

**FACTORS THAT INFLUENCE ADHERENCE TO  
ANTIRETROVIRAL THERAPY AMONG ADULTS AT NEKEMTE  
REFERRAL HOSPITAL IN ETHIOPIA**

by

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## DECLARATION

I declare that **FACTORS THAT INFLUENCE ADHERENCE TO ANTIRETROVIRAL THERAPY AMONG ADULTS AT NEKEMTE REFERRAL HOSPITAL IN ETHIOPIA** 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 and that this work has not been submitted before for any other degree at any other institution.



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25 July 2012  
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# FACTORS THAT INFLUENCE ADHERENCE TO ANTIRETROVIRAL THERAPY AMONG ADULTS AT NEKEMTE REFERRAL HOSPITAL IN ETHIOPIA

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## Abstract

The objectives of the study were (1) to quantify adherence rate among the study participants in the ART unit and (2) to identify factors that contribute to non-adherence. This cross sectional study was carried out at Nekemete referral clinic. Data was collected using a self-developed structured questionnaire where a total of 338 participants grouped into adherent and non-adherent based on a score derived from an adherence assessment were interviewed. Data was analysed using the Statistical Package for Social Sciences (SPSS) version 17.0. By using multivariate analysis of variables identified as correlates of adherence, non-adherence was common among those; with age between 18-30 yrs, with no education, who were not married, who had no pipe water supply, those with no electricity in the house, who perceived had no access to assistance from providers, who perceived the health care providers (HCPs) did not keep information confidentially, who had a language barrier with providers, and who were treated with a psychiatric illness. The study concludes that adherence is multi-factorial and varies significantly by individual and care setting. Psychosocial factors were found to impact adherence and should be analysed in more detail by further studies. Three psychosocial factors were independently associated with poor adherence: the study found that patients perceiving poor access; those perceiving problems in information confidentiality (and possibly experiencing stigmatisation); and having psychiatric morbidity (and possibly with less social support) are more likely to be non-adherent. Furthermore, individuals without electricity and those without piped water supply, implying low income, are at risk for non-adherence.

**KEY CONCEPTS:** Adherence to antiretroviral therapy; antiretroviral drugs; CD4+ cell count; clinical response; cross-sectional study; drug resistance; antiretroviral therapy; immunologic response; multivariate analysis; virological response; viral suppression.

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## *Dedication*

*This work is dedicated to people living with  
HIV and those affected by it.*

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## List of abbreviations

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AIDS	Acquired Immuno-deficiency Syndrome
ANC	Antenatal Care
AOR	Adjusted odds ratio
ART	Antiretroviral Therapy
CD4	Cluster Differentiation T-lymphocyte
CI	Confidence Interval
COR	Crude odds ratio
CSA	Central Statistic Agency
EDHS	Ethiopian Demographic and Health Survey
GFATM	Global Fund to Fight AIDS, TB and Malaria
HAPCO	HIV/AIDS Prevention and Control Office
HCP	Health Care Provider
HIV	Human Immuno-deficiency Virus
HIV DR	HIV Drug Resistance
K	Sample Frame
MOH	Ministry of Health
N	Sample Size
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitors
NRTI	Nucleoside Reverse Transcriptase Inhibitors
NtRTI	Nucleotide Reverse Transcriptase Inhibitors
OI	Opportunistic Infections
OR	Odds Ratio
PEP	Post-Exposure Prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PI	Protease Inhibitors
PLWH	People Living with HIV
PITC	Provider Initiated Testing and Counselling
RLS	Resource Limited Settings
RRS	Resource Rich Settings
SPSS	Statistical Package for Social Sciences
SSA	Sub-Saharan Africa
TB	Tuberculosis
UNAIDS	United Nations Programme on HIV/AIDS
UNICEF	United Nations International Children's Emergency Fund
UNGASS	United Nations General Assembly Special Session
USA	United States of America
VCT	Voluntary Counselling and Testing
WHO	World Health Organization

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Annexure A Approval from UNISA

Annexure B Letter seeking consent from Nekemte Referral Hospital

Annexure C Letter of approval from Nekemte Referral Hospital

Annexure D Questionnaire

# CHAPTER 1

## ORIENTATION TO THE STUDY

### 1.1 INTRODUCTION

Patient adherence is a dynamic phenomenon broadly affected by patient, medications, disease, provider and systems factors. Poor adherence has been associated with a number of factors in the United States of America (USA) and western Europe, including treatment side-effects; complex regimens; lack of social support; mental illness; active substance use; stigma; low level of literacy; poverty issues (transportation problems, food insecurity), asymptomatic status of patient prior to initiation of treatment, poor understanding of regimen, inadequate pharmacy service and lack of confidence or trust in the health care service (Horizons ... 2004:18-19; Tusiime, Orelland & Bangsberg 2008:209; Rachlis, Mills & Cole 2011:8; Ingersoll & Cohen 2008:2; Federal HAPCO and Federal MOH 2007:75).

### 1.2 BACKGROUND INFORMATION

Ethiopia initiated a fee-based antiretroviral therapy (ART) programme in July 2003, and in January 2005, a free ART programme was launched and implemented across the country. ART services rapidly expanded over a few years. Facilities providing ART service have grown from three in 2004 to 481 in June 2009 (in 136 hospitals and 345 health centres) (HIV/AIDS Prevention and Control Office [HAPCO] 2008-2009:37). According to United Nations Programme of HIV/AIDS (UNAIDS) (2010:98), the adult treatment coverage need in Ethiopia, according to 2010 guideline, ranges from 52% to 65%. These figures illustrate the magnitude of the task to provide prevention, care and treatment and support services for all who need them and strongly indicate the need to come up with strategies to maximise long-term ART adherence to ensure success as Ethiopia scale up ART programmes countrywide.

It is clear that adherence to ART is a multidimensional phenomenon comprising multiple interrelated factors, and as such, requires a multidisciplinary approach

(El-Sadr, Affrunti, Gamble & Zerbe 2010:5-6; Horizons ... 2004:51). The lack of adherence to treatment is an interaction between the patient, the regimen, the providers of therapy, and the environment in which this occurs (Tusiime et al 2008:208). This interaction is the context in which adherence does or does not occur. The issue of adherence requires expertise, collaboration, and coordination of services within primary care, specialist care, social service settings and the broad multidisciplinary team (UNAIDS 2010:106).

Non-adherence to treatment regimens is not unique to people living with HIV (PLWH). From the literature, it is clear that non-adherence is ubiquitous. For example, adherence to anti-hypertension medication regimen varies between 26% and 51%. Data on patients with depression reveal that between 40% and 70% adhere to antidepressant therapies. In PLWH, reports of adherence range from 37% to 83% (World Health Organization [WHO] 2003:8).

In a cohort study adherence to protease inhibitor therapy of 95% or greater was required to optimise virological outcome for the human immunodeficiency virus (HIV) positive persons. Eighty per cent to 94,9% adherence has been associated with failure to achieve complete viral suppression in 61% of patients (Paterson, Swindells, Mohr, Brester, Vergis, Squier, Wagener & Singh 2000:22). Many of the barriers associated with non-adherence in resource-rich settings also apply to resource-limited settings. These include frequency of dosing, younger age, being single, depression, male gender, forgetfulness, being too busy or away from home, regimen complexity, psychosocial factors, intolerance, alcohol consumption and a lack of belief in efficacy of ART.

Nonetheless, there are many additional barriers that are unique to resource-limited settings such as the cost of medication, long distance to the treatment centres, stigma/fear of disclosure, medication stock outs, a lack of access and privacy, and language barrier between the patient and the provider (Tusiime et al 2008:209).

However, contrary to early concerns, adherence in developing countries has been found to be generally better than adherence in developed countries. Most studies done in resource-limited settings have found excellent rates of adherence with subsidised/free ART (adherence levels of greater than 90%) with the majority of them from SSA. While

this is largely unknown, it is clear that severe poverty does not preclude excellent adherence and there are several potential explanations for this. People in these settings start therapy at later stages of disease and may have more dramatic improvements in health and functional status with initiation of therapy and these likely reinforce early adherence. HIV positive parents who have lost spouses and other relatives because of acquired immunodeficiency syndrome (AIDS) may be caring for large numbers of dependent children, which has been described as a central motivation for adherence (Tusiime et al 2008:210).

### **1.3 RESEARCH PROBLEM**

Adherence is not well addressed as a central component at health facilities and patient levels in Ethiopia. A significant proportion of all hospital admissions are due to drug non-adherence. If adherence is low, treatment failure will occur and the likelihood of development of resistant virus is high.

### **1.4 RESEARCH PURPOSE**

The purpose of this study is to investigate the factors that influence adherence in terms of the magnitude of non-adherence and major factors contributing to non-adherence.

### **1.5 RESEARCH OBJECTIVES**

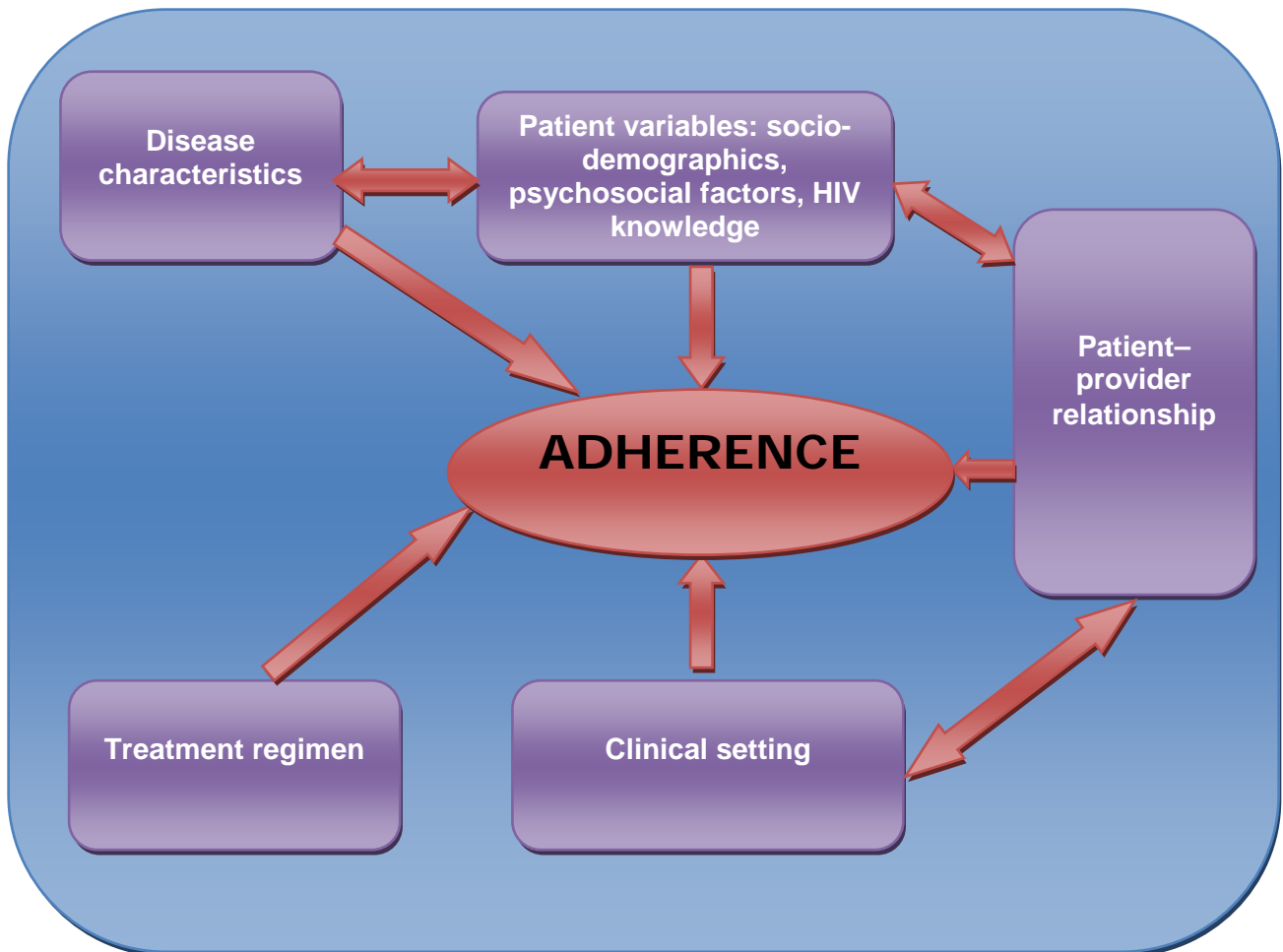
The objectives of the study are to

- quantify the adherence rate among the study participants in the ART unit
- identify factors that influence adherence

### **1.6 FOUNDATIONS OF THE STUDY**

The researcher has adapted the following framework to analyse determinants of adherence at an individual patient level for an ambulatory client who is living in the community.





**Figure 1.1 Conceptual map of factors that influence adherence**

(Adapted from Horizons ... 2004:18)

## 1.7 SIGNIFICANCE OF THE STUDY

Evidence related to adherence to ART in Ethiopia is scarce. Literature search by the researcher has shown that there are only a handful of studies conducted in Ethiopia that are related to adherence to ART (Tiyou, Belachew, Almseged & Biadgilign 2010:1; Gusdal, Obua, Andualem, Wahstrom, Tomson, Peterson, Ekstrom, Thorson, Charlker & Forschen 2009:1382; Markos, Alemayehu & Davey 2008:176). In light of this, it is relevant to investigate and document the prevalence and socio-economic, behavioural and other factors linked to adherence to ART. The study, therefore, will provide further insight helpful in designing and implementing evidence-based interventions in regional

as well as national programmes by policy-makers and any governmental or non-governmental organisations working with PLWH in creating conducive environment for optimising adherence to ART.

## **1.8 ETHICAL CONSIDERATIONS**

The ethical protection of respondents was maintained throughout this study. Before the study began, ethical clearance was obtained from the Higher Degrees Committee of the Department of Health Studies at Unisa (Annexure A). Institutional consent was obtained from the medical director's office of Nekemte Hospital after communicating through a formal letter (Annexure B).

## **1.9 RESEARCH METHODOLOGY**

### **1.9.1 Research design**

This is a quantitative, cross-sectional, institution-based study with descriptive and analytic components.

### **1.9.2 Setting**

The study was conducted at a district hospital, Nekemte Hospital, located in the Western part of Ethiopia, and the South Western part of Oromiyya region. This is a referral hospital in the East Wollega zone with a catchment population of 2,8 million people in 2011.

### **1.9.3 Population and sample**

The study population in this study consisted of all PLWH on ART in Nekemte Hospital aged 18 years old and above who were started on ART in Nekemte Hospital and had been taking ART for a minimum of 12 months at the time of the interview.

## 1.10 OPERATIONAL DEFINITIONS USED IN THE RESEARCH REPORT

**ART adherence** is the ability of the person living with HIV to be involved in choosing, starting, managing and maintaining a given ART regimen to control HIV replication and improve the immune function. It means taking the correct doses of drugs at the correct time and in the correct way (such as with the right type of food or fluid) and sticking to the treatment plan. It also means looking after drugs to make sure they are safe and effective to use. Adherence is different from compliance in that the latter is not based upon shared decision-making between the patient and provider (Horizons ... 2004:16).

**Non-adherence to ART** includes the missing a dose or doses of antiretroviral drugs; stopping medicine for a day or days; taking the medicine at the wrong time and taking the medicine without dietary instructions (Horizons ... 2004:17).

**Level of adherence:** The percentage of prescribed doses swallowed by the patient following instructions given by the provider.

**Adherence rate:** The proportion/percentage of patients who adhered to the regimen according to the definition of adherence based on the score by the operational definition for adherence.

**Calculation of the adherence assessment score:** The assessment score was calculated by asking the patient skipped doses, or delayed doses for more than two hours, over the last seven days, and calculating the adherence rate by the following formula:

Number of doses taken/Number of doses supposed to take for seven days X 100%

ART adherence level is said to be "Good" if  $\geq 95\%$ .

Patients were asked for missed doses for the last 24 hours, 72 hours, and seven days. But for assessment, the past seven days were taken and assessment was done by counting how many dose(s) were missed (taking also delayed doses for  $\geq 2$  hours as missed) the previous seven days.

A patient will be labelled as adherent if he/she took all doses in the previous seven days, and non-adherent if he/she skipped or took with delay of  $\geq 2$  hours even a single dose in the previous seven days. This is based on the above formula and considering good ( $\geq 95\%$ ) or near to perfect adherence necessary for ART.

## **1.11 ORGANISATION OF THE DISSERTATION**

The dissertation is divided in the following chapters:

**Chapter 1:** Introduction and background information of the research study

**Chapter 2:** Literature review for the research study

**Chapter 3:** Research methodology

**Chapter 4:** Research results

**Chapter 5:** Discussion of the study

**Chapter 6:** Conclusions, limitations and recommendations

## **1.12 CONCLUSION**

This introductory chapter provided an overview of the study. It includes an introduction to the chapter, background information on adherence and ART as used in Ethiopia. The research problem, significance of the study, purpose of the study, objectives of the study, methods of research used in the study and the ethical considerations as used in the study. The chapter concludes by providing the structure for the study.

## **CHAPTER 2**

### **LITERATURE REVIEW**

#### **2.1 INTRODUCTION**

Chapter 2 presents a review of the literature related or relevant to the factors that influence adherence to ART among adults. The chapter's review of literature is structured as follows:

- Overview of HIV infection and antiretroviral therapy
- Overview of antiretroviral therapy in resource-limited settings
- Goals of antiretroviral therapy
- Adherence to antiretroviral therapy
- Measurement instruments used for adherence assessment
- Factors that influence adherence to antiretroviral therapy
- Patient variables
- Clinical setting
- Treatment regimen
- Conclusion

#### **2.2 OVERVIEW OF HIV INFECTION AND ANTIRETROVIRAL THERAPY**

A key factor to the successful treatment of chronic HIV is good adherence to ART. Studies demonstrate the importance of adherence to achieve the best virological response, lower the risk that drug resistance will develop, and reduce morbidity and mortality. These benefits critically depend on patients achieving and maintaining high levels of medication adherence. Very high level of adherence (>95%) is required for ART to be effective and to prevent the emergence of resistant viral strains (Horizons ... 2004:16; Tusiime et al 2008:207).

The overview of infection and ART are discussed under goals of antiretroviral therapy and overview of antiretroviral therapy in resource-limited settings.

## 2.2.1 Goals of antiretroviral therapy

Antiretroviral therapy constitutes the election therapy for chronic HIV infection. It was first introduced in the developed world in 1996. Since it delays clinical progression, it increases survival significantly and diminishes hospital admissions and associated costs. It consists of at least three drugs from the three original drug classes:

- (1) Nucleoside reverse transcriptase inhibitors (NRTI) and nucleotide reverse transcriptase inhibitors (NtRTI)
- (2) Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
- (3) Protease inhibitors (PI) (Merry & Flexner 2008:171; Federal HAPCO and Federal MOH 2007:50-62)

From the point of view of patients, the goals of antiretroviral therapy can be summarised as follows:

- durable suppression of viral replication to undetectable levels in the blood (<50 copies/mm<sup>3</sup> in routine viral load assay)
- stabilisation or improvement in immune function as measured by CD4 cell count
- improvement in quality of life by reduction of HIV-related complications, and improvement in overall survival

Individuals living with HIV who receive treatment and optimal care live longer and healthier lives. With ART, HIV can be approached as a chronic, manageable condition rather than a shorter-term issue of palliative care (Rouleau, Fortin, Trottie, Lalonde, Lapointe, Cote, Routy, Matte, Tsarevsky & Baril 2011:53). From a public health point of view, it results in possible reduction in transmission of HIV.

Specific antiviral regimens should be selected with the goal of maximising viral suppression, minimising side effects and preventing or delaying the emergence of viral resistance in order to preserve future treatment options. For the success of ART, in addition to appropriate adherence counselling, time of initiation of therapy, use of effective first-line regimen and proper monitoring for side effects are important (Rouleau et al 2011:52, 53).

## **2.2.2 Overview of antiretroviral therapy in resource-limited settings**

The agreement between the United Nations Programme on HIV/AIDS (UNAIDS) and major pharmaceutical companies for antiretroviral drugs price reductions, primarily for Sub-Saharan Africa (called the Accelerating Access Initiative) and the Durban AIDS conference held in 2000 brought about a breakthrough for access to ART in resource-poor settings. Subsequently, the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS declared that antiretroviral treatment is an essential component of HIV and AIDS prevention strategies. The World Health Organization (WHO) included antiretroviral drugs in the essential medicines list and formulated guidelines for the development of a public health approach to treatment of HIV infections in resource-limited settings (RLS). New and substantial funding agencies, such as the World Bank, the Global Fund to Fight AIDS, TB and Malaria (GFATM), and President's Emergency Plan for AIDS Relief (PEPFAR) were established. These developments, together with decreasing drug prices, have resulted in successful ART scale-up in RLS (WHO, UNAIDS, UNICEF 2011:2; Lange, Katabira & Sow 2008:615).

The scale-up in SSA has been the most successful. At the end of 2009, 37% of adults and children eligible for ART were receiving it in the region overall (UNAIDS 2010:96). The rapid scale-up of ART is, however, associated with the challenges of ensuring that HIV care delivered to clients is of the highest quality. An unintended consequence of treatment scale-up is the inevitable emergence of HIV drug resistance (HIV DR) in populations even when patient adherence to ART is optimally supported. Sustaining and expanding ART coverage in RLS will depend upon the ability of ART programmes to deliver ART in a way that minimises the emergence of HIVDR. Fortunately, current evidence demonstrates that HIVDR in RLS has neither emerged nor been transmitted to the degree that had initially been feared; many reports indicate optimal treatment follow-up of ART patients in SSA (Mills, Nachega, Buchan, Orbinski, Attaran, Singh, Rachlis, Wu, Cooper, Thabane, Wilson, Guyatt & Bangsberg 2009:685; Rosen, Fox & Gill 2007:1695-1696).

## **2.3 ADHERENCE TO ANTIRETROVIRAL THERAPY**

Adherence to antiretroviral therapy will be discussed under adherence as a concept, measurement instruments used in the assessment of adherence and factors that influence adherence to ART.

### **2.3.1 Adherence as a concept**

Adherence means a collaborative process between the patient and provider in addition to sticking to medications and other health services (Laufs, Rettig-Ewen & Böhm 2010:260). The WHO adherence project defines adherence as “the extent to which a person’s behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider” (WHO 2003:3). The patient plays a more active role in his/her treatment and makes a commitment to follow the prescribed regimen as best as possible.

Adherence is often used synonymously with compliance but the two concepts differ. For clinicians, compliance usually means “the extent to which the patient takes the medications as prescribed”, it makes the provider task-oriented rather than patient-oriented and the patient passive receiver of command, implying thereby a lack of discussion and mutual decision-making required facilitating adherence (WHO 2003:3-4). Instead of “compliance,” it has been suggested that the term adherence be used. It puts more of a burden on the clinician to form a therapeutic alliance with the patient, which enables the patient to discuss and to be part of decision-making. Thereby it increases behavioural compliance and possibly enhancing the therapeutic effect of the medication administered (Laufset al 2010:264).

A key factor to the successful treatment of HIV is good adherence to ART, which is critical to obtain its full benefits: maximal and durable suppression of viral replication, reduced destruction of cluster differentiation T-lymphocyte (CD4) cells, prevention of viral resistance, promotion of immune reconstitution and slowed disease progression. Several studies have indicated that adherence greater than 95% is required for ART to achieve clinical, immunologic and virologic success (Steel, Nwokike & Joshi 2007:2).



Non-adherence can vary from missing one dose of a medication to missing a single dose of all three or four medications to missing multiple doses or all doses a day or week. Not observing instructions regarding dietary or fluid intake or not taking medications at prescribed time intervals also constitutes non-adherence. Several studies have shown that a significant number of patients are non-adherent to ART with varying levels of adherence to antiretroviral drugs ranging from 37% to 83% depending on the type of antiretroviral drug under study (Steel et al 2007:3) and with the average non-adherence to ART ranging from 55% to 77% among patients in Africa and the USA, respectively (Mills et al 2009:679). Non-adherence can lead to inadequate suppression of viral replication, continued destruction of CD4 cells, progressive decline in immune function and fast disease progression. Non-adherence is also an important reason for the emergence of multi-drug resistant viral strains (Steel et al 2007:4).

### **2.3.2 Measurement instruments used for adherence assessment**

Adherence with ART can be difficult to assess. Rates of virological failure can give a general indication of the level of compliance within a clinic population. This information can be augmented by knowledge of viral resistance patterns so that virological failure due to resistance can be distinguished from that due to poor adherence to medication schedules. There is no single superior or gold standard instrument for measuring adherence and using multiple instruments brings more accurate result than using one instrument (Steel et al 2007:8).

Adherence is traditionally estimated in several direct and indirect ways; self-report, pill count, pharmacy refill tracking, electronic devices, and measuring drug levels are some of them. Patient self-report is simple to collect, but it may be inaccurate if patients wish to deceive the provider or simply cannot recall medication schedules well enough. Patients often tend to overestimate compliance.

At times, however, patient self-reporting can be sufficiently accurate and has been shown to correlate with virological response to ART. Pill counts, whether by patient or provider, often provide more accurate information than patient self-reporting, although overestimates of compliance are also possible by this measure. Drug-refill tracking is an important tool to trace those patients who are missing appointments, and as result, to

conclude poor adherence because of running out of drugs. Besides, it is a useful early warning indicator of virological and immunologic failure.

However, there are patients who have perfect adherence to drug-refill but it cannot be confirmed if they are swallowing their pills or not. Although the measuring of drug levels can provide important information about compliance, drug level assays are expensive and not generally available. The correlation between blood levels and therapeutic effect may not be as strong as it is for intracellular levels for some agents.

Finally, drug levels at best provide information only about recent compliance and may therefore overestimate overall compliance. Electronic monitoring systems can record each time the bottle is opened. Even such systems may not provide a fully accurate indication of compliance, because they are not able to determine the number of pills removed or swallowed (Steel et al 2007:6-7).

### **2.3.3 Factors that influence adherence to antiretroviral therapy**

Most of our understanding to adherence to antiretroviral therapy comes from studies in resource rich settings (RRS). Adherence study results in RRS may not, however, be replicated to RLS because of differences in patient dynamics in the two settings.

According to Tusiime et al (2008:208), a number of factors have been associated with non-adherence to ART, which can be categorised to include: patient factors, treatment regimen, disease characteristics, clinical settings and patient-provider relationship.

#### **2.3.3.1 Patient variables**

Studies on adherence show that it is impossible to predict adherence based on patient demographics such as age, gender, ethnicity and socioeconomic status, which patients will achieve high adherence (Haubrich, Little, Currier, Forthal, Kemper, Beall, Johnson, Dube, Hwang & McCutchan 1999:1099-1107; Fong, Ho, Fung, Lee, Tse, Yuen, Sin & Wong 2003:133-138).

Tusiime et al (2008:208-209) said studies report conflicting evidence about the association between socio-demographic factors and adherence behaviour. When an

association is found, the direction is towards lower levels of adherence with younger age, being single, non-white race/ethnicity, and lower income, which may be due to uncontrolled confounding by other factors.

On the other hand, a number of psychosocial factors have been found to strongly influence adherence. These include psychiatric morbidity (particularly depression), active drug use or alcohol use, stressful life events, lack of social support, HIV and AIDS related stigma and fear, harmful cultural and traditional practices and poor health literacy (Panelon Antiretroviral ... 2012:K1; Tusiime et al 2008:208).

A patient's knowledge of his medication regimen and his/her understanding of the relationship between non-adherence and build-up of resistance to medication have been found to predict better adherence (Panelon Antiretroviral ... 2012:K1).

### **2.3.3.2 Clinical setting**

Although existing data is limited, aspects of the clinical setting may be associated with improved adherence. Ease of access to medication refills, convenience in scheduling appointments, and presence of social workers/peer educators has been associated with good adherence (Reda & Biadgilign 2012:3). According to Tusiime et al (2008:208), other aspects of the clinical setting that may contribute to better adherence include:

- access to ongoing primary care or decentralisation of ART services
- involvement in a dedicated adherence programme
- availability of transportation or geographical access of health facilities
- perceived privacy of the clinical environment
- extended ART service over the weekends and holidays
- satisfaction with past experiences in the health care system

Although correlates of adherence are described, the factors that influence adherence are almost as unique as the people taking the drugs (Tusiime et al 2008:208).

### **2.3.3.3 Patient-provider relationship**

Provider-related determinants include a trusting patient-provider relationship and provider experience. The patient-provider relationship plays an important role in improving adherence to prescribed medications in chronic diseases. A friendly, supportive and non-judgmental attitude of health care providers is believed to be a motivating factor for adherence to ART. Perceived trust or confidentiality in providers has been found to influence adherence positively (Tusiime et al 2008:208).

### **2.3.3.4 Treatment regimen**

The main factors related to the treatment regimen are the number of pills prescribed, the specific type of antiretroviral drugs, and medication adverse effects and side effects. ART consists of a complex regimen that can require swallowing multiple pills a day and it will be even worse if the patient is taking other medications for prophylaxis or treatment of opportunistic infections. It is sometimes further tightened with specific food and fluid related instructions. These are often difficult to follow for patients and contribute to poor adherence. The higher the pill burden, the lower is the adherence (Tusiime et al 2008:208).

### **2.3.3.5 Disease characteristics**

Disease-related predictors include stage of HIV infection and presence of prior-opportunistic infections (OI). Patients who have had previous OI may understand the severity of their illness and tend to adhere to their treatment (Tusiime et al 2008:208).

## **2.4 CONCLUSION**

The use of ART has resulted in reduced AIDS incidence and mortality. However, little is known about the therapeutic process necessary to promote acceptance of and adherence to ART among HIV-positive persons in RLS. Studies have confirmed that adherence to ART regimens is of fundamental importance to ART success. Even minor deviations from prescribed drug schedules can result in early emergence of resistant viral strains (Gardner, Burman, Steiner, Anderson & Bangsberg 2009:9).

## **CHAPTER 3**

### **RESEARCH METHODOLOGY**

#### **3.1 INTRODUCTION**

This chapter outlines and justifies the methods used in this study. Four main topics discussed are:

- research design
- sampling
- methods of data collection
- methods of data analysis

As part of data analysis, issues around internal and external validity of data were considered. Lastly, the summary of the chapter is given.

#### **3.2 RESEARCH DESIGN**

A research design is a blueprint for conducting the study that maximises control over factors that could interfere with the validity of the findings (Burns & Grove 2005:2; Stommel & Wills 2004:3). Quantitative design will be adopted for this study. Stommel and Wills (2004:3) refers to quantitative research as “the systematic development of new knowledge via a process of assembling empirical evidence”, and Burns and Grove (2005:24) point out that quantitative studies seek to describe variables, investigate relationships among variables, and determine cause and effect relationships between variables.

##### **3.2.1 Rationale for choosing a quantitative cross-sectional design**

Time pressure, resources and financial constraints of conducting this study forced the researcher to conduct a cross-sectional study. A cross-sectional study is the simplest variety of descriptive or observational epidemiology that can be conducted on

representative samples of a population. It is used as a useful way to gather information (Joubert & Ehrlich 2007:7).

### **3.3 RESEARCH METHOD**

#### **3.3.1 Study setting and period**

Ethiopia is a low-income country in east Africa, with a total population of 73,8 million according to the 2007 population and housing census (CSA 2012:3). The overall adult HIV prevalence in Ethiopia has remained low. The HIV prevalence among adults aged 15 to 49 in the 2011 Ethiopian Demographic and Health Survey (EDHS) is 1,5% and it was 1,4% in the 2005 EDHS (CSA 2012:234). The estimate in 2012 is 1,3% based on Ethiopian Demographic and Health Survey (EDHS) 2011 and antenatal care (ANC) 2009 (Federal HAPCO 2012:1).

This study was conducted at a district hospital, Nekemte Hospital, located in the Western part of Ethiopia, and the south-western part of Oromiyya region. This is a referral hospital in the East Wollega zone with a catchment population of 2,08 million people in 2011. The hospital has 12 general practitioners and nine specialists (two general surgeons, two gynaecologists, one internist, one paediatrician, one orthopaedic surgeon, and two ophthalmologists) and has 178 in-patient beds.

The hospital provides general outpatient and in-patient services, including surgical and obstetric emergency care. Infectious diseases account for most of the inpatient and outpatient visits. The hospital has been providing voluntary counselling and testing (VCT), services for more than a decade and provider initiated testing and counselling (PITC) services for the past four years. A free ART service was started in January 2006. The adult HIV prevalence (among women and men aged 15 to 49 who were tested) of the Oromiyya region was 1.0% in 2011 EDHS (CSA 2012:235). The study period was six weeks and it started in 1 June until 12 July 2012.

# Oromiya Region



**East Wollega Zone**

Figure 3.1 Map of the Oromiya regional state of Ethiopia (Oromia map 2005: [1])

### **3.3.2 Study population**

The study population/target population were all PLWH who are currently on ART in Nekemte Hospital.

### **3.3.3 Sampling, sampling procedure, sample size and the sample population**

#### **3.3.3.1 Sampling**

Sampling involves selecting a group of people, events, behaviours, or other elements from a larger population or universe, with which to conduct a study. The objective of the sampling theory is to determine mathematically the most effective way of acquiring a sample that would accurately reflect the population under study. A probability-sampling plan better ensures precision in the accurate estimation of the population parameters, thus reducing sampling errors (Burns & Grove 2005:365). For the current study, a sampling procedure was designed to ensure it represented of the study population.

#### **3.3.3.2 Sampling procedure**

The concept of systematic sampling was applied when choosing participants for structured interviews. Systematic sampling refers to selecting, from a population list or “sampling frame,” every  $k$ th individual, using a starting point selected randomly. The population size is divided by the desired sample size, giving  $k$ , the size of the gap between elements selected from the list. For this study, Nekemte Hospital was selected conveniently. The participants were only included if they fulfilled the criteria, i.e. patients who were 18 years of age and older and who were 12 months and more on ART. These participants were recruited when they came into the clinic to collect their medication or had doctors’ appointments by using systematic random sampling. The first participant was selected at random. Then each fourth individual exiting from the ART clinic was included as patients come to the clinic to attend according to their appointment and queue.

The sampling frame (adult appointment calendar/logbook) contained names of patients on ART who were expected to attend the health facility in the time decided to collect



data. The sampling frame contains all patients on ART as every patient is appointed every month for follow-ups.

### 3.3.3.3 Sample size

Patients meeting the inclusion criteria were selected until the required sample size was obtained. The sampling interval was:  $K = \text{Sampling frame (N)}/\text{Sample size (n)} = 1462/340 = 4.3 \approx 4$ . The starting participant was selected randomly and every fourth person on the list was included in the sample. The health facility, Nekemte Hospital, where the study was carried out, had 1 462 registered patients who were on ART at the time of the study.

The sample was determined using the single population proportion formula by Le (2003:452). The assumptions were that the sample was representative; the sampling error was small, the sample was viable in the context of funds available for the research study, systematic bias was controlled in a better way and results from the sample study will be generalisable.

Assuming random sampling and normal distribution, a response rate of 90%, 50% for anticipated proportion and a significance level of 0,05, the sample size needed was calculated using the formula below:

$$n_o = \frac{z^2 p(1-p)}{d^2}$$

Where:

p= anticipated population proportion (50%, since there is no previous study done)

d=the precision required on either side of the proportion (=0,05)

z=the cut-off value of the Normal distribution (=1,96 at level of significance of 0,05)

$$n_o = \frac{z^2 p(1-p)}{d^2} = \frac{1.96^2 \cdot 0.5(1-0.5)}{(0.05)^2} = 384,16 \approx 384$$

, since sampling is from a finite population of N=1462 (Adults  $\geq$  18 years of age currently on ART in the hospital (adult ART clinic).

$$n = \frac{n_o}{1 + \frac{n_o}{N}} = \frac{384}{1 + \frac{384}{1462}} = 304$$

For a response rate of 90%,  $n_f = \frac{304}{0,9} = \underline{\underline{338,6 \approx 338}}$ , where  $n_f$  = the final sample size.

#### **3.3.3.4 Sample population**

The sample population was composed of PLWH aged 18 years and above who were started on ART in Nekemte Hospital and currently taking ART in Nekemte Hospital ART clinic, and have been taking ART for a minimum of one year.

The inclusion criteria comprised of outpatients who were at least 18 years of age, and were willing to participate in the study (able to give informed consent), and not seriously sick, and have been taking ART for a minimum of one year.

The following patients were excluded from the study:

Those patients on second line regimen after treatment failure, and those on short-course ART for post-exposure prophylaxis (PEP) and for prevention of vertical transmission of HIV.

#### **3.3.4 Ethical issues related to sampling**

The age of consent in Ethiopia is 15 years old and above; the study has complied with that (FMOH and Federal HAPCO 2007:4) which requires that study participants can consent from the age of 15. The ethical protection of the respondents was maintained throughout this study. The following ethical principles were adhered to:

##### **3.3.4.1 Informed consent**

Informed verbal consent of participants was sought and recorded in writing. The objectives of the study were discussed with each participant. The participants were told that there would be no incentive but would have benefits in the long run, that the study had no risks and that they had full right to discontinue the questioning at any time during the session. The cell phone number of the principal investigator was given to the participants for any queries. All this information was given both orally and in written leaflet to each participant.

#### **3.3.4.2 Risk and discomfort**

Participating in this research project had no risks or discomfort. However, to avoid participants feeling like their time was being wasted, it was explained to them that answering questions would take a maximum of 30 minutes.

#### **3.3.4.3 Benefits**

Participants were told that their participation in the study might not give those direct benefits, but their participation would enable the researcher to identify barriers and facilitators of adherence to ART, which subsequently can be utilised by the relevant health care workers to provide evidence-informed and appropriate ART adherence counselling and support based on the study.

#### **3.3.4.4 Incentive**

There were no incentives for participating in the study.

#### **3.3.4.5 Confidentiality**

The information that we collected from this research project was kept confidential. Information collected from the study was stored in a file, which does not have names of respondents on it, but a code number assigned to it. Which number belongs to which name is kept in secrecy indefinitely.

#### **3.3.4.6 Right to refuse or withdraw**

Participants were told that they had the full right to refuse to participate in the research (they could choose not to respond to some or all questions). It was further explained to the participants that if they did not wish to participate in the study it would not affect their treatment or health care that they get from this health facility in any way. Participants were also told that they had full right to withdraw from the interview at any time they wished to, without losing any of their right as clients in this health institution.

### **3.3.5 Data collection**

#### ***3.3.5.1 Data collection approach and method***

Quantitative method of data collection was applied by using only one mode of data collection: asking questions (self-report). Face-to-face exit interview was selected as the preferred mode of administration of the written questionnaire as it was personal (one-on-one) setting. ART outpatients were the sources of data.

#### ***3.3.5.2 Development and testing of the data collection instrument***

Researchers who have tried to measure adherence have realised that there is no gold standard by which adherence can be quantified (Steel et al 2007:8). This study had selected and developed the structured questionnaire as a measurement tool.

The questionnaire was adopted from the public domain, but five questions were formulated from the scratch in an effort to make the questionnaire comprehensive and complete. However, pilot testing with members of the target population was conducted for preliminary evaluation of individual items: comparison of response rate of newly formulated items with those of other items and variation in responses for all items was checked. It was found that all the items have very good response rate and reasonably high variation in responses. After the questionnaire was developed, 20 structured interviews were conducted. This was after translation and preparation of the questionnaire (Oromifa), which is a local language used in the district. The items were translated by the principal investigator and back translated by another skilful interpreter.

#### ***3.3.5.3 Characteristics of the data collection instrument***

The structured questionnaire was composed of predominantly closed questions and some open questions, which were rated for quantification. The information that was collected included age, sex, marital status, religion, household size and quality of housing, level of education, employment and average monthly income, knowledge of HIV and AIDS, and knowledge, attitude, perception and practice on use of antiretroviral drugs by patients; patients' perception towards health care providers and setting; patients' disease history, psychosocial support, psychological health and coping

methods and, self-recall of missed doses: Patients were asked how they took their medicines in the last, three and seven days prior to interview.

This has the advantage of a short time-span (seven days) and gives a chance and time for the interviewee to try to recall three times over the last seven days, which means that memory of medicine intake is likely to be good. However, patients may feel ashamed to report specific instances of non-adherence that occurred in the seven days prior to visiting the health facility, especially if they have to specify exactly when they failed to take a pill.

#### **3.3.5.4 *Data collection process***

Data was collected by one medical doctor (who was the supervisor) and four nurses trained on basic ART who were not employees of the hospital to make the participants free from possible fear of judgment by the staff during subsequent visits. Training was given on data collection techniques, and there was observation during data collection process and 5% of the collected data was assessed daily for its completeness for implementation of early correctional measures for the following day activities.

Data was collected for six weeks to get all the finite population according to the sampling method selected, as every ART patient is appointed every one month for refill and reassessment. The daily patient flow according to appointment was found to be 60 to 70 clients. Assuming this and participating every fourth client seven days a week (as the ART clinic is open in the weekends) attained the calculated sample size. The two weeks were added to get those who have come days after the appointment date because of different reasons.

#### **3.3.5.5 *Ethical considerations related to data collection***

- Permission to carry out the research study was obtained from the Higher Degrees Committee of the Department of Health Studies at Unisa for ethical clearance (Annexure A).
- Data was collected after getting written consent from the medical director's office of Nekemte Hospital after communicating through a formal letter (Annexure B).

### **3.3.6 Data analysis**

Data was sorted, coded, and entered into the computer using a Statistical Package for Social Sciences (SPSS) software version 16.0. Data was presented using charts, graphs and frequency tables.

The primary outcome variable was adherence with ART. This was defined as patient self-report of whether any antiretroviral drug had been skipped the previous day, the previous three days and the previous seven days. For the comparison assessment, the adherence in the previous seven days was used.

Self-reported adherence to all antiretroviral agents was summarised as the ratio of the average daily number of antiretroviral drugs adhered to correctly according to the standard instructions over the total number of antiretroviral medication prescribed. The results were then expressed as a percentage, and patients aggregated into two groups consisting of those adherent (took >95% antiretroviral drugs correctly) and non-adherent (took <95% antiretroviral drugs correctly).

The analysis consisted of basic summaries of patient characteristics, univariate binary logistic analysis of the relation between dose skipping and various factors, and multivariate logistic regression analysis to adjust values of the dependent variable for the influence of the likely confounding explanatory variables.

By using binary logistic regression model, the magnitude of the association between the different variables in relation to the adherence to treatment was measured through odds ratios (OR) and their 95% confidence interval (CI).

Comparisons for which P-values were below 0,05 were considered statistically significant.

## **3.4 INTERNAL AND EXTERNAL VALIDITY OF THE STUDY**

By using adequate sample size and pre-tested questionnaire, which was adapted from standardised questionnaires for Ethiopian setting, precision of the measurement instruments is optimised.

By using strong inclusion and exclusion criteria and using random selection of study subjects from the study population, and making the participants/sample population representative of the study population, selection bias is prevented in this study. To minimise information bias, all variables were measured in the same way on all participants; and, since it is a cross-sectional study design, unlike a case-control study, data collectors knew little about the participants which can help to additionally prevent information bias in the study. Furthermore, the source of data is a primary source (at point of service) and external validity is maintained.

### **3.4.1 Pretesting of the research instrument**

The research instrument was pre-tested to increase the validity and reliability of the responses. The questionnaire was pretested using the same procedure and with a similar target group. Pre-testing was done on 20 respondents; these respondents did not participate in the actual study.

The pre-tested findings showed that the questionnaires were well developed. The research assistants were well trained before participating in the study. Regular cross checking, inspection and scrutinising of information on the research instruments were done to ensure accuracy, relevance, completeness, consistency and uniformity of the data collected.

## **3.5 CONCLUSION**

Chapter 3 outlined the research methods used to answer the research question. The population sampling, data collection, instrument, ethical considerations, and data analysis were also discussed. Chapter 4 will present the results of the study.

## **CHAPTER 4**

### **RESEARCH RESULTS**

#### **4.1 INTRODUCTION**

The research objectives for the study were to quantify adherence rate among the study participants in the ART unit and to identify factors that influence adherence. The findings of the study aimed at meeting the study objectives and are presented according to the sequence in the questionnaire and are presented according to the following sub-headings:

- socio-demographic data
- health care facility and providers influence on adherence to ART
- disease factors
- psychosocial factors (family support and illness factors)
- HIV and ART knowledge
- reasons for missing antiretroviral drugs
- patient reported rate of adherence
- overview of research findings

Tables, graphs, charts and descriptions are used to present the findings and ends up with a conclusion.

#### **4.2 SOCIO-DEMOGRAPHIC DATA**

##### **4.2.1 Age of participants**

The age of study participants ranged from 18 years to 51 years and above. The majorities were between 20 and 50, and 52% of the participants are between 31 and 40.

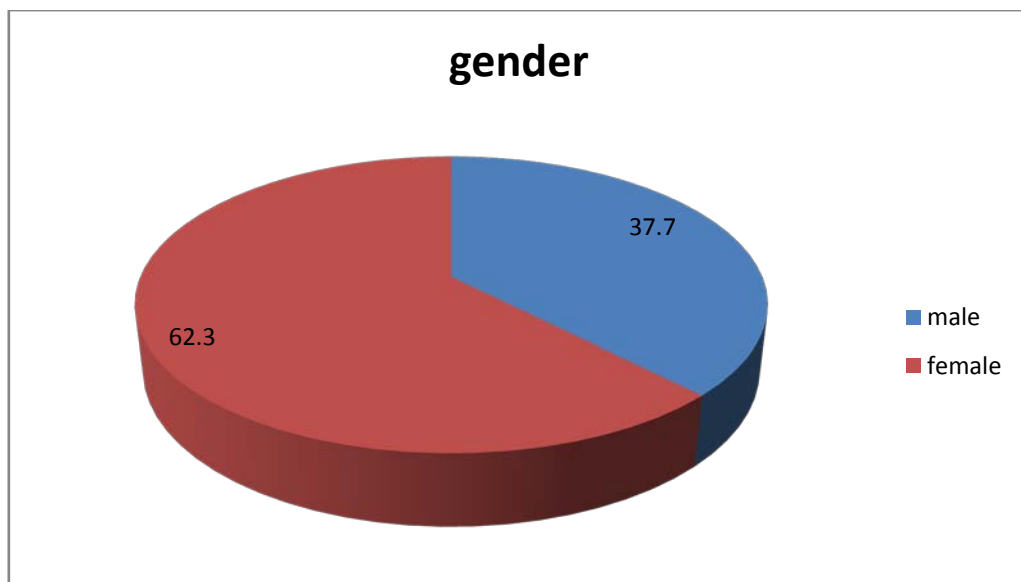


**Table 4.1 Age of participants**

Age in years	Number	Percentage
18 to 19	8	2,4
20 to 30	111	32,8
31 to 40	176	52,1
41 to 50	39	11,5
Over 50	4	1,2
<b>TOTAL</b>	<b>338</b>	<b>100,0</b>

#### 4.2.2 Gender of participants

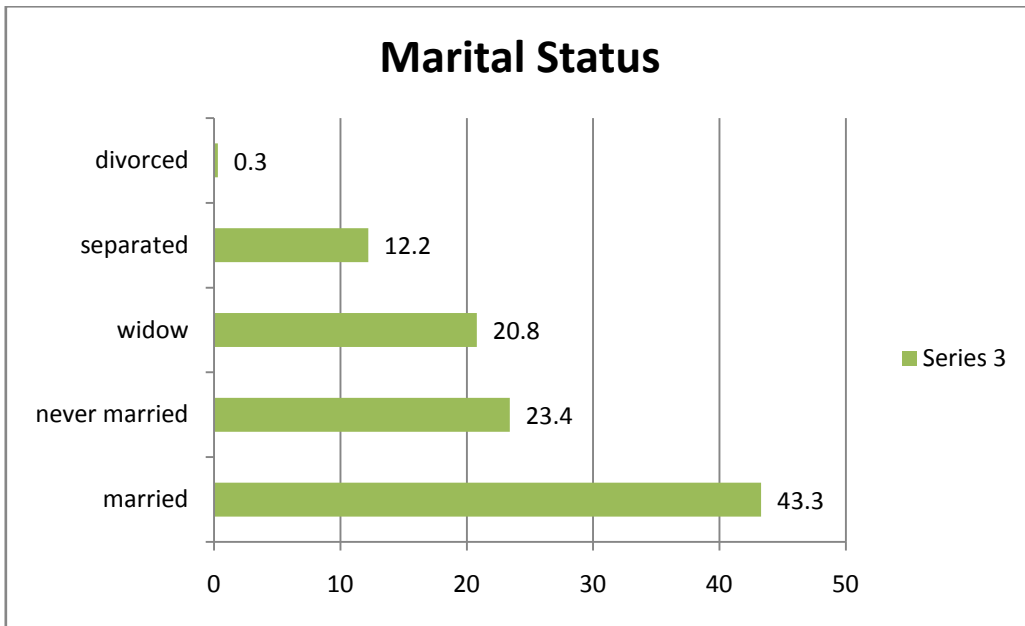
A total of 126 male and 208 female subjects participated in the study as depicted in figure 4.1; the rest four of the participants' gender was not filled in.



**Figure 4.1 Gender of participants**

#### 4.2.3 Marital status

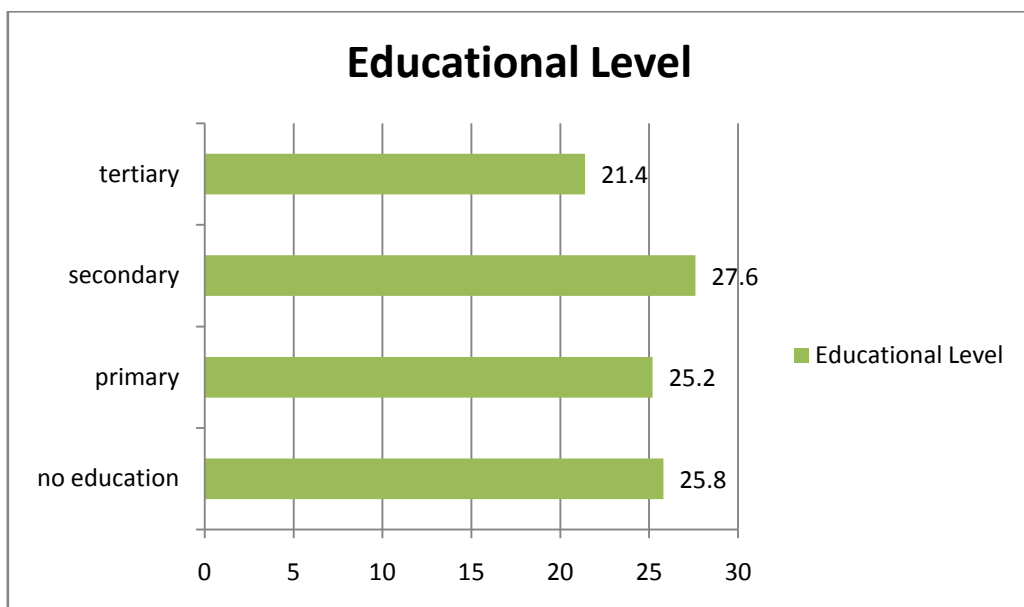
A total of 146 of the patients interviewed were married, 79 never married, 70 widows, 41 separated and one participant was divorced. The majority being married (43,3%) followed by single (23,4%). Depicted in the figure below in percentages:



**Figure 4.2 Marital status**

#### 4.2.4 Level of education

Their average educational attainment was relatively high, 27,6% had completed high school and 21,4% had a tertiary education qualification. Participants who are in primary and secondary schools were 85 and 93 respectively. Participants who never went to school were 87. Seventy-two of the participants have attended tertiary education.



**Figure 4.3 Educational level**

#### 4.2.5 Average monthly income

Different levels of income were reported with 63,1% reporting to have less than 500 birr per month, 10% between 500 and 1000 birr, 5,6% b/n 1000 and 1500 birr and 21,3% more than 1 500 birr. It is resented in the following figure as percentage.

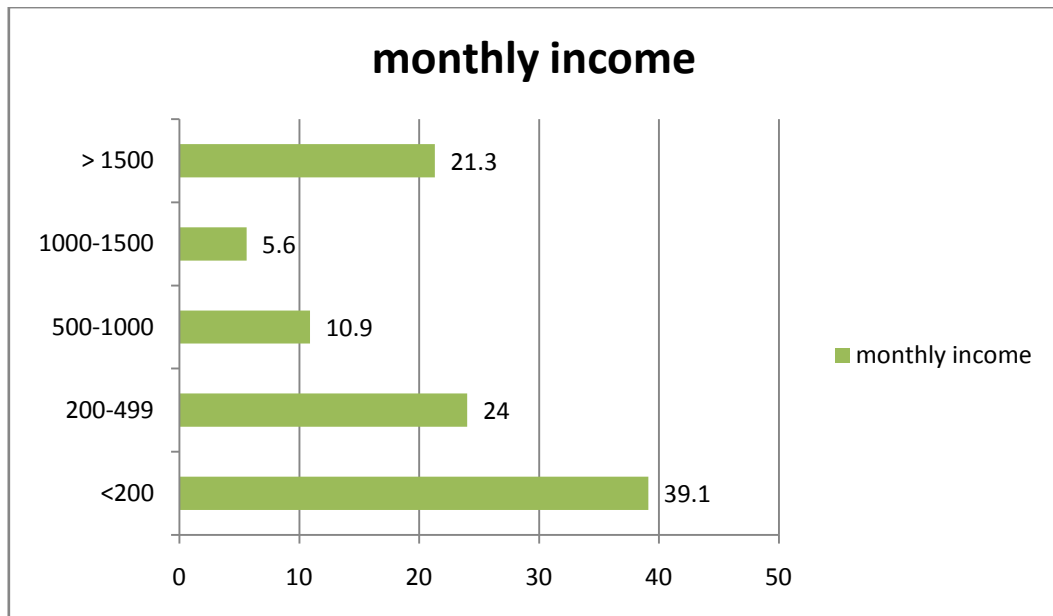
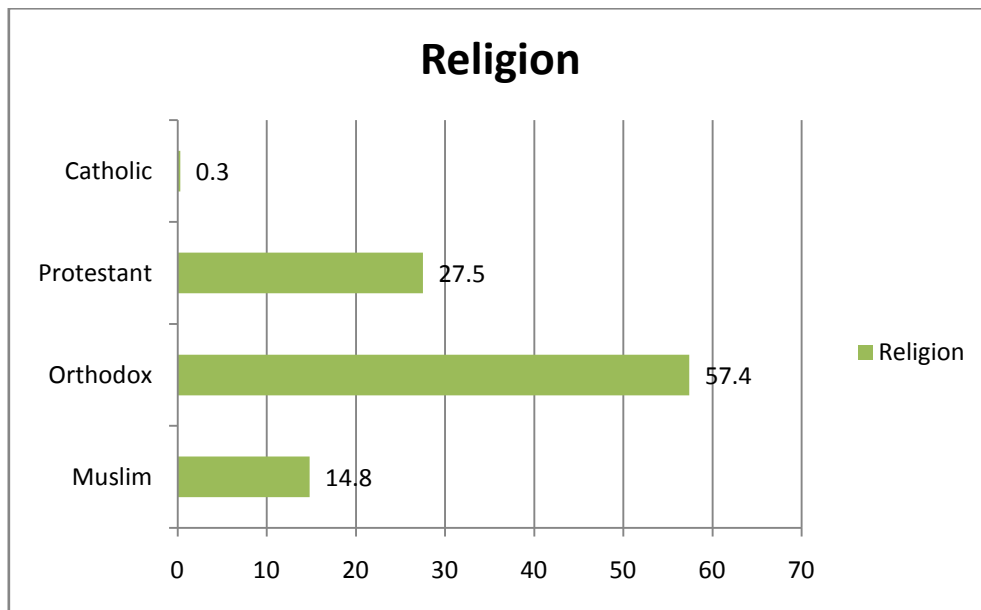


Figure 4.4 Monthly incomes

#### 4.2.6 Religion

Of the participants, 57,4% were Orthodox, followed by Protestant (28%), Muslim (15%), and Catholic (0,3%). Also depicted below:



**Figure 4.5 Religion**

### **4.3 HEALTH CARE FACILITY AND PROVIDERS INFLUENCE ON ADHERENCE TO ART**

#### **4.3.1 Respectful treatment**

Ninety seven percent of the patients perceive that the health care provider (HCP) involves them as a partner and supports their decisions after counselling.

#### **4.3.2 Confidentiality**

Ninety seven per cent of the patients feel that the information about their disease and treatment history is being treated with confidentiality.

#### **4.3.3 HCP access**

Ninety seven percent of the patients witnessed that the HCPs are easily available for consultation and other supply services in the facility.

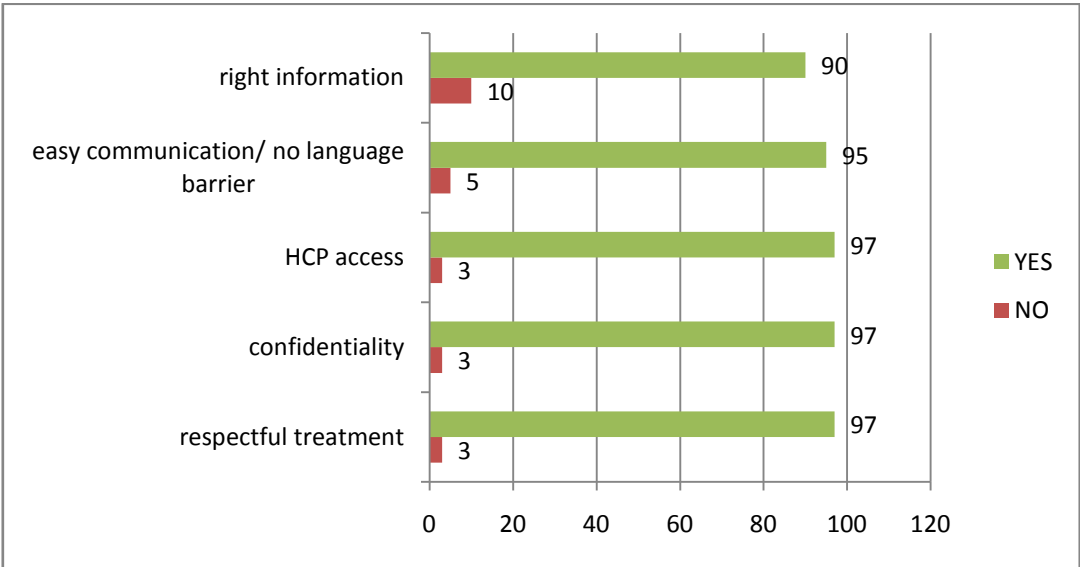
**4.3.4 Communication easiness/language barrier**

Only 5% reported they had a language barrier during their visit to communicate with the HCPs.

**4.3.5 Information given to patients**

Ninety percent of the participants reported that the HCPs helped them to understand their care.

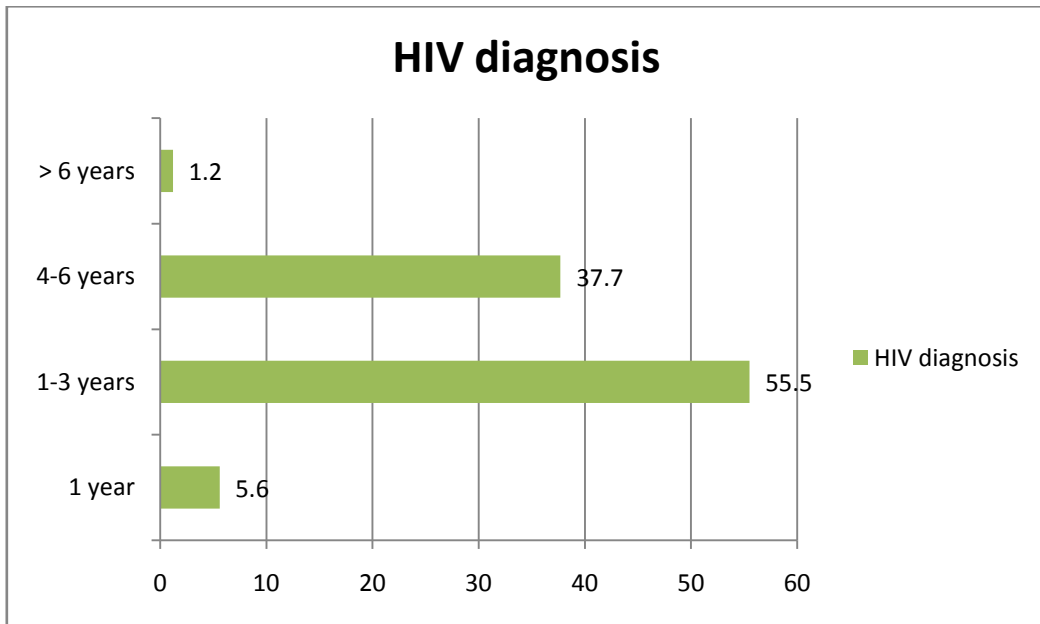
These characteristics are depicted below:



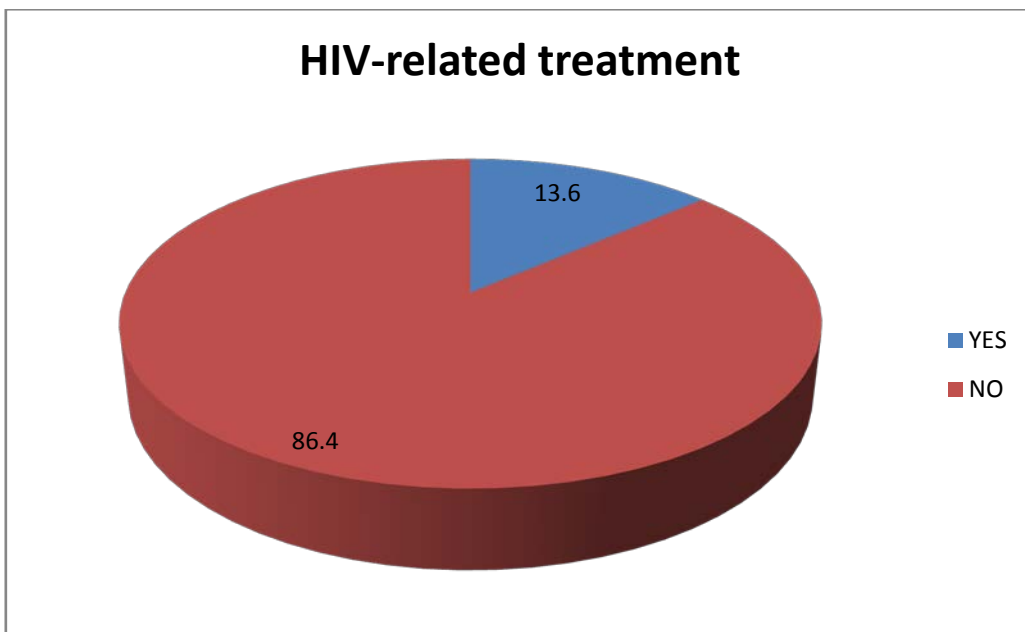
**Figure 4.6 Patient-provider relationship and clinical setting characteristics of respondents**

**4.4 DISEASE FACTORS**

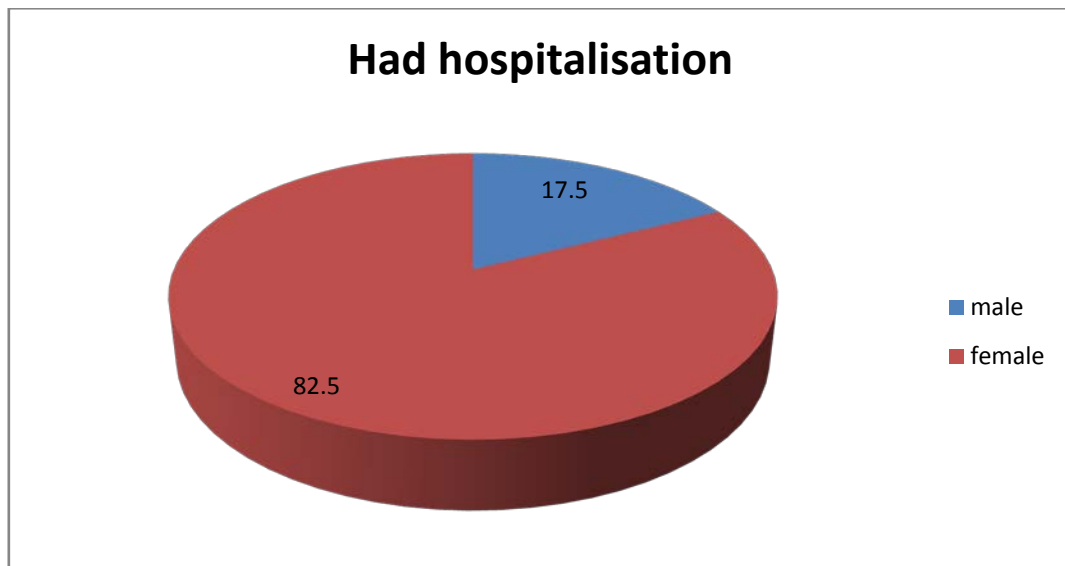
Fifty five per cent of patients said they were diagnosed with HIV about one to three years ago, while 38% said four to six years have passed since they were diagnosed. Eighty six per cent of the patients had HIV-related treatment at the time of the interview and 83% had been hospitalised in the past year prior to interview:



**Figure 4.7** Time when patients were diagnosed with HIV



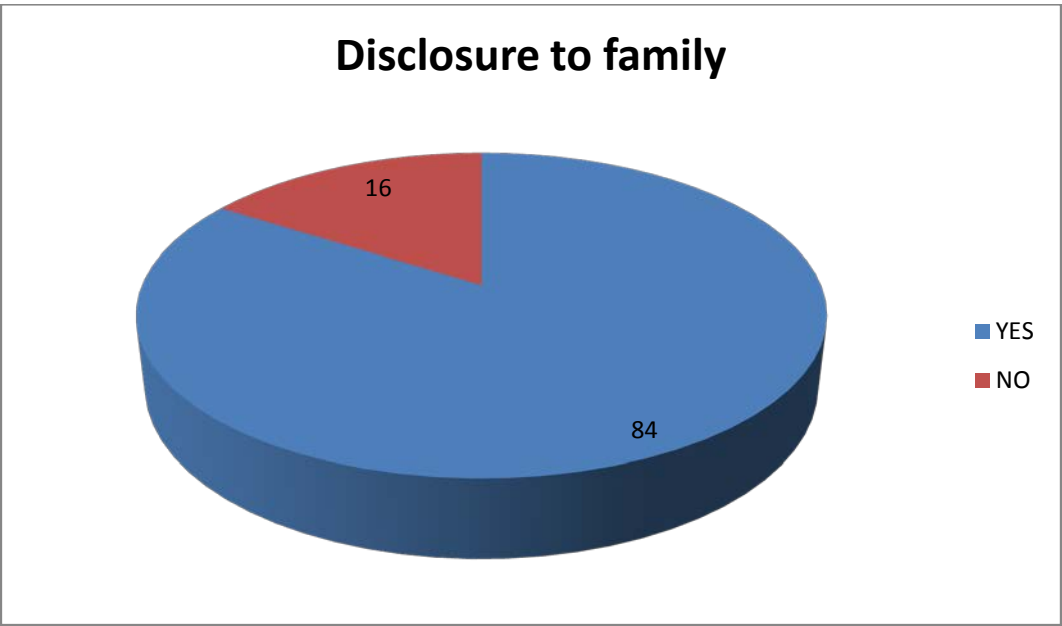
**Figure 4.8** HIV-related treatments currently



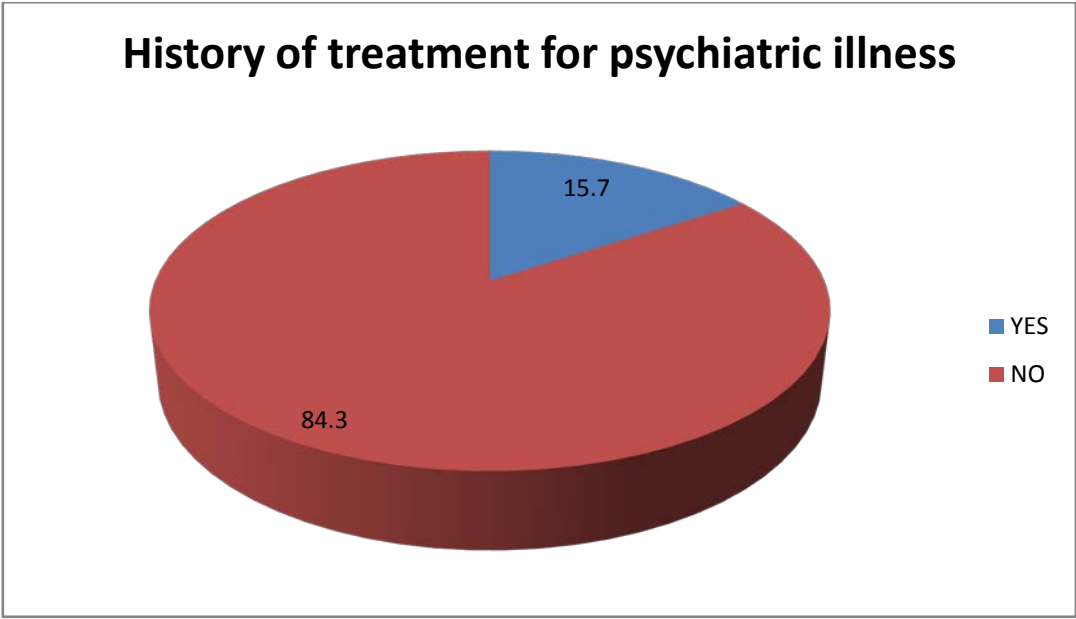
**Figure 4.9 Hospitalisation over last one year**

#### **4.5 PSYCHOSOCIAL FACTORS (FAMILY SUPPORT AND ILLNESS FACTORS)**

About 16% of the participants reported that they were treated for a psychiatric illness in the past. About 10% reported to have had depression. Only 2% reported active substance use while on ART. Some 75% claimed to have no one to talk to while the rest (25%) reported to have someone close to talk to while depressed. Around 84% had disclosed their statuses to their family members and 13% reported that they were receiving help from their family.

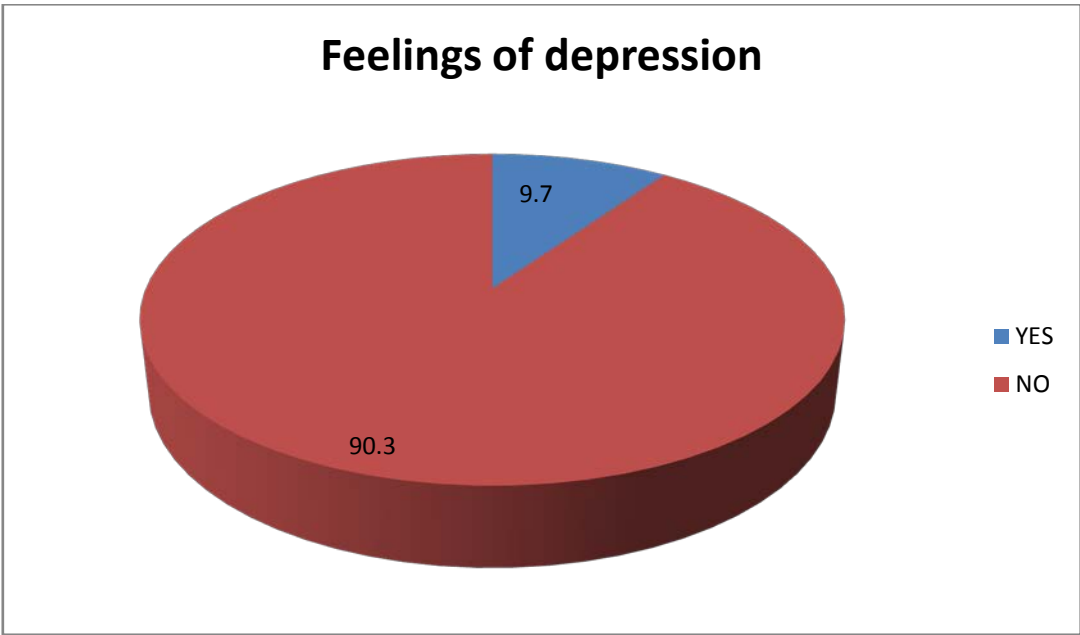


**Figure 4.10 Disclosure to family**

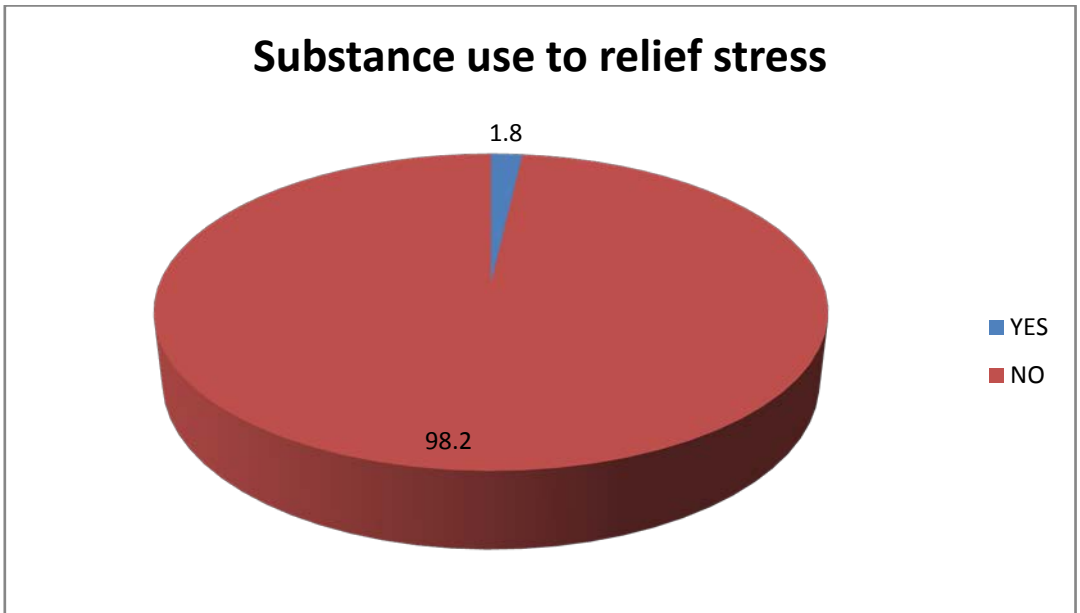


**Figure 4.11 History of treatment for psychiatric illness**





**Figure 4.12 Feelings of depression**



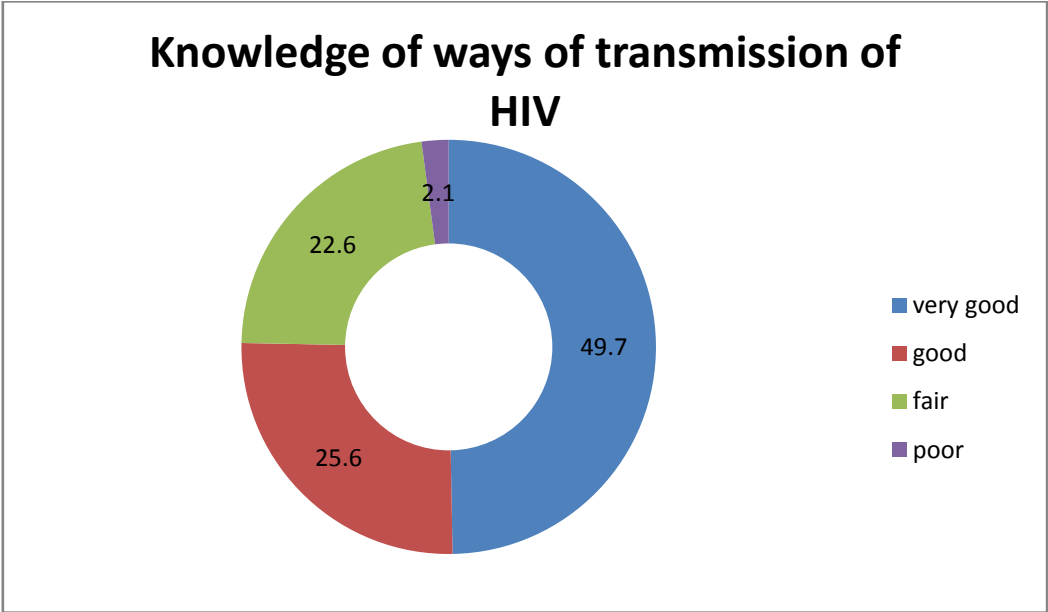
**Figure 4.13 Active substance use while on ART**

**4.6 HIV AND ART KNOWLEDGE**

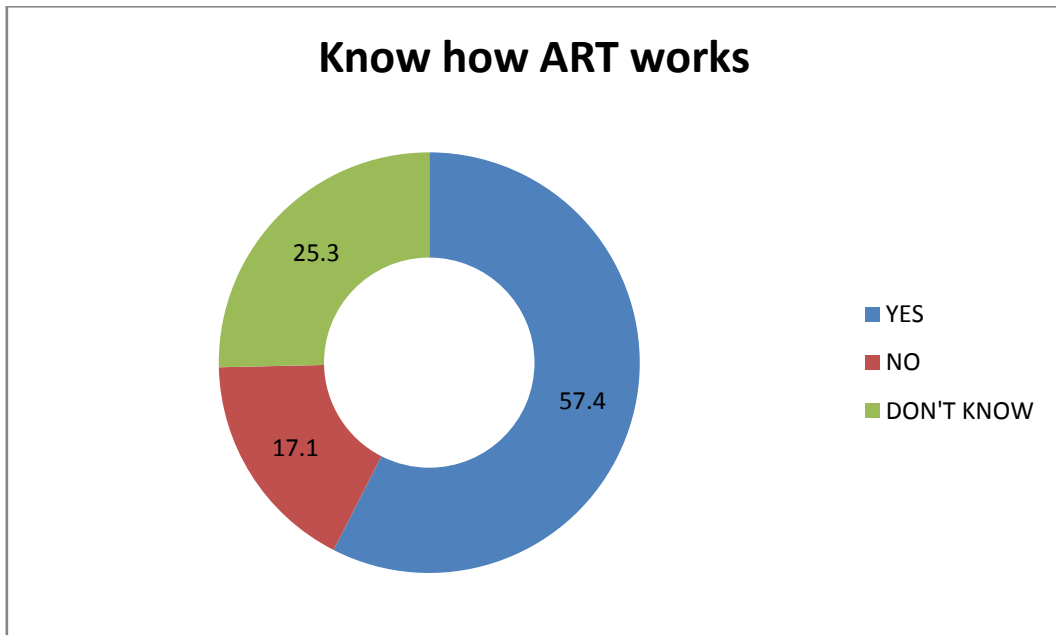
Half of the respondents were found to have a very good knowledge of HIV and AIDS including ways of transmission while 2% had poor knowledge.

Although 25,3% accepted that they had no idea about the benefits of ART and 17,1% claimed that they had some doubts about antiretroviral drugs, 57,4% believed the ART would benefit them. When further assessments were done on those who claimed that they knew that ART would benefit them, 59% were found to have a very good knowledge about how ART works.

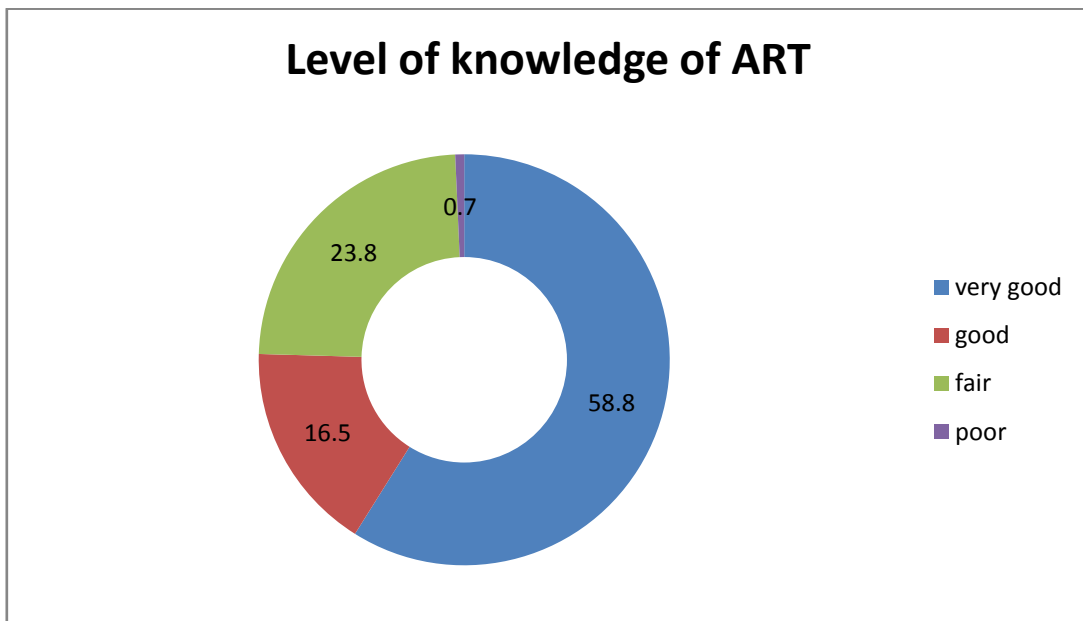
The proportion of participants knowledgeable (that is all answers correct) on issues concerning ART medicines was found to be 247/340 (73%) while the proportion of participants knowledgeable about HIV and AIDS was 172/334 (52%).



**Figure 4.14 Knowledge of ways of HIV transmission**



**Figure 4.15 ART knowledge**



**Figure 4.16 Assessment of level of knowledge of ART among those who said that they knew how it works**

#### 4.7 REASONS FOR MISSING TO TAKE ANTIRETROVIRAL DRUGS

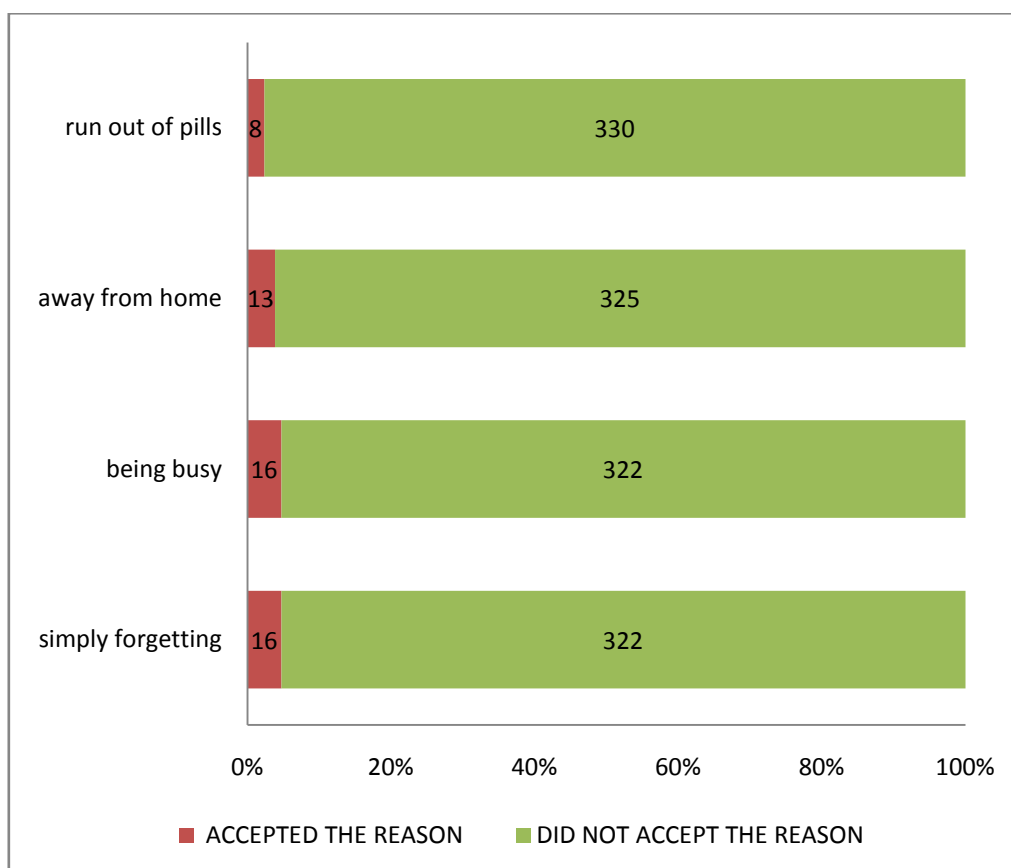
All 338 participants were asked to choose from 13 reasons for missing antiretroviral drugs listed in the questionnaire. They were advised to choose as many reasons as they wanted. The results were as follows:

- 16 respondents asserted that they simply forgot to take their medication
- 16 reported that they missed their doses due to being too busy
- 13 patients missed their pills when they were away from home
- eight patients ran out pills
- five had a change in their daily routine
- five did not want others to notice that they were taking medicine

Other barriers to treatment included: fear of side effects (two respondents), being burdened by too many pills to take (two respondents), feeling sick (two respondents), feeling asleep (one respondent), feeling depressed or overwhelmed (one respondent), too many times to take pills (one respondent), and problems taking pills with instructions (one respondent).

**Table 4.2 Reasons of respondents for missing to take antiretroviral drugs**

No	Reason for missing antiretroviral drugs	Proportion	%
1	Simply forgot	16/338	21,9
2	Too busy	16/338	21,9
3	Away from home	13/338	17,8
4	Ran out of pills	8/338	10,9
5	Secrecy to swallow pills	5/338	6,8
6	A change in daily routine	5/338	6,8
7	Fear side-effects	2/338	2,8
8	Too many pills	2/338	2,8
9	Felt sick	2/338	2,8
10	Felt depressed/overwhelmed	1/338	1,4
11	Unable to comply with dietary instructions	1/338	1,4
12	Felt asleep	1/338	1,4
13	Too many times to swallow pills	1/338	1,4



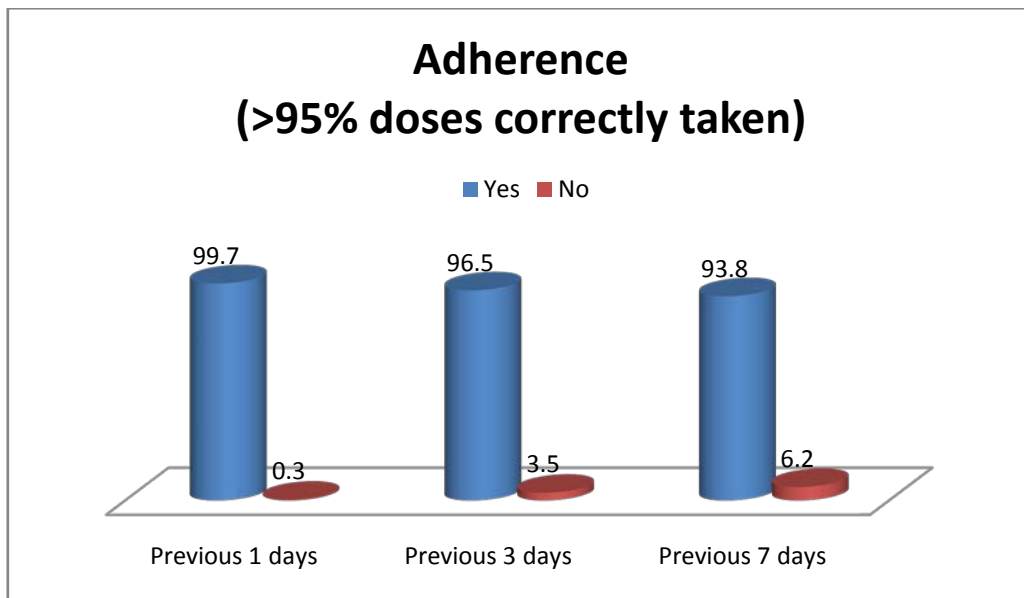
**Figure 4.17 Major reasons for missing pills**

#### 4.8 PATIENT REPORTED RATE OF ADHERENCE

Adherence assessments to ART are summarised in table 4.3. About 93,8% of the participants claimed never to have missed a single dose of medication in the week before the assessment and hence found to be adherent by self-report, based on the definition outlined in the methods above. The one day and three days adherence rate was 99,7% and 96,5% respectively.

**Table 4.3 Self-reported adherence among respondents**

	Adherence (>95 % doses correctly taken)	
	Yes	No
Previous 1 day	339 (99,7%)	1 (0,3%)
Previous 3 days	328 (96,5%)	12 (3,5%)
Previous 7 days	319 (93,8%)	21 (6,2%)



**Figure 4.18 Self-reported adherence score**

#### 4.9 OVERVIEW OF RESEARCH FINDINGS

Presented below are variables associated with adherence: Univariate and multivariate binary logistic regression analysis. All variables were dichotomised to fit the model and they were screened to identify candidate variables by using univariate analysis at a P-value of 0,25. A higher P-value (0,25) was used not to miss potential variables for entry into the multivariate model. Table 4.2 shows the crude ORs for variables identified as correlates of adherence, which were statistically significant in the univariate binary logistic regression analysis.

Non-adherence was common among those: aged between 18 and 30 years, with no education; who were not married; who had no pipe water supply; those without electricity in their homes; who perceived a lack of assistance from providers; who perceived the HCPs did not keep information confidentially; who had language barriers with providers; as well as those who were treated with a psychiatric illness.

All the other variables included under socio-demography, disease, patient-provider relationship and clinical setting, family support and illness, and HIV and ART knowledge related factors were not found to be significantly associated with adherence at  $P < 0.25$ .

Candidate variables significantly associated with ART adherence in the univariate analysis at  $P < 0.25$  were also re-evaluated again with adherence as a dependent variable using the multivariate logistic model.

All the variables found to be associated with adherence on the univariate analysis remained significantly associated with adherence on the multivariate analysis (table 4.4)

**Table 4.4 Factors predicting adherence among respondents**

Characteristics	Did you miss $\geq$ one dose over the last seven days		COR (95%)	AOR (95%)
	No	Yes		
2. Age in years <input type="checkbox"/> 18-30 <input type="checkbox"/> over 31	107 210	12 9	2.61(1.06-6.40)* 1	3.45 (1.11-10.66)* 1
3. Your level of education <input type="checkbox"/> no education <input type="checkbox"/> educated	74 242	13 8	5.31(2.12-13.31)*** 1	5.06 (1.64-15.60)** 1
4. Marital status <input type="checkbox"/> none married <input type="checkbox"/> married( incl. de facto)	174 142	17 4	3.46 (1.14-10.53)*** 1	2.37 (1.65-8.60)* 1
9. Is your water supply source from a pipe? <input type="checkbox"/> yes <input type="checkbox"/> no	273 42	13 7	0.28 (0.10-0.75)** 1	0.37 (0.05-0.92)* 1
10. Is there electricity in your house? <input type="checkbox"/> yes <input type="checkbox"/> no	290 26	16 5	0.28 (0.09-0.84)* 1	0.33 (0.08-0.98)* 1
16. The HCP is accessible when I need her/him <input type="checkbox"/> yes <input type="checkbox"/> no	311 6	16 5	0.06 (0.01-0.22)*** 1	0.11(0.01-0.99)* 1
17. The HCP keeps information discussed confidentially <input type="checkbox"/> yes <input type="checkbox"/> no	311 6	17 4	0.08(0.02-0.31)*** 1	0.33( 0.03-0.58)** 1
18. Do you have language barrier with providers? <input type="checkbox"/> yes <input type="checkbox"/> no	12 307	4 17	6.02 (1.75-20.64)** 1	2.76 (1.61-12.44)* 1
24. Have you ever been treated for a psychiatric illness? <input type="checkbox"/> yes <input type="checkbox"/> no	44 267	8 13	3.73 (1.46-9.52)** 1	3.56 (1.16-10.93)* 1

\*\*\* Significant at  $p < 0.001$ , \*\* significant at  $p < 0.01$ , \* significant at  $p < 0.05$

#### **4.10 CONCLUSION**

The main contents included in this chapter are: socio-demographic data, health care facility and providers influence on adherence to ART, disease factors, psychosocial factors (family support and illness factors), HIV and ART knowledge, reasons for missing antiretroviral drugs, patient reported rate of adherence, overview of research findings, and finally, a conclusion with respect to the chapter.



## **CHAPTER 5**

### **DISCUSSIONS OF THE STUDY**

#### **5.1 INTRODUCTION**

This chapter presents a discussion based on the major findings presented in chapter 4. Findings that are discussed include demographic characteristics, healthcare facility and providers influence on adherence to ART, psychosocial factors (family support and illness factors), reasons for missing antiretroviral drugs, and patient reported rate of adherence.

From the study data there were a number of individual (socio-demographic), psychosocial, healthcare facility and providers (health care system) variables, which were significantly associated with adherence. These are young age, low level of education, being single, poor housing infrastructure (lack of electricity and pipe water), perception of difficult access to providers and lack of trust in information confidentiality in the facility, language barrier with providers, and past treatment history of psychiatric illness.

#### **5.2 DISCUSSION ON SOCIO-DEMOGRAPHIC DATA**

There were more females than males who participated in the study. Sixty-two percent (n=208) of the total respondents were females and this confirms the fact that more females than males are enrolled in care in this hospital. This may also confirm the fact that women have a higher HIV prevalence (1,9%) than men (1%) in Ethiopia (CSA 2012:231).

The respondents who participated in this study were aged from 18 to 51 years old and above. The majority of them were aged between 20 and 50. According to EDHS 2011, for women, HIV prevalence increases with age to a peak of 3.7% at the ages of age 30 to 34.

For men, HIV prevalence increases from 0% at the age of 15 to 19 to 3% at ages of 35 to 39 and drops thereafter (CSA 2012:234). In this study, 52% of the participants were

aged between 31 and 40, which have confirmed the national findings: Nationally, for both genders HIV prevalence is higher at ages 30 to 40 (CSA 2012:234).

This indicates that age is an important demographic factor that should be given due attention in designing important interventions for people living with HIV.

The study showed that the majority of the participants were married (43,3%) followed by single (23,4%); this is, however, against the national pattern. The EDHS documented that widowed and divorced respondents (12,2% and 5,2%, respectively) are much more likely to be HIV positive than those who are married and those who have never been married (CSA 2012:236). This finding raises a need for more effort to be geared towards partner testing and disclosure to avoid marital HIV infection in discordant couples and to fight stigma at home.

Younger ages, low level of education, being single and lack of pipe water and electricity, were found to be statistically significantly associated with non-adherence in this study. It has been shown that demographic factors are not consistently associated with adherence to ART (Fong et al 2003:133-138).

However, demographic factors are closely linked to socioeconomic status or livelihood, which encompasses access to resources such as food, electricity, pipe water, educational opportunities, housing, and health facilities (Rachlis et al 2011:1). The literature on livelihood and ART adherence is at its early stage (Rachlis et al 2011:6).

Education level and income were the two most frequently studied livelihood factors and the latter demonstrated a significant association with adherence. Education level is a determinant factor for self-efficacy, which is defined as the conviction that one can successfully execute a specific behaviour (Barclay, Hinkin, Castellon, Mason, Reinhard, Marion, Levine & Durvasula 2007:3). Self efficacy is in turn a positive determinant for adherence although some argue that educated patients might be busy and get no time to take their pills (Rachlis et al 2011:6).

A 2011 meta-analysis focused on ART programmes in resource-poor settings reported that when medications were provided free-of-charge, there was a higher probability of achieving adherence and undetectable viral loads compared to situations where

patients were required to pay for treatment (Ivers, Kendrick & Doucette 2005:217-224). Even in the availability of free drugs, however, the cost of transportation to go to the clinic can still be a barrier to adherence.

Patients who are sources of income choose either to feed their family or to spend the small money for transportation (Rachlis et al 2011:8). Food insecurity as a result of low income was also mentioned to be associated with decreased adherence to antiretroviral drugs in Africa. This may be as a result of patients' thinking that antiretroviral drugs need to be taken with food to avoid gastrointestinal upset, which may lead to poor adherence (Rachlis et al 2011:8).

Social factors such as marital status and having children can affect adherence possibly in two opposite ways: While the desire to care for families may be a strong motivator for patients to adhere, patients may fear to disclose to their sexual partner to avoid stigmatisation, discrimination, and potentially abandonment. The lack of family support because of failure to reveal HIV status can lead to poor adherence (Atkinson, Schönnesson, Williams & Timpson 2008:2; Rachlis et al 2011:8).

Tusiime et al (2008:208-209) said studies report conflicting evidence about the association between socio-demographic factors and adherence behaviour; when an association is found, the direction is towards lower levels of adherence with younger age, being single, non-white race/ethnicity, and lower income, which may be due to uncontrolled confounding by other factors.

The results from this study demonstrate that age, marital status, level of education and poor housing conditions have an effect on ART adherence. This could be due to significantly interacting with other variables, which possibly include whether a patient resides in an urban or a rural setting, has food insecurity, own a cell phone, what their reasons are for taking the first HIV test, and so forth, which this study failed to show but other studies did (Maqutu, Zewotir, North, Naidoo & Grobler 2010:6).

### **5.3 DISCUSSION ON HEALTHCARE FACILITY AND PROVIDERS INFLUENCE ON ADHERENCE TO ART**

This study demonstrates that perception of difficult access to providers, lack of trust in information confidentiality in the facility, and language barrier with providers, are associated with non-adherence to ART. This is consistent with a previously published study that reported that poor self-reported access to medical care is strongly associated with HIV stigma (Sayles, Wong, Kinsler, Martins & Cunningham 2009:1107). It could itself be as a result of the perceived discrimination and social inequities that are key to the development of stigma (Sayles et al 2009:1105) that is, PLWH who experience greater stigmatisation might perceive more difficulty accessing care because fear of rejection and discrimination (consequences of stigma) may lead them to perceive the healthcare setting as intolerant and inaccessible.

Sayles et al (2009:1105) further describe that mental health attenuates the association between stigma and suboptimal ART adherence, implying that the relationship between stigma and ART adherence is partially mediated by low mental health status. However, the interrelationship and pathways between stigma and other factors known to be associated with adherence such as social support, self-efficacy and attitudes toward medication need to be further delineated in future studies in order to identify targets for effective intervention programs.

### **5.4 DISCUSSION ON PSYCHOSOCIAL FACTORS (FAMILY SUPPORT AND ILLNESS FACTORS)**

While past history of treatment for psychiatric illness was significantly associated with adherence, depression was not specifically found to be significantly associated with adherence in this study. However, the literature demonstrates that depression is prevalent among persons with HIV infection and has been linked to suboptimal adherence to ART (Kacanek, Jacobson, Spiegelman, Wanke, Isaac & Wilson 2010:5; Walkup, Wei, Sambamoorthi & Crystal 2008: 1-2).

Kacanek et al (2010:5) state that although several cross sectional studies and a few longitudinal studies have found associations between depression and suboptimal adherence, the causal pathways relating depression to poor adherence remain unclear.

Kacanek et al (2010:5) further report: *A meta-analysis of depression and adherence to medical care regimens in general (not only HIV antiretroviral drugs) found that patients with depression had a three-fold higher odds of poor adherence and suggested possible mechanisms linking depression to poor adherence to medical treatments. Included in these possible mechanisms were the feeling of hopelessness, which often accompanies depression, social isolation, and an absence of social support.*

Since it is one of the modifiable predictors of adherence that could be targeted in interventions, awareness of depression among health professionals caring for HIV positive patients needs to be increased in order to intervene appropriately (Amberbir, Woldemichael, Getachew, Girma & Deribe 2008:7-8; Walkup et al 2008:6).

In this study, a significant number of patients did not disclose their HIV status to their family. Although family support was not significantly associated with adherence in the study, social support in general may enhance adherence, either directly in the form of reminders, financial help, and emotional backing, or indirectly by buffering the effect of those variables that might interfere with adherence, e.g. substance use, life's stresses, anxiety, and depression (Tiyou et al 2010:39; Lehavot, Huh, Walters, King, Andrasik & Simoni 2011:186-187).

## **5.5 DISCUSSION ON REASONS FOR MISSING ANTIRETROVIRAL DRUGS**

The reasons patients cited for missing ART doses in this study were similar to what is found by many others (Awel 2008:19-20; Maqutu et al 2010:118; Amberbir et al 2008:5) (figure 4.17). The most frequently given reasons were: simply forgetting and being too busy followed by being away from home and running out of pills.

This was consistent with the findings of many other studies as just cited. The rest of the reasons included: a change in daily routine, trying not to be noticed while taking pills, the burden of taking pills, fear of side effects, too many pills to take, feeling sick, feeling asleep, being depressed or overwhelmed, too many pill times and problems of taking pills with dietary instructions. The major reasons are one way or another, all associated with either forgetting to take their pills or forgetting/unable to attend their appointments for refill.

A 2006 large-scale meta-analysis of both quantitative and qualitative studies from developing and developed nations of patient-reported reasons for non-adherence found that important barriers to adherence are similar across multiple settings and heterogeneous countries and identified that fear of disclosure; forgetfulness; a lack of understanding of treatment benefits; complicated regimens; and being away from their medications were consistent barriers to adherence across developed and developing nations. More important to poor settings were issues of access, including financial constraints and an interruption of access to medicines (stock-outs) (Mills, Nachega, Bangsberg, Singh, Rachlis, Wu, Wilson, Buchan, Gill & Cooper 2006: 2039, 2056).

As mentioned in this study, patients have a range of reasons for failing to comply strictly with their regimens. These reasons should be assessed for each patient and patients be targeted with comprehensive individualised interventions employing behavioural educational strategies to improve ability to fit therapy in their own individual lifestyle and treatment cue training such as placing medication at a strategic location and using memory aids such as diaries, calendars and pillboxes are likely to impact forgetfulness (Horizons ... 2004:45; Federal HAPCO and Federal MOH 2007:77).

## **5.6 DISCUSSION ON PATIENT REPORTED RATE OF ADHERENCE**

In the study, the seven days (before the study), three days and one day adherence rate for the respondents was found to be 93,8%, 96,5% and 99,7%, respectively. This shows that adherence rate drops as the cumulative number of days on ART increases. However, it does not prove that adherence decreases the longer patients are on ART. To conclude this safely, patients should be monitored for their adherence over time.

The researcher measured ART adherence by self-report using structured interview questions that can be subject to overestimation, as patients tend to overstate their adherence to treatment. Other measures of adherence, such as pill counts, pharmacy records, electronic devices, or therapeutic drug monitoring were not available for the study. Even so, measuring adherence using patients' self-report can be easily replicated in most resource-limited settings including Ethiopia making it a good measure for comparison (Amberbir et al 2008: 5-7; Reda & Biadgilign 2012:2).

In the study, 93,8% of patients were adherent with >95% prescribed doses. This study found a better adherence level than previously reported from Ethiopia (Awel 2007:40; Tadios & Davey 2006:41) except a study by Amberbir et al (2008:7). It is comparable with or relatively higher than those reported in other African countries excluding Rwanda (Musiime, Muhairwe, Rutagengwa, Mutimura, Anastos, Hoover, Qihu, Munyazes, Emile, Uwineza & Cowan 2011:1), and much higher than that of North America.

According to Reda and Biadgilign (2012:2) pooled analysis, for North American studies adherence was 55% (95% CI 49% to 62%), while for African studies adherence was 77% (95% CI 68% to 85%). To see country specific data, in a study assessing factors associated with medication adherence in HIV-infected adults in Nigeria, overall adherence was 74% (Igwegbe, Ugboaja & Nwajiaku 2010:238).

A Rwandan study indicates that self-reported adherence to antiretroviral treatment 12 months after initiating therapy was 100% (354/354) in a cohort of HIV positive Rwandan women (Musiime et al 2011:1) while a study from Kenya reports 82% adherence (Wakibi, Ng'ang'a & Mbugua 2011:1). These data leave adherence rate of this study within the range of adherence rates of PLWH to ART in African settings. These data from other African settings and from this study suggest that patients of low socio-economic status are able to achieve excellent rates of adherence with access to routine medical care, subsidised or free ART and free laboratory monitoring (Amberbir et al 2008:7).

## **5.7 CONTRIBUTIONS OF THE STUDY**

The finding in this study suggests implications for research and practice. The contributions of the study are the following:

- Its findings could sensitise programme managers and policy makers to evaluate currently practiced strategies and to update them or even change them with new ones.
- The study has a room for further research as it has new questions arising from the discussion of the findings.

## **5.8 CONCLUSION**

The chapter presented discussion of study findings by using different literatures. The subheadings used under this chapter were introduction, discussion on socio-demographic data, discussion on healthcare facility and providers influence on adherence to ART, discussion on psychosocial factors (family support and illness factors), discussion on reasons for missing antiretroviral drugs, discussion on patient reported rate of adherence and finally the conclusion.



## **CHAPTER 6**

### **CONCLUSIONS, LIMITATIONS AND RECOMMENDATIONS**

#### **6.1 INTRODUCTION**

The aim of the study was to investigate factors that influence adherence to ART among adults at Nekemte Hospital in Ethiopia. This chapter presented conclusions based on results of a study to answer objectives formulated in Chapter 1 as follows:

- to quantify adherence rate among the study participants in the ART unit
- to identify factors that influence adherence

The chapter also presented some possible limitations of the study. The findings cited in Chapter 4 served as a basis for recommendations in this chapter to bring about better adherence and access to ART service in the future, especially for high-risk persons for non-adherence to ART, by tackling the factors affecting adherence to ART.

#### **6.2 CONCLUSIONS MADE FROM THIS STUDY**

- From the above discussion, the study concludes that adherence is multi-factorial and varies significantly by individual and care setting. Psychosocial factors were found to impact adherence and should be analysed in more detail by further studies. Three psychosocial factors were independently associated with poor adherence: the study found that patients perceiving poor access, and those perceiving problem in information confidentiality (and possibly experiencing stigmatisation), and having psychiatric morbidity (and possibly with less social support) are more likely to be non-adherent. Furthermore, individuals without electricity and those without pipe water supply, implying low income, are at risk for non-adherence.

- Using the identified reasons for non-adherence i.e., working on status disclosure to family/friend/community and hence having a treatment partner in the community, linking patients with financial constraints to community support networks, making ART accessible both geographically as well as personal access to providers, and providing facility reminders such as pill boxes are likely to further improve adherence. Lastly, early diagnosis and management of mental illnesses like depression needs special focus.
- The main reason identified in this study as reason for missing to take antiretroviral drugs was forgetfulness. A number of strategies have been proposed to improve memory to take antiretroviral drugs as prescribed, including electronic reminders, easier-to-follow regimens, medication under supervised settings, self-monitoring, counselling sessions and other strategies. However, some strategies to improve ART adherence require considerable resources, and adherence is typically not sustained after the intervention is withdrawn. An adherence strategy is needed to be both cost effective and has to account for patient outcome, development, and transmission of resistant strains of HIV at public health perspective.
- It is of concern that participants with perceived difficult access and confidentiality to care were less likely to be adherent, suggesting the need for sustained effort to emphasise better access to care and patient information confidentiality, which also helps to fight stigma.
- The adherence rate in this group of patients may be considered as success, adherence was 95% or greater for 93,8% of the patients. That means adherence was quite low in a small subset of patients, but the researcher believes there is a tremendous need to strengthen the existing qualities and keeping in mind the correlates identified in our study. Adherence has to be improved and monitored using multifaceted and repetitive interventions. Since adherence is a dynamic process and patient's behaviour can change over time, there is also a need to have a follow-up design, which could yield a more valid average measure of adherence as well as its determinants than a cross-sectional self-reported adherence assessment.

- Unless adherence is closely monitored, the dangers of non-adherence, especially drug resistance, may eliminate the only hope available to prolong survival of PLWH.
- Determinants like regimen, treatment knowledge, and disease status, found to be consistently associated with adherence in many studies were not found to be significantly associated with adherence in this study. The lack of significant association of regimen and treatment knowledge with adherence in the study needs to be rechecked with coverage of more institutions at different settings.

### **6.3 RECOMMENDATIONS**

Based on the results of this study it would be important to recommend that health care providers need to:

- Detect and manage depression among patients on ART with a multidisciplinary approach.
- Provide patients with information about their treatment plans.
- Keep the ART regimens as simple as possible.
- Involve patients in the treatment plan so that it fits into their daily routine.
- Ensure that communication with patients is clear during appointments in their ART units; this includes a need to assess and be aware of language barriers.

The health care system needs to:

- Improve patients' confidence, trust, and satisfaction with their relationship with healthcare providers, specifically, as these participants indicated, the system needs to assess patient information confidentiality gap and to thrive to bring perceived confidentiality for the patients.
- Eliminate the problem of access to the assistance and service patients need.
- Have a holistic approach to patients to the extent of assessing and dealing with their socio economic problems. For instance, the facility can look for PLWH organisations and try to find sites for community referral linkage where poor

patients can receive free services and financial support as well as being beneficiaries in income generating activities after they get seed money from these PLWH organisations. Emphasis should also be given to social supports that help to remind the patients to take their antiretroviral drugs.

The regional health bureau or the regional government needs to:

- Do broader observational prospective cohorts study of adherence with larger sample from both public and private hospitals so that more practical country specific adherence modifying strategies can be designed.
- Bring care closer to the patients by ART site expansion and increasing access to affordable transportation.
- Implement community-based livelihood development strategies targeted for PLWH.

#### **6.4 LIMITATIONS OF THE STUDY**

The researcher feels that this study has the following possible limitations that warrant mention:

First, as the study used cross-sectional design, it did not allow the researcher to establish a causal relationship between significantly associated variables and treatment adherence, as both variables were measured at the same time.

Secondly, “gold standard” for assessment of adherence does not exist, in this study adherence was measured using self-report; studies suggest self-report tends to overestimate adherence. Social desirability (projection of a positive image) could have induced an overestimation of adherence, but the researcher tried to minimise that by explaining to each patient that it was not always easy to adhere to medical treatments in general (Joubert & Ehrlich 2007:163).

The patients were also informed that their answers would not interfere with the care they received. Furthermore, structured self-report has been reliably associated with both objective measures of adherence and viral load.

The same limitation i.e. lacks of “gold standard” to assess depression, satisfaction, access, confidentiality, and so forth, made the researcher to shift to participants’ perceived assessment.

It would have been better to utilise a combination of methodologies (both quantitative and qualitative), which could have helped the study to cover wider concepts related to ART adherence and complement the findings in each method by the other.

Another limitation of the study is that the researcher was unable to corroborate patient self-report of adherence with CD4 cell responses because of financial and logistic barriers.

The other limitation that the study possibly has is that it did not segregate patients into cohorts of treatment (at least yearly cohort batches) according to the date of initiation of ART to see issues specific to every cohort. For example, forgetfulness to take pills, which was given by the majority of the respondents as a reason for missing pills, might be a problem of beginners of treatment until a certain period of time, which can improve later as patients stay more on treatment.

This could have been unreasonably concluded as a main reason if the majority of the participants were by chance those who started ART later than the rest. On the other hand, if again only a smaller number of the participants were by chance from those who were chronically on ART, they could develop “treatment fatigue”, which is not usually mentioned and appropriately addressed as a barrier both in the literature as well as by the HIV clinicians. As a result, patients were not tightly adherent to their medication but this variable, which can be more significant in them, could have been masked by other variables predominantly cited by those newer patients (Federal HAPCO and Federal Ministry of Health 2007:75).

However, the researcher believes that this was handled by applying random sampling procedure, which provides reassurance that the sample is representative of the population of interest so that inclusion of every year of cohort of patients in the study can be safely assumed.

Finally, since the study was performed only in one public hospital in Oromiya and since it was not a longitudinal or a follow-up study, the generalisability of our findings may be limited. Whether the study findings would differ in other subpopulations of PLWH remains to be determined. As adherence and combination therapy are dynamic and continuous process there is a need for more research. The study needs to be replicated with a more diverse sample and different settings to see if the issues related to adherence are similar across the HIV patient population.

## **6.5 CONCLUDING REMARKS**

This study has shown that good adherence is achievable in resource-limited settings, however, more has to be done to achieve adherence rate of 99% or even 100% reported elsewhere.

It is important to state that self-report used to measure adherence is not gold standard for adherence measurement, but it has been reported to be sufficient enough to assess adherence when pill count is not possible and electronic monitoring devices and indirect methods like serum antiretroviral drug level measurement are not feasible.

This approach of assessing multiple interrelated barriers within a population may prove to be very useful for the development of future adherence interventions, as an individual who faces multiple barriers can be offered more than a single intervention to intervene with non-adherence.

Future adherence research and interventions should not focus solely on medication adherence, but also the clinical outcome and quality of life of patients on ART. To know appointment adherence and patient retention is equally important because those lost-to-follow-up patients might have carried drug resistant HIV strains. Tracing this group of patients, returning them to care, and preventing treatment discontinuation by enhancing adherence counselling for a higher-risk population by developing simple and inexpensive strategies that focus on improving adherence follow-up needs as equal attention as those patients in care with regards to the task of achieving adherence to treatment.

It is also important to note the ideal study of adherence would be one that occurs across several phases and incorporates both qualitative and quantitative elements because many barriers to adherence can be addressed with patients through discussion and education regarding treatment benefits to health.

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# Annexure A: Approval from UNISA



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

Date of meeting: 7 September 2011                      Project No: 4325-293-1  
Project Title: Factors that influence adherence to ART among adults at Nekemte Referral Hospital in Ethiopia  
Researcher: Dr Amsalu Belew Zeleke  
Degree: Masters in Public Health                      Code: DIS4986  
Supervisor: Prof G Thupayagale-Tshweneagac  
Qualification: D Litt et Phil  
Joint Supervisor: -

**DECISION OF COMMITTEE**

Approved                       Conditionally Approved

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

  
**Prof MC Bezuidenhout**  
**ACADEMIC CHAIRPERSON: DEPARTMENT OF HEALTH STUDIES**

PLEASE QUOTE THE PROJECT NUMBER IN ALL ENQUIRIES

## Annexure B: Letter seeking consent from Nekemte Referral Hospital

Date May 10, 2012

To

The Medical Director

Nekemte Referral Hospital

Nekemte

Subject: Application for permission to conduct a study on adherence to ART in adult outpatients currently taking ART in the hospital

Dear Sir/Madam,

If I get permission of the hospital, I have a plan to conduct a study on adherence to ART and for this I have selected your hospital if it is the interest of the hospital. The study will be conducted in outpatients taking ART in the HIV care unit of the hospital. Questionnaire, pill count and patient record review will be the sources of data. Data will be collected by one medical doctor (who will be the supervisor) and four nurses trained on Basic ART. The study is aimed at improving knowledge and practice in initial and ongoing adherence counseling and support that help patients develop an understanding of their treatment and its challenges to cope with therapy and to adhere to treatment lifelong.

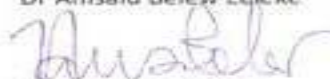
The study it will not pose any risk, neither will it have direct benefits to the participants. The clients will be briefed about the purpose of the study. Only willing patients will be involved after getting oral consent which will be documented. Confidentiality will be assured and maintained to the study participants throughout the study.

In the end, the results and recommendations of the study will be disseminated to the hospital for utilisation for its clients.

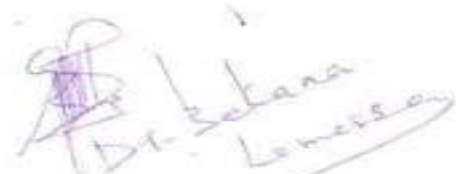
Thanking you in advance for the permission that the hospital will give me and the cooperation that I anticipate from the ART team, I am,

Cell phone +2519 20720570

Dr Amsalu Belew Zeleke

  
Principal Investigator



  
Dr. Bekana  
Lemessa

Annexure C: Letter of approval from Nekemte Referral Hospital

May 20, 2012

NEKEMTE REFERRAL HOSPITA

Ref. No 032-11/04

Date 18/10/04



Reference:

TO

Dr Amsalu Belew Zeleke

ICAP Ethiopia,

South west regional office

Nekemte

Mootummaa Naannoo Oromiyaatti  
Mana Yaalaa Naqamtee  
The Council of Oromiya  
Nekemte Hospital  
በክርምቲ ስዕል  
የብሔራዊ ማህተም ማዘጋጀት ህዝብ

SUBJECT: RESEARCH PERMIT FOR THE STUDY TITLE "FACTORS THAT INFLUENCE ADHERENCE TO ART AMONG ADULTS AT NEKEMTE REFERRAL HOSPITAL IN ETHIOPIA"

With reference to your application for a research permit for the above stated study at Nekemte Referral Hospital, the hospital management committee has discussed it and granted permission to conduct the above mentioned study. This approval is valid for a period of one month and two weeks as you requested, effective starting from June 1, 2012.

The research should be conducted as outlined in the approved proposal. Furthermore, you are kindly requested to submit at least one hard copy of the report to the hospital which can help us improve the quality of our service and hence the quality of life of our ART clients based on your recommendations out of the study.

Best Regards,



Dr Tamene Abera

Hospital Medical Director

## Annexure D: Questionnaire

The purpose of this questionnaire is to collect information on factors that affect your ability to take your antiretroviral medicines as prescribed; to assess how best to measure your adherence, and to develop strategies to assist you better with taking your medications exactly as prescribed.

Date \_\_\_\_\_

Interviewer Self

Both

Code no \_\_\_\_\_ How Administered?

1

2  3

---

### SECTION A: Socio-Demographic

#### 1. Sex:

Male  Female

#### 2. Age in years:

18-19  20-30  31-40  41-50  over 51

#### 3. Your level of education:

No education  Primary  Secondary  Tertiary

#### 4. Marital status:

Never married  Married (incl. de facto)  
 Separated  Divorced  Widow/widower

#### 5. Religion

Muslim  Orthodox  Protestant  Catholic  Other

#### 6. Do you live with family?

Yes  No

#### 7. How many people live in the house including you?

Less than 3  3 to 6  7 to 9  More than 10

#### 8. How many bedrooms are there in the house?

1  2  3  More than 3

#### 9. Is your water supply source from a pipe?

Yes  No

#### 10. Is there electricity in your house?

Yes  No



**11. Are you employed?**

Yes  No

**12. What is your average monthly income? (Include pension, public assistance, support from family/friends, etc.)**

Less than ETBR 200  ETBR 200-499  ETBR 500- 1000  
 ETBR 1000-1500  More than 1500 ETBR

**SECTION B: PATIENT-PROVIDER RELATIONSHIP AND CLINICAL SETTING**

**(Care factors)**

13. The HCP involves me as a partner in care  Yes  No

14. The HCP helps me to understand their care  Yes  No

15. The HCP supports decisions  Yes  No

16. The HCP is accessible when I need her/him  Yes  No

17. The HCP keeps information discussed confidentially  Yes  No

18. Do you have language barrier with providers  Yes  No

**SECTION C: DISEASE CHARACTERISTICS (Disease factors)**

**19. How long has it been since you were diagnosed with HIV infection?**

1 year  1-3 years  4-6 years  more than 6 years

**20. Do you have HIV-related treatment currently?**

Yes  No

**21. Have you had hospitalisations over the last one year?**

Yes  No

**SECTION D: PSYCHOSOCIAL HISTORY (Family support and illness factors)**

**22. Is your family aware of your HIV status?**

Yes  No  Don't know

**23. If Yes and you are taking antiretroviral medication do they help you take your medication?**

A lot  Somewhat  A little  Never  Not applicable

**24. Have you ever been treated for a psychiatric illness?**

Yes  No

**25. In the past four (4) weeks, have you been unable to cope with all the things you need to do?**

Never  Sometimes  Often  Always

**26. In the past four (4) weeks, have you felt down (depressed)?**

Never  Sometimes  Often  Always

**27. If you are feeling down (depressed), is there someone you can talk to?**

Yes  No

**28. Do you use substance to relieve stress or when you have a problem?**

Yes  No

## **SECTION E: HIV and HAART Knowledge**

**29. Do you understand ways of HIV transmission**

Yes  No  Don't know

**If Yes, please explain:**

---

---

**It will be marked by a physician as:**

Very good  Good  Fair  Poor

**30. Do you understand the difference between HIV and AIDS?**

Yes  No  Don't know

**If Yes, please explain:**

---

---

**It will be marked by a physician as:**

Very good  Good  Fair  Poor

**31. Do you know what a CD4+ T cell count measures?**

Yes  No  Don't know

**If Yes, please explain:**

---

---

**It will be marked by a physician as:**

Very good  Good  Fair  Poor

**32. Do you know how antiretrovirals work?**

Yes  No  Don't know

**If Yes, please**

**explain:**

---

---

**It will be marked by a physician as:**

Very good  Good  Fair  Poor

**The following statements are attempts to capture your knowledge and beliefs about taking antiretroviral medicines.**

**33. I have to take them for the rest of my life.**

Strongly Agree  Agree  Don't know  Disagree  Strongly Disagree

**34. Some antiretrovirals have to be taken on an empty stomach and others may be taken with food.**

Strongly Agree  Agree  Don't know  Disagree  Strongly Disagree

**35. The time at which the medication is taken will influence its effectiveness.**

Strongly Agree  Agree  Don't know  Disagree  Strongly Disagree

**36. Missing doses and/or taking them late or incorrectly will determine if the treatment works.**

Strongly Agree  Agree  Don't know  Disagree  Strongly Disagree

**37. For my medicine to work best, I should not miss a dose, nor take it late or incorrectly.**

Strongly Agree  Agree  Don't know  Disagree  Strongly Disagree

**38. Drug resistance develops when my antiretrovirals are missed and/or taken late or incorrectly.**

Strongly Agree  Agree  Don't know  Disagree  Strongly Disagree

## **SECTION F: Treatment Regimen Adherence Assessment**

**(Note: IF YOU TOOK ONLY A PORTION OF A DOSE, OR TOOK WITH DELAY OF  $\geq 2$  HRS ON ONE OR MORE OF THESE DAYS, PLEASE REPORT THE DOSE(S) AS BEING MISSED.)**

**39. How many doses should you take per day?**

One  Two

**40. Did you miss  $\geq$ one dose in last 24 hrs?**

Yes  No

**41. Did you miss  $\geq$ one dose in the last 72 hours?**

Yes  No

**42. Did you miss  $\geq$ one dose over the last seven days?**

Yes  No

## SECTION G: Reasons for missing ARVs

People may miss taking their medications for various reasons. Here is a list of possible reasons why you may miss taking your medications. Don't worry about telling us that you don't take all your pills. We need to know what is really happening, not what you think we "want to hear."

How often have you missed taking your medications because you: *(Circle one response for each question.)*

	Never	Rarely	Sometimes	Often
43. Were away from home?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
44. Were busy with other things?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
45. Simply forgot?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
46. Had too many pills to take?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
47. Too many times to take the pills	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
48. Wanted to avoid side effects?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
	Never	Rarely	Sometimes	Often
49. Did not want others to notice you taking medication?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
50. Had a change in daily routine?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
51. Fell asleep/slept through dose time?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
52. Felt sick or ill?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
53. Felt depressed/overwhelmed?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
54. Had problems taking pills with instructions (With meals, empty stomach, etc.)?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
55. Ran out of pills?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

**Thank you very much for participating in this study and completing these questions!**

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