Evaluation of factors that affect antiretroviral adherence in Siavonga District, Zambia.

By

Bwalya Chibende

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Supervisors: Professor Baboo K. S.

Professor Siziya S.

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ABSTRACT

Zambia is among the countries with high prevalence of HIV in the world, estimated at 16% among the adult population (ZDHS 2002). Noting the importance of adherence in HIV/AIDS treatment a case controlled study was conducted to understand factors that make people on Antiretroviral drugs (ARVs) not to adhere to treatment in two health facilities in Siavonga district. The study was conducted between May 2007 and May 2008. Both qualitative and quantitative research methods were used. These included the use of semi structured questionnaires and interviews with patients receiving ARV treatment and health care providers. Data coding, checking and cleaning was done before entry into the computer statistical package, EPI-INFO version 6.04 and SPSS. Qualitative data proportions comparisons were checked using the chi-square and a p-value of less than 0.05 was used to determine significance. The non adherent patients were identified by pill count, pill identification test and lack of improvement in clinical parameters. The clinical parameters used in this case were improvement in haematological cell lines including CD4 count. The average defaulter rate in Siavonga District was estimated at around 11.4% compared with provincial rate of 12.6%.

Socioeconomic factors affecting adherence were not examined in this study because several studies which have been done on this have shown consistently that there is no association (Fredrick Mulenga 2003). The study concentrated on patient's factors affecting adherence. The study found an association between the physical state of the patient and adherence. Respondents who were symptomatic (Diarrhoea) at initiation of

ARVs were 3.7 time more likely to be adhering to treatment as asymptomatic patients (p value 0.001). Another association was found between the number of pills taken and adherence. Non adherents were 95% more likely to be on Septrin prophylaxis as adherent patients (p value 0.001). The more pills the patient takes the less likely that they will adhere to treatment.

The study found no association between adherence and the type of regimen the patient is on, the level of education, and side effects. On the type of the regime the study found that there was no significant difference in terms of adherence among the different types of ARVs combination (p value 0.024).On side effects and adherence, the results were not statistically significant (p value 0.3). An association was found between the distance to the health facility and adherence. Adherent patients were two times more likely to be staying near the clinic as non-adherent patients (odds ratio 2).

Even though pill burden and physical state of the patient have been shown to affect adherence they can not be used on their own to predict patient's adherence or non-adherence.

DECLARATION

I, Chibende Bwalya, do hereby declare that the work presented in this dissertation for Masters in Public Health has not been presented either wholly or in part for a degree or Diploma in any other University and current not being presented for any other degree.

Signed: 

Chibende Bwalya

Date..... 6th April 2009

(Candidate)

Supervisors:

I have read this dissertation and approved it for examination

Prof. K.S.Baboo

Department of Community Medicine, School of Medicine, University of Zambia

Signature .....Date.....

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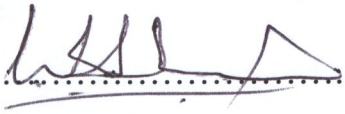
APPROVAL

This dissertation of Chibende Bwalya is approved in partial fulfillment of the requirement for the award of a Masters in Public Health (MPH) by the University of Zambia.

Examiner……  Date……06.04.09……..

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Head of Department:

Signature ……  ……Date……06.04.09……

DEDICATION

This study is dedicated to my late sister Joyce Mubanga Chibende who made it possible for me to complete my Secondary and University education. Without her this would not have been possible. May her soul rest in peace.

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All my lecturers and colleagues devoted ideas and times to the completion of this important study about antiretroviral adherence. I am especially indebted to the following people and organization:

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Operational Definition of Key concepts

1. Adherence

Taking drugs exactly as prescribed (correct numbers of pill, taken at the correct time, with consideration of food requirements and without missing doses.

2. Antiretroviral therapy

Treatment with drugs that specifically attack HIV

3. Clients

Persons who use the services.

4. Undetectable viral load

The virus is not detected in the blood after the lab test.

5. Viral load

Amount of viruses present in the blood plasma.

6. Treatment failure

Failure to achieve or maintain an undetectable level while on antiretroviral

7. Highly active antiretroviral therapy.

Antiretroviral drug combination that use three or more agents, usually from two or more drug classes in order to achieve the greatest suppression of viral load for the most sustained period of time.

LIST OF ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
ARV	Antiretroviral
ART	Antiretroviral Therapy
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
CIDRZ	Center for Infectious Diseases Research in Zambia
OIs	Opportunistic Infections
PLWHA	People Living With HIV and AIDS
UNAIDS	Joint United Nation Program of HIV/AIDS
CHAZ	Churches Health Association of Zambia
USAID	United States International Development Agency

LIST OF TABLES

LIST OF FIQURES

TABLE OF CONTENTS

CHAPTER 1

BACKGROUND

1.0 Problem identification

HIV is a pandemic infection affecting people globally. According to UNAID (2003), there are a total of 40 million people living with HIV and AIDS (PLWAS) in the world and out of these 28.5 million are found in Sub-Sahara Africa.

Current estimates are that 20-26% of people aged 15-49 are living with HIV and AIDS (Africa Health 2001). The impact of HIV and AIDS in Sub-Sahara Africa is threatening development in all sectors of society. The loss of productive workers and increases in health care and social service spending require difficult decisions about resource allocations across all government sectors (UNAIDS 2002).

Zambia's first AIDS case was reported in 1984. Today Zambia has a generalized HIV and AIDS epidemic that appears to be stabilizing (UNAIDS 2003). According to Zambia Demographic Health Survey of 2002, the national HIV Seroprevalance is 16%. Siavonga District were this study was conducted has adult HIV prevalence of 16.2%. The government's national antiretroviral therapy began in 2002 with two pilot sites at the University Teaching Hospital and Ndola Central Hospital. As of July 2004, 74 health facilities in Zambia were offering ARVs, including Central, Provincial and District hospital, health centres and private clinics. It is

expected that all hospitals and health centres in Zambia will be providing antiretroviral therapy by the year 2009.

Zambia has developed policies and guidelines for both testing and treatment of HIV and AIDS. The HIV testing policy requires full pre-testing counseling. It also requires that diagnostic testing and counseling be offered to HIV-positive people as part of a comprehensive HIV and AIDS care package. The government has put in place an opt-out HIV testing policy.

The number of people receiving antiretroviral treatment in low and middle income countries has tripled since the end of 2001. According to the 2005 UNAIDS/WHO '3 by 5' progress report, around 1.3 million people living with HIV are receiving ARV therapy in low and middle income countries. This means that 20% of those in need of treatment are now receiving it.

With the rapid scale up program being under taken by the Ministry of Health, the issue of adherence will be particularly important. In tying to meet the set target quality of care might be compromised in the process. The Ministry has failed to meet the set targets for the past two years. As at February 28, 2007 there were 75,000 patients on ARVs against the national target of 140,000.

Taking ARVs regimens is not very easy, since it is a lifetime treatment. The challenge of adherence in the face of potential viral resistance, treatment failure, associated toxities and disease progression is worrying. Patients on long-term HAART with undetectable HIV in plasma still harbour replication competent virus (Furtado, et al, 1999). 100% adherence is difficult under

any circumstances, the complexity of HAART regimes, and associated short and long-term toxicity all pose particularly difficult challenges for patients.

While the government and cooperating partners are determined to increase accessibility to ARVs, specific initiatives towards adherence to ARVs need to be in place to insure rational ARVs use at all levels including the community.

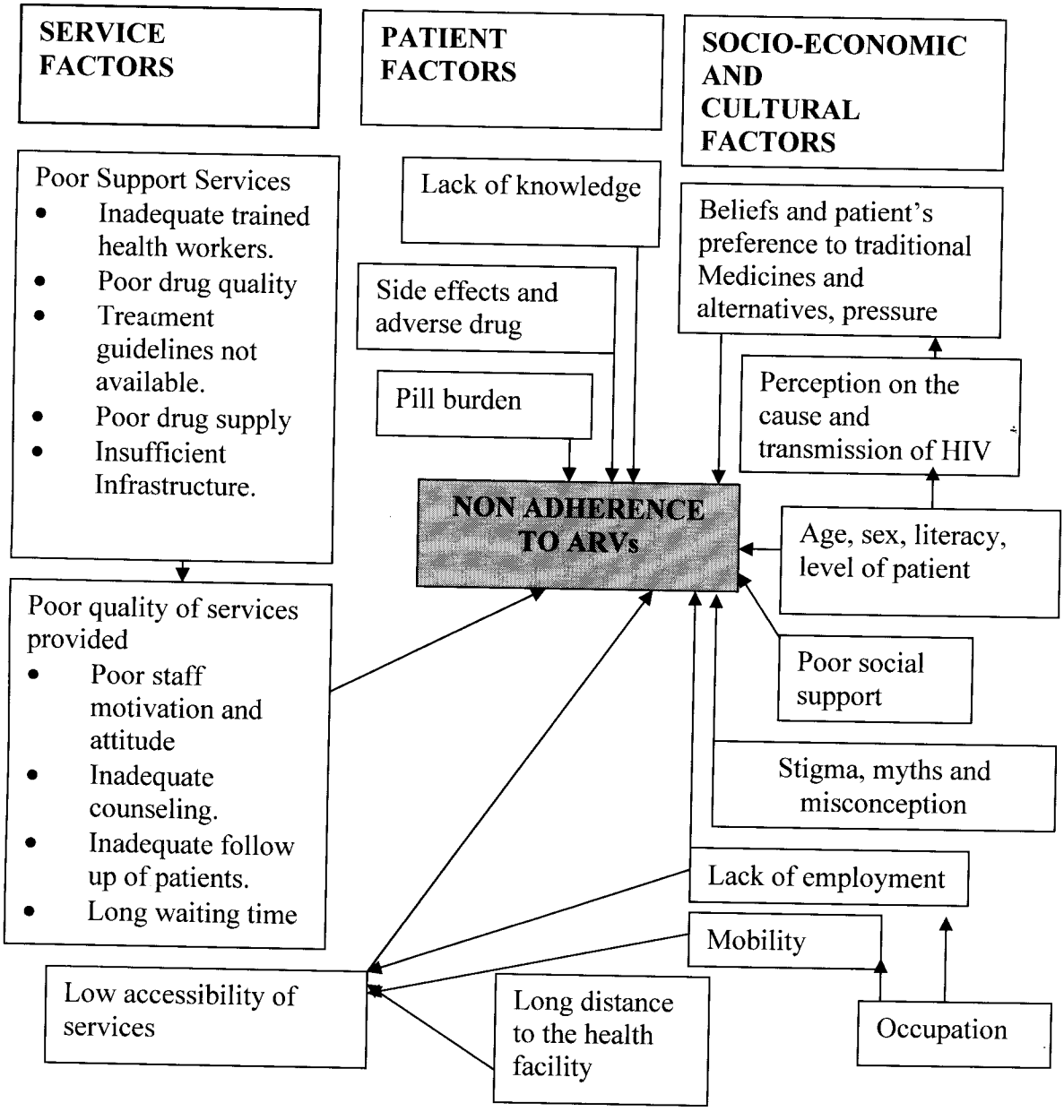
A study conducted in Botswana indicated that 54% of patient were adherent by self –report while 56%were adherent by provider assessment (S. Weiser 2003). The study showed that patients had to overcome great odds to adhere to treatment. They lacked adequate funds, and traveled long distances, to clinics providing ARVs.

There is a lack of proper documentation on ARVs treatment adherence and possible factors contributing to ARV non-adherence in Zambia. Studies in other countries have described a range of factors affecting ARV treatment of various levels. The current defaulter rate among patients on antiretroviral therapy is 12.6% in Southern province of Zambia (HIMS-2007). Siavonga has a defaulter rate of 11.4%, Livingstone 11.8%, Gweembe 12.9 and Kalomo14.4%.

ADHERENCE PROBLEMS ANALYSIS DIAGRAM

Figure 1 Adherence problem analysis diagram

Below are various variables analyzed as possible factors associated with non-adherence?



2.0 Justification of the study

Antiretroviral drugs can increase the length and quality of life and productivity of patients. Current data from Ministry of Health, Health Information Management System (HIMS), suggest that antiretroviral regimens have improved survival and decreased the incidence of opportunistic infections in people with HIV to a certain extent. Strict adherence to HAART regimens is crucial in order to maintain a low viral load and prevent the development of drug resistant Virus. However, some clients do not return for follow up on schedule and are likely to be non-adherent to prescribed ARVs regimens. There is growing concern about loss to follow-up and non-adherence to antiretroviral therapy as significant barriers to care in Zambia.

The largest provider of this ART services is the Ministry of Health. Others are Church Health Association of Zambia, CIDRZ and private clinics. All these providers have reported many cases of patient failure to turn up for re-supply. This is one of the indicators of the obvious problem of adherence as indicated in an analysis diagram.

This study will focus on patients who are accessing ART through government facilities where monitoring and follow-up may not be as adequate as in other organizations with better facilities and resources such as the private clinics.

In HIV infected patients on HAART, 95% adherence is associated with high viral suppression and 80%-90% adherence with failure to achieve complete viral suppression in 50% of patients (Paterson, et al, 1999). The failure to

suppress viral replication is very high, if the patient is non-complaint, and this requires to be investigated.

A study done on socioeconomic factors affecting adherence in Zambia concluded that there was no association between socioeconomic factors and adherence (Fredrick Mulenga 2007). The researcher pointed out limitations of the study which need to be followed up with another study. The follow up study should have the power of 80 instead of 50. The study should have a large sample size. It is for this reason that this study should be done.

CHAPTER 2

LITERATURE REVIEW

Currently there is an overwhelming amount of evidence from clinical trials which have been published validating the use of HAART for the treatment of HIV infection. The goals of ARV therapy are to

- Reduce the amount of HIV Viruses in the body.
- Support and help the immune system
- Improve the quality of life
- Reduce HIV related illness and deaths
- Reduce risk of HIV transmission to other.

In countries where access to standard of care is available, AIDS related morbidity and mortality have significantly declined (Palleta, et al 1998).

Maximum and durable suppression of HIV Viral replication to undetectable level is necessary to achieve biological and clinical goals of ARV therapy. Near- perfect adherence is required to achieve success. Failure to suppress viral replication completely, leads to the emergency of drug resistant strains, limiting the effectiveness of therapy (Chondra, 1998). Non-adherence in patients on ARVs is the strongest predictor of failure to achieve Viral suppression below undetectable level (Steven Deeks, 1997), and faulty adherence to ARVs most often underlies treatment failure. Taking 95% of doses is necessary to adequately suppress viral replication, (Paterson, 1999). This means that missing more than one dose of regimen per week may be enough to cause treatment failure.

A Number of variables have been shown to affect adherence to HAART, some more than others (McAllister 2000).

1.1 Socioeconomic Factors of Patients on HAART Regimes.

The literature consistently demonstrates that demographic characteristics are not strong predictors of adherence though some do correlate with the level of adherence.

1.1.1 ***Age***

Age may influence adherence. Studies have shown that apart from the most elderly adherence increases with age (Wruger, Gifford, Liu, Chisney & Golin, 1999). In two studies associated with HAART, adherence and non-adherence showed a positive correlation with younger age (Klosinski & Brooks, 1998, Nakashima and Kaplan, 1999).

1.1.2 ***Level of Education***

A lower level of general education and poorer literacy impacts negatively on some patient's ability to adhere whilst a higher level of education has a positive impact (Kochman, 1999).

1.1.3 ***Financial Resources.***

Patients on higher incomes have less difficulty with adherence (Valdes & Santana, 1998). However, poverty is an increasing feature of the face of HIV especially in third world.

1.1.4 ***Social Support.***

Living alone and a lack of support have been associated with an increase in non-adherence (Williams & Fredland, 1997) and social isolation is predictive of non adherence (Besch 1995). Having a partner, social or family support, peer interaction and better physical interactions and relationships are characteristics of adherent patients (Craker, etat 1984, Holzemer & Nokes, 1998).

2.1 Side Effects of HAART on Adherence.

2.1.1 ***The drug regimen.***

All people who are using ARVs are on a drug combination of three or more drugs. The likelihood of a patient's adherence to a given regimen declines with the number of pills being taken, the frequency of dosing, the frequency and severity of the regimen (Williams & Friedland, 1997). Anticipation and fear of side effects also impacts upon adherence (Broers, 1994). Poor adherence has been associated with patient's desire to avoid embarrassing side effects in certain situation, for example, whilst on a date or attending a job interview (Burgos, etat, 1998).

Apart from ARVs, patients also take drugs for OIs and symptomatic relief of ARVs side effects. This further adds to the pill burden and toxicity

2.1.2 ***Dietary Restriction Attached to a Drug.***

Some types of ARVs require to be taken with special consideration to the type of food. This is particularly difficulty if workmates, family or friends are unaware of the patient's HIV status (Grierson, etat 2000). Physical

aspects of a particular medication such as taste, and size may also affect adherence (Crespo – Fierro, 1997).

2.2. Physical State of the Patient

2.2.1 ***Physical State and disease stage***

Lack of symptoms despite laboratory evidence of need for HAART, may affect adherence (Jones, et al, 1999) Prior opportunistic infection (Singh, et al 1996), severity of symptoms and low counts (Erlon & Mellors 1999) can impact on adherence improved in virological parameters may be an incentive to maintain adherence (Kaphn, 1999).

2.2.2 ***Depression and Severe Anxiety.***

Adherent patients demonstrate significantly less depression or other CNS disturbances (Singh et al, 1996, Prattetadal 1998) cognitive deficits in AIDS Dementia Complex do impact negatively on adherence. Some patients may on account of ignorance stop taking ARVs on account of improved health.

2.3 Beliefs and Knowledge.

Patient's level of knowledge about HIV disease, a belief that is effective (Klosinski & Brooks, 1998) and prolong life and a recognition that Viral resistance and treatment failure all impact positively upon a patient's ability to adhere. Conversely, a lack of interest in becoming knowledgeable about HIV and a belief that HAART may cause harm adversely affect adherence (Home, Reason, Leake, fisher, Weiuman 1999).

2.4 Aspects of the clinic and service provision.

Proximity to the patient's home or place of work, the expense of getting there, lengthy delays between appointments, clinic opening and closing times, long waiting times, lack of services such as child care, privacy, confidentiality and unsympathetic staff impact negatively on adherence. (Kammann, et al, 1999).

2.5 Difficulties with HAART Re-Supply.

Lengthy waits in health facilities that do not have extended hours may also impede adherence (Rierson, et al 2000).

CHAPTER 3

OBJECTIVES OF THE STUDY

1.0 General Objective.

To asses determinants of ARVs adherence in Siavonga District, Zambia.

2.0 Specific Objectives are to:

a) To determine associations between the pills taken and adherence
b) To determine associations between types of ARVs regimes and adherence.
c) To identify associations between distance to the health facility and adherence.
d) Collect information from ARVs users and support groups on improving ARV adherence.
e) Recommendations.

3.0 Null hypotheses

I. There is no association between the numbers of pill being taken and ARVs adherence
II. There is no association between the type of ARVs regime and ARVs adherence
III. There is no association between side effects and adherence
IV. There is no association between education and adherence
V. There is no association between the physical state of patient and adherence.

VI. There is no association between the distance to the health facility and ARVs adherence

CHAPTER 4

METHODOLOGY

1.1 Study Design.

This was a case control study in which both qualitative and quantitative methods of data collection was used. It was done between April and September 2007.

1.2 Study Area.

The study was conducted in two health facilities in Siavonga Districts. These included one first level hospital, Siavonga District Hospital and one rural health Centre, Lusitu.

1.3 Sampling Strategies and Sample Size.

Convenience sampling method was used to select sites. One Hospital based site and one rural health facility site.

For patients, a simple random sampling method was used for the sample size of 68 participants calculated using the formula as below.

We assumed improvement from 90% to 95% and considering the power of 80% and a one tailed test at a significance level of 5%. Then the required sample size is:

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

$$n = \frac{(90*10) + (95*5)}{(90-95)^2} * 6.18$$

$$\frac{900 + 475}{25} * 6.18$$

55 * 6.18

n = 339.9=340

Where P1 is the expected proportion in the control and P2 in the case group.

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

$$\frac{340}{0.9} = 377.7 = 380$$

Six health workers were chosen purposively to complement information on operating structures, processes and suggestions for improving adherence to ART

In addition, selected community leaders and PLWHA from within the catchments areas of health facilities participated.

1.4 Study Population.

The study population included patients attending ART clinics from Lusitu rural health centre, Siavonga and Mtendere hospitals, as well as staff working in these facilities and community leaders from the respective localities. Total number of patients on ARVs in Siavonga was 1940.

Cases in the study were those who were adhering to the treatment and controls were those not adhering. The cases were identified through self reporting, pill identification test and pill count.

Inclusion criteria

Patients

- Adults ,18 years and above
- Have been on ARVs treatment for 3 months or more
- Patient's ARVs treatment records for the last 3 months

Health workers

- Routine staff at the ART clinic for more than one month.
- Well informed about the patient and the study

Exclusion criteria

Patients

- ARVs treatment initiated from a different clinic apart from the study centres
- Below the age of 18
- On ARVs treatment for less than 3 months

Health workers

- Working at the care and treatment unit for less than a month
- Not in direct interaction with patient

Identification of Variables

Table 1 Identification of variables

Type of variable	**Indicator**	**Scale of measurement**
Level of knowledge on ARVs	Poor, average ,good	Set of question
Drug availability	Shortages, always available, sometimes.	
Employment	Formal, business, not doing anything	
Social support	Married, divorced, widow, staying alone, HBC, others	
Drug regimen	D4t/3tc/nvp, d4t/3tc/efv, azt/3tc/nvp, azt/3tc/efv, d4t/3tc/pi, azt/3tc/pi, second line.	
Formulation	Fixed dose, 3 tablet, 2 tablets	Tablets
Side effects	Burning feet, vomiting, diarrhoea, others	
Food restriction	yes , no	
Frequency of doses	3 times, 2 times, once daily	
Stage of disease	Stage 1,2,3,4	WHO staging system
Diseases	Type of disease	
Distance to the clinic	Less than 1km, 1km-8km, 8km-above	km
Mode of transport to the clinic	Walking, buses, others	
Waiting time	Less than 10 min, 10-30min, 30-60, 60min and above	minutes
Appointment period	2 weeks,1 month,3 months,6 months	Months

1.5 Data Collection Methods.

Different methods were used for this study. These included:

1.5.1 ***Semi structured interviews.***

Semi structured interviews to collect background information, aspect of knowledge, attitude, perception and practice on the use of ARVs. The interview also solicited demographic and socioeconomic and cultural information, general assessment of adherence, report of adherence in the previous three months, reasons for non –adherence or abandonment of treatment, motivation aspect of treatment, opinion on the quality of care provided and how to improve adherence.

1.5.2 ***Review of patients records.***

To determine level of adherence and gather clinical data of patients, records for all patients interviewed were retrieved to substantiate information regarding demographic data and disease state information, ARVs use and adherence. A data capture sheets were used to collect information from patient's records.

1.5.3 ***Observation.***

Observations were made during consultation to collect information on the operating structures. Checklists were used to collect this information.

1.5.4 ***Exit interviews.***

Exit interviews were conducted in order to assess the quality of care received.

1.5.5 ***Focus group discussions.***

These were used with the community and PLWHA to explore community knowledge, beliefs, attitudes, and behavior on the use of ARVs, social support to PLWHA and to obtain suggestions on how to improve adherence to ARVs.

CHAPTER 5

DATA ANALYSIS AND PRESENTATION.

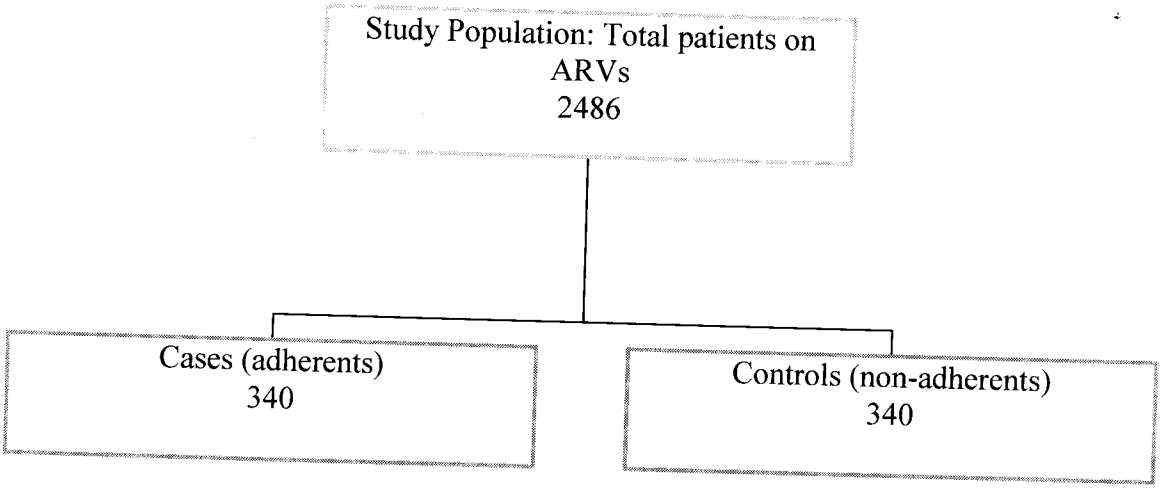
Data coding, checking and cleaning was done before entry into the computer statistical package, EPI-INFO version 6.04 and SPSS.

Qualitative data proportions comparisons were checked using the chi-square and a p-value of less than 0.05 was used to determine significance.

1.1 Study profile

Antiretroviral and adherence

Figure 2 .Study profile: cases and cases



10% were not included due to incompleteness of the records

1.2 Baseline characteristics of cases and controls

1.2.1 Baseline characteristics of cases and controls: Age

Antiretroviral and adherence

Table 2.Age

Age	Cases		Controls (%)	(%)
%	n	%		n
19 – 23	10	2.9	4	1.2
24 – 29	28	8.2	76	22.4
30 – 35	98	28.8	136	40.0
36 – 41	148	43.5	76	22.4
42 – 47	32	9.3	42	12.4
>48	24	7.1	6	1.8
Total	**340**	**100**	**340**	**100**

1.2.2 Baseline characteristics of cases and controls: Sex

Antiretroviral and adherence

Table 3 Sex

	Case		Control		Total		Chi Sq	p Value
	n	(%)	n	(%)	n	(%)	2.8	0.096
Male	148	(43.5)	118	(34.7)	**266**	**(39.1)**		
Female	192	(56.5)	222	(65.3)	**414**	**(60.9)**		
Total	**340**	**(100)**	**340**	**(100)**	**680**	**(100)**		

1.3 Results for different categories

1.3.1 Age and adherence

Table 4 Age and adherence

	Case		Control		Total		Chi Sq	p Value
	n	(%)	n	(%)	n	(%)	33	0.001
18-23	10	(2.9)	4	(1.2)	**14**	**(2.1)**		
14-29	280	(8.2)	76	(22.4)	**104**	**(15.3)**		
30-35	98	(28.8)	136	(40.0)	**234**	**(34.4)**		
36-41	148	(43.5)	76	(22.4)	**224**	**(32.9)**		
42-47	32	(9.4)	42	(12.4)	**74**	**(10.9)**		
>48	24	(7.1)	6	(1.8)	**30**	**(4.4)**		
Total	**340**	**(100.0)**	**340**	**(100.0)**	**680**	**(100.0)**		

The results above show that there is no association between age and adherence. However, we have learnt from the these results that most of the people taking ARVs in Siavonga District had the mean age of 36 years (30-41 years).

1.3.2 Education and adherence

Table 5 Education and adherence

	Case		Control		Total		Chi Sq	p Value
	n	(%)	n	(%)	n	(%)	93.6	0.001
College	4	(1.2)	16	(4.7)	**20**	**(2.9)**		
Secondary	56	(16.5)	206	(60.6)	**262**	**(38.5)**		
Primary	244	(71.8)	72	(21.2)	**316**	**(46.5)**		
None	36	(10.6)	46	(13.5)	**82**	**(12.1)**		
Total	340	(100.1)	340	(100.0)	**680**	**(100.0)**		

There is no association between the level of education and adherence.

1.3.3 Quality of health before ARVs and adherence

Table 6 Quality of health before ARVs and adherence

	Case		Control		Total		Chi Sq	p Value
	n	(%)	n	(%)	n	(%)	3.57	0.06
Better	44	(12.9)	70	(20.6)	**114**	**(16.8)**		
Worse	296	(87.0)	270	(79.4)	**566**	**(83.2)**		
Total	**340**	**(100)**	**340**	**(100)**	**680**	**(100)**		

Those who perceived health before starting ARVs to have been worse are more likely to adhere to treatment than those who did not. But the p value of 0.06 indicates that the results could have occurred by chance.

1.3.4 Quality of health while on ARVs and adherence

Table 7 Quality of health while on ARVs and adherence

	Case		Control		Total		Chi Sq	p Value
	n	(%)	n	(%)	n	(%)	55.59	0.001
Good	339	(99.7)	244	(71.8)	**583**	**(85.7)**		
Bad	1	(0.3)	96	(28.2)	**97**	**(14.3)**		
Total	**340**	**(100)**	**340**	**(100)**	**680**	**(100)**		

Those who experienced good health while on treatment are more likely to continue adhering to treatment than those who do not. The p value of 0.001 is statistically significant.

1.3.5 ARVs contribution to good health

Table 8 ARVs contribution to good health

	Case		Control		Total		Chi Sq	p Value
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	51.6	0.001
Yes	338	(100.0)	250	(72.9)	**588**	**(86.5)**		
No	0	(0)	92	(27.0)	**92**	**(13.5)**		
Total	**340**	**(100)**	**340**	**(100)**	**680**	**(100)**		

Those who believe that ARVs work are more likely to be adhering to treatment than those who do not. About 26% of those who do not adhere to treatment believed that ARVs have not contributed anything to make their lives better compared to none among those who adhere to treatment. The results were statistically significant with p value of 0.001.

1.3.6 WHO Staging at ARVs initiation and adherence

Table 9 WHO Staging at ARVs initiation and adherence

	Case		Control		Total		Chi Sq	p Value
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	8.47	0.04
Stage 1	6	(1.8)	2	(.6)	**8**	**(1.2)**		
Stage 2	18	(5.3)	4	(1.2)	**22**	**(3.3)**		
Stage 3	276	(81.2)	318	(93.5)	594	**(88.9)**		
Stage 4	40	11.7	16	4.7	44	**6.6**		
Total	**340**	**100.0**	**340**	**100.0**	**680**	**100.0**		

There is no association between the WHO stage at initiation of the treatment and adherence. But the most important finding from these results is that in

Siavonga District most patients on ARVs were started on treatment while in stage 3.

1.3.7 Presence of opportunistic infection and adherence

Results: Crude

Table 10 Crude: Presence of opportunistic infection and adherence

	Case		Control		Total		Chi Sq	p Value
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	10.08	0.001
Yes	340	(100.0)	318	(93.5)	**658**	**(96.8)**		
No	0	(0)	22	(6.5)	**22**	**(3.2)**		
Total	**340**	**(100)**	**340**	**(100)**	**680**	**(100)**		

There is high proportion of symptomatic patients among those who adhere to treatment than those who do not. From these we can conclude than being symptomatic at the start of treatment is a motivation to take medications than without symptoms.

Results: Tuberculosis

Table 11 Tuberculosis

	Case		Control		Total		Chi Sq	p Value
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	.362	0.55
Yes	185	(54.4)	174	(51.2)	**359**	**(52.8)**		
No	155	(45.6)	166	(48.8)	**321**	**(47.2)**		
Total	**340**	**(100)**	**340**	**(100)**	**680**	**(100)**		

The p value of 0.55 indicates that the results here could have occurred by chance, though the results indicate that those who had Tuberculosis at one time are more likely to adhere to treatment than those who did not.

Results: Meningitis

Table 12 Meningitis

	Case		Control		Total		Chi Sq	p Value
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	1.0	0.32
Yes	2	(.6)	0	(0)	**2**	**(.3)**		
No	338	(99.4)	340	(100.0)	**678**	**(99.7)**		
Total	**340**	**(100)**	**340**	**(100)**	**680**	**(100)**		

The p value of 0.32 indicates the result could have occurred by chance.

Results: Diarrhoea

Table 13 Diarrhoea

	Case		Control		Total		Chi Sq	p Value
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	33.19	0.001
Yes	246	(72.2)	140	(41.2)	**386**	**(56.8)**		
No	94	(27.8)	200	(58.8)	**294**	**(43.2)**		
Total	**340**	**(100)**	**340**	**(100)**	**680**	**(100)**		

Patients who at one time in the early treat experienced diarrhoea are more likely to adhere to the treatment than those who did not. There were high proportion of patients with diarrhoea among those who adhered (72%) than those who did not (41%). The results were statistically significant with p value of 0.001.

Results: Kaposis Sarcoma

Table 14 Kaposis Sarcoma

	Case		Control		Total		Chi Sq	p Value
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	2.7	0.09
Yes	10	(2.9)	2	(.6)	**12**	**(1.8)**		
No	330	(97.1)	338	(99.4)	**668**	**(98.2)**		
Total	**340**	**(100)**	**340**	**(100)**	**680**	**(100)**		

The p value of 0.09 indicates that the results in the table above could have occurred by chance.

Results: Other infections

Table 15 Other infections

	Case		Control		Total		Chi Sq	p Value
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	15.8	0.001
Yes	32	(8.9)	0	(0)	**32**	**(4.7)**		
No	308	(91.1)	340	(100.0)	**648**	**(95.3)**		
Total	**340**	**(100)**	**340**	**(100)**	**680**	**(100)**		

Patients who had other infections are more likely to adhere to treatment than patients who do not. The p value of 0.001 is statistically significant.

1.3.8 Number of tablets being taken and adherence

Results: Crude

Table 16 Crude: Number of tablets being taken and adherence

Tablets	Case		Control		Total		Chi Sq	p Value
	n	(%)	n	(%)	n	(%)	20.74	0.001
>5	18	(5.3)	26	(7.6)	**44**	**(6.5)**		
5	10	(2.9)	12	(3.5)	**22**	**(3.2)**		
4	70	(20.6)	134	(39.4)	204	**(30)**		
2	242	(71.2)	168	(49.4)	410	**(60.3)**		
Total	**340**	**(100)**	**340**	**(100)**	**680**	**(100)**		

The results here show us that the more drugs the patients are taking the more likely that they will not adhere to their treatment. The p value of 0.001 indicates the significance of these results.

Results: Taking Septrin

Table 17 Taking Septrin

	Case		Control		Total		Chi Sq	p Value
	n	(%)	n	(%)	n	(%)	127.63	0.001
Yes	92	(27.1)	292	(85.9)	**384**	**(56.5)**		
No	248	(72.9)	48	(14.1)	**296**	**(43.5)**		
Total	**340**	**(100)**	**340**	**(100)**	**680**	**(100)**		

There were more patients who were taking Septrin among non-adherents (85.9%) than adherents (27%)

This highlights the negative effect of pill burden on adherence. The p value of 0.001 is statistically significant.

1.3.9 Type of ARVs regimen and adherence

Table 18 Type of ARVs regimen and adherence

	Case		Control		Total		Chi Sq	p Value
	N	(%)	n	(%)	n	(%)	12.96	0.024
D4t, 3TC, NVP	268	(78.8)	240	(70.6)	**508**	**(74.7)**		
AZT, 3TC, NVP	56	(18.5)	80	(23.5)	**136**	**(20)**		
AZT, 3TC, EFV	6	(1.9)	6	(1.9)	**12**	**(1.8)**		
D4T, 3TC, EFV	0	(0)	8	(2.3)	**8**	**(1.2)**		
TDF, FTC, EFV	0	(0)	6	(1.9)	**6**	**(.9)**		
Total	**340**	**(100.0)**	**340**	**(100.0)**	**680**	**(100.0)**		

The results above indicate that there is no association between the type of ARVs regimen and adherence.

1.3.10 Side effect and adherence

Table 19 Side effect and adherence

	Case		Control		Total		Chi Sq	p Value
	n	(%)	n	(%)	n	(%)	1.06	0.3
No effects	338	(99.4)	326	(95.9)	**664**	**(97.6)**		
Sicker	2	(.6)	14	(4.1)	**16**	**(2.4)**		
Total	**340**	**(100)**	**340**	**(100)**	**680**	**(100)**		

The p value of 0.3 indicates that the results in this table could have occurred by chance.

1.3.11 Distance to the health facility and adherence

Table 20 Distance to the health facility and adherence

	Case		Control		Total		Chi Sq	p Value
	n	(%)	n	(%)	n	(%)	11.77	0.008
<5km	218	(64.1)	232	(68.2)	**450**	**(66.2)**		
5-15km	86	(25.3)	76	(22.4)	**162**	**(23.8)**		
16-20km	22	(6.5)	2	(.6)	**24**	**(3.5)**		
>20	14	(4.1)	30	(8.8)	**44**	**(6.5)**		
Total	**340**	**(100.0)**	**340**	**(100.0)**	**680**	**(100.0)**		

There is an association between the distance to the health centre and adherence. The p value of 0.008 indicates the significance of these results. Adherent patients are 2 times more likely to be staying near the clinic as non-adherent patient (odds ratio 2).

CHAPTER 6

DISCUSSION OF RESULTS

Introduction

The study examined various clinical factors that may affect adherence. These factors included stage of the disease at initiation of treatment; type of regimen the patient is taking, number of pills the patient is taking including Septrin prophylaxis, presence of opportunistic infection at initiation, distance to the health facility, and knowledge about ARVs effectiveness, side effects and the level of education.

1.1 limitations of the study

The following limitations of the study were identified:

- Incompleteness of data from the records, misplaced or not recorded leading to bias
- Patients who refuse to be interviewed might be having important information.
- Primary resistance in some patients might have affected classification of some patients in two groups

1.2 Age and adherence

Studies have shown that apart from the most elderly adherence increases with age (Wruger, Gifford, Liu, Chisney & Golin, 1999). In two studies associated with HAART, adherence non-adherence showed a positive

correlation with younger age (Klosinski & Brooks, 1998, Nakashima and Kaplan, 1999).The findings in this research did not find any association between age and adherence. In this study we only concentrated on adults and not paediatric patients. In term of the age the exclusion criteria was 18 years and below.

1.3 Education and adherence

In this study we found that there was no association between ones level of education and adherence. However in the previous studies they found that a lower level of general education and poorer literacy impacts negatively on some patient's ability to adhere (Gallani & Tomazin 1999) whilst a higher level of education has a positive impact (Catz, Heckman & Kochman, 1999)

1.4 Presence of opportunistic infections and adherence

The findings in this study have supported the earlier studies that have shown that lack of symptoms despite laboratory evidence of need for HAART, may affect adherence (Jones, et al, 1999). Hundred percent (100%) of those who adhere had symptoms compared to 93% who did not adhere to treatment. Being symptomatic at initiation is the motivation to take ARVs. Among those who adhered to treatment 72% had diarrhoea compare to 41% among those who did not.

1.5 Number of tablets being taken and adherence

In this study we have found that the more pills one takes the more likely that he will not adhere to treatment. For instance among those who did not adhere to treatment 85% were taking Septrin compare to 23% among those

who adhere. Similar studies have shown that the likelihood of a patient's adherence to a given regimen declines with the number of pills being taken, the frequency of dosing, the frequency and severity of the regimen (Williams & Friedland, 1997).

1.6 Side effects and adherence

In this study we did not find any relation between the side effects and adherence for the current ARVs being used in Zambia.

1.7 Drug regimen and adherence

A study by Williams and Friedland (1997) found that the likelihood of a patient's adherence to a given regimen declines with the severity of the regimen (Williams & Friedland, 1997).However; in this study we have found that there is no relation between the type of regimen and adherence.

1.8 Distance to the health facility and adherence

Literature reviews have shown proximity of the health facility to the patient's home or place of work, and the expense of getting there, impact negatively on adherence (Kammann, et al, 1999). In this study we also found that there is an association between the distance to the health facility and adherence. The p value of 0.008 indicates the significance of these results. Adherent patients are 2 times more likely to be staying near the clinic as non-adherent patient (odds ratio 2).

1.9 Service related factors

Exit survey conducted on patients receiving ARVs found that daily schedules interfere greatly in ARVs medications more than the number of pills and distance to the health facilities. At all the facilities staff attitude was not among the concerns to the patients. Stock outs of drugs and laboratory reagents were not found in all the facilities. Work overload especially with the introduction of Smartcare forms was the major complaint from the health services provider. Smartcare is the type of Health Information Management System.

Chapter 7

CONCLUSION

The problem of antiretroviral adherence can be minimized. It will, however, take time, money, and a combined effort on the part of many individuals, families and organizations including governments. More community involvement and outreach to people affected by HIV and currently on medications to prolong life would help promote adherence. The findings from this research cannot be used per se as the sole pointers to the difficulties the patients on ARVs medications face but it should supplement earlier efforts from previous research in solving the issues of adherence.

The following are the major findings from my research:

1. There is an association between the numbers of pill being taken and ARVs adherence. The more pills the patient takes the more likely that will not adhere to treatment.
2. There is an association between the physical state of the patient at initiation of treatment and adherence. Patients who are symptomatic at initiation of treatment are more likely to adhere to treatment than those who are not.
3. There is an association between the distance to the health facility and ARVs adherence. Adherent patients are 2 times more likely to be staying near the clinic as non-adherent patient
4. There is no association between the type of ARVs regime and ARVs adherence. Patients on different regimes adhere to the treatment equally.

5. There is no association between side effects and adherence. Proper selection of the current regimens in Zambia which have fewer side effects and fixed dose combinations have improved adherence.
6. There is no association between one level of education and adherence
7. There is no association between the age of the patient and adherence
8. Exit survey conducted on patients receiving ARVs found that daily schedules interfere greatly in ARVs medications more than the number of pills and distance to the health facilities.

To properly understand the cause of non-adherence more research should be encouraged.

CHAPTER 8

RECOMMENDATIONS

1. Before putting the patient on ARVs adequate counseling should be provided. Clinician should not rush to put patients on ARVs without adequate preparation.Particular attention should be paid to those who have been put on ARVs without symptoms because they believe they have no reason why they should take medication without being sick. These are patients who came for voluntary counseling and testing, found positive and commenced on treatment using the CD4 count criteria.
2. Health worker should avoid burdening patients with a lot of tablets unless when necessary. When it is necessary to give more medication follow ups should be very strict and more frequent to maximize adherence.
3. In order to maximize adherence and in view of health worker shortage non medical should be used in adherence counseling and filling in of smartcare form.
4. To improve adherence related to distance and accelerate ART roll out nurses in health facilities should be used in managing stable patients.
5. In view of daily schedules interference in medication adherence, drugs which are given once a day should be encouraged unless there is a contraindication. These drugs include Truvada an Atripla.

CHAPTER 9

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CHAPTER 10

QUESTIONNAIRE

ADHERENCE QUESTIONAIRE

SUBJECT ID .....

DATE .....

INSTRUCTION TO THE INTERVIEWER: Have the patient answer the questions if you have already obtained the consent.

INSTRUCTIONS TO THE PATIENTS: Please answer the following questions.

1.0 DEMOGRAPHIC PROPHILE

101. SEX .....

102. AGE .....18-23.....1

24-29.....2

30-35.....3

36-41.....4

42-47.....5

>48.....6

103. RESIDENTIAL AREAS .....

104 .EDUCATION LEVEL

University 1

College 2

Secondary 3

Primary 4

None 5

2.0PATIENTS KNOWLEDGE

	QUESTIONS AND FILTERS	**CODING CATEGORIES**	**RESPONSES**
201	In general, what would you say your health is now?	Excellent	1
		Very good	2
		Good	3
		Fair	4
		Poor	5
202	What would you say your health was before starting ARVs?	Better	1
		Worse	2
203	Do you think ARVs have	Yes	1

	contributed to you current state of health?	No	2
204	If the answer is NO what could have contributed to your current state of health?		

3.0SIDE EFFECTS, STAGE OF DISEASE, PILL BURDEN AND ADVERSE DRUG REACTIONS

	QUESTIONS AND FILTERS	**CODING CATEGORIES**	**RESPONSES**
301	State the WHO stage of the patient at initiation of ARVS therapy.	Stage 1 Stage 2 Stage 3 Stage 4	1 2 3 4
302	State the opportunistic infection the patient has suffered from.	None T.B Meningitis	1 2 3

		Diarrhoeal K.S Others	4 5 6
303	Have ever suffered from any other illness while on treatment?	Yes No	1 2
304	Are you taking septrin prophylaxis?	Yes No	1 2
305	How many tablets of medicine are you taking each day?	>5 <5 4 2	1 2 3 4
306	State the current ARVs regimen the patient is on.		
307	How many time have the ARVs regimen been changed?	1 2 3 4	1 2 3 4

308	How do you feel after taking ARVs?	No effects Sicker	1 2

4.0 DISTANCES TO THE HEALTH FACILITY

	QUESTIONS AND FILTERS	CODING CATEGORIES	RESPONSES
403	How far is your home to this health facility?	< 5km 5km – 15km 16 – 20km > 20 km	1 2 3 4

CHAPTER 11

INFORMED CONSENT FORM

Research Ethics Committee

- Biomedical Research Ethics Committee
- Ridgeway Campus, P.O Box 50110, Lusaka, Zambia
- Tel : 256067

Researcher

- Name: Chibende Bwalya
- Address: Siavonga District Hospital, P.O BOX 16, Siavonga.
- Phone: 095 5 862221

Thank you for agreeing to participate in this study which will take place from..... to.....

This form outlines the purposes of the study and provides a description of your involvement and right as a participant.

The purposes of this project are:

1) To fulfill a course requirement for Masters in Public by University of Zambia

2) To gain insight and experience in the topic of antiretroviral adherence

The methods to be used to collect information for this study are explained below. From this information, we will write a case report about adherence and how to improve medication compliance to antiretroviral drugs.

You are encouraged to ask any questions at any time about the nature of the study and the methods that I am using. Your suggestions and concerns are important to me; please contact me at any time at the address/phone number listed above.

I will use the information from this study to write a case report about you (the respondents).The case report we be available to any person to be read from the University of Zambia Library.

I guarantee that the following conditions will be met:

1) Your real name will not be used at any point of information collection, or in the written case report; instead, you and any other person involved will be given numbers that will be used in all verbal and written records and reports.

2) Your participation in this research is voluntary; you have the right to withdraw at any point of the study, for any reason, and without any prejudice, and the information collected, records and reports written will be turned over to you.

3) The relevant sections of any of your medical notes and data collected during the study may be looked at by responsible individuals from, regulatory authorities, where it is relevant to your taking part in this research. I give permission for these individuals to have access to my records.

I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. Therefore I agree to the terms and grant permission to be quoted directly?

Respondent _____ Date _____

I agree to the terms: Researcher _____ Date _____

ANNEX

THE UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

Telephone: 096-454879/097-849302
Telegram: UNZA, Lusaka
Telex: UNZALU ZA 44370
Fax: + 260-1-250783

Dean's Office
P.O. Box 50100
Lusaka, Zambia
Your Ref:

4th December, 2007

Dr. B. Chibende,
MPH Student
School of Medicine

Dear Dr. Chibende,

Re: GRADUATE PROPOSAL PRESENTATION

Your research proposal for the Master of Public Health entitled: **"Patients Factors Affecting Antiretroviral Adherence "** was presented at the Graduate Studies Committee of the School held on 29th November, 2007.

I am pleased to inform you that your correct proposal is now accepted.

Kindly proceed to Ethics review stage.

I wish you every success in your studies.

Yours sincerely,

Mr Kasonde Bowa
MSc,M.Med,FRCS,FACS
ASSISTANT DEAN, POSTGRADUATE

c.c Director, Graduate Studies
Dean, School of Medicine
Head, Department of Community Medicine
Prof. S. Baboo, Department of Community Medicine

All correspondence should be
addressed to the District Director of Health
Telefax: +260 1 511077

In reply please quote

No.....

REPUBLIC OF ZAMBIA

MINISTRY OF HEALTH

SIAVONGA DISTRICT HEALTH OFFICE
P.O. Box 16
SIAVONGA

12/12/07

Dr. B. Chibende
MPH Student
School of Medicine.

Dear Sir,

RE: GRADUATE PROPOSAL DATA COLLECTION

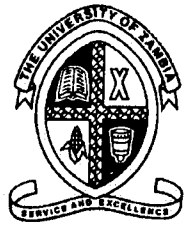
Reference is made to your correspondence of 7Th December, 2007, concerning the above mentioned subject.

I am pleased to inform you that you request to collect data in our facilities for your research **'Evaluation of factors that affect antiretroviral adherence in Siavonga District, Zambia'** has been approved.

Yours in community services,

Mr. Edward Milambo
Manager Administration
For the District Director of Health

Cc: File



THE UNIVERSITY OF ZAMBIA

RESEARCH ETHICS COMMITTEE

Telephone: 260-1-256067
Telegrams: UNZA, LUSAKA
Telex: UNZALU ZA 44370
Fax: + 260-1-250753
E-mail: unzarec@zamtel.zm

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

Assurance No. FWA00000338
IRB00001131 of IORG0000774

APPLICATION FOR ETHICAL APPROVAL FOR PROPOSED RESEARCH INVOLVING HUMAN PARTICIPANTS

To be submitted in 25 copies to the Secretary of the Research Ethics Committee

1. TITLE OF STUDY: PATIENTS FACTORS AFFECTING ANTIRETROVIRAL ADHERENCE

2. PRINCIPAL INVESTIGATOR:

Name: **DR. CHIBENDE BWALYA** Qualifications: **MbCHB**
Present Appointment/Affiliations: **Student of Masters in Public Health**

3a. OTHER INVESTIGATORS:
Name: Qualifications:
Present Appointment/Affiliations:
Name: Qualifications:
Present Appointment/Affiliations:
(Other names to be included on a separate page.)

3b. SUPERVISORS:
Name: **PROF. K.S. BABOO** Qualifications: **PROFFESSOR PUBLIC HEALTH**
Present Appointment/Affiliations: **LECTURER UNZA**
Name: **PROF. SIZIYA** Qualifications: **PROFFESSOR BIOSTATISTICS**
Present Appointment/Affiliations: **LECTURER UNZA**

4. SUMMARY OF PROPOSED RESEARCH:

1.0 **General Objective.**

The main objective of this study is to evaluate factors leading to non-adherence to ARVs in selected government sites in Siavonga District of Zambia.

Specific Objectives are to:

a) To determine associations between the numbers of pills the patient is taking and adherence

b) To determine associations between types of ARVs regimes and adherence.

c) To identify associations between distance to the health facility and adherence.

d) To determine association between patients knowledge and adherence.

e) Collect information from ARVs users and support groups on improving ARV adherence.

Null hypotheses

I. **There is no association between the numbers of pill being taken and ARVs adherence**

II. **There is no association between the type of ARVs regime and ARVs adherence**

III. **There is no association between the distance to the health facility and ARVs adherence**

IV. **There is no association between patient knowledge and adherence.**

2.0 METHODOLOGY

2.1 Study Design.

This will be a case control study in which both qualitative and quantitative methods of data collection will be used. It will be done between December, 2007 and June, 2008.

2.2 Study Area.

The study will be conducted in Siavonga at Siavonga District Hospital ART centre.

2.3 Sampling Strategies and Sample Size.

Convenience sampling method will be used to select the site.

For patients, a simple random sampling method will be used for the sample size of 130 participants calculated using the formula as below.

We assume improvement from 90% to 95% and considering the power of 80% and a one tailed test at a significance level of 5%. Then the required sample size is 130.

3.0 Study Population.

The study population includes patients attending ART clinics in Siavonga District, as well as staff working in these facilities and community leaders from the respective localities. Total number of patients on ARVs in Siavonga is 1940.

4.0 Data analysis.

Data coding, checking and cleaning will be done before entry into the computer statistical package, EPI-INFO version 6.04 and SPSS.

5. ARE THE PARTICIPANTS DEPENDENT ON ANY OF THE INVESTIGATORS?

As students:	No	As employees:	No
As patients:	Yes	In other ways:	No

If 'Yes" to any of the above, give details:

I usually attend to patients receiving ARVs in clinics as a Medical Doctor.

6. POSSIBLE BENEFITS TO PARTICIPANTS: **Improvement in the quality of life because antiretroviral treatment depend on adherence.**

7. POSSIBLE RISKS TO PARTICIPANTS: **No risk**

8. POSSIBLE BENEFITS TO THE COMMUNITY: **It is expected that the findings generated from this study will contribute to the knowledge and understanding of non-adherence to ARVs and be useful in developing interventions that will be undertaken to address ARV adherence.**

9. BUDGET:

(a) Financial support (requested or granted): Yes **Sponsor: student research allowance**

(b) Are there costs which will be carried by other institutions (e.g. the Hospital)? **No**

(c) Are there costs which will be carried by the participants involved (e.g. travel, accommodation, meals, treatment)? **No**

(d) Will the care or the time spent in hospital be prolonged? **No**

If 'Yes" to any of the above, give details:

10. SUBMISSION:

Attachments include the following in 4 copies each:

(a) The full protocol **Yes**

(b) Forms of Questionnaire **Yes**

(c) Informed Consent Form **Yes**

(d) Approval from the appropriate Research Committee **Yes**

* Delete as appropriate. NA: Not applicable

11. DECLARATION:

I **DR.CHIBENDE BWALYA** (Full Name)
Apply to the Research Ethics Committee of the University of Zambia for approval of the above research proposal involving human participants, as conforming with recognized ethical standards and as not impinging on the rights of the individuals.

Date: 20/12/07 Signed: .....
PRINCIPAL INVESTIGATOR

Contact Address: SIAVONGA DISTRICT HOSPITAL
P-O BOX 16, SIAVONGA

Telephone No.: 01 511077 Fax No: 01511077 Email: bchibende@yah

Full name of Head of Department: DR GAVIN B. SILWAMBA

Signed: ..... Date: 04.01.08
HEAD OF DEPARTMENT

HEAD COMMUNITY MEDICI
SCHOOL OF ...INE
UNIVERSITY O...
P.O. BOX 50110, LUSAKA

Full name of Supervisor: PROF. KUMAR SRIDUTT BABOO

Signed: ..... Date: 4/12/08
SUPERVISOR

6.3 Candidate: Dr Chibende Bwalya, MBCHB
Title of proposal: **"Patients factors affecting Antiretroviral Adherence"**
(Ref.: 004-01-08)

6.3.1 RECEIVED the proposal and NOTED the following:-

(i) The title is too limited, include site, suggest "Evaluation of factors that affect antiretroviral treatment adherence in Siavonga District, Zambia";
(ii) Specify statement saying that the study has not been done in Zambia, need for more review of literature on the subject;
(iii) On references please include those from Zambia;
(iv) Include Information Sheet and rewrite the consent form, and include rationale in the consent form;
(v) Differentiate patient factors from those of commodity factor according to the objectives of the study;
(vi) Submit budget for the study;
(vii) Include more information in the questionnaire; and

6.3.2 Supervisor to deal with the issue of consent.
6.3.3 The proposal was APPROVED subject to corrections/clarifications.

1.