COLLEGE OF MEDICINE AND HEALTH SCIENCES

SCHOOL OF PUBLIC HEALTH

INCIDENCE AND PREDICTORS OF LOSS TO FOLLOW-UP AMONG ADULTS ON ANTIRETROVIRAL THERAPY AT PUBLIC HEALTH FACILITIES IN HAWASSA, SIDAMA REGION, ETHIOPIA, 2024

RETROSPECTIVE FOLLOW UP STUDY

MPH THESIS

RUTH TESFAYE (BSc.)

JUNE, 2024

HAWASSA, ETHIOPIA

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RUTH TESFAYE (BSC)

A RESEARCH THESIS SUBMITTED TO THE SCHOOL OF PUBLIC HEALTH, COLLEGE OF MEDICINE AND HEALTH SCIENCE, HAWASSA UNIVERSITY

IN A PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF PUBLIC HEALTH IN EPIDEMIOLOGY

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JUNE, 2024

HAWASSA, ETHIOPIA

DECLARATION

I, Ruth Tesfaye, the undersigned, declare and affirm that this MPH thesis paper entitled "Incidence and Predictors of Loss to Follow-Up among Adult HIV Patients on Antiretroviral Therapy at Public Health Facilities in Hawassa, Sidama, Ethiopia. A Retrospective follow up study." is my own work. I have followed all ethical guidelines in the preparation, planning, data collection, analysis, and completion of this thesis. All scholarly matter that is included in the thesis has been given recognition through citation. I affirm that all sources used in this document have been cited and referenced. Every attempt has been made to prevent plagiarism in the preparation of this thesis. I solemnly declare that this thesis has not been submitted to any other organization anywhere for the award of any academic degree, diploma or certificate.

Name_____ Signature _____Date_____

This MPH thesis has been submitted with my approval as a thesis advisor.

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We the undersigned, members of the Board of Examiners of the final open defense by Ruth Tesfaye Fichala have read and evaluated her thesis entitled "INCIDENCE AND PREDICTORS OF LOSS TO FOLLOW-UP AMONG ADULTS ON ANTIRETROVIRAL THERAPY AT PUBLIC HEALTH FACILITIES IN HAWASSA, SIDAMA, ETHIOPIA. A RETROSPECTIVE FOLLOW UP STUDY" and examined the candidate, this is therefore, to certify that the thesis has been accepted in partial fulfillment of the requirement for the master's degree of MPH in Epidemiology.

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Final approval and acceptance of the thesis is contingent upon the submission of the final copy of the thesis to the school of graduate studies (SGS) through the department/ school graduate committee (DGC/SGC) of the candidate department.

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ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
BMI	Body Mass Index
CD4	Clusters of differentiation 4
CPT	Cotrimoxazole Prophylactic Treatment
Hgb	Hemoglobin
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
INH	Isoniazid
IRB	Institutional Review Board
LTFU	Lost to Follow up
MRN	Medical Registration Number
OI	Opportunistic Infection
PEP	Post-Exposure Prophylaxis
PLHIV	People Living With HIV/AIDS
PLWHA	People Living With HIV/AIDS
PrEP	Pre-Exposure Prophylaxis
PYs	Person Years
TB	Tuberculosis
UNAIDS	United Nations Program on HIV/AIDS
WHO	World Health Organization

ABSTRACT

Background: Despite significant progress in treatment and prevention, the global HIV/AIDS pandemic remains a serious threat to public health. HIV-related mortality and morbidity have greatly decreased as a result of ART, transforming HIV into a chronic, manageable condition. However, loss to follow-up hinders efforts to manage the HIV pandemic and is a substantial challenge.

Objectives: The objective of this study was to determine the incidence and predictors of loss to follow up among adults on ART in Hawassa, Sidama, Ethiopia 2024.

Methods: An institution-based retrospective follow up study was conducted. The study utilized data from four selected ART clinics, collected retrospectively on 459 study participants from September 11, 2018 to September 11, 2023. A simple random sampling technique was employed. Data were extracted from patients' charts and registration books using KOBO Toolbox and exported to SPSS for analysis. The incidence of LTFU was calculated using cumulative incidence and incidence density rates. Kaplan-Meier survival curves were employed, providing insights into LTFU patterns. Predictors of LTFU were determined using multivariable Cox proportional-hazard regression.

Result: A total of 459 participants were included in the study, contributing 1386 person-years of follow-up. The cumulative incidence of loss to follow-up (LTFU) was 16.6%, with an incidence density rate of 5.48 per 100 person-years [95% CI: 4.37- 6.86]. Significant predictors of LTFU included younger age groups (AHR 2.77, 95% CI: 1.06 - 7.19), lack of education (AHR 4.08, 95% CI: 1.34 - 12.43), WHO stage III (AHR 3.06, 95% CI: 1.04 - 8.99), WHO stage IV (AHR 4.64, 95% CI: 1.82 - 11.85), and being bedridden (AHR 3.63, 95% CI: 1.42 - 9.32). These factors were identified as significant predictors of LTFU in this cohort of ART patients in Hawassa, Ethiopia.

Conclusions: This study found that the incidence of LTFU was moderate relative to certain global and local findings. Age, education, WHO clinical stage, functional status and CPT treatment are found significant predictors of LTFU. These findings highlight the need for targeted interventions to address the specific challenges faced by the identified vulnerable groups.

Key-words: Loss to follow-up, ART, Predictors, HIV/AIDS, Hawassa, Ethiopia.

CHAPTER ONE- INTRODUCTION

1.1. Background

Antiretroviral therapy (ART) is a crucial strategy for the treatment and prevention of HIV. Although HIV infection cannot be cured, ART strengthens the immune system by inhibiting viral replication (1). Additionally, ART can prevent HIV transmission, as individuals without HIV can take ART medications to avoid infection. In high-risk situations, individuals may consider post-exposure prophylaxis (PEP) or pre-exposure prophylaxis (PrEP) (2). Timely access to ART and ongoing support during treatment are essential for improving the health of HIV-positive individuals and preventing further transmission (1). Despite significant advances in treatment and prevention, the global HIV/AIDS pandemic remains a serious public health threat (2). ART has substantially reduced HIV-related mortality and morbidity, transforming HIV into a manageable chronic condition (2). However, consistent participation in treatment programs is necessary to fully benefit from ART (3).

Regular follow-up is vital for monitoring treatment response and adherence, both of which are crucial for the effectiveness of ART (3). LTFU poses a major obstacle to managing the HIV pandemic (4). LTFU occurs when patients miss scheduled clinic visits for extended periods, jeopardizing their continuity of care (5). LTFU is problematic as it can lead to treatment failure and increased transmission risks (5). Factors contributing to patient disengagement include socioeconomic challenges, health system barriers, and stigma (4, 6).

The global distribution of LTFU varies, with higher rates often observed in low- and middle-income countries due to socioeconomic challenges, inadequate healthcare infrastructure, and pervasive stigma (7). In Ethiopia, the ART scale-up has been notable, with a significant increase in the number of patients receiving treatment. Nevertheless, LTFU remains a challenge, with rates varying widely across different studies and regions within the country (8, 9, 10).

Reducing LTFU is critical for the success of ART programs and for controlling the HIV pandemic on a global scale (11).

1.2. Statement of the problem

HIV/AIDS significantly impacts daily life for many people worldwide, with approximately 39 million individuals living with the virus, at the end of 2022, two thirds of whom (25.6 million) are in the WHO African Region (2). At the end of December 2022, 29.8 million people (76% of all people living with HIV) were accessing antiretroviral therapy, up from 7.7 million in 2010 (12). The successful management of Human Immunodeficiency Virus (HIV) with antiretroviral therapy (ART) is contingent upon patient retention and adherence to treatment regimens (13). Loss to follow-up (LTFU) is a significant impediment within HIV care programs, leading to detrimental outcomes such as increased HIV-related morbidity, mortality, and the potential spread of drug-resistant HIV strains (9).

A critical challenge to the success of ART programs in Africa is the low retention rates (5). A systematic review revealed that only 64% of patients who started ART in sub-Saharan Africa remained in care after three years (5). A study done in South Africa, indicated that 71% remained in care after 24 months and 59.6% after 48 months, with an increasing proportion lost to follow-up (14). LTFU is the most common cause of attrition, followed by death, which is often underreported (5).

In Ethiopia, where the HIV pandemic remains a major public health concern, the phenomenon of LTFU poses a substantial challenge to the national response to HIV/AIDS (15). Recent evidence from Ethiopian studies indicates that LTFU rates are alarming, with one study documenting a cumulative incidence of 40.8% among adults in Amhara Northwest Ethiopia (9). Similar trends are observed in other populations, where cumulative incidence has been reported to be 20.62% in South Gondar (16). These statistics underscore the urgency to address LTFU.

As ART programs expand, LTFU presents a significant challenge for countries like Ethiopia. Various factors contribute to LTFU, including demographic, clinical, socioeconomic, and behavioral dimensions (17). Younger age, being unmarried, and a low baseline BMI are demographic risk factors for LTFU (18). Clinically, patients with high viral loads at ART initiation and those experiencing treatment side effects are more likely to drop out (19, 20). Socioeconomic challenges and poor medication adherence further increase LTFU risk (4).

The consequences of LTFU are severe. Patients who miss ART appointments risk uncontrolled viral replication, increased susceptibility to opportunistic infections, and ultimately, higher mortality rates (2). Additionally, LTFU impairs program effectiveness by obstructing accurate monitoring of HIV treatment success and affecting efforts to control the pandemic at the population level (21).

While existing research offers some insights, further studies are needed to fully understand the specific factors influencing LTFU in Hawassa. This includes confirming the local relevance of previously identified factors. Additionally, exploring the influence of social determinants of health on treatment adherence in Hawassa is crucial. Furthermore, investigating the long-term impact of the recently implemented "treat-all" strategy on LTFU rates in Hawassa is important.

So this study has determined the incidence and predictors of LTFU among a cohort of HIV-infected patients on ART over five years in Hawassa. The findings help to inform strategies to reduce ART program dropout rates and aid healthcare workers and program managers in developing effective interventions. It also is essential to optimize program design and resource allocation.

1.3. Significance of the Study

LTFU during ART remains a major challenge in achieving successful HIV treatment outcomes, particularly in resource-limited settings like Ethiopia. There is significant importance in studying the incidence and determinants of LTFU among adults receiving ART at public health institutions in Hawassa, Ethiopia.

This study aims to understand the magnitude of the problem by estimating the incidence rate of LTFU among adult HIV patients attending different ART clinics in Hawassa. This data is crucial for quantifying the local impact of LTFU. With this knowledge, we can tailor initiatives to effectively address the LTFU issue within the Hawassa community.

Simply knowing the incidence of LTFU is not enough so it proceeds ahead to identify the predictors of LTFU among patients. By examining socio-demographic, clinical, and other factors, the study has uncovered the underlying reasons why patients fall out of care. Unmasking these predictors allows us to design targeted interventions that address the specific challenges faced by different patient groups, ultimately improving adherence, and reducing LTFU.

The findings of this study hold valuable potential for impacting both local and national LTFU reduction strategies.

Data regarding lost to follow-up are scarce in the area, and not that many studies have been conducted regarding the incidence rate or risk factors of LTFU following the start of ART around Hawassa. So by conducting this research, this retrospective follow up study has contributed in closing this crucial gap. Healthcare professionals, legislators, and program implementers will find great value in the study's conclusions as they work to enhance the region's HIV care continuum and HIV-positive population's health outcomes. It also has provided a baseline data and paved the way for future study.

CHAPTER TWO- LITERATURE REVIEW

2.1. Overview of Loss to Follow up

In the struggle against HIV/AIDS, the development of ART has been a crucial turning point (2). ART reduces HIV-related morbidity and mortality and stops the virus from progressing into AIDS by blocking HIV replication (2). In 2022 alone, an estimated 29.8 million lives were saved due to ART access, showcasing its life-saving potential (12). However, LTFU in HIV care remains a fundamental problem that jeopardize treatment results and efforts to stop the virus from spreading (22).

LTFU refers to patients who discontinue taking their antiretroviral medication (23). LTFU may result in an increase in viral load, raising the risk of opportunistic infections, the development of AIDS, and subsequent transmission (24). Larger-scale, LTFU interferes with HIV control initiatives by making it more difficult to track viral suppression and fueling the development of medication resistance (24). A lack of social support, accessibility issues, and stigma are a few of the factors that lead to LTFU (23). According to studies done by the WHO, maintaining enrollment in HIV treatment is crucial to attaining viral suppression and stopping the virus's global spread (25).

Ethiopia has implemented tactics like combining ART treatments with other health services and decentralizing ART services to health posts and clinics closer to patients' homes to tackle LTFU (26).

LTFU is a complex issue that requires context-specific solutions to deal with the various obstacles that patients encounter (23). Maintaining the progress gained in the battle against HIV/AIDS requires unique approaches and ongoing observation (23).

2.2. Incidence of Loss to Follow Up

The incidence of LTFU in HIV care exhibit notable regional and contextual variations (27). Estimates indicate that by the third year of ART, over 30% of patients will be LTFU, which poses a significant problem to the management of HIV worldwide (27). According to a 10 year retrospective study conducted in Asia, 9% of HIV-positive individuals who underwent ART experienced a loss to follow-up (28). The percentage of cases that were lost to follow-

up varied across settings. A retrospective cohort study in South Africa (29) and a 5-year retrospective cohort study in a hospital in southern Nigeria (30) found 16.4% and 28%, respectively. According to the retrospective research conducted in Nigeria, the incidence rate of treatment interruption peaked at 18.2/100 PYs during the first six months of ART then fell to 8.8/100 PYs (30). LTFU from treatment increased by 1.30 times for each calendar year in the study in South Africa (29). LTFU rates within the first year of ART initiation have been reported to range from 15% to 40% in sub-Saharan Africa, the region with the highest HIV burden (4). A five-year retrospective follow-up from public sector HIV treatment clinics in sub-Saharan Africa found that 24.6% of patients were LTFU (17).

According to a retrospective cohort study undertaken using 542 HIV patients from January 1, 2008, to December 30, 2017, at Bichena Health center the cumulative incidence of LTFU among adults in the Amhara Region of Northwest Ethiopia is 40.8%, suggesting that the rates are worrisome (8). In a multi-facility-based retrospective follow-up study conducted in south Gondar governmental hospitals, from September 11, 2017–September 10, 2022, the cumulative incidence was found to be 20.62% and the incidence rate of LTFU was 6.7/100 PYs (16). A case-control study conducted at Wukro primary Hospital in Tigray Region showed 11% of LTFU (31), and an unmatched case–control study conducted in randomly selected ART service delivery institutions from February 2015 to April 2015 in Oromia Region showed incidence was 21.3% (32). According to the retrospective study conducted from January 2012–December 2016 the overall cumulative incidence of LTFU was 11.6/100 adult-years at Pawi General Hospital in Ethiopia (33). 8.2/100 PYs in a retrospective cohort study conducted in Aksum St. Marry Hospital (34), and 12.26/100 PYs in a retrospective follow up study conducted from January 2012 to January 2018 at Gondar Specialized Comprehensive Hospital in Ethiopia (35). The incidence density rate of lost to follow up among HIV positive adults on ART was found to be 8.9 per 100 adult years observation in a retrospective follow up study conducted at North Shewa zone, public hospitals between 2015 and 2020 (36).

2.3. Predictors of Loss to Follow Up

2.3.1. Socio-Demographic Factors

Sociodemographic factors are crucial in predicting LTFU among individuals undergoing ART for HIV/AIDS globally (18). In a systematic review done from January 1, 2000, to December 31,2012 younger individuals were more prone to LTFU due to factors such as stigma and a sense of well-being despite the infection (18), while men are less likely to remain in care, possibly due to later presentation for treatment and lower healthcare utilization according to a cohort study conducted in Khayelitsha, South Africa (37). A Systematic Review and Meta-analysis done in low- and middle-income countries showed being single is associated with higher LTFU rates, potentially due to the lack of a supportive partner, and those from lower socioeconomic backgrounds face financial barriers to accessing care, increasing their LTFU risk (4). Similarly, in Ethiopia An unmatched case–control study conducted in randomly selected ART service delivery institutions in Oromia region and a Systematic Review and Meta-analysis done in low- and middle-income countries showed, young people, particularly men and single individuals, face higher LTFU rates due to cultural and economic challenges, such as stigma and work prioritization over health (4, 32). Sex and marital status were identified as the major predictors of LTFU in an institution-based cohort study conducted on adults enrolled in Bahirdar hospital ART clinic (38). Several studies like the unmatched case–control study conducted in Oromia have identified key predictors of LTFU, which includes lower educational levels (32). Specifically, patients with no formal education are at a higher risk of LTFU, possibly due to difficulties in understanding treatment instructions and recognizing the importance of ART drug adherence (32, 39). The 5-year retrospective study done in Arbaminch general hospital has showed treatment attrition was more common among younger persons and among those living in rural regions (40).

2.3.2. Clinical factors

Clinical variables serve as significant predictors of LTFU in HIV/AIDS patients, encompassing the disease stage at diagnosis, OIs, ART side effects, and concurrent medical conditions (41). A Longitudinal analysis done in Canada showed advanced disease stages and AIDS-defining illnesses often correlate with a higher likelihood of LTFU, as the

severity and complex treatment regimens can overwhelm patients (19). A Collaborative analysis of prospective studies done in South Africa, Europe, and North America showed ART side effects can lead to treatment discontinuation without medical advice, increasing the risk of LTFU (41). Moreover, A Systematic Review and Meta-analysis done on 8 RCTs that are conducted in Africa, Asia, and the United States identified comorbidities like TB and hepatitis intensify the complexity of managing HIV, potentially resulting in missed appointments and care disengagement (42). In Ethiopia, in a hospital based cross-sectional study that is conducted at University of Gondar Referral Hospital in 2017 and in a prospective cohort study conducted in Oromia region between 2012 and 2013 similar patterns are observed, with late-stage HIV at ART initiation, prevalent OIs like TB, and the challenges of managing ART side effects and comorbid conditions, including mental health disorders, influencing LTFU rates (20, 43).

An observational retrospective cohort study from 2008 to 2014 done in Kenya showed patients with lower CD4 counts, advanced WHO clinical stages, are more likely to be lost to follow-up (39). In a multi-site, prospective, observational cohort study of adult, age > 18 years, started in the national ART program at seven university-affiliated hospitals from January 2009 - July 2013 showed the presence of comorbidities, particularly tuberculosis, has also been associated with an increased risk of LTFU, suggesting that integrated care models may improve retention (44). In contrast to other studies, a retrospective study conducted in Mizan-Aman General Hospital Patients with advanced clinical stage (III and IV) at entry were less likely to be lost to follow-up and TB co-infection was not associated with LTFU (11). Enhanced clinical management, patient support, and service integration are crucial to improve care retention and outcomes for HIV/AIDS patients (39).

2.3.3. Treatment- related factors

Treatment-related factors such as complex ART regimens, high pill burden, drug interactions, and medication side effects play a significant role in LTFU among HIV/AIDS patients (19). A Longitudinal Analysis done in Canada showed the complexity and strict scheduling of ART can lead to non-adherence and increased LTFU risk, while a high number of pills can deter patients from sticking to their treatment, with simplified, once-daily dosing shown to be beneficial (19). Interactions between ART and other medications

can cause toxicity or reduced efficacy, discouraging patients from continuing treatment, and side effects from medications are a common reason for patients to stop treatment (45). In Ethiopia, in a hospital based cross-sectional study that is conducted at University of Gondar Referral Hospital in 2017 and in a retrospective cohort study conducted on patients attending ART clinic at public health facilities in Arba Minch town, southern Ethiopia, it has been showed the challenges of treatment-related factors are compounded by the healthcare system and medication availability, with complex regimens and high pill burden hindering adherence, and drug interactions and side effects from ART leading to LTFU, especially where alternative treatments or support are lacking (20, 46). Time to ART initiation and ART drug adherence level were identified as the major predictors of LTFU in a study conducted on adults enrolled in ART in Felegehiwot Comprehensive Specialized Hospital (38). The 5-year retrospective study done in Arba Minch general hospital has shown treatment attrition was more common among those with fair to poor adherence (40). Enhancing patient retention in care therefore requires a focus on education, regimen simplification, and side effect management (19).

2.3.4. Functional and Nutritional Status

Functional and nutritional status are critical indicators of LTFU in HIV/AIDS patients, with low functional levels and malnutrition impacting ART effectiveness and health outcomes (47). In a pre-post pilot study of peer nutritional counseling and food insecurity and nutritional outcomes among antiretroviral therapy patients in Honduras, Malnutrition, common in low and middle-income countries, is linked to increased LTFU risk due to its effect on the immune system and potential worsening of the disease, leading to treatment discontinuation (48). Similarly, A systematic review done on Exercise and mental health of people living with HIV in 2017 showed poor functional status correlates with lower clinic attendance and treatment adherence, often due to physical or psychological barriers (49). In Ethiopia, malnutrition is a pressing issue, with undernourished HIV patients being more prone to LTFU; hence, nutritional support programs have been established to aid in improving adherence and reducing LTFU (50). Treatment attrition was more common among those with baseline weights over 60 kg (40). Additionally, impaired functional

status can hinder access to healthcare, especially in remote areas, necessitating interventions to enhance mobility and support during clinic visits (49).

2.3.5. Support and Family Conditions

Patients' adherence to ART and retention in HIV care are significantly influenced by support and family dynamics. Social support whether from friends, family, or community networks is a critical component in lowering LTFU (51).

Given Ethiopia's cultural background, where family and community are extremely important in people's lives, the need of support and family circumstances is even more apparent (51). A prospective cohort study conducted in Oromia region, Ethiopia showed the impact of family conditions, such as having family members who are also HIV positive, can influence retention in care (43). It also has shown families affected by HIV may face compounded stigma and financial burdens, which can lead to LTFU if not adequately addressed by support programs (43). Disclosure status was identified as the major predictor of LTFU in a study conducted on adults enrolled in ART in Felegehiwot Comprehensive Specialized Hospital (38).

Healthcare professionals and legislators must put policies in place to increase patient retention in care. Some of these strategies include tracking down and monitoring patients who disappear from follow-up and offering focused interventions to address the root causes of the disappearance (52). To sum up, among people living with HIV, loss to follow-up is a fundamental problem that must be addressed. To gain a better understanding of the incidence and predictors of loss to follow-up among adults living with HIV in various contexts and communities, more research is required.

2.4. Conceptual framework

This conceptual framework is developed after revision of various literatures. Broken arrows mean there might be an association between those variables but that is not in the interest of the principal investigator.

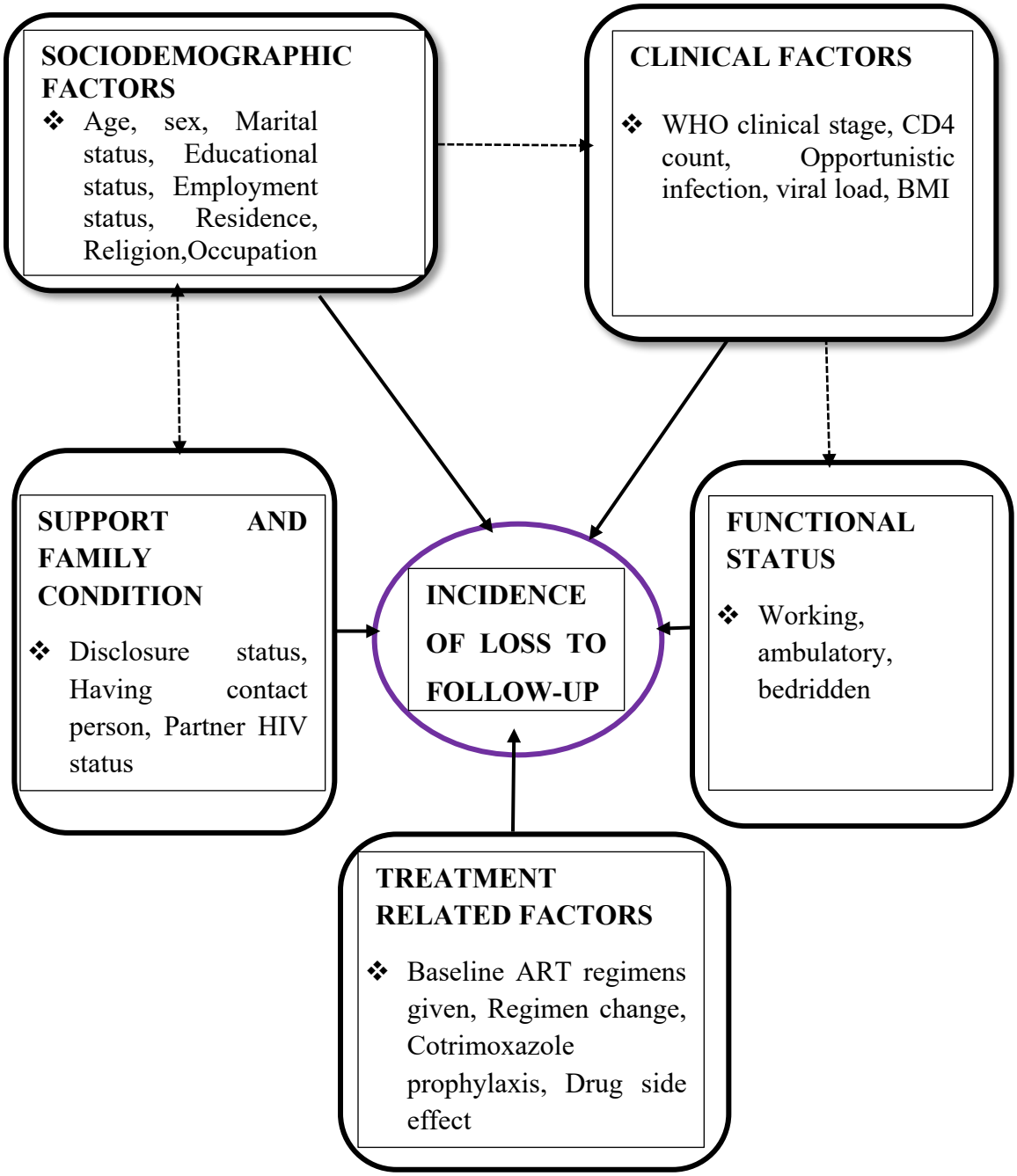

Figure 1: Conceptual framework showing possible predictors lost follow up among PLWHA in Hawassa, Sidama, Ethiopia (18, 19, 41, 49, 51).

CHAPTER THREE- OBJECTIVES

3.1. General objective

- To determine the incidence and predictors of loss to follow-up among adults on antiretroviral therapy in Hawassa, Sidama, Ethiopia.

3.2. Specific objectives

- To determine the incidence rate of loss to follow-up among adults on antiretroviral therapy attending different ART clinics in Hawassa.
- To identify predictors of LTFU among adults on antiretroviral therapy.

CHAPTER FOUR- METHODOLOGY

4.1. Study area and period

The study was conducted in Hawassa City, Sidama Regional State, Ethiopia. Hawassa is located at 273 km from Addis Ababa, the capital city of Ethiopia. The city is serving as the capital of Sidama region. The city administration is divided into 8 sub-cities and 32 kebeles. There are 4 governmental hospitals and 12 health centers. The study has collected data from 4 different ART clinics in selected facilities that are found in Hawassa, between September 2018 and September 2023. The selected facilities were Hawassa University Comprehensive Specialized Hospital, Adare Hospital, Millennium Health center and Hawella Tulla General Hospital.

4.2. Study design

This research employed an institution-based retrospective follow up study design to investigate the incidence and predictors of loss to follow-up among adult HIV patients on ART from 2018-2023 at selected public health facilities in Hawassa, Sidama, Ethiopia.

4.3. Population

4.3.1. Source Population: All adult HIV patients (18 years and above) receiving ART that were registered in the four selected antiretroviral therapy (ART) clinics found in Hawassa, Ethiopia.

4.3.2. Study population: Adult HIV patients (18 years of age and older) who started antiretroviral therapy at one of the public health institutions in Hawassa, Sidama, between September 11, 2018, and September 11, 2023, has made up the study population.

4.4. Inclusion and Exclusion Criteria

4.4.1. Inclusion Criteria

- Adult HIV patients (18 years and above)

- Patients enrolled in and receiving ART at the selected public health facilities in Hawassa, Sidama, Ethiopia, who was registered from September 11, 2018 to September 11, 2023.
- Patients who initiated ART at least 6 months prior to the start of the study period (to allow for initial follow-up and stabilization) had been included in the study.

4.4.2. Exclusion Criteria

- HIV positive adult patients, with incomplete data and missing medical files were excluded from the study.

4.5. Sample size Determination

The sample size was determined using double population proportion formula by considering CD4 as the major predictor variable considering the following assumptions: CI 95%, power 80%, the proportion of exposed (CD4<200) 7.29% (36), the proportion of non-exposed (CD4≥200) 15.97% (36), and assuming non-response rate of 10% a sample size of 464 was computed. Epi info version 7.2 statistical package was used to calculate sample size.

Table 1: Sample Size Determination

Parameter	**Value**	**Representation**	**Description**
Formula		**$n = ((Z\alpha/2)\sqrt{[(1+1/r)\ p1(1-p1)]} + Z\beta\sqrt{[p1(1-p1) + p2(1-p2)/r)]} / (p1-p2)^2$**	
N	422	$n = ((1.96)\sqrt{[(1+1/0.174)\ 0.0729(1-0.0729)]} + (0.84)\sqrt{[0.0729(1-0.0729) + 0.1597(1-0.1597)/0.174]} / (0.0729-0.1597)^2$	Initial sample size (without non-response adjustment)
Non-response rate	10%	-	Expected proportion of participants who will not respond

Adjustment factor	42.2	**0.10 * n** 0.10 * 422	Number of additional participants needed to compensate for non-response
Adjusted sample size	464	**n + (0.10 * n)** 422 + 42.2	Final sample size required to achieve desired power and account for non-response (rounded up)

Where:

- n = required sample size
- Zα/2: Critical value for the desired confidence level (e.g., 1.96 for 95% CI).
- Zβ: Critical value for the desired power (e.g., 0.84 for 80% power).
- p1 = proportion of exposed group (CD4<200) = 0.0729
- p2 = proportion of non-exposed group (CD4≥200) = 0.1597
- r: Ratio of the sample sizes in the two groups (n1/n2).

4.6. Sampling procedures

The estimated sample size was proportionally allocated to the ART clinics in the selected four hospitals according to their total population and the data were collected by simple random sampling. The medical registration number (MRN) of patients on ART was taken from the ART clinic log-book. A computer generated random number for simple random sampling technique was employed to select participants into the study. Finally, by proportional allocation 230 records of patients on ART from Adare general hospital, 111 records of patients on ART from Hawassa Referral Hospital, 101 records of patients on ART from Millennium health center and 22 records of patients on ART from Tulla general hospital were selected. Medical records of patients on ART attached to selected MRN were reviewed, and those records that met the eligibility criteria were included in the analysis.

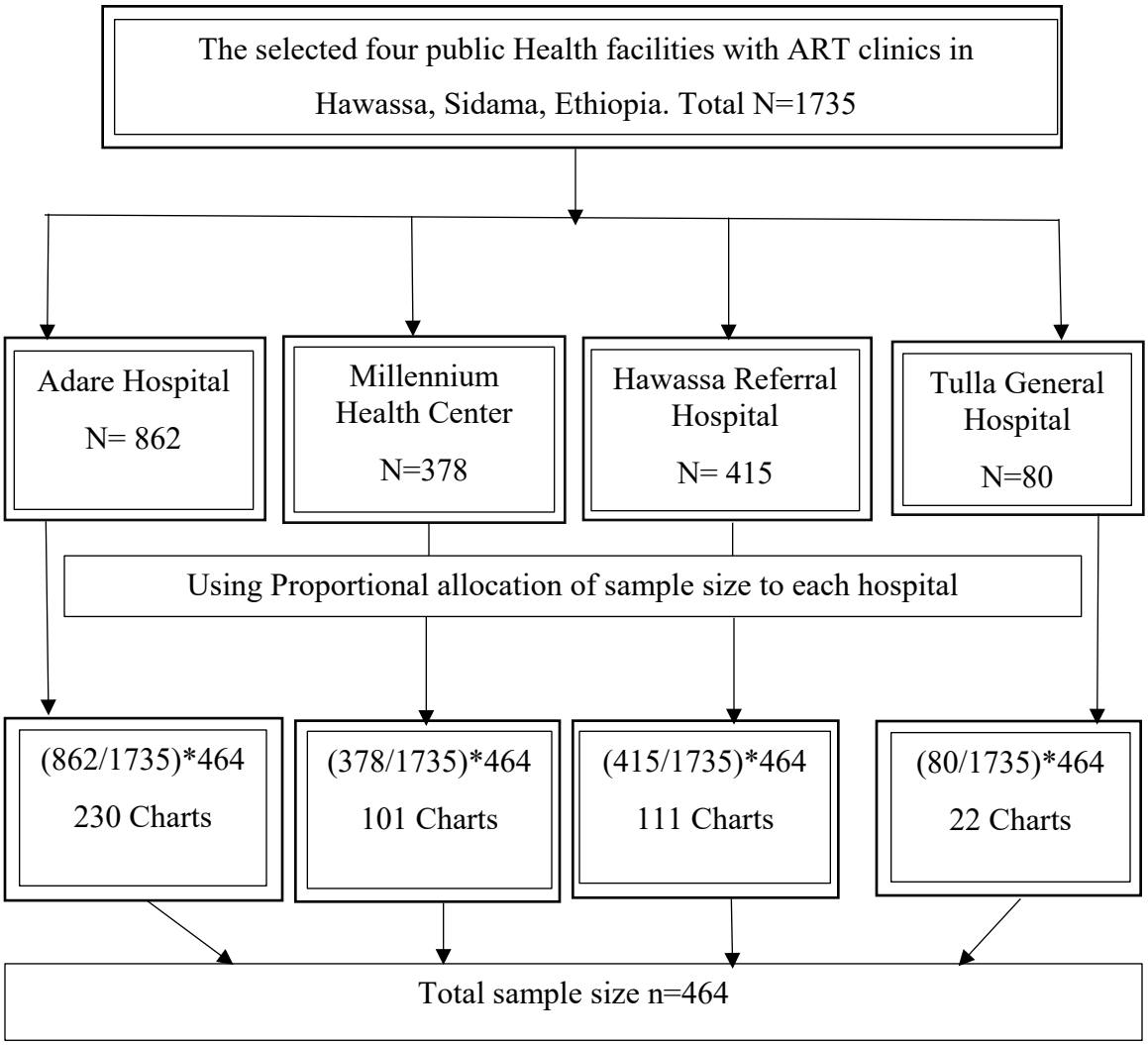

Figure 2: Diagram of Sampling procedure

4.7. Study Variables

4.7.1. Dependent variable

- Loss to follow-up (LTFU) among adult HIV patients on Antiretroviral Therapy.

4.7.2. Independent variables

- Socio-demographic factors (e.g., gender, educational status, occupation, age, marital status)
- Baseline clinical factors (e.g., Presence of OI, CD4, WHO clinical stage, viral load, functional status)

- Treatment-related factors (e.g., ART regimen and adherence, OI prophylaxis (INH and CPT), ART regimen change)
- Support and family condition- (e.g., Disclosure status, Having contact person, Partner HIV status)

4.8. Data collection methods and procedures

Data collection procedure: Data were collected by health professionals who are working in the selected ART clinics using structured data abstraction material from patients' cards and registers at the selected ART clinics in Hawassa, Ethiopia.

Data Source: The data for this research was secondary data recorded routinely in the hospital for clinical monitoring and evaluation purposes which are follow-up medical records during the follow-up time ART.

Patient intake forms, follow-up cards, and ART registers were used as data sources. Other clinical information including laboratory test results were used to collect the CD4 cell counts. MRN was used to identify individual patient cards.

Socio-demographic characteristics, baseline and follow-up clinical and laboratory data, and the primary outcome variable (LTFU) from ART follow-up care after initiation of treatment, confirmed by reviewing medical registration at the hospital, noted by ART adherence supporters was collected from patient cards.

Data recording was started from the date that patients started regular HIV care in the clinic until the end of the study to the confirmation of the final event in the study period was extracted by data abstraction material by trained personnel.

4.9. Data quality control

To ensure the quality of data, data collectors were health professionals who are working in the selected ART clinics. Training was given on the objective of the study, how to review documents as per the structured checklist for records review and on the method of extracting the needed data from patient's records and how to fill the extracted data on kobo

collect. Pretest was carried out for consistency of understanding of tools and completeness of data and modification was taken according to the findings. There was strict oversight and monitoring during the data collection period.

4.10. Data analysis plan and statistical methods

Data was exported to SPSS version 26 for further analysis. The information was summarized using descriptive statistics. Patient characteristics were described using frequency tables for categorical variables like sex and marital status, while measures of central tendency (mean, median) and dispersion (standard deviation, interquartile range) were summarized for continuous variables like age and CD4 count. Cumulative incidence (proportion experiencing LTFU by a specific time) and incidence density rate (average risk per person-time) of LTFU were used to calculate the incidence of LTFU. Kaplan-Meier curves were utilized to visually depict and compare the probability of remaining in follow-up over time across different groups providing insights into LTFU patterns. Survival analysis method was used to model the time to LTFU and estimate hazard ratios for different factors. Multivariable cox proportional-hazard regression was used to determine the predictors of loss to follow up after initiation of ART among HIV positive adult patients. Both Crude Hazard Ratio (CHR) and Adjusted Hazard Ratio (AHR) were estimated with their 95%CI to quantify the strength of association between predictors and the risk of LTFU, while adjusting for other covariates. Model fitness check, Schoenfeld residuals and tests were used to assess the proportional hazards assumption in the Cox model and in the overall model fitness, Likelihood ratio tests and score tests, were used to assess the overall fitness. Those variables with $p< 0.25$ in the univariate regression model were entered into the multivariate model. Then, variables statistically significant ($p<0.05$) in the final model were considered as independent predictors of LTFU among the study participants. The result is presented by using texts, tables, charts, and graphs.

4.11. Operational definitions

- **Lost to follow-up (LTFU):** An adult HIV patient (18 years and above) receiving ART at a public health facility in Hawassa, Sidama, Ethiopia, is considered LTFU if they meet the following criteria:

- Absence of contact with the healthcare system for a continuous period of three months or more since their last scheduled appointment without documented evidence of transfer out, death, or treatment completion during the three-month period or any time before.

❖ **Time to Lost to Follow-up** is the time interval between the date of ART initiation at the study clinic and the date on which the patient is confirmed LTFU according to the above definition. It is calculated by subtracting the date of ART initiation from the date the patient is confirmed LTFU.

❖ **Event:** The specific event of interest in this study is LTFU from the ART clinic within the study period (September 11, 2018, to September 11, 2023). This event signifies the point at which a patient no longer receives routine care at the study clinic for more than the defined LTFU duration.

❖ **Death:** A patient is considered deceased if their death is confirmed by a physician through medical records or documented communication with family members. Additional documentation such as death certificates may be used for verification if available.

❖ **Transferred out**: A patient is considered transferred out if they are officially documented as transferring to another healthcare facility for continued ART treatment. Documentation of transfer should include details of the receiving facility and confirmation from the receiving facility if possible.

❖ **Transfer in:** A patient is considered transferred in if they are formally documented as transferring from another healthcare facility and entering the study clinic for ART treatment. Documentation of transfer should include details of the referring facility and their ART history if available.

❖ **Censored:** A patient is censored if they have not experienced the event of LTFU by the end of the study observation period (September 11, 2023) and their follow-up status is known up to a certain point. This includes patients who:

- Completed the ART course.
- Transferred to another healthcare facility.
- Remained in regular follow-up without experiencing LTFU.

- The specific date of censoring for each individual should be recorded, based on the last date their follow-up was confirmed.

4.12. Ethical considerations

Ethical clearance letter was obtained from the Institutional Review Board (IRB) of Hawassa University College of Medicine and Health Sciences. In addition, support letter was obtained from Sidama National Regional State, Hawassa City Administration Health Department for each health facility. Confidentiality of patient information was maintained throughout the study. Patient data was anonymized or de-identified to uphold confidentiality and privacy. The study prioritized minimizing harm by justifying the research's potential benefits. Medical record number was recorded rather than the patient's name. Written informed consent was taken from the hospital manager for accessing the medical records of patients on ART. No attempts were made to contact participants for further evaluation. Data sharing is governed by agreements, and findings will be openly accessible for maximized benefit.

CHAPTER FIVE- RESULTS

5.1. Socio demographic characteristics

A total of 459 participants were included in the study the response rate being 98.9% for 5 year observation with median follow up time of 2.79 years, IQR 2.95. One-third 157 (34.2%) were age between 25-34 years and majority 260 (56.6%) were females. Most of (41.2%) the participants completed secondary education while nearly half 211 (46%) were married and majority 230 (54%) were daily laborer/self-employed/merchants in occupation.

Table 2: Socio-demographic characteristics, patients on ART in Hawassa, Ethiopia, 2018-2023.

Socio demographic characteristics	**Frequency**	**Percentage**
Age		
18-24	61	13.3
25-34	157	34.2
35-44	128	27.9
>44	113	24.6
Sex		
Female	260	56.6
Male	199	43.4
Residency		
Rural	50	10.9
Urban	409	89.1
Education		
No formal education	84	18.3
Primary school	122	26.6
Secondary school	189	41.2
Higher education	64	13.9
Marital status		
Single	118	25.7
Married	211	46.0
Widowed	63	13.7
Divorced	67	14.6
Occupation		

Government Employee	69	16.3
Daily laborer/self-employed/merchant	230	54.2
Students	7	1.7
Unemployed	81	19.1
Sex worker	29	6.8
Others	8	1.9

5.2. Clinical and follow up characteristics

More than one-fourth 131 (28.5%) had experienced opportunistic infections (OIs); of which more than half 73 (55.7%) had tuberculosis which was the most prevalent type of OI. Most of the study subjects 295 (64.3%) were classified as WHO stage I, and WHO stage IV accounts for 49 (10.7%). Regarding CD4 count, the largest group 164 (37.3%) had counts between 250-500 cells/mm3. And viral load was undetectable in the vast majority 376 (93.1%) of individuals. Moreover, most study subjects 366 (79.7%) functional status was working, while 65 (14.2%) were ambulatory and bedridden 28 (6.1%). Regarding support and disclosure, 272 (59.3%) had a contact person and 304 (66.2%) had unknown partner HIV status.

Table 3: Clinical and follow up characteristics, ART patients, Hawassa, 2018-2023.

Clinical and follow up characteristics	**Frequency**	**Percentage**
Opportunistic infections(OIs)		
No	328	71.5
Yes	131	28.5
Type of Opportunistic Infection		
Herpes Zoster	21	16.0
Tuberculosis	73	55.7
Pneumonia	21	16.0
Oral thrush	10	7.6
Others	6	4.6
WHO Stages		
Stage I	295	64.3
Stage II	52	11.3
Stage III	63	13.7
Stage IV	49	10.7
CD4 count (cells/mm3)		

<250	136	30.9
250-500	164	37.3
>500	140	31.8
Viral Load		
Undetectable	376	93.1
High	28	6.9
Functional status		
Working	366	79.7
Ambulatory	65	14.2
Bed ridden	28	6.1
Have contact person		
No	187	40.7
Yes	272	59.3
Disclosure status		
No	272	59.3
Yes	187	40.7
Partner HIV status		
Negative	32	7.0
Positive	123	26.8
Unknown	304	66.2

5.3. Treatment related characteristics

The majority 399 (86.9%) of individuals were on the ART regimen 1J, and 411 (89.5%) had not experienced regimen changes, thus, only 48 (10.5%) had regimen changed, the main reasons were changing to a new drug per instructions 26 (54.1%) and drugs being out of stock 19 (39.6%). Cotrimoxazole (CPT) treatment was received by 171 (37.3%) of patients. Regarding ART side effect, only 19 (4.1%) of cases were experiencing the side effects.

Table 4: Treatment related characteristics, among ART patents, Hawassa, Ethiopia, 2018-2023.

Treatment related characteristics	**Frequency**	**Percentage**
ART Regimen		
1E (TDF-3TC-EFV)	44	9.6
1J (TDF+3TC+DTG)	399	86.9

Other	16	3.5
Regimen change		
No	411	89.5
Yes	48	10.5
The reason for change		
Change by instruction (new drug)	26	54.1
Drugs out of stock	19	39.6
Other	3	6.3
Cotrimoxazole (CPT) treatment		
No	288	62.7
Yes	171	37.3
Isoniazid (INH) prophylaxis		
No	121	26.4
Yes	338	73.6
ART side effect		
No	440	95.9
Yes	19	4.1

5.4. Loss to follow up and Survival status

The cohort contributed a total of 1386 person-years of follow up with 76 failure and providing loss to follow-up rate of 5.48 [95% CI: 4.37, 6.86] per 100 person years observation. Out of 459 study subjects, 76 (16.6%) lost the follow-up and a 40 (8.7%), were transferred out to other facilities, while 21 (4.6%) of individuals died during the study period. (Figure 3)

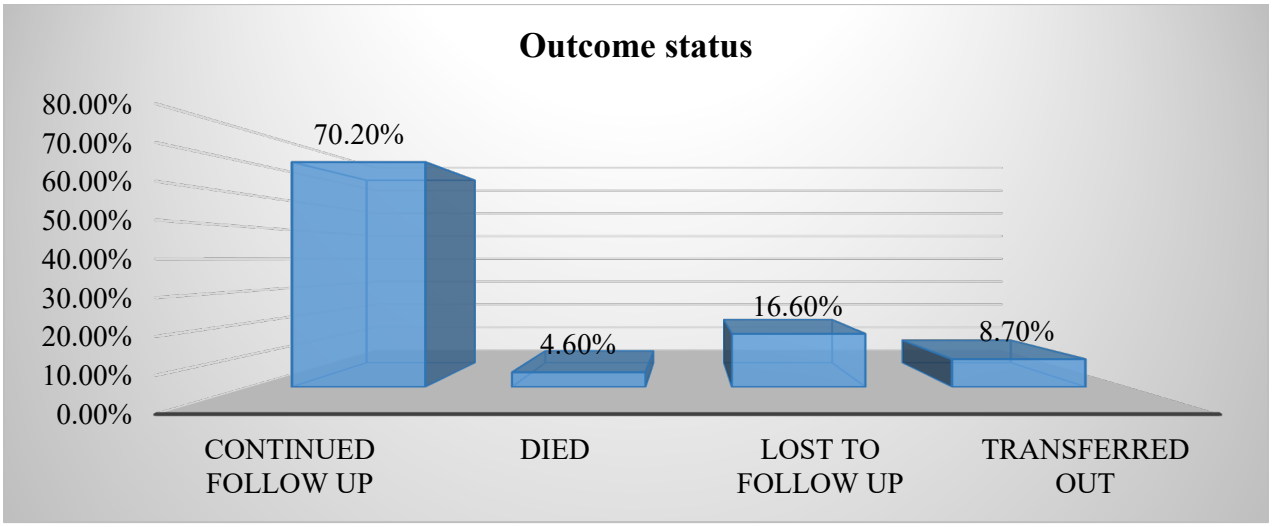

Figure 3: Outcome status, among ART patents, Hawassa, Ethiopia, 2018-2023.

5.5. Kaplan-Meier analysis

The mean survival duration was 8.638 years, 95% CI, [7.996, and 9.280]. Kaplan-Meier survival estimation showed that overall estimated survival duration after ART initiation was 10.87 years.

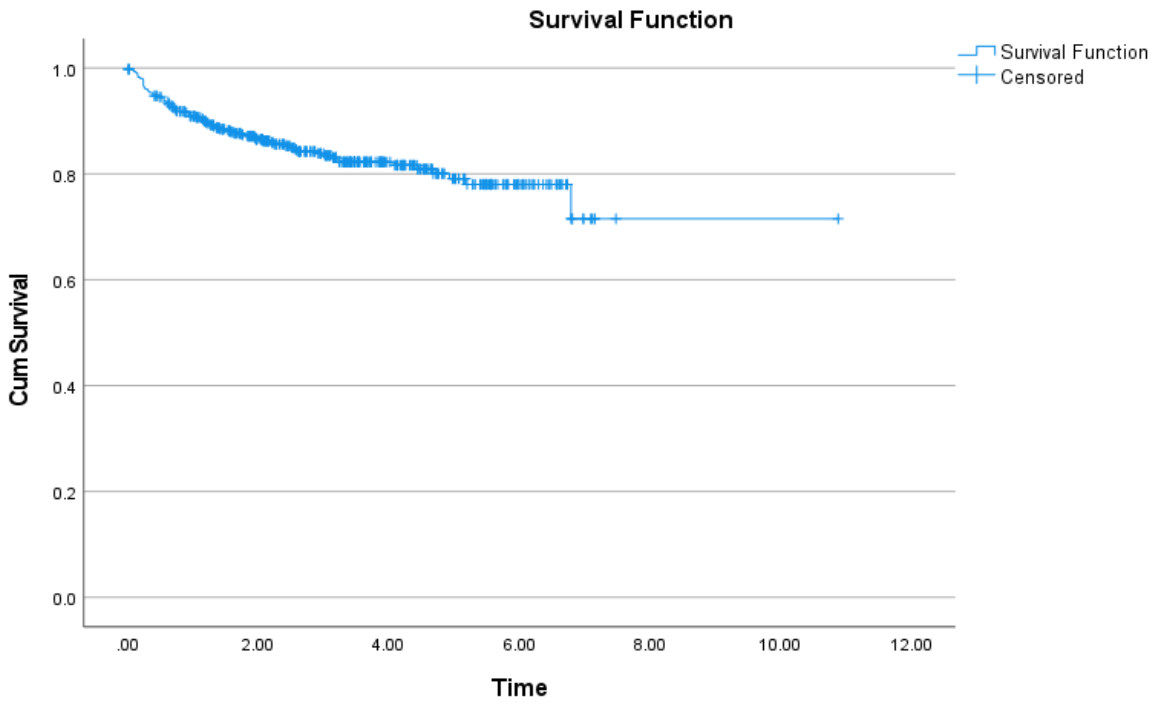

Figure 4: Kaplan-Meier follow-up survival curve of Adult HIV infected patients under ART follow up in Hawassa health facilities, 2018-2023.

Kaplan-Meier analysis of survival status revealed significant differences in follow-up survival among different patient groups on ART. Patients aged 18-24 demonstrated lower follow-up survival rates compared to older age groups, indicating a higher incidence of loss to follow-up (log-rank test, P<0.01). Additionally, patients with a functional status of bedridden had significantly poorer cumulative survival compared to those who were working or ambulatory (log-rank test, P<0.01). Furthermore, patients in WHO Stage I exhibited higher cumulative follow-up survival than those in more advanced stages (log-rank test, P<0.01).

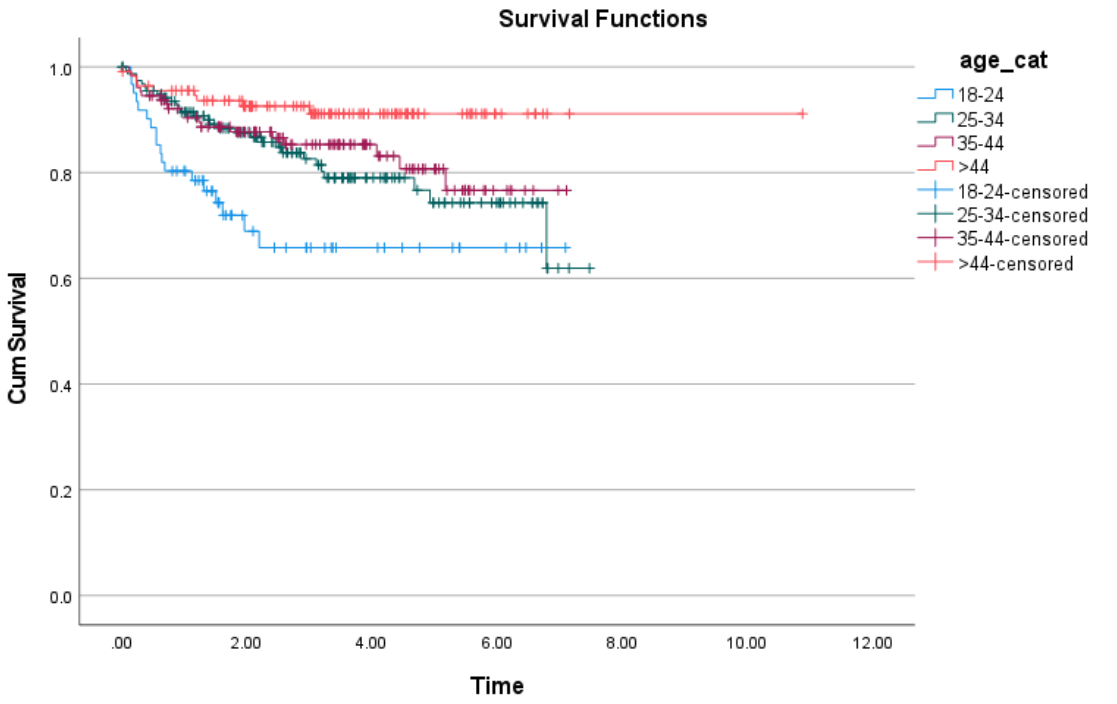

Figure 5: Follow-up Kaplan-Meier follow-up Survival functions of patients on ART by age categories in Hawassa, Ethiopia, 2018-2023. (Log-rank test P<0.01)

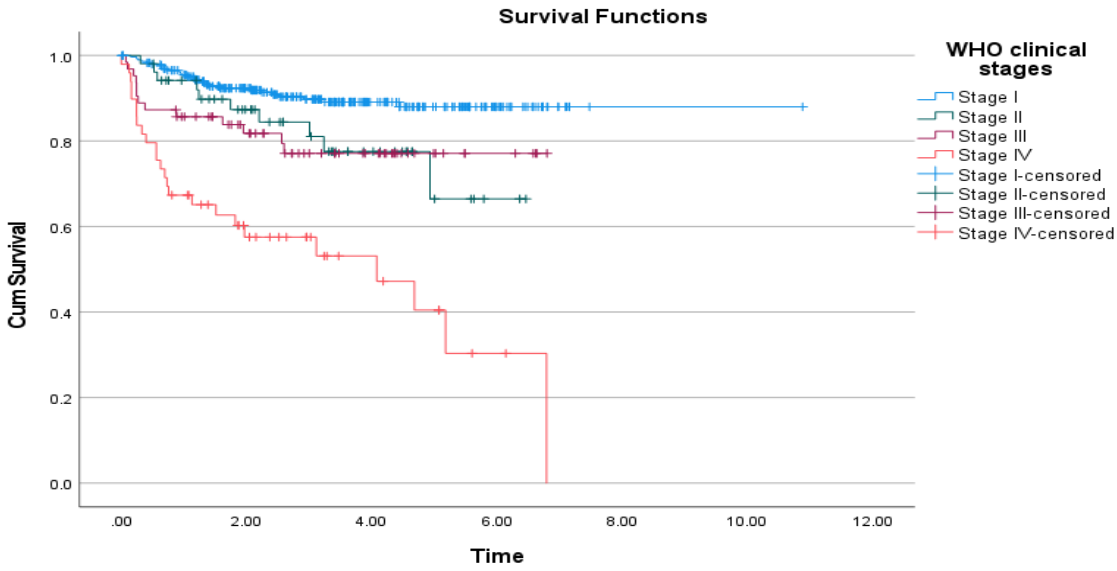

Figure 6: Follow-up Kaplan-Meier follow-up Survival functions of patients on ART by WHO clinical staging in Hawassa, Ethiopia, 2018-2023. (Log-rank test P<0.01)

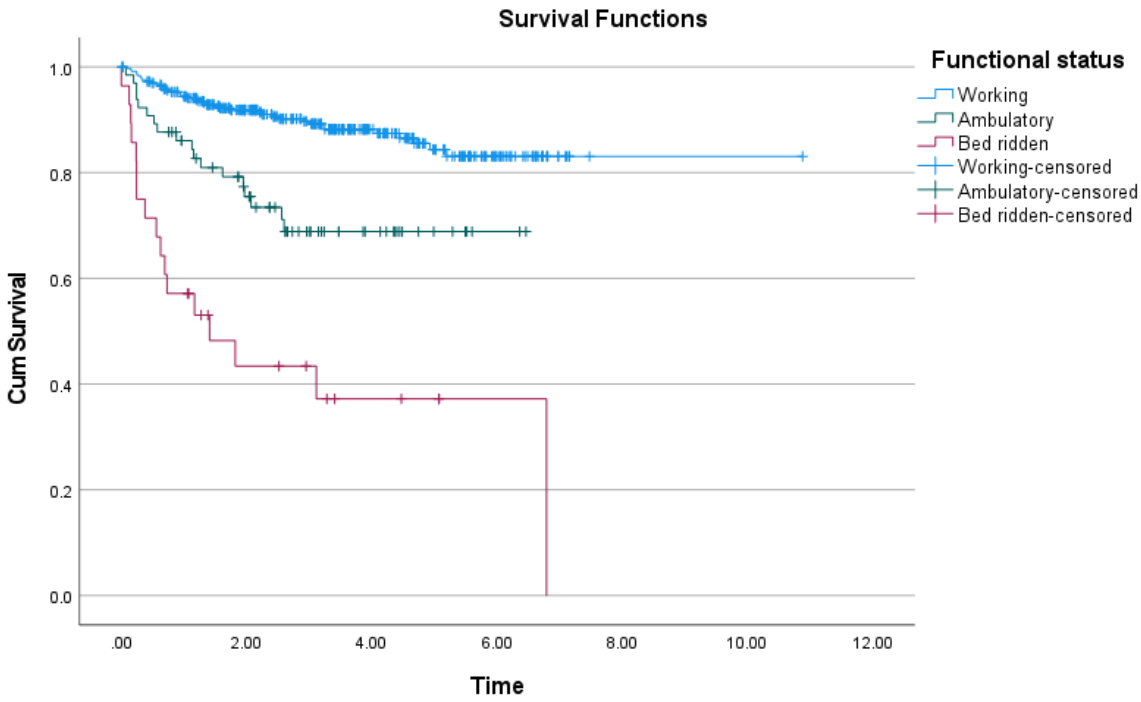

Figure 7: Follow-up Kaplan-Meier follow-up Survival functions of patients on ART by Functional status in Hawassa, Ethiopia, 2018-2023. (Log-rank test P<0.01)

5.6. Predictors of loss to follow-up

Cox-proportional hazard regression was conducted to identify predictors of loss to follow-up. The assumption of the Cox proportional model called Test of proportional-hazards assumption based on Schoenfeld residual was checked and fulfilled. Then, both bi-variable and multivariable cox proportional hazard regression model was conducted and those variables with p-value ≤ 0.25 in the bi-variable model were considered for multivariable cox proportional hazard model.

Based on the multivariable cox regression model, age of patents was a significant predictor, with those aged 18-24 years having 2.77 times higher risk of loss to follow-up (95% CI: 1.066 - 7.196) compared to those over 44 years old. Moreover, Lack of formal education was associated with a 4.08 times higher risk of loss to follow-up (95% CI: 1.338 - 12.433) compared to those with higher education. Regarding clinical factors, advanced WHO stage III (AHR 3.06, 95% CI: 1.040 - 8.991) and stage IV (AHR 4.64, 95% CI: 1.816

- 11.857) were associated with higher risk of loss to follow-up compared to stage I. furthermore, being bedridden functional status had more than threefold higher risk (AHR 3.63, 95% CI: 1.415 - 9.316) compared to those working. Receiving cotrimoxazole prophylaxis was linked to a 2.56 times higher risk of loss to follow-up (AHR 2.56, 95% CI: 1.347 - 4.871). However, other variables such as marital status, opportunistic infections, CD4 count, BMI, having a contact person, disclosure status or partner's HIV status were not significant predictors after adjusting for other variables.

Table 5: Cox- proportional regression for predictors of loss to follow-up among patients under ART in Hawassa, Ethiopia, 2018-2023.

Factors	**Loss to follow-up status**		**Crude hazard ratio (95%CI)**	**Adjusted hazard ratio(95% CI)**	**P-value**
Age	No	Yes			
18-24	43	18	4.721 (2.117 10.527)**	2.769 (1.066 7.196)*	0.037
25-34	128	29	2.465 (1.166 5.209)*	1.683 (.723 3.922	0.227
35-44	108	20	2.058 (.937 4.521)	1.641 (.695 3.878)	0.259
>44	104	9	1	1	
Education					
No formal education	60	24	4.224 (1.611 11.074)**	4.079 (1.338 12.433)*	0.013
Primary school	95	27	3.082 (1.186 8.009)*	2.897 (.977 8.590)	0.055
Secondary school	169	20	1.301 (.488 3.467)	1.449 (.477 4.400)	0.513
Higher education	59	5	1	1	
Marital status					
Single	91	27	1.331 (.660 2.685)	.876 (.390 1.968)	0.749
Married	179	32	.936 (.472 1.857)	.896 (.406 1.977)	0.785
Widowed	57	6	.537 (.198 1.451	.710 (.235 2.147)	0.545
Divorced	56	11	1	1	
Opportunistic infection(OI)					
No	285	43	1	1	
Yes	98	33	2.123 (1.348 3.342)**	2.021 (.851 4.800)	0.111
WHO stages					
Stage I	267	28	1	1	
Stage II	42	10	2.177 (1.056 4.488)*	1.881 (.786 4.502)	0.156
Stage III	50	13	2.382 (1.233 4.601)*	3.058 (1.040 8.991)*	0.042
Stage IV	24	25	7.217 (4.202 12.395)**	4.640 (1.816 11.857)**	0.001
CD4 count (cells/mm3)					

1=<250	104	32	1.949 (1.093 3.473)	.539 (.243 1.195)	0.128
2=250-500	140	24	1.127 (.612 2.077)*	.965 (.488 1.905)	0.917
3=>500	122	18	1	1	
Functional status					
Working	325	41	1	1	
Ambulatory	47	18	2.818 (1.617 4.914)**	1.481 (.703 3.118)	0.302
Bedridden	11	17	8.310 (4.705 14.676)**	3.631 (1.415 9.316)**	0.007
BMI					
< 18 kg.m2	59	17	1.519 (.886 2.606)	.586 (.297 1.155)	0.122
± 18 kg/m2	324	59	1	1	
Cotrimoxazole					
No	260	28	1	1	
Yes	123	48	3.161 (1.982 5.039)**	2.562 (1.347 4.871)**	0.004
Have contact person					
No	149	38	1	1	
Yes	234	38	1.412 (.901 2.215)	1.265 (.665 2.407)	0.474
Disclosure status					
No	221	51	1	1	
Yes	162	25	1.392 (.862 2.246)	.866 (.454 1.652)	0.663
Partner status					
Negative	29	3	.458 (.143 1.461)	.622 (.173 2.238)	0.467
Positive	108	15	.651 (.369 1.149)	.507 (.240 1.069)	0.074
Unknown	246	58	1	1	

Note *P< 0.05; **P<0.05; 1: Reference category

CHAPTER SIX - DISCUSSION

The significant burden of loss to follow-up among patients receiving antiretroviral therapy in this context in Ethiopia is brought to light by this study. Total of 76 individuals were not followed up on, yielding an overall rate of 5.48 per 100 person-years for loss to follow-up. The total incidence of loss to follow-up was 16.6%. The findings reveal a concerning rate of LTFU, exceeding acceptable thresholds and posing a significant challenge to optimizing treatment outcomes and achieving pandemic control. The total incidence of loss to follow-up agrees with the study done in South Africa (29). The observed incidence rate, though comparable to findings in South Africa, is notably lower than rates reported in Nigeria (30), Amhara Region of Northwest Ethiopia (8) and Gondar (16). This suggests that while the issue is prevalent, the extent varies across different regions, potentially due to varying healthcare infrastructure, patient management practices, or socioeconomic factors.

Moreover, this rate is higher than reports from Uganda (53), in Kenya (54) and in Asia (28) suggesting setting-specific challenges in retention. The rate of loss to follow-up in this study is notably higher than the thresholds often cited in the literature as acceptable for minimizing bias (55).

However, the incidence rate in this study is still lower than other similar studies such as the incidence rate of LTFU reported in Gondar Specialized Comprehensive Hospital (35), in Nigeria (30), at Pawi General Hospital in Ethiopia (33), in a retrospective cohort study conducted in Aksum St. Marry Hospital (34).

Patients lost to follow-up miss out on essential medical care, jeopardizing their health through uncontrolled viral replication, increased susceptibility to opportunistic infections, and ultimately, higher mortality rates (2). Furthermore, LTFU undermines program effectiveness by obstructing accurate monitoring of treatment success and impairing efforts to control the HIV pandemic at the population level. In the context of this study, this translates to missed opportunities to suppress viral loads, potentially fueling viral transmission within the community.

To increase patient retention in care and treatment programs, it is imperative to identify risk factors and execute tailored treatments, as evidenced by the high rate of follow-up loss (10).

In this group, a number of predictors became significant after controlling for confounders. Sociodemographic characteristics were shown to be very significant predictors of loss to follow-up in the current investigation. There was a higher chance of follow-up loss among younger ages, 18–24 years of age range. This finding is consistent with prior research, which has demonstrated time and time again that a lower age is a risk factor for inadequate adherence to HIV therapy (18, 56). The finding might be explained by a number of factors, such as difficulties maintaining long-term treatment plans, conflicting goals, and a lack of perceived sensitivity to HIV-related problems among younger people (57). Younger patients were more likely to be lost to follow-up, potentially due to difficulties managing long-term treatment plans, conflicting priorities, or a lack of perceived vulnerability to HIV (5). This underscores the need for age-tailored interventions, such as peer support groups or mobile phone medication reminders, to enhance adherence among younger patients (58).

Moreover, lower educational levels have been found in several studies to be a predictor of LTFU (32), which is consistent with the study's findings. As per the study report, individuals without formal education are more susceptible to LTFU. This might be attributed to challenges they have in comprehending treatment guidelines and realizing the significance of adhering to antiretroviral therapy (32, 39). Individuals with low educational attainment may find it challenging to comprehend the specifics of HIV care, which might result in poor adherence and a higher chance of patient disengagement from treatment (59). This emphasizes the importance of integrating health literacy training into existing programs to improve treatment comprehension and self-management skills.

Advanced HIV disease stage was a significant predictor, with patients at increased risk of death being lost from follow-up if they were in WHO stages III and IV. A Longitudinal Analysis conducted in Canada revealed similar to this study report that advanced disease stages and AIDS-defining diseases frequently correspond with a higher chance of LTFU because of the severity and complicated treatment regimens that might overwhelm patients (19). Moreover, a report from Kenya reported advanced WHO clinical stages were linked

with being lost to follow-up (39). This is due to probably the result of many factors. HIV-related problems and opportunistic infections are more common in patients with more severe immunosuppression (20). This may make it harder for patients to consistently attend clinic appointments because of their lower level of functioning, increased healthcare expenses, and decreased sense of self-efficacy (60). It also can be attributed to the severity of their illness and the complexity of treatment regimens, leading to feelings of overwhelm and discouragement (61). Exploring the specific challenges faced by this group is needed to inform interventions that improve treatment engagement.

Similar to this study report, others have found that low functional status levels in HIV/AIDS patients affect the efficacy of ART and their health outcomes (47). Functional status is a significant indication of LTFU in these patients. Furthermore, studies conducted all throughout sub-Saharan Africa have consistently shown a relationship between being bedridden and a greater likelihood of follow-up failure (5). According to this study (62), there is a correlation between low functional status and reduced clinic attendance and treatment adherence. This is generally because of psychological or physical impediments (49). Furthermore, poor functional status might make it more difficult to get treatment, particularly in rural regions, therefore programs to improve mobility and assistance during clinic visits may be necessary (49).

Interestingly, receiving cotrimoxazole prophylaxis increased the chance of missing follow-up appointments. This finding is consistent with a study done at North Shewa zone public Hospitals, Northeast Ethiopia in 2022, which also found receiving cotrimoxazole therapy was statistically associated to LTFU (36). Cotrimoxazole has been demonstrated to increase survival rates and is advised for the prevention of opportunistic infections (63). While cotrimoxazole is crucial for preventing opportunistic infections, its potential side effects might discourage patients from adhering to both medications. Further research is needed to explore this association and identify strategies to mitigate potential side effects and improve adherence to both cotrimoxazole and ART.

CHAPTER SEVEN- STRENGTHS AND LIMITATIONS

7.1. Strengths of the study

This study has several strengths. It utilizes a five-year longitudinal data, enhancing the reliability of findings on loss to follow-up (LTFU) trends. The comprehensive analysis of demographic, clinical, socioeconomic, and behavioral factors provides a detailed understanding of LTFU predictors. By focusing on public health facilities in Hawassa, Sidama, Ethiopia, the study offers context-specific insights for targeted interventions. The retrospective cohort design allows for the examination of real-world outcomes over an extended period, contributing valuable data to the broader understanding of ART program challenges in Ethiopia. Lastly, the study contributes significantly to the existing literature by filling a gap regarding the incidence and predictors of LTFU in the specific context of Hawassa, thereby offering valuable data to the broader understanding of ART program challenges in Ethiopia and similar settings.

7.2. Limitations of the study

As the study uses a retrospective study design, reliance on existing medical records limits the ability to collect detailed information on potential influencing factors the information might not be documented, leading to bias and impacting the accuracy of results. Due to the use of secondary data review in the study, selection bias may result from the exclusion of incomplete data. It is possible that patients who were determined lost to follow-up passed away or self-referred to alternative hospitals. Furthermore, because baseline sociodemographic, clinical, and treatment-related characteristics were employed in this investigation, these variables could change after time.

CHAPTER EIGHT - CONCLUSION AND RECOMMENDATIONS

8.1. Conclusions

A total of 459 participants were included in the study, contributing 1386 person-years of follow-up. The cumulative incidence of loss to follow-up (LTFU) was 16.6%, with an incidence density rate of 5.48 per 100 person-years. The factors that were identified as significant predictors of LTFU in this cohort of ART patients in Hawassa, Ethiopia included younger age groups, lack of education, Advanced WHO stages, low functional level and use of cotrimoxazole prophylaxis.

This study underscores the significant burden of loss to follow-up (LTFU) among patients receiving antiretroviral therapy (ART) in Ethiopia, which is moderate when compared to some regions and lower than others in Ethiopia. These findings highlight the need for targeted interventions to address the specific challenges faced by the identified vulnerable groups.

8.2. Recommendations

The study's findings led to the forwarding of the following recommendations.

For Healthcare Workers/Clinicians:

- **Implement Age-Specific Interventions:** Use peer support groups and mobile phone reminders to improve adherence among younger patients.
- **Enhance Health Literacy:** Provide comprehensive health literacy training to help patients, especially those with lower educational levels, understand the importance of ART adherence.
- **Manage Advanced Disease Stages:** Offer additional support such as counseling, home-based care, and financial assistance to patients in advanced stages of HIV to help them manage complex treatment regimens and improve clinic attendance.
- **Address Functional Status:** Improve mobility support for patients with low functional status, particularly in rural areas, to ensure consistent clinic attendance.
- **Monitor and Manage Side Effects:** Regularly monitor patients on cotrimoxazole prophylaxis for side effects and manage them appropriately to encourage continued adherence.

For Program Managers:

- **Strengthen Monitoring Systems:** Use mobile health applications and automated reminders to improve patient monitoring and follow-up.
- **Establish Follow-Up Teams:** Create dedicated follow-up teams to re-engage patients who miss appointments.
- **Integrate Community-Based Support:** Leverage community health workers and local support networks to maintain patient engagement in ART programs.
- **Tailor Programs to Local Needs:** Develop programs that are responsive to the specific challenges faced by different patient demographics, such as younger individuals and those with low functional status.

For Researchers:

- More exploratory and implementation research are needed to better understand the reasons for LTFU across various situations. Future research with a larger, prospective follow up could explore additional contributing factors.

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ANNEXES

INFORMATION SHEET

Title of the Research Project: Incidence and predictors of loss to follow-up among adults on antiretroviral therapy at public health facilities in Hawassa, Sidama, Ethiopia, 2024.

Name of Principal Investigator: Ruth Tesfaye

Introduction: Greetings! My name is Ruth Tesfaye. I am a Masters student at Hawassa University College of Medicine and Health sciences, School of public health epidemiology track. As part of this degree, I am undertaking a research project on the Incidence and predictors of loss to follow-up among adults on antiretroviral therapy at public health facilities in Hawassa, Sidama, Ethiopia, 2024.

Purpose of the Research Project: This study aims to determine the incidence and predictors of loss to follow-up among adults on antiretroviral therapy at public health facilities in Hawassa, Sidama, Ethiopia, 2024. The information gained from this research will be used to make recommendations to improve patient retention in ART programs.

Procedure: The data collection will be conducted in HUCSH, Adare Hospital, Millennium Health center and Hawella Tulla General Hospital ART clinics. All necessary information will be extracted by using a data extracting tool adapted from the standard follow up format that is used in the ART clinics in Ethiopia.

Risk and /or Discomfort: Data will be extracted from medical records, so it will not impose any harm on patients.

Confidentiality: During data extraction, the patients' names will not be taken; instead they will be identified by their card number in the registration book. All forms collected will be kept confidential. The information extracted will be used only for research purposes.

Right to Refusal or Withdraw: Approval of the manager of the hospital will be required to start data collection.

Person to contact: If you would like to receive further information about the project, please contact: **Phone**: +251 91091334 **Email**: tesfayeruth7@gmail.com

INFORMED CONSENT FOR FACILITY

Based on the above information provided, I, as the head of the facility, give consent for the data collection of the research entitled “Incidence and predictors of loss to follow-up among adults on antiretroviral therapy at public health facilities in Hawassa, Sidama, Ethiopia, 2024.”

Name_____**Signature**_____**date**_____

DATA COLLECTION FORMAT

This checklist is prepared for collecting information on Incidence and predictors of loss to follow-up among adults on antiretroviral therapy at public health facilities in Hawassa, Sidama, Ethiopia, 2024.

Facility Name _____

MRN_____

No.	Questions	Response	Remark
Part 1. Socio-demographic characteristics			
101	Age	----------	
102	Sex	0. Male 1. Female	
103	Residence	0. Urban 1. Rural	
104	Educational level	0. No formal education 1. Primary school 2. Secondary school 3. Higher education	
105	Marital status	0. Single 1. Married 2. Widowed 3. Divorced	
106	Religion	0. Protestant 1. Orthodox 2. Muslim 3. Catholic 4. Others (specify) ---------	
107	Occupational status	0. Merchant 1. Private employee 2. Government employee 3. Day laborer 4. Farmer 5. Driver 6. Sex worker 7. Self-employee 8. Unemployed	

		9. Others (specify)_____	
Part 2. Baseline and Clinical factors			
201	Date of start ART (DD/MM/YYYY/	_____	
202	Opportunistic infections(OIs)	0. No 1. Yes	
203	Type of Opportunistic Infection	0. Herpes Zoster 1. TB 2. Pneumonia 3. Oral thrush 4. Other (Specify)_____	
204	Baseline Weight	----------(KG)	
205	Baseline Height	----------(cm)	
206	Baseline BMI	----------	
207	WHO clinical stages	0. Stage I 1. Stage II 2. Stage III 3. Stage IV	
208	CD4 count (cells/mm3)	0. <250 1. 250-500 2. >500	
209	Viral Load	0. High 1. Not detectable	
210	Functional status	0. Working 1. Ambulatory 2. Bedridden	
211	Baseline hemoglobin (hg)	_____	
Part 3. Treatment-related factors			
301.	Baseline ART regimen	----------	

302.	Regimen Change	0. No 1. Yes	
303.	Current ART regimen:	----------	
304.	If regimen is changed, what is the reason for change?	----------	
305.	Cotrimoxazole treatment	0. No 1. Yes	
306.	Isoniazid (INH) treatment	0. No 1. Yes	
307.	ART side effect	0. No 1. Yes	
Part 4. Support And Family Condition			
401.	Disclosure status	0. No 1. Yes	
402.	Have contact person	0. No 1. Yes	
403.	Partner HIV status	0. Negative 1. Positive 2. Unknown	
Part 5. Loss to follow-up			
501	Last follow-up status	0. Lost to follow up 1. Continued follow up 2. Dead 3. Transferred out	
502	If Lost to follow up, Date of last visit to the clinic before Loss to follow up: (DD/MM/YYYY/	----------	