INCIDENCE RATE AND ASSOCIATED FACTORS OF LOSS TO FOLLOW UP AMONG PATIENTS INITIATED ANTIRETROVIRAL THERAPY PROGRAM IN HIWOT FANA SPECIALIZED UNIVERSITY HOSPITAL, HARAR-

A RETROSPECTIVE COHORT STUDY

MPH THESIS

Tenaye Abate (BSc.)

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Haramaya University, Harar

Incidence Rate and Associated Factors of Loss to Follow up Among Patients Initiated Antiretroviral Therapy Program in Hiwot Fana Specialized University Hospital, Harar-

A Retrospective Cohort Study

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Tenaye Abate (BSc.)

Major Advisor: **Lemessa Olijira (PhD)**

Co-advisor: **Yadeta Dessie (PhD, Assistant prof)**

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Haramaya University, Harar

APPROVAL SHEET

HARAMAYA UNIVERSITY

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I hereby certify that I have read and evaluated this Thesis entitled incidence rate and associated factors of loss to follow up among patients initiated on antiretroviral therapy program in Hiwot Fana specialized university hospital, Harar Prepared under my guidance by Tenaye Abate I recommend that it be submitted as fulfilling the thesis requirement.

Lemessa Olijira (PhD)	_____	_____
Major Advisor	Signature	Date
Yadeta Dessie (PhD, Assistant. prof)	_____	_____
Co-Advisor	Signature	Date

As a member of the Board of Examiners of the MPH Thesis Open Defence Examination, I certify that I have read and evaluated the Thesis prepared by Tenaye Abate and examined the candidate. I recommend that the thesis be accepted as fulfilling the Thesis requirements for the degree of Master of Public Health in General public health.

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Name: Tenaye Abate

Signature: _____

Date: _____

School/Department: General public health

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ACRONYMS/ABBREVIATIONS

ART	Antiretroviral Therapy
AHR	Adjusted Hazard Rate
BMI	Body Mass Index
CD4	Cluster of Differentiation 4
CBIs	Community Based Institutions
CIs	Confidence Intervals
CPT	Cotrimoxazole Preventive Therapy
CHR	Crude Hazard Ratio
DHS	Demographic Health Survey
EPHI	Ethiopian Public Health Institute
FMOH	Federal Ministry of Health
HRHB	Harari Regional Health Bureau
HAART	Highly Active Antiretroviral Therapy
HFSUH	Hiwot Fana Specialized University Hospital
HIV	Human Immunodeficiency Virus
HR	Hazard Ratio
IQR	Inter Quartile Range
INH	Isoniazid
LTFU	Loss to Follow-Up
MOPD	Medical Out Patient Department
OIs	Opportunistic Infections
PLHIV	People Living With HIV
SPSS	Statistical Package for Social Sciences
SOP	Standard Operating Procedure
UNAIDS	United Nations Programme on HIV/AIDS
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

ABSTRACT

Background: The long-term survival of patients on antiretroviral treatment depends on lifetime adherence to antiretroviral therapy. Patients who are lost to follow-up while on treatment have been a challenge to carry out the antiretroviral therapy programmes effectively in terms of patient outcomes. Most studies in sub Saharan Africa have reported high rates of loss to follow up among patients enrolled in HIV care and treatment programmes. Few studies have been conducted among HIV infected patients in Hiwot Fana specialized university hospital, Harari region, Eastern Ethiopia.

Objective: The aim of this study is to determine the incidence rate of loss to follow up and associated factors among human immunodeficiency virus infected patients attending in the antiretroviral clinic at Hiwot Fana Specialized university Hospital, Harari region, Eastern Ethiopia from February 1 to 28, 2018.

Method: Kaplan Meier was used to estimate rates at particular times and generate a survival curve. Log Rank test was used to test the equality of survival probabilities and compared across the different groups of covariates and cox proportional hazards models to include additional covariates.

Results: A total of 572 patients were contributed for 17,606 person months of follow up with a median survival time of event 13 months (IQR: 5-33). At the end of the study period 21% (95%CIs: 17.7, 24.4) of patients become LTFU giving a loss rate of 8.2 per 100 person years. Being male sex (Adjusted Hazard Ratio[AHR]= 2.10; 95% Confidence intervals [CIs]: 1.33, 3.30), Those patients who resided outside the region (AHR=2.14;95%CIs:1.37, 3.33), patients who are not disclosed their sero status (AHR=1.88;95%CIs:1.23, 2.89), being ambulatory or bedridden functional status (AHR=3.86;95%CIs:2.33, 6.38) and Tb/HIV co infection (AHR=3.45;95% CIs:2.23, 5.33) were significantly associated with loss to follow up in patients living with HIV/AIDS after initiation of anti-retro viral therapy.

Conclusion and recommendations: The results of this cohort study reports a comparatively high rate of loss to follow up at Hiwot Fana specialized university hospital which may substantially affect the program outcome. Special attention should be given for male, residents outside the town, TB HIV co- infection, undisclosed and seriously ill patients at the early periods of anti-retro viral therapy enrollment.

Key words: Loss to follow up: Hiwot Fana: Harar: Antiretroviral therapy

1. INTRODUCTION

1.1. Background

The number of people living with HIV/AIDS who are receiving treatment has been increasing dramatically after the initiation of free Highly Active Antiretroviral Therapy (HAART) program in many low- and middle-income countries worldwide (Joint United Nations Programme on HIV/AIDS, 2016). However, loss to follow-up in ART is an obstacle in the success of ART programs in resource limited countries (WHO, 2013).

In developing countries and Africa in general poor retention in care threaten to reverse the gains attained earlier on the HIV care and treatment program, and delay the achievement of the platform to ending AIDS, by 2030 (UNAIDS, 2016).

ART loss to follow up, defaulting or total stoppage of the treatment has been recognized as an impairment for attainment of the second 90 of the Joint United Nations Program on HIV and AIDS (UNAIDS) 90-90-90 treatment targets as it affects the sustainable intake of the treatment. Furthermore, discontinuation affects the performance of the third 90 of the UNAIDS 90-90-90 that aimed at achieving 90% of the virological success of patients on ART (UNAIDS, 2016). This is because the discontinuation of ART can lead to drug resistance, diminishing the number of CD4 cells, increases the number of viral counts, AIDS-related illnesses and death (Gesesew HA, et al .2017).

A 2010 review of 39 sub-Saharan ART cohorts reported that approximately 75% of patients were still in care after 2 years of treatment with ART. Attrition was mostly due to losses to follow-up (Fox MP, Rosen S. 2010). Patients lost to follow-up (LTFU) may be dead or alive. Those patients who are alive may have self-transferred themselves to another ART clinic; or may not be on any ART treatment anywhere (Geng EH, et al, 2010).

In Ethiopia on the basis of the 2010-2014 strategic plan ART coverage for adults has reached 79.6 % but the coverage remains low (23.5%) for children living with HIV. An ART implementation status and outcome study for the September 2005 to May 2010 treatment cohorts conducted in Ethiopia in 2011 confirms there is an 82.4% of 12 months retention after initiation of ART, 78% of five year survival

rate and 2% switch to second line treatment after five years (FHAPCO, an investment case approach, 2014).

Despite the presence of prior studies that showed risk factors associated with LTFU from ART program , most of them encountered a challenge in predicting characteristics of a patients who will become lost and the time when this risk is highest; Some contributory factors like type of ART regimen, drug side effect, and poor clinical status at ART initiation have more impact in the early stage of treatment; other factors such as family influences and fear of disclosure of HIV status can also lead to LTFU. (Beth S. R, 2013).

1.2. Statement of the problem

Loss to ART follow-up is a great obstacle in the success of ART programs in resource-poor settings (Geng EH, et al, 2010). It has been shown to contribute to poorer health outcome for patients and constitutes resource wastage, as well as the promotion of HIV drug resistance (Onoka CA, et al 2012).

In a systematic review of 154 general adult patient cohorts comprising 1,554,773 patients from 42 low- and middle-income countries published from 2008 to 2013 estimated that ART retention averaged 65% in Africa, 80% in Asia, and 64% in Latin America and the Caribbean after 36 months of ART initiation.(Matthew P Fox, Sydney Rosen,2015).

Similarly in a systematic review of published retention rates from ART clinics in sub-Saharan Africa (SSA) showed that the proportion of patients retained two years after starting therapy was approximately 60% (Fox MP, Rosen S, 2010).

A combination of clinical, sociodemographic and healthcare related factors contribute to LTFU. For instance, Younger age and marital status are among sociodemographic factors; Clinical factors like poor nutritional status, lower CD4 count, Tuberculosis (TB) co infection, advanced clinical staging; whereas gaps in services, and accessibility to services are some of the healthcare related predictors reported to be associated with LTFU (Berheto TM, et al, 2013).

In Ethiopia routine data supplied to the HIV/AIDS prevention and control office indicated that many patients had dropped out of ART. By the end of 2012, 81.3% of the patients were alive and on ART after 12 months of treatment initiation, out of the patients who had been started on ART (Federal HAPCO report, 2014).

Mortality and loss to follow-up were major reasons for the non-retention (Oromia Regional Health Bureau Annual Report, 2014).

According to existing data from Harari regional health bureau as of Aug 2016 the region has retained only 65% of ever started patients on ART (HRHB, annual report, 2016).

Although there are published evidences on risk factors affecting loss to follow-up among ART patients across some regions of the country such as Northern, southern, and south western parts of Ethiopia, these determinants vary across populations, region and countries because of the difference in the retention of patients on ART (Abebe N, et al 2014; Winnie M.S, 2013). Although there are available few studies on the incidence rate of loss to follow up in Ethiopia, the major factors associated with LTFU were not investigated in a recent cohort of patients enrolled on ART program.

1.3. Significance of the study

The findings from this study will assist as an input for program planners in targeting specific intervention that can ultimately lead to a reduction in LTFU. Planners and programmers at different levels of government institutions can use the information generated by the study to plan and implement effective HIV treatment and care programs. In addition, provision of baseline information on this issue can serve the service providers working at the ART clinic of Hiwot Fana specialized university hospital to give due attention on major risk factors which affect loss to follow up during patient preparation for the treatment and follow-up counseling.

1.4. Objectives

1.4.1. General objective

The objectives of this study was to determine the incidence rate of loss to follow up and associated factors among HIV infected patients attending in the ART clinic at Hiwot Fana Specialized university Hospital, Harari region, Eastern Ethiopia from February 1 to 28, 2018**.**

1.4.2. Specific objectives

1. To determine the incidence rate of loss to follow up.
2. To identify the factors associated with LTFU.

2. LITRATURE REVIEW

2.1. Incidence of loss to follow up

In developing countries, HIV care and treatment programmes have rapidly expanded over the past decade. The success of these programmes depends on regular patient follow-up, monitoring and evaluation. Overall, it is estimated that 21% of patients in HIV programmes are lost to follow-up 6 months after starting ART. Most studies in Sub-Saharan Africa have reported 20-40% incidence of LTFU among patients at all levels. This variation of incidence was attributed to the definition of LTFU in the various studies (Brinkhof MW, et al, 2010).

Loss to follow-up is more common in resource-poor settings. In an Antiretroviral Treatment in lower income countries study, loss to follow-up after 1 year was above 40% in some programs, and associated with more advanced clinical disease and lower CD4 cell counts (Schöni-Affolter F, et al, 2011). Retention of patients in care remains a major challenge to the health care and program mangers (Assefa Y, et al, 2011).

A retrospective observational cohort study conducted in South Africa reported that the incidence rate of LTFU was 103 per 1000 person-years in the first year on ART and increased to 405 per 1000 person-years in the eighth year of taking ART which indicate the incidence rate of LTFU increases with additional years on ART (Mberi et al. 2015).

A multi -site cohort study conducted in ten randomly selected health facilities in Ethiopia in 2016 shows that 37% of patients were LTFU at least once. Patients were followed for a total period of 29,696 person-years. This makes the incidence of LTFU 22 per 100 person-years of follow-up. (Alula M. T, Kesetebirhan D. Y, 2016)

A cohort study of 2133 people attending an ART clinic between 2005 and 2013 at Mizan-Aman General Hospital in Ethiopia the incidence rate was estimated to be 8.8 per 1000 person-months and the prevalence of LTFU from ART was 26.7% (Berheto TM, et al, 2014). A similar study conducted in Aksum St. Marry hospital found an estimated incidence rate of LTFU rate of 8.2 per 100 person- years. (Tadesse K, Haile F, 2014)

2.2. Factors associated with loss to follow up

Report from the British HIV Association has shown that the risk of LTFU increases with decreasing CD4 counts at the entry point of ART, whereas in Switzerland there was an opposite trend in the risk of LTFU; patients with higher CD4 cell counts were more likely to be lost to follow-up (Schoni-Affolter, et al, 2011).

A five year cohort study in India reported that no significant difference observed between attrition due to mortality and attrition due to LTFU. Having CD4 counts <100 cells/µl and being homeless [adjusted hazard ratio (aHR) 3.1, 95% CI 2.6–3.8] were associated with a higher risk of attrition, and female gender (aHR 0.64, 95% CI 0.6–0.8) was associated with a reduced risk of attrition. Being single (aHR 1.6, 95% CI 1.2–2.3), illiteracy (aHR 1.3, 95% CI 1.1–1.6), and age <25 years (aHR 1.3, 95% CI 1–1.8) were associated with an increased risk of LTFU. Patients who started anti-tuberculous treatment before ART had similar attrition to patients without tuberculosis (36 vs. 35.2%, *P*=0.19) after four years of follow-up (Gerardo Alvarez-Uria, et al, 2013)

Male sex was associated with an increased risk of attrition (AHR 1.24; p=0.004). Baseline WHO stage IV was associated with an increased risk of attrition (AHR 1.73; p=0.012) as compared with WHO stages I/II. A baseline CD4 cell count<50 (HR 1.36, p=0.05) was associated with higher attrition as compared with CD4 cell count >200 in univariate analysis, however, no associations between CD4 cell count and attrition were observed in the final multivariable survival model. Patients with baseline weights of 45–60 kilograms (AHR 1.25; p=0.02) and <45 kilograms (AHR 2.03; p=.000) at baseline had an increased risk of attrition as compared with those patients with weights >60 kilograms. While the majority of patients were prescribed cotrimoxazole prophylaxis at baseline, those who did not receive a cotrimoxazole prescription had significantly increased risk of attrition (AHR 1.94; p=.007).Initiating ART at an urban site, as compared with a rural site, was marginally associated with attrition (AHR 2.13; p=0.06) (Mutasa-Apollo T, et al 2014)

In a systematic review of twenty-nine studies from sub-Saharan Africa (SSA), only a quarter of patients with HIV started ART and loss to follow-up was two times higher among patients not eligible for ART at enrollment compared to eligible patients. ART initiation at advanced disease status is associated with lower rate of LTFU, despite of high rates of early mortality. In addition

to starting ART with advanced HIV, factors associated with mortality in patients on ART include male gender and older age (Lessells RJ, 2011.et al,).

In a cohort study conducted in South Africa, factors associated with becoming LTFU included not having a committed partner (Adjusted Hazard Ratio (aHR): 2.9, 95 % Confidence Interval (CI):1.19-6.97, $p = 0.019$), being self-employed (aHR: 13.9, 95 % CI:2.81 - 69.06, $p = 0.001$), baseline CD4 count > 200 cells/ml (aHR: 3.8, 95 % CI: 1.85-7.85, $p < 0.001$), detectable last known Viral Load (VL) (aHR: 3.6, 95 % CI:1.98 - 6.52, $p < 0.001$) and a last known World Health Organization clinical stage three or four (aHR: 2.0, 95 % CI:1.22-3.27, $p = 0.006$). Patients that previously had an ART adverse event had a lower risk (aHR: 0.6, 95 % CI: 0.38 - 0.99, $p = 0.044$) of becoming LTFU than those that had not (Mberi et al. 2015).

According to the analysis done in routinely-collected data on HIV-infected patients ≥15 years enrolled at 41 healthcare facilities in Rwanda from 2005 to 2010, in ART patients, LTFU was associated with male gender (adjusted hazard ratio (aHR) 1.4, 95%CI 1.2–1.7) and younger age (21–30 years vs. 31–40 aHR 1.4, 95%CI 1.2–1.7). Being married was protective against LTF in ART patients (married vs. single aHR 0.6, 95%CI 0.4–0.9) ART patients with lower CD4 counts were less likely to be LTFU than those with low CD4 counts (CD4 <100 vs. ≥350 aHR 0.64, 95%CI 0.4–0.9). WHO stage was not a significant predictor of LTFU for patients on treatment (Veronicah Mugisha.et al. 2014)

In Cameroon study conducted in 2013, major factors associated with high LTFU rate were: distance to clinic of over 5 km (aHR = 1.25, 95% CI: 1.00-1.55), being single, having partners with unknown HIV status or taking no treatment and with CD4 count >500 cells/µl. Two- thirds (66.7%) of traced LTFU patients were dead (Bekolo, et al. 2013)

In a rural Mozambique study conducted in 2013, two-year LTFU was 38.1% (95% CI: 36.9–39.3%) and mortality was 14.2% (95% CI 13.2–15.2%). Patients arrived from voluntary counseling and testing (VCT) sites (51%), general outpatient clinics (21%), antenatal care (8%), inpatient care (3%), HIV/tuberculosis/laboratory facilities (<4%), or other sources of referral (14%). Compared with VCT, patients referred from inpatient, tuberculosis, or antenatal care had higher hazards of LTFU. Patients referred to care from these sites generally have higher WHO stage and lower BMI, hemoglobin, and CD4 count at ART initiation. Transfer in status was found to be highly predictive of LTFU and mortality (Meridith Blevins 2013, et al,)

In multivariable analysis of study conducted in Togo reported that the factors associated with loss to follow-up during the first 6 months of ART were: age below 35 years (OR=1.6; 95%CI: 1.2-2.2), female sex (OR=1.8; 95%CI: 1.3-2.5), WHO stage III or IV (OR=1.7; 95%CI: 1.3-2.2), existence of an opportunistic infection (OR=2.3; 95%CI: 1.5-3.1), and follow-up in a public center (OR=1.9; 95%CI: 1.2-3.3. Among the subset of patients for whom this information was available, a major reason for lost to follow-up is death (Bayaki Saka, et al, 2013).

A retrospective cohort study conducted in Tigray Aksum St. Marry hospital shows 41% of LTFU occurred within the first Six months of ART initiation. The median survival time to LTFU was 14 months with Interquartile range of 8 to 27 months. There is also decrement in cumulative stay over time 95% to 85% at 12 and 60 months. In multivariable Cox regression, patients diagnosed with TB had a 2-fold higher risk of LTFU (Adjusted Hazard Ratio (AHR) =2.05, 95% CI: 1.02, 4.12) than individuals who were TB negative. Being male have almost 3 fold higher risk of loss (AHR=2.7, 95% CI: 1.31, 5.66). Likewise, patients with weight above 60 kg have 76% lower risk of being loss to follow up than their counter parts (AHR=0.24,95% CI: 0.06, 0.96) and those with at regimen AZT-3TC-NVP have around 3.5 times increased risk of loss to follow up than those individual who were using d4t (30)-3TC-NVP (AHR=3.47, 95% CI :1.02,11.83) (Tadesse K, Haile F, 2014).

A similar study conducted in 2014 at Mizan Aman General Hospital, Ethiopia, shows that Patients with regimen substitution (HR 5.2; 95% CIs 3.6-7.3), non-isoniazid (INH) prophylaxis (HR 3.7; 95% CIs 2.3-6.2), adolescent (HR 2.1; 95% CIs 1.3-3.4), and had a baseline CD_4 count < 200 cells/mm^3 (HR 1.7, 95% CIs 1.3-2.2) were at higher risk of LTFU. WHO clinical stage III (HR 0.6; 95% CIs 0.4-0.9) and IV (HR 0.8; 95% CIs 0.6-1.0) patients at entry were less likely to be LTFU than clinical stage I patients. The study also found that adolescents were twice, and adults 1.4 times, more likely to become lost to follow-up than children. There was no significant difference in risk of LTFU in males and females. TB co-infection was not associated with LTFU. (Berheto TM, et al, 2014).

2.3 CONCEPTUAL FRAME WORK

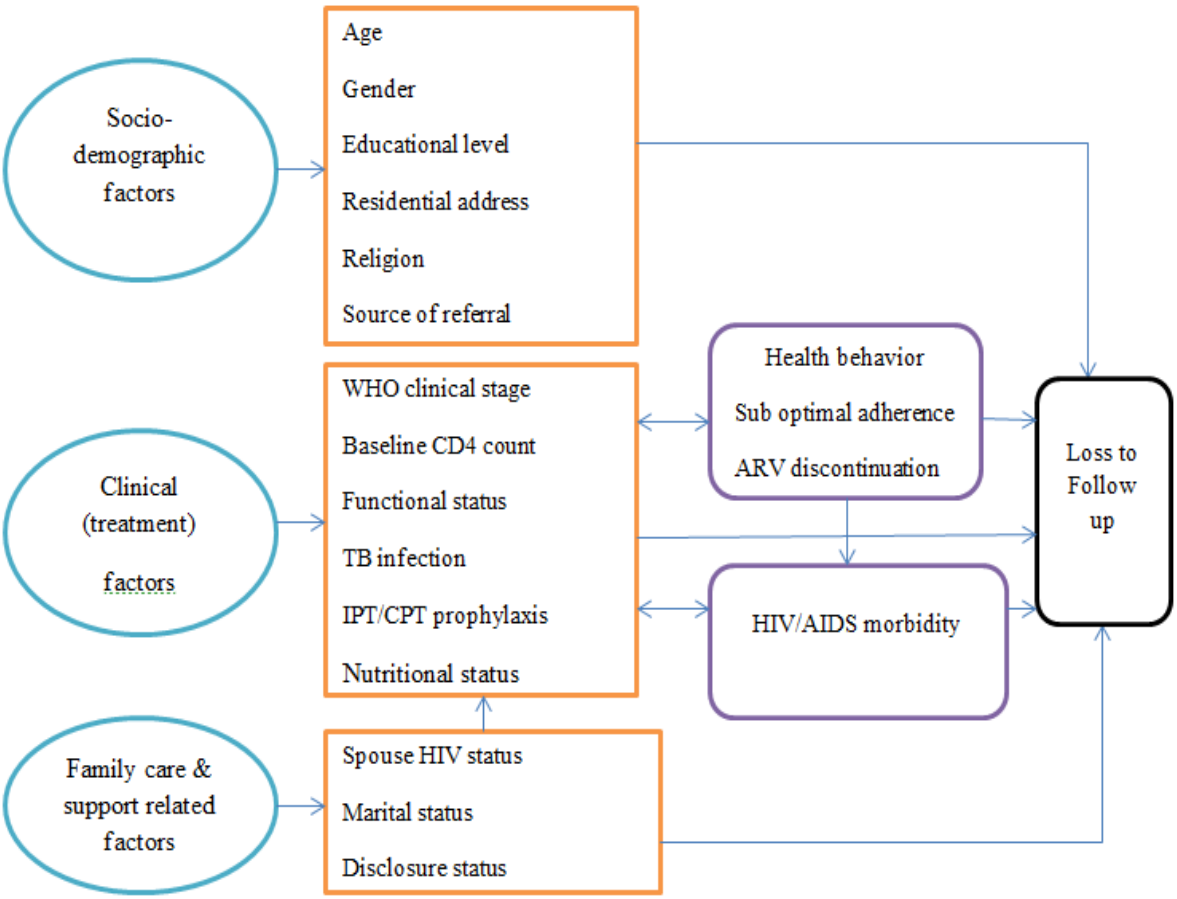

Figure 2.1: Conceptual framework describing factors associated with loss to follow up among ART clinic attendants. (Adapted from WHO access to adherence.2006)

3. METHODOLOGY

3.1 Study Area and Period

This study was conducted at Hiwot Fana specialized university hospital. It is found in the eastern part of Ethiopia, Harari 525 Kilometers away from Addis Ababa. The projection from the most recent demographic data indicates a total population of 246,000 in 2017, and is comprised of 3 rural and 6 administrative Woredas (Central Statistical Agency, 2017). The adult HIV prevalence of the region was 2.95% with an estimation of 4,874 PLHIV populations in the year 2017. There are also an estimated of 199 new all age HIV infections in 2017. (EPHI 2015, HIV Related Estimates and Projections for Ethiopia). Despite the relatively high HIV Prevalence of the region, the yield of getting new HIV positive patients remains below 0.5% over the 2 years, showing the need for strengthening of targeted HIV testing service. (FMOH catch up campaign report, 2016).

Nine health facilities have been providing ART service in addition to the other comprehensive HIV services for the population living in and nearby communities living outside the region. Hiwot Fana Specialized University Hospital is the regions high load referral hospital which accompanies more than 50% of the HIV treatment and follow up service. The Hospital runs HIV clinic that was started early in 2004, during the study period 2234 patients were attending in the ART clinic. HIV testing is performed at different service outlets, when patients become tested positive enrolled to chronic care after a range of procedures including pre and posttest counseling, result delivery and linkage. Retesting of HIV positive individuals done before ART initiation and irrespective of WHO staging criteria and or CD4 count, ART is commenced immediately if there was no concern for adherence preparation and patient willingness. Patient records are kept in two forms the hard copy files and the electronic medical record. The Electronic Medical Record is done in the ART clinic by assigned data clerks and the patients' physical file is updated in the computer at the end of each clinic day. The HIV clinic is headed by a medical Doctor (Harari Regional Health Bureau SOP, 2015).

The study was conducted from February 1 to 28, 2018

3.2. Study design

A five years retrospective cohort study from Feb. 1, 2012 to Feb. 28, 2017 was performed.

3.3. Source population

For this study the source population was all HIV infected patients enrolled in the antiretroviral clinic in Hiwot Fana specialized university Hospital.

3.4. Study population

The study populations were patients receiving an antiretroviral therapy from Feb. 1, 2012 to Feb. 28, 2017.

3.5. Inclusion and exclusion criteria

3.5.1. Inclusion criteria

All PLHIV's attending in the ART clinic with in the specified study period, were enrolled into the study.

3.5.2. Exclusion criteria

Patient with incomplete records of baseline and follow up data, ART initiation or termination date was missing, patients who were transferred from other facilities and enrolled in the hospital for continuation of ART were excluded.

3.6. Sample size determination

Objective 1: the sample size required for the study is calculated by using Collett, D: Modelling Survival Data in Medical Research, Second Edition - 2003. The required total number of events, L, can be found using,

$$L = \frac{\left(Z_{\alpha/2} + Z_{\beta/2}\right)^2}{\varphi_1 \varphi_2 (log\ HR)^2} \quad ; \quad \varphi_2 = 1 - \varphi_1$$

Where: φ_1=.27 taken from prevalence of lost in previous study conducted in south west Ethiopia (Berehto,et al, 2014)

α=0.05 and so $Z_{0.025}$=1.96 β=0.10 and so $Z_{0.05}$=1.28 HR=0.6

$=\frac{(1.96+1.28)^2}{0.27*0.73(log\ 0.6)^2}$ ……log0.6=-0.22 n_1=85 $n_2= n_1 * \left(\frac{\varphi_2}{\varphi_1}\right)$

=85*0.73/0.27

Total sample size for the first objective=240

Objective 2: The sample size was calculated by taking the risk of LTFU rate in two groups of PLHIV on ART based on the most significant predictor of loss to follow up, age category of patients from previous study as exposure status. Adult patients were at an increased relative hazard of being lost as compared to pediatric patients (p value <0.05) (Alula M. T, Kesetebirhan D. Y, 2016; Berheto et al, 2014).With the assumption of 5% type I error, 80% power, effect size of 1.4 and exposed to unexposed ratio 0.15, the total sample size was calculated by using Stata stpower log rank and found 598.

3.7. Sampling procedure

Study participants were selected by simple random sampling from a list of random number table generated using patients' medical record- number. If the data in the selected participant is incomplete, another study participant was randomly selected.

Profiles of all patients on ART between Feb.1 2012 and Feb. 28, 2017 were evaluated. Then patients in the exclusion list were excluded. Data about LTFU were collected from patents' charts.

3.8. Data collection methods

The data for this research was secondary data collected routinely in the hospital for clinical monitoring and evaluation purposes. Basic information obtained from patient charts were entered in an ART electronic database and updated during the follow-up time. A standard checklist was used for recording information extracted from patient cards. The checklist is developed by using the National standardized ART intake and follow up form employed by the ART clinic. Lost data was retrieved both from electronic data base and patient medical records. Completeness, consistency and accuracy of the data collection was done by the investigator using the checklist prepared for the study

The research assistants consisted of two nurses, one supervisor, and one data clerk working in the ART clinic. The nurses collect the data, the data clerk assist in retrieving the files and filling the case record forms in the electronic data and a supervisor supervised the data collection process.

Patients who missed their clinic appointments are usually documented in the defaulter tracing register. The register captures, name and clinic number of the patient, whether on ART or not, dates of missed appointment, client's telephone number and physical address, type of tracing done and outcome. Patients who miss appointments are contacted by the adherence supporters by phone after a week, if they still don't come; they are contacted again after a month and outcome status labeled 'lost'. The date of LTFU was recorded as the date of the most recent visit or one month after ART initiation if patients only attended the initiation visit.

3.9. Study variables

3.9.1. Outcome variable/Dependent variable

Time to loss to follow up

3.9.2. Independent variables

Age, Sex, Marital status, Educational status, occupation, religion, residence, CD4 cell count/Viral load, nutritional status, WHO clinical stage, TB status, functional status, HIV disclosure status, source of referral, ARV adherence, eligibility criteria.

3.10. Operational definition

Loss to follow up: defined as failure to present for HAART medication refill at the treatment-initiating health facility, with inability to be traced back by phone or home visit for more than 1 month, without a documented reason for failing to present (eg. no confirmed death nor decision to stop treatment in agreement with health care worker *(*Federal Ministry of Health. Ethiopia. 2010). Those who are not present for more than one month since the last appointment date for ART medication refill identified as exposed (failure).

ARV medication discontinuation: those patients interrupt medication and absent from the clinic for less than a month.

Incidence Rate of loss to follow up was calculated as the number of patients who are loss from care over the 5 year period divided by the total person years multiplied by one hundred. The incidence rate was reported as x per 100 person years.

Transfer out: when a patient is referred from the facility where s/he started ART to another health facility.

Transfer in: when a patient is received from another health facility after s/he is started on ART at that facility.

Retention to care: defined as patients under study known to be alive and receiving ART regularly at the treatment initiating facility.

Attrition: discontinuation of anti-retro viral therapy for reasons related to death or loss to follow up.

Survival: being alive & on ART and not experiencing the event (LTFU) during the study period.

Adherence: Adherence is defined as the correct and timely dosing of prescribed medication by the health care provider.

The following table shows estimation of adherence during follow up visit.

category	%	Of 30 doses	Of 60 doses
Good	95	<=2 doses	<=3 doses
Fair	85-94	3-5 doses	3-9 doses
Poor	<85	<=6doses	>9 doses

Antiretroviral drugs: These are the drugs that specifically work to suppress HIV replication.

Nutritional status: BMI for adults: not malnourished (>18.5), Moderate mal nutrition (16-18.5), severe malnutrition (<16).

MUAC (mid upper arm circumference) for pregnant, postpartum and bed ridden patients: Not malnourished (>22cm), Moderate mal nutrition (19-22cm), severe malnutrition (<19cm for pregnant and postpartum) <18 cm for bed ridden.

Children and adolescents: W/H and BMI for age (5-18yrs) Normal >-1Zscore, Mild (<-1and >-2), moderate mal nutrition (<-2 and >-3Zscore), severe malnutrition (<-3Z score).

Detected viral load: Viral load above 1000 copies/mL

Not detected: Viral load <= 1000 copies/mL

Baseline clinical conditions: were defined as the value on the date closest to ART start date but not more than 3 months.

3.11. Data quality control

To ensure data quality, the research assistants were trained on the data collection tools, the relevance of the study, how to review available documents and ethical issues. The data extraction format was pre-tested and checked for consistency. During the data collection, the supervisor closely monitors the data collectors for the validity of the data. Data was checked for completeness before data entry by the investigator.

3.12. Data processing and analysis

Data was first entered Epi data version 3.1, and exported to SPSS version 20 for cleaning and analysis. Descriptive analysis was carried out to describe patient cohort characteristics in terms of mean/median value for continuous data and percentage for categorical data. LTFU cases were confirmed by reviewing patient charts and registration by ART adherence supporters. Kaplan-Meier test was applied to measure the association of patient's characteristics with time from ART initiation to loss to follow up. Log rank test was used to assess statistical difference among groups (for equality of survival distributions). Cox proportional-hazard regression was used to compute the crude and adjusted hazard rate to determine independent determinants of time to loss to follow up. Variables significant at $P < 0.25$ level in the bivariate analysis were included in the final multivariable model. Multicollinearity was excluded using variance inflation factor (VIF) with a cutoff point 10. The survival time was calculated in months using the time interval between the date of ART initiation and the date of the event (LTFU) or date of censoring. Patients were considered censored, if dead (based on reported date or last visit date) or if they were alive at the end of the study period. Data was censored on Feb. 28/2018.

3.13. Ethical consideration

Ethical approval was obtained from Haramaya university institutional Health research review committee. Consent was obtained from head of Hiwot Fana specialized university hospital. No personal identifiers were stated in the data set prepared for the analysis. Informed, voluntary written and signed consent were not need because this was analysis of secondary data retrieved from patient records and an electronic database of the Hospital.

3.14. Communication of results

The result of the study will be presented to Haramaya University as part of thesis defense for partial fulfillment of MPH. The soft and hard copies of the results will be given to the university. The recommendations will also be discussed with Harari RHB, Hiwot Fana SU Hospital through workshop. Further efforts will be done to publish the findings of the study and disseminated through different journals and scientific publications.

4. RESULTS

4.1. Descriptions of the study participants

4.1.1. Socio-demographic characteristics

A total of 598 patients have been enrolled to start ART between Feb. 1, 2012 and Feb. 28, 2017. A proportion of HIV patients 26(4.3%) were transferred out to continue their ART medication to other institutions and were therefore excluded from the analysis. The remaining 572 patients were included in the analysis. About 60% of the patients were females. The mean or median age of the cohort at the start of ART was 32 years. Three hundred thirty one (58%) of the samples were residing in Harari region. Two hundred twenty three (39%) of the patients were married. More than half of patients (54%) were orthodox Christian by religion. Two hundred forty five (43%) of the study subjects had a primary level education and 115(20%) had no education. Twenty seven percent of the patients were day laborers by employment status at the time of enrollment to chronic care. Majority (41%) of patients referred from the hospital VCT clinic to be enrolled to ART clinic for chronic care follow up. (Table1)

Table1. Sociodemographic characteristics of patients in Hiwot Fana Specialized university hospital, Eastern Ethiopia, Harar town, February 2018

Sociodemographic characteristics	**Frequency(N)**	**Percent (%)**
Sex		
Male	229	40
Female	343	60
Age(Years)		
Children <=10yrs	35	6.1
Adolescents 11-19yrs	49	8.6
Adults >=20yrs	488	85.3
Place of residence		
Harar town	331	58
Outside Harar town	241	42
Marital status(n=488)		

Never married	90	18
Married	204	42
Divorced/ separated	128	26
Widowed/er	66	14
Religion(n=571)		
Orthodox	306	53
Muslim	181	32
Protestant	69	12
catholic	13	2.5
Other	2	0.5
Educational status(n=570)		
No education	115	20
Primary	245	43
Secondary	140	25
College & above	70	12
Employment status at enrollment (n=479)		
Un employed	102	21.3
Gov. employee	72	15
Day laborer	127	26.5
Merchant	32	6.7
House wife	54	11.3
Others	92	19.2
Source of referral at enrollment		
VCT	138	41
Medical OPD	237	24
TB clinic	32	6
In patient ward	56	10
Other Dept.	36	6
Outside hospital	73	13

4.1.2. Past illness and family condition of patients at enrollment to chronic HIV care

More than half (57%) of patients had no opportunistic illness infections at the time of enrollment to chronic care follow up. About one in ten 63 (11%) patients had a history of TB treatment before enrollment to chronic care. One hundred twenty three (22%) of the patients spouse or partner were HIV positive and 56(10%) had a discordant result against their spouse or partner. Of those parents enrolled in care 71 (14%) of their children were HIV infected. Majority 406(71%) of the patients disclosed their HIV status to someone who had close relation (Table2).

Table2 past illness and family condition of patients in Hiwot Fana Specialized university hospital, Eastern Ethiopia, Harari, February 2018

Characteristics	Frequency(N)	Percent (%)
History of OI illness(n=571)		
Present	247	43
Absent	324	57
History of TB treatment		
Yes	63	11
No	509	89
Disclosure status of the patient at enrollment		
Disclosed	406	71
Not Disclosed	166	29
Partner or spouse HIV status(n=499)		
No partner or spouse	237	41
Tested positive	123	22
Negative	48	8
Not tested	91	16
Children HIV status(n=527)		
No children at home	230	44
Tested positive	71	14
Tested negative	103	20
Not tested	119	22

4.1.3. Baseline clinical condition of patients

About one in five 120 (21%) of patients were malnourished at entry of which 96(80%) provided plumby nut/sup food treatment. Baseline CD4 count was determined for 88% of the patients of which 299(59%) had a CD4 count >=200 cells/cm^3 with a median CD4 count of 246 cells/cm^3 (IQR: 120-372). Only 86(15%) were ambulatory or bedridden during enrollment to chronic care. Seventy eight (13.6%) have TB co infection during Pre ART. More than half (54.8%) of patients started ART based on CD4 only WHO recommendation. At enrollment to care and treatment about two-third of patients 376(66%) were stage 1 or 2 condition. More than a quarter 156 (27.3%) of patient started Cotrimoxazole preventive therapy, and almost similar proportion 146(25.5%) of patients were provided with isoniazid preventive therapy at enrollment to chronic care. About three-fourth (76%) of patients started first line regimen by Tenofovir based (Table3).

Table3 Baseline clinical condition of patients before enrollment to antiretroviral therapy program in Hiwot Fana Specialized university hospital, Eastern Ethiopia, Harari, February 2018

Clinical characteristics	Frequency(N)	Percent (%)
Nutritional status at enrollment to care		
Not malnourished	416	73
Moderate malnutrition	61	11
Severe malnutrition	59	10
Unknown	35	6
Food treatment given		
Yes	96	80
No	476	20
Baseline CD4 category (n=503)		
<50	46	9
50-100	56	11
>100	408	80
Baseline functional status		
Working	486	85
Ambulatory/bedridden	86	15
Baseline WHO clinical staging (n=569)		

Stage 1 or 2	377	66
Stage 3 or 4	192	34
INH preventive therapy before HAART		
Yes	146	25.5
No	426	74.5
TB co infection before HAART		
Yes	78	13.6
No	494	86.4
Cotrimoxazole preventive therapy (n=571)		
Yes	156	27.3
No	415	72.7
Eligibility criteria for ART initiation(n=566)		
CD4 only	310	54.8
WHO clinical stage only	53	9.4
Both CD4 and clinical stage	103	18.2
Test and treat all policy	100	17.6
Initial ARV regimen		
AZT/3TC/NVP	54	9.4
AZT/3TC/EFV	53	9.3
TDF/3TC/EFV	421	73.6
TDF/3TC/NVP	13	2.3
Other first line	31	5.4

4.1.4. Clinical condition of patients during ART follow up

Two hundred twenty one (38%) of the patients had been on ART for more than three years with a mean duration of ART 31 months. Until last visit 207(36%) taking Cotrimoxazole preventive therapy. Almost half of the patients have been taken INH preventive therapy while on ART. Only 6% of the patients developed TB while on ART. Regarding adherence, 39 (7%) of the patients were found to be fairly or poorly compliant for ART medication at their last follow up visit. Majority (96%) of the study participants had a normal functional status at last visit. Eighteen (3.2%) had developed ART medication side effect during their follow up period. First line regimen was changed for only 11(3.5%) of the patients of which more than a half (55%) of

regimen change was due to side effect or toxicity. Four percent of patients had a detectable viral load result above 1000 copies/mL. About one in eight patients restart ART after first lost during their follow up period (Table4).

Table4 Clinical condition of patients during ART follow up period until last visit in Hiwot Fana Specialized university hospital, Eastern Ethiopia, Harari, February 2018

Clinical characteristics	Frequency(N)	Percent (%)
Duration in months since ART initiation		
<12 months	90	16
12 to 24 months	143	25
25 to 36months	118	21
>36 months	221	38
Cotrimoxazole preventive therapy		
Yes	207	36
Yes, but now stopped	249	44
No	116	20
IPT started while on HAART		
Yes	276	48
No	295	52
TB co infection during HAART		
Yes	29	6
No	542	94
Recent functional status		
Working	550	96
Ambulatory/bedridden	22	4
Last ARV medication adherence		
Good	530	93
Fair or poor	39	7
ARV medication side effect		
Yes	18	3.2
No	554	96.8
Regimen change(n=570)		

Yes	20	3.5
No	550	96.5
Reason for regimen change(n=20)		
Toxicity/side effect	11	55
Treatment failure	1	5
Other	8	40
Viral load(n=570)		
Not detected	214	37.5
Detected	24	4.5
Un known	332	58
History of lost and restart while on ART		
Yes	39	7
No	533	93

4.2. Survival analysis of time until LTFU

4.2.1. Incidence rate of LTFU

A total of 572 patients were followed for a median of 31.5 months (IQR: 18-46) and contributed for 17,606 person months of follow up. The median survival time for the event (LTFU) was 13 months (IQR: 5-33). About three fourth of patients 75.9% (95%CIs: 72.4, 79.2) were alive and on ART at the end of the study period and 21% (95%CIs: 17.7, 24.4) of patients loss giving a LTFU rate of 8.2 per 100 person years. Of those losses to follow up 57/120(47.5%) occurred within the first year after ART initiation (HR: 0.01). At the end of the follow up period 3.1% (95%CI: 1.7, 4.7) were found dead. The overall proportion of attrition due to both LTFU and death during the study period was 24%. The estimated probability of LTFU (95%CIs) at 12, 24, 36, 48 and 60 months after initiation of ART was 10%,14%,19%, 24% and 38% respectively. The cumulative proportion of staying in this cohort shows decrement over time 90% to 62% at 12 and 60 months respectively (Table5).

Table5. Life table estimate of cumulative failure in patients started ART between Feb. 1 2012 and Feb. 28, 2017.

Interval Start Time	Number Entering Interval	Number of LTFU	Cum. Proportion Surviving	Hazard Rate
0	572	57	.90	0.01
12	489	20	.86	0.00
24	346	16	.81	0.00
36	233	12	.76	0.01
48	130	14	.62	0.02
60	12	1	.53	0.00

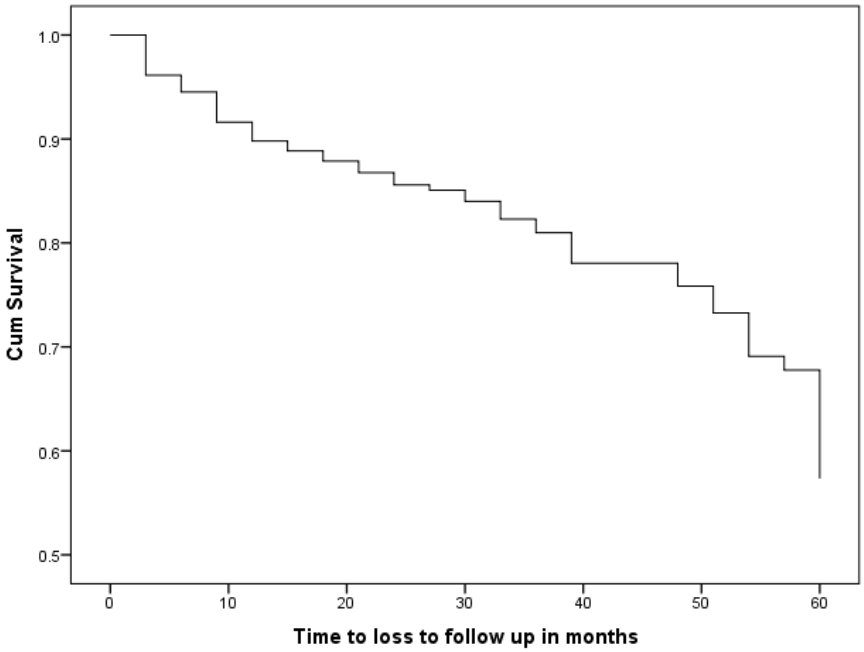

Fig. 4:1 cumulative survival of patients on ART between Feb. 1, 2012 and Feb.28, 2017 at Hiwot Fana specialized university hospital

The median survival time estimate of LTFU for patients who disclosed their HIV status to someone who had close relatives was 19 months (95% CI 12.85, 25.14), whereas for patients who did not disclose their HIV status to anyone when enrolling into ART care was 8 months (95% CI, 6.30, 9.69). The observed difference was statistically significant (p< 0.001) (Fig. 4:2).

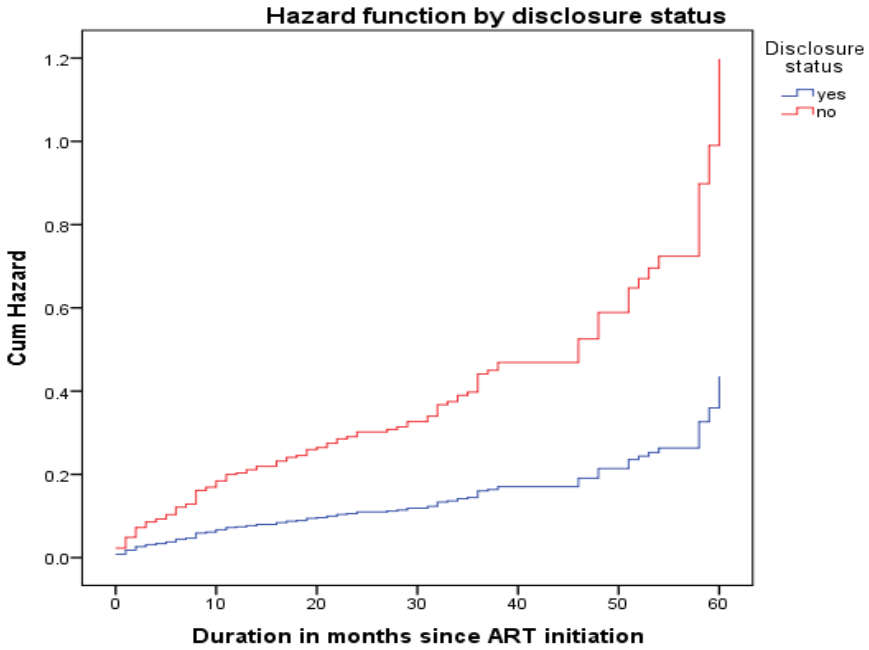

Fig. 4:2 Cumulative hazard of patients started ART between 2012 and 2017 at Hiwot Fana specialized university hospital by disclosure status.

4.2.2. Factors associated with time to LTFU

Bi variate cox regression analysis of factors associated with LTFU

Compared to adults adolescents have a twofold higher risk (Crude Hazard Rate [CHR]=2.21; 95%CIs: 1.34, 3.62) to become LTFU. Being a discordant partner or spouse was less likely to become LTFU (CHR=0.40;95%CIs:0.17, 0.93) as compared to those who had no partner or spouse, patients with a baseline CD4 count below 50 cells/cm^3 had a higher risk (CHR=1.87; 95%CIs; 1.05, 3.30) to become LTFU than those with CD4 count > 100 cells/cm^3. The presence of WHO clinical stage 3 or 4 conditions before enrollment to ART had a 1.5 times higher hazard (CHR= 1.53; 95%CIs; 1.06, 2.20) of being LTFU as compared to stage 1 or 2 condition. Patients who were not received IPT while on ART have higher risk (CHR=1.48; 95%CIs: 1.53, 3.27) of becoming LTFU as compared to those not received INH (table 6).

Table: 6. Bivariate Cox-regression analysis of factors associated with LTFU in patients started antiretroviral therapy between Feb. 1, 2012 and Feb. 28, 2017 in Hiwot Fana Specialized university hospital, Harar, Ethiopia

Variables	Survival status		Crude HR	95%CI	P-value
	Event (LTFU)	Mean survival			
Sex					
Male	64	45.7	1.97	(1.37,2.82)	**<0.001**
Female	56	52.6	1	1	1
Age					
children <=10yrs	4	53.8	.612	0.22, 1.66	.337
Adolescents 11-19yrs	19	38.8	2.208	1.34, 3.62	**.002**
Adults >=20yrs	97	50.6	1	1	1
Marital status					
Never married	31	43.7	1.77	1.13, 2.75	**0.012**
Widowed/er	13	49.9	0.82	0.45, 1.51	0.536
Divorced/separated	23	51.9	0.77	0.47, 1.26	0.301
Married	52	52.3	1	1	1
Educational status					
No education	23	48.7	1	1	1
Primary	54	49.2	0.965	0.597, 1.576	0.886
Secondary	26	51.6	0.799	0.455, 1.402	0.434
College and above	17	47.8	1.164	0.621, 2.181	0.636
Place of residence					
Harari	55	52.4	1	1	1
Outside Harari	65	46.1	1.825	1.273, 2.615	**0.001**
History of OI illness					
Present	47	50.4	0.86	0.56, 1.25	0.441
Absent	72	49.5	1	1	1
History of past TB treatment					
Yes	12	50.9	0.84	0.46,1.53	0.576

No	108	49.9	1	1	1
Disclosure status					
Disclosed	70	52.5	1	1	1
Not Disclosed	50	43.1	2.25	1.56, 3.24	**<0.001**
Partner HIV status					
No partner or spouse	60	48.4	1	1	1
Tested positive	30	49.8	.953	0.61, 1.47	.830
Negative	6	54.6	.402	0.17, 0.93	**.034**
Not tested	20	48.8	.914	0.55, 1.51	.728
Baseline CD4 category					
<50	14	44.9	1.87	1.05, 3.30	**.032**
50-100	13	48.2	1.39	.77, 2.50	.273
>100	76	51.6	1	1	1
Baseline F. status					
Working	80	52.3	1	1	1
Ambulatory/bedridden	40	38.5	3.072	2.01, 4.49	**<0.001**
Baseline WHO stage					
Stage 1 or 2	69	51.5	1	1	1
Stage 3 or 4	51	46.5	1.53	1.06, 2.20	**0.021**
INH					
Yes	24	52.0	1	1	1
No	96	49.1	1.48	0.94,2.31	0.087
TB co infection					
Yes	44	34.8	4.176	2.87, 6.05	**<0.001**
No	76	52.8	1	1	1
CPT					
Yes	23	50.8	1	1	1
No	97	49.5	1.27	0.81, 2.02	0.298
Last ARV medication adherence					
Good	112	54.1	1	1	1
Fair or poor	8	49.7	0.632	0.29, 1.35	0.240

In the multivariable Cox regression analysis, each variable was checked to fit the model by adjusting for all variables significant at P<0.25 level in the bivariate analysis. The result showed that being male sex (Adjusted Hazard Ratio[AHR]= 2.10; 95% CI: 1.33, 3.30), Those patients who resided outside the region (AHR=2.14;95%CIs:1.37, 3.33), patients who are not disclosed their sero status (AHR=1.88;95%CIs:1.23, 2.89), being ambulatory or bedridden functional status (AHR=3.86;95%CIs:2.33, 6.38) and Tb/HIV co infection (AHR=3.45;95% CIs:2.23, 5.33) were significantly associated with LTFU among patients living with HIV/AIDS after initiation of ART (Table 7).

Table7: Multivariable Cox-regression analysis to determine factors associated with LTFU in patients initiated ART between Feb. 1, 2012 and Feb. 28, 2017 at Hiwot Fana Specialized university hospital.

Variables	**Survival status**		**Crude HR (95%CI)**	**Adjusted HR (95%CI)**
	Event (LTFU)	**Mean survival**		
Sex				
Male	64	45.7	1.97 (1.37, 2.82)*	**2.10(1.33,3.30)***
Female	56	52.6	1	1
Age				
children <=10yrs	4	53.8	.612(0.22, 1.66)	1.05(.373, 2.94)
Adolescents 11-19yrs	19	38.8	2.21(1.34, 3.62)*	1.52(.83, 2.80)
Adults >=20yrs	97	50.6	1	1
Place of residence				
Harari	55	52.4	1	1
Outside Harari	65	46.1	1.82(1.27, 2.61)*	**2.14(1.37, 3.33)***
Disclosure status				
Disclosed	70	52.5	1	1
Not Disclosed	50	43.1	2.75(1.92, 3.94)*	**1.88(1.23, 2.89)***
Baseline CD4 category				
<50	14	44.9	2.48(1.39, 4.41)*	1.46(.80, 2.66)
50-199	13	48.2	1.39(0.90, 2.14)	1.13(.61, 2.13)
>200	76	51.6	1	1
Baseline functional				

status				
Working	80	52.3	1	1
Ambulatory/bedridden	40	38.5	3.07(2.01, 4.49)*	**3.86(2.33, 6.38)***
Baseline WHO stage				
Stage 1 or 2	80	87.2	1	1
Stage 3 or 4	40	12.8	1.53(1.06, 2.20)*	0.83(0.52,1.32)
TB co infection				
Yes	44	34.8	4.17(2.87, 6.05)*	**3.45(2.23, 5.33)***
No	76	52.8	1	1
ARV adherence				
Good	112	54.1	1	1
Fair or poor	8	49.7	0.63(0.29, 1.35)	0.76(0.30, 1.91)

NB: * p<0.05

Male patients have a twofold (AHR= 2.10; P<0.01) increase in LTFU than female patients (Fig.4:4). Those patients who resided outside the region (AHR=2.14; p<0.01) have an increased risk of LTFU compared to those living in the town (Fig. 4:3).

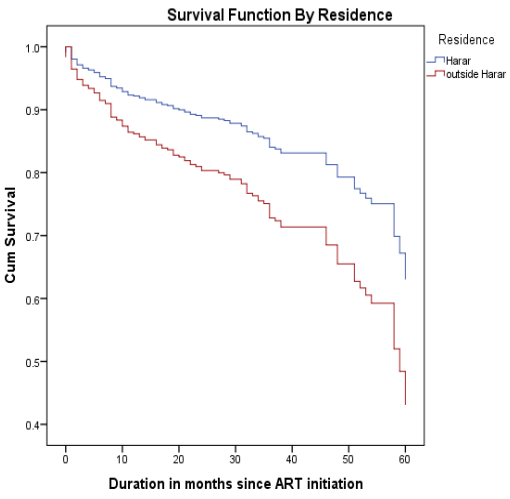

Fig. 4:3 Cumulative survival of patients started ART between 2012 and 2017 at Hiwot Fana specialized university hospital by residence

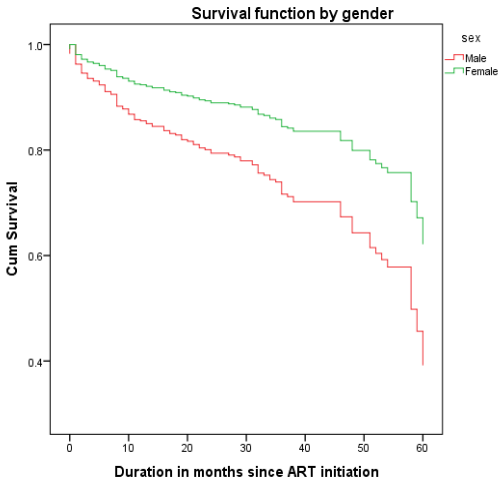

Fig. 4:4 Cumulative survival of patients started ART between 2012 and 2017 at Hiwot Fana specialized university hospital by gender

Patients who are not disclosed their sero status (AHR=1.88;p<0.01) have an increased relative hazard of being lost as compared to those who are disclosed. Ambulatory or bedridden functional status (AHR=3.86;p<0.01) have more than a threefold risk of LTFU(Fig.4:5) and patients who have a TB co infection before starting ART (AHR=3.45;P<0.01) were three times more likely to become LTFU than those without Tb/HIV co infection (Fig.4:6)

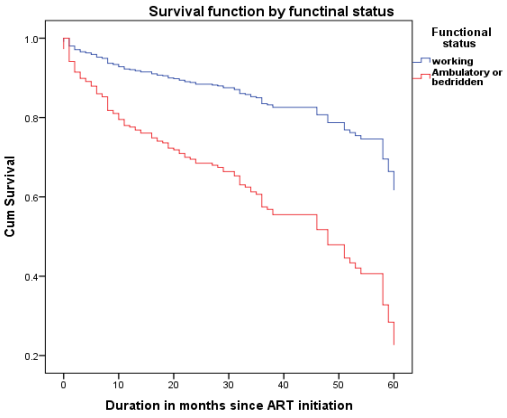

Fig. 4:5 Cumulative survival of patients started ART between 2012 and 2017 at Hiwot Fana specialized university hospital by functional status

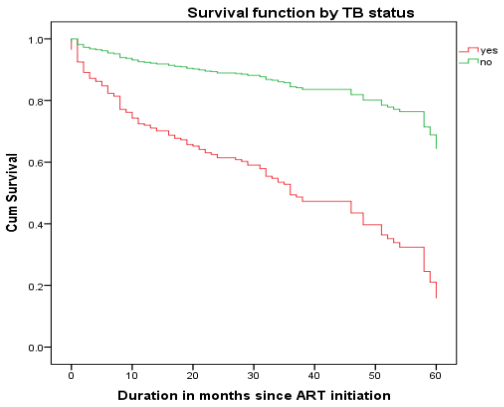

Fig. 4:6 Cumulative survival of patients started ART between 2012 and 2017 at Hiwot Fana specialized university hospital by TB status

5. DISCUSSION

This study assessed that the rate of LTFU and its associated factors in the ART clinic enrolled patients. It was revealed that a total of 120 (21%) (95%CI: 17.7-24.4) of patients who initiate ART are LTFU after 5 years of follow-up giving a loss to follow up rate of 8.2 per 100 person years. Male, patients living outside Harar town, TB HIV co infected patients, patients who are not disclosed their sero status and ambulatory or bedridden patients were found to be factors strongly associated with LTFU.

The rate of incidence in the current study is lower than other previous studies from sub-Saharan Africa (M P Fox, S Rosen, 2015), and a study performed in the Oromia and southern Ethiopia (Abebe M., 2016, Berehto, 2014), which found that 33% and 26% respectively. However, the incidence was higher than the ones reported in studies from North West Ethiopia and Tigray region (Mamo W, 2012, Kidane T, 2014) which found that 18% and 9.8% respectively. This difference in incidence rate might be due to variation in awareness, geographical differences and relative prevalence of substance abuse.

Being a male was found to be two times more likely experienced LTFU than their counterparts. The relationship between male gender and risk of loss in this study is similar with other recent studies that have documented a significantly higher LTFU in males than females (Tadesse K, Haile F, 2014;Gerardo Alvarez-Uria, et al, 2013; Mutasa-Apollo T, et al 2014; Veronicah Mugisha.et al. 2014). This difference might be due to instability and a high risk of drug addiction in men that may affect adherence (Alvarez-Uria G, 2013).

Patients who resided outside the region had twofold increase in LTFU compared to those living in Harar town. Similar finding was reported by study done in the Oromia region and Nekmete hospital in Ethiopia. Distance to clinic, transport related costs, level of patient's awareness of the treatment, and social stigma are main factors for defaulting from care (Abebe M. et al, 2016). This might be due to people need to take time off from work to travel long distances and wait for the service all day. This may discourage patients to come back for ART treatment clinical appointments (Tesfaye A, et al. 2013).

The study demonstrates that patients who had not disclosed their serostatus to any one were nearly two times more likely to become LTFU. Studies from other countries also similarly showed that HIV positive people experience isolation from society, which further discourages disclosure of their HIV status. As a result, disclosure and health-seeking behavior could be

adversely affected (Asgary R. et al, 2012). Disclosure of HIV status has been shown to be associated with higher retention in care and benefits in improving adherence to ART (Arrive et al, 2012).

Among the clinical factors patients who had CD4 cell count <50cell/mm^3 was 1.48 times more likely to become LTFU in the bivariate analysis. This could be due to patients of a low CD4 measurement being too sick to continue follow up, transferring to nearby institutions closer to them or they might be died (Tweya etal,2013). Starting ART at higher CD4 cell counts could have a major impact on reducing the mortality and LTFU after ART initiation. Current national guidelines have revised the ART starting criteria that all patients should have to start ART as soon as diagnosed with HIV regardless of CD4 count (FMOH, 2016 supplemental GL). However, in this study 41% of patients were initiated ART when their CD4 count was <200 cells/µl. When patients deferred to start ART until their CD4 count dropped this might aggravate the patient condition and increase the incidence of LTFU (WHO, 2013).

Although it has been known that Tb/HIV co-infection mortality and morbidity was reduced dramatically in the era of ART, in this study LTFU was more than three times higher in Tb/HIV co-infected patients than in patients without TB infection. These results are consistent with findings from earlier studies (Bassett IV, et al. 2012; Rachilis B. et al. 2016). Tb enables the progression of HIV disease to advanced stage quickly and thereby barring patient adherence (Gesesew H, 2016). In addition, Tb/HIV co-infection could be another factor for ART interruption due to pill burden (UNAIDS: 2014).

Functional status at the initiation of HAART was a strong predictor of loss to follow-up, indicating that patients who were ambulatory or bedridden were nearly four times more likely to be LTFU when compared to patients who were working. In line with this finding, a study done in Gonder University Hospital showed that ambulatory and bedridden functional status was significantly associated with loss to follow-up (Mamo w, et al**.** 2012). This might be due to the fact that this group of patients is financially dependent and need close supervision to ensure drug adherence. They are also more likely to die due to ART side effects during the early periods ART initiation (Assefa T, et al. Wechenko E, et al. 2012).

In the current study most 57/120 (47.5%) LTFU occurred within the first year after ART initiation (HR: 0.01). This finding is consistent with many other studies, which reported that a large proportion of patients loss from care within the first year of ART, the peak period being

the first 6 months of ART. This might be because of most treatment related side effects; opportunistic infections and immune reconstitution inflammatory syndrome (IRIS) are occurred during this period. These factors add to existing barriers for adherence such as problems in access, lack of family or social support and stigma (WHO, 2013). In addition, it has been suggested to be due to less awareness at these early periods about the cons and prons of treatment outcomes (Berheto et al, 2014).

Strength and limitations of the study

The follow-up period of five years and involved the town's special referral hospital which contribute more than 50% of HIV patient data (HRHB report, 2017) were relative strengths of this study. The retrospective nature of the cohort, inclusion of patient profile which have complete information only which may bias the results of the study. The current study did not determined the true outcomes of the patients who were documented as being LTFU, as tracing of LTFU patients was not easy. Results from traced patients showed that LTFU patients found deaths and transfers, suggesting both contribute to LTFU (Tweya et al., 2013).

6. Conclusion and recommendations

The results of this cohort study reports a comparatively high rate of LTFU at Hiwot Fana specialized university hospital which may substantially affect the program outcome. Additionally the risk of LTFU increases in the first year after ART initiation. Being male, patients living outside Harar town, TB HIV co infected patients, patients who are not disclosed their sero status and ambulatory or bedridden patients were found to be factors strongly associated with LTFU. Based on the findings from the study the following recommendations are suggested:

To Hiwot Fana specialized university hospital

- Continuous and comprehensive follow up is needed to reduce LTFU in an acceptable level and special attention should be given for male, patients living outside Harar town, TB HIV co infected patients, patients who are not disclosed their sero status and seriously ill patients at the early periods of ART enrollment.
- Complete documentation of patient profile during subsequent clinic visit.
- Track patients early as per the national guideline.

To Regional Health bureaus (In Harari and surrounding regions)

- Build the capacity of health care providers working in the ART clinic on identifying and managing high risk patients at the early stage.
- Implement strategies for better tracking services and minimizing LTFU from HIV care at early. Monitoring LTFU to ART programs is important because they possibly threaten not only their own life, but also contribute to increased HIV drug resistance due to ART default.
- Prospective cohort studies are needed to assess other causes of patients' attrition.

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8. INFORMATION SHEET AND INFORMED VOLUNTARY CONSENT FORM

8.1. Information Sheet and Informed Voluntary Consent Form for Head of Hiwot Fana specialized university hospital.

My name is _____I am working as a data collector for the study being conducted in this institution by Tenaye Abate who is studying for her Master's degree at Haramaya University, College of Health and Medical Sciences. I kindly request you to lend me your attention to explain you about the study and your institution being selected as the study setting.

Study title: Incidence rate and associated factors of loss to follow up among ART clinic attendants in Hiwot fana specialized university hospital.

Purpose of the study: The findings of this study can be of a paramount importance for the Hospital to find conditions to retain HIV infected patients in care and treatment programs, to have patients of improved clinical outcome and helps to investigate why patients drop out from continuous lifelong follow up. Moreover, the aim of this study is to write a thesis as a partial requirement for the fulfillment of master in public health for the Principal Investigator.

Procedure and duration: The study will be conducted through reviewing secondary data found in the ART clinic.

Risks and benefits: The risk of participating in this study is minimal. There would not be any direct payment for participating in this study, but the findings from this research reveal important information for the local health planners.

Confidentiality: The information that we will be provided will be kept confidential. No personal identifiers will be stated in the data set prepared for the analysis. The findings of the study will be general for the study community and will not reflect anything particular of individual persons. No reference will be made in oral or written reports that could link participants to the research.

Contact address: If there, are any questions or enquires any time about the study or the procedures, please contact: Mobile phone of investigator: +251913046050 (Tenaye Abate) Email address of investigator: tenayeabate@ymail.com Institutional research

ethics review committee (IRERC) Haramaya University: Office phone: 0254662011: P.O.BOX: 235, Harar.

Declaration of informed voluntary consent: I have read the participant information sheet. I have clearly understood the purpose of the research, the procedures, the risks and benefits, issues of confidentiality and the contact address for any queries. I have been given the opportunity to ask questions for things that may have been unclear. I am also informed that the health facilities has the right to stop this study from being conducted in the health facilities if any misdeeds and unethical procedures are observed during the data collection process in the health facility's premises. Therefore, I declare my voluntary consent on behalf of _____ management to allow this study to be conducted in the health facilities with my initials (signature).

Name and Signature of Head of the hospital: _____

Name and Signature of Data Collector: _____

Thank you for your cooperation!

9. ANNEXES

9.1. Data Extraction Format

INTRODUCTION

This patient information collection sheet is intended to assess the incidence rate and associated factors of loss to follow up among ART clinic attendants in Hiwot Fana specialized university hospital, Harari region, Eastern Ethiopia. The study will be conducted through reviewing secondary data. The study is aimed to fill the information gap and provide empirical evidence for program planner, decision makers and ART program implementer at the different level by enabling them to access a base line data on determinants loss to follow up. Moreover it assists in improving the outcome of ART program.

Date of review [___/___/_____]

Name of the reviewer _____Signature _____

Time (Started/ Ended) [_____/_____]

Supervisor Name _____

Signature _____ Date [___/____/_____]

Study ID. NO. _____

Reviewed Patient's card No. from _____to_____

Available Data: I. Complete____ II. Incomplete_____ III. Excluded____

Action taken for the incomplete data:

_____
_____
_____
_____
_____
_____
_____
___

(Please use additional blank paper if the space is not enough)

PART I. SOCIO-DEMOGRAPHIC CHARACTERISTICS

NO	VARIABLES	CODING CATEGORIES	SKIP
101	Age	_____	
102		1. Male 2. Female	
103	Religion	1. Muslim 2. Protestant 3. Orthodox 4. Catholic 5. Other (Specify)_____ 99. Missing	
104	Marital status (ignore if Child)	1. Never married 2. Married 3. Divorced 4. Widowed 5. Separated. 99. Missing	
105	Educational status	1. No education 2. Primary 3. Secondary 4. College/ Above 99. Missing	
106	Occupational status	1. Merchant 2. Government employee 3. Non-government organizations (NGO) 4. Military 5. Day laborer 6. Farmer 7. Driver 8. unemployed 9. House wife 10. Other (Specify)_____ 99. Missing	

107	Residence Address	1. Harar 2. Dire Dawa 3. Oromia 4. Somali 5. Other (specify) _____ 99. Missing	
108	Source of referral	1. Medical OPD 2. TB clinic 3. VCT 4. Inpatient ward 5. PMTCT 6. Public Hosp. 7. Health center 8. NGO 9. Other: specify_____ 99. Missing	
PART II: PAST ILLNESS AND FAMILY CARE INFORMATION			
201	History of OI illness	1. Present 2. Absent 99. Missing	
202	Hx of TB treatment	1. Yes 2. No 99. Missing	
203	Ever disclosed	1. Yes 2. No 99. Missing	
204	Spouse/partner HIV status(ignore if child)	1. Test positive 2. Test negative 3. Not tested 4. No spouse/partner 99. Missing	
205	children HIV status	1. Test positive 2. Test negative 3. Not tested 4. No children 5. Other specify_____ 99. Missing	

Part III. Baseline clinical and Laboratory information			
NO	VARIABLES	CODING CATEGORIES	SKIP
301	Date confirmed HIV+	[___/___/___]	
302	Enrollment date	[___/___/___]	
303	Nutritional status before HAART initiation	1. Normal 2. Moderate 3. Severe 4. Not done 99. Missing	
304	Food treatment provided	1. Yes 2. No 99. Missing	
305	Baseline functional status	1. Working 2. Ambulatory 3. Bedridden 99. Missing	
306	Baseline CD4 count	_____ [___/___/___]	
307	Baseline WHO staging	1. Stage I 2. 2.Stage II 3. 3.Stage III 4. 4.Stage IV 99. Missing	
308	Screened for TB	1. No 2. Yes positive 3. Yes Negative	
309	INH preventive therapy	1. Yes 2. No 3. Taken but not completed	
310	TB treatment before HAART	1. Yes 2. No	
311	Cotrimoxazole prophylaxis	1. Yes 2. No if no specify reason _____	

PART IV: CLINICAL CHARACTERISTICS OF PATIENT WHILE ON ART FOLLOW UP PERIOD			
401	Eligible date for ART	[___/___/___]	
402	ARV eligibility criteria used	1. CD4 2. Clinical stage 3. Both WHO stage & CD4 4. Pregnancy 5. Test and treat all policy 6 Other: specify_____ 99.Missing	
403	ART initiation date	[___/___/___]	
404	Initial ARV regimen	1. 1a (30) =d4t (30)/3TC/NVP 2. 1a (40) =d4t (40)/3TC/NVP 3. 1b (30) =d4t (30)/3TC/EFV 4. 1b (40) =d4t (40)/3TC/EFV 5. 1c= AZT/3TC/NVP 6. 1d=AZT/3TC/EFV 7. 1e=TDF/3TC/EFV 8. 1f=TDF/3TC/NVP 9. 4c =AZT/3TC/NVP 10. 4d= AZT/3TC/EFV 11. others specify_____	
405	Current ARV regimen	1. 1c 2. 1d 3. 1e 4. 1f 5. 4c 6. 4d 7. 2nd line regimen (2a/2b/2c/2d) 8. Other: specify____ 99. Missed	
406	Recent ARV medication adherence	1. Good 2. Fair 3.Poor 99. Missing	

407	If fair or poor, reason for fair or poor adherence	1. Forgot 7. Toxicity/side effect 2. Share with others 8. Lost/run out of pills 3. Drug stock out 9. Stigma disclosure 4. Felt better 10.Inability to pay 5. Too ill 11. Alcohol 6. Delivery/travel problems 12. Depression 99. Other (specify)_____	
408	ARV drug side effects	1. Yes 2. No	
419	Regimen change	1. Yes 2. No	
410	Reason for regimen change	1. Toxicity/side effect 2. Pregnancy 3. Risk of pregnancy 4. Due to new TB 5. New drug available 6. Drug out of stock 7. Clinical failure 8. Immunological failure 9. Virological failure 10. Other (specify)_____	
411	Recent functional status	1. Working 2. Ambulatory 3. Bedridden 99. Missing	
412	Recent WHO staging	1. T Stage I 2. T Stage II 3. T Stage III 4. T Stage IV 99. Missing	
413	Current nutritional status	1. Normal 2. Moderate 3. Severe 4. Not done	
414	Taking CPT until last visit	1. Yes taking until last visit 2. Yes but now stopped 3. No 4. Other specify _____	

415	IPT provision while on HAART	1. Yes 2. No	
416	TB co infection while on HAART	1. Yes 2. No	
417	The most recent CD4 count while on ART	_____ [__/___/____]	
418	The most recent viral load result while he was on HAART	1. Not detected 2. Detected 3 Not done 99. Missing	
419	status of patient before tracing	1. Alive & on ART 2. Lost/Drop out 3. Transferred out 4. Dead	If 2 →**420** **421**
420	Lost date	[__/___/____]	
421	Total No. of visit from ART enrollment to lost	_____month/year	
422	Is patient tracked back	1. yes 2. No	If 1 →**423** If 2 →425
423	What was the final outcome after tracing	1. Alive 2. Dead 3. Unknown/confirmed lost	
424	If alive what was the reason of lost/drop	1. Self-transferred out 2. Having extra medication 3. Refill from other institutions 4. Religious/holy water 5. Promised to come back 6. Refuse to come 7. Other specify	
425	Reason why patient not tracked back	1. No telephone No. was mentioned in medical record 2. Unreachable with the mentioned phone No. 3. Other specify_____	
426	History of lost and restart while on ART follow up	1. Yes 2. No	If 1 →**427**
427	Date of first lost	[__/___/____]	
428	Last follow up date	[__/___/____]	
429	Last appointment date	[__/___/____]	

9.2. Appendix B: Curriculum Vitae (CV)

Personal profile

Name……Tenaye Abate Temesgen

Sex…….Female

Date of birth……1982

Birth place……..…. Babile

Marital status…….Married

Address ……. Dire Dawa

Nationality……Ethiopian

Cell phone……+251(091)304-60 50

E-mail …….tenayeabate@ymail.com

Professional Profile:

Since now I am working here in ICAP with the position of regional M&E officer at Harar regional office. I have been working as zonal project coordinator at SNNPR for the last two years. Since the transition time I provide technical assistance to the zonal health departments. Currently I have been delegated to assist Harari RHB in HIV/AIDS program area. So far I have been worked as regional nurse advisor and PMTCT/MNCH officer at CU-ICAP Ethiopia for five consecutive years at Dire Dawa, Harari, Somali and Oromia regions. When I was working in those regions I have been directly involved and responsible to provide technical assistance to the regional and zonal health bureau. I have also a professional experience and involvement in clinical system mentorship, joint supportive supervision, CAM, referral networking, perform training need assessment and other related activities.

Educational background

Academic year	**Name of the school**	**Educational level**
2015-2016	Haramaya University	MPH(candidate)
2010	Haremaya University	BSC nurse
2008	Harar health science college Haramaya university	Clinical nurse Accounting

1997	Harar Med. Comp. sec school	High school
1993	Babile elementary school	Elementary

Work experiences

	Position	**Region**	**Time Frame**
1	Regional M&E officer	Harar	2016 to present
2	Zonal project coordinator	SNNPR	2014-2015
3	ICAP Ethiopia as regional nurse advisor& PMTCT/MNCH officer	Dire Dawa	2011 to 2014
4	Facility HIV/AIDS coordinator	Dire Dawa	2008 to 2011

Trainings and skills

- Quality improvement training organized by SNNPR RHB and ICAP.
- TOT on HIV/AIDS clinical mentoring organized by FMOH/HPDPGD in collaboration with USAID, AED/FANTA-2 and WHO
- TOT on Clinical nutrition care for PLHIV organized by FMOH/HPDPGD in collaboration with USAID, AED/FANTA-2 and WHO
- District Coordinators on Comprehensive HIV Prevention, Care & Treatment Organized by DDRHB in collaboration with WHO
- Health management information system(HMIS) organized by Dire dawa RHB
- Long acting Family Planning Methods organized by Engender Health in Collaboration with DDRHB
- Basic adult ART training organized by Haramaya university in collaboration with Harari RHB and ICAP
- TB/HIV training organized by DDRHB in collaboration with ICAP
- TB infection control organized by DDRHB in collaboration with TB CAP and USAID.
- Nurse capacity initiative leader ship organized by ICAP
- PMTCT Option B+ organized by Dire dawa RHB and ICAP
- Provider initiative HIV counseling and testing(PITC)
- HIV/AIDS care and Pediatric ARV therapy training organized by DDRHB and ICAP
- Integrated management of New born and Child hood illness (IMNCI) organized by FMOH
- Computer applications (MS-Word, MS-Excel, MS-Access, MS-Power point)

Language

	Listening	Reading	Writing	Speaking
Amharic	Excellent	Excellent	Excellent	Fluently
English	Excellent	Excellent	Excellent	Very good
Oromic	Excellent	Excellent	Very good	Very good

Hobbies

- Travel
- Reading
- cooking

References

Bruck Getachew (MD)-CU-ICAP Ethiopia Regional Director, Dire Dawa

Mobile No.: +251(091)508-2501

E-mail:gbruck@yahoo.com

Getinet Abera (MD, MPH)- CDC Ethiopia Senior Technical Advisor Dire Dawa RHB

Mobile No.: +251(091)165-3362

E-mail:

Tekabe Abdosh (Internist)- CU-ICAP Ethiopia Regional Director, Harar

Mobile No.: +251(091)140-4990

E-mail: abdoshtekabe@gmailcom