

PRE-ANTIRETROVIRAL SERVICES IN RURAL ETHIOPIA:  
PATIENT RETENTION, FACTORS ASSOCIATED WITH LOSS  
TO FOLLOW UP, AND REASONS FOR DISCONTINUATION

by

ZINASH DEWO ROBI

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SUPERVISOR: Dr. T NEGUSSIE

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Student number 45079234

I declare that PRE-ANTIRETROVIRAL SERVICES IN RURAL ETHIOPIA: PATIENT RETENTION, FACTORS ASSOCIATED WITH LOSS TO FOLLOW UP, AND REASONS FOR DISCONTINUATION is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references.

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SIGNATURE (Mrs Z D ROBI)

.....

DATE

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## ABSTRACT

This study was conducted to determine retention rate and factors associated with loss to follow-up (LTFU) of adult pre-ART patients in St. Luke hospital, Ethiopia. Cross-sectional study with quantitative and qualitative data collection techniques was used. Review of patient records, focus group discussions and review of program guidelines was conducted to determine level of adherence among pre-ART patients. In addition, pre-ART service quality and perceived reasons for discontinuation was explored.

The study revealed that only 38.2% of the 335 patients enrolled in the pre-ART care were retained after 12 months of follow-up in the program. More than half (55.6%), of the LTFU occurred during the first 6 months of follow-up. Fear of discrimination, high transportation cost and mistrust in the pre-ART service were perceived reasons for LTFU. Absences of clear pre-ART service package and implementation guideline were also identified as important factors that may be related to LTFU.

The findings call for improved quality of care and a better pre-ART service packaging that will address the gaps identified in order to increase patient retention.

## KEY CONCEPTS

HIV, Pre-ART care, pre-ART loss to follow up

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# CHAPTER 1

## ORIENTATION TO THE STUDY

### 1.1. INTRODUCTION

The human immunodeficiency virus (HIV) has created an enormous challenge worldwide and Ethiopia is among the countries most affected by the epidemic. Substantial scale up of HIV/AIDS services has been done in the past decade, particularly in sub-Saharan Africa (SSA) where the epidemic is home to an estimated 22.4 million people representing around two-thirds of the people living with HIV globally (UNAIDS & WHO 2009, p. 21).

However, various challenges have emerged with the scale up of HIV/AIDS programmes at different levels of service provision. Attrition of patients from care especially of those on Anti-retroviral Therapy (ART) was reported to be a critical barrier to the scale up of these services. The main cause of attrition has been identified as lost to follow up (LTFU) which accounts for up to 56% of attrition in ART programmes (UNAIDS & WHO, 2009, p. 22).

More attention has recently been given to strengthen adherence of patients on ART and various care packages and loss to follow up tracing mechanisms have been implemented in Ethiopia. The standard of care for patients diagnosed HIV positive but not yet eligible for ART (the period usually known as pre ART) is however not well-optimized and thus the extent of drop out from care and its determinants are not well understood.

St. Luke Catholic Hospital and College of Nursing and midwifery is situated in Wolisso Town, south west Shoa zone of Oromia Regional State in Ethiopia. Owned by the Ethiopian Catholic Church, the hospital serves over 1.2 million people (Hospital, 2011: 12).

The hospital began service in January 2001 and currently has 144 beds. While HIV prevention and care services were available from the start, the ART program began only in 2006. By December 2010, the hospital had initiated 1,531 patients on ART of which 43% were still on ART (Hospital Service Statistics, 2011).

## **1.2. BACKGROUND INFORMATION ABOUT THE RESEARCH PROBLEM**

Since its discovery, HIV has infected close to 70 million people worldwide, and more than 30 million have died due to acquired immunodeficiency syndrome (AIDS), (UNAIDS & WHO 2009:7). SSA remains the region most heavily affected by HIV worldwide, accounting for over two thirds (67%) of all people living with HIV and for nearly three quarters (72%) of AIDS-related deaths resulting in more than 14 million orphans (UNAIDS & WHO 2009:21).

With a population estimated at 80,713,000 million in mid-2008, Ethiopia is the second most populous country in Africa (UN 2008). Since the first case of HIV was reported in the country in 1984, HIV/AIDS has remained to be major public health problem affecting people of productive age group. According to the 2011 Ethiopian Demographic and Health Survey (DHS) the adult (15-49 years) HIV prevalence is reported to be 1.5%. The prevalence rate showed variation among the gender groups with women having a higher rate of 1.9% than men who had only 1.0% (CSA & ICF 2012:234).

The Federal Ministry of Health (FMOH) in Ethiopia reported that, there was an estimated 1.2 million people living with HIV in 2010, of which close to 398,000 were eligible for ART. There were an estimated 137,464 new HIV infection (57% Female) and 28,073 AIDS-related deaths (57% Female). The total estimated number of HIV-positive pregnant women and annual HIV positive births in the same year were 90,311 and 14,276 respectively (MOH 2007:8-9).

The FMOH of Ethiopia officially started a fee-based ART program in 2003. After a number of initiatives by the government and partner organizations to increase access to ART, a national, free HIV/AIDS care and treatment program was launched in January 2005. (Assefa et al. 2009:2). Since this time, thousands of people have accessed care and treatment services, including ART throughout the country. By year 2010, more than 200,000 people in need of ARVs have been initiated on treatment in about 532 facilities throughout the country (ARC 2010).

The impact of ART program on survival and quality of life of patients has also been visible in Ethiopia (HAPCO and MOH, 2008). But despite the recent gains, universal access to ART is still far from being achieved. Of the estimated 397,818 patients in need of ART by 2010 (MOH 2007), only 246,347 (62%) were ever started ART as of February 2010 (ARC 2010).

One of the biggest concerns of care and treatment programs is the ability of patients to achieve near-perfect adherence over the long-term from enrollment to care and throughout. According to a systematic review of pre-antiretroviral (pre-ART) care in sub-Saharan Africa more than two-thirds of people who tested positive for HIV but weren't yet eligible for treatment when diagnosed were lost from care (Rosen & Fox 2011: 6-8).

In many settings, especially in SSA there is a growing concern that patients who have been diagnosed with HIV infection and registered for HIV care drop out, only to present themselves later with advanced HIV infection necessitating immediate ART initiation.

Most strategies to improve follow-up generally focus on bringing lost patients back into the health care system through outreach teams and collaboration with community organizations. An attempt to trace LTFU patients from HIV programme in Malawi determined that 50% had died, 27% could not be found, and most of the rest had stopped ART (Yu et al. 2007:551-552). In a systematic review on outcomes of patients lost from HIV care and treatment programs in resource limited settings, 20-60% of patients who could be traced had died (Brinkhof, Pujades-Rodriguez & Egger 2009:3-4).

These studies point to two critical public health problems for patients who are LTFU – a large percentage of avoidable deaths and compromised quality of life among those who would survive.

LTFU is therefore a major challenge in HIV care because tracing patients is evidently resource-intensive and often unsuccessful. Given that most of these patients may have already died, it has been suggested that preventing LTFU by directing major efforts towards earlier HIV diagnosis, effective linkage to and retention in care and timely initiation of ART may be more effective at improving outcomes (HAPCO & MOH 2008:8).

HIV testing identifies infected persons and is an entry point to a continuum of HIV health care and social services. Eligibility for ART initiation is determined based on the clinical stage and social factors and the CD4 count is used to guide treatment and follow-up. The clinical criteria that need to be met to make patients eligible for ART initiation in Ethiopia are a CD4 count below 200, World Health Organization (WHO) stage IV and WHO stage II and III with total lymphocyte count (TLC) less than 1200 (MOH, Guideline for implementation of Anti Retro Viral Therapies in Ethiopia, 2005). The social factors considered include that the client should be resident within the facility's catchment area and that the patient doesn't have any identified barriers to adherence. Identified barriers to adherence include alcoholism, substance abuse and lack of support system (WHO et al. 2006:156).

Except for some additional criterias to ensure gender equity and adress most vulnerable groups before the introduction of free ART services, these clinical and social eligibility criterias have been in place since ART was introduced in the country in 2003. (MOH 2005:1)

Once eligibility status is known, the patient is either put on ART or enrolled into pre-ART care. The pre-ART period is arbitrarily defined to be the time between client referral to the clinic and ART initiation. The length of stay in the pre-ART care depends on how

soon the patient progresses towards meeting the eligibility criteria which also depends on how early after acquiring HIV infection the client was tested and got enrolled to the care. This could vary from as short period as a month to years.

Currently, there are no standardized guidelines that describe the type of care patients receive during the pre-ART period both globally and in Ethiopia. The Ethiopian national ART implementation guideline heavily focuses on the care during the ART time and it doesn't mention the standard procedures and the dynamics of pre-ART services. While patients in the pre-ART period are generally referred to as "patients on care", various implementation partners have different definition of what "care" means. As a result, the pre ART care of HIV patients is not well defined, and the type of service provided is not standardized. Proper patient follow up and tracing mechanisms are not in place and it is very likely that some of them drop out from care or die before ART initiation. These problems are likely to get bigger and complex as the cumulative number of people living with HIV/AIDS keeps on rising resulting in huge mortality and morbidity burden in a country like Ethiopia where 80 million people live.

### **1.3. RESEARCH PROBLEM**

Retaining patients infected with HIV in medical care after diagnosis is essential to initiate lifesaving antiretroviral therapy and facilitate the delivery of important prevention messages for reducing HIV transmission. New HIV infections in the future are by and large projected to come from people who live with the virus, know their sero-status and not enrolled in care services or drop-out of from the service. Keeping these clients in care has potential impact not only in reducing AIDS related mortality but also preventing new infections.

Currently, the period of pre-ART care, its service goals, service packages and measures of retention in Ethiopia are not well defined and documentations on the outcomes of LTFU during the period are not available in most cases. As a result, the dynamics of pre ART care, including the magnitude of LTFU and associated reasons including quality of care during pre-ART period are not known. Although lack of enrolment in care has been associated with negative clinical outcomes including delayed ART initiation, virologic failure, and mortality (Ulett, Willig & Lin 2009:23), few studies have examined the rate of LTFU among ART ineligible patients and reasons why these patients fail to be retained in care.

## **1.4. AIM OF THE STUDY**

### **1.4.1. Research purpose**

The purpose of this research is to describe the type and organization of pre ART care and determine factors associated with LTFU and perceived reasons for discontinuation of care among adult patients enrolled to pre ART program in Ethiopia.

### **1.4.2. Research objectives**

The objectives of this research are:

- To assess the type of services that are provided as part of pre-ART programs and determine the system that guides the service delivery
- To determine the level of loss-to-follow-up among adult patients enrolled in the pre ART program in St. Luke Catholic Hospital
- To identify factors (socio-economic, cultural and disease -related) perceived to be reasons for discontinuation of care among pre-ART adult patients

## **1.5. SIGNIFICANCE OF THE STUDY**

Little is known about the patient care during the pre- ART period in Ethiopia. As there is no standard pre ART care guideline, services at the facility level are not uniform. There are no country level studies conducted in the area and thus the pre ART service in general and its challenges are not well understood.

Successful implementation of HIV/AIDS programs need scientific evidence generated in the appropriate settings. This study will try to answer some questions that remain unanswered regarding implementation of patient care during the pre ART period in Ethiopia. The study will attempt to describe pre ART care and provide a suggestion to help define a program package of services in Ethiopian context. The study is believed to produce important evidence that will be useful in understanding the dynamics of pre ART care.

The study findings will contribute to the body of knowledge in HIV AIDS care and will be useful in influencing the development and modification of guidelines in the country. Finally, understanding the factors associated with LTFU in pre ART care will also be helpful at health facility level to improve the standard of care and provide targeted follow up for different patient groups.

## **1.6. DEFINITION OF TERMS**

Pre ART period- The period between patient enrolment to care and ART initiation

Lost to follow up- There are different types of LTFU definitions used by various agencies. LTFU in this study is defined as per the US Centres of Disease Prevention and Control (CDC) guideline and refers to when a patient doesn't show up for clinic appointments for at least 3 months (CDC 2006).

Adherence- Engagement and accurate participation of informed patient in a plan of care without skip from appointment for the last 3 months (CDC 2006).

In this study, retention rate is determined and factors associated with lost to follow up are described. These two key terms are frequently used in this study as the research aims to touch on both determining retention rates among pre ART patients and factors associated with loss to follow up. Although the two terms (retention and loss to follow up) are not used interchangeably with same meaning, the concepts are reported in a mixed manner throughout the literature review.



## **1.7. FOUNDATION OF THE STUDY**

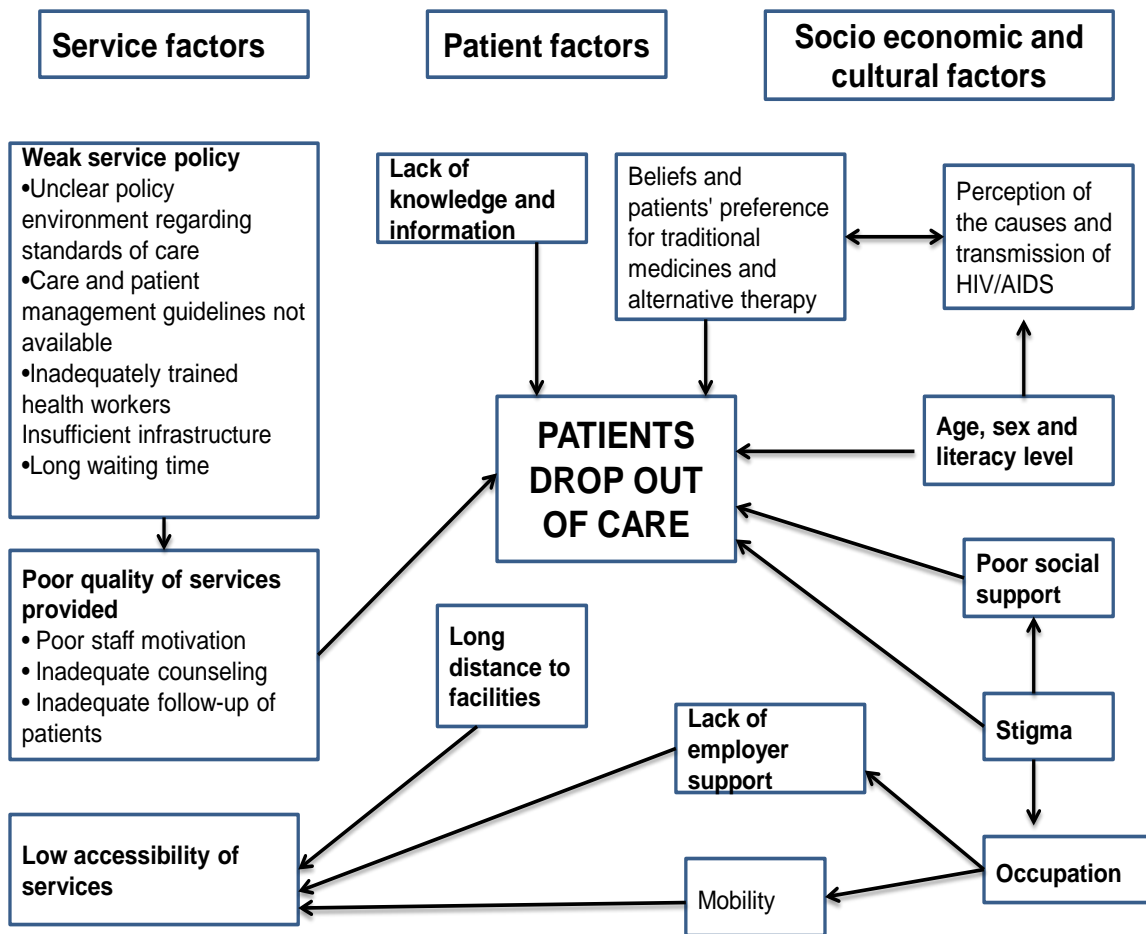
### **1.7.1. Meta-theoretical assumptions**

According to Polit and Beck (2004:13), an assumption is basic principle that is believed to be true, without needing proof or verification. The following assumptions served as starting points for this study:

- Lack of comprehensive service package and standard delivery mechanisms is a barrier to engage and retain HIV positive patients in care
- Socio economic and cultural norms can negatively affect retention in care
- Patient's demographic characteristics influence their perception of adherence to care services
- A significant percentage of patients enrolled in care will be lost-to-follow-up before they are initiated on ART
- Majority of these patients will die; some of them will return back to care with severe illness and compromised immunity.
- Patients LTFU will continue to be the source of new HIV infection in the community as they are less likely to either disclose their HIV sero-status or adhere to preventive behaviours.

### **1.7.2. Conceptual framework**

The conceptual framework for this study identifies service factors, patient factors and socioeconomic and cultural factors leading directly and indirectly to sub - optimal adherence to care. This study aims to investigate majority of the identified factors to assess the most important one in the study area context. Figure 1.1 below illustrates the various concepts.



**Figure 1.1 Research conceptual frameworks**

## 1.8. RESEARCH DESIGN AND METHODS

Chapter three of this report will present a detailed discussion of the research approach and methodology. The summary of that discussion is highlighted below.

In this study a cross-sectional research design with a mix of quantitative and qualitative data collection methods were used to determine rates of loss-to-follow-up during pre-ART care and associated factors. The reasons for the choice of this design are elaborated in chapter three of this report.

The study population included all HIV positive patients enrolled into the pre ART care program in a rural hospital in Ethiopia between January 2009 and December 2010.

Data were collected through patient records review to determine the level of adherence to HIV/AIDS care and Focus group discussion to solicit general information on healthcare demand, perception on quality of HIV/AIDS services and socio-economic and cultural factors associated with adherence to care.

Logistic regression analysis, crude odds ratio was done to determine whether any association exists between the independent and outcome variable with a confidence interval of 95%. Qualitative data analysis techniques were used to analyse data from focus group discussion.

### **1.9. SCOPE OF THE STUDY**

The research has explored the program environment towards pre ART cares in Ethiopia referring to available documents and resources. In addition, the findings determined the magnitude of pre ART loss to follow up and factors contributing to pre ART loss to follow up.

### **1.10. STRUCTURE OF DISSERTATION**

This report is organized in five major chapters outlined below:

- Chapter one: is the introduction chapter and gives an overview of the background information on the research problem, the research objectives and the definitions of concepts used in the study.
- Chapter two: is the literature review of scientific sources reviewed in this study
- Chapter three: is the research methodology and provides overview of the research design, methodologies used in data collection and the ethical principles observed during the study.

- Chapter four: this chapter discusses the data analysis techniques and the research findings
- Chapter five: is a chapter where conclusion and recommendations are made based on research findings.
- The final part of this research report consists of the bibliography and annexure containing the data collection tools, the consent form and the authorization to conduct the research.

### **1.11. CONCLUSION**

This chapter introduces the entire study and provides highlights of the importance of studying in detail the pre ART care, adherence during the period and factors that are associated with loss to follow up. The background to the research problem brings to light evidences related to health care service, HIV disease burden and pre ART care services both at national and global levels.

Key concepts and terms used throughout the study were operationally defined and the problem statement, objective and purpose of the study are also well elaborated in this chapter while the methodology is highlighted in brief.

Finally this chapter presented the way the research report is organized with short explanation about summary of their contents.

## **CHAPTER 2**

### **LITRATURE REVIEW**

#### **2.1. INTRODUCTION**

This chapter discusses the literature reviewed for this study highlighting the types, quantities and content of consulted sources and also the way in which they are acquired. The general purpose of a literature review is to gain an understanding of the current state of knowledge about the research topic (Johnson & Christensen 2004:61).

For this study the literature was reviewed to gain more understanding on pre-ART services, lost to follow up from care and factors associated with them. The review was specifically helpful to:

- Refine the research problem and document background information
- Familiarize the researcher with current knowledge of pre-ART care and identify literature gaps supporting the study topic
- Identify the relevant concepts to be included in the research questions
- Identify and refine the study methodology and processes
- Develop the data collection instrument

The review covers theoretical and empirical sources related to the main concepts found in this study. For this study, the literature review was conducted before data collection and documents were consulted after being acquired from various sources like the internet, Medline search, and published documents.

## **2.2. SCOPE OF THE LITERATURE REVIEW**

Both theoretical and empirical resources were included in the literature review. While primary sources are the most consulted, secondary sources were also used.

### **2.2.1. Theoretical resources**

The various types of theoretical sources used for the study can generally be grouped in to research methodology sources and conceptual and theoretical sources. Sources on research methodology reviewed to refine the research design and processes for this study mostly included textbooks on research methodology and journal articles. Sources on conceptual and theoretical references included textbooks on health education and health promotion theories, and sociology. These resources were important for identifying and refining concepts relevant to adherence and health seeking behaviors.

### **2.2.2. Empirical literature sources**

#### **2.2.2.1. Primary sources**

The literature review was based mainly on primary empirical sources contained in scientific journals and text books. During the review, it was found that while there are many studies conducted on patient retention and factors associated with lost follow up for patients on ART, there are few studies conducted on patients during the pre ART period . The few studies on retention during the pre-ART period in Africa are from South Africa and there was only one study from Ethiopia.

#### **2.2.2.2. Secondary sources**

Secondary sources were also consulted not only to support primary sources but also to help in the identification of additional primary studies from systematic reviews on pre ART care. These sources included technical and policy-related publications from the global (UNAIDS, WHO) and local (HAPCO, MOH and many others) institutions.

## **2.3. CURRENT UNDERSTANDING OF THE QUESTIONS IN THE STUDY**

### **2.3.1. What type of services are provided at pre-ART programs and what technical and programmatic principles guide the service delivery**

#### **2.3.1.1. HIV/AIDS care and treatment**

The primary goal of care and support of people living with HIV/AIDS (PLWHA) in clinical setting is to play an important role in preventing the spread of HIV/AIDS, improve quality of life and prevent premature death.

According to Ministry of health of Ethiopia, (2005:12), people suffering from HIV illnesses can access care at different levels of the health care system including public or private hospitals and health centers. The Ministry also describes the aim of the HIV/AIDS Care and Treatment services to be ensuring regular and standardized treatment, follow-up, and referral of patients to ensure that people living with HIV can be treated throughout the course of their illness (MOH, 2005).

#### **2.3.1.2. Organization of Care and Treatment Programs**

##### **Patient enrollment into the Care and Treatment Program**

All patients who test HIV positive in St. Luke Hospital are referred to an evaluating clinician who could be a health officer, physician or nurse. All patients who enter the care and treatment program receive a unique ID number at their first visit and are recorded in the pre-ART register. (If previously had been on ART and transferred from another facility, they are given a chart with their old unique ID and recorded in the ART register). HIV Patient Care and Treatment Record is filled out at the first visit, and updated at each subsequent follow-up visits both manually and electronically.

The initial visit focuses on determining the patient's eligibility for ART and Cotrimoxazole Preventive Therapy (CPT) (MOH, 2005). Some of the routine procedures on first visit include:

- Complete physical and WHO clinical staging, including all questions in the Symptom Checklist
- Baseline laboratory tests (including CD4 and TLC if available,)
- Cotrimoxazole prophylaxis, if necessary
- Assessment and treatment of OIs, including TB (MOH, 2005)

Patient counseling and contact establishment is also main part of initial visits. Some of the topics discussed by the counselor include basics of HIV care and treatment, importance of adherence to clinic visits, medication, HIV disclosure and positive living.

### **Patient visit plan**

Patients initiated on ART will be scheduled for follow-up visits frequently within the first six months for clinical care and monitoring of response to therapy. During these visits, they will see a nurse, an evaluating clinician as required, pick up their medication, and meet with case managers for adherence counseling. If the patient's condition has stabilized, after six months, he or she will be requested to visit the clinic at less frequent intervals for medication and counseling and as needed for clinical care. Every six months, CD4+ counts and basic blood tests will be performed and patients will see a clinician for follow-up and evaluation of response to therapy. All patients are advised to come to the clinic immediately should their condition deteriorate prior to their next scheduled visit (MOH, 2005).

Patients who do not meet the clinical and laboratory criteria for initiation of ART are reevaluated by a clinician with a clinical history and physical exam taken approximately every 3 months. Patients with acute illness are assessed at any time as needed. CD4 count testing and clinical staging is performed every 3 months to follow the trend of the disease.

Patients are monitored at each visit for the development of any stage 3 or 4 symptoms. Patients who become eligible for ART begin preparation for ART initiation which involves adherence counseling, social support and orientation on medication taking and nutrition.



All patients that are not eligible for ARVs are offered all other aspects of supportive treatment, including CPT if appropriate and early treatment of opportunistic infections. Cotrimoxazole is given to all patients who are WHO stage 2, 3 and 4. In addition, sexual partners and family members (such as children of HIV positive parents) are encouraged to attend a clinic for VCT and counseling and referral services are provided as appropriate.

#### **2.3.1.3. Standard pre-ART service package**

There is lack of structure and services provided for people with HIV during pre-ART period. The e-survey from 20 countries (Baggaley, 2012) demonstrated that during the pre-ART period, apart from some ad hoc opportunistic infection screening and prevention, very little consideration was given to other services. Although there are well-described support packages of care for people with HIV, (CDC, 2007) there is little agreement on a start-out set of pre-ART services which in practice translates to poor retention of clients.

Although there have been many efforts to develop programs for people with HIV following diagnosis (Geng, et al., 2011: e21797), insufficient attention has been given to implementation. A beneficial package of care, support and prevention for people with HIV in the pre-ART stage would support people to remain engaged in care throughout this period and facilitate timely assessment of ART eligibility and commencement of treatment.

For example, following a positive diagnosis, if a patient is not eligible to be enrolled in ART care there are opportunities to offer a range of services which have wide benefits and could prevent loss to follow-up during this period, including provision of HIV prevention services, cotrimoxazole prophylaxis, screening for TB and provision of IPT, safe water, insecticide-treated bed nets (where appropriate) nutritional assessment, psychosocial support, support for partner testing, and PMTCT, family planning and reproductive health services, and linkages to community care and support, in addition to periodic clinical and immunological assessment so that patients can move from pre-ART services to ART care as soon as they become eligible (WHO, 2011:22).

## **2.3.2. What is the level of adherence by adult patients to pre ART**

### **2.3.2.1. Defining adherence**

Due to the fact that pre-ART care is very poorly understood and given less attention, there has been no proper definition of the term “retention” or “loss to follow up” during the pre -ART period. As a result, literature shows unclear and inconsistent use of terms that has made synthesis of evidences on retention very difficult (Matthew, Bruce & Sydney 2012:2).

In order to address these challenges, Matthew et.al (2012:3) recently developed practical standardized definitions for reporting retention in the three stages of pre-ART care. They include:

- Stage1: a period from testing HIV-positive to initial ART eligibility assessment;
- Stage2, a period of initial assessment for ART eligibility; and
- Stage3, a period after ART eligibility assessment until ART initiation.

Stage1 retention rate is defined as the proportion of patients who completed initial ART eligibility assessment within 3 months of HIV testing, with reporting of cohort outcomes at 3 and 12 months after HIV testing. Patients who end Stage1 eligible for ART move directly to Stage3.

Stage2 retention is defined as the proportion of patients who either complete all possible ART eligibility re-assessments within 6months of the sites standard visit schedule or had an assessment within 1year of the time reported to and were not ART eligible at the last assessment. Retention should be reported at 12-month intervals.

Stage3 retention is defined as the proportion of patients eligible for ART who initiate ART (i.e. ARVs dispensed) within 3 months of determining ART eligibility, with reporting at 3months after eligibility and 3 monthly intervals thereafter (Matthew et.al 2012:5).

Others have defined patient retention (not specifically pre ART patients) as missed appointments, missed visit rates, and the percentage of patients who miss appointments over a defined period (Catz et al. 1999:362, Israelski et al. 2001:473).

Mugavero et al (2009:248) defined missed appointments as appointments that are not cancelled or rescheduled; missed appointment rates are the proportion of total appointments that are missed and are also referred to as a missed visit proportion, which has been used with a threshold of 25% to compare association with independent variables.

Regardless of which definition is to be followed however, the conceptualization and investigation of patient retention should be based on which measures best capture the essence of an established provider-patient relationship, which patients fall out of care, and the types of interventions that will be targeted to maintain ongoing engagement in care. (Elizabeth et al. 2010:3).

For this study a definition by CDC used at country level is used for both Adherence and loss to follow up. Accordingly, adherence is engagement and accurate participation of informed patient in a plan of care without skip from appointment for the last 3 months (CDC 2006) and loss to follow up is when a patient doesn't show up for clinic appointments for at least 3 months (CDC 2006).

### **2.3.2.2. Level of patient retention in pre-ART care**

Retention in care after the initiation of ART has been the focus of much published work from sub-Saharan Africa and is seen as a key indicator of program performance (Rosen, et al., 2007). However, few studies have exclusively assessed pre-ART LTFU in Africa (Larson et al. 2010; Bassett et al. 2010; Amuron et al. 2009; Losina et al. 2010; Lessells et al. 2011; Lessells et al. 2011; Rosen et al. 2011).

According to a systematic review of pre-ART care in sub-Saharan Africa by Sydney Rosen and Matthew Fox (2011:7), more than two-thirds of people who tested positive for HIV but weren't yet eligible for treatment when diagnosed with HIV were lost from care. This study that has reviewed 28 different studies reported that there was a substantial loss of patients at every step of care, starting with patients who do not return

for their initial CD4 count results and ending with those who do not initiate ARVs despite eligibility.

Bassett et al (2009:3), also conducted a study in South Africa which showed that fewer than 50% individuals not yet eligible for ART returned to health facility within 13 months for repeat CD4 cell count; 16.4% of these patients were lost within three months of follow-up before ART initiation (Bassett et al. 2009:5).

A similar study was also conducted in South Africa to estimate loss to follow up between initial enrolment and the first scheduled return medical visit of a pre-ART care program. The result showed that 74% of patients scheduled to return in 6 months for a first medical visit did not return within one year and only 6% of patients scheduled to return in 3 months returned within 4 months while 41% returned within one year (Bruce A. et al. 2010:1).

A study conducted in a district hospital in southern Ethiopia to assess pre-ART and on-ART patient outcomes showed that a quarter of pre ART patients were lost to follow-up (Zewdie, Degu & Bernt 2010:2).

A study from Kenya showed that 33.6% of pre ART patients were reported to be lost from care and 53.9% these patients were lost as early as before the second visit (Amin S et al 2012:82). Faal M et al (2012:5) also reported that high pre-ART losses persist with almost 1- in- 2 patients failing to collect their laboratory CD4 result one week after HIV diagnosis

### **2.3.2.3. Benefits of retention in HIV care**

Studies show that retaining HIV-infected patients has the potential to help contain health care costs by improving HIV-specific health outcomes and reducing emergency department visits and hospitalizations (Cree et al. 2006:5, Gill & Mainous 2000:4). In addition, retention provides the opportunity to implement preventive health care interventions and to promote health behavior change that may decrease HIV transmission (Elizabeth et al. 2010:106). Retention in pre ART care has also been shown to contribute to improved patient retention in ART care as it allows adequate

preparation giving them extra time to adjust to the need for lifelong therapy and to attend multiple group education sessions (Elena et al. 2010:4).

Poor retention in care is associated with decreased likelihood of receiving antiretroviral therapy, higher rates of antiretroviral therapy failure, increased HIV transmission risk behavior, increased hospitalization and reduced survival rates (Elizabeth et al. 2010:108, Giordano, Hartman & Gifford 2009:300). In general, retention in care prevents new HIV infections, promotes good quality of life for those living with HIV infection and reduces mortality from AIDS-related illnesses.

### **2.3.3. Socio-demographic, cultural and disease –related factors that contribute to non-adherence/adherence among Pre-ART patients**

Consulted literature revealed several key reasons for the poor retention of pre-ART care patients. Rosen and Fox (2011:5) wrote that patients may not perceive themselves as requiring medical care as most are asymptomatic during the pre-ART period. Lessels et al (2009:5) also provide similar evidence showing lack of incentive for asymptomatic individuals to return for clinical monitoring as a possible explanation for poor retention indicating that the majority return to care at the time of symptoms. The fact that package of care for individuals not yet eligible for ART is limited in most African setting, was also mentioned to have likely limited the effectiveness of programs (pre-ART) as individuals will often return to care with opportunistic infections, possibly requiring hospitalization, and ART will continue to be initiated late with consequent sustained high mortality rates (Ndiaye, Ould-Kaci & Salleron 2009).

Tom and colleagues (2011:4) reported that lack of availability of comprehensive HIV care services may be a reason for low retention in care in the pre-ART period. Patients who are simply asked to return for repeat CD4 testing after 6 months may be less inclined to return than patients offered a comprehensive service package upon diagnosis.

In Uganda, inadequate post-test counseling and competition from holistic and less stigmatizing traditional/spiritual healers were cited as the main reasons for loss during the pre-ART period (Lubega, et al., 2009). While, age, sex and marital status were not shown to be associated with being lost to follow-up in some studies, (Zewdie et al 2010:3), others indicated gender to affect both access to and retention in care (Richard J. et al. 2011:84). The proportion of males in the pre-ART population was shown to be lower than that seen in antiretroviral treatment cohorts and likely reflects the different entry points to HIV care, with a large number of asymptomatic females enrolled in HIV care through antenatal HIV testing (Braitstein, et al., 2008). Male sex and full-time employment were associated with lower rates of retention in this same study. However, another study showed that being employed to be positively associated with a patient adherence to care (Bruce A. et al. 2010:45)

Having high CD4 count is associated with patients not seeing the point of engaging in care as they feel well (Faal, et al 2010:3, Bruce A. et al. 2010: Bassett et al 2009:140). A study from Ethiopia showed that being in less advanced WHO clinical stage at diagnosis, and being a rural resident to be independent predictors of loss to follow-up. (Zewdie et al 2010:2).

While the above study by Zewdie, et al (2010:2) reported age, sex and marital status not to be associated with being lost to follow-up, Amin S, et al (2012) reported distance from health facility and marital status to have independently predicted LTFU during the pre-ART period.

In the study done in South Africa, Elena et al (2010) wrote that factors associated with higher rates of lost to follow up were: living  $\geq 10$  km from the health center, a history of TB treatment, and referral for HIV testing by a health care provider as opposed to self-referral.

Also, transportation costs, long waiting time, lack of incentives to seek pre-ART care by healthy looking patients and gender inequalities were mentioned as some of the perceived reasons for the high loss (Zewdie et al 2010:3).

In general, studies show that patients may not come to the clinic for monitoring and may choose to wait and see what happens if they lack resources for transport, risk losing employment by taking time off work, or fear being recognized as a client of an HIV clinic.

#### **2.3.4. Strength and weakness of studies done on pre-ART retention and factors associated with pre-ART loss to follow up**

The few available studies on pre ART all showed the magnitude of problems in retaining patients in pre ART care. However all the studies used different set of terms definition (such as...) and followed different patterns of reporting findings. This is a reflection of lack of common understanding on the minimum package of services required during the pre-ART period and the standard measures of program performance even at a global level. While all of these studies focused on assessing the retention, few investigated the service environment and program designs to care for patients during the pre-ART period. In their systematic review, Rosen and Fox (Rosen & Fox 2011:8) reported that none of the studies in their review followed a cohort of patients through all three stages of pre-ART care, with most studies reporting on only one stage. It was also mentioned that aggregations of results were difficult across the studies reviewed as enrolment criteria, terminology, endpoints, follow-up, and outcomes varied widely and were often poorly defined.

## **2.4. CONCLUSION**

The literature review was conducted to gain better understanding on pre ART care, retention and factors associated with lost to follow up. Various sources including internet, text books and others were assessed to identify the literature. The literatures consulted assisted the researcher to better understand the research question and conceptualize the important knowledge gap in the study topic and decide on the variables that the study needs to measure/assess.

## **CHAPTER 3**

### **RESEARCH METHODOLOGY**

#### **3.1. INTRODUCTION**

This chapter discusses the research methodology including the design, study population and sampling, data collection techniques, approaches to data analysis and ethical issues.

#### **3.2. RESEARCH DESIGN**

A cross-sectional research design with a mix of quantitative and qualitative data collection methods was used. This technique is selected to obtain the complementary strengths of the resulting mixture of the two techniques. While the quantitative technique assisted in describing the data and measuring statistical associations to generalize findings, the qualitative techniques contributed to the search for pattern, theme and holistic feature with representation of viewpoints from the interviewee.

#### **3.3. RESEARCH METHOD**

A cross sectional descriptive study design was used to examine the level of adherence to pre ART care among adult HIV positive patients and the various factors associated with patients lost to follow up. According to Polit and Beck (2004:192), the purpose of descriptive designs is to observe, describe and document aspects of a situation as it naturally occurs in a given population. Cross sectional designs are conducted in the present time to examine what currently exists and they are fundamentally characterised by the fact that all data are collected at one time (Brink & Wood 1998:6).

According to Brink and Wood (1998:161), correlation design is used when the investigator has reason to suspect a relationship between variables and can support this suspicion from literature or previous research. Brink and Wood, (1998:163) give the following additional assumptions for correlation design: the variables have not been shown to co-vary in previous studies of similar populations; and there is no tested



theory on which to predict the possible relationship between the variables. These variables exist in the population and they are studied as they exist naturally without manipulation. Finally the sample needs to be representative.

Descriptive method was applied to describe patterns and provide information about study variable characteristics. The study was also cross sectional as it is conducted in the present and all the data were collected at the same time. The study's correlation aspect comes in the fact that the suspicion of a relationship between dropping out from care and the different socio demographic and disease related factors emanated from the review of the literature is tested.

Focus group was used as an additional method for data collection in this study. Focus group interviews are particularly useful in obtaining multiple perspectives about a topic in a concise manner while providing insight into the shared understanding held by group participants (Gibbs 1997:1-7). Attitudes, feelings and beliefs are more likely to be revealed through the group process unique to focus group methodology (McLafferty 2004:190). Focus groups have been used by other investigators doing research with HIV/AIDS individuals (Nyamathi & Shuler 1990, Reynolds 2004).

Guidelines on HIV care and treatment were analyzed to produce comprehensive report about what standard operating procedures guide the pre ART care service.

### **3.3.1. SAMPLING**

#### **3.3.1.1. Research Population**

The study population in this research included all HIV positive patients enrolled into the pre- ART care program in St Luke Hospital. The following were inclusion and exclusion criteria:

##### *Inclusion criteria*

- Adult patients (- 18 years and above).
- Enrolled to the Pre ART care during the period from January 1<sup>st</sup> 2009 to December 31<sup>st</sup> 2010.
- Patient's follow up chart and electronic record available in the health facility.

##### *Exclusion criteria*

- Patient not officially registered and enrolled to Pre ART care in St. Luke hospital's ART clinic
- Patients aged below 18 years
- Patients follow up chart and electronic record not available

#### **3.3.1.2. Sampling technique and sample size**

Two aspects: record review and focus group discussions

All pre-ART adult patients (n=760) who enrolled to HIV care between January 2009 and December 2010 at St. Luke hospital, Ethiopia were selected for chart review in this study. Therefore, no sampling procedure was applied to identify the study subjects for the record review aspect of this study other than the inclusion and exclusion criteria. Patient data was available both computer record and patient chart. The electronic version is extracted for this study with occasional cross reference to the paper records in case of incomplete information. However, the data on the computer record and patient chart found to be identical.

A convenience sample of 30 HIV-infected patients receiving care at an outpatient HIV clinic in St. Luke hospital, attended one of three focus groups with 10 discussants in each. Patients were selected from subjects who have been enrolled to pre ART care during the study period and were reported to be loss to follow up or were traced back to care afterwards. Convenient sampling was used to ensure participants represent gender and age group categories desired to represent the study population.

During the initial contact process patients were notified that they are invited to participate in focus groups and were informed that they are free to agree to or refuse participation.

Patients were initially eligible to participate in the focus groups if they were HIV positive, enrolled in the pre ART care in St. Luke hospital and hasn't started taking ARV. Phone numbers and additional contact information were retrieved from the patients' medical records. Times and dates for focus groups were established by the investigator based on participant's preferences once an adequate number of participants were recruited for a group session.

Patients who could be contacted via telephone were recruited to one of three prescheduled focus group sessions. No refusals were recorded although more than half of the eligible patients were unable to be contacted, due to a disconnected line or wrong number.

### **3.3.2. Data collection**

#### **3.3.2.1. Data collection approach and method**

Structured chart review checklist was used to capture data from patient records regarding patient socio-demographic and follow up history and retention status. Focus Group Discussion was held to solicit data information on socio-cultural factors associated with patient loss to follow up from care.

#### **3.3.2.2. Development and testing of the data collection instrument**

The chart review format and FGD guide was specifically developed for this study purpose. Reference was made to literature and other similar studies but it was not fully adopted. As advised by Brink and Wood (1998:247) and Boynton and Greenhalgh (2005:1313), different approaches were simultaneously used to develop the items included in the instrument.

Chart review format development was guided by the literature review and findings from previous studies. Studies such as Larson et al. 2010; Bassett et al. 2010; Amuron et al. 2009; Losina et al. 2010; Lessells et al. 2011; Lessells et al. 2011; Rosen et al. 2011 were some of the studies referenced. The researcher's field experience on HIV/AIDS care and treatment in Ethiopia also contributed in the development of some of the questionnaire.

The FGD guide was initially developed in English language and then translated into Oromifa the local language, which was back translated into English to check for consistency. The translation and back translation process was conducted by bilingual expert.

#### **Pre testing of the instrument**

Both chart review form and focus group discussion guide was sent to three medical professional colleagues for review and feedback. Comments received from the peer review included keeping the questionnaire simple and categorizing discussion areas based on the variables desired to be shared.

Following the peer review, the chart review format and FGD guide were both tested before using them for this study. The chart review format was tested to extract data from 50 pre ART patient charts in Chitu health center in South west Shoa zone. The FGD guides were pilot-tested on support group members in a rural community located in South west Shoa zone and modified based on the debriefing with facilitator and interviewed participants.

The instrument was modified based on the feedback from the pre test, and the post pre test version was used to collect the final data.

### **3.3.2.3. Characteristics of the data collection instrument**

Instruments used to conduct this research included chart review checklist, focus group discussion check list and referencing available programs and guidelines at the national and global levels. In addition, non-participant observation was conducted during patient consultation to collect information on the nature of services provided to pre ART patients.

#### **Guide to the research instrument**

The chart review (Annex 1) has a total of 22 items grouped in to three sections. Each section is composed of questions related to one of the three categories of variables. All questions were close-ended meant to gather data as it appear on the chart. The following provides detail guideline to the content of each section.

- Section 1 comprises 8 questions and assesses data on client socio demographic data
- Section 2 has 4 questions and focuses on Client's clinical, biological information up on enrollment
- Section 3 has 10 questions on follow-up data

Discussion guide was developed to conduct focus groups. The FGD guide has talking points on Opinion of patients on the pre-ART program activities in St. Luke hospital, reasons for discontinuation, individual and social influences/barriers and client

experience with pre-ART. The discussion guide was used to direct the FGD towards the information required but was kept open ended for participants to talk about the issue freely. Probing techniques were used to go in depth in each point to obtain an in-depth insight.

Krueger and Casey (2000) suggest that five categories of questions be used in conducting the focus group interview: opening, introductory, transition, key and ending questions. Opening questions establish rapport and get interaction between group members. Questions should be easy to answer in a brief way and are not typically analyzed. Introductory questions are used to introduce the topic of discussion and get participants to begin thinking about the topic of interest using an open-ended approach. Transition questions serve as a bridge from the introductory to the key questions and serve to make a connection between the participant and the topic being investigated. Key questions serve as the main focus of the study. Finally, ending questions are used to bring a sense of closure to the interview and serve to reflect on and summarize what has occurred.

### **Variables measured**

The sets of variables (dependent and independent) this study assessed include:

- Service factors: include the service delivery environment during the pre-ART care, especially assessing presence of guidelines and standard operating procedures, trained health care workers in the field and availability of basic infrastructures.
  - Patient factors: demographic, clinical social data at enrolment and during follow-up period
  - Socio economic and cultural factors: demographic, social and economical background of clients and their fellow peers
- i. The variable service factor

The service factor in this study was measured by collecting information on type of services provided during pre ART care, describing the packages of clinical and psychosocial services provided in each visit and analysing the available guidelines and SOPs on patient care. The conceptual framework developed for this study was used as a point of reference in identifying this variable.

ii. The variable patient factor

Patient factors were measured using focus group discussions to solicit data on patients' experience with pre-ART, reasons for discontinuation, individual and social influences/barriers and opinion on the pre-ART program activities in St. Luke hospital

iii. The variable Socio economic and cultural factors: demographic, social and economical background of clients

Socio economic, cultural, social and demographic data were collected through both chart review and focus group discussions.

#### **3.3.2.4. Data collection process**

Patient records were reviewed as proposed to determine the level of adherence to HIV/AIDS care. The review was conducted using data capturing format that contains demographic, socioeconomic, clinical status and follow up history information. Client electronic database was used as main document during this process. Critical evaluation of policies, guidelines and operating procedures regarding HIV care and treatment in the country was conducted to assess the service and program environment. In addition, observation was made during consultation to collect information on the nature and services provided to the patients on ARVs.

Three focus group discussions were conducted in a quiet room at the multipurpose rooms of St. Luke College of Nursing in Wolisso town. This location was chosen as it is in a central and accessible location for most of the participants and had adequate and private meeting rooms which were provided free of charge.

As HIV can be a sensitive topic and to minimize observer bias, the FGD was carried out by trained moderator and note taker for all the three groups, local language skills needed for all the sessions and familiarity with the sites. The moderator and note taker were provided with half day orientation in which they were informed about the purpose of the study, ethical issues and the consent procedure, the FGD facilitation process and methods of probing.

The focus group discussion was initiated using open-ended questions in the main areas of 1) Experience with pre-ART services 2) Perceived reasons for discontinuation 3) Individual and social influences/barriers for retention 4) Opinion on the pre-ART program activities and its qualities in St. Luke hospital. In addition, several probing questions were used that pertained to how they see the service, what has been helpful in being adherent, what has been problematic, role of health care providers and relationship with health care providers.

Demographic information, including patient age, gender, religion and level of education was obtained from a brief interview with the patients prior to each focus group.

Each focus group was conducted by the moderator and audio taped so it could later be transcribed for data analysis. A note taker took detail notes as discussion was going on.

#### **3.3.2.5. Ethical consideration related to data collection**

Major ethical considerations that needs to be taken care of in relation to data collection for research include the voluntary nature of participation, reduction of risk for participants, obtaining of informed consent, ensuring confidentiality and privacy of participants, and institutional ethical issues which include obtaining authority to conduct research and scientific honesty (Babbie and Mouton, 2001: 552, Bless and Higson-Smith, 1995: 102, Katzenellenbogen, Joubert and Abdoo IKarim, 1997: 27, Mouton, 2004: 238, Polit and Beck, 2004: 143 )

Steps taken to ensure the above issues are adhered to for this study include:



- **Voluntary participation:** participants had the right to take part in the study or not as they chose. For the chart review, the hospital management had the right to grant or refuse permission to access the data.
- **Informed consent:** participants were provided with adequate information on the research before the focus group discussion. The hospital was informed adequately regarding the scope and intention of the study. Written consent was obtained from the hospital as well as individual research participants.
- **Confidentiality and anonymity:** anonymity and confidentiality were ensured by making the responses anonymous and identifying patients on record only through unique identifier codes and without their names. Information obtained remained confidential and were not revealed to people other than the research team.
- **Minimizing risk to participants:** the research was carried out with minimum risk to respondents. Counseling services were made available for FGD participants in case of any emotional stress during the sessions.
- **Authorization to conduct the research:** authority to conduct the research was obtained from St. Luke hospital authorities and UNISA Research and Ethics Committee. (see annex 7 and 8)
- **Competency:** competency of the researcher to conduct research was approved after passing the theoretical Masters in Public health modules in health measurement and research methodology courses offered by the University of South Africa.

### 3.3.3. Data analysis

A data imported from The ART database was analyzed using SPSS version 15 statistical package. Frequency distribution and percentage calculation was made to describe socio-demographic characteristics and to determine the prevalence of lost of follow up. Logistic regression analysis, crude odds ratio was done to determine whether any association exists between the independent and outcome variable with a confidence interval of 95%. Audiotapes of the focus groups were transcribed verbatim.

The investigator reviewed the transcripts for accuracy and to capture the interactions within the group. The transcripts were analyzed to develop codes for data analysis.

Categories of responses were coded using an emergent approach described by Haney et al (1998:40), which consists of several steps. First, the transcript was reviewed in depth to condense responses into classifications to which a coding scheme could be applied. Second, the findings were reviewed again and final coding scheme established. The coding schemes were based on the topics in the focus groups. Third, the coding scheme was used to code a second transcript. Fourth, the results of the coding of the second transcript were checked to determine the reliability of the coding.

The information gathered through FGD was used to complement and strengthen the findings obtained through quantitative data sources. The findings were crucial in obtaining answers to some of the research questions such as patient experiences and opinions about pre-ART services and reasons for discontinuation that are not possible to identify through quantitative methods.

### **3.4. VALIDITY AND RELIABILITY OF THE STUDY**

#### **3.4.1. Internal and external validity of the study**

Validity refers to the question whether there is evidence to support the assertion that the methods are really measuring the abstract concepts that they are meant to measure. Validity also concerns the quality of the researcher's evidence regarding the effect of the independent variable on the dependent variable (Polit & Beck 2004:38)

#### **Internal validity**

Burns and Groove (2005:2015) define internal validity as the extent to which the findings of a study are a true reflection of reality, rather than the result of extraneous variables. Descriptive research is said to be low in terms of internal validity as it allows for limited control over the research variables and the research setting. The internal validity of qualitative research is the degree to which the interpretations and concepts

have mutual meanings between the participants and the researcher. Some of the strategies used to enhance the validity of the qualitative data from FGD include:

- Verbatim accounts of literal statements of participants and quotations from documents
- Use of tape recorder
- Use of participant recorded perceptions in notes for corroboration

### **External validity**

External validity is defined as the degree to which the study results can be generalised to other people and other research settings (Brink 2000:209). In this study, a large representative sample from two years' period was used to ensure the findings will be generalisable to the population. In addition, the research design was carefully constructed to ensure

### **3.4.2. Reliability**

Polit and Beck (2004:35) defined reliability as the accuracy and consistency of information obtained in a study and state that the term is most associated with the methods used to measure research variables. Reliability problems in studies commonly arise when respondents don't understand the question, are asked about they don't clearly recall or are asked about something of little relevance to them (Fisher & Foreit 2002:45). The use of standard chart review protocol for all charts reviewed in this research and the use of similar discussion guides for all FGD groups are some of the techniques used to increase the reliability of this research.

### **3.5. CONCLUSION**

This chapter presented the methodology used to conduct this study. A mixed quantitative and qualitative approach was used and descriptive, cross sectional and correlational research design was adopted. Purposive sampling technique was used for FGD while patients enrolled to care between January 2009 and December 2010 in St. Luke hospital were all included in the chart review.

The data collection method and instruments used in this study were also discussed in this chapter. Structured patient chart review checklist containing 22 items and a focus group guide were used to gather data that measured the rate of adherence to pre ART care and factors associated with loss to follow up. The other components discussed in the chapter include validity, reliability and ethical consideration followed by data analysis plans.

## **CHAPTER 4**

### **ANALYSIS, PRESENTATION AND DESCRIPTION OF THE RESEARCH FINDINGS**

#### **4.1 INTRODUCTION**

This chapter discusses the analysis and interpretation of data. The presentation of data is organized as quantitative data analysis, FGD report and review and assessment of guidelines and program documents.

#### **4.2. DATA MANAGEMENT AND ANALYSIS**

Data were collected through quantitative and qualitative methods. Chart review and FGD were implemented in April 2012. Review of guidelines and program documents was conducted before the other data were collected as part of the literature review. Chart review was done for 765 adult patients enrolled into the pre-ART HIV care program in St. Luke Hospital over 2 years period - between January 2009 and December 2010. Four hundred and thirty (56%) of these were put on ART during the 2 years period while three hundred thirty five (44%) were still followed under pre-ART program. Patients who started ART during this period were excluded from the current study. Focus group discussion was held with thirty participants who are currently on pre ART.

Quantitative data was analyzed using statistical computer software and qualitative data was processed using qualitative techniques described in Chapter Three.

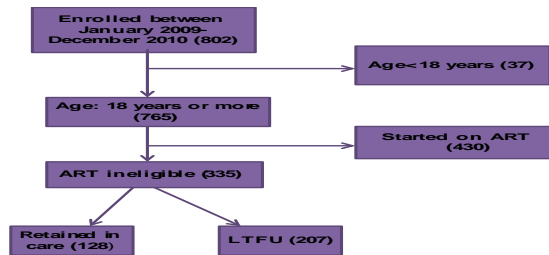


Figure 4.1 Flow diagrams of study participants

### 4.3. RESEARCH RESULTS FROM CHART REVIEW

The results of the analysis of the data are presented below using tables, graphs and summary statistics.

#### 4.3.1. socio-demographic characteristics

Of the 335 patients included in the analysis, 71.3% (n=239) were female and 96 (28.7%) were males. Age of participants ranged from 18 to 58 years with mean age of 34.3 years (standard deviation= 9.4). Table 4.1 depicts detailed socio-demographic characteristics of the study subjects.

**Table 4.1: Socio demographic characteristics of participants**

Characteristics	Female (n=239) Frequency (%)	Male (n=96) Frequency (%)	Total (%)
<b>Age in years</b>			
18-24	47(19.7%)	4(4.2%)	51 (15.2%)
25-34	134(57.3%)	29(30.2%)	166 (49.6%)
35-44	41(17.2%)	36(37.5%)	77(23.0%)
45-54	9(3.8%)	21(21.9%)	30(9.0%)
55+	5(2.1%)	6(6.3%)	11(3.3%)
<b>Level of education</b>			
No education	99(41.4%)	19(19.8%)	118(35.2%)
Completed Primary school (up to grade 8)	100(41.8%)	48(50.0%)	148(44.2%)
Completed secondary school and higher	40(16.7%)	29(30.2%)	69(20.6%)
<b>Marital status</b>			
Never Married	15(6.3%)	15(15.6%)	30(9.0%)
Married	139(58.1%)	67(70.8%)	207(61.8%)
Separated	47(19.6%)	8(8.3%)	55(16.4%)
Divorced	4(1.7%)	1(1.0%)	5(1.5%)
Widow	34(14.2%)	4(4.2%)	38(11.3%)
<b>Religion</b>			
Muslim	30(12.5%)	10(10.4%)	40(11.9%)

Christian - Orthodox	160(66.9%)	74(77.1%)	234(69.9%)
Other Christians ( Protestant and catholic)	49(20.5%)	12(12.5%)	61(18.2%)
Employment status			
Employed (public or private institutions)	86(38.5%)	41(42.7%)	133(39.7%)
Self employed	50(22.1%)	50(52.1%)	103(30.7%)
Un employed	92(39.3%)	4(5.2%)	99(29.6%)

#### 4.3.1.2. Outcomes of Pre-ART Follow-up

The charts reviewed showed that WHO staging, weight measurement and assessment for opportunistic infections were done at every visit to Hospital. CD4 counts on the other hand were measured every three months. Viral load measures were not done for any of the subjects.

Proportion of patients in the various WHO stages at enrolment into the pre-ART program and following 6 and 12months is illustrated in the table below (Table 4.2). The table also shows the status of initial and repeat CD4 counts performed, diagnosis of opportunistic infections and mean weight across time.



Table 4.2: Distribution of WHO staging, CD4 count, OI diagnosis and mean weight of pre-ART patients at first, 6 month and 12 month visits

Characteristic	At first visit	At 6 months follow-up;	At 12 months follow-up
<b>WHO stage</b>			
I	201(60%)	109 (61.6%)	67(62%)
II	72(21.5%)	47(26.6%)	32(29.6%)
III	53(15.8%)	18(10.2%)	9(8.3%)
IV	9(2.7%)	3(1.7%)	-
<b>Total observed</b>	335	177	108
<b>CD4 Count done</b>	330(98.5%)	71 (21.2%)	80 (23.9%)
<b>OI Diagnosis done</b>	335 (100%)	177 (100%)	108 (100%)
<b>Weight taken</b>			
Mean	52.6	53.9	52.8
SD	9.1	9.2	8.2

#### 4.3.1.3. Pre-ART Loss to follow up

Of the 335 patients enrolled in pre-ART care, 128 (38.2%) were retained in care and the remaining 207 (61.8%) were lost to follow up after 12 months. More than half (55.6%) of the LTFU took place within 6 months. The rate of LTFU declined and remained steady afterwards (Figure 4.2).

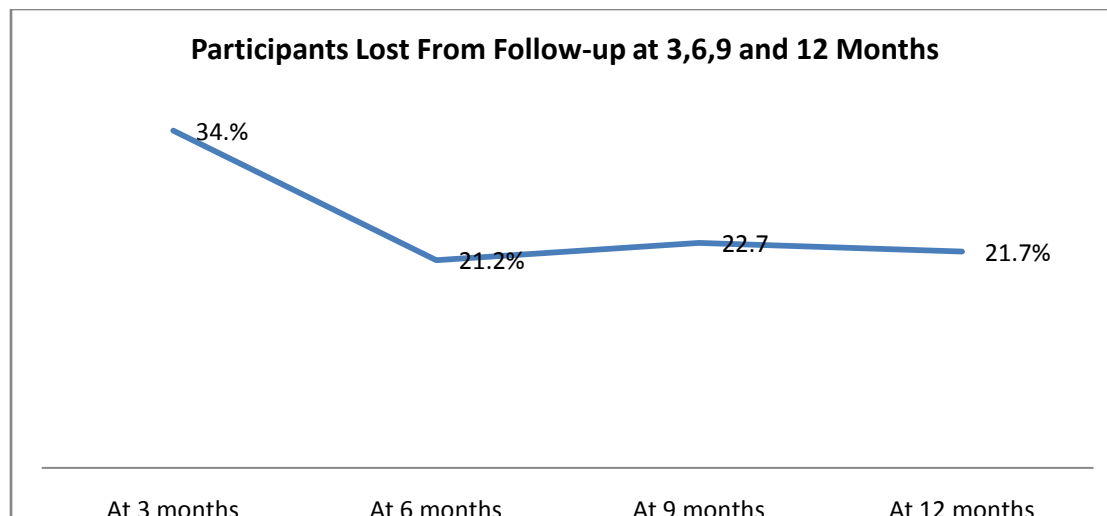


Figure 4.2: Proportion of participants who were lost from follow-up at 3, 6, 9 and 12 months

One's religion and having child significantly predicted pre-ART LTFU (Table 4.3). Compared to Christians, Muslim patients had three times higher chances of loss to follow up (crude odds ratio [95% CI],  $p$ -value; 3.44[1.39-8.49],  $p < 0.05$ ). Patients who didn't have children were more likely to be loss to follow up than those who had children (2.05[1.05-4.01],  $p < 0.05$ ). The analysis didn't show any association between loss to follow up and age, sex, residential address (urban/rural) disease category and CD4 count at enrolment.

**Table 4.3: Factors associated with lost to follow up among pre ART patients**

Variables	Categories	Retained care (128)	LTFU (207)	Crude OR (95% CI)
Gender	Female	96	143	1.34( 0.81-2.20)
	Male	32	64	1.0
Age Group (years)	18-24	21	31	1.01(0.52-1.97)
	25-34	58	107	1.28(0.79-2.09)
	35-44	49	69	1.0
Marital Status	Non Married	46	81	1.12(0.71-1.78)
	Married	81	126	1.0
Educational status	No education	48	70	0.89(0.48-1.64)
	Primary	54	94	1.06(0.58-1.92)
	Secondary and above	26	43	1.0
Employment status	Employed (public or private institutions)	60	85	0.82 (0.43-1.72)
	Self employed	40	60	1.0
	Un employed	28	62	1.05 (0.52-1.83)
Religious denomination	Muslim	9	31	3.44(1.39-8.49)*
	Orthodox Christian	90	144	1.60(0.89-2.85)
	Protestant Christian	29	29	1.0
Have child	Yes	115	168	1.0
	No	19	39	2.05(1.05-4.01)*
Pregnant on enrollment	Yes	5	11	1.0
	No	123	196	0.72(0.24-2.13)

\*= p value < 0.05

#### 4.4. ANALYSIS AND INTERPRETATION OF FOCUS GROUP DISCUSSION PARTICIPANTS BACKGROUND INFORMATION

##### 4.4.1. Background Information

Three FGDs were conducted with 10 participants in each group. The majority of participants on the FGD, 80% (n=24) were females. As shown in the table 4.5 below the majority of the FGD participants; 67% (n=20) were married and only 60% (n=18) have attended primary.

All discussants were HIV positive and were not started on ART by the time of the FGD. 20 of the patients were former LTFU who are retraced back to care. The remaining 10 are currently reported as LTFU. Selection was done through hospital case managers. Please refer to methods section for details.

**Table 4.4: background information of Focus Group Participants**

Characteristics	Number	Percent
<b>Gender</b>		
Male	6	20.0%
Female	24	80.0%
<b>Age categories</b>		
18-27	7	23.0%
28-37	16	53.0%
38-47	5	17.0%
48-57	2	7.0%
<b>Marital status</b>		
Never Married	2	7.0%
Married	20	67.0%
Divorced	2	7.0%
Widow/Widower	6	20.0%
<b>Level of education</b>		
No education	7	23.0%
Attended Primary school	18	60.0%
Attended Secondary school	5	17.0%
<b>Participants employment status</b>		
Paid employment	6	20.0%

Self employed	9	30.0%
Unemployed	15	50.0%
<b>Place of residence</b>		
Urban	5	16.7%
Rural	25	83.3%
Total	30	100.0%

#### 4.5. FINDINGS FROM FOCUS GROUP DISCUSSION

The data from all three focus groups were analyzed as described in the methods section above. The concept of adherence as a process from diagnosis to present emerged from the analysis of the data. For most participants becoming adherent to a clinic appointments was described as a “process”. Some participants claimed to have been adherent from the start, however, all reported encountering struggles accepting their diagnosis, needing to be on routine follow up schedules and/or the social life implications being seen in the health facility has “caused them in their lives”. Overtime the participants moved toward acceptance of their HIV status and the need to take their follow up seriously. As they get used to the social isolation and discrimination it became easier to cope with life of their own type. Most participants identified supportive others who played a role in their transition to acceptance of their diagnosis and the need to be on clinic follow up for HIV. The relationship with their healthcare provider, (predominantly a nurse or adherence counselor), was identified as significant in the process of becoming maintaining adherence behavior. All participants in the study reported that adherence to their follow schedules has a positive impact in terms of their health outcome.

The findings are presented under three thematic areas. The first objective was to describe experience of HIV positive people on pre ART care regarding general information on healthcare demand. The second objective was to describe what these

people perceive about the quality of HIV/AIDS service that are provided at pre ART programs currently and the third objective was to describe what socio economic and cultural factors they perceive as a factor to determine their adherence/non adherence.

In addition, several probing questions were used to ascertain what things had been helpful and problematic in adherence, what role did other people play in the adherence process and qualities of the relationship with the health care provider. Findings are presented as summary points and in some cases quotations are cited verbatim as stated by the discussants.

#### **4.5.1. Experience of FGD participants with pre-ART program**

All participants identified some level of difficulty accepting their HIV positive status which resulted in difficulties in adhering to clinic follow ups during the initial phase

##### **A) Learning the Diagnosis and about the service**

Many participants were diagnosed with HIV during to ante-natal care follow-up, childbirth, as a result of a serious illness or general change in their physical appearance. Some participants learned their diagnosis while hospitalized with an opportunistic infection, such as Tuberculosis, or another life threatening condition. A few reported seeking an HIV test in relation to the illness or death of an intimate other.

There were a number of individuals, who sought HIV testing voluntarily. Almost all participants learned about the pre-ART care service on the day they learned their diagnosis. The initial reaction to having HIV included a range of emotions such as depression, fear, anger, self-blame, and denial. One female participant expressed her initial reaction to her test results as *"I wanted to disappear or kill myself when I was told I had HIV"*.

Others identified fear as one of their early reactions as they believed they would die quickly because of HIV. This was mentioned by one participant as *"I thought I was going to die immediately, I didn't know people lived with the disease"*.

People whom they sought help from about their HIV status after diagnosis included PLHIV association, Red Cross society local offices and health workers. All participants said that they learned about HIV care and treatment service at the time of counseling from the health care workers.

Most participants said that people diagnosed with HIV don't tell their status to other people. Reason given for this was fear of stigma and discrimination. All participants reported some difficulty dealing with the stigma, real or perceived, of being HIV positive and showing at HIV clinic. Stigma, related to letting others know their health status, could impact multiple aspects of their lives; such as employment, and relationships with significant others. Many participants reported believing that avoiding stigma was easier if they didn't have to go to clinic all the time.

Many reported that they were forced to isolate themselves from important social activities such as coffee ceremony, Idir<sup>1</sup> and Mahber<sup>2</sup> due to the stigma. This was expressed by one participant as *"I had to stop drinking coffee with my neighbors because they started fearing I might give them AIDS by using their cups"*. For many participants, this concern about stigma resulted in missing clinic appointments to keep their status hidden: *"I often cancel my plan to go to clinic if I suspect someone I know is also going there at the same date, because I don't want them see me in the HIV clinic"*. For others, the impact of stigma led to feelings of shame: *"I felt ashamed; I always hid my medication from my children"*.

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<sup>1</sup>Idir is a traditional social support system (burial society) in Ethiopia in which communities support each other on death of family members and other occasions such as weddings. It serves as a community insurance scheme also

<sup>2</sup>Mahber is traditional community association

## **B) The pre-ART service**

Most discussants said that they consider the service they receive at the pre ART clinic as “good”. Discussants also mentioned that the service in the pre-ART program included counseling on topics ranging from positive living, nutrition and adherence to follow-up of medication. They all also agreed that regular laboratory testing, physical examinations and treatment of opportunistic infections were part of the services provided.

### **Appointment schedule**

Participants reported different timetable of appointment schedules in the clinic. Some reported that they have a monthly appointment schedule while others said they have appointment every 3-6 months. There are no fixed appointment patterns among the various participants.

### **Appointment day routines**

All participants in the three discussion groups agreed that the clinic routines began with seeing the adherence counselor for counseling and assessment who also prepares their cards and refer them to the consultation rooms for physical examination (including history taking, weight and PB). Every three month of the visit, they reported that they give blood for CD4 testing. The consulting clinician provides medicines for prophylaxis of opportunistic infections (OIs) or treatment of illnesses as indicated and they collect it from pharmacy. Adherence counselors provide information regarding any available community level services including linkage to psychosocial or income generating possibilities.

### **Relationship with health care workers**

All participants spoke highly of their health care workers in St. Luke Hospital and said they are very kind to them. Some individuals mentioned that they rely on health care workers for support, information and open discussion one participant said: “*we have confidence on health care workers because we trust them*”.



Other discussants reported that they feel the health care workers are truly concerned about them as a person and that they give them strength to go on with their daily life as HIV positive. One participant who recently had baby said: *“While I was pregnant, I couldn’t have survived the stress if it hadn’t been for the advice and supports I received from health care workers”*.

### **Waiting hours**

All participants mentioned that while the waiting hours are usually considered “fair”, it is extremely long on some days especially on the days that they are scheduled to give blood sample for CD4 test. Waiting hour on such days is reported to last up to 6 hours for patients who come to facility early in the morning. These waiting hours are considered by all participants to be very long.

### **4.5.2. Reasons for dropping out from pre ART care**

When asked about the reasons why people drop-out of the pre ART program, participants provided the following several reasons:

Some participants mentioned that some disappear just after they hear their HIV test result because they are shocked and they don’t want to hear about it again. Other participants also said that some people do not trust the pre ART service because they don’t believe it works. Good majority of the participants said that follow up during pre-ART period seem irrelevant sometimes because they know they are not getting the actual anti-retroviral treatment. They mentioned that most people who drop out of the pre ART care sometimes do it with intention of coming back when they are properly eligible for proper treatment. One participant was quoted saying *“I don’t see the reason for coming every month while I am told I am doing well and not yet ready for treatment”*.

Fear of being identified as HIV positive was mentioned by several participants as a reason for dropping out of care. In addition, fear of medication side effect, forgetfulness associated with alcoholism and absence of motivation to care for one self were also

mentioned by good number of participants as reasons for discontinuing care. In addition, some respondents mentioned that transportation cost to and from health facility for every follow up is costly even though the health facility doesn't charge them for the service.

Several participants reported that being HIV positive have exposed them to economic problems as they are excluded from most of the businesses and available job opportunities because of their HIV status. A number of them also mentioned that they were dismissed from jobs when the employers learned that they were positive: *"I used to cook injera<sup>3</sup> for households before and it was my only source of income, I was able to feed my children and send them to school with the money. After it was learned in the community that I was HIV positive, all my customers refused to use my service so I had to stop"*.

Other participants mentioned that engaging in small business and daily labors especially in the service provision sector for HIV positive persons is difficult because people are afraid to use their services. They also mentioned that people are afraid either because they think HIV positive people lack the capacity and power to work as non positives or they are afraid of getting the disease from them. Most people said being HIV positive has exposed them to economic problems. Few participants said that they are able to engage in the work force like anybody else despite their status.

#### **4.5.3 Outcome of patients who drop out of care**

When asked about what happens to patients who drop out of care, some participants replied that these patients do not inform anyone, and suffer from diseases and eventually die. Others said that some of the patients start "holy water" treatment, start new faith, practice fasting for healing or go for prayers in a believe that they will get cure from it after they drop out of care. Regardless of what they think these patients do, all participants agreed that patients who drop out of pre-ART care usually suffer from frequent illnesses while the ones that adhere to follow up live relatively normal life.

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<sup>3</sup> A bread used as a main food in Ethiopia

### **Chances of drop-out patients returning to follow up**

All participants agreed that there is a possibility for the patients that discontinued care to return if they are traced and contacted by health workers. One participant shared her own experience of being lost from care once and how the community volunteers and health workers persuaded her to comeback: *"I had decided to die at home, but the volunteers shared so many experiences with me and they were persistent in advising me to get back to care, which made me to resume follow up"*. However, the respondents believe that there should be strong counseling provided at the initial stage and throughout the periods to ensure patients understand the consequences of stopping follow up.

### **Factors perceived to facilitate adherence**

Many participants reported some factors that helped them adhere to their medical follow up for HIV care. For some women who learned their HIV status through antenatal care and childbearing process, the possibility of having HIV free baby was mentioned as great motivation factor to adhere to follow ups. Other people mentioned a wish to live long and happy life for the sake of staying around for their children as a reason for their perseverance. Some also mentioned that seeing other people with HIV live longer and happier life was a motivation for them to stay in care and hope for better life.

Fear of illness or death was also seen as a motivator for some participants: *"I don't want to die yet, I have to stay healthy to stay alive"*.

### **What should be done to promote retention?**

Most participants suggested that focus should be given for more counseling and health education to create awareness about importance of adherence to pre ART Care in order to avoid misconception. All of them also added that government should support HIV positive people financially and assist them in finding jobs and other income generating activities: *"Since we are all poor and we spend a lot of time in health facilities, we need to be supported"*.

A good number of participants also suggested that special focus should be given to strengthen the role of community volunteers and support groups as they believe them to be very important in identifying lost patients, linking with health facilities and forming peer support networks and activities.

#### **4.7. CONCLUSION**

This chapter discussed the analysis and interpretation of both quantitative and qualitative data. The analysis for the quantitative data was conducted using computer software SPSS and results were presented according to the chart review checklists and FGD guide.

The findings highlighted that large percentage of patients in pre-ART period will be lost to follow-up, especially during the first 3-6 months of enrolment to the program. Common factors associated with LTFU are religion, having or not having child, unmet expectation of patients from the pre-ART service, travel cost, long distance, stigma and poverty are key factors that greatly contribute to patients' LTFU.

## **CHAPTER 5**

### **CONCLUSION AND RECOMMENDATION**

#### **5.1. INTRODUCTION**

This chapter presents conclusions on the research findings and recommendations drawn. The major contribution of this study and limitations are also highlighted. The study findings in line

#### **5.2. RESEARCH DESIGN AND METHOD**

A cross-sectional research design with a mix of quantitative and qualitative data collection methods will be used to examine the level of adherence to pre ART care among adult HIV positive patients and the various factors associated with patients lost to follow up.

Quantitative data was collected through chart review of pre ART patients enrolled to HIV care in St. Luke hospital between January 2009 and December 2010. Qualitative data was obtained from three focus group discussions held with pre ART patients. In addition national policy documents were reviewed and analyzed.

#### **5.3. SUMMARY AND INTERPRETATION OF THE RESEARCH FINDINGS**

The findings from the study are presented below according to the research objectives which were to:

- Determine the level of adherence by adult patients to pre ART program in St. Luke Catholic Hospital
- Identify factors (socio-economic, cultural and disease -related) contributing to non-adherence/adherence among Pre-ART adult patients

- Assess the type of services that are provided at pre-ART programs and determine the system that guides the service delivery

### **5.3.1. Level of adherence by adult patients to pre ART program in St. Luke Catholic Hospital**

The findings from this study conducted in a routine rural hospital HIV care clinic in Ethiopia indicate that only about one third (38.2%) of HIV-infected patients enrolled to HIV care and not yet eligible for ART are retained care after 12 months. This research study report an overall dropout rate of 61.8%.

Although different definitions of LTFU were used in various previous researches that studied pre-ART LTFU in SSA, the rate found in this study is similar with similar studies that found up to 74% of pre ART LTFU ( Bassett et al. 2009:3).

However, this rate of loss to follow-up may not indicate that a patient has dropped out of care permanently. Some patients may have returned to the same site after the data for the study were censored or the study's definition of loss to care reached. Many patients may have simply transferred, usually without the knowledge of health workers. Tracing such transfer-in and transfer-outs in a setting like Ethiopia where unique patient identifiers are not regularly used to track patients is difficult. Moreover, the guideline to define LTFU is not clear thus the data collection system is inaccurate or mostly does not exist. Further studies are required to determine the outcome of patients who are LTFU.

It is possible that many of the patients who dropped-out of pre-ART care will return to the health-care system at some later date, most likely once they become seriously ill. Without an effective health information system that allows patients to be tracked from site-to-site and over time, as they come and go from care, it is impossible to assess the extent to which patients are cared for through referral structures.

In view of the fact that literature suggests high rates of early mortality after ART initiation in Africa (Lawn et al. 2008, Bassett et al. 2010), it is plausible that recently diagnosed HIV-infected clients register for care and dropout while they are still healthy, only to present later with advanced HIV disease necessitating immediate ART initiation. In fact a significant number of them die at home not captured by the healthcare system. In both cases, a patient will have continued to transmit HIV virus to loved ones or any other sexual contact during the time he/she has been lost-to-follow up.

The Ethiopian Health Sector Development Plan IV developed for the period of 2010/2011-2014/2015 has put an ambitious target to increase number of patients ever started on ART from 216,724 to 484,966 and increase Proportion of patients who are currently on ART from 70% to 90 % (MOH 2010:44). The low rate of retention observed at the very beginning of the HIV care program however does not promise well for achieving the country's stated goal. In order to achieve this goal, it is important to increase the number of patients that enter in to the HIV care and ensure they are retained in care starting from the early stages and throughout. Pre-ART care ensures start-up of patients on ART as early as possible through monitoring disease progression, structured treatment preparation and counseling.

While pre-ART loss to care may not pose as immediate mortality threat as loss of patients who already have clinical AIDS, it is still a major impediment to improving the outcomes of HIV care and HIV prevention (Rosen & Fox 2011:8). Focusing on patient retention in care both before and after ART initiation is important not only to prevent HIV related mortality and morbidities, but also as a means of reducing ongoing transmissions which will reduce the number of new infections. Patients who drop out of care at this stage usually either come back after the disease has advanced as late presenters or die even before that. Pre ART care is thus an essential link in the chain that connects HIV positive patients to the desired lifelong treatment.

However, the result from this study shows that this link is broken or functioning well. It is important to invest on pre ART care in order to maintain this chain intact and achieve increased access to treatment for patients living with HIV in Ethiopia.

### **5.3.2. Factors (socio-economic, cultural and disease -related) contributing to non-adherence/adherence among Pre-ART adult patients**

Religion and having child independently predicted pre ART LTFU. From the qualitative data analysis, fear of being identified as HIV positive, transportation cost and not trusting the pre ART service were identified as main causes for patients drop out from pre ART care.

Compared to Christians, patients who are Muslims had three times higher loss to follow up rates. There are no similar reports as to why religion could be a factor for patient drop out from care; however this could be due to certain religious practices in the Muslim religion that might negatively affect strict adherence to HIV care possibly through stigma and discrimination. Further study is required to investigate these specific factors in Ethiopian context.

Patients who didn't have children were more likely to be loss to follow up than those who had children. This may be because having children is a motivating factor for parents to want to live longer and be able to provide care for their children. This finding is supported by the FGD findings as some of the participants identified having children as a factor facilitating adherence. People who do not have children on the other hand, do not have parental commitments and thus a drive for living for a child and thus more likely to be affected negatively by HIV related stigma. It is also likely that this group may be single and young which has been found to be a risk factor for LTFU (Karcher et al. 2007, Ochieng-Ooko et al 2010)

This study also found that patients who did not use family planning had greatest odds of being loss to follow up compared to those who reported to be family planning users. A plausible explanation for this could be that patients who used family planning are much more familiar with health care set up and received counseling at each visit which will result in a patient being more informed about her follow up and importance of



adherence compared to the ones who do not use family planning. Services other than direct HIV care could be a means for engaging patients in their health care services and provide them with more extended package of services which will contribute to their treatment outcomes directly or indirectly.

Stigma has been mentioned to be the reason for dropping out of pre ART care by most of FGD participants. This finding is consistent with other studies that identified HIV related stigmas to be an important barrier to adherence and retention in care (Merten et al. 2010). HIV positive patients drop out of care because they do not want to be seen in the HIV clinic and risk chance of being seen by someone they know. Stigma and discrimination shows in a different forms and could cost their social interaction, business opportunities and their chance of living in harmony with people in their surroundings. According to some FGD participants, people do not disclose their status even to their close family members (including spouse and children) which forces them to stop from going to health facility in order to keep the secret.

Even though the government is intensively working on social mobilizations and community conversations that are aimed at increasing awareness and prevent stigma and discrimination against PLHIV, the findings from the three FGD sessions show that it still has great impact on patient retention in HIV care.

Cost of transportation to and from health facility during follow up visits was also identified as important factor associated with LTFU. Although HIV treatment is freely available to all in Ethiopia, all FGD participants mentioned that the cost of transportation during each visit is hindering some of them from attending their care regularly. Other related studies in Africa also found similar results indicating cost of transport to be major barriers to access and remain in HIV care (Amuron et al. 2009, Maskew et al. 2007)

Inability to afford transportation costs is associated with the fact that most patients are unemployed. Unemployment and other economic related problems mean that many PLHIV in this study have no sustainable source of income, and are therefore unable to meet basic daily requirements, or to get the services they need to cope with their treatment (e.g. transportation, availability of adequate nutrition). A number of FGD

participants indicated that employers are not interested in hiring known HIV positive persons because their infection reportedly prevents patients from earning a living, forces resignation or limits career options.

Another important factor mentioned to be a reason for high rates of LTFU is the fact that some people do not trust the pre ART service and do not believe it is necessary. Most patients enrolled at pre-ART are asymptomatic and may not perceive themselves as requiring medical care. Since very little therapeutic care is offered during the pre-ART period, patients must take it on faith that making the effort to come to the clinic for monitoring is worth the costs of doing so (Rosen & Fox 2011). One female FGD participant said; *“I don’t see the reason for coming every month while I am told I am doing well and not yet ready for treatment.”*

Participants also mentioned that most people who drop out of the pre ART care sometimes do it with intention of coming when they are “properly eligible” for ARV treatment. Because the pre ART care package is not standardized and not clearly engaging patients in a regular basis, the period is confusing both for health care providers and the patients. Literatures on pre ART mention that lack of comprehensive pre ART care services, limited pre ART care package and lack of incentives for patients during pre ART are factors that contribute to such high pre ART attrition rates (Lessels et al 2009, Rosen & Fox 2011; Zewdie et al 2010).

A structured framework of counseling and support at both testing and registration into HIV care that has been applied in ART programs with relative success to enhance retention and ART adherence in different settings could be applied in the pre-ART care package (Etienne et al. 2010). Patient tracking mechanisms such as tracing LTFU using community volunteers, organizing patients in to various support groups and use of structured patient preparations systems proved to be effective for patients on ART could be adopted for pre-ART clients.

In addition, pre-ART care service packages may include nutritional support in the form of food programs, provision of multivitamins, prophylactic anthelmintics, isoniazid

preventive therapy (IPT) and engaging patients in various social networking activities such as support groups. Economic support and job creations could be included in the latter activity. These interventions may serve as an incentive for follow up and compensate for indirect costs incurred to attend care for those coming from far. An improved pre-ART package of care will not only serve to enhance retention, but also slow disease progression, enable timely initiation on ART for those eligible, reduce early mortality and prolong overall survival. Indeed, cotrimoxazole, which is one of the pre-ART services currently offered in Ethiopian setting, has been shown to reduce morbidity and slow HIV disease progression substantially (Anglaret et al. 1999). Intervention studies on anthelmintics and IPT have also shown that these cheap and readily available interventions administered in pre-ART patients have the potential to slow HIV disease progression by reducing tuberculosis incidence, lowering viral load and increasing CD4 count (Walson et al. 2008; Grant et al. 2005 ).

### **5.3.3. Type of services that are provided at pre-ART programs and determine the system that guides the service delivery**

The services provided to pre ART patients included laboratory testing for CD4 count, and other haematological tests, physical examinations and prophylaxis, diagnosis and treatment of opportunistic infections. In addition, counseling on topics ranging from positive living, nutrition, adherence and medication follow up is part of the services. Appointment schedules varied from patient to patient who reported to have varying periods from monthly to biannual appointment intervals. A reason for varied appointment patterns are not fixed and depend on each assessing clinician's decision. The Ethiopian Government has developed considerable policies and guidelines to effectively respond to the HIV pandemic. The guidelines prepared to manage the various aspects of HIV care (PMTCT, VCT, ART etc.) are encouraging and provide valuable guidance. However, these guidelines are not comprehensive enough to address the crucial aspect of HIV care; the pre ART period. All of these guidelines focus on the detail management of patients on ART and the pre ART period as well as what it

involves is not well defined and care and support for these patients are not clearly stated.

In general, the various guidelines provide detail description and scope for their specific topic area, but the pre ART period seem to be a portion of this continuum of care that has been neglected. Policy makers have overlooked the fact that the Pre ART period by itself has its own dynamics and needs structured service delivery. Also the fact that large proportion of patients testing positive are meant to stay in the pre ART period seems to be less acknowledged.

#### **5.4. CONCLUSION**

The study revealed the alarmingly high lost to follow up rates among pre ART patients in Ethiopia and the need for directing focus on patients newly diagnosed and enrolled to care. The national goal to accelerate universal access to treatment highly depends on how efficiently retained new patients are even when they are not yet eligible for ART.

Secondly, the study showed the lack of standard definition of terminologies in pre ART. The term loss to follow up is widely used for patients on ART and pre ART loss to follow (Bassett et al. 2009) up is perceived differently in different settings. Moreover, there are no health information systems that allow pre ART patients to be tracked between service delivery points resulting in loss to follow ups going unnoticed. Loss to follow up in pre ART is not recorded in routine HIV log books nor is reported to authorities. In order to improve pre ART care, it is vital to implement effective patient tracking systems that will generate accurate information on attrition in pre ART and identify characteristics of patients most likely to be lost.

The third point that came to light in this study is the need for policies and guidelines to ensure more standardized pre ART care package is available so that HIV patients are cared for and retained through this crucial period of HIV care and are successfully put on treatment afterwards.

Finally the research highlighted some socio-demographic and service factors associated with patient loss to follow up from pre ART care. Focused attention should be given to patients that are more prone to HIV-related stigmas and it is important to increase patients' engagement in care through different service outlets.

If the target set to achieve universal access to HIV/AIDS treatment is to be achieved, government and implementing organizations need to invest in developing the pre ART care and standardize services. Patient care should be viewed from its comprehensive perspective that encompasses all periods starting from enrollment. Policies and guidelines that address pre ART period and health care workers and facilities need to be equipped with necessary tools to care for patients not eligible for ART.

## **5.5. RECOMMENDATIONS**

The various individual, provider, health system, environmental, and other barriers to retention identified in this study, including those factors that influence health care-seeking decision-making, and the weak links between diagnosis and care enrolment needs to be addressed to facilitate engagement in care. Some of the recommendations based on the findings are summarized as follows:

- Defining and developing interventions that improve retention in the pre-ART period and providing a 'pre-ART package of prevention and care'. A beneficial package of care, support and prevention for people with HIV in the pre-ART stage would support people to remain engaged in care throughout this period and facilitate timely assessment of ART eligibility and commencement of treatment.
- Decentralization and integration of HIV services through robust systems to improve linkages and retention along the continuum of care.
- Greater involvement of people with HIV is important so that they feel engaged and empowered in decisions about their care and that their real needs are being taken into consideration.
- Develop and maintain community systems and engage lay and peer workers to support retention in care and decrease stigma and discrimination. In addition,

appropriate and context-specific engagement with other community support structures (e.g. spiritual leaders, traditional healers, community leaders, women's groups, CBOs etc.) should be explored and supported as a tool for fighting stigma and widening patient support base.

- Evaluation of strategies such as implementation of longer drug refill periods and task shifting to trained lay care providers for stable patients or refunding transportation costs is needed to ensure cost of transportation is not a barrier to access health care service.
- Increase the CD4 count level eligibility criteria to initiate ART from the current level of 250 to 350 as per the WHO recommendation (WHO 2009) in order to reduce long waiting time for ART initiation thus risking high rate of LTFU during pre-ART period.
- Strengthen patient education and counseling to reduce stigma and anxiety about ART side effects or fear of inadvertent disclosure once on ART
- Develop effective pre ART monitoring systems with clear definitions and unique patient identifiers to facilitate monitoring and reporting of pre ART care retention and loss to follow up
- Use communication technologies (e.g. SMS messaging, phone calls) and more efficient patient tracking strategies that are relevant in Ethiopian contexts.

## **5.6. CONTRIBUTIONS OF THE STUDY**

This study sheds more light on the burden of pre-ART drop out and identifies risk factors for potential interventions. Given that there are only limited studies conducted to assess pre ART care services and the rate of LTFU globally and almost no studies exist in Ethiopia, this research will be a valuable resource in the HIV care. The findings of this study will be used to inform policy makers and health care providers about pre ART care and the extent of the attrition.

In general, the research will be an important contribution for public health in general and HIV care and treatment services in particular. In addition, the researcher believes that the findings from this study will inspire other researchers who might be interested to further study the various aspects of pre ART care.

## **5.7. LIMITATIONS OF THE STUDY**

This study had several limitations. Firstly, it was conducted at only one facility in Ethiopia and it is possible that experience might be different at other sites. Secondly, different definitions have been used to assess drop out in different studies. Although the researcher used an operational definition for pre ART LTFU, the definition was drawn from ART LTFU definition and applying the definition on a pre-ART may not be appropriate as the two periods vary in many ways. Lastly, quantitative data for this study was collected from patient chart and variables had to be limited to what and how the data has been captured in the chart.

None of these limitations however is sufficient to alter the core finding of this study, which is that more than 60% of patients are lost from pre-ART care and that the system for pre ART care provision is weak and unstructured. Despite these limitations, this study has several methodological strengths. Qualitative and quantitative data sources were used to triangulate the information and obtain a more reliable data set. In addition, FGD were conducted by trained moderator and note takers who were bilingual in English and Afan Oromo, ensuring clear communication.

## **5.8. CONCLUDING REMARKS**

In conclusion, HIV care services in Ethiopia heavily focus on care of patients on ART. Pre ART period is not very well understood and structures that allow proper interventions during this period are not in place. Even though loss to follow up from pre ART care is not well defined, it is found to be extremely high.

The findings call for consideration of a better pre-ART care package aimed at improving retention in care. Improved retention has the potential to prevent HIV transmission, slow HIV disease progression, enable timely initiation of ART, reduce early mortality after starting ART and prolong overall survival. Hence, an improved pre-ART care package especially targeted at those who are more at risk of dropping out of care may be both beneficial and cost effective in the long term.

This study has generated a finding that could be used as a starting point for understanding the nature and scope of the problem of pre-ART loss to care. Further researches are needed to answer questions that are not addressed in this study.



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## **Annex 1: Chart review Checklist**

### **1. Client socio demographic data**

1.1. Age in completed years\_\_\_\_\_

1.2. Sex

\_\_\_ Female (1.2.1)

\_\_\_ Male (1.2.2)

1.3. The highest level of education attended

\_\_\_ No education (1.3.1)

\_\_\_ Primary (1.3.2)

\_\_\_ Secondary (1.3.3)

\_\_\_ Tertiary (1.3.4)

1.4. Religion

\_\_\_ Protestant Christian (1.4.1)

\_\_\_ Muslim (1.4.2)

\_\_\_ Orthodox Christian (1.4.3)

\_\_\_ Catholic Christian (1.4.4)

\_\_\_ Other (1.4.5)

1.5. Current Marital stats

\_\_\_ Never Married (1.5.1)

\_\_\_ Married (1.5.2)

\_\_\_ Divorced (1.5.3)

\_\_\_ Separated (1.5.4)

\_\_\_ Widow/Widower (1.5.5)

1.6. Ethnicity:

Oromo (1.6.1)

Gurage(1.6.2)

Amhara (1.6.3)

Tigre (1.6.4)

Other (1.6.5) (describe \_\_\_\_\_)

1.7. Usual residential location \_\_\_\_\_

1.8. occupation

salaried (public or private) (1.8.1)

self-employed (1.8.2)

unemployed (1.8.3)

Student (1.8.4)

other (1.8.5) \_\_\_\_\_

**2. Client's clinical, biological information up on enrollment**

2.1. Registration date \_\_\_\_\_

2.2. WHO stage on enrolment \_\_\_\_\_

2.3. CD4 count on enrollment \_\_\_\_\_

2.4. Viral load \_\_\_\_\_

**3. Follow-up data**

3.1. CD4

Yes (3.1.1)

No (3.1.2)

3.2. Viral load

Yes (3.2.1)

No (3.2.2)

3.3. Diagnosis of OI and treatments

\_\_\_ Yes (3.3.1)

\_\_\_ No (3.3.2)

3.4. Prophylaxis (IPT, co-trimoxazole)

\_\_\_ Yes (3.4.1)

\_\_\_ No (3.4.2)

3.5. Weight measurement

\_\_\_ Yes (3.5.1)

\_\_\_ No (3.5.2)

3.6. Blood count

\_\_\_ Yes (3.6.1)

\_\_\_ No (3.6.2)

3.7. last scheduled appointment date \_\_\_\_\_

3.8. date last attended follow up \_\_\_\_\_

3.9. Patient current status

\_\_\_ On ART (3.9.1)

\_\_\_ In-care (3.9.2)

\_\_\_ Eligible but not started (3.9.3)

3.10. If lost or drop out, what are the known reasons? \_\_\_\_\_

4. Follow up variables through time line

variables	@6 month	@12 month
CD4		
Viral load		
OIs		
wt		
Missed appointment		
Status		



## Annex 2: FGD Participants' Basic Information

FGD Session Code \_\_\_\_\_ Moderator \_\_\_\_\_ rapporteur \_\_\_\_\_

### Area Identifier:

Tape Code # \_\_\_\_\_ (transfer the tape label (code) onto this form.)

Date,  
Time:  
Place:

Participant's code	Q1 Sex	Q2 Age	Q3 Education	Q4 Occupation
	Female (1.1) Male (1.2)	18 to 27 years (2.1) 28 to 37 years (2.2) 38 to 47 years (2.3) 48 to 57 years (2.4) 58 to 67 years (2.5) 68 and above (2.6)	No education (3.1) Primary (3.2) Secondary (3.3) Tertiary (3.4)	Employed (4.1) Self employed (4.2) unemployed (4.3) Student (4.4) other (4.5)
P1				
P2				
P3				
P4				
P5				
P6				
P7				
P8				
P9				
P10				

### **Annex 3: Focus group discussion (FGD) guide**

#### Introductions:

1. Thank participants for their willingness to participate on the FGD
2. Introduce facilitators, reporters and explain their role
3. Describe the detail of FGD using the following information:

This focus group discussion is conducted to collect data for a research we are conducting to describe the type and organization of pre ART care and determine factors associated with LTFU from care among patients enrolled to pre ART program in Ethiopia.

The information you provide will be used to assess PLHIVs opinions about pre ART care and barriers to adherence. The final results will be shared with representatives of St. Luke hospital and South West Shoa zone health office, and concerned community groups to help improve for patients during pre ART period.

During a focus group discussion, you are allowed to talk freely and spontaneously everything you know about issues that your facilitator will raise concerning pre ART care. We will tape the session and make a written copy for further analysis. The focus group session will last approximately 1.5 hours. As every one's ideas are highly valid, you are kindly asked to actively participate, listen to each other, and respect each other's opinion. It is not allowed to criticize others' idea during the FGD and even outside.

The information collected will remain confidential. This means that your identity as a participant and the information that you will provide will not be revealed to people other than the facilitators. We are not taking your name and address during the discussion. All research material will be submitted to UNISA for official documentation purpose. All audio recordings will be erased upon completing the study.

We do not anticipate that participation in this study will pose physical or psychological risks beyond what you encounter in everyday life. However, Participation in this study is voluntary and if you are uncomfortable answering a particular question, you are free to refuse to answer the question, and you are free to quit the study at any time. If you have concerns you may ask the facilitators at any time of this discussion.

Topic/Focus	Core Questions
Experience with pre-ART	<ul style="list-style-type: none"> <li>• How do people get enrolled into the pre-ART? (Probe on: From whom/where people get the information about the program? Where do people usually seek (care) the first time they know they are HIV positive? How do people decide to be enrolled in the pre-ART? Who assist in their decision?)</li> <li>• How do people like you describe their experience of the pre-ART? (Probe on: type of services, for how long, follow-up period, counseling, its benefits, etc.)</li> <li>• Do people on care inform their families about them being on the pre-ART program? Why and why not? What support is available in the community, in the family, in the workplace? (Probe on: care and support services, discrimination, and stigma.) How do you think you are being treated (handled) by the health workers while on pre-ART? (Probe on: in relation to privacy, confidentiality, respect, being listened to, time spent with patient, waiting time, integration with other services, etc.)</li> <li>• What does the counseling provided as part of the pre-ART follow up in St. Luke hospital look like? Are there PLHIV that were on pre-ART but later on declined to start on ART despite being advised by health workers to start on ART? (Probe on: Why did they decline? Economic problem, stigma, fear of side effect, etc? Probe on: for personal experience, holy water as an option for this?)</li> </ul>
Reasons for discontinuation	<ul style="list-style-type: none"> <li>• Why do people like you discontinue follow up? What do they do after discontinuation? (Probe on: treatment options.)</li> <li>• How does health situation of people who discontinue care compared before and after discontinuation? Do these people want to restart on the program? What needs to happen for these people to restart? What do you think could be done to help people like you to continuously follow their appointments?</li> </ul>
Individual and social influences/barriers	<ul style="list-style-type: none"> <li>• Do people enrolled in HIV care clinic face any socioeconomic and other problems because of their medical condition? (Probe on: poverty, hunger, transport problems, lack of support, etc.)</li> <li>• How does the community view people who are HIV positive? (Probe on: stigma, discrimination, supportive attitude, negative attitude, etc.)</li> </ul>
Opinion on the pre-ART program activities in St. Luke hospital	<ul style="list-style-type: none"> <li>• How do you assess the effectiveness of the pre-ART program in transferring ART eligible patients to the service? (Probe on: patient volume, follow-up activities, patient handling practices, whether there is a delay between eligibility and actual initiation of ART, counseling efforts to encourage ART use, etc.)</li> <li>• What should be done to ensure that those PLHIV on pre-ART are retained on Care and successfully transferred to the ART service when eligible for treatment?</li> </ul>

Conclusion remark

Thank you very much for your cooperation and input. Your information has been very useful. Please contact W/t. Emebet for your transportation cost reimbursement.

#### **Annex 4: CONSENT FORM (Focus Group Discussion)**

My name is Zinash Dewo and I am student at the University of South Africa (UNISA). I am doing a research on Pre ART care as partial fulfillment of master's degree in public health. You have been selected to participate in this study to be conducted at St. Luke hospital.

The purpose of the study is to describe the type and organization of pre ART care and determine factors associated with LTFU from care among patients enrolled to pre ART program in Ethiopia allowing the government and other actors, increase uptake of pre-ART services in the facilities. In addition, the study results will further reveal PLHIVs opinions about pre ART care and barriers to adherence. The final results will be shared with representatives of St. Luke hospital and South West Shoa zone health office, and concerned community groups to help improve for patients during pre ART period.

If you decide to participate in this study, you will join other participants of a similar background in a discussion led by a facilitator. During a focus group discussion, you are allowed to talk freely and spontaneously everything you know about issues that your facilitator will raise concerning pre ART care. We will tape the session and make a written copy for further analysis. The facilitator's questions will relate to your opinions about pre ART service and barriers faced by people living with HIV in adhering to care services that you may know of. The focus group session will last approximately 1.5 hours.

The information collected will remain confidential. This means that your identity as a participant and the information that you will provide will not be revealed to people other than the facilitators. We are not taking your name and address during the discussion. All research material will be submitted to UNISA for official documentation purpose. All audio recordings will be erased upon completing the study.

We do not anticipate that participation in this study will pose physical or psychological risks beyond what you encounter in everyday life. However, Participation in this study is voluntary and if you are uncomfortable answering a particular question, you are free to refuse to answer the question, and you are free to quit the study at any time.

You will not receive any payment to participate in the focus group discussion. However, you will be given 100 Eth. Birr as a reimbursement for expenses incurred as a result of participation, including travel and time lost.

If you have concerns about this study or would like to receive a copy of the study's results, please contact Zinash Dewo at 0911803439.

Your signature below shows that you understand the above statement and willingly agree to participate in this focus group discussion.

This consent form has been read and explained to me. I voluntarily consent to participate in this study:

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

I have explained the study for the above subject and I have sought his/her understanding for informed consent

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## **Annex 5: Translated consent form**

### Waraqaa Eeyyamaa

Koodii:

Maqaankoo Zinnaash Dawoo jedhama, University South Afrikaa (UNISA) jedhamutti barattuu fayyaa hawaasaati. Barumsakoo xumuruufis qorannoo hojjechuun waan narraa eegamuuf, qorannoo tajaajila fayyaa yeroo qorich HIV otoo hinjalqabiin(pre ART) hospitaala St. Luke keessatti kennamurratti hojechaan jira.

Kaayyoon qorannoo kanaa akaakuufii akkaataa tajaajila fayyaa yaalamtoota qoricha HIV hinjalqabneef kennamu ballinaan qorachuufii sababoota Ethiopia keessatti yaalii addaan kutuu faana walqabatan adda baasanii baruudha. Beekkumsi qorannoo kana irraa argamus mootummaan Ethiopia fii dhaabbileen adda addaa tajaajila HIV/AIDS irratti kennamu akka ballisaniif isaan gargaara. Dabalataanis, namoonni HIVn dhiiga isaanii keessatti argamu tajaajila fayyaa fii hordoffii fayyaa ilaalchisee yaada isaan qaban akka ibsan ni gargaara. Bu'aan qorannoo kanaa hoggantoota hospitaal St. Luke, biiroo eegumsa fayyaa naannoo kibba lixa shawaa fii dhaabbile hawaasaa adda adda kan dhimmisaa isaan ilaalu hundaafuu ni kennama. Isaanis taajjila fayyaa ittiin fooyyesuuf itti fayyadamu.

Yoo marii kana irratti qooda fudhachuuf murteessite, namoota akka kee fii gaggeessitoota faana yaada ballinsaan waljijjiruu irratti hirmaatta. Yeroo marii kana, gaaffilee gaggeessituun marii kanaa kaasuu irratti hundoofttee yaada keef tajaajila fayyaa yaroo pre-ART wanta beektu mara bilisaan akka ibsitu siif hayyamama.

Yaadota marii kana irratti ka'an mara sirriitti qabachuuf akka nutti toluuf, mariisaa teeppiidhaan niwaraabna. Gaaffiin gaggeessitootaan ka'u tajaajila yeroo pre-ART fii rakkolee namoonni tajaajila kana argachaa jiran hordoffii yaalii ilalchisee quunnaman kan ilaaludha. Mariin kun tilmaamaan sa'aatii tokkoof wallakaa fudhata.

Odeeffannoon marii kanarraa guurramu marti iccitii ta'a. Kana jechuunis, odeeffannoon ati nuuf kennitu namoota qorannoo kana gaggeessaniin ala nama biraatiif dabarsamee hinkennamu. Marii kana irratti maqaa kee hin galmeessinu. Odeeffannoon martiyyuu University south Afrikaatti akka keewwamu ni ergama. Teeppiin waraabbame marti yeroo odeeffannoosaa irraa fudhanne ni balleessama.

Marii kana irratti hirmaachuukeetiif dhiibbaan qaamaas ta'e kan sammuu kan sirra gahu hinjiru. Haata'u malee, marii kana irraatti hirmaachuun feedhii bilisaa irratti kan hundaahedha. Gaffileewwan ka'an deebisuuf yoo fedhii dhabde, deebisuu baachuu nidandeessa. Marii kana yeroo feetee addan kuttee deemuus ni dandeessa.

Marii kanarraatti hirmaachuukeetiif kanfaltii homaayyuu hin argattu. Garuu, baasii geejjibaa fii tilmaama yeroo kee deebisuuf qarshii 100 siif kennina.

Marii kana ilaalchisee gaaffii yoo qabaatte, lakkoofsa bilbilaa 0911803439 irratti Zinnaash Dawoo jedhaa gaafadhaa.

Yoo kaayyoo qorannoo kanaa sirritti siif galeefii marii kanarratti hirmaachuuf bilisaan fedhii yoo qabaattee sarara kana gadii irratti mallatteessi.

Waraqaan eeyyamaa kun naaf dubbifamee kaayyoosaa irrattis ibsi naaf godhameera. Feedhii mataakootiin marii kana irratti hirmaachuuf nan fedha.

Mallattoo: \_\_\_\_\_ Guyyaa: \_\_\_\_\_

Waa'ee qorrannaa kanaa sirritti ibsa keennee, waligaltee isaaniifii eeyyama isaanii fudhadheera.

Mallattoo: \_\_\_\_\_ Guyyaa: \_\_\_\_\_

**Annex 6: Annex 10: Facility permission request letter**

**Date:** \_\_\_\_\_

To: St. Luke Catholic Hospital and College of Nursing and Midwifery  
Wolisso,  
Ethiopia

Re: **Permission request to conduct research**

Dear Sir/Madam,

My name is Zinash Dewo and I am student at the University of South Africa (UNISA). I am doing a research on Pre ART care as partial fulfillment of master's degree in public health.

The purpose of the study is to describe the type and organization of pre ART care and determine factors associated with LTFU from care among patients enrolled to pre ART program in Ethiopia allowing the government and other actors, increase uptake of pre-ART services in the facilities. In addition, the study results will further reveal PLHIVs opinions about pre ART care and barriers to adherence. The final results will be shared with St. Luke hospital, South West Shoa zone health office, and concerned community groups to help improve for patients during pre ART period.

Data for this study will be collected through chart review and focus group discussion. The information collected will remain confidential and will be used for this research purpose only. In addition, there are no anticipated physical or psychological risks to the participants as a result of the study.

This is thus to kindly request your office grant me permission to conduct this study and access the patient data. Please refer to attached proposal document for detail information about the research design.

If you have any questions, I can be reached at 0911803439 or through my email [zinu22@yahoo.com](mailto:zinu22@yahoo.com).

With Regards

Zinash Dewo



## Annex 7: Ethical Clearance; Facility



ቅዱስ ሊቃስ የካቶሊክ ሆስፒታልና የነርሶች ኮሌጅ  
Qidoos Luuqaas Hospitaalaa Kaatoliki fi Kooleeji Narsootaf  
St. Luke Catholic Hospital and College of Nursing

Date April 14, 2012

Zinash Dewo Robi  
Addis Ababa, Ethiopia

Dear Zinash,

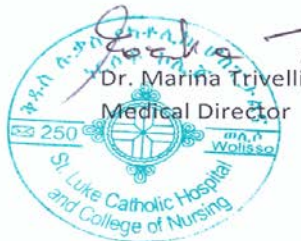
Thank you for your application seeking approval to conduct research titled “Pre-ART services in rural Ethiopia: Patient retention and factors associated with loss to follow up” in St. Luke Catholic hospital HIV unit. I wish to inform you that the hospital management after thoughtful consideration has approved your request to conduct research and access the patient data.

This approval means that you can access the patient records for pre ART patients enrolled during the time period you proposed in your application and approach the HIV care providers and data clerks for any further service provision related inquiries.

At the conclusion of your study, you are required to provide a summary of your research results and any published paper resulting from this study in line with your University regulations.

Should you require further assistance on the course of your research, do not hesitate to contact us.

Yours Sincerely



Dr. Marina Trivelli  
Medical Director

*Trivelli*  
ዶ/ር ማርና ትሪቭሊ  
ሜዲካል ዲሬክቶር  
DR. MARINA TRIVELLI  
Medical Director

Owned by Ethiopian Catholic Church

Tel. +251-11-341 0714 / 341 0800  
Fax +251-11-341 0150

P.O.Box 250 and 246  
WOLISSO

**Annex 8: Ethical Approval; UNISA**



**UNIVERSITY OF SOUTH AFRICA  
Health Studies Higher Degrees Committee  
College of Human Sciences  
ETHICAL CLEARANCE CERTIFICATE**

**HSHDC/25/2012**

Date of meeting: 14 March 2012 Student No: 4507-923-4  
Project Title: Pre-ART services in rural Ethiopia: Patient retention and factors associated with loss to follow up.  
Researcher: Zinash Dewo Robi  
Degree: Masters in Public Health Code: DIS4986  
Supervisor: Dr N Taffa  
Qualification: PhD  
Joint Supervisor: -

**DECISION OF COMMITTEE**

Approved  Conditionally Approved

*Prof E Potgieter*  
**Prof E Potgieter**  
**CHAIRPERSON: HEALTH STUDIES HIGHER DEGREES COMMITTEE**

*Dr MM Moleki*  
**Dr MM Moleki**  
**ACTING ACADEMIC CHAIRPERSON: DEPARTMENT OF HEALTH STUDIES**

PLEASE QUOTE THE PROJECT NUMBER IN ALL ENQUIRES

PRE-ANTIRETROVIRAL SERVICES IN RURAL ETHIOPIA:  
PATIENT RETENTION, FACTORS ASSOCIATED WITH LOSS  
TO FOLLOW UP, AND REASONS FOR DISCONTINUATION

by

ZINASH DEWO ROBI

submitted in accordance with the requirements for the degree of

MASTER OF PUBLIC HEALTH

at the

UNIVERSITY OF SOUTH AFRICA

SUPERVISOR: Dr. T NEGUSSIE

JUNE 2013

Student number 45079234

I declare that PRE-ANTIRETROVIRAL SERVICES IN RURAL ETHIOPIA: PATIENT RETENTION, FACTORS ASSOCIATED WITH LOSS TO FOLLOW UP, AND REASONS FOR DISCONTINUATION is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references.

.....

SIGNATURE (Mrs Z D ROBI)

.....

DATE

## **ACKNOWLEDGMENT**

I am deeply grateful to my advisor Dr. Negussie Taffa for his patience, motivation, enthusiasm, and immense knowledge. His guidance and attention to my work gave me the confidence to explore my research interests and to avoid getting lost in my exploration. He also threw enough research questions my way to keep me busy the rest of my life.

I can't thank enough St. Luke hospital management and ART unit staff for ensuring the data collection process was facilitated and answering many of my questions.

I am indebted to my family who were always there for me. My father made sure I felt his confidence and encouragement, and his advice was consistently timely and useful. My mother, sisters and brothers were always by my side and supported me throughout.

In 2008, Kebe and I decided that I would enroll in the MPH program with UNISA, and throughout this time I always knew this project belonged to us both. My shadow and my light, he encouraged, supported, understood, and loved me at every moment, and I am intellectually indebted to his ideas and our conversations. None of this could have happened without Keb. This thesis is dedicated to him.

Finally, I would also like to acknowledge the FGD participants who kindly and patiently gave me their time and important information that responded to the study objectives.

## ABSTRACT

This study was conducted to determine retention rate and factors associated with loss to follow-up (LTFU) of adult pre-ART patients in St. Luke hospital, Ethiopia. Cross-sectional study with quantitative and qualitative data collection techniques was used. Review of patient records, focus group discussions and review of program guidelines was conducted to determine level of adherence among pre-ART patients. In addition, pre-ART service quality and perceived reasons for discontinuation was explored.

The study revealed that only 38.2% of the 335 patients enrolled in the pre-ART care were retained after 12 months of follow-up in the program. More than half (55.6%), of the LTFU occurred during the first 6 months of follow-up. Fear of discrimination, high transportation cost and mistrust in the pre-ART service were perceived reasons for LTFU. Absences of clear pre-ART service package and implementation guideline were also identified as important factors that may be related to LTFU.

The findings call for improved quality of care and a better pre-ART service packaging that will address the gaps identified in order to increase patient retention.

## KEY CONCEPTS

HIV, Pre-ART care, pre-ART loss to follow up

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# CHAPTER 1

## ORIENTATION TO THE STUDY

### 1.1. INTRODUCTION

The human immunodeficiency virus (HIV) has created an enormous challenge worldwide and Ethiopia is among the countries most affected by the epidemic. Substantial scale up of HIV/AIDS services has been done in the past decade, particularly in sub-Saharan Africa (SSA) where the epidemic is home to an estimated 22.4 million people representing around two-thirds of the people living with HIV globally (UNAIDS & WHO 2009, p. 21).

However, various challenges have emerged with the scale up of HIV/AIDS programmes at different levels of service provision. Attrition of patients from care especially of those on Anti-retroviral Therapy (ART) was reported to be a critical barrier to the scale up of these services. The main cause of attrition has been identified as lost to follow up (LTFU) which accounts for up to 56% of attrition in ART programmes (UNAIDS & WHO, 2009, p. 22).

More attention has recently been given to strengthen adherence of patients on ART and various care packages and loss to follow up tracing mechanisms have been implemented in Ethiopia. The standard of care for patients diagnosed HIV positive but not yet eligible for ART (the period usually known as pre ART) is however not well-optimized and thus the extent of drop out from care and its determinants are not well understood.

St. Luke Catholic Hospital and College of Nursing and midwifery is situated in Wolisso Town, south west Shoa zone of Oromia Regional State in Ethiopia. Owned by the Ethiopian Catholic Church, the hospital serves over 1.2 million people (Hospital, 2011: 12).

The hospital began service in January 2001 and currently has 144 beds. While HIV prevention and care services were available from the start, the ART program began only in 2006. By December 2010, the hospital had initiated 1,531 patients on ART of which 43% were still on ART (Hospital Service Statistics, 2011).

## **1.2. BACKGROUND INFORMATION ABOUT THE RESEARCH PROBLEM**

Since its discovery, HIV has infected close to 70 million people worldwide, and more than 30 million have died due to acquired immunodeficiency syndrome (AIDS), (UNAIDS & WHO 2009:7). SSA remains the region most heavily affected by HIV worldwide, accounting for over two thirds (67%) of all people living with HIV and for nearly three quarters (72%) of AIDS-related deaths resulting in more than 14 million orphans (UNAIDS & WHO 2009:21).

With a population estimated at 80,713,000 million in mid-2008, Ethiopia is the second most populous country in Africa (UN 2008). Since the first case of HIV was reported in the country in 1984, HIV/AIDS has remained to be major public health problem affecting people of productive age group. According to the 2011 Ethiopian Demographic and Health Survey (DHS) the adult (15-49 years) HIV prevalence is reported to be 1.5%. The prevalence rate showed variation among the gender groups with women having a higher rate of 1.9% than men who had only 1.0% (CSA & ICF 2012:234).

The Federal Ministry of Health (FMOH) in Ethiopia reported that, there was an estimated 1.2 million people living with HIV in 2010, of which close to 398,000 were eligible for ART. There were an estimated 137,464 new HIV infection (57% Female) and 28,073 AIDS-related deaths (57% Female). The total estimated number of HIV-positive pregnant women and annual HIV positive births in the same year were 90,311 and 14,276 respectively (MOH 2007:8-9).

The FMOH of Ethiopia officially started a fee-based ART program in 2003. After a number of initiatives by the government and partner organizations to increase access to ART, a national, free HIV/AIDS care and treatment program was launched in January 2005. (Assefa et al. 2009:2). Since this time, thousands of people have accessed care and treatment services, including ART throughout the country. By year 2010, more than 200,000 people in need of ARVs have been initiated on treatment in about 532 facilities throughout the country (ARC 2010).

The impact of ART program on survival and quality of life of patients has also been visible in Ethiopia (HAPCO and MOH, 2008). But despite the recent gains, universal access to ART is still far from being achieved. Of the estimated 397,818 patients in need of ART by 2010 (MOH 2007), only 246,347 (62%) were ever started ART as of February 2010 (ARC 2010).

One of the biggest concerns of care and treatment programs is the ability of patients to achieve near-perfect adherence over the long-term from enrollment to care and throughout. According to a systematic review of pre-antiretroviral (pre-ART) care in sub-Saharan Africa more than two-thirds of people who tested positive for HIV but weren't yet eligible for treatment when diagnosed were lost from care (Rosen & Fox 2011: 6-8).

In many settings, especially in SSA there is a growing concern that patients who have been diagnosed with HIV infection and registered for HIV care drop out, only to present themselves later with advanced HIV infection necessitating immediate ART initiation.

Most strategies to improve follow-up generally focus on bringing lost patients back into the health care system through outreach teams and collaboration with community organizations. An attempt to trace LTFU patients from HIV programme in Malawi determined that 50% had died, 27% could not be found, and most of the rest had stopped ART (Yu et al. 2007:551-552). In a systematic review on outcomes of patients lost from HIV care and treatment programs in resource limited settings, 20-60% of patients who could be traced had died (Brinkhof, Pujades-Rodriguez & Egger 2009:3-4).

These studies point to two critical public health problems for patients who are LTFU – a large percentage of avoidable deaths and compromised quality of life among those who would survive.

LTFU is therefore a major challenge in HIV care because tracing patients is evidently resource-intensive and often unsuccessful. Given that most of these patients may have already died, it has been suggested that preventing LTFU by directing major efforts towards earlier HIV diagnosis, effective linkage to and retention in care and timely initiation of ART may be more effective at improving outcomes (HAPCO & MOH 2008:8).

HIV testing identifies infected persons and is an entry point to a continuum of HIV health care and social services. Eligibility for ART initiation is determined based on the clinical stage and social factors and the CD4 count is used to guide treatment and follow-up. The clinical criteria that need to be met to make patients eligible for ART initiation in Ethiopia are a CD4 count below 200, World Health Organization (WHO) stage IV and WHO stage II and III with total lymphocyte count (TLC) less than 1200 (MOH, Guideline for implementation of Anti Retro Viral Therapies in Ethiopia, 2005). The social factors considered include that the client should be resident within the facility's catchment area and that the patient doesn't have any identified barriers to adherence. Identified barriers to adherence include alcoholism, substance abuse and lack of support system (WHO et al. 2006:156).

Except for some additional criterias to ensure gender equity and adress most vulnerable groups before the introduction of free ART services, these clinical and social eligibility criterias have been in place since ART was introduced in the country in 2003. (MOH 2005:1)

Once eligibility status is known, the patient is either put on ART or enrolled into pre-ART care. The pre-ART period is arbitrarily defined to be the time between client referral to the clinic and ART initiation. The length of stay in the pre-ART care depends on how

soon the patient progresses towards meeting the eligibility criteria which also depends on how early after acquiring HIV infection the client was tested and got enrolled to the care. This could vary from as short period as a month to years.

Currently, there are no standardized guidelines that describe the type of care patients receive during the pre-ART period both globally and in Ethiopia. The Ethiopian national ART implementation guideline heavily focuses on the care during the ART time and it doesn't mention the standard procedures and the dynamics of pre-ART services. While patients in the pre-ART period are generally referred to as "patients on care", various implementation partners have different definition of what "care" means. As a result, the pre ART care of HIV patients is not well defined, and the type of service provided is not standardized. Proper patient follow up and tracing mechanisms are not in place and it is very likely that some of them drop out from care or die before ART initiation. These problems are likely to get bigger and complex as the cumulative number of people living with HIV/AIDS keeps on rising resulting in huge mortality and morbidity burden in a country like Ethiopia where 80 million people live.

### **1.3. RESEARCH PROBLEM**

Retaining patients infected with HIV in medical care after diagnosis is essential to initiate lifesaving antiretroviral therapy and facilitate the delivery of important prevention messages for reducing HIV transmission. New HIV infections in the future are by and large projected to come from people who live with the virus, know their sero-status and not enrolled in care services or drop-out of from the service. Keeping these clients in care has potential impact not only in reducing AIDS related mortality but also preventing new infections.

Currently, the period of pre-ART care, its service goals, service packages and measures of retention in Ethiopia are not well defined and documentations on the outcomes of LTFU during the period are not available in most cases. As a result, the dynamics of pre ART care, including the magnitude of LTFU and associated reasons including quality of care during pre-ART period are not known. Although lack of enrolment in care has been associated with negative clinical outcomes including delayed ART initiation, virologic failure, and mortality (Ulett, Willig & Lin 2009:23), few studies have examined the rate of LTFU among ART ineligible patients and reasons why these patients fail to be retained in care.



## **1.4. AIM OF THE STUDY**

### **1.4.1. Research purpose**

The purpose of this research is to describe the type and organization of pre ART care and determine factors associated with LTFU and perceived reasons for discontinuation of care among adult patients enrolled to pre ART program in Ethiopia.

### **1.4.2. Research objectives**

The objectives of this research are:

- To assess the type of services that are provided as part of pre-ART programs and determine the system that guides the service delivery
- To determine the level of loss-to-follow-up among adult patients enrolled in the pre ART program in St. Luke Catholic Hospital
- To identify factors (socio-economic, cultural and disease -related) perceived to be reasons for discontinuation of care among pre-ART adult patients

## **1.5. SIGNIFICANCE OF THE STUDY**

Little is known about the patient care during the pre- ART period in Ethiopia. As there is no standard pre ART care guideline, services at the facility level are not uniform. There are no country level studies conducted in the area and thus the pre ART service in general and its challenges are not well understood.

Successful implementation of HIV/AIDS programs need scientific evidence generated in the appropriate settings. This study will try to answer some questions that remain unanswered regarding implementation of patient care during the pre ART period in Ethiopia. The study will attempt to describe pre ART care and provide a suggestion to help define a program package of services in Ethiopian context. The study is believed to produce important evidence that will be useful in understanding the dynamics of pre ART care.

The study findings will contribute to the body of knowledge in HIV AIDS care and will be useful in influencing the development and modification of guidelines in the country. Finally, understanding the factors associated with LTFU in pre ART care will also be helpful at health facility level to improve the standard of care and provide targeted follow up for different patient groups.

## **1.6. DEFINITION OF TERMS**

Pre ART period- The period between patient enrolment to care and ART initiation

Lost to follow up- There are different types of LTFU definitions used by various agencies. LTFU in this study is defined as per the US Centres of Disease Prevention and Control (CDC) guideline and refers to when a patient doesn't show up for clinic appointments for at least 3 months (CDC 2006).

Adherence- Engagement and accurate participation of informed patient in a plan of care without skip from appointment for the last 3 months (CDC 2006).

In this study, retention rate is determined and factors associated with lost to follow up are described. These two key terms are frequently used in this study as the research aims to touch on both determining retention rates among pre ART patients and factors associated with loss to follow up. Although the two terms (retention and loss to follow up) are not used interchangeably with same meaning, the concepts are reported in a mixed manner throughout the literature review.

## **1.7. FOUNDATION OF THE STUDY**

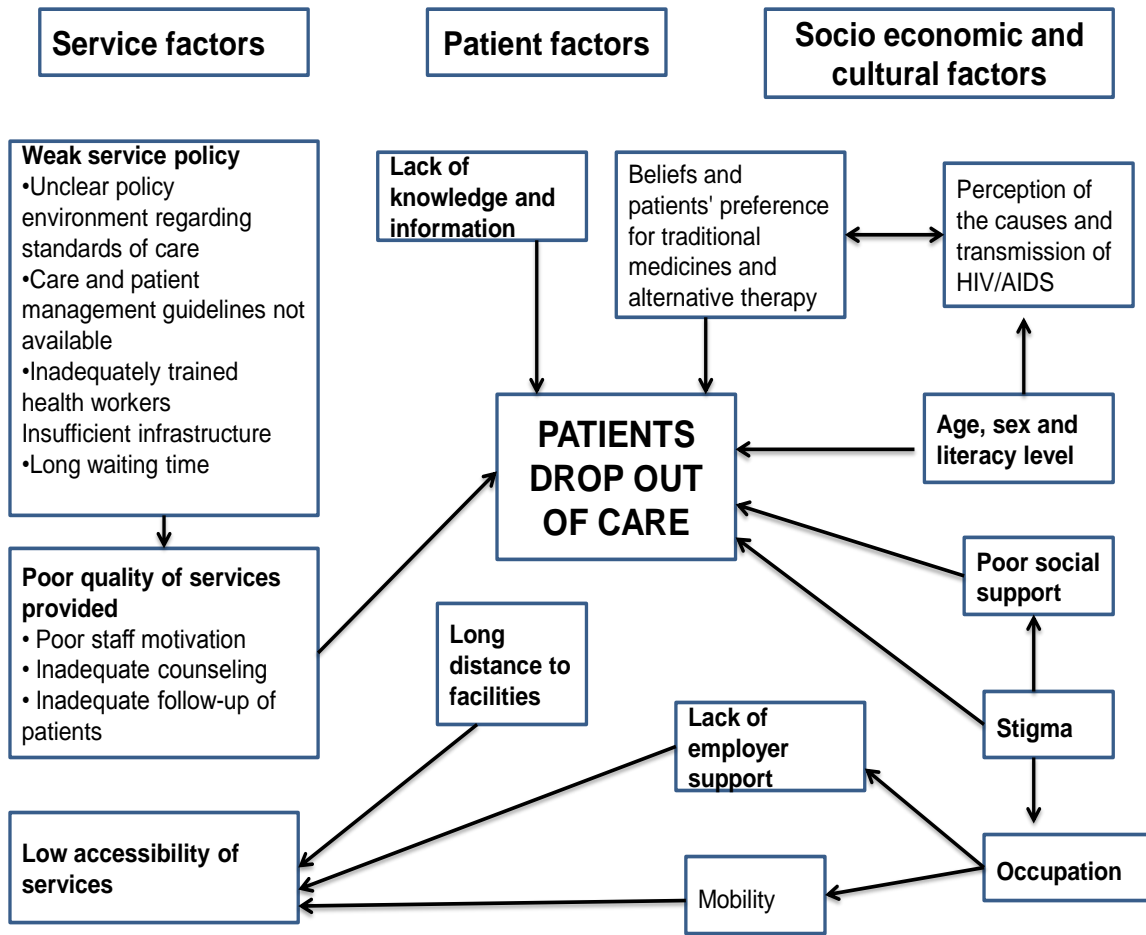
### **1.7.1. Meta-theoretical assumptions**

According to Polit and Beck (2004:13), an assumption is basic principle that is believed to be true, without needing proof or verification. The following assumptions served as starting points for this study:

- Lack of comprehensive service package and standard delivery mechanisms is a barrier to engage and retain HIV positive patients in care
- Socio economic and cultural norms can negatively affect retention in care
- Patient's demographic characteristics influence their perception of adherence to care services
- A significant percentage of patients enrolled in care will be lost-to-follow-up before they are initiated on ART
- Majority of these patients will die; some of them will return back to care with severe illness and compromised immunity.
- Patients LTFU will continue to be the source of new HIV infection in the community as they are less likely to either disclose their HIV sero-status or adhere to preventive behaviours.

### **1.7.2. Conceptual framework**

The conceptual framework for this study identifies service factors, patient factors and socioeconomic and cultural factors leading directly and indirectly to sub - optimal adherence to care. This study aims to investigate majority of the identified factors to assess the most important one in the study area context. Figure 1.1 below illustrates the various concepts.



**Figure 1.1 Research conceptual frameworks**

## 1.8. RESEARCH DESIGN AND METHODS

Chapter three of this report will present a detailed discussion of the research approach and methodology. The summary of that discussion is highlighted below.

In this study a cross-sectional research design with a mix of quantitative and qualitative data collection methods were used to determine rates of loss-to-follow-up during pre-ART care and associated factors. The reasons for the choice of this design are elaborated in chapter three of this report.

The study population included all HIV positive patients enrolled into the pre ART care program in a rural hospital in Ethiopia between January 2009 and December 2010.

Data were collected through patient records review to determine the level of adherence to HIV/AIDS care and Focus group discussion to solicit general information on healthcare demand, perception on quality of HIV/AIDS services and socio-economic and cultural factors associated with adherence to care.

Logistic regression analysis, crude odds ratio was done to determine whether any association exists between the independent and outcome variable with a confidence interval of 95%. Qualitative data analysis techniques were used to analyse data from focus group discussion.

### **1.9. SCOPE OF THE STUDY**

The research has explored the program environment towards pre ART cares in Ethiopia referring to available documents and resources. In addition, the findings determined the magnitude of pre ART loss to follow up and factors contributing to pre ART loss to follow up.

### **1.10. STRUCTURE OF DISSERTATION**

This report is organized in five major chapters outlined below:

- Chapter one: is the introduction chapter and gives an overview of the background information on the research problem, the research objectives and the definitions of concepts used in the study.
- Chapter two: is the literature review of scientific sources reviewed in this study
- Chapter three: is the research methodology and provides overview of the research design, methodologies used in data collection and the ethical principles observed during the study.

- Chapter four: this chapter discusses the data analysis techniques and the research findings
- Chapter five: is a chapter where conclusion and recommendations are made based on research findings.
- The final part of this research report consists of the bibliography and annexure containing the data collection tools, the consent form and the authorization to conduct the research.

### **1.11. CONCLUSION**

This chapter introduces the entire study and provides highlights of the importance of studying in detail the pre ART care, adherence during the period and factors that are associated with loss to follow up. The background to the research problem brings to light evidences related to health care service, HIV disease burden and pre ART care services both at national and global levels.

Key concepts and terms used throughout the study were operationally defined and the problem statement, objective and purpose of the study are also well elaborated in this chapter while the methodology is highlighted in brief.

Finally this chapter presented the way the research report is organized with short explanation about summary of their contents.

## **CHAPTER 2**

### **LITRATURE REVIEW**

#### **2.1. INTRODUCTION**

This chapter discusses the literature reviewed for this study highlighting the types, quantities and content of consulted sources and also the way in which they are acquired. The general purpose of a literature review is to gain an understanding of the current state of knowledge about the research topic (Johnson & Christensen 2004:61).

For this study the literature was reviewed to gain more understanding on pre-ART services, lost to follow up from care and factors associated with them. The review was specifically helpful to:

- Refine the research problem and document background information
- Familiarize the researcher with current knowledge of pre-ART care and identify literature gaps supporting the study topic
- Identify the relevant concepts to be included in the research questions
- Identify and refine the study methodology and processes
- Develop the data collection instrument

The review covers theoretical and empirical sources related to the main concepts found in this study. For this study, the literature review was conducted before data collection and documents were consulted after being acquired from various sources like the internet, Medline search, and published documents.

## **2.2. SCOPE OF THE LITERATURE REVIEW**

Both theoretical and empirical resources were included in the literature review. While primary sources are the most consulted, secondary sources were also used.

### **2.2.1. Theoretical resources**

The various types of theoretical sources used for the study can generally be grouped in to research methodology sources and conceptual and theoretical sources. Sources on research methodology reviewed to refine the research design and processes for this study mostly included textbooks on research methodology and journal articles. Sources on conceptual and theoretical references included textbooks on health education and health promotion theories, and sociology. These resources were important for identifying and refining concepts relevant to adherence and health seeking behaviors.

### **2.2.2. Empirical literature sources**

#### **2.2.2.1. Primary sources**

The literature review was based mainly on primary empirical sources contained in scientific journals and text books. During the review, it was found that while there are many studies conducted on patient retention and factors associated with lost follow up for patients on ART, there are few studies conducted on patients during the pre ART period . The few studies on retention during the pre-ART period in Africa are from South Africa and there was only one study from Ethiopia.

#### **2.2.2.2. Secondary sources**

Secondary sources were also consulted not only to support primary sources but also to help in the identification of additional primary studies from systematic reviews on pre ART care. These sources included technical and policy-related publications from the global (UNAIDS, WHO) and local (HAPCO, MOH and many others) institutions.



## **2.3. CURRENT UNDERSTANDING OF THE QUESTIONS IN THE STUDY**

### **2.3.1. What type of services are provided at pre-ART programs and what technical and programmatic principles guide the service delivery**

#### **2.3.1.1. HIV/AIDS care and treatment**

The primary goal of care and support of people living with HIV/AIDS (PLWHA) in clinical setting is to play an important role in preventing the spread of HIV/AIDS, improve quality of life and prevent premature death.

According to Ministry of health of Ethiopia, (2005:12), people suffering from HIV illnesses can access care at different levels of the health care system including public or private hospitals and health centers. The Ministry also describes the aim of the HIV/AIDS Care and Treatment services to be ensuring regular and standardized treatment, follow-up, and referral of patients to ensure that people living with HIV can be treated throughout the course of their illness (MOH, 2005).

#### **2.3.1.2. Organization of Care and Treatment Programs**

##### **Patient enrollment into the Care and Treatment Program**

All patients who test HIV positive in St. Luke Hospital are referred to an evaluating clinician who could be a health officer, physician or nurse. All patients who enter the care and treatment program receive a unique ID number at their first visit and are recorded in the pre-ART register. (If previously had been on ART and transferred from another facility, they are given a chart with their old unique ID and recorded in the ART register). HIV Patient Care and Treatment Record is filled out at the first visit, and updated at each subsequent follow-up visits both manually and electronically.

The initial visit focuses on determining the patient's eligibility for ART and Cotrimoxazole Preventive Therapy (CPT) (MOH, 2005). Some of the routine procedures on first visit include:

- Complete physical and WHO clinical staging, including all questions in the Symptom Checklist
- Baseline laboratory tests (including CD4 and TLC if available,)
- Cotrimoxazole prophylaxis, if necessary
- Assessment and treatment of OIs, including TB (MOH, 2005)

Patient counseling and contact establishment is also main part of initial visits. Some of the topics discussed by the counselor include basics of HIV care and treatment, importance of adherence to clinic visits, medication, HIV disclosure and positive living.

### **Patient visit plan**

Patients initiated on ART will be scheduled for follow-up visits frequently within the first six months for clinical care and monitoring of response to therapy. During these visits, they will see a nurse, an evaluating clinician as required, pick up their medication, and meet with case managers for adherence counseling. If the patient's condition has stabilized, after six months, he or she will be requested to visit the clinic at less frequent intervals for medication and counseling and as needed for clinical care. Every six months, CD4+ counts and basic blood tests will be performed and patients will see a clinician for follow-up and evaluation of response to therapy. All patients are advised to come to the clinic immediately should their condition deteriorate prior to their next scheduled visit (MOH, 2005).

Patients who do not meet the clinical and laboratory criteria for initiation of ART are reevaluated by a clinician with a clinical history and physical exam taken approximately every 3 months. Patients with acute illness are assessed at any time as needed. CD4 count testing and clinical staging is performed every 3 months to follow the trend of the disease.

Patients are monitored at each visit for the development of any stage 3 or 4 symptoms. Patients who become eligible for ART begin preparation for ART initiation which involves adherence counseling, social support and orientation on medication taking and nutrition.

All patients that are not eligible for ARVs are offered all other aspects of supportive treatment, including CPT if appropriate and early treatment of opportunistic infections. Cotrimoxazole is given to all patients who are WHO stage 2, 3 and 4. In addition, sexual partners and family members (such as children of HIV positive parents) are encouraged to attend a clinic for VCT and counseling and referral services are provided as appropriate.

### **2.3.1.3. Standard pre-ART service package**

There is lack of structure and services provided for people with HIV during pre-ART period. The e-survey from 20 countries (Baggaley, 2012) demonstrated that during the pre-ART period, apart from some ad hoc opportunistic infection screening and prevention, very little consideration was given to other services. Although there are well-described support packages of care for people with HIV, (CDC, 2007) there is little agreement on a start-out set of pre-ART services which in practice translates to poor retention of clients.

Although there have been many efforts to develop programs for people with HIV following diagnosis (Geng, et al., 2011: e21797), insufficient attention has been given to implementation. A beneficial package of care, support and prevention for people with HIV in the pre-ART stage would support people to remain engaged in care throughout this period and facilitate timely assessment of ART eligibility and commencement of treatment.

For example, following a positive diagnosis, if a patient is not eligible to be enrolled in ART care there are opportunities to offer a range of services which have wide benefits and could prevent loss to follow-up during this period, including provision of HIV prevention services, cotrimoxazole prophylaxis, screening for TB and provision of IPT, safe water, insecticide-treated bed nets (where appropriate) nutritional assessment, psychosocial support, support for partner testing, and PMTCT, family planning and reproductive health services, and linkages to community care and support, in addition to periodic clinical and immunological assessment so that patients can move from pre-ART services to ART care as soon as they become eligible (WHO, 2011:22).

## **2.3.2. What is the level of adherence by adult patients to pre ART**

### **2.3.2.1. Defining adherence**

Due to the fact that pre-ART care is very poorly understood and given less attention, there has been no proper definition of the term “retention” or “loss to follow up” during the pre -ART period. As a result, literature shows unclear and inconsistent use of terms that has made synthesis of evidences on retention very difficult (Matthew, Bruce & Sydney 2012:2).

In order to address these challenges, Matthew et.al (2012:3) recently developed practical standardized definitions for reporting retention in the three stages of pre-ART care. They include:

- Stage1: a period from testing HIV-positive to initial ART eligibility assessment;
- Stage2, a period of initial assessment for ART eligibility; and
- Stage3, a period after ART eligibility assessment until ART initiation.

Stage1 retention rate is defined as the proportion of patients who completed initial ART eligibility assessment within 3 months of HIV testing, with reporting of cohort outcomes at 3 and 12 months after HIV testing. Patients who end Stage1 eligible for ART move directly to Stage3.

Stage2 retention is defined as the proportion of patients who either complete all possible ART eligibility re-assessments within 6months of the sites standard visit schedule or had an assessment within 1year of the time reported to and were not ART eligible at the last assessment. Retention should be reported at 12-month intervals.

Stage3 retention is defined as the proportion of patients eligible for ART who initiate ART (i.e. ARVs dispensed) within 3 months of determining ART eligibility, with reporting at 3months after eligibility and 3 monthly intervals thereafter (Matthew et.al 2012:5).

Others have defined patient retention (not specifically pre ART patients) as missed appointments, missed visit rates, and the percentage of patients who miss appointments over a defined period (Catz et al. 1999:362, Israelski et al. 2001:473).

Mugavero et al (2009:248) defined missed appointments as appointments that are not cancelled or rescheduled; missed appointment rates are the proportion of total appointments that are missed and are also referred to as a missed visit proportion, which has been used with a threshold of 25% to compare association with independent variables.

Regardless of which definition is to be followed however, the conceptualization and investigation of patient retention should be based on which measures best capture the essence of an established provider-patient relationship, which patients fall out of care, and the types of interventions that will be targeted to maintain ongoing engagement in care. (Elizabeth et al. 2010:3).

For this study a definition by CDC used at country level is used for both Adherence and loss to follow up. Accordingly, adherence is engagement and accurate participation of informed patient in a plan of care without skip from appointment for the last 3 months (CDC 2006) and loss to follow up is when a patient doesn't show up for clinic appointments for at least 3 months (CDC 2006).

### **2.3.2.2. Level of patient retention in pre-ART care**

Retention in care after the initiation of ART has been the focus of much published work from sub-Saharan Africa and is seen as a key indicator of program performance (Rosen, et al., 2007). However, few studies have exclusively assessed pre-ART LTFU in Africa (Larson et al. 2010; Bassett et al. 2010; Amuron et al. 2009; Losina et al. 2010; Lessells et al. 2011; Lessells et al. 2011; Rosen et al. 2011).

According to a systematic review of pre-ART care in sub-Saharan Africa by Sydney Rosen and Matthew Fox (2011:7), more than two-thirds of people who tested positive for HIV but weren't yet eligible for treatment when diagnosed with HIV were lost from care. This study that has reviewed 28 different studies reported that there was a substantial loss of patients at every step of care, starting with patients who do not return

for their initial CD4 count results and ending with those who do not initiate ARVs despite eligibility.

Bassett et al (2009:3), also conducted a study in South Africa which showed that fewer than 50% individuals not yet eligible for ART returned to health facility within 13 months for repeat CD4 cell count; 16.4% of these patients were lost within three months of follow-up before ART initiation (Bassett et al. 2009:5).

A similar study was also conducted in South Africa to estimate loss to follow up between initial enrolment and the first scheduled return medical visit of a pre-ART care program. The result showed that 74% of patients scheduled to return in 6 months for a first medical visit did not return within one year and only 6% of patients scheduled to return in 3 months returned within 4 months while 41% returned within one year (Bruce A. et al. 2010:1).

A study conducted in a district hospital in southern Ethiopia to assess pre-ART and on-ART patient outcomes showed that a quarter of pre ART patients were lost to follow-up (Zewdie, Degu & Bernt 2010:2).

A study from Kenya showed that 33.6% of pre ART patients were reported to be lost from care and 53.9% these patients were lost as early as before the second visit (Amin S et al 2012:82). Faal M et al (2012:5) also reported that high pre-ART losses persist with almost 1- in- 2 patients failing to collect their laboratory CD4 result one week after HIV diagnosis

### **2.3.2.3. Benefits of retention in HIV care**

Studies show that retaining HIV-infected patients has the potential to help contain health care costs by improving HIV-specific health outcomes and reducing emergency department visits and hospitalizations (Cree et al. 2006:5, Gill & Mainous 2000:4). In addition, retention provides the opportunity to implement preventive health care interventions and to promote health behavior change that may decrease HIV transmission (Elizabeth et al. 2010:106). Retention in pre ART care has also been shown to contribute to improved patient retention in ART care as it allows adequate

preparation giving them extra time to adjust to the need for lifelong therapy and to attend multiple group education sessions (Elena et al. 2010:4).

Poor retention in care is associated with decreased likelihood of receiving antiretroviral therapy, higher rates of antiretroviral therapy failure, increased HIV transmission risk behavior, increased hospitalization and reduced survival rates (Elizabeth et al. 2010:108, Giordano, Hartman & Gifford 2009:300). In general, retention in care prevents new HIV infections, promotes good quality of life for those living with HIV infection and reduces mortality from AIDS-related illnesses.

### **2.3.3. Socio-demographic, cultural and disease –related factors that contribute to non-adherence/adherence among Pre-ART patients**

Consulted literature revealed several key reasons for the poor retention of pre-ART care patients. Rosen and Fox (2011:5) wrote that patients may not perceive themselves as requiring medical care as most are asymptomatic during the pre-ART period. Lessels et al (2009:5) also provide similar evidence showing lack of incentive for asymptomatic individuals to return for clinical monitoring as a possible explanation for poor retention indicating that the majority return to care at the time of symptoms. The fact that package of care for individuals not yet eligible for ART is limited in most African setting, was also mentioned to have likely limited the effectiveness of programs (pre-ART) as individuals will often return to care with opportunistic infections, possibly requiring hospitalization, and ART will continue to be initiated late with consequent sustained high mortality rates (Ndiaye, Ould-Kaci & Salleron 2009).

Tom and colleagues (2011:4) reported that lack of availability of comprehensive HIV care services may be a reason for low retention in care in the pre-ART period. Patients who are simply asked to return for repeat CD4 testing after 6 months may be less inclined to return than patients offered a comprehensive service package upon diagnosis.

In Uganda, inadequate post-test counseling and competition from holistic and less stigmatizing traditional/spiritual healers were cited as the main reasons for loss during the pre-ART period (Lubega, et al., 2009). While, age, sex and marital status were not shown to be associated with being lost to follow-up in some studies, (Zewdie et al 2010:3), others indicated gender to affect both access to and retention in care (Richard J. et al. 2011:84). The proportion of males in the pre-ART population was shown to be lower than that seen in antiretroviral treatment cohorts and likely reflects the different entry points to HIV care, with a large number of asymptomatic females enrolled in HIV care through antenatal HIV testing (Braitstein, et al., 2008). Male sex and full-time employment were associated with lower rates of retention in this same study. However, another study showed that being employed to be positively associated with a patient adherence to care (Bruce A. et al. 2010:45)

Having high CD4 count is associated with patients not seeing the point of engaging in care as they feel well (Faal, et al 2010:3, Bruce A. et al. 2010: Bassett et al 2009:140).

A study from Ethiopia showed that being in less advanced WHO clinical stage at diagnosis, and being a rural resident to be independent predictors of loss to follow-up. (Zewdie et al 2010:2).

While the above study by Zewdie, et al (2010:2) reported age, sex and marital status not to be associated with being lost to follow-up, Amin S, et al (2012) reported distance from health facility and marital status to have independently predicted LTFU during the pre-ART period.

In the study done in South Africa, Elena et al (2010) wrote that factors associated with higher rates of lost to follow up were: living  $\geq 10$  km from the health center, a history of TB treatment, and referral for HIV testing by a health care provider as opposed to self-referral.

Also, transportation costs, long waiting time, lack of incentives to seek pre-ART care by healthy looking patients and gender inequalities were mentioned as some of the perceived reasons for the high loss (Zewdie et al 2010:3).



In general, studies show that patients may not come to the clinic for monitoring and may choose to wait and see what happens if they lack resources for transport, risk losing employment by taking time off work, or fear being recognized as a client of an HIV clinic.

#### **2.3.4. Strength and weakness of studies done on pre-ART retention and factors associated with pre-ART loss to follow up**

The few available studies on pre ART all showed the magnitude of problems in retaining patients in pre ART care. However all the studies used different set of terms definition (such as...) and followed different patterns of reporting findings. This is a reflection of lack of common understanding on the minimum package of services required during the pre-ART period and the standard measures of program performance even at a global level. While all of these studies focused on assessing the retention, few investigated the service environment and program designs to care for patients during the pre-ART period. In their systematic review, Rosen and Fox (Rosen & Fox 2011:8) reported that none of the studies in their review followed a cohort of patients through all three stages of pre-ART care, with most studies reporting on only one stage. It was also mentioned that aggregations of results were difficult across the studies reviewed as enrolment criteria, terminology, endpoints, follow-up, and outcomes varied widely and were often poorly defined.

## **2.4. CONCLUSION**

The literature review was conducted to gain better understanding on pre ART care, retention and factors associated with lost to follow up. Various sources including internet, text books and others were assessed to identify the literature. The literatures consulted assisted the researcher to better understand the research question and conceptualize the important knowledge gap in the study topic and decide on the variables that the study needs to measure/assess.

## **CHAPTER 3**

### **RESEARCH METHODOLOGY**

#### **3.1. INTRODUCTION**

This chapter discusses the research methodology including the design, study population and sampling, data collection techniques, approaches to data analysis and ethical issues.

#### **3.2. RESEARCH DESIGN**

A cross-sectional research design with a mix of quantitative and qualitative data collection methods was used. This technique is selected to obtain the complementary strengths of the resulting mixture of the two techniques. While the quantitative technique assisted in describing the data and measuring statistical associations to generalize findings, the qualitative techniques contributed to the search for pattern, theme and holistic feature with representation of viewpoints from the interviewee.

#### **3.3. RESEARCH METHOD**

A cross sectional descriptive study design was used to examine the level of adherence to pre ART care among adult HIV positive patients and the various factors associated with patients lost to follow up. According to Polit and Beck (2004:192), the purpose of descriptive designs is to observe, describe and document aspects of a situation as it naturally occurs in a given population. Cross sectional designs are conducted in the present time to examine what currently exists and they are fundamentally characterised by the fact that all data are collected at one time (Brink & Wood 1998:6).

According to Brink and Wood (1998:161), correlation design is used when the investigator has reason to suspect a relationship between variables and can support this suspicion from literature or previous research. Brink and Wood, (1998:163) give the following additional assumptions for correlation design: the variables have not been shown to co-vary in previous studies of similar populations; and there is no tested

theory on which to predict the possible relationship between the variables. These variables exist in the population and they are studied as they exist naturally without manipulation. Finally the sample needs to be representative.

Descriptive method was applied to describe patterns and provide information about study variable characteristics. The study was also cross sectional as it is conducted in the present and all the data were collected at the same time. The study's correlation aspect comes in the fact that the suspicion of a relationship between dropping out from care and the different socio demographic and disease related factors emanated from the review of the literature is tested.

Focus group was used as an additional method for data collection in this study. Focus group interviews are particularly useful in obtaining multiple perspectives about a topic in a concise manner while providing insight into the shared understanding held by group participants (Gibbs 1997:1-7). Attitudes, feelings and beliefs are more likely to be revealed through the group process unique to focus group methodology (McLafferty 2004:190). Focus groups have been used by other investigators doing research with HIV/AIDS individuals (Nyamathi & Shuler 1990, Reynolds 2004).

Guidelines on HIV care and treatment were analyzed to produce comprehensive report about what standard operating procedures guide the pre ART care service.

### **3.3.1. SAMPLING**

#### **3.3.1.1. Research Population**

The study population in this research included all HIV positive patients enrolled into the pre- ART care program in St Luke Hospital. The following were inclusion and exclusion criteria:

##### *Inclusion criteria*

- Adult patients (- 18 years and above).
- Enrolled to the Pre ART care during the period from January 1<sup>st</sup> 2009 to December 31<sup>st</sup> 2010.
- Patient's follow up chart and electronic record available in the health facility.

##### *Exclusion criteria*

- Patient not officially registered and enrolled to Pre ART care in St. Luke hospital's ART clinic
- Patients aged below 18 years
- Patients follow up chart and electronic record not available

#### **3.3.1.2. Sampling technique and sample size**

Two aspects: record review and focus group discussions

All pre-ART adult patients (n=760) who enrolled to HIV care between January 2009 and December 2010 at St. Luke hospital, Ethiopia were selected for chart review in this study. Therefore, no sampling procedure was applied to identify the study subjects for the record review aspect of this study other than the inclusion and exclusion criteria. Patient data was available both computer record and patient chart. The electronic version is extracted for this study with occasional cross reference to the paper records in case of incomplete information. However, the data on the computer record and patient chart found to be identical.

A convenience sample of 30 HIV-infected patients receiving care at an outpatient HIV clinic in St. Luke hospital, attended one of three focus groups with 10 discussants in each. Patients were selected from subjects who have been enrolled to pre ART care during the study period and were reported to be loss to follow up or were traced back to care afterwards. Convenient sampling was used to ensure participants represent gender and age group categories desired to represent the study population.

During the initial contact process patients were notified that they are invited to participate in focus groups and were informed that they are free to agree to or refuse participation.

Patients were initially eligible to participate in the focus groups if they were HIV positive, enrolled in the pre ART care in St. Luke hospital and hasn't started taking ARV. Phone numbers and additional contact information were retrieved from the patients' medical records. Times and dates for focus groups were established by the investigator based on participant's preferences once an adequate number of participants were recruited for a group session.

Patients who could be contacted via telephone were recruited to one of three prescheduled focus group sessions. No refusals were recorded although more than half of the eligible patients were unable to be contacted, due to a disconnected line or wrong number.

### **3.3.2. Data collection**

#### **3.3.2.1. Data collection approach and method**

Structured chart review checklist was used to capture data from patient records regarding patient socio-demographic and follow up history and retention status. Focus Group Discussion was held to solicit data information on socio-cultural factors associated with patient loss to follow up from care.

#### **3.3.2.2. Development and testing of the data collection instrument**

The chart review format and FGD guide was specifically developed for this study purpose. Reference was made to literature and other similar studies but it was not fully adopted. As advised by Brink and Wood (1998:247) and Boynton and Greenhalgh (2005:1313), different approaches were simultaneously used to develop the items included in the instrument.

Chart review format development was guided by the literature review and findings from previous studies. Studies such as Larson et al. 2010; Bassett et al. 2010; Amuron et al. 2009; Losina et al. 2010; Lessells et al. 2011; Lessells et al. 2011; Rosen et al. 2011 were some of the studies referenced. The researcher's field experience on HIV/AIDS care and treatment in Ethiopia also contributed in the development of some of the questionnaire.

The FGD guide was initially developed in English language and then translated into Oromifa the local language, which was back translated into English to check for consistency. The translation and back translation process was conducted by bilingual expert.

#### **Pre testing of the instrument**

Both chart review form and focus group discussion guide was sent to three medical professional colleagues for review and feedback. Comments received from the peer review included keeping the questionnaire simple and categorizing discussion areas based on the variables desired to be shared.

Following the peer review, the chart review format and FGD guide were both tested before using them for this study. The chart review format was tested to extract data from 50 pre ART patient charts in Chitu health center in South west Shoa zone. The FGD guides were pilot-tested on support group members in a rural community located in South west Shoa zone and modified based on the debriefing with facilitator and interviewed participants.

The instrument was modified based on the feedback from the pre test, and the post pre test version was used to collect the final data.

### **3.3.2.3. Characteristics of the data collection instrument**

Instruments used to conduct this research included chart review checklist, focus group discussion check list and referencing available programs and guidelines at the national and global levels. In addition, non-participant observation was conducted during patient consultation to collect information on the nature of services provided to pre ART patients.

#### **Guide to the research instrument**

The chart review (Annex 1) has a total of 22 items grouped in to three sections. Each section is composed of questions related to one of the three categories of variables. All questions were close-ended meant to gather data as it appear on the chart. The following provides detail guideline to the content of each section.

- Section 1 comprises 8 questions and assesses data on client socio demographic data
- Section 2 has 4 questions and focuses on Client's clinical, biological information up on enrollment
- Section 3 has 10 questions on follow-up data

Discussion guide was developed to conduct focus groups. The FGD guide has talking points on Opinion of patients on the pre-ART program activities in St. Luke hospital, reasons for discontinuation, individual and social influences/barriers and client

experience with pre-ART. The discussion guide was used to direct the FGD towards the information required but was kept open ended for participants to talk about the issue freely. Probing techniques were used to go in depth in each point to obtain an in-depth insight.

Krueger and Casey (2000) suggest that five categories of questions be used in conducting the focus group interview: opening, introductory, transition, key and ending questions. Opening questions establish rapport and get interaction between group members. Questions should be easy to answer in a brief way and are not typically analyzed. Introductory questions are used to introduce the topic of discussion and get participants to begin thinking about the topic of interest using an open-ended approach. Transition questions serve as a bridge from the introductory to the key questions and serve to make a connection between the participant and the topic being investigated. Key questions serve as the main focus of the study. Finally, ending questions are used to bring a sense of closure to the interview and serve to reflect on and summarize what has occurred.

### **Variables measured**

The sets of variables (dependent and independent) this study assessed include:

- Service factors: include the service delivery environment during the pre-ART care, especially assessing presence of guidelines and standard operating procedures, trained health care workers in the field and availability of basic infrastructures.
  - Patient factors: demographic, clinical social data at enrolment and during follow-up period
  - Socio economic and cultural factors: demographic, social and economical background of clients and their fellow peers
- i. The variable service factor



The service factor in this study was measured by collecting information on type of services provided during pre ART care, describing the packages of clinical and psychosocial services provided in each visit and analysing the available guidelines and SOPs on patient care. The conceptual framework developed for this study was used as a point of reference in identifying this variable.

ii. The variable patient factor

Patient factors were measured using focus group discussions to solicit data on patients' experience with pre-ART, reasons for discontinuation, individual and social influences/barriers and opinion on the pre-ART program activities in St. Luke hospital

iii. The variable Socio economic and cultural factors: demographic, social and economical background of clients

Socio economic, cultural, social and demographic data were collected through both chart review and focus group discussions.

#### **3.3.2.4. Data collection process**

Patient records were reviewed as proposed to determine the level of adherence to HIV/AIDS care. The review was conducted using data capturing format that contains demographic, socioeconomic, clinical status and follow up history information. Client electronic database was used as main document during this process. Critical evaluation of policies, guidelines and operating procedures regarding HIV care and treatment in the country was conducted to assess the service and program environment. In addition, observation was made during consultation to collect information on the nature and services provided to the patients on ARVs.

Three focus group discussions were conducted in a quiet room at the multipurpose rooms of St. Luke College of Nursing in Wolisso town. This location was chosen as it is in a central and accessible location for most of the participants and had adequate and private meeting rooms which were provided free of charge.

As HIV can be a sensitive topic and to minimize observer bias, the FGD was carried out by trained moderator and note taker for all the three groups, local language skills needed for all the sessions and familiarity with the sites. The moderator and note taker were provided with half day orientation in which they were informed about the purpose of the study, ethical issues and the consent procedure, the FGD facilitation process and methods of probing.

The focus group discussion was initiated using open-ended questions in the main areas of 1) Experience with pre-ART services 2) Perceived reasons for discontinuation 3) Individual and social influences/barriers for retention 4) Opinion on the pre-ART program activities and its qualities in St. Luke hospital. In addition, several probing questions were used that pertained to how they see the service, what has been helpful in being adherent, what has been problematic, role of health care providers and relationship with health care providers.

Demographic information, including patient age, gender, religion and level of education was obtained from a brief interview with the patients prior to each focus group.

Each focus group was conducted by the moderator and audio taped so it could later be transcribed for data analysis. A note taker took detail notes as discussion was going on.

### **3.3.2.5. Ethical consideration related to data collection**

Major ethical considerations that needs to be taken care of in relation to data collection for research include the voluntary nature of participation, reduction of risk for participants, obtaining of informed consent, ensuring confidentiality and privacy of participants, and institutional ethical issues which include obtaining authority to conduct research and scientific honesty (Babbie and Mouton, 2001: 552, Bless and Higson-Smith, 1995: 102, Katzenellenbogen, Joubert and Abdoo IKarim, 1997: 27, Mouton, 2004: 238, Polit and Beck, 2004: 143 )

Steps taken to ensure the above issues are adhered to for this study include:

- **Voluntary participation:** participants had the right to take part in the study or not as they chose. For the chart review, the hospital management had the right to grant or refuse permission to access the data.
- **Informed consent:** participants were provided with adequate information on the research before the focus group discussion. The hospital was informed adequately regarding the scope and intention of the study. Written consent was obtained from the hospital as well as individual research participants.
- **Confidentiality and anonymity:** anonymity and confidentiality were ensured by making the responses anonymous and identifying patients on record only through unique identifier codes and without their names. Information obtained remained confidential and were not revealed to people other than the research team.
- **Minimizing risk to participants:** the research was carried out with minimum risk to respondents. Counseling services were made available for FGD participants in case of any emotional stress during the sessions.
- **Authorization to conduct the research:** authority to conduct the research was obtained from St. Luke hospital authorities and UNISA Research and Ethics Committee. (see annex 7 and 8)
- **Competency:** competency of the researcher to conduct research was approved after passing the theoretical Masters in Public health modules in health measurement and research methodology courses offered by the University of South Africa.

### 3.3.3. Data analysis

A data imported from The ART database was analyzed using SPSS version 15 statistical package. Frequency distribution and percentage calculation was made to describe socio-demographic characteristics and to determine the prevalence of lost of follow up. Logistic regression analysis, crude odds ratio was done to determine whether any association exists between the independent and outcome variable with a confidence interval of 95%. Audiotapes of the focus groups were transcribed verbatim.

The investigator reviewed the transcripts for accuracy and to capture the interactions within the group. The transcripts were analyzed to develop codes for data analysis.

Categories of responses were coded using an emergent approach described by Haney et al (1998:40), which consists of several steps. First, the transcript was reviewed in depth to condense responses into classifications to which a coding scheme could be applied. Second, the findings were reviewed again and final coding scheme established. The coding schemes were based on the topics in the focus groups. Third, the coding scheme was used to code a second transcript. Fourth, the results of the coding of the second transcript were checked to determine the reliability of the coding.

The information gathered through FGD was used to complement and strengthen the findings obtained through quantitative data sources. The findings were crucial in obtaining answers to some of the research questions such as patient experiences and opinions about pre-ART services and reasons for discontinuation that are not possible to identify through quantitative methods.

### **3.4. VALIDITY AND RELIABILITY OF THE STUDY**

#### **3.4.1. Internal and external validity of the study**

Validity refers to the question whether there is evidence to support the assertion that the methods are really measuring the abstract concepts that they are meant to measure. Validity also concerns the quality of the researcher's evidence regarding the effect of the independent variable on the dependent variable (Polit & Beck 2004:38)

#### **Internal validity**

Burns and Groove (2005:2015) define internal validity as the extent to which the findings of a study are a true reflection of reality, rather than the result of extraneous variables. Descriptive research is said to be low in terms of internal validity as it allows for limited control over the research variables and the research setting. The internal validity of qualitative research is the degree to which the interpretations and concepts

have mutual meanings between the participants and the researcher. Some of the strategies used to enhance the validity of the qualitative data from FGD include:

- Verbatim accounts of literal statements of participants and quotations from documents
- Use of tape recorder
- Use of participant recorded perceptions in notes for corroboration

### **External validity**

External validity is defined as the degree to which the study results can be generalised to other people and other research settings (Brink 2000:209). In this study, a large representative sample from two years' period was used to ensure the findings will be generalisable to the population. In addition, the research design was carefully constructed to ensure

### **3.4.2. Reliability**

Polit and Beck (2004:35) defined reliability as the accuracy and consistency of information obtained in a study and state that the term is most associated with the methods used to measure research variables. Reliability problems in studies commonly arise when respondents don't understand the question, are asked about they don't clearly recall or are asked about something of little relevance to them (Fisher & Foreit 2002:45). The use of standard chart review protocol for all charts reviewed in this research and the use of similar discussion guides for all FGD groups are some of the techniques used to increase the reliability of this research.

### **3.5. CONCLUSION**

This chapter presented the methodology used to conduct this study. A mixed quantitative and qualitative approach was used and descriptive, cross sectional and correlational research design was adopted. Purposive sampling technique was used for FGD while patients enrolled to care between January 2009 and December 2010 in St. Luke hospital were all included in the chart review.

The data collection method and instruments used in this study were also discussed in this chapter. Structured patient chart review checklist containing 22 items and a focus group guide were used to gather data that measured the rate of adherence to pre ART care and factors associated with loss to follow up. The other components discussed in the chapter include validity, reliability and ethical consideration followed by data analysis plans.

## **CHAPTER 4**

### **ANALYSIS, PRESENTATION AND DESCRIPTION OF THE RESEARCH FINDINGS**

#### **4.1 INTRODUCTION**

This chapter discusses the analysis and interpretation of data. The presentation of data is organized as quantitative data analysis, FGD report and review and assessment of guidelines and program documents.

#### **4.2. DATA MANAGEMENT AND ANALYSIS**

Data were collected through quantitative and qualitative methods. Chart review and FGD were implemented in April 2012. Review of guidelines and program documents was conducted before the other data were collected as part of the literature review. Chart review was done for 765 adult patients enrolled into the pre-ART HIV care program in St. Luke Hospital over 2 years period - between January 2009 and December 2010. Four hundred and thirty (56%) of these were put on ART during the 2 years period while three hundred thirty five (44%) were still followed under pre-ART program. Patients who started ART during this period were excluded from the current study. Focus group discussion was held with thirty participants who are currently on pre ART.

Quantitative data was analyzed using statistical computer software and qualitative data was processed using qualitative techniques described in Chapter Three.

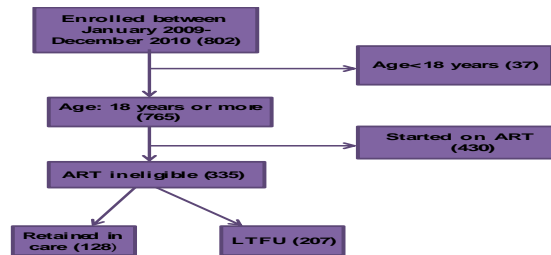


Figure 4.1 Flow diagrams of study participants

### 4.3. RESEARCH RESULTS FROM CHART REVIEW

The results of the analysis of the data are presented below using tables, graphs and summary statistics.

#### 4.3.1. socio-demographic characteristics

Of the 335 patients included in the analysis, 71.3% (n=239) were female and 96 (28.7%) were males. Age of participants ranged from 18 to 58 years with mean age of 34.3 years (standard deviation= 9.4). Table 4.1 depicts detailed socio-demographic characteristics of the study subjects.



**Table 4.1: Socio demographic characteristics of participants**

Characteristics	Female (n=239) Frequency (%)	Male (n=96) Frequency (%)	Total (%)
<b>Age in years</b>			
18-24	47(19.7%)	4(4.2%)	51 (15.2%)
25-34	134(57.3%)	29(30.2%)	166 (49.6%)
35-44	41(17.2%)	36(37.5%)	77(23.0%)
45-54	9(3.8%)	21(21.9%)	30(9.0%)
55+	5(2.1%)	6(6.3%)	11(3.3%)
<b>Level of education</b>			
No education	99(41.4%)	19(19.8%)	118(35.2%)
Completed Primary school (up to grade 8)	100(41.8%)	48(50.0%)	148(44.2%)
Completed secondary school and higher	40(16.7%)	29(30.2%)	69(20.6%)
<b>Marital status</b>			
Never Married	15(6.3%)	15(15.6%)	30(9.0%)
Married	139(58.1%)	67(70.8%)	207(61.8%)
Separated	47(19.6%)	8(8.3%)	55(16.4%)
Divorced	4(1.7%)	1(1.0%)	5(1.5%)
Widow	34(14.2%)	4(4.2%)	38(11.3%)
<b>Religion</b>			
Muslim	30(12.5%)	10(10.4%)	40(11.9%)

Christian - Orthodox	160(66.9%)	74(77.1%)	234(69.9%)
Other Christians ( Protestant and catholic)	49(20.5%)	12(12.5%)	61(18.2%)
Employment status			
Employed (public or private institutions)	86(38.5%)	41(42.7%)	133(39.7%)
Self employed	50(22.1%)	50(52.1%)	103(30.7%)
Un employed	92(39.3%)	4(5.2%)	99(29.6%)

#### 4.3.1.2. Outcomes of Pre-ART Follow-up

The charts reviewed showed that WHO staging, weight measurement and assessment for opportunistic infections were done at every visit to Hospital. CD4 counts on the other hand were measured every three months. Viral load measures were not done for any of the subjects.

Proportion of patients in the various WHO stages at enrolment into the pre-ART program and following 6 and 12months is illustrated in the table below (Table 4.2). The table also shows the status of initial and repeat CD4 counts performed, diagnosis of opportunistic infections and mean weight across time.

Table 4.2: Distribution of WHO staging, CD4 count, OI diagnosis and mean weight of pre-ART patients at first, 6 month and 12 month visits

Characteristic	At first visit	At 6 months follow-up;	At 12 months follow-up
<b>WHO stage</b>			
I	201(60%)	109 (61.6%)	67(62%)
II	72(21.5%)	47(26.6%)	32(29.6%)
III	53(15.8%)	18(10.2%)	9(8.3%)
IV	9(2.7%)	3(1.7%)	-
<b>Total observed</b>	335	177	108
<b>CD4 Count done</b>	330(98.5%)	71 (21.2%)	80 (23.9%)
<b>OI Diagnosis done</b>	335 (100%)	177 (100%)	108 (100%)
<b>Weight taken</b>			
Mean	52.6	53.9	52.8
SD	9.1	9.2	8.2

#### 4.3.1.3. Pre-ART Loss to follow up

Of the 335 patients enrolled in pre-ART care, 128 (38.2%) were retained in care and the remaining 207 (61.8%) were lost to follow up after 12 months. More than half (55.6%) of the LTFU took place within 6 months. The rate of LTFU declined and remained steady afterwards (Figure 4.2).

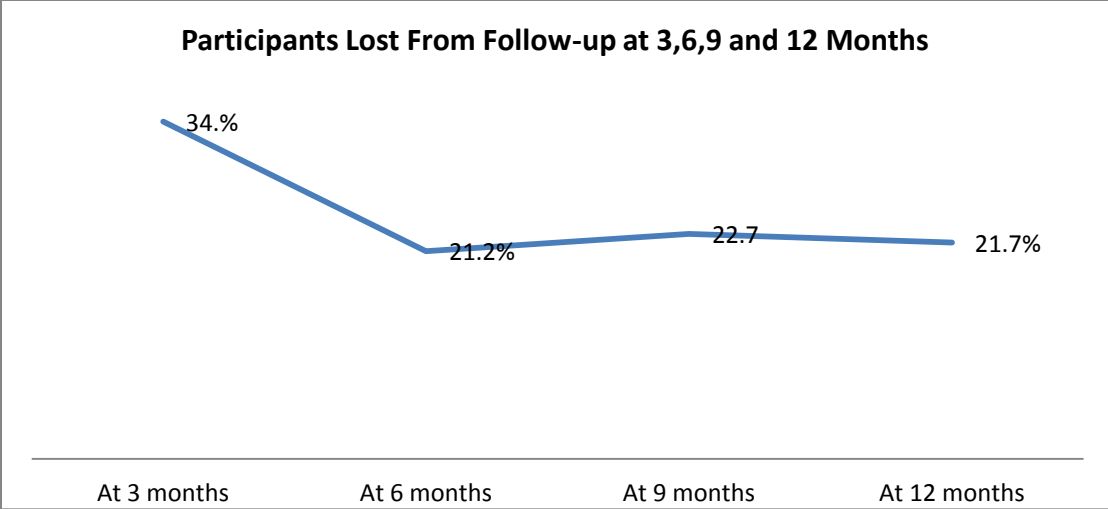


Figure 4.2: Proportion of participants who were lost from follow-up at 3, 6, 9 and 12 months

One's religion and having child significantly predicted pre-ART LTFU (Table 4.3). Compared to Christians, Muslim patients had three times higher chances of loss to follow up (crude odds ratio [95% CI],  $p$ -value; 3.44[1.39-8.49],  $p < 0.05$ ). Patients who didn't have children were more likely to be loss to follow up than those who had children (2.05[1.05-4.01],  $p < 0.05$ ). The analysis didn't show any association between loss to follow up and age, sex, residential address (urban/rural) disease category and CD4 count at enrolment.

**Table 4.3: Factors associated with lost to follow up among pre ART patients**

Variables	Categories	Retained care (128)	LTFU (207)	Crude OR (95% CI)
Gender	Female	96	143	1.34( 0.81-2.20)
	Male	32	64	1.0
Age Group (years)	18-24	21	31	1.01(0.52-1.97)
	25-34	58	107	1.28(0.79-2.09)
	35-44	49	69	1.0
Marital Status	Non Married	46	81	1.12(0.71-1.78)
	Married	81	126	1.0
Educational status	No education	48	70	0.89(0.48-1.64)
	Primary	54	94	1.06(0.58-1.92)
	Secondary and above	26	43	1.0
Employment status	Employed (public or private institutions)	60	85	0.82 (0.43-1.72)
	Self employed	40	60	1.0
	Un employed	28	62	1.05 (0.52-1.83)
Religious denomination	Muslim	9	31	3.44(1.39-8.49)*
	Orthodox Christian	90	144	1.60(0.89-2.85)
	Protestant Christian	29	29	1.0
Have child	Yes	115	168	1.0
	No	19	39	2.05(1.05-4.01)*
Pregnant on enrollment	Yes	5	11	1.0
	No	123	196	0.72(0.24-2.13)

\*= p value < 0.05

#### 4.4. ANALYSIS AND INTERPRETATION OF FOCUS GROUP DISCUSSION PARTICIPANTS BACKGROUND INFORMATION

##### 4.4.1. Background Information

Three FGDs were conducted with 10 participants in each group. The majority of participants on the FGD, 80% (n=24) were females. As shown in the table 4.5 below the majority of the FGD participants; 67% (n=20) were married and only 60% (n=18) have attended primary.

All discussants were HIV positive and were not started on ART by the time of the FGD. 20 of the patients were former LTFU who are retraced back to care. The remaining 10 are currently reported as LTFU. Selection was done through hospital case managers. Please refer to methods section for details.

**Table 4.4: background information of Focus Group Participants**

Characteristics	Number	Percent
<b>Gender</b>		
Male	6	20.0%
Female	24	80.0%
<b>Age categories</b>		
18-27	7	23.0%
28-37	16	53.0%
38-47	5	17.0%
48-57	2	7.0%
<b>Marital status</b>		
Never Married	2	7.0%
Married	20	67.0%
Divorced	2	7.0%
Widow/Widower	6	20.0%
<b>Level of education</b>		
No education	7	23.0%
Attended Primary school	18	60.0%
Attended Secondary school	5	17.0%
<b>Participants employment status</b>		
Paid employment	6	20.0%

Self employed	9	30.0%
Unemployed	15	50.0%
<b>Place of residence</b>		
Urban	5	16.7%
Rural	25	83.3%
Total	30	100.0%

#### 4.5. FINDINGS FROM FOCUS GROUP DISCUSSION

The data from all three focus groups were analyzed as described in the methods section above. The concept of adherence as a process from diagnosis to present emerged from the analysis of the data. For most participants becoming adherent to a clinic appointments was described as a “process”. Some participants claimed to have been adherent from the start, however, all reported encountering struggles accepting their diagnosis, needing to be on routine follow up schedules and/or the social life implications being seen in the health facility has “caused them in their lives”. Overtime the participants moved toward acceptance of their HIV status and the need to take their follow up seriously. As they get used to the social isolation and discrimination it became easier to cope with life of their own type. Most participants identified supportive others who played a role in their transition to acceptance of their diagnosis and the need to be on clinic follow up for HIV. The relationship with their healthcare provider, (predominantly a nurse or adherence counselor), was identified as significant in the process of becoming maintaining adherence behavior. All participants in the study reported that adherence to their follow schedules has a positive impact in terms of their health outcome.

The findings are presented under three thematic areas. The first objective was to describe experience of HIV positive people on pre ART care regarding general information on healthcare demand. The second objective was to describe what these

people perceive about the quality of HIV/AIDS service that are provided at pre ART programs currently and the third objective was to describe what socio economic and cultural factors they perceive as a factor to determine their adherence/non adherence.

In addition, several probing questions were used to ascertain what things had been helpful and problematic in adherence, what role did other people play in the adherence process and qualities of the relationship with the health care provider. Findings are presented as summary points and in some cases quotations are cited verbatim as stated by the discussants.

#### **4.5.1. Experience of FGD participants with pre-ART program**

All participants identified some level of difficulty accepting their HIV positive status which resulted in difficulties in adhering to clinic follow ups during the initial phase

##### **A) Learning the Diagnosis and about the service**

Many participants were diagnosed with HIV during to ante-natal care follow-up, childbirth, as a result of a serious illness or general change in their physical appearance. Some participants learned their diagnosis while hospitalized with an opportunistic infection, such as Tuberculosis, or another life threatening condition. A few reported seeking an HIV test in relation to the illness or death of an intimate other.

There were a number of individuals, who sought HIV testing voluntarily. Almost all participants learned about the pre-ART care service on the day they learned their diagnosis. The initial reaction to having HIV included a range of emotions such as depression, fear, anger, self-blame, and denial. One female participant expressed her initial reaction to her test results as *"I wanted to disappear or kill myself when I was told I had HIV"*.



Others identified fear as one of their early reactions as they believed they would die quickly because of HIV. This was mentioned by one participant as *“I thought I was going to die immediately, I didn’t know people lived with the disease”*.

People whom they sought help from about their HIV status after diagnosis included PLHIV association, Red Cross society local offices and health workers. All participants said that they learned about HIV care and treatment service at the time of counseling from the health care workers.

Most participants said that people diagnosed with HIV don’t tell their status to other people. Reason given for this was fear of stigma and discrimination. All participants reported some difficulty dealing with the stigma, real or perceived, of being HIV positive and showing at HIV clinic. Stigma, related to letting others know their health status, could impact multiple aspects of their lives; such as employment, and relationships with significant others. Many participants reported believing that avoiding stigma was easier if they didn’t have to go to clinic all the time.

Many reported that they were forced to isolate themselves from important social activities such as coffee ceremony, Idir<sup>1</sup> and Mahber<sup>2</sup> due to the stigma. This was expressed by one participant as *“I had to stop drinking coffee with my neighbors because they started fearing I might give them AIDS by using their cups”*. For many participants, this concern about stigma resulted in missing clinic appointments to keep their status hidden: *“I often cancel my plan to go to clinic if I suspect someone I know is also going there at the same date, because I don’t want them see me in the HIV clinic”*. For others, the impact of stigma led to feelings of shame: *“I felt ashamed; I always hid my medication from my children”*.

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<sup>1</sup>Idir is a traditional social support system (burial society) in Ethiopia in which communities support each other on death of family members and other occasions such as weddings. It serves as a community insurance scheme also

<sup>2</sup>Mahber is traditional community association

## **B) The pre-ART service**

Most discussants said that they consider the service they receive at the pre ART clinic as “good”. Discussants also mentioned that the service in the pre-ART program included counseling on topics ranging from positive living, nutrition and adherence to follow-up of medication. They all also agreed that regular laboratory testing, physical examinations and treatment of opportunistic infections were part of the services provided.

### **Appointment schedule**

Participants reported different timetable of appointment schedules in the clinic. Some reported that they have a monthly appointment schedule while others said they have appointment every 3-6 months. There are no fixed appointment patterns among the various participants.

### **Appointment day routines**

All participants in the three discussion groups agreed that the clinic routines began with seeing the adherence counselor for counseling and assessment who also prepares their cards and refer them to the consultation rooms for physical examination (including history taking, weight and PB). Every three month of the visit, they reported that they give blood for CD4 testing. The consulting clinician provides medicines for prophylaxis of opportunistic infections (OIs) or treatment of illnesses as indicated and they collect it from pharmacy. Adherence counselors provide information regarding any available community level services including linkage to psychosocial or income generating possibilities.

### **Relationship with health care workers**

All participants spoke highly of their health care workers in St. Luke Hospital and said they are very kind to them. Some individuals mentioned that they rely on health care workers for support, information and open discussion one participant said: “*we have confidence on health care workers because we trust them*”.

Other discussants reported that they feel the health care workers are truly concerned about them as a person and that they give them strength to go on with their daily life as HIV positive. One participant who recently had baby said: *“While I was pregnant, I couldn’t have survived the stress if it hadn’t been for the advice and supports I received from health care workers”*.

### **Waiting hours**

All participants mentioned that while the waiting hours are usually considered “fair”, it is extremely long on some days especially on the days that they are scheduled to give blood sample for CD4 test. Waiting hour on such days is reported to last up to 6 hours for patients who come to facility early in the morning. These waiting hours are considered by all participants to be very long.

### **4.5.2. Reasons for dropping out from pre ART care**

When asked about the reasons why people drop-out of the pre ART program, participants provided the following several reasons:

Some participants mentioned that some disappear just after they hear their HIV test result because they are shocked and they don’t want to hear about it again. Other participants also said that some people do not trust the pre ART service because they don’t believe it works. Good majority of the participants said that follow up during pre-ART period seem irrelevant sometimes because they know they are not getting the actual anti-retroviral treatment. They mentioned that most people who drop out of the pre ART care sometimes do it with intention of coming back when they are properly eligible for proper treatment. One participant was quoted saying *“I don’t see the reason for coming every month while I am told I am doing well and not yet ready for treatment”*.

Fear of being identified as HIV positive was mentioned by several participants as a reason for dropping out of care. In addition, fear of medication side effect, forgetfulness associated with alcoholism and absence of motivation to care for one self were also

mentioned by good number of participants as reasons for discontinuing care. In addition, some respondents mentioned that transportation cost to and from health facility for every follow up is costly even though the health facility doesn't charge them for the service.

Several participants reported that being HIV positive have exposed them to economic problems as they are excluded from most of the businesses and available job opportunities because of their HIV status. A number of them also mentioned that they were dismissed from jobs when the employers learned that they were positive: *"I used to cook injera<sup>3</sup> for households before and it was my only source of income, I was able to feed my children and send them to school with the money. After it was learned in the community that I was HIV positive, all my customers refused to use my service so I had to stop"*.

Other participants mentioned that engaging in small business and daily labors especially in the service provision sector for HIV positive persons is difficult because people are afraid to use their services. They also mentioned that people are afraid either because they think HIV positive people lack the capacity and power to work as non positives or they are afraid of getting the disease from them. Most people said being HIV positive has exposed them to economic problems. Few participants said that they are able to engage in the work force like anybody else despite their status.

#### **4.5.3 Outcome of patients who drop out of care**

When asked about what happens to patients who drop out of care, some participants replied that these patients do not inform anyone, and suffer from diseases and eventually die. Others said that some of the patients start "holy water" treatment, start new faith, practice fasting for healing or go for prayers in a believe that they will get cure from it after they drop out of care. Regardless of what they think these patients do, all participants agreed that patients who drop out of pre-ART care usually suffer from frequent illnesses while the ones that adhere to follow up live relatively normal life.

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<sup>3</sup> A bread used as a main food in Ethiopia

### **Chances of drop-out patients returning to follow up**

All participants agreed that there is a possibility for the patients that discontinued care to return if they are traced and contacted by health workers. One participant shared her own experience of being lost from care once and how the community volunteers and health workers persuaded her to comeback: *"I had decided to die at home, but the volunteers shared so many experiences with me and they were persistent in advising me to get back to care, which made me to resume follow up"*. However, the respondents believe that there should be strong counseling provided at the initial stage and throughout the periods to ensure patients understand the consequences of stopping follow up.

### **Factors perceived to facilitate adherence**

Many participants reported some factors that helped them adhere to their medical follow up for HIV care. For some women who learned their HIV status through antenatal care and childbearing process, the possibility of having HIV free baby was mentioned as great motivation factor to adhere to follow ups. Other people mentioned a wish to live long and happy life for the sake of staying around for their children as a reason for their perseverance. Some also mentioned that seeing other people with HIV live longer and happier life was a motivation for them to stay in care and hope for better life.

Fear of illness or death was also seen as a motivator for some participants: *"I don't want to die yet, I have to stay healthy to stay alive"*.

### **What should be done to promote retention?**

Most participants suggested that focus should be given for more counseling and health education to create awareness about importance of adherence to pre ART Care in order to avoid misconception. All of them also added that government should support HIV positive people financially and assist them in finding jobs and other income generating activities: *"Since we are all poor and we spend a lot of time in health facilities, we need to be supported"*.

A good number of participants also suggested that special focus should be given to strengthen the role of community volunteers and support groups as they believe them to be very important in identifying lost patients, linking with health facilities and forming peer support networks and activities.

#### **4.7. CONCLUSION**

This chapter discussed the analysis and interpretation of both quantitative and qualitative data. The analysis for the quantitative data was conducted using computer software SPSS and results were presented according to the chart review checklists and FGD guide.

The findings highlighted that large percentage of patients in pre-ART period will be lost to follow-up, especially during the first 3-6 months of enrolment to the program. Common factors associated with LTFU are religion, having or not having child, unmet expectation of patients from the pre-ART service, travel cost, long distance, stigma and poverty are key factors that greatly contribute to patients' LTFU.

## **CHAPTER 5**

### **CONCLUSION AND RECOMMENDATION**

#### **5.1. INTRODUCTION**

This chapter presents conclusions on the research findings and recommendations drawn. The major contribution of this study and limitations are also highlighted. The study findings in line

#### **5.2. RESEARCH DESIGN AND METHOD**

A cross-sectional research design with a mix of quantitative and qualitative data collection methods will be used to examine the level of adherence to pre ART care among adult HIV positive patients and the various factors associated with patients lost to follow up.

Quantitative data was collected through chart review of pre ART patients enrolled to HIV care in St. Luke hospital between January 2009 and December 2010. Qualitative data was obtained from three focus group discussions held with pre ART patients. In addition national policy documents were reviewed and analyzed.

#### **5.3. SUMMARY AND INTERPRETATION OF THE RESEARCH FINDINGS**

The findings from the study are presented below according to the research objectives which were to:

- Determine the level of adherence by adult patients to pre ART program in St. Luke Catholic Hospital
- Identify factors (socio-economic, cultural and disease -related) contributing to non-adherence/adherence among Pre-ART adult patients

- Assess the type of services that are provided at pre-ART programs and determine the system that guides the service delivery

### **5.3.1. Level of adherence by adult patients to pre ART program in St. Luke Catholic Hospital**

The findings from this study conducted in a routine rural hospital HIV care clinic in Ethiopia indicate that only about one third (38.2%) of HIV-infected patients enrolled to HIV care and not yet eligible for ART are retained care after 12 months. This research study report an overall dropout rate of 61.8%.

Although different definitions of LTFU were used in various previous researches that studied pre-ART LTFU in SSA, the rate found in this study is similar with similar studies that found up to 74% of pre ART LTFU ( Bassett et al. 2009:3).

However, this rate of loss to follow-up may not indicate that a patient has dropped out of care permanently. Some patients may have returned to the same site after the data for the study were censored or the study's definition of loss to care reached. Many patients may have simply transferred, usually without the knowledge of health workers. Tracing such transfer-in and transfer-outs in a setting like Ethiopia where unique patient identifiers are not regularly used to track patients is difficult. Moreover, the guideline to define LTFU is not clear thus the data collection system is inaccurate or mostly does not exist. Further studies are required to determine the outcome of patients who are LTFU.

It is possible that many of the patients who dropped-out of pre-ART care will return to the health-care system at some later date, most likely once they become seriously ill. Without an effective health information system that allows patients to be tracked from site-to-site and over time, as they come and go from care, it is impossible to assess the extent to which patients are cared for through referral structures.



In view of the fact that literature suggests high rates of early mortality after ART initiation in Africa (Lawn et al. 2008, Bassett et al. 2010), it is plausible that recently diagnosed HIV-infected clients register for care and dropout while they are still healthy, only to present later with advanced HIV disease necessitating immediate ART initiation. In fact a significant number of them die at home not captured by the healthcare system. In both cases, a patient will have continued to transmit HIV virus to loved ones or any other sexual contact during the time he/she has been lost-to-follow up.

The Ethiopian Health Sector Development Plan IV developed for the period of 2010/2011-2014/2015 has put an ambitious target to increase number of patients ever started on ART from 216,724 to 484,966 and increase Proportion of patients who are currently on ART from 70% to 90 % (MOH 2010:44). The low rate of retention observed at the very beginning of the HIV care program however does not promise well for achieving the country's stated goal. In order to achieve this goal, it is important to increase the number of patients that enter in to the HIV care and ensure they are retained in care starting from the early stages and throughout. Pre-ART care ensures start-up of patients on ART as early as possible through monitoring disease progression, structured treatment preparation and counseling.

While pre-ART loss to care may not pose as immediate mortality threat as loss of patients who already have clinical AIDS, it is still a major impediment to improving the outcomes of HIV care and HIV prevention (Rosen & Fox 2011:8). Focusing on patient retention in care both before and after ART initiation is important not only to prevent HIV related mortality and morbidities, but also as a means of reducing ongoing transmissions which will reduce the number of new infections. Patients who drop out of care at this stage usually either come back after the disease has advanced as late presenters or die even before that. Pre ART care is thus an essential link in the chain that connects HIV positive patients to the desired lifelong treatment.

However, the result from this study shows that this link is broken or functioning well. It is important to invest on pre ART care in order to maintain this chain intact and achieve increased access to treatment for patients living with HIV in Ethiopia.

### **5.3.2. Factors (socio-economic, cultural and disease -related) contributing to non-adherence/adherence among Pre-ART adult patients**

Religion and having child independently predicted pre ART LTFU. From the qualitative data analysis, fear of being identified as HIV positive, transportation cost and not trusting the pre ART service were identified as main causes for patients drop out from pre ART care.

Compared to Christians, patients who are Muslims had three times higher loss to follow up rates. There are no similar reports as to why religion could be a factor for patient drop out from care; however this could be due to certain religious practices in the Muslim religion that might negatively affect strict adherence to HIV care possibly through stigma and discrimination. Further study is required to investigate these specific factors in Ethiopian context.

Patients who didn't have children were more likely to be loss to follow up than those who had children. This may be because having children is a motivating factor for parents to want to live longer and be able to provide care for their children. This finding is supported by the FGD findings as some of the participants identified having children as a factor facilitating adherence. People who do not have children on the other hand, do not have parental commitments and thus a drive for living for a child and thus more likely to be affected negatively by HIV related stigma. It is also likely that this group may be single and young which has been found to be a risk factor for LTFU (Karcher et al. 2007, Ochieng-Ooko et al 2010)

This study also found that patients who did not use family planning had greatest odds of being loss to follow up compared to those who reported to be family planning users. A plausible explanation for this could be that patients who used family planning are much more familiar with health care set up and received counseling at each visit which will result in a patient being more informed about her follow up and importance of

adherence compared to the ones who do not use family planning. Services other than direct HIV care could be a means for engaging patients in their health care services and provide them with more extended package of services which will contribute to their treatment outcomes directly or indirectly.

Stigma has been mentioned to be the reason for dropping out of pre ART care by most of FGD participants. This finding is consistent with other studies that identified HIV related stigmas to be an important barrier to adherence and retention in care (Merten et al. 2010). HIV positive patients drop out of care because they do not want to be seen in the HIV clinic and risk chance of being seen by someone they know. Stigma and discrimination shows in a different forms and could cost their social interaction, business opportunities and their chance of living in harmony with people in their surroundings. According to some FGD participants, people do not disclose their status even to their close family members (including spouse and children) which forces them to stop from going to health facility in order to keep the secret.

Even though the government is intensively working on social mobilizations and community conversations that are aimed at increasing awareness and prevent stigma and discrimination against PLHIV, the findings from the three FGD sessions show that it still has great impact on patient retention in HIV care.

Cost of transportation to and from health facility during follow up visits was also identified as important factor associated with LTFU. Although HIV treatment is freely available to all in Ethiopia, all FGD participants mentioned that the cost of transportation during each visit is hindering some of them from attending their care regularly. Other related studies in Africa also found similar results indicating cost of transport to be major barriers to access and remain in HIV care (Amuron et al. 2009, Maskew et al. 2007) Inability to afford transportation costs is associated with the fact that most patients are unemployed. Unemployment and other economic related problems mean that many PLHIV in this study have no sustainable source of income, and are therefore unable to meet basic daily requirements, or to get the services they need to cope with their treatment (e.g. transportation, availability of adequate nutrition). A number of FGD

participants indicated that employers are not interested in hiring known HIV positive persons because their infection reportedly prevents patients from earning a living, forces resignation or limits career options.

Another important factor mentioned to be a reason for high rates of LTFU is the fact that some people do not trust the pre ART service and do not believe it is necessary. Most patients enrolled at pre-ART are asymptomatic and may not perceive themselves as requiring medical care. Since very little therapeutic care is offered during the pre-ART period, patients must take it on faith that making the effort to come to the clinic for monitoring is worth the costs of doing so (Rosen & Fox 2011). One female FGD participant said; *“I don’t see the reason for coming every month while I am told I am doing well and not yet ready for treatment.”*

Participants also mentioned that most people who drop out of the pre ART care sometimes do it with intention of coming when they are “properly eligible” for ARV treatment. Because the pre ART care package is not standardized and not clearly engaging patients in a regular basis, the period is confusing both for health care providers and the patients. Literatures on pre ART mention that lack of comprehensive pre ART care services, limited pre ART care package and lack of incentives for patients during pre ART are factors that contribute to such high pre ART attrition rates (Lessels et al 2009, Rosen & Fox 2011; Zewdie et al 2010).

A structured framework of counseling and support at both testing and registration into HIV care that has been applied in ART programs with relative success to enhance retention and ART adherence in different settings could be applied in the pre-ART care package (Etienne et al. 2010). Patient tracking mechanisms such as tracing LTFU using community volunteers, organizing patients in to various support groups and use of structured patient preparations systems proved to be effective for patients on ART could be adopted for pre-ART clients.

In addition, pre-ART care service packages may include nutritional support in the form of food programs, provision of multivitamins, prophylactic anthelmintics, isoniazid

preventive therapy (IPT) and engaging patients in various social networking activities such as support groups. Economic support and job creations could be included in the latter activity. These interventions may serve as an incentive for follow up and compensate for indirect costs incurred to attend care for those coming from far. An improved pre-ART package of care will not only serve to enhance retention, but also slow disease progression, enable timely initiation on ART for those eligible, reduce early mortality and prolong overall survival. Indeed, cotrimoxazole, which is one of the pre-ART services currently offered in Ethiopian setting, has been shown to reduce morbidity and slow HIV disease progression substantially (Anglaret et al. 1999). Intervention studies on anthelmintics and IPT have also shown that these cheap and readily available interventions administered in pre-ART patients have the potential to slow HIV disease progression by reducing tuberculosis incidence, lowering viral load and increasing CD4 count (Walson et al. 2008; Grant et al. 2005 ).

### **5.3.3. Type of services that are provided at pre-ART programs and determine the system that guides the service delivery**

The services provided to pre ART patients included laboratory testing for CD4 count, and other haematological tests, physical examinations and prophylaxis, diagnosis and treatment of opportunistic infections. In addition, counseling on topics ranging from positive living, nutrition, adherence and medication follow up is part of the services. Appointment schedules varied from patient to patient who reported to have varying periods from monthly to biannual appointment intervals. A reason for varied appointment patterns are not fixed and depend on each assessing clinician's decision. The Ethiopian Government has developed considerable policies and guidelines to effectively respond to the HIV pandemic. The guidelines prepared to manage the various aspects of HIV care (PMTCT, VCT, ART etc.) are encouraging and provide valuable guidance. However, these guidelines are not comprehensive enough to address the crucial aspect of HIV care; the pre ART period. All of these guidelines focus on the detail management of patients on ART and the pre ART period as well as what it

involves is not well defined and care and support for these patients are not clearly stated.

In general, the various guidelines provide detail description and scope for their specific topic area, but the pre ART period seem to be a portion of this continuum of care that has been neglected. Policy makers have overlooked the fact that the Pre ART period by itself has its own dynamics and needs structured service delivery. Also the fact that large proportion of patients testing positive are meant to stay in the pre ART period seems to be less acknowledged.

#### **5.4. CONCLUSION**

The study revealed the alarmingly high lost to follow up rates among pre ART patients in Ethiopia and the need for directing focus on patients newly diagnosed and enrolled to care. The national goal to accelerate universal access to treatment highly depends on how efficiently retained new patients are even when they are not yet eligible for ART.

Secondly, the study showed the lack of standard definition of terminologies in pre ART. The term loss to follow up is widely used for patients on ART and pre ART loss to follow (Bassett et al. 2009) up is perceived differently in different settings. Moreover, there are no health information systems that allow pre ART patients to be tracked between service delivery points resulting in loss to follow ups going unnoticed. Loss to follow up in pre ART is not recorded in routine HIV log books nor is reported to authorities. In order to improve pre ART care, it is vital to implement effective patient tracking systems that will generate accurate information on attrition in pre ART and identify characteristics of patients most likely to be lost.

The third point that came to light in this study is the need for policies and guidelines to ensure more standardized pre ART care package is available so that HIV patients are cared for and retained through this crucial period of HIV care and are successfully put on treatment afterwards.

Finally the research highlighted some socio-demographic and service factors associated with patient loss to follow up from pre ART care. Focused attention should be given to patients that are more prone to HIV-related stigmas and it is important to increase patients' engagement in care through different service outlets.

If the target set to achieve universal access to HIV/AIDS treatment is to be achieved, government and implementing organizations need to invest in developing the pre ART care and standardize services. Patient care should be viewed from its comprehensive perspective that encompasses all periods starting from enrollment. Policies and guidelines that address pre ART period and health care workers and facilities need to be equipped with necessary tools to care for patients not eligible for ART.

## **5.5. RECOMMENDATIONS**

The various individual, provider, health system, environmental, and other barriers to retention identified in this study, including those factors that influence health care-seeking decision-making, and the weak links between diagnosis and care enrolment needs to be addressed to facilitate engagement in care. Some of the recommendations based on the findings are summarized as follows:

- Defining and developing interventions that improve retention in the pre-ART period and providing a 'pre-ART package of prevention and care'. A beneficial package of care, support and prevention for people with HIV in the pre-ART stage would support people to remain engaged in care throughout this period and facilitate timely assessment of ART eligibility and commencement of treatment.
- Decentralization and integration of HIV services through robust systems to improve linkages and retention along the continuum of care.
- Greater involvement of people with HIV is important so that they feel engaged and empowered in decisions about their care and that their real needs are being taken into consideration.
- Develop and maintain community systems and engage lay and peer workers to support retention in care and decrease stigma and discrimination. In addition,

appropriate and context-specific engagement with other community support structures (e.g. spiritual leaders, traditional healers, community leaders, women's groups, CBOs etc.) should be explored and supported as a tool for fighting stigma and widening patient support base.

- Evaluation of strategies such as implementation of longer drug refill periods and task shifting to trained lay care providers for stable patients or refunding transportation costs is needed to ensure cost of transportation is not a barrier to access health care service.
- Increase the CD4 count level eligibility criteria to initiate ART from the current level of 250 to 350 as per the WHO recommendation (WHO 2009) in order to reduce long waiting time for ART initiation thus risking high rate of LTFU during pre-ART period.
- Strengthen patient education and counseling to reduce stigma and anxiety about ART side effects or fear of inadvertent disclosure once on ART
- Develop effective pre ART monitoring systems with clear definitions and unique patient identifiers to facilitate monitoring and reporting of pre ART care retention and loss to follow up
- Use communication technologies (e.g. SMS messaging, phone calls) and more efficient patient tracking strategies that are relevant in Ethiopian contexts.

## **5.6. CONTRIBUTIONS OF THE STUDY**

This study sheds more light on the burden of pre-ART drop out and identifies risk factors for potential interventions. Given that there are only limited studies conducted to assess pre ART care services and the rate of LTFU globally and almost no studies exist in Ethiopia, this research will be a valuable resource in the HIV care. The findings of this study will be used to inform policy makers and health care providers about pre ART care and the extent of the attrition.

In general, the research will be an important contribution for public health in general and HIV care and treatment services in particular. In addition, the researcher believes that the findings from this study will inspire other researchers who might be interested to further study the various aspects of pre ART care.



## **5.7. LIMITATIONS OF THE STUDY**

This study had several limitations. Firstly, it was conducted at only one facility in Ethiopia and it is possible that experience might be different at other sites. Secondly, different definitions have been used to assess drop out in different studies. Although the researcher used an operational definition for pre ART LTFU, the definition was drawn from ART LTFU definition and applying the definition on a pre-ART may not be appropriate as the two periods vary in many ways. Lastly, quantitative data for this study was collected from patient chart and variables had to be limited to what and how the data has been captured in the chart.

None of these limitations however is sufficient to alter the core finding of this study, which is that more than 60% of patients are lost from pre-ART care and that the system for pre ART care provision is weak and unstructured. Despite these limitations, this study has several methodological strengths. Qualitative and quantitative data sources were used to triangulate the information and obtain a more reliable data set. In addition, FGD were conducted by trained moderator and note takers who were bilingual in English and Afan Oromo, ensuring clear communication.

## **5.8. CONCLUDING REMARKS**

In conclusion, HIV care services in Ethiopia heavily focus on care of patients on ART. Pre ART period is not very well understood and structures that allow proper interventions during this period are not in place. Even though loss to follow up from pre ART care is not well defined, it is found to be extremely high.

The findings call for consideration of a better pre-ART care package aimed at improving retention in care. Improved retention has the potential to prevent HIV transmission, slow HIV disease progression, enable timely initiation of ART, reduce early mortality after starting ART and prolong overall survival. Hence, an improved pre-ART care package especially targeted at those who are more at risk of dropping out of care may be both beneficial and cost effective in the long term.

This study has generated a finding that could be used as a starting point for understanding the nature and scope of the problem of pre-ART loss to care. Further researches are needed to answer questions that are not addressed in this study.

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## **Annex 1: Chart review Checklist**

### **1. Client socio demographic data**

1.1. Age in completed years\_\_\_\_\_

1.2. Sex

\_\_\_ Female (1.2.1)

\_\_\_ Male (1.2.2)

1.3. The highest level of education attended

\_\_\_ No education (1.3.1)

\_\_\_ Primary (1.3.2)

\_\_\_ Secondary (1.3.3)

\_\_\_ Tertiary (1.3.4)

1.4. Religion

\_\_\_ Protestant Christian (1.4.1)

\_\_\_ Muslim (1.4.2)

\_\_\_ Orthodox Christian (1.4.3)

\_\_\_ Catholic Christian (1.4.4)

\_\_\_ Other (1.4.5)

1.5. Current Marital stats

\_\_\_ Never Married (1.5.1)

\_\_\_ Married (1.5.2)

\_\_\_ Divorced (1.5.3)

\_\_\_ Separated (1.5.4)

\_\_\_ Widow/Widower (1.5.5)



1.6. Ethnicity:

Oromo (1.6.1)

Gurage(1.6.2)

Amhara (1.6.3)

Tigre (1.6.4)

Other (1.6.5) (describe \_\_\_\_\_)

1.7. Usual residential location \_\_\_\_\_

1.8. occupation

salaried (public or private) (1.8.1)

self-employed (1.8.2)

unemployed (1.8.3)

Student (1.8.4)

other (1.8.5) \_\_\_\_\_

**2. Client's clinical, biological information up on enrollment**

2.1. Registration date \_\_\_\_\_

2.2. WHO stage on enrolment \_\_\_\_\_

2.3. CD4 count on enrollment \_\_\_\_\_

2.4. Viral load \_\_\_\_\_

**3. Follow-up data**

3.1. CD4

Yes (3.1.1)

No (3.1.2)

3.2. Viral load

Yes (3.2.1)

No (3.2.2)

3.3. Diagnosis of OI and treatments

\_\_\_ Yes (3.3.1)

\_\_\_ No (3.3.2)

3.4. Prophylaxis (IPT, co-trimoxazole)

\_\_\_ Yes (3.4.1)

\_\_\_ No (3.4.2)

3.5. Weight measurement

\_\_\_ Yes (3.5.1)

\_\_\_ No (3.5.2)

3.6. Blood count

\_\_\_ Yes (3.6.1)

\_\_\_ No (3.6.2)

3.7. last scheduled appointment date \_\_\_\_\_

3.8. date last attended follow up \_\_\_\_\_

3.9. Patient current status

\_\_\_ On ART (3.9.1)

\_\_\_ In-care (3.9.2)

\_\_\_ Eligible but not started (3.9.3)

3.10. If lost or drop out, what are the known reasons? \_\_\_\_\_

4. Follow up variables through time line

variables	@6 month	@12 month
CD4		
Viral load		
OIs		
wt		
Missed appointment		
Status		

## Annex 2: FGD Participants' Basic Information

FGD Session Code \_\_\_\_\_ Moderator \_\_\_\_\_ rapporteur \_\_\_\_\_

### Area Identifier:

Tape Code # \_\_\_\_\_ (transfer the tape label (code) onto this form.)

Date,

Time:

Place:

Participant's code	Q1 Sex	Q2 Age	Q3 Education	Q4 Occupation
	Female (1.1) Male (1.2)	18 to 27 years (2.1) 28 to 37 years (2.2) 38 to 47 years (2.3) 48 to 57 years (2.4) 58 to 67 years (2.5) 68 and above (2.6)	No education (3.1) Primary (3.2) Secondary (3.3) Tertiary (3.4)	Employed (4.1) Self employed (4.2) unemployed (4.3) Student (4.4) other (4.5)
P1				
P2				
P3				
P4				
P5				
P6				
P7				
P8				
P9				
P10				

### **Annex 3: Focus group discussion (FGD) guide**

#### Introductions:

1. Thank participants for their willingness to participate on the FGD
2. Introduce facilitators, reporters and explain their role
3. Describe the detail of FGD using the following information:

This focus group discussion is conducted to collect data for a research we are conducting to describe the type and organization of pre ART care and determine factors associated with LTFU from care among patients enrolled to pre ART program in Ethiopia.

The information you provide will be used to assess PLHIVs opinions about pre ART care and barriers to adherence. The final results will be shared with representatives of St. Luke hospital and South West Shoa zone health office, and concerned community groups to help improve for patients during pre ART period.

During a focus group discussion, you are allowed to talk freely and spontaneously everything you know about issues that your facilitator will raise concerning pre ART care. We will tape the session and make a written copy for further analysis. The focus group session will last approximately 1.5 hours. As every one's ideas are highly valid, you are kindly asked to actively participate, listen to each other, and respect each other's opinion. It is not allowed to criticize others' idea during the FGD and even outside.

The information collected will remain confidential. This means that your identity as a participant and the information that you will provide will not be revealed to people other than the facilitators. We are not taking your name and address during the discussion. All research material will be submitted to UNISA for official documentation purpose. All audio recordings will be erased upon completing the study.

We do not anticipate that participation in this study will pose physical or psychological risks beyond what you encounter in everyday life. However, Participation in this study is voluntary and if you are uncomfortable answering a particular question, you are free to refuse to answer the question, and you are free to quit the study at any time. If you have concerns you may ask the facilitators at any time of this discussion.

Topic/Focus	Core Questions
Experience with pre-ART	<ul style="list-style-type: none"> <li>• How do people get enrolled into the pre-ART? (Probe on: From whom/where people get the information about the program? Where do people usually seek (care) the first time they know they are HIV positive? How do people decide to be enrolled in the pre-ART? Who assist in their decision?)</li> <li>• How do people like you describe their experience of the pre-ART? (Probe on: type of services, for how long, follow-up period, counseling, its benefits, etc.)</li> <li>• Do people on care inform their families about them being on the pre-ART program? Why and why not? What support is available in the community, in the family, in the workplace? (Probe on: care and support services, discrimination, and stigma.) How do you think you are being treated (handled) by the health workers while on pre-ART? (Probe on: in relation to privacy, confidentiality, respect, being listened to, time spent with patient, waiting time, integration with other services, etc.)</li> <li>• What does the counseling provided as part of the pre-ART follow up in St. Luke hospital look like? Are there PLHIV that were on pre-ART but later on declined to start on ART despite being advised by health workers to start on ART? (Probe on: Why did they decline? Economic problem, stigma, fear of side effect, etc? Probe on: for personal experience, holy water as an option for this?)</li> </ul>
Reasons for discontinuation	<ul style="list-style-type: none"> <li>• Why do people like you discontinue follow up? What do they do after discontinuation? (Probe on: treatment options.)</li> <li>• How does health situation of people who discontinue care compared before and after discontinuation? Do these people want to restart on the program? What needs to happen for these people to restart? What do you think could be done to help people like you to continuously follow their appointments?</li> </ul>
Individual and social influences/barriers	<ul style="list-style-type: none"> <li>• Do people enrolled in HIV care clinic face any socioeconomic and other problems because of their medical condition? (Probe on: poverty, hunger, transport problems, lack of support, etc.)</li> <li>• How does the community view people who are HIV positive? (Probe on: stigma, discrimination, supportive attitude, negative attitude, etc.)</li> </ul>
Opinion on the pre-ART program activities in St. Luke hospital	<ul style="list-style-type: none"> <li>• How do you assess the effectiveness of the pre-ART program in transferring ART eligible patients to the service? (Probe on: patient volume, follow-up activities, patient handling practices, whether there is a delay between eligibility and actual initiation of ART, counseling efforts to encourage ART use, etc.)</li> <li>• What should be done to ensure that those PLHIV on pre-ART are retained on Care and successfully transferred to the ART service when eligible for treatment?</li> </ul>

### Conclusion remark

Thank you very much for your cooperation and input. Your information has been very useful. Please contact W/t. Emebet for your transportation cost reimbursement.

#### **Annex 4: CONSENT FORM (Focus Group Discussion)**

My name is Zinash Dewo and I am student at the University of South Africa (UNISA). I am doing a research on Pre ART care as partial fulfillment of master's degree in public health. You have been selected to participate in this study to be conducted at St. Luke hospital.

The purpose of the study is to describe the type and organization of pre ART care and determine factors associated with LTFU from care among patients enrolled to pre ART program in Ethiopia allowing the government and other actors, increase uptake of pre-ART services in the facilities. In addition, the study results will further reveal PLHIVs opinions about pre ART care and barriers to adherence. The final results will be shared with representatives of St. Luke hospital and South West Shoa zone health office, and concerned community groups to help improve for patients during pre ART period.

If you decide to participate in this study, you will join other participants of a similar background in a discussion led by a facilitator. During a focus group discussion, you are allowed to talk freely and spontaneously everything you know about issues that your facilitator will raise concerning pre ART care. We will tape the session and make a written copy for further analysis. The facilitator's questions will relate to your opinions about pre ART service and barriers faced by people living with HIV in adhering to care services that you may know of. The focus group session will last approximately 1.5 hours.

The information collected will remain confidential. This means that your identity as a participant and the information that you will provide will not be revealed to people other than the facilitators. We are not taking your name and address during the discussion. All research material will be submitted to UNISA for official documentation purpose. All audio recordings will be erased upon completing the study.

We do not anticipate that participation in this study will pose physical or psychological risks beyond what you encounter in everyday life. However, Participation in this study is voluntary and if you are uncomfortable answering a particular question, you are free to refuse to answer the question, and you are free to quit the study at any time.

You will not receive any payment to participate in the focus group discussion. However, you will be given 100 Eth. Birr as a reimbursement for expenses incurred as a result of participation, including travel and time lost.

If you have concerns about this study or would like to receive a copy of the study's results, please contact Zinash Dewo at 0911803439.

Your signature below shows that you understand the above statement and willingly agree to participate in this focus group discussion.

This consent form has been read and explained to me. I voluntarily consent to participate in this study:

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

I have explained the study for the above subject and I have sought his/her understanding for informed consent

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## **Annex 5: Translated consent form**

### Waraqaa Eeyyamaa

Koodii:

Maqaankoo Zinnaash Dawoo jedhama, University South Afrikaa (UNISA) jedhamutti barattuu fayyaa hawaasaati. Barumsakoo xumuruufis qorannoo hojjechuun waan narraa eegamuuf, qorannoo tajaajila fayyaa yeroo qorich HIV otoo hinjalqabiin(pre ART) hospitaala St. Luke keessatti kennamurratti hojechaan jira.

Kaayyoon qorannoo kanaa akaakuufii akkaataa tajaajila fayyaa yaalamtoota qoricha HIV hinjalqabneef kennamu ballinaan qorachuufii sababoota Ethiopia keessatti yaalii addaan kutuu faana walqabatan adda baasanii baruudha. Beekkumsi qorannoo kana irraa argamus mootummaan Ethiopia fii dhaabbileen adda addaa tajaajila HIV/AIDS irratti kennamu akka ballisaniif isaan gargaara. Dabalataanis, namoonni HIVn dhiiga isaanii keessatti argamu tajaajila fayyaa fii hordoffii fayyaa ilaalchisee yaada isaan qaban akka ibsan ni gargaara. Bu'aan qorannoo kanaa hoggantoota hospitaal St. Luke, biiroo eegumsa fayyaa naannoo kibba lixa shawaa fii dhaabbile hawaasaa adda adda kan dhimmisaa isaan ilaalu hundaafuu ni kennama. Isaanis taajjila fayyaa ittiin fooyyesuuf itti fayyadamu.

Yoo marii kana irratti qooda fudhachuuf murteessite, namoota akka kee fii gaggeessitoota faana yaada ballinsaan waljijjiruu irratti hirmaatta. Yeroo marii kana, gaaffilee gaggeessituun marii kanaa kaasuu irratti hundoofttee yaada keef tajaajila fayyaa yaroo pre-ART wanta beektu mara bilisaan akka ibsitu siif hayyamama.

Yaadota marii kana irratti ka'an mara sirriitti qabachuuf akka nutti toluuf, mariisaa teeppiidhaan niwaraabna. Gaaffiin gaggeessitootaan ka'u tajaajila yeroo pre-ART fii rakkolee namoonni tajaajila kana argachaa jiran hordoffii yaalii ilalchisee quunnaman kan ilaaludha. Mariin kun tilmaamaan sa'aatii tokkoof wallakaa fudhata.

Odeeffannoon marii kanarraa guurramu marti iccitii ta'a. Kana jechuunis, odeeffannoon ati nuuf kennitu namoota qorannoo kana gaggeessaniin ala nama biraatiif dabarsamee hinkennamu. Marii kana irratti maqaa kee hin galmeessinu. Odeeffannoon martiyyuu University south Afrikaatti akka keewwamu ni ergama. Teeppiin waraabbame marti yeroo odeeffannoosaa irraa fudhanne ni balleessama.

Marii kana irratti hirmaachuukeetiif dhiibbaan qaamaas ta'e kan sammuu kan sirra gahu hinjiru. Haata'u malee, marii kana irraatti hirmaachuun feedhii bilisaa irratti kan hundaahedha. Gaffileewwan ka'an deebisuuf yoo fedhii dhabde, deebisuu baachuu nidandeessa. Marii kana yeroo feetee addan kuttee deemuus ni dandeessa.



Marii kanarraatti hirmaachuukeetiif kanfaltii homaayyuu hin argattu. Garuu, baasii geejjibaa fii tilmaama yeroo kee deebisuuf qarshii 100 siif kennina.

Marii kana ilaalchisee gaaffii yoo qabaatte, lakkoofsa bilbilaa 0911803439 irratti Zinnaash Dawoo jedhaa gaafadhaa.

Yoo kaayyoo qorannoo kanaa sirritti siif galeefii marii kanarratti hirmaachuuf bilisaan fedhii yoo qabaattee sarara kana gadii irratti mallatteessi.

Waraqaan eeyyamaa kun naaf dubbifamee kaayyoosaa irrattis ibsi naaf godhameera. Feedhii mataakootiin marii kana irratti hirmaachuuf nan fedha.

Mallattoo: \_\_\_\_\_ Guyyaa: \_\_\_\_\_

Waa'ee qorrannaa kanaa sirritti ibsa keennee, waligaltee isaaniifii eeyyama isaanii fudhadheera.

Mallattoo: \_\_\_\_\_ Guyyaa: \_\_\_\_\_

## Annex 6: Annex 10: Facility permission request letter

Date: \_\_\_\_\_

To: St. Luke Catholic Hospital and College of Nursing and Midwifery  
Wolisso,  
Ethiopia

Re: **Permission request to conduct research**

Dear Sir/Madam,

My name is Zinash Dewo and I am student at the University of South Africa (UNISA). I am doing a research on Pre ART care as partial fulfillment of master's degree in public health.

The purpose of the study is to describe the type and organization of pre ART care and determine factors associated with LTFU from care among patients enrolled to pre ART program in Ethiopia allowing the government and other actors, increase uptake of pre-ART services in the facilities. In addition, the study results will further reveal PLHIVs opinions about pre ART care and barriers to adherence. The final results will be shared with St. Luke hospital, South West Shoa zone health office, and concerned community groups to help improve for patients during pre ART period.

Data for this study will be collected through chart review and focus group discussion. The information collected will remain confidential and will be used for this research purpose only. In addition, there are no anticipated physical or psychological risks to the participants as a result of the study.

This is thus to kindly request your office grant me permission to conduct this study and access the patient data. Please refer to attached proposal document for detail information about the research design.

If you have any questions, I can be reached at 0911803439 or through my email [zinu22@yahoo.com](mailto:zinu22@yahoo.com).

With Regards

Zinash Dewo

## Annex 7: Ethical Clearance; Facility



ቅዱስ ሊቃስ የካቶሊክ ሆስፒታልና የነርሶች ኮሌጅ  
Qidoos Luuqaas Hospitaalaa Kaatoliki fi Kooleeji Narsootaf  
St. Luke Catholic Hospital and College of Nursing

Date April 14, 2012

Zinash Dewo Robi  
Addis Ababa, Ethiopia

Dear Zinash,

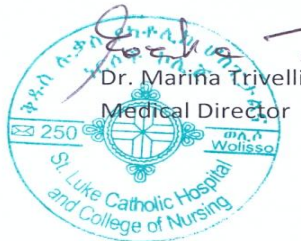
Thank you for your application seeking approval to conduct research titled “Pre-ART services in rural Ethiopia: Patient retention and factors associated with loss to follow up” in St. Luke Catholic hospital HIV unit. I wish to inform you that the hospital management after thoughtful consideration has approved your request to conduct research and access the patient data.

This approval means that you can access the patient records for pre ART patients enrolled during the time period you proposed in your application and approach the HIV care providers and data clerks for any further service provision related inquiries.

At the conclusion of your study, you are required to provide a summary of your research results and any published paper resulting from this study in line with your University regulations.

Should you require further assistance on the course of your research, do not hesitate to contact us.

Yours Sincerely



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ግዳታ ዳይሬክተር  
Dr. MARINA TRIVELLI  
Medical Director

Owned by Ethiopian Catholic Church

Tel. +251-11-341 0714 / 341 0800  
Fax +251-11-341 0150

P.O.Box 250 and 246  
WOLISSO

**Annex 8: Ethical Approval; UNISA**



**UNIVERSITY OF SOUTH AFRICA  
Health Studies Higher Degrees Committee  
College of Human Sciences  
ETHICAL CLEARANCE CERTIFICATE**

**HSHDC/25/2012**

Date of meeting: 14 March 2012 Student No: 4507-923-4  
Project Title: Pre-ART services in rural Ethiopia: Patient retention and factors associated with loss to follow up.  
Researcher: Zinash Dewo Robi  
Degree: Masters in Public Health Code: DIS4986  
Supervisor: Dr N Taffa  
Qualification: PhD  
Joint Supervisor: -

**DECISION OF COMMITTEE**

Approved

Conditionally Approved

*E Potgieter*  
**Prof E Potgieter**

**CHAIRPERSON: HEALTH STUDIES HIGHER DEGREES COMMITTEE**

*MM Moleki*  
**Dr MM Moleki**

**ACTING ACADEMIC CHAIRPERSON: DEPARTMENT OF HEALTH STUDIES**

PLEASE QUOTE THE PROJECT NUMBER IN ALL ENQUIRES