (missing more than two drug refill appointments) and patient/psycho-social, drug and service factors.

A) Patient/Psycho-social characteristics

Out of a hundred and five (105) respondents interviewed, 58.1% were female.

Table 2: Age group of the respondents by sex

	SEX		Total
	Male	Female	
18 - 25 yrs	3 6.8%	16 26.2%	19 18.1%
26 - 35 yrs	16 36.4%	21 34.4%	37 35.2%
36 - 45 yrs	19 43.2%	15 24.6%	34 32.4%
46 yrs and above	6 13.6%	9 14.8%	15 14.3%
Total	44 100.0%	61 100.0%	105 100.0%

Table 2 shows that the majority of the respondents (35.2%) were in the 26-35 years age group. Men were from a much older age group (43.2% from 36-45 years), while the majority of women (34.4%) tended to be younger (26-35 years age group). Association between age group and sex was significant (Chi-square = 8.10 and $p = 0.044$).

Table 2: Age group of the respondents by missed clinic appointments

Age	Missed appointment		Total
	Yes	No	
18 - 25 yrs	13 20.6%	6 18.8%	19 18.1%
26 - 35 yrs	30 47.7%	7 29.9%	37 33.3%
36 and above	30 47.6%	19 59.4%	49 46.7%
Total	63 100.0%	32 100.0%	105 100.0%

Table 2 shows that the majority of respondents who missed their clinic appointments were from the 26-35 age group (47.7%). The least were from the 18-25 age group (20.6%). Association between age group and missing more than two clinic appointments was not significant (Chi-square = 3.94 and $p = 0.140$).

Table 3: Education level by missed clinic appointments

Education level	Missed appointment		Total
	Yes	college	
Never and primary	43 58.9%	13 40.8%	56 53.3%
Secondary, college and university	30 41.1%	19 59.2%	49 46.7%
Total	73 100.0%	32 100.0%	105 100.0%

Table 3: shows that, the majority of the respondents who missed more than two clinic appointments came from the Never and primary bracket (58.9%), with secondary, college and university having 41.1% of the respondents.

No significant association was observed between education level and missing more than two clinic appointments (Chi-square = 2.99 and $p = 0.084$).

Table 4: Marital status of the respondents by missed clinic appointments

Marital Status	Missed Appointment		Total
	Yes	No	
Single	20 27.4%	6 18.8%	26 24.8%
Married	29 39.7%	26 81.2%	55 52.4%
Divorced/widowed	24 32.9%	0 0%	24 22.9%
Total	73 100.0%	32 100.0%	105 100.0%

Table 4 shows that the combination of the singles and the divorced were in the majority (60.3%) among those who missed more than two clinic drug refill appointments. However, association between marital status and missing more than two clinic appointments was significant (Chi-square = 18.52 and $p < 0.001$).

Table 5: Occupation of the respondents by missed clinic appointments

Occupation	Missed appointment		Total
	Yes	No	
Student	5 5.4%	4 11.8%	9 8.6%
Worker (fomal / informal)	30 32.6%	8 23.5%	30 28.6%
Business/ farmer	25 27.1%	8 23.5%	33 31.4%
Unemployed	32 34.0%	14 41.2%	47 44.8%
Total	92 87.6%	34 32.4%	105 100.0%

Table 5 shows that the majority (34.0%) of the respondents who missed more than two clinic appointments were unemployed. The least were the student with 5.4% respondents. Association between missed clinic appointments and occupation was not significant (Chi-square = 2.48 and $p = 0.480$).

Table 6: explored social factors that affects clinic appointments

	N	%
Medications and clinic visits expensive	34	32.4
Education level Vs clinic appointments	33	31.4
Hashish Vs clinic appointments	1	1.0
Alcohol Vs clinic appointments	17	16.2
Hunger Vs clinic appointments	32	30.5
Dietary restrictions Vs clinic appointments	32	30.5
Social support Vs clinic appointments	55	52.4
Living alone Vs clinic appointments	15	14.3
Live with relatives but minus support	33	31.4

From table 6, 52.4% of the respondents had sited social support versus drug intake as one of the prominent psychosocial factor which contributes to non-adherence. The other factors mentioned were; medications versus clinic visits were expensive 32.4%, education level versus missed clinic appointments 31.4%, dietary restrictions versus missed clinic appointments 31.4% and hunger versus missed clinic appointments 30.5%.

Table 7: The responsibility for taking medication is entirely mine by missing clinic appointments

Drug taking responsibility	Missed Appointment		Total
	Yes	No	
Yes	42	7	49
	85.7%	14.3%	100.0%
No	31	25	56
	55.4%	44.6%	100.0%
Total	73	32	105
	69.5%	30.5%	100.0%

From the table 7, it can be seen that the 42 (89.7%) of the respondents who felt that, taking medication was not their responsibility also missed more than two clinic appointments. An association between missing clinic appointments and responsibility for taking medication was significant (Chi-square = 11.37 and $p = 0.001$)

Table 8: Social support by missing clinic appointments

Social support	Missed appointment		Total
	Yes	No	
Yes	29	24	53
	54.7%	45.3%	100.0%
No	44	8	52
	84.6%	15.4%	100.0%
Total	73	32	105
	69.5%	30.5%	100.0%

Table 8 shows that the majority of the respondents (84.6%) who missed their clinic appointments did not receive any social support from spouses and relatives. There was a significant association

between missing clinic appointments and social support.
(Chi-square = 11.07 and $p = 0.001$)

B) Drug factors

Table 9: Drug factors affecting drug non-adherence

	n	%
I skip medication	57	54.3
Clinic distance is a factor	27	25.7
Not keen to take drugs	77	73.3
Have reason for missing doses	30	28.6
Drug Changes Vs compliance	10	9.5
Side effects Vs compliance	65	61.9
Discomforts Vs compliance	66	62.9
Large capsules Vs compliance	17	16.2
Side effects cause me changed looks	49	46.7

From table 9, the most frequent drug factors attributed to missing clinic appointments by respondents were; not keen to take drugs 73.3%, drugs give some discomfort 62.9% and drugs have side effects 61.9%.

Table 10: Not keen to take drugs by missed clinic appointment;

Not keen	Missed appointment		Total
	Yes	No	
Always	58 75.3%	19 24.7%	77 100.0%
Rarely	15 53.6%	13 46.4%	28 100.0%
Total	73 69.5%	32 30.5%	105 100.0%

Table 10 shows that 75.3% of respondents who were always not keen to take drugs missed their clinic appointments. Association between not being keen to take drugs and missing clinic appointments was significant (Chi-Square = 4.59 and $p = 0.032$).

Table 11: Side effects by Missed clinic appointment

Side effects	Missed appointment		Total
	Yes	No	
Disagree	27 69.2%	12 30.8%	39 100.0%
Agree	46 69.7%	20 30.3%	66 100.0%
Total	73 69.5%	32 30.5%	105 100.0%

Table 11 shows that 69.7% of the 105 respondents, who experienced side effects, also missed their clinic appointments. (Chi-square < 0.01 and p= 0.960).

Table 12: Discomforts by missed clinic appointments

Discomforts	Missed appointment		Total
	yes	No	
Not at all	27 69.2%	12 30.8%	39 100.0%
Very much	46 69.7%	20 30.3%	66 100.0%
Total	73 69.5%	32 30.5%	105 100.0%

Table 12 shows that 69.7% (46) of the respondents who felt that drugs caused them discomforts also missed their clinic appointments (Chi-square < 0.01 and p = 0.960).

C) Service factors

Table 13: Service factors that affects my clinic appointments

Service		
	n	%
Medicines run out at clinic	11	10.5
Staff follow-ups poor	61	58.1
Waiting times are long	64	61.0
Staff education to patients is poor	60	57.1

From table 16, of the 105 respondents, 10.5% (11) said that medicines ran out at clinic, 58.1% (61) said there staff follows were poor, 61% (64) said waiting times were long and 57.1% (60) felt staff did not educate them enough.

Table 14: Staff educated me to understand by missed clinic appointments

Staff educated me	Missed appointment		Total
	Yes	No	
Not at all	46 76.7%	14 23.3%	60 100.0%
Very much	27 60.0%	18 40.0%	45 100.0%
Total	73	32	105
Total	69.5.0%	30.5%	100.0%

Table 14 shows that, 46 (76.7%) of the respondents who felt that, they did not receive adequate patient education missed their clinic appointments (Chi-square value = 3.37 and $p = 0.066$).

Table 15: Drugs ran out at the clinic by missed clinic appointments

Drugs ran out	Missed appointment		Total
	Yes	No	
Not at all	66 70.2%	28 29.8%	94 100.0%
Very much	7 63.6%	4 36.4%	11 100.0%
Total	73 69.5%	32 30.5%	105 100.0%

Figure 15 shows that 70.2% (66) of respondents felt that their missing of clinic refill appointment was not because drugs ran out at the clinic (fisher's exact test $p = 0.732$).

Table 16: Clinic waiting times by missed appointment

Waiting times	Missed appointment		Total
	Yes	No	
Not at all	41 64.0%	23 35.9%	64 100.0%
Very much	32 78.0%	10 22.0%	41 100.0%
Total	73 74.3%	32 25.7%	105 100.0%

Table 16 shows that 78% (32) of the respondents felt that waiting times at the clinic were not ok also missed their clinic appointments. No association was observed between clinic waiting times and missed clinic appointments (Chi-square = 1.74 and $p = 0.187$).

Table 17: Staff follow-up effort by missed appointment

Staff follow-up	Missed appointment		Total
	Yes	No	
Min.	40 65.6%	21 34.4%	61 100.0%
Max.	33 75.0%	11 25.0%	44 100.0%
Total	73 69.5%	32 30.5%	105 100.0%

Table 17 shows that 65.6% of the respondents who missed their clinic appointments felt that, staff did not put in enough effort on follow-ups. No association was observed between missing clinic appointments and staff follow-up effort (Chi-square = 1.07 and $p = 0.301$)

D) Factors independently associated with missed clinic appointments

Married respondents were 48% (AOR = 0.52, 95% CI [0.31, 0.87]) less likely to miss clinic appointments, compared to respondents who were single.

Respondents who had social support were 47% (AOR = 0.5 95% CI [0.32, 0.90]) less likely to miss clinic appointments, compared to those who did not have social support.

Respondents who were not keen to take medication were 72% (AOR = 1.72, 95% CI [1.03, 2.86]) more likely to miss clinic appointments compared to those who were keen to take medication.

CHAPTER 6- DISCUSSION OF RESULTS AND CONCLUSION

6.0 Introduction

This study explored known factors responsible for ART non adherence at Choma from a representative sample of 105 respondents who had defaulted on their ART treatment. Patient/psycho-social, treatment and health service factors were examined.

6.1 Limitations of the study

Limitations encountered in this study were;

- Resources: These were stretched as there was a lot of travelling involved.
- HIV and AIDS: still remains a sensitive issue for public discussion in our communities.
- Small sample size; this was determined (n = 105) by calculation from the total number of defaulters. A larger sample size would be recommended.

6.2 Discussion on Patient/psycho- social factors

6.2.1 Sex, age distribution

From the current study, it was observed that there were more females (58.1%) than males (41.9%) enrolled into the survey. Majority of the respondents (35.2%) were in the 26-35 years age group. Men were from a much older age group (43.2% from 36-45 years), while the majority of women (34.4%) tended to be younger (26-35 age group). According to Abah *et al.*, 2004, in his study in South Africa, found that, Gender and age were factors which influenced ART adherence. The young had poorer adherence compared to older age group and there was a preponderance of females in their study. Findings in the present study compare with Abah *et al.*, 2004 as there were more females and the majority age group younger. Men were said to be busy.

6.2.2 Education

This study showed that, the majority of the respondents who missed more than two clinic appointments came from the never and primary bracket (.9%) while the least came from college/university bracket (5.7%).

A lower level of general education and poorer literacy may impact negatively on some patients' ability to adhere, while a higher level of education has a positive impact (Catz *et al.*, 1999).

6.2.3 Occupation

Thirty four percent (34.0%) of the respondents who missed more than clinic appointments were unemployed. The least percentage came from the farmer bracket (6.5%)

Literature reveals that, patients on higher incomes have less difficulty with adherence (Marques, *et al.*, 1998). More people with some form of occupation had defaulted in this study contrasting Marques findings.

6.2.4 Social support and marital status

This study showed that the combination of the singles and the divorced were in the majority (60.3%) among those who missed more than two clinic appointments.

It also showed that the majority of the respondents (84.6%) who missed their drug refill appointment did not receive any social support from spouses and relatives.

Literature shows that the single largest social factor impacting adherence with patients is their family. Family adhesiveness, family members' support, and shared values have been found to have inordinate influence on patients and their adherence to treatment (Robinson *et al.*, 2002). Negative attitude of relatives, family rejection, or high levels of criticism and expressed emotion are powerful predictors of non-adherence and relapse (Sullivan *et al.*, 1995). This corresponds to the findings in this study

6.3 Treatment factors

Outstanding drug factors attributed to non-adherence in this study were; not keen to take drugs 79.5% (58), drugs give them discomfort 63% (46) and side effects 63% (46).

Literature shows that, drug toxicities are the most common reasons for poor adherence to medications (Mellors *et al.*, 1996). Almost all of those who are currently on ART are on a regimen of three or more ARVs and experience some side effects (Grierson *et al.*, 2000). Another author also says that, the most common biomedical predictor of non-adherence is the development of side effects from the prescribed medication (Bordenave-Gabriel *et al.*, 2003; Loffler *et al.*, 2003).

6.4 Service factors

Only 10.5% of the respondents said that, medicines run out at the clinic. Fifty eight percent said staff follow-ups were poor, 61% said waiting times were long and 57.1% staff did not educate them enough. From this information, it can be observed that Health service variables have a significant contribution towards non-adherence. A new entrant to the ART programme would feel discouraged if 10.5% of the clients revealed that, drugs ran out at the clinic. It is even worse if 61% said waiting times are long. In this context, staff should be implored to work harder to address these concerns.

Literature says that, long waiting time, insufficient personnel, inadequate room, poor supply of drugs, insufficient counseling and inadequate home visits have been reported as having a negative effect on adherence (Nakiyemba, *et al.*, 2004). McAllister (2000) too in his study observed that 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/unethical and inconsistent staff. In developing countries, long waiting hours leads to poor adherence (Grierson, *et al.*, 2000).

Three studies in Uganda, Tanzania and Botswana (Hardon, 2005) showed that the problem of long waiting times was cited as a major challenge to adherence. In Tanzania, the mean time spent at the clinic was six hours. About half (12/28) of the health workers interviewed in Tanzania identified long waiting times as a problem. In Botswana, most respondents reported that they spent around four hours at the clinic. Nearly half of respondents spent even more than that, with the longest wait being 12 hours. Inaccessible service, long traveling distance and lack of transport was also reported that expenses incurred attending hospital, unfriendly staff, inadequate confidentiality, seeing different health workers each time, poor communication style (use of jargon, patronizing language, lack of information, no opportunity for questions and lack of participation in interview) seemed to make patients de-motivated to take ARVs. Staffing is another factor that seems to affect ARV adherence (www.aidsmap.com).

6.5 Factors independently associated with missed clinic appointments

Married respondents were 48% (AOR = 0.52, 95% CI [0.31, 0.87]) less likely to miss clinic appointments, compared to respondents who were single. Respondents who had social support were 47% (AOR = 0.53, 95% CI [0.32, 0.90]) less likely to miss clinic appointments, compared to those who did not have social support, while Respondents who were not keen to take medication were 72% (AOR = 1.72, 95% CI [1.03, 2.86]) more likely to miss clinic appointments.

6.6 CONCLUSION:

The concluding remarks are:

1. Levels of ART non- adherence at Choma ART clinic were 10%.
2. There was significant association between patient/psychosocial factors; social support, marital status and not keen to take medication to ART adherence.
3. There was no association between treatment factors; side effects, discomforts and adherence.

CHAPTER 7- RECOMMENDATIONS

To enhance ART adherence, the study recommends that;

1. All patients should be encouraged to receive adherence counseling (Poppa et al., 2003).
This will reduce on the number of patients defaulting on their treatment.
2. Ministry of Health should intensify Health education campaigns to promote social support for people living with HIV/AIDS and those on ART.
3. Ministry of Health should encourage and motivate staff to more patient education sessions motivate them to improve patient waiting time and perform community outreaches.

APPENDICES

Appendix I: References

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Appendix II; Perceptions of ARV Medication Scale (PAMS)

You have been selected by chance with other people to help us know what may relate to you and the ARVs you are taking. Please read /listen to each item carefully and decide to what extent it is characteristic of you. Give each item a rating that applies to you by using a scale that is given for each question. Please remember to respond to all items. There is indeed no right or wrong answers. Your answers will be kept by me in the envelope that I have given you in strictest confidence for only six months which time I shall have examined all the responses. There after I shall destroy them. There will be no identification mart that relates to you on the questionnaire. I am sure that you will be open in responding to these statements.

Patient/ psychosocial factors

1. Sex

Sex	Tick only one
Male	
Female	

2. Age-----

3. Age range: sixteen to twenty five----- twenty six to thirty five..... thirty six to forty fiveand over forty six.....

4. What is your occupation?

Occupation	Tick only one
Student at College/University	
Student at Secondary School/Primary	
Administrator	
I am in sales and clerical jobs	
I am a professional	
I am in business	

Farmer	
Driver/Conductor	
Sex worker	
Other:	

5. How far have you gone in school?

Level of Education	Never	Primary	Lower Secondary	Upper secondary	College /University
Tick					

6. What is your marital status?

Marital Status	Tick only one
Single	
Married	
Divorced/widowed	

7. Do the ARVs create any dietary restrictions? Yes _____ No _____
8. Are you living alone? Yes _____ No _____
9. Who is helping you to take your drugs? The responsibility for taking your medication is entirely mine. yes _____ No _____
10. Do you get support. Yes _____ No _____
11. Do you have a trend of forgetting to take drugs. Yes _____ No _____
12. Have you missed doses over the last week? Yes _____ No _____
13. Did you miss more than two clinic refill appointments? Yes _____ No _____

There may be something about you that makes it difficult to comply with the regimen. Circle the number that best indicates your position.

14. Medications and clinic visits cost money and this affects my clinic appointments

Not all	1	2	3	Very much
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15. My level of education affects my clinic appointments

Not all	1	2	3	Very much
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16. I take hashishi and this affects my clinic appointments

Not all	1	2	3	Very much
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17. I drink beer (castle, chibuku, seven days e.t.c.) and this affects my clinic appointments

Not all	1	2	3	Very much
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18. I am living in hunger and this affects my clinic appointments

Never	1	2	3	Always
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19. I receive social support from relatives a partner and and this does not affect my drug intake

Not all	1	2	3	Very much
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20. The responsibility for taking medication is entirely mine, I skip the medication and this affects my clinic appointments

Not all	1	2	3	Very much
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21. The distance to the clinic is not a factor to get refills and this affects my clinic appointments

Very much disagree	1	2	3	Agree very much
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Treatment factors

There may be something about drugs that makes it difficult to comply with the regimen. Circle the number that best indicates your position.

22. I am not keen to take drugs and this affects my clinic appointments

Rarely	1	2	3	Always
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23. Do side effects force you to miss doses

Very much disagree	1	2	3	Agree very much
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24. I experience discomforts due to side effects of drugs and this affects my clinic appointments

Not all	1	2	3	Very much
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25. Side effects cause changes to my looks and this affects my clinic appointments

Disfigures my body and I do not like it	1	2	3	Suits my body and I like it
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Service factors

There may be something Health service delivery that makes it difficult to comply with the regimen. Circle the number that best indicates your position.

26. Do the medicines run out at the clinic

Not all	1	2	3	Very much
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27. Health care staffs make follow-ups and this helps my drug intake

Minimum effort	1	2	3	Much effort
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28. The waiting times are ok and this helps my drug intake

Not all	1	2	3	Very much
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29. Doctors and nurses have made me understand about taking my medication and I do not miss any.

Not all	1	2	3	Very much
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Appendix III Budget

Total Budget is estimated at ten million kwacha and the study to complete in 6 months.

Table 19: Budget breakdown

No.	Item	Total
1	Travel expenses	6,000,000.00
2	Data collector allowances	3,500,000.00
3	Stationery	500,000.00
Total		10,000,000.00

Appendix IV: Consent Forms and information sheet

TITLE OF STUDY:

PATIENT/PSYCHO-SOCIAL, TREATMENT AND HEALTH SERVICE FACTORS
AFFECTING ART ADHERENCE IN CHOMA (ZAMBIA)

Researcher- Supervisors

Richard Nsakanya

Principal investigator

School of Medicine

UNZA

Dr Nzala

Department of Community Medicine

School of medicine

UNZA

Prof. Seter Siziya

Head of 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 ART defaulting

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 (were respondent is not able to read, information and consent form, will be read out to them). 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: _____

Investigator's signature: _____

Date: _____

Consent (Tonga)

Ndabala zyilembelwe awa achipepa alimwi adazi nhwa (kuti sikutolalubazu katako nzi kubala chipepa echi, inga bamubalila).

Alimwi ndatelela kuti ndakonzya kubuzya mibuzyo olo kuleka kufumbwa chiindi. Ndazumina kuola lubazu mu kwiiya oku kwasunu.

Ndasaina/munwe; _____

Buzuba mwa mwezi; _____

Ethical matters

This protocol and any subsequent alterations shall be reviewed by the University of Zambia Biomedical Sciences Research Ethics Committee. Since this study involves human subjects, it is paramount to obtain consent from the participants or social actors, University teaching Hospital Management and the University of Zambia Biomedical Research and ethics committee. It therefore follows that all relevant parties would require obtaining informed consent prior to data collection. In this vein, letters expressing purposes, benefits and risks will be sent/given to all eligible participants and authorities.

Informed Consent

Consent to participate in this study will be guaranteed as a right so that the person involved should have legal capacity to give consent and exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion. To do so, all participants be availed with sufficient knowledge and comprehension of the elements of the subject matter involved as to enable them to make an understanding and enlightened decision. This latter element will require that before acceptance of an affirmative decision by the participants, it shall be made known to them the nature, duration, and purpose of the research; the method and by which it is to be conducted all possible inconveniences. Participants shall be informed of their rights to withdraw from the study at any time without any sanctions (Miley et al., 2007).

Risks

The researcher does not anticipate any risks or harm to the participants. Respondents will be informed of what will be done and how they will be involved in the study. The respondents will be asked to answer a survey questionnaire. The time to be spent with the participants will take less than thirty minutes and provided the researcher does not disrupt their social life negatively.

They will be guaranteed that their names will not be on any paper and the questionnaire will be destroyed after six months following the analysis. They will be assured that by participating in the study, possible risks are not there at all. However if they felt some discomfort or in case they were anxious about some questions or spending some time with the researcher and felt to decline

to take part or stop everything, they would have to do so voluntarily. This is because the decision to be part of the study is entirely up to them. Whatever they decided will not be held against them. They will be made aware by the researcher's disclosure to understand that the researcher who would be responsible for the study was not a member of any health management or regulatory board and that their participation will not have any harm in any way.

Benefits:

There are however no guaranteed direct benefits to the participants immediately on account of this research.

Confidentiality:

The participation in this study will confer confidentiality to the extent permitted by law. None of the information will identify the respondent by name. All information provided by the participants will be considered confidential and grouped with responses from other participants and shall be stored only for six months under lock and key only accessible by the researcher. Research data shall be destroyed at the end of the study. This will guarantee the participants that no any other person will have information related to them.

Rights and complaints:

If they have concerns about the study, they may contact the Chair Person, University of Zambia Biomedical Sciences Research Ethics Committee, Ridgeway campus, PO BOX 5011 .