THE UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE
DEPARTMENT OF COMMUNITY MEDICINE

RETENTION IN CARE FOR PATIENTS RECEIVING HIGHLY ACTIVEANTIRETROVIRAL THERAPY AT HEALTH CARE FACILITIES: THE SITUATION IN ZAMBIA

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A dissertation submitted to the University Of Zambia in partial fulfillment of the requirements for the Masters in Public Health

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I Deophine Lembela do hereby certify that this dissertation is the product of my own work, and in submitting it for my Masters in Public Health program further attest that it has not been submitted in part or in whole to another university.

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I Dr. Selestine Nzala, being the supervisor and having read this dissertation I am satisfied that this is the original work of the author under whose name it is being presented. I confirm that the work has been completed satisfactorily and is hereby ready for presentation to the examiners.

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This dissertation of Deophine Lembela is approved as fulfilling the requirements for the award of the degree of Masters of Public Health by the University of Zambia.

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II. DEDICATION

I dedicate this dissertation to the two most important men in my life, my husband Frank Bwalya for the love and support without which it would not have been possible for me to complete my studies. My dad Mr. Raymond Musenge Lembela, your value for education has made me achieve this level of education as it makes me always want to please you by excelling academically. To my lovely children Kabwe Bwalya and Lembela Bwalya who, though young, understood and accepted the adjustment in our lifestyle and never disturbed me whenever I locked myself up to study.

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III. ACRONYMYS

3TC	Lamivudine
ABC	Abacavir
AIDS	Acquired Immune Deficiency Syndrome
ART	Active Anti-retro Viral Therapy
AZT	Zidovudine
BU	Boston University
CI	Confidence Interval
CSPro	Census and Survey Processing System
D4T	Stavudine
EFV	Efavirez
FTC	Emtricitabine
HAART	Highly Active Anti-retro Viral Therapy
HIV	Human Immune Virus
LFTU	Lost to Follow up
LPV/r	Lopinavir
NVP	Nevirapine
PLW	People Living with
TDF	Tenofovir
UNZA	The University of Zambia
ZCAHRD	Zambia Centre for Applied Health Research and Development
ZDHS	Zambia Demographic Health Survey

1. ABSTRACT

Background

Retaining in care for patients initiated on HAART is a challenge for health care facilities where patients are being lost at different points in the continuum of care.

General Objective

To determine the extent of retention in care for patients receiving highly active antiretroviral therapy (HAART)12 months after initiating antiretroviral therapy at health care facilities in Zambia.

Methods

This study was a retrospective cohort study using secondary data from a study conducted by Boston University and the Zambia Center for Applied Health Research and Development. The study sample included 896 patients from six treatment sites in Zambia.

We enrolled a total of 896 adult patients (>15 years of age) who initiated HAART in 2007 and 2008 at 6 six health care facilities in Zambia. Pearson's chi-squared test was used to determine the association of each independent variable with retention in care. Binomial logistic regression was used to calculate risk ratios and confidence intervals for variables that were found to be significantly associated with retention in care.

Results

A total of 73.9% patients remained in care one year after HAART initiation. The median age at HAART initiation was 34.9 years [IQR 26.8-42.5); median CD4 cell count was 145cells/µL [IQR 82-212]; and 40.0% of the cohort were males. Retention was not significantly associated with site, facility level (hospital, clinic), setting (urban, rural), year of treatment initiation (2007, 2008), age at initiation, regimen at initiation, or gender, although there were observed variations. Retention in care varied significantly based on CD4 count, from as high as 81.2% for patients with CD4 cell counts at initiation of 200-350 cells/µL to as low as 62.0% for patients with CD4 cell

counts ≥350 cells/μL. Furthermore, patients with CD4 cell count of below 100 cells/μL had a higher retention rate (67.0%) compared to those with CD4 cell count of above 350 cells/μL. Patients with CD4 cell count of between 100 and 200 cells/μL, and between 200 and 350 cells/μL were 1.6 and 2.1 times more likely to remain in care compared with those patients with CD4 cell count of below 100 cells/μL respectively. Patients with CD4 cell count of above 350cells/μL were less likely to remain in care compared to those with CD4 cell count of below 100cells/μL [RR= (0.93, 95% CI.92-1.19)].

Conclusion

A large proportion of adult patients initiating HAART in Zambia are not retained in care one year after initiation. Of all the variables that were examined only CD4 count was significantly associated with retention in care. Significantly worse retention for patients with lower CD4 cell count at initiation suggests the need for earlier identification and initiation of patients on HAART, enhanced linkages with community based HIV/AIDS organizations, and opportunity for targeted retention interventions for this higher risk group. The findings are comparable with other studies on retention and attrition rates in HAART programmes in Africa.

Finally, this study might be an indication that calendar year of HAART initiation, gender, regimen at HAART initiation, age at initiation, facility type (setting and level) might not be cardinal in efforts to address retention issues.

2. INTRODUCTION

Globally an estimated 34 million people were living with HIV by the end of 2010 (Global HIV/AIDS response epidemic update, 2011). Sub-Saharan Africa bears most of the world's HIV burden with 68% of the estimated 34 million people living with HIV residing in this part of Africa as per UNAIDS estimates (UNAIDS, 2010). The HIV/AIDS epidemic has stabilized or dropped in the countries with high numbers of people affected by the disease such as Ethiopia, Nigeria, Zambia and Zimbabwe. Regardless of this positive development, we still have patients needing treatment still unable to access it thus achieving universal access to antiretroviral treatment (ART) still remains a big challenge. According to the global HIV/AIDS response epidemic update (2011) "more than 50% of the people eligible for treatment do not have access to antiretroviral therapy globally, including many people living with HIV who are unaware of their HIV status".

Fortunately, more and more countries are developing aggressive scale up plans with emphasis on early initiation and effective treatment. Due to this rapid scale up, the number of people accessing antiretroviral therapy in low- and middle-income countries has increased whilst HIV-related deaths has decreased. "At the end of 2010, more than 6.6 million people out of 15 million in need of HAART were receiving antiretroviral therapy in low- and middle-income countries; sub-Saharan Africa accounts for the vast majority of the averted deaths: about 1.8 million"(Global HIV/AIDS response epidemic update, 2011).

Zambia's population of 13 million persons is among the world's lower-middle income countries and severely affected by acquired immunodeficiency syndrome (AIDS). Nationwide, 14.3% of adults are estimated to be infected with human immunodeficiency virus (HIV) according to the 2007 Zambia Demographic Health Survey (ZDHS). The prevalence of HIV in Zambia is higher in urban areas compared to rural areas (10% and 20% respectively). Zambia, like other countries has also scaled up treatment rapidly with 72% of patients needing antiretroviral treatment receiving it at the end of 2010(Global HIV/AIDS Response, 2011). By 2010, approximately 440 health facilities were providing HAART across nine provinces. The impact of HAART scale-up has been noticeable in Zambia, given its impact on

mortality rates, with a reduction of HIV-related deaths for adults from about 82% of the total all-cause related deaths in 1996 to 54% in 2007 (National AIDS Council, 2009).

Regardless of the proven and documented huge benefits of HAART (Coetzee et al., 2004; Laurent et al., 2005), ensuring patients who are started on treatment are retained in care continues to be one of the biggest challenges facing most antiretroviral treatment programmes as the scale up continues. A number of people living with HIV are lost at different times in the continuum of care. A number of studies have shown that the proportions of patients that remain in care following HAART initiation are low and retention in care remains a big challenge in many countries with a high burden of HIV/AIDS (Rosen, 2007; Fox, 2010, Franziska, 2011). Evidence according to a study by Rosen suggests that a large number of PLWH in sub-Saharan Africa who have started HAART in treatment programs are not retained in care (Rosen, 2007). A review of 33 patient cohorts taking HAART in 13 African countries suggested only 60 percent of patients remain enrolled in programs after two years, with LTFU accounting for 56 percent of all attrition (Rosen, 2007).The results of a systematic review of patient retention in HAART programs up to 3 years on treatment in sub-Saharan Africa (Fox, 2010) indicated retention of 70% and 64.6% at 24 and 36 months respectively after adjusting for variable follow-up time.

Retention in care is one of the critical issues that needs to be addressed as countries seek to reduce the number of new HIV infections. This is because patients who are lost to follow up have an increased chance of infecting others and if they turn up again for treatment their health condition might be worse off than they were before being lost to follow up. Therefore, retention in care of patients on antiretroviral treatment needs to be given the attention it deserves by both the providers and public health agencies if the world has to halt and begin to reverse this pandemic.

To this effect, this study is aimed at determining the extent of retention in care for patients receiving highly active antiretroviral therapy (HAART) 12 months after initiation at health care facilities in Zambia.

2.1 STATEMENT OF THE PROBLEM

HIV prevalence remains high in Zambia, standing at 14.3% (ZDHS 2007). The introduction of HAART and its rapid scale up has led to the improvement of quality of life of people living with HIV and AIDS (PLWH); however, deaths due to HIV/AIDS was still high with a total of 31,000 deaths in 2011 (UNAIDS, 2011). Amongst the reasons for this high mortality is that not all eligible persons are on HAART and those that are may not be adhering to treatment or remaining in care.

2.2 RATIONALE OF THE STUDY

The rationale for the study is based on the devastating effect of HIV/AIDS coupled with the high attrition rates for patients initiating HAART. According to Fox (2010) in a systematic review of patient retention in ART programs up to 3 years on treatment in sub-Saharan Africa indicated attrition rates of 30% and 35.4% at 24 and 36 months respectively (Fox et al, 2010). "Although a great deal of research on daily adherence to antiretroviral therapy in sub-Saharan Africa has been published, long-term retention of patients in treatment programs has received comparatively less attention" (Rosen, 2010). There is currently scant information in Zambia on retention in care for patient receiving ART in health care facilities and no estimated rates of lost to follow according to the knowledge of the researcher. Probably Zambia has poor retention rates like other countries in Sub-Saharan Africa. Retention being a big challenge across African countries, this research will contribute to the body of knowledge on the retention of patients in HAART programmes to better understand retention factors and groups that need to be targeted with retention interventions.

2.3 RESEARCH QUESTIONS

1. What proportions of patients are retained in care 12 months after initiating HAART?

2. Does retention in care vary with differences in demographic and clinical characteristics?

2.4 HYPOTHESIS

Retention in care for patients receiving highly active antiretroviral therapy 12 months after initiating therapy does not differ:

- By year of initiation
- By age or gender
- By CD4 count at initiation
- By regimen at initiation
- By facility, facility type, or facility setting

2.5GENERAL OBJECTIVE

To determin**e** the extent of retention in care12 months after initiating antiretroviral therapy at health care facilities in Zambia.

2.6 SPECIFIC OBJECTIVES

1. To determine the proportion of patients retained in care 12 months after initiating HAART.
2. To determine whether patient retention in care at 12 months following HAART initiation differ by calendar year of HAART initiation over a period of two years from 2007 to 2008.
3. To determine whether patient retention in care at 12 months following HAART initiation differs by demographic characteristics.
4. To determine whether CD4 count at HAART initiation is associated with patient retention in care 12 months following HAART initiation.
5. To determine whether regimen at HAART initiation is associated with patient retention in care at 12 months following HAART initiation.
6. To determine whether patient retention in care at 12 months following HAART initiation differs by facility setting.

3. LITERATURE REVIEW

The global rapid scale up of HAART programmes in the last 15 years has substantially improved the prognosis for those infected by the HIV virus. Studies including clinical trials on HIV/AIDS have continued to demonstrate the benefits of HAART for people living with HIV/AIDS. Despite the known facts of the benefits of HAART, attrition rates continue to be high. The levels of attrition rates require health care providers and public health agencies to pay serious attention to this issue in order to improve retention rates and thereby improve patient outcomes for the larger population.

HAART eligibility criteria keep on being revised globally based on new information from clinical studies. In 2007, Zambia changed HAART treatment guidelines for adults and adolescents. The first line and second line regimens as well as the immunological conditions for HAART initiation were changed. Patients with a CD4 count below 200cells/μL were initiated on HAART regardless of the clinical stage of the patient. For patients with WHO stage 3 or 4, patients were initiated on HAART if their CD4 count was below 350cells/μL. The recommended first line regimens for patients initiating therapy was tenofovir (TDF) and emtricitabine (FTC) with either efavirenz (EFV) or nevirapine (NVP). The recommended second line regimens were either zidovudine (AZT) and lamivudine (3TC) or TDF and FTC with ritonavir-boosted lopinavir (LPV/r). The current HIV treatment guidelines were introduced in 2010; Patients with CD4 count of less than 350 should be initiated on HAART regardless of clinical stage, whilst those with WHO stage 3 or 4 initiated regardless of CD4 count.

In Zambia and sub-Saharan Africa, research has been focused on adherence to HAART, whereas few studies have been done on retention for patients on HAART. Studies in Zambia in relation to retention in care are scant. The studies that the researcher reviewed emphasized on mortality.

Chi conducted two studies in Zambia in relation to retention of patients on HAART. According to his study on CD4 cell response and subsequent risk of death among patients on antiretroviral therapy in Lusaka, Zambia (Chi, 2009), the rate of lost to follow up for those with follow up time from 6months onwards and from 12 months

onwards were 12.4% (mortality of 2.0%) and 10.9% (mortality of 1.5%) per 100 patient-years respectively. This study excluded 11% and 17% of patients that were lost to follow at either 6months or 12months of follow time respectively. In another of Chi's studies (2011), it found that regimen was not significantly associated with high mortality rate when they did an analysis of programme failure.

In another study by Stringer (2006) among adults enrolled in HIV care at primary care sites in Zambia, a multivariable analysis showed that mortality was strongly associated with CD4 count, clinical stage of the disease, weight, anemia and poor adherence. According to this study, 'mortality was strongly associated with CD4 cell count between 50cells /μL and 199 cells/μL (adjusted hazard ratio [AHR], 1.4; 95% confidence interval [CI], 1.0-2.0), CD4 cell count less than 50 cells/μL (AHR, 2.2; 95% CI, 1.5-3.1), WHO stage III disease (AHR, 1.8; 95% CI, 1.3-2.4), WHO stage IV disease (AHR, 2.9; 95% CI, 2.0-4.3), low body mass index (16; AHR,2.4; 95% CI, 1.8-3.2), severe anemia (8.0 g/dL; AHR, 3.1; 95% CI, 2.3-4.0), and poor adherence to therapy (AHR, 2.9; 95% CI, 2.2-3.9)', (Stringer, 2006).

Additionally, Schoni-Affoiter (2011) conducted a study on estimating the rate of loss to follow-up in HIV-infected patients on antiretroviral therapy: the effect of competing risk of death in Zambia and Switzerland. In this study it was found that, in Zambia, among patients starting HAART with CD4 cell counts <100 cells/μL, 29.3% were lost to follow up whilst for those with CD4 cell counts of ≥350 cells/μL15.4% were lost to follow up after 3.5 years in the CIRDZ cohort. This was before taking into account competing risk of death. In Switzerland, the opposite was true, with higher likelihood of lost to follow among patients with higher CD4 cell count at the start of treatment.

In a study by Bolton-Moore (2010) in Zambia at primary health care facilities where a total of 4975 children enrolled into HIV care and 2938 (59.1%) started HAART, mortality was found to be associated with a number of variables in a multivariate analysis. CD4 cell depletion, lower weight-for-age, younger age, and anemia were found to be associated with mortality, whilst variables such as patient sex, tuberculosis co-infection, baseline WHO clinical stage, and drug regimen at initiation were not significantly associated with mortality in the multivariate analysis. Attrition

rate was found to be 13.7%, of which 5.4% had withdrawn from care and 8.3% had died over 3018 child-years. Additionally 13.0% were at least 30 days late for clinic follow-up.

Additionally, Suttcliffe (2010) conducted a study on retention in a retrospective cohort study in Zambia. He found that among children in the rural clinics, there were no significant differences over time in the proportion of children who died or transferred out to another facility after six months of HAART. However, the proportion of children who defaulted increased significantly overtime, resulting in decreased proportion of children remaining in care.

In Africa, the studies that were reviewed showed retention rates to a challenge being faced by health care facilities. A retrospective study in Tanzania showed retention rates to be high in the study sites. The study revealed significantly worse retention rates among younger adults on HAART Somi (2009). The study found attrition rates of 37% without significant variation by HAART initiation date across the study period. However, it was found out that attrition was significantly higher in those with baseline CD4 cell counts below 50, males and those below 30 years.

Furthermore, According to the findings by Ahonkhai (2012) in a study in South Africa, it was established that retention rates were below 65% and attrition being above 35%. This finding is consistent with other studies which have been revealed. Their finding in terms of retention across calendar years showed 61% patients being retained in care in 2004 and 65% in 2008.

In a four-year study of treatment outcomes of adult patients enrolled in Mozambique's rapidly expanding antiretroviral therapy program it was found that one-year attrition was 21% (95% CI, 17–25%) with 15% LTFU (95% CI, 11–18%), 5% mortality (95% CI, 4–6%), and 1% stopping HAART (95% CI, 0–3%). The other variables that were found to be associated with higher risk of attrition were; weight ≤45, WHO stage IV and severe anemia (Auld AF, 2011).

1.0 VARIABLES

Dependent Variable	Independent Variables
Patient Outcome (In care at 12 months and no longer in care at 12 months)	1. Calendar year of HAART initiation 2. Gender 3. Regimen at HAART Initiation 4. Age at HAART initiation 5. CD4 count at HAART initiation 6. Site 7. Facility setting 8. Facility level

3.1 Operational Definitions of Variables

a) Patient outcome in this study is defined as either in care or no longer in care. In care (retention) refers to patients not known to have died or been lost to follow up (<3 months late for the scheduled medication pick up or clinical follow up) 12 months after initiating HAART. Patients are considered to be no longer in care (attrition) when they are ≥3 months late for the scheduled medication pick up or clinical follow up before 12 month endpoint for any reason, including death or loss to follow-up. Patients with recorded transfer to another HAART facility during the first 12 months after initiating HAART were excluded from the study and therefore, not regarded as no longer in care.

b) Calendar year of HAART initiation is the year each study participant initiated HAART.

c) Regimen at HAART initiation is the HAART combination which each study participant was started on at the time of HAART initiation. These were grouped into abacavir (ABC), tenofovir (TDF), stavudine (D4T) or zidovudine (AZT) based regimens.

d) CD4 count at HAART initiation is the CD4 cell count test result prior to HAART initiation and one used as part of the basis for HAART initiation.

e) Site is in this study defined as the health care facility.

f) Facility is defined as the setting (rural or urban) and level (hospital or clinic) of the health facility where data was collected.

4. RESEARCH METHODOLOGY

4.1 Study Design

This study was a retrospective cohort study using secondary data from a study on the costs and outcomes of models for delivering adult antiretroviral therapy in Zambia conducted by Boston University and the Zambia Center for Applied Health Research and Development (ZCAHRD).

The BU/ZCAHRD study was a cost-outcome analysis using unlinked, retrospective medical record data. The study collected facility-level cost data and patient-level data on resource utilization and outcomes. Convenience sampling was used to identify health care facilities; this was with the goal to identify facilities that were an example of particular models of care in Zambia. Data was collected from total of 15 cohorts from 8 facilities namely; George clinic, Chelstone clinic, Lewanika General Hospital; Siavonga Hospital; Ndeke Clinic; Macha Mission Hospital; St Francis Mission Hospital; and Kara Counseling Trust.

At each facility, a sample of 150 patients was enrolled bringing the total sample to 2250. The study patients were selected consecutively from the HAART register, starting from one year prior to the start of data collection (to ensure 12 months of follow up for all study participants) and moving back in time until each cohort had reached a sample size of 150 per cohort. Patients found to be ineligible during the screening and sample selection process (starting HAART at another clinic, transferred to another study during the observation period after initiation, or aged <15 years at ART initiation) were not enrolled in the study.

The main objective of the original study was to approximate the average cost of resources at 1, 2, or 3 years following HAART initiation for each patient who remain in care and responding to HAART (UNZA Protocol No.: 003-06-07). For this study, a minimum sample size of 150 was enrolled from each site to generate a robust estimate of the average cost per patient remaining in care and responding at each time interval. The BU/ZCAHRD study is described in the protocol entitled “Costs and outcomes of models for delivering antiretroviral therapy for HIV/AIDS in Zambia” (UNZA Protocol No.: 003-06-07).

This research used only the patient-level data that was collected by the BU/ZCAHRD study described above.

4.2 Study Sites

This study included six (6) health care facilities namely; George Clinic and Chelstone Clinic in Lusaka; Lewanika General Hospital in Mongu; Siavonga District Hospital in Siavonga; Ndeke Clinic in Kitwe and; Macha Mission Hospital in Choma. George Clinic is located in the high density area of Lusaka catering for middle to low income households, whilst Chelstone Clinic is located in the low to medium density area of Lusaka and caters for a varied population comprising of high, middle income and low income households. Lewanika General Hospital is located in Mongu(Western Province) and is a referral hospital for the province. Therefore, the hospital caters for the population of Western Province. However, the HAART clinic caters mostly for the population around Mongu town. Similarly, Siavonga District Hospital is a district referral hospital whose HAART clinic serves the population near and around Siavonga town. Ndeke Clinic provides services to low and medium income households in Kitwe District of the Copperbelt Province. Macha Mission Hospital is a mission hospital serving a rural population in Choma District of Southern Province.

Classification of Study Sites

Name of the Study Site	**Setting**
George Clinic	Urban (Lusaka)
Chelstone Clinic	Urban (Lusaka)
Lewanika General Hospital	Urban (Mongu)
Macha Mission Hospital	Rural(Choma)
Ndeke Clinic	Urban (Kitwe)
Siavonga District Hospital	Urban (Siavonga)

Population

The study populations were adult patients who had received care for HIV/AIDS from participating sites. Data from consecutive samples of adult patients who initiated HAART at each of the study sites between 2007 and 2008 and met the inclusion criteria were included in the study.

4.7 Inclusion and Exclusion Criteria

Inclusion Criteria:

- ≥ 15 years old at HAART initiation.
- Initiated HAART at the study site during the time period indicated.
- Did not transfer to another treatment site in the first 12 months after initiation.

Exclusion criteria:

- < 15 years old.
- Pre-ART patients.
- Transfer-in when already on HAART treatment
- Transferred to another treatment site during the 12 months after treatment initiation.

4.3 Site Selection and Sampling Strategy

The 6 cohorts from 6 sites were purposively sampled for the study. The weakness of this type of sampling is its subjective nature. The selection of participants is based on the researcher's judgment, for this reason, the results generated cannot be generalized to the all population. However, purposive sampling enable the participant to select populations that are of interest to the researcher and that will enable him fulfill the set objectives. The cohorts that were sampled were those from the BU/ZCAHRD study that had a representative sample which included eligible patients in its sample regardless of the regimen at HAART initiation. One cohort from each site of the sites was included in the study.

4.4 Sample Size

A total of 896 patients were included in this study.All the patients in the sampled cohorts were included in the study as long as they were in the parent study.

4.5 Data Collection

Data collection for the parent study took place between 2008 and 2011. Data was collected from the paper patient medical records on site using CSPro software. Pre-existing electronic medical records were also used when available. For this study, the following variables of interest were imported into STATA.

Patient Medical Record Data:

For each study participant, the following data fields were sorted, cleaned and imported into STATA 12 for analysis:

- Unique ID
- Age in years
- Gender
- Date of HAART initiation
- CD4 count at HAART initiation if done
- Regimen at HAART initiation
- Patient outcome at last date of patient visit
- Facility name

The following new variables were created in STATA 12 based on the facility name variable

- Level of facility (hospital or health centre)
- Setting of the facility (rural or urban). Macha Mission Hospital is the only site that is rural and the rest of the sites are urban sites.

4.8 Data Management and Analysis

Data for patients from George Health Centre, Chelstone Health Centre, Lewanika General Hospital, Siavonga District Hospital, Ndeke Health Centre and Macha Mission Hospital for 12 months after HAART initiation was imported into STATA 12. The following variables relevant to this study were imported from the ZCAHRD dataset for data cleaning and data analysis; age in years, gender, date of HAART initiation, CD4 count at HAART initiation, HAART regimen at HAART initiation, patient status at last date of patient visit and facility name.

Each independent variable was tested using chi-square (two way table) to ascertain association with patient retention. Log-binomial regression model was used to calculate risk ratios and confidence intervals for variables that had significance association with retention.

Assignment of Patient Outcome Status

Each study participant was assigned a single outcome on the basis of attendance status, one year after initiating HAART. Two outcomes were allocated: In care at site

and no longer in care at site at the end of 12 months following HAART initiation. The criteria that were used for defining patient outcome are shown in the Table below.

Patient Outcome Assignment

Outcome Status	Criteria for assigning outcome	Medical record data required to use each criterion
No longer in care at site	≥3 months late for last scheduled consultation or medication pickup before 12-month endpoint*	Date of last scheduled consultation or medication pickup
In care at site	<3 months late for last scheduled consultation or medication pickup before 12-month endpoint*	Date of last scheduled consultation or medication pickup

**A visit to the ART clinic was either by the patient in person or by the treatment supporter on behalf of the patient*

5. RESULTS

Demographic and Clinical Characteristics of Patients

Baseline characteristics of the patients are given in Table I. Of the 896 patients in the study sample, 59 %(532) were female whilst 41 %(364) were males. The median age at HAART initiation was 34.9years (IQR [26.8-42.5]). In the study sample there were more patients receiving treatment from urban health facilities at 83.3 % compared with 16.7% from rural health facilities.

Half of the patients in the sample were being managed at clinics whilst half were being managed at the hospital level. Out of 896 patients in the sample, 841 patients had CD4 cell count at initiation recorded. The median CD4 cell count at the time of HAART initiation was 145cells/µL (IQR [82-212])

Table I: Cohort characteristics

Description	**Mean**	**95% ℃I**
Age at initiation (years)	37	[36-37]
Gender	**Frequency**	**Percentage**
Female	532	59.4%
Male	364	40.6%
Facility Name		
Chelstone	149	16.6%
George	149	16.3%
Lewanika	149	16.3%
Macha	150	16.7%
Ndeke	149	16.3%
Siavonga	150	16.7%
Facility Setting		
Rural	746	83.3%
Urban	150	16.7%
Facility Level		
Hospital	449	50.1%
Clinic	447	49.9%
Total	896	100.0%
Description	**Mean**	**95% ℃I**
CD4 Cell Count	160	[153-168]

℃I: confidence interval

Retention Outcomes

1. **Patient Outcomes at 12 Months**

Of the 896 patients in the sample, 73.9% (662) of patients remained in care 12 months after HAART initiation whilst 26.1% (234) of the patients did not remain in care.

Table II: Patient outcomes

Outcome	**Frequency**	**Percentage**
In Care	662	73.9%
No Longer in Care	234	26.1%
Total	896	100.0%

2. **Site**

Retention in care varied across site from as low as 68.7% at Siavonga District Hospital to as high as77.9% at Chelstone clinic and Lewanika General Hospital. However, the variation was not statistically significant (P=0.262).

Table III: Site Level outcomes

Site	*In Care*	*No Longer in Care*	*χ^2 (df)*	*P Value*
	n(%)	*n(%)*		
Chelstone	*116 (77.9%)*	*33 (22.2%)*		
George	*103 (69.1%)*	*49 (30.9%)*		
Lewanika	*116 (77.9%)*	*33 (22.2%)*		
Macha	*113 (75.3%)*	*37 (24.7%)*		
Ndeke	*111 (74.5%)*	*38 (25.5%)*		
Siavonga	*103 (68.7%)*	*38 (31.3%)*	*6.4875 (3)*	*0.262*

3. Calendar year of HAART initiation

It was found that, there were differences in retention based on the calendar year of HAART initiation. Patients initiating in 2007 had a retention rate of 71.1% (28.9% no longer in care) and 75.6 for 2008 (24.4% no longer in care). However, the difference in retention rates between these two calendar years was not statistically significant (P=0.229)

Table IV: Calendar year of HAART initiation

Outcome	**Calendar Year of Initiation**		**Total**
	2007	2008	
In Care	246	416	662
	71.1%	75.6%	73.9%
No Longer in Care	100	134	234
	28.9%	24.4%	26.1%
Total	346	550	896
Pearson Chi^2 (1) = 2.2668 P=0.132			

4. Regimen at HAART initiation

Retention in care varied based on the regimen at HAART initiation. The proportion of patients retained in care 12 months following HAART initiation was higher for those patients on an AZT based regimen (76.1%), with those on D4T based regimen having the lowest number of patients being retained in care at 71.1% 12 months following HAART initiation. However, HAART regimen at initiation was not significantly associated with retention in care (P= 0.640)

Table V: Regimen at Initiation

Endpoint	Regimen at HAART Initiation				Total
	ABC	AZT	D4T	TDF	
In Care	90	105	92	373	660
	74.4%	76.1%	71.1%	73.1%	73.5%
No Longer in Care	31	33	37	137	238
	25.6%	23.9%	28.68%	26.9%	26.5%
Total	121	138	129	510	898
	100%	100%	100%	100%	100%
Pearson chi^2 (3) = 1.6883 P=P=P=0.640					

5. Age at initiation

Age at HAART initiation was not significantly associated with retention rates (P=P=0.761), even though there was variation depending on age at HAART initiation. Older patients 50 years and above had better retention with 78% of the patients being retained in care a year following HAART initiation.

Table VI: Age at Initiation

Outcome	Age at Initiation (Years)				Total
	<30	≤30 and <40	≥40 and <50	≥50	
In Care	168	282	134	72	657
	73.0%	73.5%	73.2%	78.3%	73.8%
No Longer in Care	62	102	49	20	233
	27.0%	26.5%	26.8%	21.7%	26.2%
Total	230	385	183	91	890
	100%	100%	100%	100%	100%
Pearson chi^2 (3) = 1.0638 P=P= 0.786					

6. CD4 cell count at initiation

Retention in care varied widely based on CD4 count at the time of HAART initiation from as high as 81% for those patients with initial CD4 count between 200 and 350 cells/µL. Patients with the initial CD4 count of 350 and above had the least retention rates with only 59% of these patients being retained in care whilst 41% were no

longer in care. CD4 count at the time of HAART initiation was significantly associated with retention rates (P= 0.001). This significance association was sustained when log-binomial regression model was run.

Furthermore, risk ratios were estimated using a log-binomial regression model and patients with CD4 cell count of less than 100cells/µ/L were used as reference.

This significance association was sustained when log-binomial regression model was run. Patients with CD4 cell count of between 100 and 200cells/µL, and between 200 and 350cells/µL were 1.6 and 2.1 times more likely to remain in care respectively compared with those patients with CD4 cell count of below 100cells/µL. It was further found that patients with CD4 cell count of above 350cells/µL were less likely to remain in care compared to those with CD4 cell count below 100cells/µL [RR= (0.93, .92-1.19)].

Table VII: CD4 Cell Count at Initiation

Outcome	CD4 Cell Count (cells/µL) at HAART Initiation				Total
	<100	≥100 and <200	≥200 and <350	≥350	
In Care	180	247	173	26	532
	67.0%	78.0%	81.2%	62.0%	74.4%
No Longer in Care	89	70	40	16	215
	33.1%	22.1%	18.8%	38.1%	25.6%
Total	269	317	213	42	841
	100.0%	100.0%	100.0%	100.0%	100.0%
Pearson chi^2 (3) =18.6353 P= 0.001					
Risk Ratios					
CD4 Cell Count at HAART			Risk Ratio (95% Confidence Interval)		
<100			1.00		
≥100 and <200			1.16 (1.05-1.29)		
≥200 and<350			1.21 (1.09-1.35)		
≥350			.93 (.92-1.19)		

7. Gender

There was neither wide variations in retention based on gender nor significant association between the two variables. Retention in care for females was at 73.3% whilst for males it was 74.7%.

Table VIII: Gender

Outcome	**AGE**		**Total**
	Female	Male	
In Care	390	272	662
	73.3%	74.7%	73.8%
No Longer in Care	142	92	234
	26.7%	25.3%	26.1%
Total	532	364	895
	100%	100%	100%
Pearson chi^2 (1) = 0.2249 P=P= 0.635			

8. Facility Type (setting and level)

It was found that retention in care varied on the basis of setting of the facility. The proportion of patients who remained in care between rural and urban was the similar at 75% and 74% respectively. It was revealed that people receiving care at hospitals had same retention rates with those at clinics at 74%.

Table IIIX: Facility Type

Outcome	Facility Setting		Total
	Rural	Urban	
In Care	113	549	662
	75.3%	73.6%	73.9%
No Longer in Care	37	202	234
	24.7%	26.4%	26.1%
Total	150	746	896
	100.0%	100.0%	100.0%
Pearson $chi^2(1)$ = 0.1961 P=P= 0.658			
Facility Level			
Outcome	Hospital	Clinic	Total
In Care	332	330	662
	73.9%	73.8%	73.9%
No longer in Care	117	117	234
	26.1%	26.2%	26.1%
Total	447	449	896
	100.0%	100.0%	100.0%
Pearson $chi^2(1)$ = 0.0016 P=P=0.968			

6. DISCUSSION

Information and research on retention in care still remains critical in addressing retention challenges facing ART programmes as they scale up the provision of antiretroviral treatment to patients. This study adds to the body of knowledge on retention among HAART patients which is limited in sub-Saharan Africa.

This study showed that, 26% of patients were lost to follow up one year after initiating HAART. The rates of lost to follow varied from 22% to 31% across sites, although the variation was insignificant (P=0.262). This clearly shows that at facility level there is room to improve retention rates. The study also revealed insignificant variation between calendar year and retention rates with 71% of patients initiating HAART in 2007 being retained in care and 76% in 2008. The improvement though insignificant is a positive indicator for future improvements in retention rates. This improvement could be due to different factors such as increased knowledge among the general population on issues of HIV/AIDS. These results are in line with a retrospective study by Geoffrey (2009), were they found no significant differences in terms of clinical or retention outcomes for those patients initiating HAART treatment between 2004 and August 2007.

The study also showed that, attrition rates between males and females are similar, this is an indication that both genders are prone to attrition and therefore community patient tracing programmes should be tailored to target both males and females. The findings are consistent with a study carried out by Bolton-Moore (2010) in Zambia where she found gender not associated with mortality.

Regimen at HAART Initiation varied from one regimen to another though this variation was not statistically insignificant (P=0.832). Patients with D4T starting regimen had the highest rate of attrition (29%), whilst patients on AZT based regimen the lowest attrition rates at 24%. Though the difference is insignificant, these findings do support the call by WHO to phase out D4T as part of the starting regimen. This finding on the other hand might be an indication that change in policy on first line regimen may not impact on the number of patients on HAART that remain in care 12 months following initiation though it might have effect on cost to the nation and maybe clinical outcomes. This finding in line with a study carried out in Zambia by

Chi (2011) where they established no disparity in patient outcomes when regimen was included as a component of programme failure.

Retention in care varied insignificantly (P=0.761) depending on age at HAART initiation. Older patients above 50 years had higher retention rates at 78.3% compared to those with those below the age of 50 years at 73%. These findings are consistent with a retrospective study in Tanzania by Somi (2009), where they discovered older adults to have better retention rates.

It was established that CD4 cell count at the time of HAART at initiation had significant association with retention rates. Patients with lower CD4 cell count were more likely to be lost to follow up. Therefore, early diagnosis and initiation of treatment for the larger population before the CD4 cell count falls below 100cells/µL is cardinal if greater number of patients are to be retained in care. Thus counseling and testing still remains an area for community awareness and education in order to increase the uptake of these services and timely initiation of treatment. There is opportunity for targeted retention interventions for this higher risk group including patients initiating HAART with CD4 cell count of above 350 who have the higher rate of attrition. This could be due to patients feeling better after being on treatment for a short time and therefore feel no need of continuing or these might be patients with WHO stage III and IV conditions or pregnant women. This study is consistent with a retrospective study Schoni-Affoiter (2011), were it was observed that patients with CD4 cell counts below 50cells/µL at the start of HAART had higher attrition rates in Zambia. On the other hand, the same study found that patients with higher CD4 cell count had higher attrition rates compared to those with lower CD4 cell count which in part is consistent with the findings of this study for those patients with CD4 cell count of above >350cells/µL

For setting and level of the facility, it was found that there was no significant association. Patients being treated for at clinic had equal retention rates with patients being treated at hospitals. This finding is a plus for the ministry of health and shows that the majority of the patients who receive treatment from clinics are receiving the same quality of services as the minority cared for at hospitals. On the other hand there was minimal variation in retention rates between rural and urban based health

facilities with retention rates being at 75% and 73% respectively. Though the difference is minimal, it is important to note that, rural health care facilities had better retention rates compared to urban based facilities. This could be attributed to the fact that, the rural based facility was different in that it was the only mission health care facility in the sample and the rest were public health care facilities. These findings are similar to findings by Massaquoi (2009) who found that retention in care at hospitals and health centers were similar.

7. CONCLUSIONS

With the overall retention rates being at 73.9% and attrition rates of 26.1%, these findings are an indication that retention in care is still a challenge facing HAART programmes in Zambia which needs the attention of health care providers and the Ministry of Health.

Overall lots of people are lost to follow up during the first year on HAART. Of all the variables that were examined only CD4 count was significantly associated with retention in care. Significantly worse retention for patients with lower CD4 cell count at initiation suggests the need for earlier identification and initiation of patients on HAART, enhanced linkages with community based HIV/AIDS organizations, and opportunity for targeted retention interventions for this higher risk group. Nevertheless, insignificant variation in retention rates was observed in all the variables under study with the exception of facility level where there was negligible differences in retention rates. The findings are comparable with other studies on retention and attrition rates in HAART programmes.

Finally, this study might be an indication that gender, regimen at HAART initiation, age at initiation, facility type (setting and level) might not be cardinal in efforts to address retention issues. However, the revealed variations might point to the fact that these factors should not be overlooked in HAART programme planning and implementations.

8. RECOMMENDATIONS

Retention in care is still a challenge in Zambia; therefore the government should consider continuation of community defaulter tracing programmes if patient retention is to be improved for the larger population.

The study has also shown that, attrition rates between males and females are similar, this is an indication that both genders are prone to attrition and therefore community patient tracing programmes should target both males and females.

The study has also revealed that CD4 count has significant implication on retention rates among patients receiving HAART. Therefore, early diagnosis and initiation of treatment for the larger population before the CD4 cell count falls below 100cells/µL is cardinal if greater number of patients are to be retained in care. Thus counseling and testing still remains an area for community awareness and education in order to increase the uptake of these services and timely initiation of treatment.

Furthermore, findings showed that patients with CD4 cell count of above 350cells/µL had the lowest retention rates, worse than those patients initiating with CD4 cell count of below this cell count. This finding points to the need for further studies on retention in order to inform policy as the Ministry of Health plan to embark on the implementation of initiation of antiretroviral treatment for all pregnant women in order to ascertain the impact of this kind of policy on retention and ultimately drug resistance.

9. ETHICAL ISSUES

Permission was obtained from the Zambia Center for Applied Health Research and Development in order to use the data (see appendix). Additionally, approval was sought from the UNZA Biomedical Research Ethics Committee.

The study posed minimal risk to study patients as it strictly used delinked secondary data collected by ZCAHRD which did not contain patient identifiers but only project assigned study identification numbers. Informed consent was not obtained from study patients. As explained above, the researcher had no access to identifiers because

secondary data which does not contain any study patient identifiers from medical records was used. The study therefore, posed little if any risks to these patients.

10. STUDY LIMITATIONS

This study has generated information for policy makers and program managers to better understand retention in ART facilities and associated factors to aid in programme planning.

The study was limited only to data that was collected by the parent study and therefore did not provide opportunity to check for any other potential confounders related to retention (e.g. behavioral, social and access issues) which could form the basis of future studies.

Results presented here reflect patient retention for only those patients who initiated HAART between 2007 and 2008. Therefore, changes such as revision of treatment guidelines in 2010, changes in health seeking behaviors and social factors such as changes in stigma levels are not captured by these findings. Furthermore, there was distinction between deaths and lost to follow up for patients' no longer in care at the study sites 12 months after initiating HAART.

The study included only 6 health care facilities which were not randomly selected, therefore may not be representative of retention rates in Zambia's ART programme as a whole.

11. PROJECT MANAGEMENT

11.1 Gantt Chart

ACTIVITY	July 2012	Aug 2012	Sept 2012	Oct 2012	Nov 2012	Dec 2012	Jan 2013	Feb 2013	March 2013
Writing of the research proposal									
Graduate Forum Presentation									
Submission to the University of Zambia Biomedical Research Ethics Committee									
Data Cleaning and Analysis									
Writing of the Thesis									
Submission of Thesis									
Writing of scientific paper and presentation at the scientific meeting									
Writing of Manuscript									

11.2 Detailed Budget

ACTIVITY	QUANTITY	UNIT COST(K)	TOTAL(K)
Toner	1	800	800
Bond Paper	3	30	90
The University of Zambia Research Ethics Committee	1	250	250
Binding of Thesis	3	100	300
Poster Presentation	1	300	300
Total			**740**

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13. **Data Collection Tool**

Variables Imported from Matrices and CSPRo Data Base into STATA

- Unique ID
- Age in years
- Gender
- Date of HAART initiation
- CD4 count at HAART initiation if done
- Regimen at HAART initiation
- Patient status at last date of patient visit
- Facility name

Variables created in STATA 12 based on the facility name variable

- Level of facility (hospital or health centre)
- Setting of the facility (rural or urban.