

**DETERMINANT FACTORS AFFECTING ADHERENCE TO ANTIRETROVIRAL  
THERAPY AMONG HIV INFECTED PATIENTS IN ADDIS ABABA**

by

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submitted in fulfillment of the requirements

for the degree of

**MASTER OF PUBLIC HEALTH**

in the subject

**HEALTH STUDIES**

at the

**UNIVERSITY OF SOUTH AFRICA**

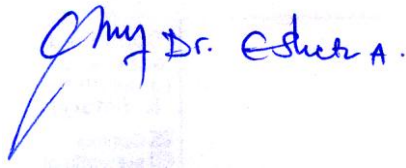
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Declaration

I declare that **DETERMINANT FACTORS AFFECTING ADHERENCE TO ANTIRETROVIRAL THERAPY AMONG HIV INFECTED PATIENTS IN ADDIS ABABA** 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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30, November 2013

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# **DETERMINANT FACTORS AFFECTING ADHERENCE TO ANTIRETROVIRAL THERAPY AMONG HIV INFECTED PATIENTS IN ADDIS ABABA**

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## **ABSTRACT**

The purpose of this study was to explore and describe the determinant factors affecting adherence to antiretroviral therapy among HIV infected patients in Addis Ababa, Ethiopia. A cross-sectional study design was used and data were collected by interviewing 290 study participants from two health facilities using structured questionnaire. The research finding revealed 80.0% of the study participants had optimal combined adherence to dose, schedule and dietary instructions in the past three days. And, the non adherence rate was 20.0%. In multivariate analysis only WHO clinical stage, change of ARV medication, knowledge about HIV disease and ART, and use of reminders were found to be independently associated with adherence to antiretroviral therapy. The most common reasons for missing HIV medications in the past one month were forgetfulness (35.1%), being busy with other things (17.5%), and running out of pills (10.5%). Adherence improving interventions should be emphasized to address multi-faceted problems. This study recommends setting of convenient appointment schedule, disclosure of one's HIV status, maintaining confidentiality of patient-related information, enhancing patient-provider relationship, use of reminders including SMS text messages, and engagement of PLHIV in adherence improving interventions through peer support, and providing regular health education to the PLHIV to improve adherence of patients to ART.

### **Key concepts:**

Antiretroviral therapy, adherence, determinant factors, HIV infection, Adults, Addis Ababa

## ACKNOWLEDGEMENTS

I would like to praise and thank the Almighty God for giving me the strength, patience and endurance to complete this dissertation. This work would not have been finalized without the support and contribution of the people around me. Thus, I would like to extend my deepest gratitude to the following individuals for their respective contribution:

- A special thanks goes to my supervisor, Dr. E S Seloilwe, for taking her valuable time to assist me in working the document, close support, constructive feedback and guidance
- Dr. Manuel Kassaye, Dr. Endalkachew Melese and Dr. Tegbar Yigzaw for their professional support to review and enrich the data collection instrument
- Mr. Fitalew Gebreyesus, for his technical support throughout preparation of data collection instrument, data entry and analysis
- Ms. Fikirte and Ms. Tsega, data collectors, for their commitment and effort to properly collect the data
- Dr. Animaw Anteneh, for professionally editing the document
- The ART clinic staffs of the health facilities for their facilitation during data collection
- The ethical committees of UNISA and Addis Ababa city administration health bureau for their ethical review and approval of the study
- Addis Ababa city administration health bureau and management of Zewditu memorial hospital and Bole 17 health center for giving me the permission to conduct the study.
- Last but not least, my wife and daughter for their understanding, closer support and encouragement during the entire dissertation work

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**List of abbreviations**

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AACTG	Adult AIDS Clinical Trial Group
AAHB	Addis Ababa Health Bureau
ABC	Abacavir
AIDS	Acquired Immuno-deficiency Syndrome
ARR	Adjusted relative risk
ART	Antiretroviral therapy
ARV	Antiretroviral
AZT	Azidothymidine
CD4	Cluster Differentiation T-lymphocyte
CI	Confidence Interval
D4T	Stavudine
EDM	Electronic Drug Monitoring
EFV	Efavirenz
FHAPCO	Federal HIV/AIDS Prevention and Control Office
FMOH	Federal Ministry of Health
HIV	Human Immuno-deficiency Virus
LW-IMB-AAQ	Life Windows Information- Motivation -Behavioural Skills ART Adherence Questionnaire
MEM	Medication Event Monitoring
MPR	Medication Possession Ratio
NNRTI	Non-nucleoside Reverse Transcriptase Inhibitor

NRTI	Nucleoside Reverse Transcriptase
NVP	Nevirapine
PEPFAR	President's Emergency Plan For AIDS Relief
PI	Protease Inhibitor
PLHIV	People Living with HIV
SNNPR	Southern Nation Nationalities and Peoples Region
SPSS	Statistical Package for Social Sciences
SRA	Self Report Adherence
SSA	Sub-Saharan Africa
3TC	Lamivudine
TDF	Tenofovir
UNAIDS	United Nations program on HIV/AIDS
UNICEF	United Nations International Children's Emergency Fund
UNISA	University of South Africa
WHO	World Health Organization
ZDV	Zidovudine

**List of Annexures**

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Annexure A	Ethical clearance letter from UNISA
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## CHAPTER 1

### ORIENTATION TO THE STUDY

#### 1.1 INTRODUCTION

This chapter of the study provides the general overview of the research problem, research purpose and objectives, significance of the study, demarcation of field of study, foundations of the study, research design and method, scope and limitation of the study, and ethical considerations.

##### 1.1.1 Global status of HIV/AIDS epidemic

The emergence of the HIV epidemic is one of the biggest public health challenges the world has ever seen in recent history. In the last three decades HIV has spread rapidly and affected all sectors of society: young people and adults, men and women, and the rich and the poor (FHAPCO 2012:1). Globally, a total of 35.3 (32.2-38.8) million people were estimated to be living with HIV in 2012. This increase was partly related from the increased number of people receiving life-saving antiretroviral therapy. During the year, around 2.3 (1.9-2.7) million new HIV infections occurred, showing a 33% decline in the number of new infections from 3.4 (3.1–3.7) million in 2001. At the same time the number of AIDS deaths is also declining with 1.6 (1.4–1.9) million AIDS deaths in 2012, down from 2.3 (2.1–2.6) million in 2005 (UNAIDS 2013:4). The decline in mortality has been related to the increased availability of antiretroviral therapy, as well as care and support, to people living with HIV, particularly in middle- and low-income countries. Besides, it results from the decreasing tendency in the incidence of HIV infection starting in the late 1990s. The effects of antiretroviral therapy are by large evident in Sub-Saharan Africa, where an estimated 320,000 (or 20%) HIV infected people died of AIDS-related causes in 2009 than in 2004, when antiretroviral therapy began to be dramatically expanded (UNAIDS 2010:19).

##### 1.1.2 HIV/AIDS epidemic in Sub-Saharan Africa

Sub-Saharan Africa continues to bear a disproportionate share of the global HIV burden. Recent reports indicated that about 68% of all people living with HIV resided in Sub-Saharan Africa in mid-2010. The total number of people living with HIV in sub-Saharan

Africa increased to 22.9 million in 2010 which was 12% more than in 2001. Reports indicate that more women than men are living with HIV in 2010, in which women comprised 59% of the people living with HIV in the region (WHO/UNAIDS/UNICEF 2011:24). Although the epidemics seem to vary considerably in different parts of the continent; HIV/AIDS severely affected the southern Africa countries (UNAIDS 2010:28).

In general, the HIV incidence rate in SSA seems to decline progressively comparing to the earlier period. Reports indicated only 1.9 million people were HIV infected in 2010 which was 16% fewer than the estimated 2.2 million people newly infected with HIV in 2001 and 27% fewer than the annual number of people newly infected between 1996 and 1998, when the incidence of HIV in sub-Saharan Africa peaked overall (WHO/UNAIDS/UNICEF 2011:11). This trend reflects a combination of factors, including the impact of HIV prevention efforts and the natural course of HIV epidemics (UNAIDS 2010:16). However, still enormous effort and needs required to further curb the incidence of HIV and its public health impact in the future especially in SSA.

With regards to the mortality, AIDS has claimed the lives of a large number of nations in Sub-Saharan Africa since 1998. Data showed that the estimated number of people dying from AIDS related illnesses was 1.2 million in 2010 which was 29% fewer than in 2005. The number of people dying from AIDS-related causes has steadily decreased due to wider availability of free antiretroviral therapy in the region (WHO/UNAIDS/UNICEF 2011:25).

### **1.1.3 HIV/AIDS epidemic in Ethiopia**

Ethiopia is one of the countries significantly affected by HIV and AIDS epidemic in Sub-Saharan Africa. HIV infection was initially recognized in the early 1980s with the first two AIDS cases reported in 1986. Since then, the epidemic has rapidly spread throughout the country and peaked in the mid-1990s (FHAPCO/FMOH 2010:2). According to HIV/AIDS estimates and projections in Ethiopia, the national adult HIV prevalence was estimated at 1.3% in 2012. This revealed that around 759,268 people were estimated to be living with HIV in the country. For the same period, there were an estimated 41,444 deaths occurred due to AIDS in 2012 (HIV/AIDS estimates & projections... 2013). The number of AIDS-

related deaths would have been much higher had it not been for the free Anti-Retroviral Therapy (ART) program which has been scaled-up in an accelerated manner since 2005. With the current status, it is evident that HIV and AIDS remains a formidable development challenge to the country (FHAPCO/FMOH 2010:2).

Similar to other SSA countries, the epidemic tends to be heterogeneous. There has been wide variation in HIV prevalence among different administrative regions, and between urban and rural settings. For instance, according to the Ethiopian Demographic and Health Surveys HIV prevalence in the country ranges from 0.9% in SNNPR and 1.0% in Oromiya region to 5.2% in Addis Ababa and 6.5% in Gambella region in 2011 (FHAPCO 2012:14).

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

### **1.2.1 The source of the research problem**

Free antiretroviral treatment has been provided to people living with HIV in many of the health facilities in Ethiopia since 2005. The number of patients receiving ART has remarkably increased from time to time with rapid scale up of ART program throughout the country. It has been emphasized that for patients on antiretroviral therapy to benefit maximally at least 95% of adherence to their prescribed medications needs to be achieved. This indicates that adherence of patients is very crucial element in the scale up and implementation of ART program in resource limited settings like Ethiopia. In a routine clinical practice of ART clinics in Ethiopia maintaining high level of adherence to antiretroviral treatment has been a challenge to health care providers as well as the ART program. Besides, in many areas of the country the number of lost to follow up patients is high in the health facilities and it is commonly observed that patients do not adhere to their prescribed antiretroviral medications for different reasons. According to the report of FHAPCO, the total number of ever started clients on antiretroviral treatment had reached to 52,585 in Addis Ababa by the end of February 2010. Among these 32,279 clients were found to be currently receiving antiretroviral treatment (Monthly HIV care and ART update 2010). The level of adherence to antiretroviral therapy of HIV infected patients and determinant factors affecting their adherence have not been well studied in health facilities in Addis Ababa.

## **1.2.2 Background of the research problem**

With the introduction of ARV drugs, AIDS has been changed in to a treatable chronic disease. Even in a resource constrained setting with increasing people with AIDS accessing services, a decline in death rates has become clearly visible. In Ethiopia, the public health approach has been an overarching principle of the ART program which is actually recommended by WHO for resource-poor settings. By this approach, large numbers of people has been able to access ART and survival is maximized (FMOH 2008:46-47). Free access to antiretroviral therapy was launched in Ethiopia in January 2005 in hospitals and rapidly expanded to the health centres in 2006 (FMOH 2007:10). In order to ensure universal access great effort has been made in decentralization of comprehensive HIV care and treatment services including antiretroviral therapy to hospitals and health centres throughout the country. However, with rapid expansion of ART service the issue of adherence of patients has increasingly become a serious challenge.

### **1.2.2.1 Adherence to ART**

The WHO (2006:78) states that adherence to ART has been recognized as an essential component of individual and programmatic treatment success. Higher level of adherence greater than 95% is necessary to get the best outcome out of antiretroviral treatment. Studies on drug adherence in the developed world demonstrated that higher levels of drug adherence are associated with improved virological, immunological and clinical outcomes. Adherence to antiretroviral therapy has also been documented as the second strongest predictor of progression to AIDS and death, after CD4 count in PLHIV receiving treatment (Machtinger & Bangsberg 2006). Nonetheless, adherence creates a special challenge and requires commitment from the patient and the health care team since HIV treatment is a lifelong endeavour and patients may be initiated on treatment while they are healthy and even they get better with treatment (Panel on antiretroviral guideline... 2009:111).

Although near perfect adherence is required for better and long term clinical benefits, incomplete adherence prevails in all groups of treated individuals. The average rate of adherence to ART remains approximately 70% (Machtinger & Bangsberg 2006). The concern of suboptimal adherence especially was recognized as a major obstacle to scale up of antiretroviral therapy in resource limited settings due to the risk of development of drug resistant strains and transmission to the population (Sarna, Pujari, Sengar, Garg, Gupta & Van Dam 2008:28-29). The continuity of HIV treatment is also emphasized in



terms of maximizing the efficacy, extending the period patients spend on the first-line ART regimen, and reduce the risk of developing drug resistance and treatment failure (Nakanjako, Colebunders, Coutinho & Kanya 2009:185-186). For instance, since the inception of large scale ART access early in this decade, ART programs in Africa have retained about 60% of their patients at the end of two years, with loss to follow-up as a major cause of attrition, followed by death. The percentage of loss to follow-up varies widely across programs and ranges from 3.7 to 44% in resource limited settings (Nakanjako et al 2009:185). Therefore, greater attention should be given to ensure improved patient retention in ART programs as well as enhancing their adherence behaviour for ultimate benefit of the population in general and HIV infected patients in particular.

### ***1.2.2.2 Factors affecting adherence***

A number of factors have been identified to be associated with non adherence to ART. The factors associated with medication adherence are categorized in to five: patient related variables, treatment related factors, disease characteristic, patient-provider relationship and clinical setting. Understanding these factors help to identify adherence at risk individuals as early as possible and inform the development of interventions to improve adherence (Machtinger & Bangsberg 2006).

Various studies have been conducted about adherence of patients to ART both in developed and developing countries. In the meta-analysis of adherence to antiretroviral therapy in Sub-Saharan Africa and North America indicated a pooled estimate of 55% of the populations in North America and 77% of the populations in Africa found to achieve adequate levels of adherence (Mills, Nachega, Buchan, Orbiniski, Attaran, Singh, Rachlis, Wu, Cooper, Thabane, Wilson, Guyatt & Bangsberg 2006a:679). In Ethiopia there have been few studies conducted to assess the magnitude of adherence to ART and its barriers. The level of adherence to ART seems to vary across different settings and contexts. The literature review section discussed the findings of the studies in different contexts in detail. There have been limited studies conducted on the magnitude of adherence and determinant factors that affect adherence to antiretroviral therapy in Adult patients in Addis Ababa.

### **1.2.3 Statement of the problem**

Adherence to antiretroviral therapy has been found as a major challenge in the treatment of HIV infected patients both in developed and developing countries. The rate of adherence of patients to ART varies in different settings. A meta-analysis of adherence levels found that a pooled estimate of only 77 percent of people taking antiretroviral medications in sub-Saharan Africa adhered to the regimen (Mills et al 2006a:679). Studies suggested that sub-optimal adherence to antiretroviral therapy will lead to increased risk of drug resistance, treatment failure and clinical deterioration with increased risk of death (Enriquez & Mckinsey 2011:46). Adherence of patients may be affected by various factors as mentioned in the literature. People living with HIV on antiretroviral therapy in Ethiopia may also suffer from multiple factors that could compromise their adherence as in other resource limited settings. There have been limited studies conducted in Addis Ababa to reveal the magnitude of adherence of HIV infected adult patients receiving antiretroviral therapy and determinant factors that could influence their adherence. Besides, the variation in the level of adherence overtime may necessitate evaluating about adherence of patients periodically in order to inform adherence interventions. In light of this, this particular study was conducted to investigate the determinant factors affecting adherence to antiretroviral therapy among adult patients infected with HIV in Addis Ababa.

## **1.3 AIM OF THE STUDY**

The aim of this study was to contribute to existing body of knowledge with regard to the magnitude of adherence of HIV infected adult patients to antiretroviral treatment and determinant factors affecting adherence in the context of Ethiopian setting.

### **1.3.1 Research purpose**

The purpose of this study was to explore and describe the determinant factors affecting adherence to antiretroviral therapy among HIV infected adult patients in Addis Ababa, Ethiopia.

### **1.3.2 Research objectives**

The objectives of the study were to:

- describe the level of adherence of HIV infected adult patients to antiretroviral therapy in Addis Ababa;

- explore the determinant factors that could affect patients' adherence to their antiretroviral therapy;
- identify the association of socio-demographic and other patient related factors with the level of adherence; and
- recommend appropriate interventions with regards to ways of improving adherence of patients based on the research finding.

#### **1.4 SIGNIFICANCE OF THE STUDY**

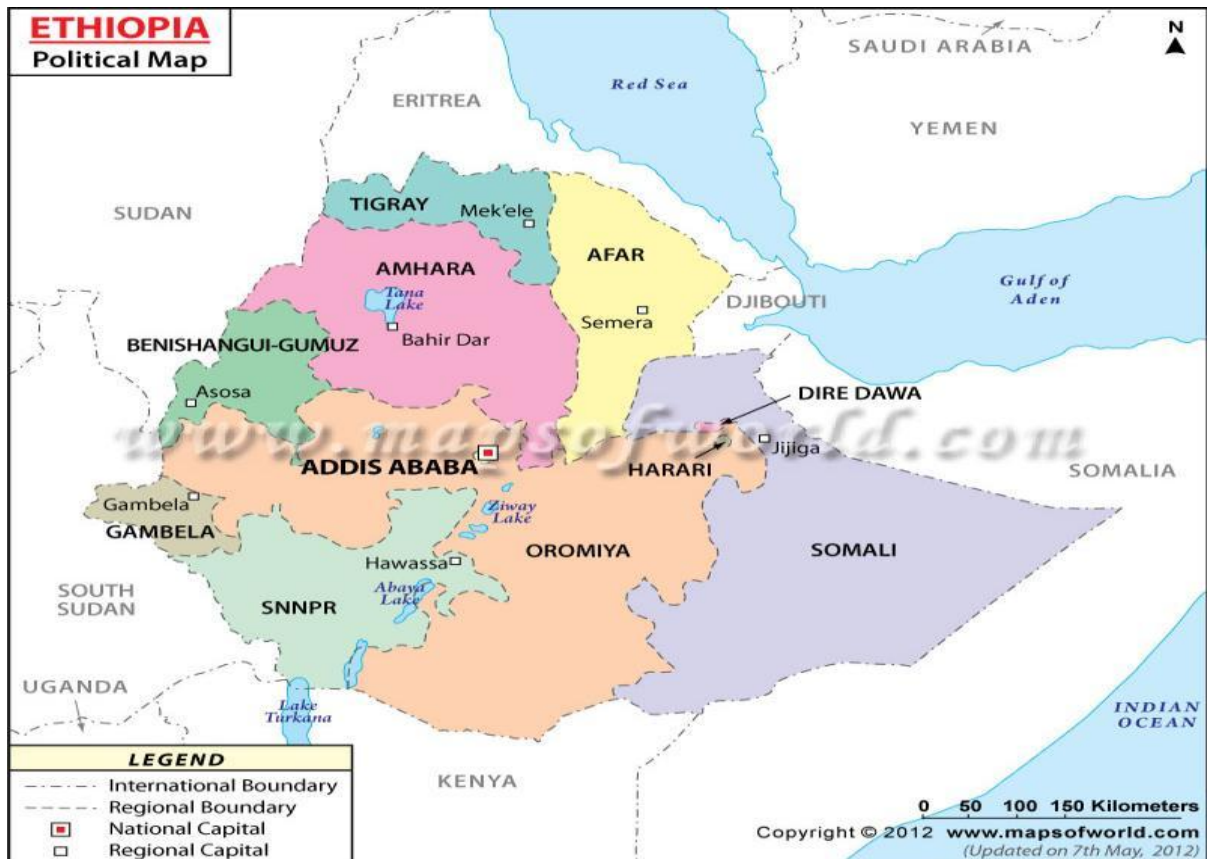
Different studies in African context indicated that there is a deficit in the level of adherence of patients to ART and multiple factors have been mentioned to contribute to the existing gap. This study provides knowledge on the level of adherence of HIV infected adult patients and understand the potential barriers to optimal adherence in Ethiopian context. Moreover, it provided important information with regard to aspects of adherence and forwarded recommendations to health care providers, health facilities and policy makers in enhancing the implementation of ART program and development of evidenced-based interventions to improve adherence to antiretroviral therapy. This study benefits the clients directly or indirectly through provision of appropriate and relevant information to the patients and their health care providers about the pervasiveness of non adherence and contribute to help them understand the need for patients to play active role in achieving the maximum required adherence level with due emphasis on the focus areas of improving adherence.

#### **1.5 DEMARCATION OF FIELD OF STUDY**

The research was conducted in Addis Ababa, which is a capital city of Ethiopia. Ethiopia is the tenth largest country in Africa, bordered by Eritrea in the north and northeast, by Djibouti and Somalia on the east, by Kenya in the south, and by Sudan in the west and southwest. It is a country with great geographical diversity and its topography shows a variety of contrasts ranging from high peaks of 4,550m above sea level to a low depression of 110m below sea level (FMOH 2010:1).

The Federal Democratic Republic of Ethiopia is composed of nine Regional States: Tigray, Afar, Amhara, Oromia, Somali, Southern Nation Nationalities and Peoples Region (SNNPR), Benishangul-Gumuz, Gambella, and Harari; and two City Administrations

council of Dire Dawa and Addis Ababa (FMOH 2010:2). The administrative regions of Ethiopia are clearly demarcated in the following map.



(Source: Adapted from: <http://www.mapsofworld.com> )

**Figure 1.1 Map of administrative regions of Ethiopia**

According to the projections from the 2007 population and housing census the total population of Ethiopia for the year 2010 is estimated to be 79.8 million. The country is among the least urbanized countries in the world with 83.6% of the total population living in rural areas whilst 16.4% living in urban areas. And, Addis Ababa which is the largest city in the country estimated to have a total population of 2.7 million, accounting for nearly 4% of the entire population (FMOH 2010:1). The pyramidal age structure of the population has remained predominately young with 44% under the age of 15 years, and over half (52%) of the population lies in the age group of 15 and 65 years. The population in the age group of over 65 years accounts for only 3% of the total. While the sex ratio between male and female is almost equal, women in the reproductive age group constitute 24% of the population (FMOH 2010:1).

## **1.6 DEFINITIONS OF TERMS**

### **1.6.1 Adherence**

Adherence is defined 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). In the context of this study optimal adherence to antiretroviral therapy refers to taking at least 95% of ARV medications at appropriate schedule and in accordance with instructions of dietary requirement in the past three days as prescribed by health care providers. While, sub optimal adherence to antiretroviral therapy refers to taking less than 95% of prescribed ART medications by people living with HIV/AIDS and/or not taking the medications at the right time and/or not following instructions to dietary requirements provided by health care providers in the past three days.

### **1.6.2 Highly active antiretroviral therapy (HAART)**

It refers to the complex medical regimens of therapies directed against HIV that are likely to stop its replication and mutation (Bartlett & Finkbeiner 2006:349). In the context of the study the HAART entails a combination of ARV drug regimen used to treat patients infected with HIV based on the Ethiopian national guideline recommendations.

### **1.6.3 Determinant factors**

It refers to correlates and predictors of adherence and non adherence. These include aspects of the complexity and duration of treatment, characteristics of the illness, iatrogenic effects of treatment, costs of treatment, and characteristics of health service provision, interaction between practitioner and patient, and socio-demographic variables (WHO 2003:137). In the context of this study the determinant factors referred to those inter-connected patient related variables, treatment related factors, disease characteristics, aspects of patient-provider relationship and clinical setting that may affect the adherence of HIV infected adult patients receiving antiretroviral therapy.

## **1.7 FOUNDATIONS OF THE STUDY**

### **1.7.1 Metatheoretical assumptions**

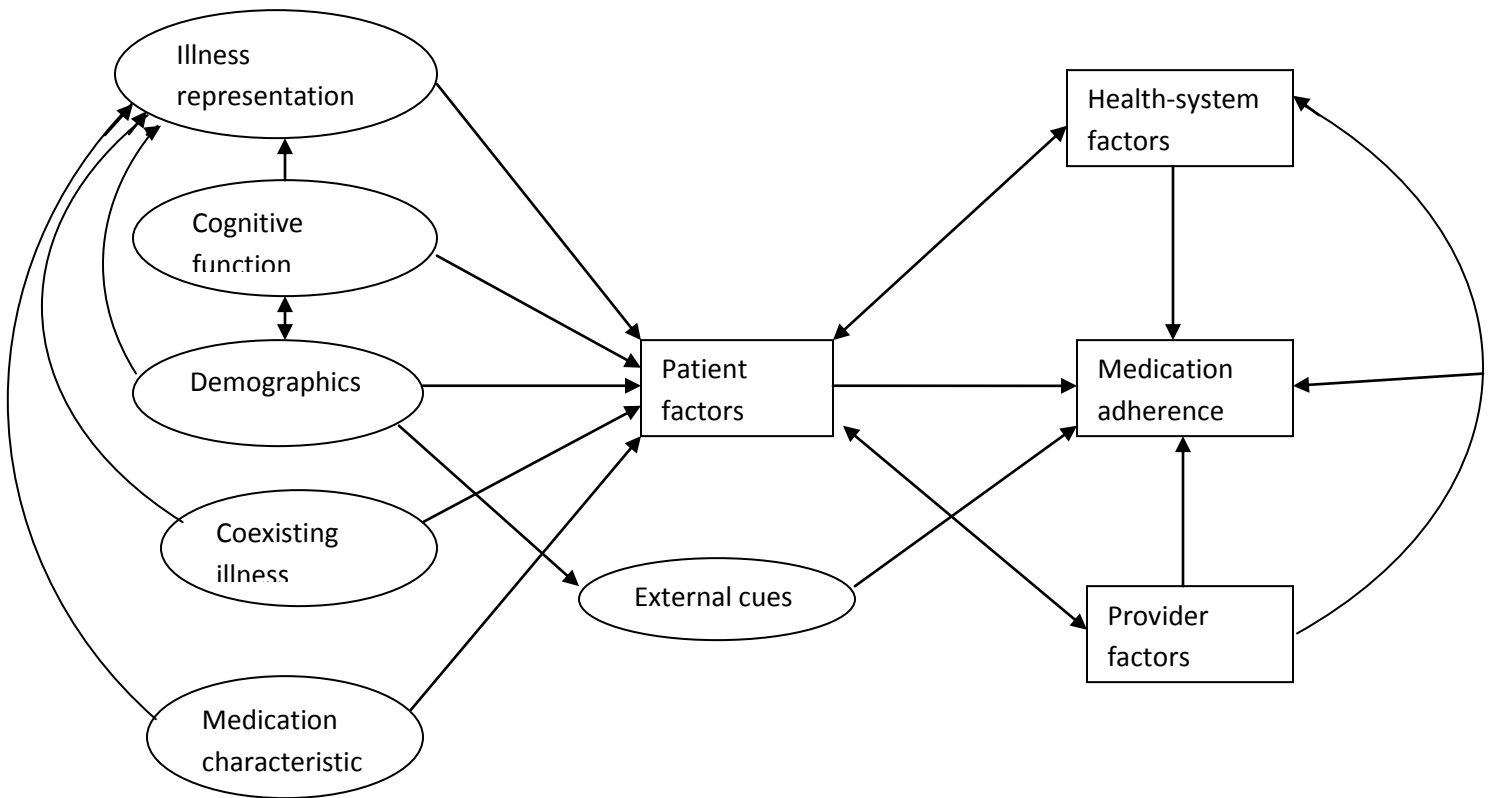
The researcher opted to conduct the study under the metatheoretical assumptions of positivism. The assumption of positivism is that there is a reality out there that can be studied and known. It values objectivity and attempt to hold personal beliefs and biases in check to avoid contaminating the phenomena under study. This scientific approach involves using orderly, disciplined procedures with tight controls of the research situation to test researchers' hunches about the phenomena being studied and relationships among them (Polit & Beck 2012:12).

The researcher conducted the study with an assumption that all HIV infected adult patients taking antiretroviral therapy are not able to achieve >95% adherence level in resource limited settings like Ethiopia. Various factors have been mentioned to interfere with proper adherence of patients to their medications. Thus, this study empirically measured the level of adherence and explored the determinant factors affecting adherence of HIV infected patients receiving antiretroviral treatment.

### **1.7.2 The conceptual framework**

A framework is the overall conceptual underpinnings of a study. If a study is based on a theory, the framework is referred to as the theoretical framework; while a study that has its roots in a specified conceptual model, the framework is often called the conceptual framework although the terms conceptual framework and theoretical framework are frequently used interchangeably (Polit & Beck 2012:128).

The factors associated with medication adherence are commonly divided into five intersecting categories. These include patient related variables, factors related to treatment regimen, disease characteristic, patient-provider relationship and clinical setting (Machtinger & Bangsberg 2006). In view of these inter-related factors the researcher adopted a conceptual framework developed by Gellad, Grenard and McGlynn (2009:5-6) for reviewing barriers to medication adherence. The conceptual framework helped to guide the literature review and the accomplishment of the research. The model constitutes the interaction of patient related factors, health system related factors and providers factors to influence the adherence behaviour of patients. The conceptual framework of the study was illustrated in the diagram depicted below.



**Figure 1.2 Conceptual framework of the study**

(Source: Adapted from Gellad et al (2009:6))

*Patient Factors:* Patients are influenced by each of the following factors as demonstrated in the above figure. Illness representation includes important elements of health beliefs, including beliefs about medications (both positive and negative) and knowledge about illness and treatment.

Cognitive function includes comprehension and memory. Demographics include age, gender, and ethnicity, as well as health literacy, and unstable living situations. Coexisting illness includes medical and psychiatric conditions, as well as alcohol use and smoking. Medication characteristics include regimen complexity, number of medications, and side-effect profiles (Gellad et al 2009:5).

*Health-System Factors:* In addition to cost (specifically, the effect of cost-sharing and out-of-pocket costs on patient adherence), health-system factors include formularies, prior-authorization requirements and benefit caps, fragmentation of care, and access to care (Gellad et al 2009:6).

*Provider Factors:* These include patient-provider trust and satisfaction; time spent discussing medications, and other communication issues (Gellad et al 2009:6). Also confidentiality issue and support in helping patients in taking their medications was also addressed.

The determinant factors that influence adherence of patients were discussed in detail in the literature review section.

## **1.8 RESEARCH DESIGN AND METHOD**

### **1.8.1 Research design**

According to Joubert and Ehrlich (2007:77) a study design refers to the structured approach followed by researchers to answer a particular research question. It has been called the 'architecture' of the study, because the choice of the study design determines how we sample the population, collect measurements and analyse the data. Burns and Grove (2005:40) also describes a research design as a blue print for the conduct of a study that maximizes control over other factors that could interfere with the study's desired outcome. There are numerous types of research design that are appropriate for the different types of research projects. The choice of which design to apply depends on the nature of the problems posed by the research aims. Each type of research design has a range of research methods that are commonly used to collect and analyse the type of data that is generated by the investigations (Walliman 2011:9).

The researcher followed an observational, analytic, cross-sectional study design to conduct this particular study.

#### **1.8.1.1 Quantitative study**

Quantitative research is a formal, objective, systematic process in which numerical data are used to describe variables, examine relationships among variables, and determine cause and effect interactions between variables (Burns & Grove 2005:747).

Fouché and Delport in De Vos et al (2005:73) also describe quantitative approach as follow:



- The researcher's role is that of an objective observer whose involvement with the phenomena being studied is limited to what is required to obtain necessary data.
- Studies are focused on relatively specific questions or hypotheses that remain constant throughout the investigation.
- Plans about the research procedures – design, data collection methods, types of measurement and so on – are developed before the study begins.
- Data collection procedures applied in a standardised manner
- Data collectors are expected to obtain only the data called for and to avoid adding their own impressions or interpretations.
- Measurement is normally focused on specific variables that are, if possible, quantified through rating scales, frequency counts and other means.
- Data analysis proceeds by obtaining statistical breakdowns of the distribution of variables and by using statistical methods to determine associations (or differences) between variables.

#### ***1.8.1.2 Analytical study design***

The analytical study design is used to figure out the causes of or risk factors for a disease by assessing whether particular exposures are related to diseases and other health outcomes. Thus, it entirely focuses on examining associations rather than just describing how much outcome of interest available (Joubert & Ehrlich 2007:78). In this study the researcher carried out statistical analysis to determine a relationship between dependent and independent variables.

#### ***1.8.1.3 Cross-sectional study design***

Cross-sectional designs involve the collection of data at one point in time: the phenomena under study are captured during one period of data collection. They are appropriate for describing the status of phenomena or for describing relationships among phenomena at a fixed point in time. They are relatively easy and economical to conduct (Joubert & Ehrlich 2007:87; Polit & Beck 2012:184). In this study the researcher used a cross-sectional design to describe the level of adherence of adult HIV infected patients on antiretroviral therapy and explore factors that affect adherence to treatment during the specified data collection period.

## **1.8.2 Research method**

Research methods are the techniques that researchers use to structure a study and to gather and analyze information relevant to the research question (Polit & Beck 2012:12). The researcher systematically described about the research methods that were applied during conduct of the study. These included defining the study population and selecting sample, determining the sample size, data collection process and data analyses.

### ***1.8.2.1 Study population and sample selection***

When conducting a study, it is important to define clearly the group about which we want to gather information and draw conclusions. This group, called the study population, should be clearly defined in respect of person, place and time, as well as other factors relevant to the study (Joubert & Ehrlich 2007: 94).

The study population for this study were eligible HIV infected adult patients on antiretroviral therapy attending ART clinic in the selected health facility in Addis Ababa. Eligible patients were screened by the inclusion criteria of age >18 years, on antiretroviral therapy for at least three months, be able to provide consent and not involved in the pilot study.

### ***1.8.2.2 Sample***

Sampling defines the process for selecting a group of people with which to conduct a study (Burns & Grove 2005:41). The researcher used systematic sampling which is one of the probability sampling methods to determine the sample selection process. Probability sampling methods have been developed to ensure some degree of precision in estimation of the populations parameters, thus reduce sampling error (Burns & Grove 2005:365). In this research the study participants were selected using the ordered list patients on ART based on their unique ART identification numbers which was generated from computer data base.

### **1.8.2.3 Sample size**

Using a precision of 5% and 95% confidence interval the sample size was determined by the formula,

$$N = p(1-p) z^2 / d^2;$$

Where, p = estimated proportion of patients adherent to ART,

z = the cut off value of the Normal distribution and

d = the precision required on either side of the proportion.

Considering lost to follow up, transfer out, death and non-willingness, 10% of the sample size was added to the total sample size. A pooled estimate of adherence to antiretroviral therapy in Sub-Saharan Africa was found to be 77% (Mills et al 2006a:679). Therefore, the total sample size for this study was 300 using a precision of 5% and 95% confidence interval.

### **1.8.2.4 Data collection**

The researcher proceeded to data collection process after securing ethical clearance and permission from the health studies department at UNISA, Addis Ababa regional health bureau and the management of the health institutions. A data collection is the precise, systematic gathering of information relevant to the research purpose or the specific objectives, questions or hypothesis of a study (Burns & Grove 2005:42). In this particular study data were collected by interviewing study participants using a structured questionnaire. The questionnaire was piloted in a small group of HIV positive individuals on antiretroviral therapy before commencing on actual data collection. A pilot study is a small-scale version or trial run designed to test the methods to be used in a larger, more rigorous study (Polit & Beck 2012:195).

Data collectors were trained and deployed to gather data by interviewing the selected study participants attending ART clinic in Zewditu Memorial hospital and Bole 17 health centre. So they carried out a structured interview using the questionnaire. In structured interviews, the interviewers are supposed to follow a clearly structured format to prevent them from placing their own interpretation of the questions. They ask questions in a standard way, with the same probes and clarifications for each respondent, and they also record verbal

responses of the participants in a uniform way. This standardization increases the reliability of the information obtained (Joubert & Ehrlich 2007:107). The principal investigator closely followed and supervised the data collection process to ensure and guide proper data collection. This also helped to minimise the occurrence of variations and errors in the data during data gathering.

#### ***1.8.2.5 Data collection tool***

The researcher used a questionnaire (see annexure F) as a data collection tool. It was developed by reviewing different literature in such a way to gather relevant information on measurement of the level of adherence to antiretroviral therapy and its various determinant factors. The questionnaire comprised of questions related to the level of adherence, demographic, socio-economic, psychosocial, health related, clinical setting, and patient-provider relationship factors. A statistician was consulted and reviewed the questionnaire before starting data collection.

#### ***1.8.2.6 Validity and reliability of data collection instrument***

The quality of the information collected in conducting a study is necessary to produce a valid research finding. The first way of checking data quality is to review issues concerning the data collection process and the respondents. The second is a more formal evaluation of measurement error. Thus, the measurement instruments are usually evaluated for validity and reliability (Joubert & Ehrlich 2007: 116).

##### ***1.8.2.6.1 Validity of data collection instrument***

Validity: refers to the extent to which a measurement instrument actually measures what it is meant to measure (Joubert & Ehrlich 2007: 117). Although various ways of evaluating the validity of a measurement instrument have been mentioned in literatures the questionnaire was evaluated for face and content validity by experts in the field and the research supervisor and a statistician to ensure greater degree of accuracy of the measurement.

##### ***1.8.2.6.2 Reliability of data collection instrument***

According to Joubert and Ehrlich (2007: 117) reliability refers to the degree of similarity of the results obtained when the measurement is repeated on the same subject or the same

group. The reliability of the instrument was enhanced by deploying appropriately selected and well trained data collectors with strict supervision of data collection process. A statistician was also consulted for his assistance on evaluating the instrument for its reliability.

#### **1.8.2.7 Data Analysis**

Data was cleaned, coded and entered in to a computer. The data was analysed using SPSS 20.0 statistical software package. Descriptive statistics such as means, median and standard deviations were calculated to describe the basic participants' characteristics. Odds ratio, chi-square test and their 95% confidence interval were computed to identify the presence and strength of associations between the categorical independent variables and dependent variable. Independent t-test was also computed to examine relationship between continuous independent variables and dependent variable. A P-value of less than 0.05 was considered for an association to be considered as statistically significant. Multivariate regression analysis was also carried out to identify independent factors associated with low level of adherence to antiretroviral therapy. A statistician was involved in the entire data analyses process.

### **1.9 ETHICAL CONSIDERATIONS**

Ethical clearance and approval was ascertained from the Research Ethics Committee of the University of South Africa (see annexure A) and the regional health bureau of Addis Ababa city administration (see annexure C). Permission to conduct the study was requested and obtained from the management of the health institutions where the study was undertaken. The researcher took in to consideration the fundamental principles of ethical research which include justice, beneficence and respect for human dignity.

#### **1.9.1 The principle of justice:**

*Right to fair treatment:* means that researchers must treat people who decline to participate (or who withdraw from the study after initial agreement) in a non prejudicial manner; that

they must honor all agreements made with participants (including payment of any promised stipends); that they demonstrate respect for the beliefs, habits, and lifestyles of people from different backgrounds or cultures; that they give participants access to research staff for desired clarification; and that they afford participants courteous and tactful treatment at all times (Polit & Beck 2012:155-156). Every effort was made to treat participants fairly. Participants were treated properly whether they consent or not, even if they withdraw from participating in the study. The data collectors were strictly explained not to be judgmental with any aspect of the study participants.

*Right to privacy:* Participants have the right to expect that any data they provide will be kept in strictest confidence (Polit & Beck 2012:156). The researcher and the data collectors made every effort to comfort and maintain the privacy of the participants.

*Confidentiality:* According to Fain (2009:34) confidentiality refers to protecting data by not divulging information that is gathered or learned in caring for a patient without that individual's permission to do so. Various efforts were made to maintain confidentiality of information provided by the study participants in this study. There were no circumstances that information related to the participant was shared with others. The field workers were strictly informed on keeping confidentiality of information of the participants. Data was collected in a private room. They used codes rather than any identifiable information on the questionnaire. They did not give any access to the participants' information to other individuals except the principal investigator. The completed questionnaires were kept secured in a lockable cabinet till collected by the researcher. They also signed confidentiality pledge forms to strictly maintain confidentiality of information.

*Anonymity:* refers to keeping individuals nameless and limiting access to information that is gathered about a subject. Anonymity can be facilitated by using code numbers for subjects' identity to prevent others from linking reported information with them (Fain 2009: 33-34). Polit and Beck (2012:162) also describes anonymity as the most secure means of protecting confidentiality, and occurs when the researcher cannot link participants to their data. In this study, the participants were assured that there could no names or other identifier in the questionnaire, so that there was no means to link any information with a particular participant. Only codes were used in the questionnaire during data collection.

### **1.9.2 Principle of beneficence:**

*Freedom from harm:* the research participants were not exposed to any physical or psychological harm. The ethical principles were strictly followed not to infringe the participants' rights and humanity. Participants were informed on their right to withdraw from the study at any time when they consent for participation in the study.

*Freedom from exploitation:* Participants were treated fairly and they were not at any disadvantage because of participation in the study.

*Benefits from the research:* Different studies in African context indicated that there is a deficit in the level of adherence of patients to ART and multiple factors have been mentioned to contribute to the existing gap. This study helped to gain knowledge on the level of adherence of HIV infected adult patients and understand the potential barriers to adherence. Moreover, it provided important information with regard to adherence and make recommendations for health care providers, health facilities and policy makers in enhancing the implementation of ART program and development of evidenced-based interventions to improve adherence to antiretroviral therapy.

*Risk/benefit ratio:* Participants having problems with their adherence were referred to adherence counsellors and other psychosocial support organizations as necessary. Participants were also explained about the benefits with regard to the recommended adherence interventions that resulted from the research findings. Since, the participants may have risks such as physical discomfort, emotional distress and fear of stigma, every effort was made to comfort and lessen the risks. Even the participants were clearly explained that they had the right to withdraw from the study at anytime they felt like.

### **1.9.3 Principle of respect for human dignity:**

*The right to self-determination:* According to Polit and Beck (2012:154) self determination implies that prospective participants can voluntarily decide whether to take part in a study, without risk of prejudicial treatment. It also points out that people have the right to ask questions, to refuse to give information, and to withdraw from the study. The research participants were fully autonomous whether to volunteer to participate or not, to ask

questions and to refuse providing information. They were not coerced or subjected to any penalty for refusal to participate in the study.

*Informed Consent:* means that participants have adequate information about the research, comprehend that information, and have the ability to consent to or decline participation voluntarily (Polit & Beck 2012:157). The study participants were requested to provide a written informed consent before data collection. They were clearly explained about the purpose of the study, the data collection procedure and the potential risks and benefits that may occur up on participation in the study. The participation in the study was voluntary and a decline to participate did not result in any penalty or loss of benefit. They were informed that even after consenting they have the right to withdraw from the study and to refuse to provide any specific piece of information.

*The right to full disclosure:* Full disclosure means that the researcher has fully described the nature of the study; the person's right to refuse participation, the researcher's responsibilities, and likely risks and benefits (Polit & Beck 2012:154). The study participants and the health institutions were fully explained about the purpose and nature of the study, the data collection process and the potential risks and benefits of participation in the study.

*The right of vulnerable subjects:* vulnerable subjects such as those who were below 18 years of age, severely ill and mentally handicapped individuals did not participate in the study.

## **1.10 SCOPE AND LIMITATIONS OF THE STUDY**

The researcher anticipated and acknowledged the following potential limitations in conducting the study:

- The generalizability of the research findings may be compromised as the study was conducted in only few health facilities.
- Since there were no standardized methods for measurement of adherence, accurate assessment of adherence could not be possible. The researcher used 'self report' as a measure of adherence to patients' treatment which could overestimate the actual rate of adherence to treatment.



- Social desirability and recall biases of patients may affect the reliability of the data with respect to adherence.
- Lost to follow up, transfer out and death of patients may limit to find the systematically selected study participants.

### **1.11 STRUCTURE OF THE DISSERTATION**

This dissertation was structured in such a way that the research processes be presented and discussed in chapters separately. The chapters of the dissertation included:-

Chapter 1: Orientation to the study: provides overview of the research problem, research purpose and objectives, significance of the study, demarcation of field of study, foundations of the study, research design and method, and ethical considerations.

Chapter 2: Literature review: provides in-depth review of various literatures to understand the existing body of knowledge on the prevalence of adherence to antiretroviral therapy, importance of adherence, measurement of adherence and factors associated with non adherence both in developing and developed countries.

Chapter 3: Research design and method: describes the overall process of the research methodology carried out to undertake the study.

Chapter 4: Analysis, presentation and description of the research findings: include the statistical analysis, results of the study and summary of the research findings

Chapter 5: Conclusion and recommendation: include the recommendations and conclusion made based on the research findings

### **1.12 CONCLUSION**

This chapter introduced the research problem, the purpose, the objectives and the methodologies of the research to be conducted. It also highlighted the ethical principles that the researcher followed in conducting the research. Each component of the research process was further elaborated in detail in the next chapters of the dissertation. Chapter two discussed about the literature review in the next section.

## CHAPTER 2

### LITERATURE REVIEW

#### 2.1 INTRODUCTION

The literature review refers to the process of taking stock of existing knowledge in order to make informed choices about policy, practice, research direction and resource allocation (Joubert & Ehrlich 2007:66). It involves identification and analysis of relevant publications that contain information pertaining to the research problem. The major purpose of reviewing the literature is to discover what is already known about the problem. It also provides the understanding and insight necessary to develop a logical framework. In general, the literature review provides important information regarding what has been done and what needs to be done in relation to the research problem (Fain 2009:53).

According to Polit and Beck (2003:88) literature reviews can serve a number of important functions in the research process. For researchers, acquaintance with relevant research literature and the state of current knowledge can help with the following:

- Identification of a research problem and development or refinement of research questions or hypotheses
- Orientation to what is known and not known about an area of inquiry, to ascertain what research can best make a contribution to the existing base of evidence
- Determination of any gaps or inconsistencies in a body of research
- Determination of a need to replicate a prior study in a different setting or with a different study population
- Identification or development of new or refined clinical interventions to test through empirical research
- Identification of relevant theoretical or conceptual frameworks for a research problem
- Identification of suitable designs and data collection methods for a study

- For those developing research proposals for funding, identification of experts in the field who could be used as consultants
- Assistance in interpreting study findings and in developing implications and recommendations

Moreover, a literature review helps to lay the foundation for a study, and can also inspire new research ideas. A literature review also plays a role at the end of the study, when researchers are trying to make sense of their findings (Polit & Beck 2003:88).

The literature review in the current study guided the researcher to conceptualize the research problem adequately and understand the current body of knowledge related to the magnitude of adherence problems and determinant factors for non adherence. The researcher underwent a systematic and thorough identification and review of different literatures that were believed to be relevant to the research topic. Literature search was carried out using libraries and the internet sources (from pubmed, medline and google). A number of studies were obtained and reviewed to gain existing knowledge on the prevalence of adherence to antiretroviral therapy, importance of adherence, measurement of adherence and factors associated with non adherence both in developing and developed countries.

## **2.2 TREATMENT OF HIV/AIDS**

Antiretroviral treatment (ART) provides relief to HIV infected individuals by reducing the risk of developing opportunistic infections, but cannot cure HIV infection yet. Antiretroviral treatment was first introduced in 1996, since then it has brought significant improvement in the life span and quality of life for people living with HIV (Wasti, van Teijlingen, Simkhada, Randall, Baxter, Kirkpatrick & GC 2012:71). Currently, the antiretroviral therapy has been improved steadily and new drugs with new mechanisms of action, improved potency and activity even against multidrug-resistant viruses, dosing convenience, and tolerability became approved and availed for use (Panel on antiretroviral guidelines... 2011:1). The primary goals of antiretroviral therapy (ART) include reduction of HIV-associated morbidity and prolong the duration and quality of survival, restoration and preservation of immunologic function, maximal and durable suppression of plasma HIV viral load, and

prevention HIV transmission (Panel on antiretroviral guidelines... 2012:D1). This treatment definitely requires a combination of drugs from at least two, and preferably three active drugs, from two or more drug classes to achieve maximal and sustainable suppression of viral replication. Accordingly, the WHO recommends the preferred first-line regimens to include two nucleoside reverse transcriptase inhibitors (NRTIs) and one non-nucleoside reverse transcriptase inhibitor (NNRTI). For second-line regimens, preference would be given to a combination of two NRTIs (at least one of which is new) and a protease inhibitor boosted with ritonavir (Panel on antiretroviral guidelines... 2012:D1; Panel on antiretroviral guidelines... 2011:24; UNAIDS 2008:138).

The ART treatment guideline was adopted from the public health approach which is recommended by WHO for resource-poor settings. It helps to standardise and simplify the initiation and monitoring of ART in the country. The guideline recommends to use two NRTIs and NNRTI as a standard first-line treatment, reserving PIs for second-line (FHAPCO/FMOH 2008:47). Hence, as demonstrated in figure 2.1 either TDF or ZDV should be used as preferred first line NRTI drug in the treatment naïve patients in combination either with 3TC or FTC. While, D4T and ABC can be used as alternative to TDF or ZDV in selected patients, such as renal impairment or adverse effects of ZDV. The NNRTIs (NVP or EFV) are used in equal preference depending on the patient condition (FHAPCO/FMOH 2008:47).

# FIRST LINE REGIMEN: ETHIOPIAN ART PROGRAM 2008

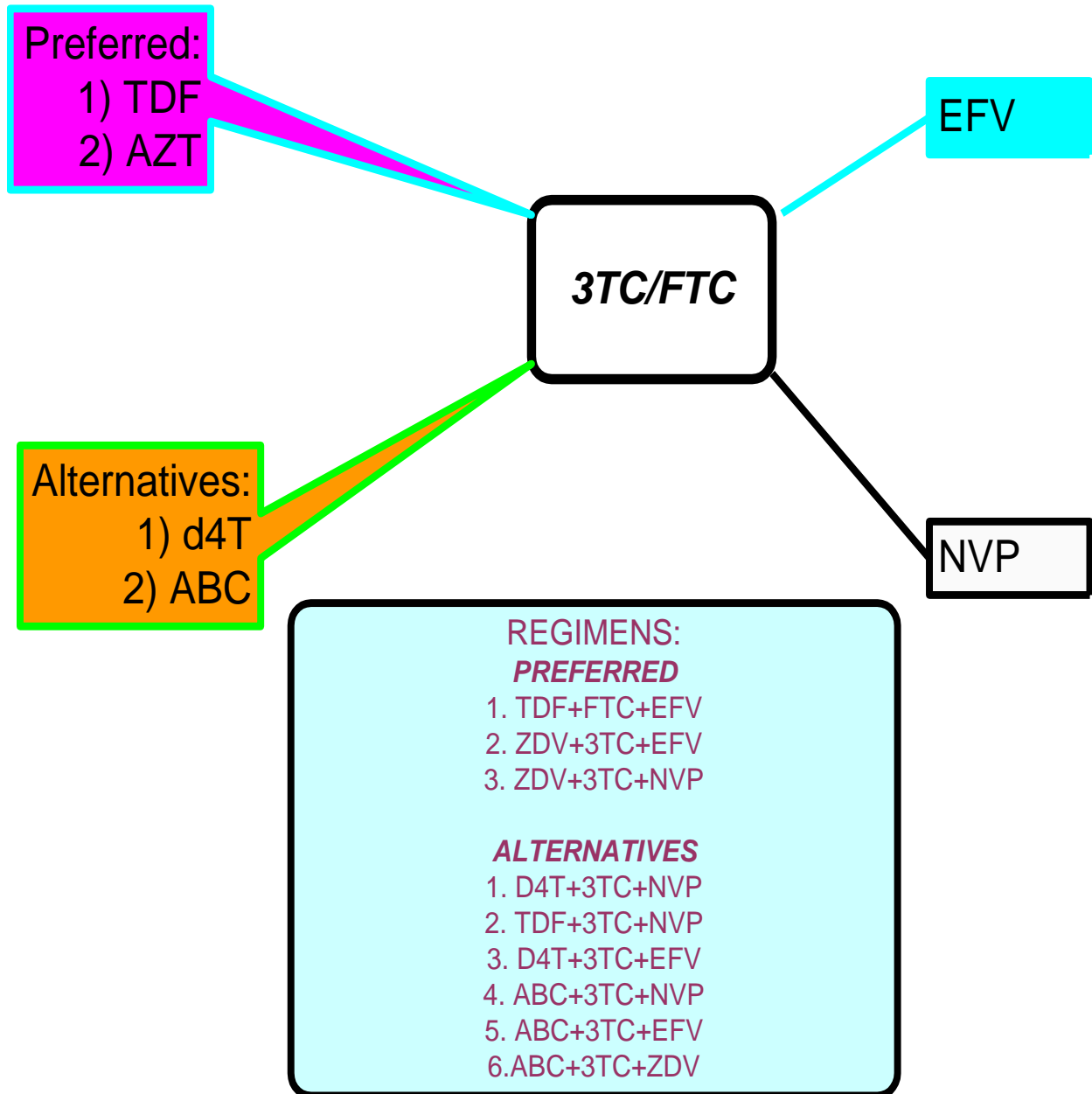


Figure 2.1 First - line antiretroviral regimen in Ethiopia

(Source: FHAPCO/FMOH 2008:52)

## **2.3 ACCESS TO ANTIRETROVIRAL THERAPY**

Antiretroviral therapy used to be unaffordable and could not be available in resource limited countries for decades, despite its benefit of reducing HIV related morbidity and mortality in high income countries (UNAIDS 2008:136). In fact, this was mainly related to concerns of suboptimal adherence to ART in African patients, which could in turn lead to the development and spread of drug resistance (Mills et al 2006a:680). However, current evidences revealed that patients in resource-limited settings can achieve levels of adherence and virologic suppression that are equivalent to or possibly better than, those seen in resource-rich settings (Machtinger & Bangsberg 2006; Mills et al 2006a:682). Poor infrastructure, inadequate logistic and human capacity, and cost-effectiveness were also incriminated as major contributing factors to delay access to treatment (Assefa, Jerene, Lulseged, Ooms & Van Damme 2009:1).

### **2.3.1 Expanding access to antiretroviral therapy in SSA**

Following the declaration of WHO 3-by-5 initiative in 2003, antiretroviral medications became widely accessible to people living with HIV in resource-constrained settings (WHO 2006:7). Since then, several enabling factors have been created for the rapid scale-up of ART in resource-limited settings, for instance, increased funds, mainly through global initiatives such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the United States President's Emergency Plan for AIDS Relief (PEPFAR) and a dramatic reduction in prices of antiretroviral drugs through considerable negotiation (Assefa et al 2009:1). Expanding access to ART has brought changes in the global HIV epidemic in momentous ways. The scaling up of ART averted an estimated 4.2 million deaths in low- and middle-income countries in 2002–2012. Moreover, the average life expectancy of people living with HIV who adhere to effective treatment now approaches the life expectancy in the general population (WHO 2013:43-45).

The rapid growth in antiretroviral therapy coverage represents one of the great success stories in recent global health history (UNAIDS 2008:136). According to the WHO/UNAIDS/UNICEF (2011:90), around 6.6 million people living with HIV were receiving antiretroviral therapy globally by the end of 2010 which showed a 17-fold increase from the

approximately 400,000 people recorded in December 2003. (WHO/UNAIDS/UNICEF 2011:21).

Despite the unprecedented efforts of national governments and international partners, the estimated global coverage of antiretroviral therapy in low- and middle-income countries remains still less than 50% in 2010 (WHO/UNAIDS/UNICEF 2011:90). The ART coverage in Sub-Saharan Africa, where 73% of the estimated treatment need in low and middle-income countries and 76% of the total number of people receiving treatment are living has reached only 49% in 2010. Only few countries such as Botswana, Namibia and Rwanda have already achieved universal access to antiretroviral therapy which is commonly understood as providing antiretroviral therapy to at least 80% of the people who need it (WHO/UNAIDS/UNICEF 2011:99). This clearly indicates that there is unmet need that calls for further strengthening the collaborative efforts of the international community and national governments to close the existing gap to achieve the universal access target in SSA.

### **2.3.2 Access to antiretroviral therapy in Ethiopia**

In Ethiopia, around 759,268 people were estimated to live with HIV by the end of 2012, and 336,106 of them were in need of antiretroviral treatment (HIV AIDS estimates & projection ...2013). The ART program was started in 2003 on fee basis mainly in the largest urban countries. But, later on a free ART roll out program was launched by the FMOH in collaboration with different global health initiatives in 2005. By mid 2006, health centres in different parts of the country started to provide treatment as part of decentralization and scaling up ART program. Hence, currently ART services have been provided both at the health centers and hospitals in the country (Assefa et al 2009:2; Kloos, Assefa, Adugna, Mulatu, & Haile Mariam 2007: [S.a]; Tiyou, Belachew, Alemseged & Biadgilign 2010:2). Reports from FHAPCO demonstrated 246,347 patients had been ever started on ART and among which 179,183 patients were receiving ART by the end February 2010. The ART coverage also reached 53% which showed significant progress compared to the baseline of 13,000 in 2005/06 (FMOH 2010:13). This results from the collaborative effort of the government of Ethiopia with its development partners towards achieving universal access to chronic HIV care and treatment services. Nonetheless, there still remains a gap to reach

to those who are in need of ART and the FMOH has planned to further expand the service in its strategic plan II (2010/11 – 2014/15).

Addis Ababa, the capital city of Ethiopia, was one of the pioneer cities to launch free antiretroviral treatment in 2005. The ART service has been provided both in public and private health facilities. The number of facilities providing HIV care and treatment services has increased gradually. Till February 2010, the total number of ever started HIV positive clients on antiretroviral treatment has reached to 52,585 in Addis Ababa. Among which 32,279 clients were found to be currently on treatment (Monthly HIV care and ART report update 2010).

### **2.3.3 Retention of patients on ART**

Apart from continuous support in the scale up of ART services, greater attention should also be given to enhance retention of patients in the ART program. Once people start ART, the retention rates are initially high and then decline gradually. For instance, data reported in 2013 from 18 countries with cohorts of at least 2000 people on ART indicate that the average retention rates decreased from about 86% at 12 months to 82% at 24 months and 72% at 60 months (WHO 2013:11). Similarly, studies demonstrated ART programs in Africa have retained only about 60% of their patients at the end of two years since the inception of large scale ART access early in this decade, with loss to follow-up as a major cause of attrition, followed by death. The percentage of loss to follow-up ranges from 3.7% to 44% which varies widely across programs in resource limited settings (Nakanjako et al 2009:185). In support of this, a recent cohort study in Kenya also reported as high as 29% of patients dropped out from the ART program and the probabilities of remaining on care and treatment in the program at 6, 12, and 24 months were 0.83, 0.74, and 0.65, respectively (Unge, Södergård, Ekström, Carter, Waweru, Ilako, Ragnarsson & Thorson 2009:399-400). This indicates a progressive decline in the number of patients in HIV care could happen along with time. Therefore, close support and improvements in the infrastructure and systems of HIV care are required to improve the quality of care as well as proper monitoring of treatment adherence and retention as programs are scaled up (UNAIDS 2010:29).



## **2.4 ADHERENCE TO ANTIRETROVIRAL THERAPY**

### **2.4.1 Importance of adherence to antiretroviral therapy**

A high level of adherence to antiretroviral therapy is required to achieve sustainable viral suppression and better clinical outcomes in HIV-infected persons (Beer, Heffelfinger, Frazier, Mattson, Roter, Barash, Buskin, Rime & Valverde 2012:123). Studies have demonstrated that higher levels of drug adherence are associated with improved virological, immunological and clinical outcomes (WHO 2006:78). Along with this, adherence has been found to be the most valuable and potentially alterable factor to determine treatment outcomes of patients living with HIV (Panel on antiretroviral guidelines... 2006:20; Matchtinger & Bangsberg 2006).

Although previous studies indicated that 95%–100% adherence was necessary to sustain viral suppression and prevent drug resistance, more-recent findings demonstrated the existence of different relationships between adherence, viral suppression, and drug resistance with different antiretroviral drugs (Bangsberg 2008:275). The studies emphasized that reliable virologic suppression is possible at moderate levels of adherence in majority of patients receiving more potent non nucleoside reverse transcriptase inhibitors (NNRTI) and ritonavir boosted PI therapy (Parienti, Das-Douglas, Massari, Guzman, Deeks, Vedon & Bangsberg 2008:1). Despite the fact that viral suppression may be possible with moderate levels of adherence, every increase in the adherence level increases the probability of viral suppression and, more importantly, reduces disease progression and mortality (Bangsberg 2006:941). This was supported by a study which revealed the decrease in the risk of virologic rebound with each 10% increase in average adherence (OR = 0.56; 95% confidence interval (CI) [0.37, 0.81], P=0.002) (Parienti et al 2008:3). Another study in Mozambique also revealed that the relationship between >95% treatment adherence and a final viral load <1000 copies/mL is closer than that between >90% treatment adherence and a viral load <1000 copies/mL in both the group that received 15–27 months of NNRTI based HAART and the group that received >27 months of HAART (San Lio, Carbini, Germano, Guidotti, Mancinelli, Magid, Narciso, Palombi, Renzi, Zimba & Marazzi 2008:1613). This implies that health care providers should strive to provide ongoing counselling and support to patients to get near perfect adherence to the

prescribed doses for all antiretroviral regimens (Panel on antiretroviral guidelines... 2011:121).

Optimal adherence to antiretroviral therapy has also brought a significant change in the quality of life of PLHIV. For instance, a study in China found a better score in the dimensions of physical function ( $P=0.001$ ), general health ( $P=0.009$ ), vitality ( $P=0.016$ ), social function ( $P=0.001$ ), and mental health ( $P=0.023$ ) in consistent adherers than non adherers (Wang, Zhou, He, Luo, Li, Yang, Fennie & Williams 2009:759). With optimal adherence, ART may also result in significant improvement in population health, reduction of the number of premature deaths, and lowering of health care costs. Studies indicate that adherence to ART is one of the important factors in reducing HIV transmission by suppressing HIV viral load (Beer et al 2012:123).

## **2.4.2 Consequences of non adherence**

### ***2.4.2.1 Clinical implications of non-adherence***

Failure to adhere to recommended medication regimens is a serious problem that has negative consequences for patients, providers, health plans, employers, industry, and society (Gellad et al 2009:1). Patients with suboptimal adherence are generally more vulnerable to the development of drug resistance, and subsequent treatment failure. They tend to develop poor health outcomes with increased morbidity and mortality as a result of disease progression (Enriquez & Mckinsey 2011:46; Vriesendorp, Cohen, Kristanto, Vrijens, Rakesh, Anand, Iwebor & Stiekema et al 2007:1116). Even the new second line regimen may be more complex than the initial regimen, thereby creating an additional barrier to adherence. The same pattern of gradual decline in adherence may necessitate an even more complex third-line regimen. Thus, failure to detect and address risky adherence patterns prior to the first viral rebound can lead to a continuous loop of less-effective, poorly tolerated therapies that require even higher levels of adherence to sustain viral suppression (Bangsberg 2008:272).

Various studies demonstrated that suboptimal adherence has been correlated with the development of drug resistance and treatment failure. For instance, a study in Zambia indicated the risk for virologic failure was higher among patients with suboptimal [adjusted

RR (ARR): 1.7; 95% CI: 1.0, 1.6] and poor adherence (ARR: 1.8; 95% CI: 1.3, 2.4) than those with optimal adherence. Based on MPR adherence categories, the risk of detectable VL increased from optimal [118/531 (22%)], suboptimal [89/306 (29%)], to poor [31/76 (41%)] (Goldman, Cantrell, Mulenga, Tambatamba, Reid, Levy, Limbada, Tylor, Saag, Vermund, Stringer & Chi 2008:1032). A recent cohort study in South Africa which followed 154 women receiving NNRTI based ART regimen for 24 weeks, found out that patients with adherence level below 80% were at high risk of developing viremia (El-Khatib, Ekstrom, Coovadia, Abrams, Petzold, Katzenstein, Morris & Kuhn 2011a:6-8). Another study in Mozambique also demonstrated the increased risk of viremia in patients with suboptimal adherence.

In this study, of the 284 patients who had treatment adherence >95%, 274 (96.5%) had a viral load <1000 copies/mL at the end of the observation period; of the 110 patients who had treatment adherence ≤95%, 92 (83.6%) had a viral load <1000 copies/mL at the end of the observation period (San Lio et al 2008:1613). A recent US study indicated non adherence to multiple measures (i.e non adherence to dose, schedule and instruction) was also associated with increased odds of a detectable viral load (Beer et al 2012:216). A study conducted in South Africa demonstrated the association of poor adherence to drug refill with virologic and immunologic failure (El-Khatib, Katzenstein, Marrone, Laher, Mohapi, Petzold, Morris & Ekström 2011b:3). A prospective cohort study also revealed that non continuous adherence and treatment interruptions are strongly related to treatment failure (Knobel, Urbina, González, Sorli, Montero, Carmona & Guelar 2009:366).

The impact of poor adherence on immunologic and other clinical outcomes has been also well established. Patients with suboptimal adherence have impaired clinical and immunologic outcomes. A study in Zambia observed an association between level of adherence and CD4 lymphocyte response. Individuals with adherence of <80% had an attenuated response at 18, 24, 30 and 36 months when compared with those at or above this MPR threshold (Chi, Cantrell, Zulu, Mulenga, Levy, Tambatamba, Reid, Mwangi, Mwinga, Bulterys, Saag & Stringer 2009:751-752). Another study conducted in China found a better mean growth of CD4 count in patients with consistent adherence. The mean growth of CD4 count was 72 cells per micro litre in consistent adherers and 27 cells per micro litre in non adherers (P=0.03). The study also demonstrated that patients with good

adherence were more likely to be free from OIs, had lower hospital expenses and shorter hospital stay, and less likely be hospitalized or re-hospitalized as compared to non-adherent participants (Wang et al 2009:760). In Kaplan–Meier analysis, individuals with <80% adherence had a significantly higher risk of death when compared with those in other adherence categories (log rank  $P=0.0001$ ). In unadjusted proportional hazards regression, the relative hazard for death was 1.7 (95% CI: 1.4–2.1) among those with poor adherence, when compared with those with optimal adherence (Chi et al 2009:751).

#### **2.4.2.2 Public health impact of non-adherence**

Non-adherence has also imposed additional public health impact beyond individual health. The financial burden of non-adherence has been substantial. As HIV-infected individuals fail ARV regimens, each subsequent medication regimen becomes not only more complex but also more costly (Enriquez & McKinsey 2011:46). Non-adherence also has negative influence on general health care system including waste of medication, increased health care costs, and increased use of medical resources such as nursing homes, hospital visits and hospital admissions (Jimmy & Jose 2011:155). Last but not least, non-adherence to HAART can result in serious health impact with risk of transmission of resistant viral strains to the general population as well (Machtiger & Bangsberg 2006).

## **2.5 MEASUREMENT OF ADHERENCE**

A variety of adherence measurement methods have been used for clinical practice and research purpose. However, none of the measurements can be used as a gold standard (Panel on antiretroviral guidelines... 2012:K2). These methods are categorized as direct and indirect measures of adherence. The direct measures include directly observed therapy, measurement of the level of a drug or its metabolite in blood or urine and detection or measurement of a biological marker added to the drug formulation, in the blood. The indirect ones include self-reports, electronic drug monitoring (EDM), pill counts, pharmacy refill records, measurement of physiologic markers and patient diaries. Each of the adherence measurements has its own strengths and limitations (Jimmy & Jose 2011:157). The following section discussed in brief the most commonly used methods for assessment of adherence.

### **2.5.1 Self report**

Patient self-report of adherence is a routine method used in assessing adherence both in clinical trials and in routine clinic settings (Steel, Nwokike & Joshi 2007: 7). Evidences indicated that self report adherence has been correlated well with clinical and virologic outcomes and other objective measures of adherence (Amico, Barta, Konkle-Parker, Fisher, Cornman, Shuper & Fisher 2009:69; Reda & Biadgilign 2012:1-2; Steel et al 2007: 7). Self report adherence was validated in various studies. For instance, a recent meta-analysis demonstrated a moderate correlation between adherence measured by MEMS and self reported questions ranging from 0.24 to 0.87 for 11 articles (Shi, Liu, Fonseca, Walker, Kalsekar & Pawaskar 2010:4). Another study in Uganda also validated self report adherence with serum level of stavudine, and the researchers found in multivariate model patients who reported 95% and above S-RA were almost eight times more likely (Adjusted Odds Ratio: 7.7, 95% CI: 3.5 to 7.0,  $P < 0.0001$ ) to have within or above therapeutic plasma stavudine concentrations, compared to those who reported less than 95% S-RA. (Balikuddembe, Kayiwa, Musoke, Ntale, Baveewo, Waako & Obua 2012:4). Self report of adherence offers the primary advantages of ease of administration, flexibility and low cost (Glass, Geest, Hirschel, Battegay, Furrer, Cavassini, Vernazza, Bernasconi, Rickenbach, Weber, Buche 2008:78). However, it tends to overestimate adherence due to its vulnerability to fabrications and to the dynamics of provider-patient relationship (Steel et al 2007:7-8). Self report is also subjected to measurement biases such as social desirability, recall bias, and response bias (Shi et al 2010:2). Despite the fact that patient self-report of adherence can predictably overestimate adherence by as much as 20%, a patient's report of suboptimal adherence is a strong indicator of non adherence and should be taken seriously (Panel on antiretroviral guidelines... 2012:K2).

### **2.5.2 Pill count**

Pill count is also a common method to measure adherence. Although clinic-based pill counts generally perform poorly, unannounced pill counts conducted in the home have been closely associated with viral suppression, the development of drug resistance, and progression to AIDS (Bangsberg 2008:274). This method is simple to use, but has many disadvantages including switching of medicines between bottles and discarding pills

before hospital visits in order to appear to be following the regimen (Jimmy & Jose 2011:157). Besides, it can overestimate adherence as the use of pills is assumed if not counted in the bottle, and also cannot give any information about timing or pattern of doses taken (Gellad et al 2009:25-26).

### **2.5.3 Pharmacy refill records**

Pharmacy-dispensing information is another potential approach to routine adherence monitoring. Pharmacy refill information can be used to calculate the drug-possession ratio, which represents the maximum possible adherence for a patient over a defined refill period (Bangsberg 2008:274). The relationship of pharmacy refill adherence and clinical outcomes has been well established. For instance, a study in South Africa found out a significant association between cumulative adherence of > 95% to drug-refill visits and virologic and immunologic failure ( $p= 0.01$ ). The researchers suggested that adherence to drug-refill visits can work as an early warning indicator for both virologic and immunologic failure (El-Khatib et al 2011b:3-5). Another study in Cameroon also demonstrated pharmacy refill adherence had even greater accuracy, with higher sensitivity and similar specificity to CD4 count changes at 6 months for predicting virological treatment failure. In this study pharmacy refill irregularity was found to be the most powerful predictor of virologic failure (Rougemont, Stoll, Eia & Ngang 2009: [S.a]).

The rates of refilling prescriptions can be used as an accurate measure of overall adherence particularly in a closed pharmacy system since refills are measured at several points in that time (Jimmy & Jose 2011:158). The limitation of this approach is that multiple pharmacies can be used by the same person, which actually complicates data collection. (Bangsberg 2008:274).

### **2.5.4 Electronic drug monitoring (EDM)**

Electronic devices to monitor medication adherence consist of medication event electronic monitoring system (MEMS), which electronically record the date and time when patients open a pill bottle. This method uses a micro switch, a battery, and flash memory to detect and record the date and time when a medication bottle is opened. These time/date stamps

create an electronic record of pill bottle–opening behaviour that is closely associated with viral suppression and drug resistance (Bangsberg 2008:274; Gellad et al 2009:25). MEMS entails the advantages of obtaining data in a computer accessible format and allowing more detailed view of non adherence patterns. It also seems to be more reliable adherence measure and less prone to respondent bias (Reda & Biadgilign 2011:2; Steel et al 2007:7). The limitation of this method includes inaccurate measure of adherence as the patients could open the container and not necessarily take the medication, take the wrong amount of medication or take multiple doses out of the container at the same time (or place multiple doses in another container), patients decanting pills, measuring only one medication at a time, and being unavailable for blister packs (Jimmy & Jose 2011:158; Steel et al 2007:7). The use of advanced technology, high cost, and logistic requirements have also precluded their wider application in Sub-Saharan Africa (Reda & Biadgilign 2011:2). However, a recent study in Tanzania indicated the feasibility and acceptability of using MEMS-bottles to monitor adherence to ART in resource limited settings (Lyimo, Boogaard, Msoka, Hospers, Ven, Mushi, D & Bruin 2011:6).

In general, the use of a single isolated method of adherence assessment seems to be inadequate and impractical. Use of more than one ART adherence measures to capture more accurate information to determine adherence levels have been recommended at recent times (Sahay, Reddy & Dhayarkar 2011:837; Steel et al 2007: 54).

## **2.6 RATES OF ADHERENCE TO ANTIRETROVIRAL THERAPY**

Adherence to antiretroviral treatment has been recognized as a major problem for patients receiving treatment. Studies evaluating adherence have been conducted both in developed and developing countries. The following section highlighted the status and variation in rate of adherence in developed and developing settings.

### **2.6.1 Adherence in developed countries**

Adherence to ART in HIV infected patients is estimated closer to 70% despite the variation of the methods used to assess adherence and the group studied (Machtiger & Bangsberg 2006). Review of the literature indicated that adherence has been found to be sub optimal

in most developed countries. In a study conducted among 154 HIV positive patients in Deep South, Mississippi, an optimal adherence rate of 81% was reported, as adherence was measured by self report (Amico et al 2009:70). A cross sectional study in United States also investigated the rate of adherence among 9088 participants from the Supplement to HIV and AIDS Surveillance (SHAS) Project. The result indicated only 84% of the participants were found to be adherent to  $\geq 95\%$  of the prescribed doses of ART in the past 48 hours before the interview (Sullivan, Campsmith, Nakamura, Begley, Schulden & Nakashima 2007:3). Similarly, an overall two-day adherence rate of 89% was reported, in a study conducted in persons living with HIV/AIDS who are homeless or unstably housed, in three US states (Royal, Kidder, Patrabansh, Wolitski, Holtgrave, Aidala, Pals & Stall 2009:451). Another study was conducted among 110 participants who were identified from the Research on Access to Care in the Homeless (REACH) cohort, a systematic sample of HIV-positive adults recruited from San Francisco, California, homeless shelters, free meal programs, and low-income, single-room-occupancy hotels. The Average rate of adherence to therapy was found to be 70% as measured by unannounced pill count and electronic medication monitoring (Bangsberg 2006:940).

In contrast, other studies showed low level of adherence in resource rich settings. A meta-analysis of adherence studies by Mills et al (2006:682) demonstrated a pooled adherence estimate of 55% in North America. This study indicated that adherence to antiretroviral treatment in resource rich setting was relatively lower despite the fact that majority (71%) of the studies used self report method which is known to overestimate adherence. Other studies conducted in Europe also demonstrated comparable findings. In a study of adherence among patients who have received antiretroviral therapy for more than ten years in Spain, only 67.5% of the study participants were adherent to  $\geq 95\%$  of their prescribed medications. The investigators assessed adherence through self report and serum drug concentration (Fumaz, Muñoz-Moreno, Moltò, Ferre, Lòpez-Blázquez, Negro, Paredes, Gómez & Clotet 2008:798). Similarly, a recent meta-analysis of adherence studies in Spain revealed the average adherence to HAART under the random effects model was 0.54 (95%CI: 0.49-0.59), showing wide heterogeneity ( $I^2 = 91.20$ ; 95%CI: 88.75-93.13) under the fixed-effects model (Ortego, Huedo-Medina, Vego & Liorca 2011:286). Adherence rate of 43% was also reported in a study conducted in United States among 272 patients with alcohol problems (Parsons, Rosof & Mustanski 2007:364). This



may reflect the influence of alcohol consumption on adherence to medications. Overall the above studies revealed that achieving optimal level of adherence to antiretroviral therapy seems to be even challenging in resource-rich settings.

### **2.6.2 Adherence in developing countries**

A growing number of studies have been also conducted to investigate the rate of adherence to antiretroviral therapy in resource limited settings. Mills et al (2006:682) demonstrated that a relatively higher level of adherence could be achieved in developing than developed countries; although, there were some concern of sub optimal adherence in African settings. In this meta-analysis of 27 adherence studies, which were from 12 Sub-Saharan African countries, the researchers found out that a pooled estimate of adherence in SSA was 77%.

A plethora of studies conducted in Sub Saharan Africa have reported even a higher level of adherence among HIV infected patients to their treatment. A recent cross sectional study conducted in Uganda found out that among 234 patients, 194 (82.9%) patients had a self report adherence of 95% and above (Balikuddembe et al 2012:3). A study conducted in Tanzania among 340 patients assessed adherence to self report of four day and one month duration, and revealed that 320 (94.1%) patients were adherent to at least 95% of their prescribed medications (Watt, Maman, Golin, Earp, Eng, Bangdiwala & Jacobson 2010: 383-384). However, another study in Tanzania reported adherence rate of 78.2% among 897 study participants using a combination of self report and pill count methods (Abaasa, Todd, Ekoru, Kalyango, Levin, Odeke & Karamagi 2008: [S.a]). Another research in Botswana also found a mean adherence level of 85% and 98% using MEMs and self-reporting of medication intake respectively (Vriesendorp et al 2007:1117-1118). A prospective study conducted in HIV infected patients in Cameroon also found out that 78% of patients were adherent to their prescribed ARV medications. However, the self report data indicated that the proportion of patients with full adherence declined from 83% at the first month to 57% at the six months (Rougemont et al 2009: [S.a]). A study conducted in Rwanda reported an overall adherence rate of 73% taking correct use of doses, on the schedule and dietary recommendation in to consideration (Jean-Baptiste 2008:15). A study in rural Zambia also assessed the rate of adherence using self-report among 518 study

participants. The investigators found that 88% of the participants had never missed ARVs in the past four days (Nozaki et al 2011:832). In a cross-sectional study in Nigeria, 80.6% of HIV positive pregnant women reported adherence level of greater or equal to 95% using 3 day recall method (Ekama, Herbertson, Addeh, Gab-Okafor, Onwujekwe, Tayo & Ezechi 2012:3).

Although majority of the adherence studies in SSA revealed a higher rate of adherence among HIV infected patients, some studies demonstrated remarkably lower adherence. For instance, a large programmatic cohort study across 18 primary care centres providing ART in Lusaka, Zambia assessed adherence by medication possession ratio (MPR). The researchers revealed, among 27,115 treatment-naïve adults initiated and continued ART for at least 12 months only 17,060 (62.9%) had optimal adherence of  $\geq 95\%$  ( Chi et al 2009:748). Similarly, other studies in Zambia showed comparable results; Goldman et al (2008:1032) reported only 58% of patients had optimal adherence as measured by MPR. Birbeck, Chomba, Kvalsund, Bradbury, Mang'ombe, Malama, Kaile, Byers, & Organeke (2009:670-671) also indicated that only 59.2% were found to be adherent among 255 study participants. A study conducted in 125 HIV infected out patients in Benin using self report and pill count, also demonstrated adherence level of  $58.1\% \pm 2.4\%$  which was significantly lower than those reported in many other sub-Saharan African countries (Erah & Arute 2008:146-150).

Studies conducted in resource limited settings other than SSA indicate comparable rate of adherence. A longitudinal study in China reported an average rate of adherence of 89% in 89 HIV infected patients, as measured by 7 day visual analogue scale. The researchers also demonstrated a slight decline in adherence across time; adherence rate was found 91%, 89% and 88% at baseline, month 3 and month 6 respectively (Wang et al 2009:759). A study on adherence among 412 study subjects in Brazil showed about 74.3% of the patients were adherent to  $> 90\%$  their prescribed treatment in the past five days (Silva et al 2009:136). A cross-sectional study in Cuba also indicated 70.6% of the study participants were highly adherent to  $> 95\%$  of their prescribed medications (Aragonés, Sánchez, Campos & Pérez 2011:19). A cross-sectional study conducted in India among 310 HIV positive patients receiving ART revealed 93% of patients had  $> 90\%$  adherence to their treatment in the past 4 days (Sarna et al 2008: 31-32). However, other studies in India

demonstrated lower rate of adherence. For instance, another study conducted by Cauldbeck, O'Connor, O'Connor, Saunders, Rao, Mallesh, Kotehalappa, Kumar, Mamtha, McGoldrick, Laing & Satish (2009:3) found out an overall medication adherence rate of 60.4% in adult HIV infected patients in India. A cross sectional analysis of 198 HIV-infected Indian patients also found about 50% of the participants had >95% adherence to ART (Venkatesh, Srikrishnan, Mayer, Kumarasamy, Raminani, Thamburaj, Prasad, Triche, Solomon & Safren 2010:799).

### **2.6.3 Adherence in Ethiopia**

Some studies have investigated the level of adherence to antiretroviral treatment and factors associated with non adherence in Ethiopia. Literature review demonstrated the rate of adherence to antiretroviral therapy in Ethiopia seems to be comparable to the findings in most of the SSA countries, and even better than those cited in some developed countries. A cross-sectional study investigated the level of adherence among 291 PLHIV taking antiretroviral medication in Yirgalem hospital, Southern Ethiopia. The investigators used self patient report and pill counts as a measure adherence. The findings showed that 72.8% of the study participants were found to be adherent in the week before the assessment and 26.1% did not follow treatment schedule and 5.5% did not follow instructions (Markos, Worku, & Davey 2008:176). Another cross-sectional study that evaluated adherence among 504 HIV infected patients on in North West Ethiopia in Gonder Univesity and Felege Hiwot hospitals, revealed 82.7% of the patients reported taking >95% of their prescribed doses of treatment (Tessema, Biadlegne, Mulu, Getachew, Emmrich & Sack 2010:5). A prospective study conducted in Jimma University hospital, South West Ethiopia demonstrated the rate of self reported adherence based on the combined indicator of the three adherence errors (dose, time and food adherence) was 79.3% at baseline and 75.7% at follow up visit at third month (Amberbir, Woldemichael, Getachew, Girma & Deribe 2008: [S.a]). This also suggested that adherence behaviour is dynamic and can vary over time.

Similarly another cross-sectional study conducted among 319 adult PLHIV in the same setting with self report adherence in a one week recall based on combined indicator. The combined indicators include self reported missed doses, self reported schedule/time

adherence and self reported food adherence. Accordingly, 303(95%) of the study subjects were adherent based on self report of missed doses (dose adherence) in a one-week recall. Two hundred fifty five (79.9%) of the study subjects always follow the schedule/ time restrictions (time adherence) agreed upon with their providers and 286(89.7%) follow dietary instruction (Food Adherence). Hence, the overall rate of self reported adherence in the study area based on the combined indicator of the dose, time and food adherence measurement was 231(72.4%) (Tiyou et al 2010:3-4).

Although studies demonstrated a comparable finding in the rate of adherence to antiretroviral therapy, the adherence definition and the methods used in measurement of adherence in various studies both in developed and developing settings have been variable and pose challenges in appropriate comparison of adherence rates.

## **2.7 FACTORS THAT INFLUENCE ADHERENCE TO ANTIRETROVIRAL THERAPY**

A number of factors have been associated with non adherence to ART. Adherence is increasingly understood as a dynamic behaviour influenced by a matrix of interrelated factors that change over time. Understanding these factors can increase a clinician's attention to adherence when working with particularly susceptible patients and can inform the development of interventions to improve adherence. These factors are commonly divided into 5 intersecting categories: patient variables, treatment regimen factors, disease characteristics, patient-provider relationships and clinical setting. Many of these factors are modifiable, or at least partially modifiable, with appropriate interventions (Enriquez & Mckinsey 2011:46; Machtinger & Bangsberg 2006).

### **2.7.1 Patient factors**

Patient related variables include socio-demographic factors (age, gender, race/ethnicity, income, education, literacy, housing status, insurance status, HIV risk factors) and psychosocial factors such as mental health, substance use, social climate and support, knowledge and attitudes about HIV and its treatment (Machtinger & Bangsberg 2006).

### Socio-demographic factors:

Studies revealed inconsistent findings about the association of adherence behaviour with various socio-demographic factors. Some studies have demonstrated significant association of non adherence with certain socio-demographic factors such as low literacy or education, lower individual or family income, unemployment, not participating in any religious activities, poor living conditions and not having any health insurance plan (Bonolo, César, Acúrcio, Ceccato, Pádua, Álvares, Campos, Carmo & Guimarães 2005:S9; Campos, Guimarães & Remien 2010:293-294; Hegazi, Bailey, Ahadzie, Alabi, & Peterson 2010: 1342; Protopopescu, Raffi, Roux, Reynes, Dellamonica, Spire, Leport & Carrieri 2009: 602; Sullivan et al 2007:3; Tiyou et al 2010:4; Venkatesh et al 2010:800; Wasti et al 2012:72). Another study showed non adherence was associated with completing secondary school (Hansana, Sanchaisuriya, Durham, Schareun, Chaleunvong, Boonyaleepun, & Schelp 2013:5). However, a study conducted by Cauldbeck et al (2009: [S.a]) showed no association between literacy and individual or family income with adherence.

Studies also demonstrated variable results on the association of age and sex with adherence behaviour. Some studies revealed that younger age and female sex were significantly associated with low level of adherence (Beer et al 2012:218; Fumaz et al 2008:799; Nozaki, Dube, Kakimoto, Yamada & Simpungwe 2011:834; Ortego et al 2011:287; Sullivan et al 2007:3; Tapp, Milloy, Kerr, Zhang, Guillemi, Hogg, Montaner & Wood 2011:3-4; Wasti et al 2012:72). Another study also documented the difference in adherence between young and old cohorts (Barclay, Hinkin, Castellon, Mason, Reinhard, Marion, Levine & Durvasula 2007:45). But, other studies did not support any association of adherence with age and sex (Aragonés et al 2011:19; Birbeck et al 2009:672; Sarna et al 2008: 32; Sharma, Khadga, Dhungana, Chitrakar 2013:51; Venkatesh et al 2010:800). Other variables such as marital status, religion, education and occupational status were also not found to be associated with adherence (De & Dalui 2012:251). This indicates that it would be difficult to predict the adherence behaviour of patients based on the socio-demographic characteristics of patients.

### Psychosocial factors:

Psychosocial factors that are consistently associated with adherence include psychological distress, active drug or alcohol use, social support, knowledge and beliefs about HIV and its treatment (Machtinger & Bangsberg 2006). Depressive symptoms and stress have been correlated significantly with non adherence (Achappa, Madi, Bhaskaran, Ramapuram, Rao, & Mahalingam 2013:222; Amberbir et al 2008: [S.a]; Beer et al 2012:218; Protopopescu 2009:602; Royal et al 2009:452-453). Studies also indicated that the severity of depression and anxiety have significant influence on adherence to medications. Patients with severe depression were found four times more likely to report lower adherence than patients with minimal depression (Sarna et al 2008:32). A multivariate analysis in another study indicated that symptoms of severe anxiety were independently associated with non-adherence (RH=1.87, 95% CI=1.14–3.06;  $p < .05$ ). But, there was no indication of statistical association between severe depression and non adherence (Campos et al 2010:293).

The use of illicit drugs and alcohol consumption has also been significantly associated with low levels of adherence (Achappa et al 2013:222; Braithwaite & Bryant 2010:285; Campos et al 2010:293; Do, Dunne, Kato, Pham & Nguyen 2013:5; Fumaz et al 2008:799; Hansana et al 2013:7; Ortego et al 2011:287). A study identified the level of alcohol consumption as most important alcoholic factor to affect adherence (Parsons et al 2007:365). Another study also demonstrated significant association between daily alcohol consumption and non adherence (Protopopescu 2009:602). Smoking and alcoholic habits were also found to be associated with non adherence to ART (Bonolo et al 2005; Sharma et al 2013:51). Therefore, addressing issues related to substance abuse would have significant influence in the management of HIV infection and adherence to treatment.

Various studies have documented that inadequate knowledge and negative beliefs about HIV disease and treatment effectiveness present an important barrier to ART adherence (Amberbir et al 2008: [S.a]). Some other studies documented the association of knowledge about ART and adherence, benefits of ART and importance of adherence with adherence of patients to ART (Markos et al 2008:176; Gari, Doig-Acuña, Smail, Malungo, Martin-Hilber & Merten 2013:7). Moreover, a study conducted in India revealed the association of information on the importance of HAART with adherence of patients (Lal, Kant, Dewan, Rai

& Biswas 2010:181). It indicated that those who were not told about the importance of HAART were 9.2 times more likely to be non adherent compared to those who reported having being told about its importance. But, studies revealed that adherence-related information about one's regimen was related to adherence behavioural skills but not significantly directly associated with 3-day self reports of dose adherence. Thus, it appears that being well-informed did not necessarily imply high levels of adherence, but did relate to one's fund of behavioural skills, which was directly related to levels of ART adherence (Amico et al 2009:73). In support of this, a study by Do et al (2013:5) indicated the association of perceived quality of information with non adherence. Another study by Fumaz et al (2008:800), however, revealed lack of association between level of information and level of adherence.

The presence of social support from family members and/or friends has been repeatedly associated with better adherence. Patients with supportive friends and/or families tended to have better adherence to HAART than those without supportive friends (Aragonés et al 2011:19; Amberbir et al 2008: [S.a]; Jean-Baptiste 2008:19; Nozaki et al 2011:834; Protopopescu et al 2009:602; Tiyou et al 2010:4). On the contrary, social networks have been found to affect adherence due to spontaneous social activities or as a result of issues complicated by stigma, disclosure and non-supportive others in the patient's environment (Parsons et al 2007:359-360). A number of studies consistently demonstrated that fear of disclosure and social stigma and discrimination have significant association with non adherence (Achappa et al 2013:222; Birbeck et al 2009:672; Mills et al 2006b:2056; Nozaki et al 2011:834; Waite, Paasche-Orlow, Rintamaki, Davis & Wolf 2008:1369-70; Wasti et al 2012:75). Nonetheless, only few studies were unable to show significant association between adherence and social support (Sarna et al 2008:32).

#### Cognitive factors:

Accurate medication adherence has a number of cognitive components including comprehension of medication instructions, organization of the individual medication instructions into a medication plan and temporal sequence that integrates multiple medications and doses; retention of the medication plan, and, remembering to take the

medication at the planned time (Reynolds 2004:209). Forgetfulness has been found as the most common factor that affects adherence of patients in a number of studies (Achappa et al 2013:221; Ekama et al 2012:3; Markos et al 2008:176; Mills, Nachega, Bangsberg, Singh, Srachlis, Wu, Wilson, Buchan, Gill & Cooper 2006b:2056). Difficulty in understanding instructions has also been reported to affect adherence. Requirements and/or restrictions on the intake of food and water, or the temporal sequences of dosing can be confusing for patients (WHO 2003:100). A lack of understanding of treatment benefits was also found to be one of the consistent barriers to adherence both in developed and developing countries (Mills et al 2006b:2056).

### **2.7.2 Treatment related factors**

Treatment related factors consists of number of pills prescribed, the complexity of the regimen (dosing frequency and food instructions), the specific type of antiretroviral drugs, and the short- and long-term medication side effects (Machtinger & Bangsberg 2006). A number of studies have indicated the association of non adherence with increased number of ARV drugs (Aragonés et al 2011:19; Beer et al 2012:218; Protopopescu et al 2009:602; Sarna et al 2008:32; Sullivan et al 2007:3). However, Fumaz et al (2008:176) reported no difference between adherences of patients taking between once- or twice-daily regimens. The frequency of ARV doses and treatment schedule are also important factors related with adherence behaviour. Taking drug regimen more than twice a day was significantly associated with poor adherence (De & Dalui 2012:251). Patients taking fixed dose combination drugs also tended to have better adherence than those taking multiple combined ARV drugs (Jean-Baptiste 2008:19). Schedule fitting to daily routine (Markos et al 2008:176) and switching of ARV regimen (Bonolo et al 2005:S9) were also found to be associated with adherence to medication.

Antiretroviral drug adverse reactions have also been significantly associated with non adherence (Cauldbeck et al 2009: [S.a]; Markos et al 2008:176; Ortego et al 2011:287; Protopopescu et al 2009:602; Tessema et al 2010:5). The commonest side-effects causing non-adherence were metabolic reasons (66%) and GI symptoms (50%) (Cauldbeck et al 2009: [S.a]). The experience of side effects and its influence on daily activities and quality of life is known to have led to treatment fatigue and ART non adherence in many other



studies. Gastrointestinal adverse events of ART were the most frequently cited reason for discontinuation of ART. It is important to note that not all side effects are seen immediately after ART initiation. Long term side effects like lipodystrophy or dystrophy leading to central obesity and thinning of limbs due to prolonged use of stavudine may arouse community suspicion leading to stress and non adherence among patients who might be otherwise stable on ART (Sahay et al 2011:840).

### **2.7.3 Disease characteristics**

Disease characteristics include the stage and duration of HIV infection, associated opportunistic infections, and HIV-related symptoms (Machtiger & Bangsberg 2006). Studies demonstrated patients with baseline CD4 count of greater than 200 cells per micro litre had an increased risk of non adherence to ART (Beer et al 2012:216; Campos et al 2010:293; Sarna et al 2008: 32). Few studies did not found significant difference in CD4 cell count between different adherence levels (Fumaz et al 2008:799).

Inconsistent findings have been demonstrated on the association of clinical staging and adherence. The WHO clinical stage was found as an independent predictor of adherence in a study conducted in Ethiopia (Tiyou et al 2010:4). Another study demonstrated that patients with asymptomatic WHO clinical stages tend to have poor adherence (Campos et al 2010:293). In contrast, Ortego et al (2011:287) revealed patients with stage A tend to have greater adherence than patients with stage B or C. But, a study in Zambia showed WHO clinical stage at baseline not predictive of non adherence (Chi et al 2009:751).

Duration of time since knowing HIV status is also an important factor influencing adherence. A study in Rwanda revealed that adherent patients had known their HIV status for a short period of time than non adherent patients (Jean-Baptiste 2008:13). Another study also showed that increased number of years since HIV diagnosis to be independently associated with non adherence (Beer et al 2012:218). However, few studies demonstrated the absence of association between adherence and time of HIV diagnosis (Aragonés et al 2011:19; Lal et al 2010:181). Another factor that may influence adherence included duration of antiretroviral treatment. A study by Lal et al (2010:181) demonstrated significant association between times elapsed since starting HAART and adherence. For instance, a

study by Venkatesh et al (2010:799) showed patients who experienced HAART for more than two years tend to have lower adherence. In the contrary, a systematic review of studies, taking ART for more than two years was positively associated with adherence in high income countries (Gari et al 2013:7).

#### **2.7.4 Patient-provider relationships**

The interpersonal dynamics of the physician–patient relationship play an important role in determining a variety of patient outcomes including patient adherence to their treatment recommendations. Cohesive partnerships and effective interpersonal communication, encouragement of participation of patients in their own care, trusting relationship between patients and physicians are important components of patient-provider relationship which promote greater patient satisfaction with medical care, which in turn foster higher levels of adherence (Martin, Williams, Haskard & Di Matteo 2005:192-193). Moreover, the patient's opinion of the provider's competence, the affective tone of the relationship (warmth, openness, cooperation, etc), the concordance of race/ethnicity between patient and provider, and the adequacy of referrals may affect treatment adherence (Machtinger & Bangsberg 2006). Studies indicated lack of trust in their medical provider was a barrier for adherence (Curioso et al 2010:5). A study done by De and Dalui (2012:251) also emphasized the influence of negative attitude of health care providers on adherence behaviour of patients. This implies that smooth and effective interaction between patients and providers has been essential in supporting patients to achieve optimal adherence. Supportive communications, agreement with positive opinions on confidence in health care providers, and perceived quality of patient-provider relationship were also associated with better adherence (Aragonés et al 2011:19; Watt et al 2010:384).

#### **2.7.5 Clinical setting**

Aspects of the clinical setting that may influence adherence include access to ongoing primary care, involvement in a dedicated adherence program, availability of transportation and childcare, pleasantness of the clinical environment, convenience in scheduling appointments, perceived confidentiality, and satisfaction with past experiences in the health

care system (Machtinger & Bangsberg 2006). In a Meta analysis of adherence studies issues of access, including financial constraints and a disruption in access to medications were identified as a more common barrier to adherence in developing countries (Mills et al 2006b: 2056).

Although access to medication is essential for continuation of treatment, free access to medication was found to negatively affect adherence. On multivariate analysis patients receiving free ARVs were 4.4 times more likely to report lower adherence than patients paying out-of-pocket for ART (Sarna et al 2008:32). Patients' follow up status in relation to adherence needs also worth mentioning. Regular clinic follow up was found to be significantly associated with good adherence (Cauldbeck et al 2009: [S.a]). In another study, respondents who missed a clinic appointment were almost three times more likely to report poor adherence, compared with those who never missed a clinic appointment (Watt et al 2010:385). A study by Chalker, Andualem, Gitau, Ntaganiara, Obua, Tadeg, Waako, Ross-Degnan & INRUD-IAA (2010: [S.a]) also revealed attendance of patients within three days of appointment was associated with adherence to ART.

Several studies have also evaluated the reasons for non adherence to antiretroviral therapy. The most commonly cited reasons were forgetfulness, being away from home and being busy with other things (Hansana et al 2013: 5; Jean-Baptiste 2008:16; Markos et al 2008:176; Sullivan et al 2007:3; Tiyou et al 2010:4; Wang et al 2009:759; Wasti et al 2012:73-75; Watt et al 2010:384). Transport costs and financial problems were also mentioned in some studies as a reason for non adherence (Mills et al 2006b:2056; Wasti et al 2012:75). Studies also identified running out of medications (Wasti et al 2012:75; Tiyou et al 2010:4), avoiding side effects (Sullivan et al 2007:3; Tessema et al 2010:5; Wang et al 2009:759) and felt sick (Amberbir et al 2008: [S.a]) as barriers to adherence.

## **2.8 CONCLUSION**

This chapter discussed the literature review section which focused on access to antiretroviral therapy, adherence importance and consequences of non adherence, measurement of adherence, rates of adherence in various settings and complex of determinant factors to adherence. The next chapter described the research methodology section.

## **CHAPTER THREE**

### **RESEARCH METHODOLOGY**

#### **3.1 INTRODUCTION**

This chapter discusses the entire process and procedures of the research methodology used to undertake this study. It clearly described the research design and method used to conduct the study, the study population, sampling and sample selection techniques, data collection instrument and procedure, data analysis, the validity and reliability of the study, ethical considerations and limitations of the study.

#### **3.2 RESEARCH SETTING**

According to Polit and Beck (2003:164), research settings are the specific places where data collection takes place. This study was conducted in respective ART clinics of two randomly selected health facilities (Zewditu hospital and Bole 17 health center) in Addis Ababa. Zewditu Memorial Hospital was one of the pioneer public hospitals that started free ART service in Addis Ababa. With the decentralization of ART services to the health centre level, Bole 17 Health Centre launched ART program later. These two health facilities had enrolled a large number of people living with HIV receiving antiretroviral therapy in comparison to other hospitals and health centres. They provide comprehensive HIV prevention, care and treatment services. The study subjects were approached and recruited to participate in the study when they came to ART clinics for regular follow-up visits. The interview was conducted in a private room to make the participants comfortable and minimise any anxiety. The level of adherence was measured using self-report adherence in the past three days before the interview and assessed the factors affecting adherence using a questionnaire. In this study 20% of the study participants were found to be non-adherent to their anti-retroviral therapy.

#### **3.3 RESEARCH DESIGN**

A research design is described as a blue print for the conduct of a study that maximizes control over other factors that could interfere with the study's desired outcome (Burns &

Grove 2005: 40). A quantitative, cross-sectional, analytical study design was used to conduct this study. This design was found suitable to investigate the research questions in the study population. A quantitative data related to level of adherence in the past three days and factors affecting adherence was collected using structured questionnaire from study participants during the specified data collection period. Descriptive and analytic statistical analyses were computed to describe, summarize and analyse quantitative data and assess relationship between level of adherence and various determinant factors.

### **3.4 RESEARCH METHOD**

Research methods are the techniques used by researchers to structure a study and to gather and analyze information relevant to the research question (Polit & Beck 2012:12). In this study, the researcher clearly described the research methods that were used to conduct the study. These include defining the study population, the sample and sampling procedure, the sample size, the data collection process, and data analyses.

#### **3.4.1 Population**

A population is the entire aggregation of cases in which a researcher is interested. The accessible population is the aggregate of cases that conform to the designated criteria and that are accessible as a pool of subjects for a study. The target population is the aggregate of cases about which the researcher would like to make generalizations (Polit & Beck 2012:273-274). Babbie (2007:190) also describes a study population as that aggregation of elements from which a sample is actually selected. The population of this study consists of HIV infected adult patients who were receiving antiretroviral therapy in selected health facilities in Addis Ababa and who fulfilled the eligibility criteria for the study. The eligibility (inclusion) criteria included those who were older than 18 years, those who had been receiving antiretroviral therapy for at least three months, those who gave their consent to participate in the study, and those who were not involved in the pilot study. The accessible population were also those adult HIV infected adult patients who met the eligibility criteria and attended follow-up visits in the ART clinic of the selected health facilities during the period of data collection.

### **3.4.2 Sample, Sampling, and sampling procedures**

#### ***3.4.2.1 Sample and sampling***

A sample is referred to as a subset of population elements (Polit & Beck 2012:275). In this study, the sample for each health facility was drawn from the sampling frame of HIV infected adults receiving antiretroviral therapy who met the inclusion criteria. The samples were supposed to refill their ARV medications in the data collection period. The researcher used a systematic sampling technique to select the samples for the study. Accordingly, with the assistance of the staff in charge of the data in the ART clinics, a sampling frame was prepared from a list of eligible adult HIV infected patients on antiretroviral therapy using their unique ART number from computer data base. Then, the first sample and the sample interval were used to eventually establish the list of the sample of participants before data collection started. The sampling procedure is described in the next section.

#### ***3.4.2.2 Sampling procedure***

The sampling procedure was described as follows;

- At the beginning, the list of health facilities providing ART service in Addis Ababa was obtained from the national AIDS resource centre website. The two health facilities (Zewditu Memorial Hospital and Bole 17 Health Centre) were chosen randomly on convenience, since they had a large number of patients from the respective list of hospitals and health centres.
- A sample of participants in each of the health facilities was selected using a systematic sampling technique. And, a sampling frame for each facility was established from the list of HIV infected adults receiving ART fulfilling the eligibility criteria. The study participants were sampled from a sampling frame of a list of eligible adult HIV infected patients on ART based on their unique ART identification numbers, which were generated from a computer data base. Medical record numbers were used in some patients transferred from other health facilities who did not have unique ART numbers.

- The first sample, as a starting point, was selected randomly from the first ten eligible patients from the ordered list of sampling frame. A proportionate number of the total sample size was determined for each of the facility depending on the number of ART clients receiving treatment in these facilities. With this, from a total of 300 sample size, the proportionate number allocated for the hospital and health centre was 240 (80%) and 60 (20%), respectively. Then, the sampling interval was calculated by dividing population size by the sample size for each facility. Finally, every 26th HIV infected adults on ART from the sampling frame was identified and selected for participation in the study in the respective health facilities.

### **3.4.2.3 Sample size**

The researcher determined the sample size of this study using a precision of 5% and 95% confidence interval by the following formula,

$$N = p(1-p) z^2 / d^2;$$

Where  $p$  = estimated proportion of patients adherent to ART,

$z$  = the cut off value of the Normal distribution, and

$d$  = the precision required on either side of the proportion.

A pooled estimate of adherence to antiretroviral therapy in Sub-Saharan Africa was found to be 77% (Mills et al 2006:679). Therefore, assuming an adherence rate of 77%, the total sample size for this study was calculated to be 300, using a precision of 5% and 95% confidence interval. Considering loss to follow-up, transfer, death, and non-willingness, 10% of the sample size was added to the total sample size.

### **3.4.3 Data collection Procedures**

The procedure followed during the data collection process was described as follows. The researcher obtained ethical clearance from UNISA and Addis Ababa City Administration Health Bureau. A support letter from the health bureau was submitted to the management of the health facilities and permission was granted to collect data in the ART clinics. The

researcher approached the staff in charge of the data in the ART clinics to access the data of ART users in the computer with their direct assistance. As previously mentioned, the list of potential study participants was sampled from each health facility.

The researcher trained and deployed two data collectors to gather data from the study participants. The data collectors were trained on the objective of the study, applying the ethical aspects, obtaining informed consent, ethically treating the study participants based on their willingness, and how to complete the questionnaires and keep the completed questionnaires confidential. The data collectors also signed a confidentiality pledge form (See annexure D) to ensure confidentiality of the data. The researcher provided the consent form and the questionnaire prepared in Amharic and the necessary stationary materials to the data collectors.

With the assistance of the staff, the researcher found a room in each of the facilities for the data collectors to interview the study participants in private. The list of study participants was used to identify the patients when they came to the ART clinic to pick up their ARV medications during the data collection period. The nurses facilitated the referral of the study participants who were willing to participate in the study to the data collectors. The data collectors explained the purpose of the study and read the written consent form to the study participants, and then a written informed consent was obtained from a participant when he/she was willing for participation. However, those study participants who can write and read were given the consent form and they were allowed to complete it by themselves. Following this, the data collectors interviewed the participants within the allocated schedule. The average time utilized for the interview was 25 minutes for each participant. Since the researcher wanted to minimize biases, as the data collection took place in the health facilities, the data collectors were told not to wear gowns so that the participants could provide genuine responses during the interview. The researcher close supervised the process and provided support to the data collectors to ensure the data collection was done properly. Finally, the completed questionnaires were collected and reviewed in a timely manner by the researcher.



### **3.4.3.1 Data collection approach and method**

The data collectors gathered data by interviewing the study participants using a pre-tested structured questionnaire. But some participants preferred to complete the questionnaires themselves with the assistance of the data collectors. The interview was conducted in Amharic, which is the national local language widely spoken in Ethiopia. Joubert and Ehrlich (2007:107) state that in a structured interview, the interviewers follow a clearly structured format to prevent themselves from placing their own interpretation of the questions. They ask questions in a standard way, with the same probes and clarifications for each respondent and record their verbal response in a uniform way. This standardization increases the reliability of the information obtained.

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

The researcher developed the structured questionnaire after thoroughly reviewing the literature aiming to gather relevant information to assess adherence to antiretroviral therapy and its various determinant factors. A supervisor, three experts on the field of study, and a statistician had assisted in the development and refinement of the questionnaire. Most of the items of the questionnaire were adapted from the widely used the Adult AIDS Clinical Trial Group (AACTG) adherence questionnaire and the Life Windows Information-- Motivation -- Behavioural Skills ART Adherence Questionnaire (LW-IMB-AAQ) with some modifications to fit the context of the research setting. The rest of the items were synthesized through reviewing other relevant literature. Most of the questions were closed-ended. The questionnaire was initially prepared in English and then later translated into Amharic, which is a commonly used local language in Ethiopia.

The questionnaire consisted of eight sections:

*Section 1:* Questions on demographic variables of respondents

These included age, sex, marital status, literacy status, occupation, religion, ethnicity and average family income.

*Section 2:* Questions related to the clinical condition of the patient

These included baseline and latest CD4 counts of patients, WHO clinical stage, duration of antiretroviral treatment, time since HIV diagnosis, and whether the patient was sick in the past one month or not.

*Section 3:* Questions related to the type of ARV regimen and level of adherence of the respondent

This section consisted of 9 items, most of which were adapted from AACTG adherence questionnaire. The respondents were asked to respond to the type of ARV regimen and frequency; and the number of missed doses in the past 3 days, in the past week and in the past month. The reviewed literature suggested that adherence can be assessed in the past three days, and modification on the number of days for recall of missed ARV doses was made. Patients were also asked whether they took their pills on specified times and in accordance with recommended food requirements by physicians. Besides, they were asked if they had a change of treatment regimen. Patients who missed their medications in the past one month were also asked about the possible reasons for missing doses of HIV medications.

*Section 4:* Questions related to knowledge about HIV disease and antiretroviral therapy

This section consisted of 10 items from 4.1 to 4.10. The items were adapted from the LW-IMB-AAQ adherence questionnaire. The respondents were asked to explain how HIV medications were supposed to be taken, what to do if a dose of HIV medication was missed, the problems with skipping HIV medications, the side effects of medications, if they thought skipping medications was okay as long as the patient felt healthy, how HIV medications worked in the body, if they knew medications would fail to cure if not taken as prescribed, if they felt they could live longer by taking HIV medications as prescribed, and the interaction of HIV medications with alcohol and other substances.

*Section 5:* Questions related to social support

The respondents were asked about disclosing their HIV status, having support from friends and/or family members, the frequency of support provided by their friends and/or family members in taking medications, and their satisfaction with the overall support provided by

their friends and/or family members. They were also asked if they used reminders for taking their medications.

*Section 6: Questions related to their perception on patient-provider relationships*

The respondents were asked whether they got appropriate information about HIV medications from health care providers, discussed problems related to taking HIV medications, were easily understood by HCPs on their problems, obtained help to solve their problems, and were satisfied with the overall support from HCPs.

*Section 7: Questions related to the clinical setting*

The respondents were asked about their belief on the confidentiality of their information, convenience with appointment schedules, missed clinic appointment frequently, shortage of ARV supply, and overall satisfaction with the health care service.

*Section 8: Questions pertaining to the use of substances by respondents*

The respondents were asked if they had ever used alcohol, cigarette or 'khat', and whether they had used substances in the past one month or not.

**3.4.3.3 Characteristics of the data collection instrument**

The researcher used a structured questionnaire to collect data. A questionnaire is a list of questions which are answered by the respondent and which give indirect measures of the variables under investigation (Joubert & Ehrlich 2007:107). Structured questionnaires are those questionnaires in which there are definite, concrete and pre-determined questions. The questions are presented with exactly the same wording and in the same order to all respondents. Resort is taken to this sort of standardization to ensure that all respondents reply to the same set of questions. The form of the question may be either closed or open but should be stated in advance and not constructed during questioning. They may also have fixed alternative questions in which responses of the informants are limited to the stated alternatives. Thus, a highly structured questionnaire is one in which all questions and answers are specified and comments in the respondent's own words are held to the minimum. They are simple to administer and relatively inexpensive to analyse (Kothari 2004:101).

#### ***3.4.3.4 Pre - testing of the data collection instrument***

The questionnaire was piloted in a small group (5% of the sample size) of HIV positive individuals on antiretroviral therapy before the actual data collection began. A pilot study is a small-scale version or trial run, designed to test the methods to be used in a larger, more rigorous study (Polit & Beck 2012:195). The purpose of pre-tests includes determining how much time it takes to administer the entire instrument package and whether participants find it burdensome. It also helps to identify parts of the instrument package that are difficult to read or understand or that may have been misinterpreted by them, to identify any instruments or questions that participants find objectionable or offensive, to determine whether the sequencing of instruments is sensible, and to determine if the measures yield data with sufficient variability (Polit & Beck 2012:296).

The data collection instrument was refined by incorporating constructive inputs from the pilot study. One problem observed during pilot study was that responses to some questions, especially those referring to the patient-provider relationship and clinical setting, were positively skewed as the data collectors were in white coat during the interview. The second one was that some patients were unable to provide data related to their clinical stage and CD4 counts.

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

In this study, the researcher took the necessary steps to ensure that ethical aspects were maintained during data collection. These include procedures to keep the privacy and dignity of the study participants and maintain the confidentiality of the data. Before the data collection started, a private room was arranged for interviewing the study participants. The data collectors explained the purpose of the study and obtained a written informed consent from the study participants. The consent form was translated into Amharic to make the study participants understand the purpose of the study. Participation in this study was completely voluntary, and data were collected from those study participants who were willing to participate in the study. The study participants were allowed to ask questions any time and they were told they could withdraw from the interview in case they were not comfortable. The questionnaires were anonymous with no personal identifiable information recorded. The interview took not more than 25 minutes per participant. While conducting the interview, psychological reassurance was provided to some patients who suffered from

different psychosocial problems, and some were referred to the ART providers when they were willing to get further counselling and support.

The researcher also emphasised on the confidentiality of the data. The data collectors were trained and made to sign a confidentiality pledge form to keep the data confidential. All the completed questionnaires were kept locked in filing cabinets, and the researcher gathered the completed questionnaires from the data collectors in time. No one was allowed to access the data.

#### **3.4.4 Data analysis**

Quantitative data analysis is the numerical representation and manipulation of observations for the purpose of describing and explaining the phenomena those observations reflect (Babbie 2007:405). Before data analysis, the data were cleaned, coded and entered into a computer. A statistician did the analysis of all the data using the latest version of SPSS statistical software. The data analysis incorporated both descriptive and inferential statistics. Descriptive statistics helps to describe data in more manageable forms. Inferential statistics assists researchers in drawing conclusions about a population from the study of a sample drawn from it (Babbie 2007:450).

Univariate analysis was made to describe and summarize basic characteristics of the participants using descriptive statistics such as percentages, means, median and standard deviations. The researcher also conducted bivariate analysis such as odds ratio, chi-square test and 95% confidence interval to examine the relationship between levels of adherence and the independent variables of categorical data. But for continuous variables independent t-test was computed to examine the relationship with the dependent variable. According to Babbie (2007:419), bivariate analysis refers to the analysis of two variables simultaneously for the purpose of determining the empirical relation between them. A P-value of less than 0.05 was considered for an association between dependent and independent variables to be statistically significant.

In addition, multivariate regression analysis was carried out to identify factors that are independently associated with low level of adherence to antiretroviral therapy. Multivariate analysis encompasses a range of statistical techniques which, on the basis of

mathematical models, can evaluate the inter-relationship of more than two variables, for example more than one dependent variable and/or more than one independent variable (Joubert & Ehrlich 2007:153). In binary logistic regression the dependent variable is a dichotomous one. The dependent variable is typically coded 1 to represent an event or a characteristic, and 0 to represent the absence of the event or characteristic (Polit & Beck 2012:449).

### **3.5 VALIDITY AND RELIABILITY OF THE STUDY**

According to Joubert and Ehrlich (2007:116), good quality of information is essential in order to ensure the soundness of study results. Although data quality can be checked by reviewing issues related to data collection process and respondents, a measurement instrument needs to be evaluated formally for its validity and reliability.

#### **3.5.1 Validity**

Validity refers to the extent to which a measurement instrument actually measures what it is meant to measure (Joubert & Ehrlich 2007: 117). Morgan et al (2005:50) also state that validity is concerned with establishing evidence for the use of a particular measure or instrument in a particular setting with a particular population for a specific purpose. The most common and useful classification schemes attempting to categorise the measurement of the underlying validity are content validity, face validity, criterion validity, and construct validity (Delpont in De Vos et al 2005:160).

*Face validity* deals with the superficial appearance or face value of a measuring instrument (Delpont in De vos et al 2005:161). The face value of the questionnaire was evaluated by professionals in the field of the research topic for its relevance to the area of interest and clarity for easy administration in data collection.

*Construct validity* involves the validity of inferences from the observed persons, settings, and cause-and-effect operations included in the study to the constructs that these instances might represent. One aspect of construct validity concerns the degree to which an intervention is a good representation of the underlying construct that was theorized as

having the potential to cause beneficial outcomes. Another concern was whether the measures of the dependent variable are good in the operationalization of the constructs for which they are intended (Polit & Beck 2012:237).

*Content validity* is concerned with the representativeness or sampling adequacy of the content of an instrument. In other words, a valid measuring device would provide an adequate or representative sample of all content, or elements, or instances of the phenomenon being measured. Content validity is established on the basis of judgement; that is, researchers or other experts make judgements about whether the measure covers the universe of facets that make up the concept (Delpont in De Vos et al 2005:161).

Although data collection instruments can be validated with any of the above-mentioned criteria, the researcher used face and content validity to enhance the quality of the questionnaire in this study. To ensure the content validity of the research instrument, the researcher designed the questionnaire by reviewing relevant literature to get a better understanding of the concepts in the area of interest. The questionnaire was also reviewed by a professional statistician, three senior experts in the area of the field, and the researcher supervisor for face and content validity. The researcher incorporated the valuable feedbacks to refine and enrich the questionnaire. All these people evaluated to what extent the items in the questionnaire measured adherence, how adequate and representative they are to indicate the factors that may affect adherence of patients to ARV medications and to what degree the phrasing of the items is free from ambiguity.

### **3.5.2 Reliability**

According to Joubert and Ehrlich (2007: 117), reliability implies the degree of similarity of the results obtained when the measurement is repeated on the same subject or the same group. Delpont in De Vos et al (2005:162) also defines reliability of a measurement procedure as the stability or consistency of the measurement. The reliability of the research questionnaire was enhanced by pretesting the instrument to ensure clarity, and by appropriately selecting and training data collectors to create a similar understanding of the questionnaire. Besides, data collection was undertaken with a strict supervision of the principal investigator. A statistician was also consulted for his assistance on evaluating the instrument for its reliability. In this study, the reliability coefficients (Cronbach's Alpha) of items for measuring knowledge about HIV disease and ART and patient-provider

relationship were found to be 0.75 and 0.82, respectively. The authors of LW-IMB-AAQ also demonstrated internal consistency for the information scale of adherence questionnaire to be 0.59. Amico et al (2009:71) in their study also revealed a moderate internal consistency to the same instrument as the items are expected to assess diverse aspects of ART information.

### **3.5.3 External and internal validity of the study**

External validity refers to the extent to which it can be inferred that relationships observed in a study hold true over variations in people, conditions, and settings, as well as over variations in treatments and outcomes (Polit & Beck 2012:250). Whereas, internal validity refers to the extent to which it is possible to make an inference that the independent variable, rather than another factor, is truly causing variation in the dependent variable (Polit & Beck 2012:244). To ensure the external validity of the research, the researcher used a probability sampling technique so that the selected participants were representative of the study population. Besides, adequate sample size was calculated to enhance the representativeness of the sample. Also, inferential statistics were calculated to draw conclusions about a population from the study of a population drawn from it.

### **3.6 ETHICAL CONSIDERATION**

The researcher took into consideration the fundamental principles of ethical research, which include justice, beneficence and respect for human dignity while conducting this study. The ethical consideration in respect to this particular research was discussed thoroughly in the first chapter. The data collectors clearly explained to the study participants what is expected from them and what to do if they decided not to proceed with the study. Whether to participate or not from the very beginning was the decision of the study participants, and they were assured that their refusal to participate in the study would have no consequences. The written informed consent form described very well what is needed and how study participants could respond. They were also told that they had the right to ask questions at any time and withdraw from the study under any circumstances. (Chapter One discussed this in more detail.)



### **3.7 CONCLUSION**

This chapter discussed thoroughly the methodology of the research including the study design, sample and sampling technique, developing a questionnaire, data collection procedure, data analyses, validity and reliability of the study and ethical considerations. The next chapter discussed the data presentation and discussion of the research findings.

## CHAPTER 4

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

#### 4.1 INTRODUCTION

The previous chapter thoroughly discussed the research design and the research methodology used to undertake this study. This chapter focuses on the data management and statistical analysis performed to summarize and present the research findings. The purpose of this study was to explore and describe the determinant factors affecting adherence to antiretroviral therapy among HIV-infected adult patients in Addis Ababa, Ethiopia.

The objectives of the study were to:

- describe the level of adherence of HIV infected adult patients to antiretroviral therapy in Addis Ababa;
- explore the determinant factors that could affect patients' adherence to their antiretroviral therapy;
- identify the association of socio-demographic and other patient-related factors with the level of adherence; and
- recommend appropriate interventions with regard to the ways of improving adherence of patients based on research findings.

#### 4.2 DATA MANAGEMENT AND ANALYSIS

The data collection was carried out from March to April 2013. A proportionate number of samples in relation to the number of HIV positive patients receiving antiretroviral therapy were allocated at the beginning of the data collection, thus 240 and 60 study participants were sampled in Zewditu Memorial Hospital and Bole 17 Health centre, respectively. The data was gathered by trained data collectors using a structured interview questionnaire in the two health facilities. Among a total sample size of three hundred participants, 290 (96.6%) were interviewed and these participants responded fully to the questionnaires after

they had been informed about the purpose of the research. The data was anonymous and kept with confidentiality in a secure place where no one was able to access it.

The questionnaire consisted of the following sections:

Section 1: Demographic characteristics of respondents

Section 2: Information on the clinical condition of patients

Section 3: The current type of ARV regimen and level of adherence of the respondent

Section 4: Respondents' knowledge about HIV disease and antiretroviral therapy

Section 5: Aspects related to social support

Section 6: Aspects of patient-provider relationships

Section 7: Aspects of the clinical care setting

Section 8: The use of substances by respondents

The data analysis was carried out using SPSS version 20.0 with the assistance of a statistician. The data was cleaned, coded and entered into the SPSS database. In the data analysis, descriptive statistics such as percentages, frequency distributions, mean, median and standard deviation were computed. Besides, bivariate analysis was performed using chi-square test and P-value to determine significance of association between adherence and independent categorical variables. For the continuous variables, independent t-test was calculated to examine the presence of statistically significant difference in the mean of the variable. Multivariate logistic regression analysis was computed to determine independent factors associated with adherence to antiretroviral therapy.

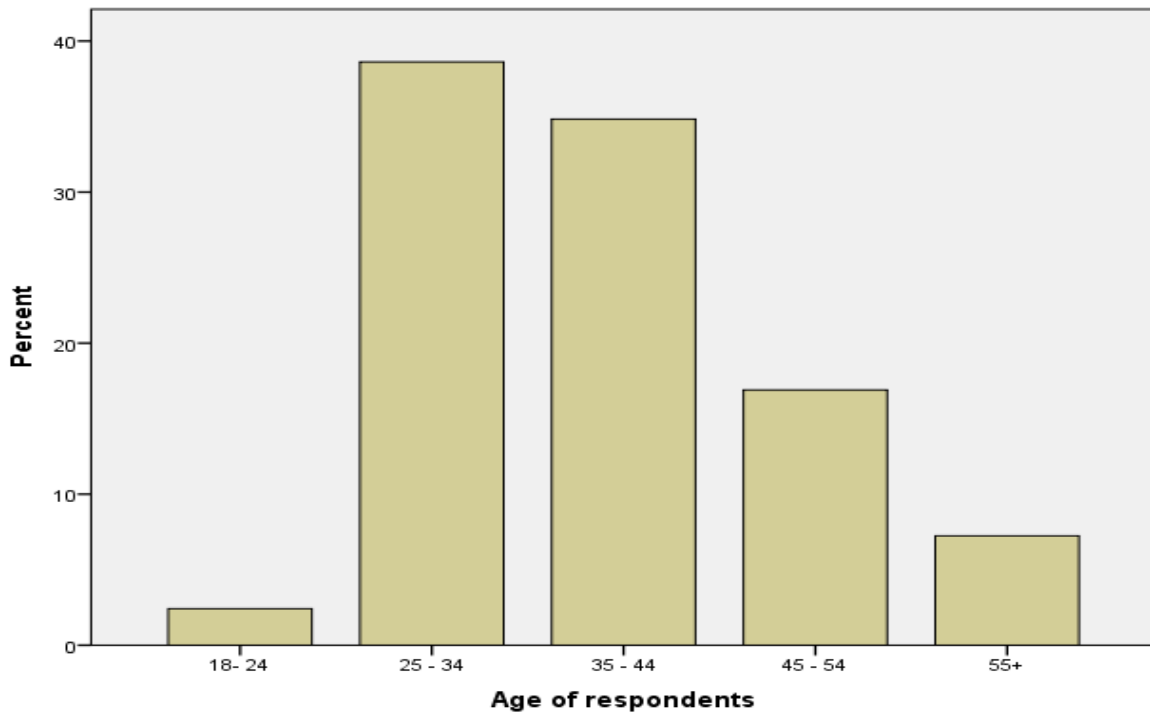
## 4.3 RESEARCH RESULTS

### 4.3.1 Demographic characteristics of the respondents

This section of the study presented the research findings on the socio-demographic characteristics of the respondents including age, sex, marital status, occupation, religion, ethnicity and average monthly family income.

#### 4.3.1.1 Age distribution of study participants

The age distribution of the study participants was illustrated in the following figure.



**Figure 4.1 Age distribution of study participants**

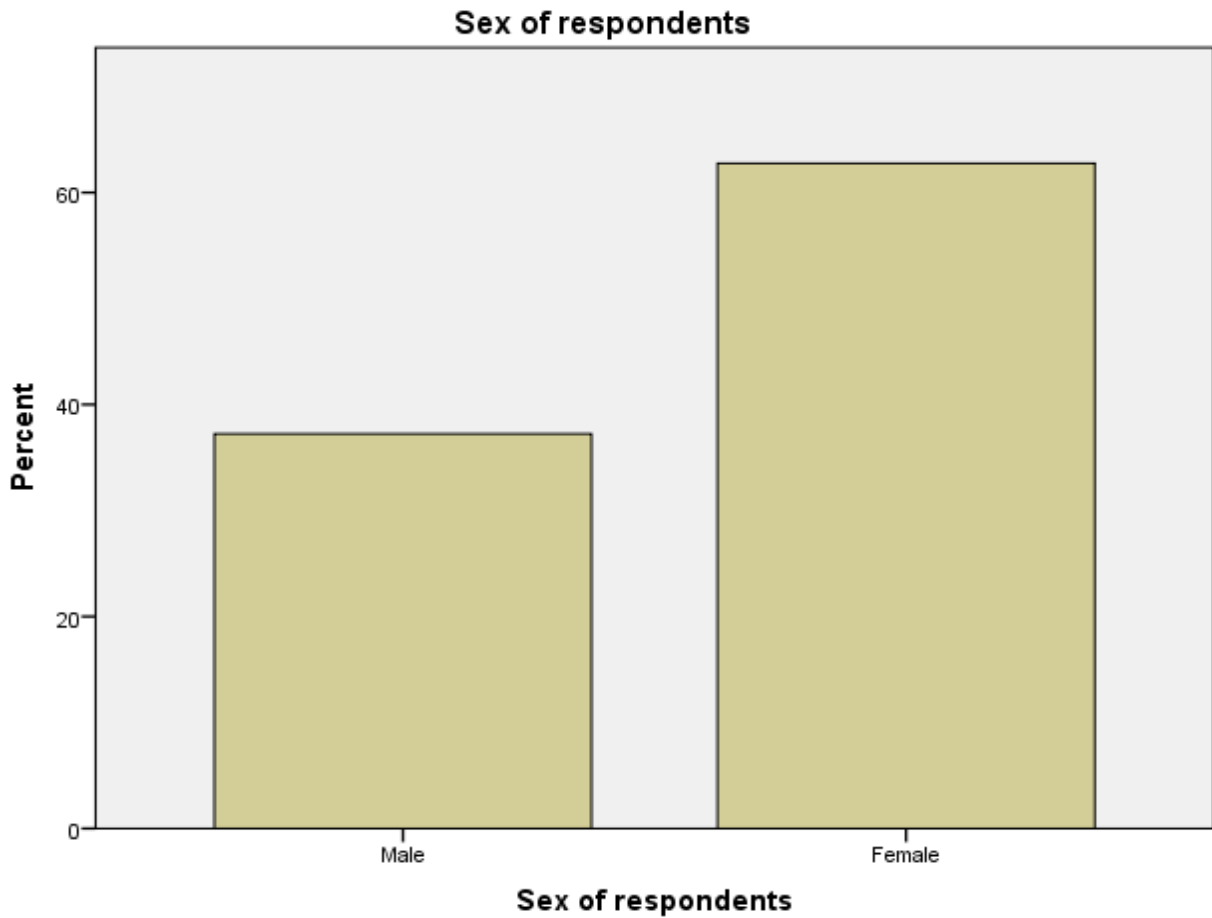
The age distribution of the respondents as displayed in Figure 4.1 indicates that 38.6% (n=112) of the participants were in the age group of 25-34 years, 34.8% (n=101) were between 35-44 years of age, 16.9% (n=49) were between 45-54 years of age, 7.2% (n=21) were 55+ years of age, and 2.4 % (n=7) were in the range of 18-24 years of age. This showed that the majority of the respondents in this study were comprised of younger age groups. The mean age of the respondents was 38 years and the range extends from 19 years to 71 years.

**Table 4.1 Association of age of study participants and combined adherence (N=290)**

Age group of study participants		Combined adherence		Total
		Optimal	Suboptimal	
18 – 24	Count	7	0	7
	% within age of participants	100.0	0.0	100.0
25 – 34	Count	93	19	112
	% within age of participants	83.0	17.0	100.0
35 – 44	Count	79	22	101
	% within age of participants	78.2%	21.8%	100.0
45 – 54	Count	38	11	49
	% within age of participants	77.6%	22.4%	100.0
55+	Count	15	6	21
	% within age of participants	71.4%	28.6%	100.0
Total	Count	232	58	290
	% within age of participants	80.0	20.0	100.0

Table 4.1 shows the association between the age of the participants and their combined adherence. In this study, there was no statistically significant association found between the age of respondents and their adherence to antiretroviral therapy ( $P=0.447$ ). This finding was in agreement with other similar studies which indicated lack of association between age and adherence (Aragonés et al 2011:19; Birbeck et al 2009:672; Sarna et al 2008: 32; Sharma et al 2013:51; Venkatesh et al 2010:800). In contrast, some other studies demonstrated a statistically significant association between age and adherence; that is, younger people tended to have lower adherence (Beer et al 2012:218; Fumaz et al 2008:799; Nozaki et al 2011:834; Ortego et al 2011:287; Sullivan et al 2007:3; Tapp et al 2011:3-4; Wasti et al 2012:72). A study conducted in Tanzania by Watt et al (2010:384) also revealed the association of age (being 19-30 years old or older than 51 years) with poor adherence. Barclay et al (2007:45) also compared the difference in the adherence rate of young and older participants, and the result showed that there was a statistically significant difference in the rate of adherence between the two cohorts.

#### 4.3.1.2 Gender distribution of study participants



**Figure 4.2 Distribution of study participants, by sex (N=290)**

The gender distribution of the participants in this study, as depicted in Figure 4.2, shows that 37.2% (n=108) of the participants were males and 62.8% (n=182) were females. This indicated that the majority of the participants interviewed in this study were females.

The relationship of gender status of study participants was shown in the following table.

**Table 4.2 Association of gender status of study participants and their combined adherence to ART (N=290)**

Gender status of study participants		Combined adherence		Total
		Optimal	Suboptimal	
Male	Count	83	25	108
	% within age of participants	76.9	23.1	100.0
Female	Count	149	33	182
	% within age of participants	81.9	18.1	100.0
Total	Count	232	58	101
	% within age of participants	80.0%	20.0%	100.0

The result in Table 4.2 revealed the relationship between gender and combined adherence to antiretroviral therapy. It indicated that among 108 males, 76.9% (n=83) reported optimal adherence and 23.1% (n=25) had suboptimal adherence. Of the 182 females who participated in the study, 81.9% (n=149) had optimal adherence while 18.1% (n=33) reported suboptimal adherence.

In this study, there was no statistically significant association found between the gender of study participants and their adherence to antiretroviral treatment ( $P=0.302$ ). This result is supported by other similar studies that revealed the lack of association between gender and adherence (Aragonés et al 2011:19; Birbeck et al 2009:672; Sarna et al 2008: 32; Venkatesh et al 2010:800; Sharma et al 2013:52). But, other studies reported contradictory findings in which females tended to be less adherent than males (Beer et al 2012:218; Fumaz et al 2008:799; Nozaki et al 2011:834; Ortego et al 2011:287; Sullivan et al 2007:3; Tapp et al 2011:3-4; Wasti et al 2012:72).

#### **4.3.1.3 Distribution of study participants, by marital status**

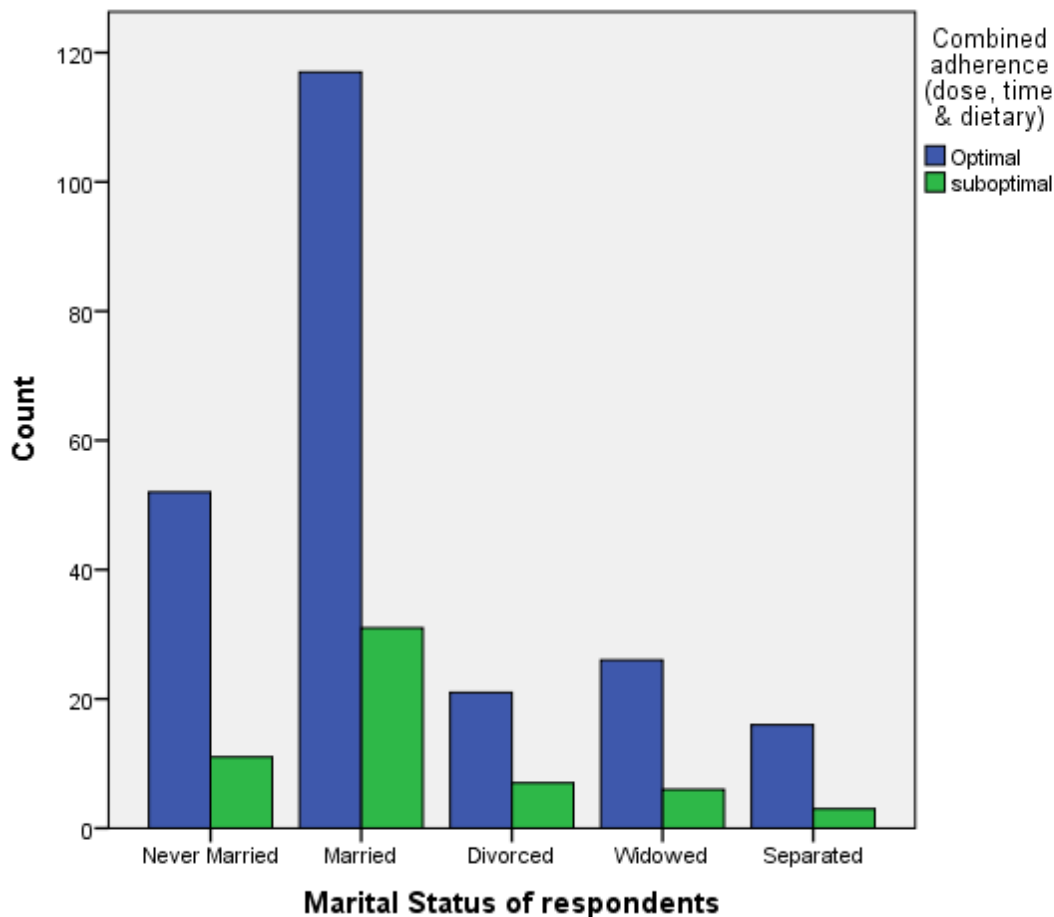
The study participants were asked to describe their marital status and the result was presented in the following table.

**Table 4.3 Distribution of study participants, by marital status (N=290)**

Marital status of respondents	Frequency	Percent
Never married	63	21.7
Married	148	51.0
Divorced	28	9.7
Widowed	32	11.0
Separated	19	6.6
Total	290	100.0

Table 4.3 depicts the marital status of the study participants. As can be seen, 51% (n=148) were married, 21.7% (n=63) were never married, 11.0% (n=32) were widowed, 9.7% (n=28) were divorced, and 6.6% (n=19) were separated. The majority of the study participants have been involved in marriage, which may have a vital influence in following their treatment properly.





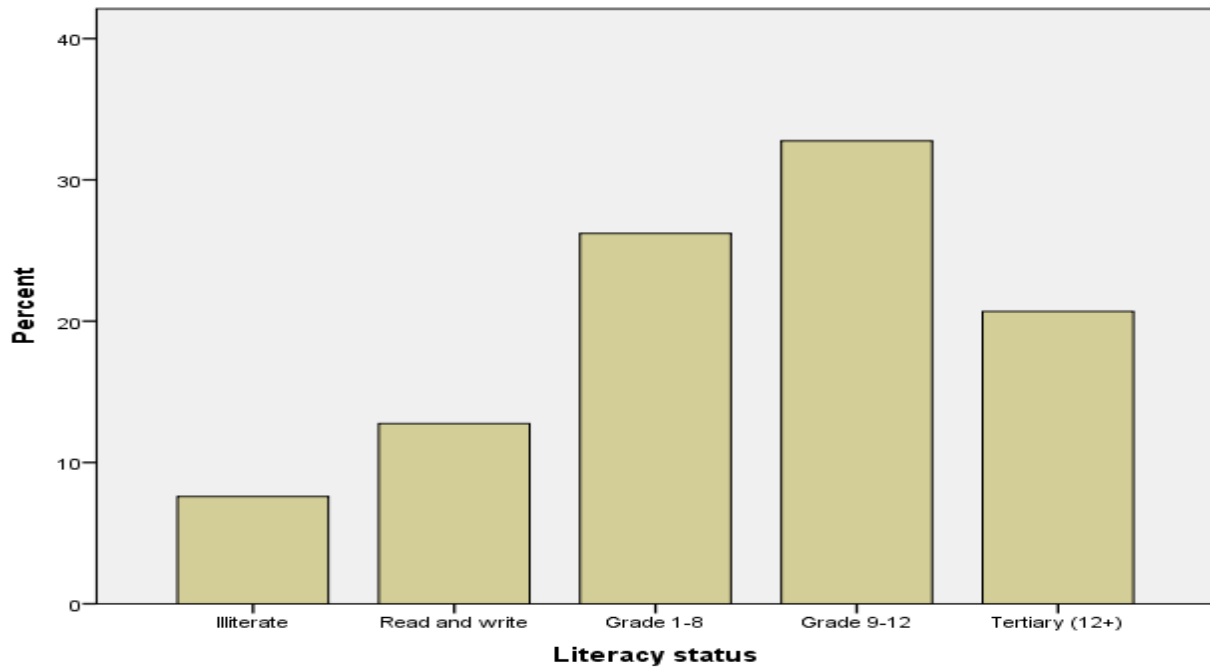
**Figure 4.3 Marital status of respondents and their adherence to antiretroviral therapy (N=290)**

Figure 4.3 depicts the marital status of the study participants with respect to their adherence behaviour. Out of 63 participants who were never married, 82.5% (n=52) and 17.5% (n=11) were found to have optimal and suboptimal adherence, respectively. Among 148 participants who were married, 79.1% (n=117) had optimal adherence and 20.9% (n=31) had suboptimal adherence. Among 28 participants who were divorced, 75.0% (n=21) had optimal adherence and 25.0% (n=7) had suboptimal adherence. Out of 32 participants who were widowed, 81.2% (n=26) reported optimal adherence and 18.8% (n=6) had suboptimal adherence. Among the 19 participants who were separated, 84.2% (n=16) and 15.8% (n=3) had optimal and suboptimal adherence, respectively.

In this study, the bivariate analysis revealed that no statistically significant association existed between marital status and self reported combined adherence to antiretroviral therapy (P=0.907). This finding was supported by the findings of other similar studies

(Birbeck et al 2009: 672; De & Dalui 2012:251). However, Watt et al (2010: 384) found out that having never been married was associated with lower rate of adherence.

#### 4.3.1.4 Distribution of study participants, by literacy status



**Figure 4.4 Distribution of study participants, by literacy status (N=290)**

As indicated in Figure 4.4, out of 290 study participants, 7.6% (n=22) were illiterate, 12.8% (n=37) were able to read and write only, 26.2% (n=76) had an elementary level of education (Grades 1-8), 32.8% (n=95) had a secondary level of education (Grades 9-12), while 20.7% (n=60) had a tertiary level of education (12+). This indicated that the majority of the study participants had formal education and had attained secondary level of education.

In this study, the bivariate analysis showed no statistically significant association between the literacy status of participants and their level of adherence to antiretroviral therapy (P=0.942). This finding was in agreement with studies conducted by Birbeck et al (2009: 672) and Caulbeck et al (2009: [S.a]), which reported that the literacy status of HIV infected patients was not statistically associated with their adherence to medication. On the contrary, Campos et al (2010: 293) revealed that lower education status was independently

associated with non adherence. Similarly, another study conducted in Tanzania also found out that patients with a lower level of education tended to have poor adherence (Watt et al 2010: 384).

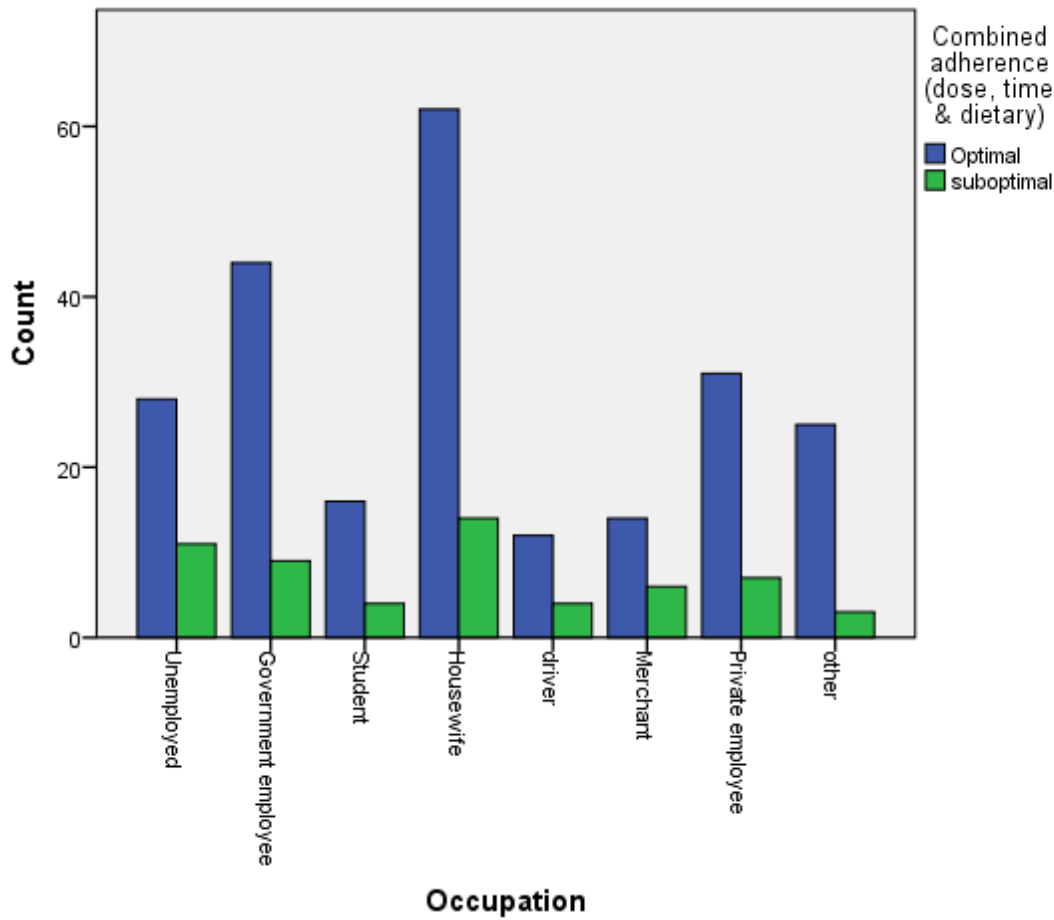
#### **4.3.1.5 Distribution of study participants, by occupation**

The occupational status of the study participants was assessed in this study, and the result was illustrated as follows.

**Table 4.4 Distribution of study participants, by occupation (N=290)**

Occupation	Frequency	Percent
Unemployed	39	13.4
Government employee	53	18.3
Student	20	6.9
Housewife	76	26.2
Driver	16	5.5
Merchant	20	6.9
Private employee	38	13.1
Other	28	9.7
Total	290	100.0

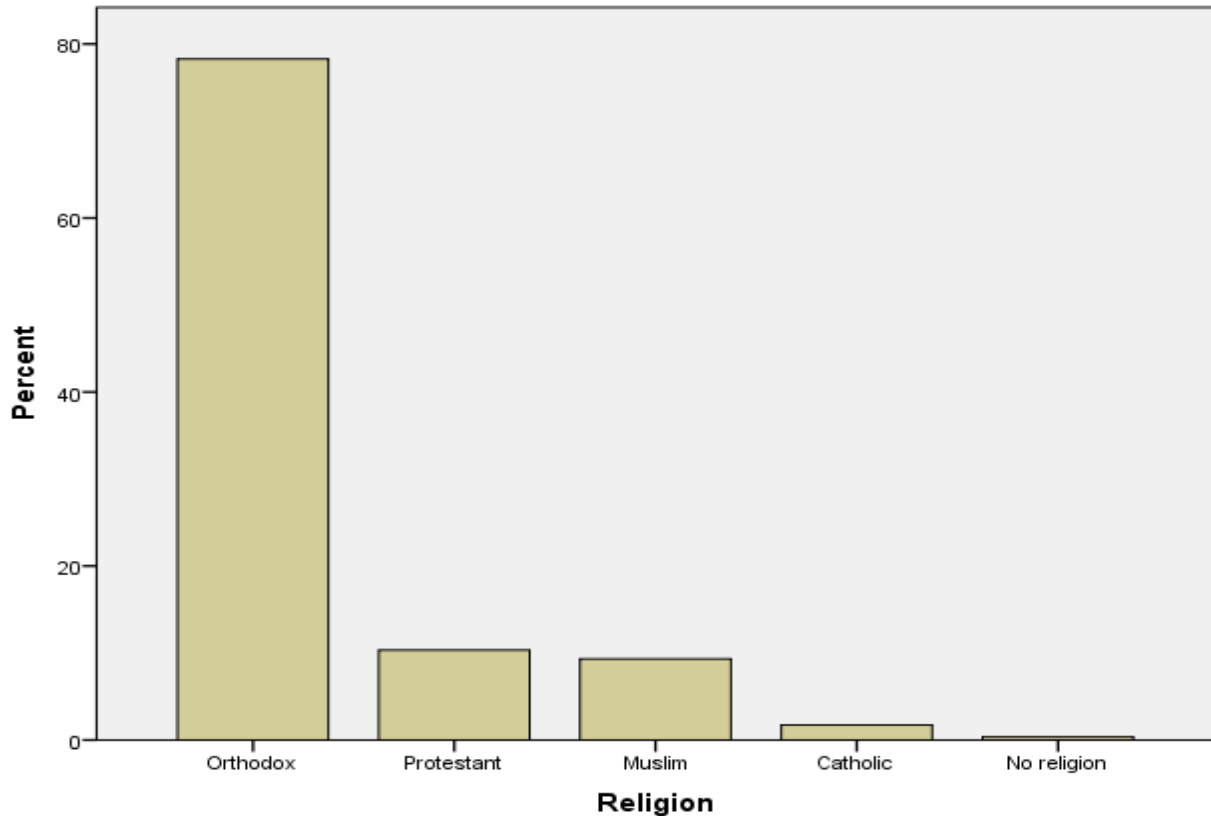
The finding on the occupational status of the respondents presented in Table 4.4 shows that out of a total of 290 participants, 26.2% (n=76) were housewives, 18.3% (n=53) were government employees, 13.4% (n=39) were unemployed, and 13.1% (n=38) were private employees. The rest were merchants (6.9%), students (6.9%), drivers (5.5%), and other occupations (9.5%).



**Figure 4.5 Occupational status of study participants and their adherence to ART (N=290)**

Figure 4.5 depicts the occupational status of the study participants in relation to their adherence to antiretroviral therapy. No statistically significant association was found between the occupational status of the respondents and their level of adherence to antiretroviral therapy (Fisher's Exact test=0.630). This implies that adherence behaviour of patients might not be influenced by the category of their occupation. However, other studies that examined the relationship between employment status and adherence to ART revealed that unemployment was associated with non adherence (Bonolo et al 2005:S9; Campos et al 2010: 293).

#### 4.3.1.6 Distribution of study participants, by religion



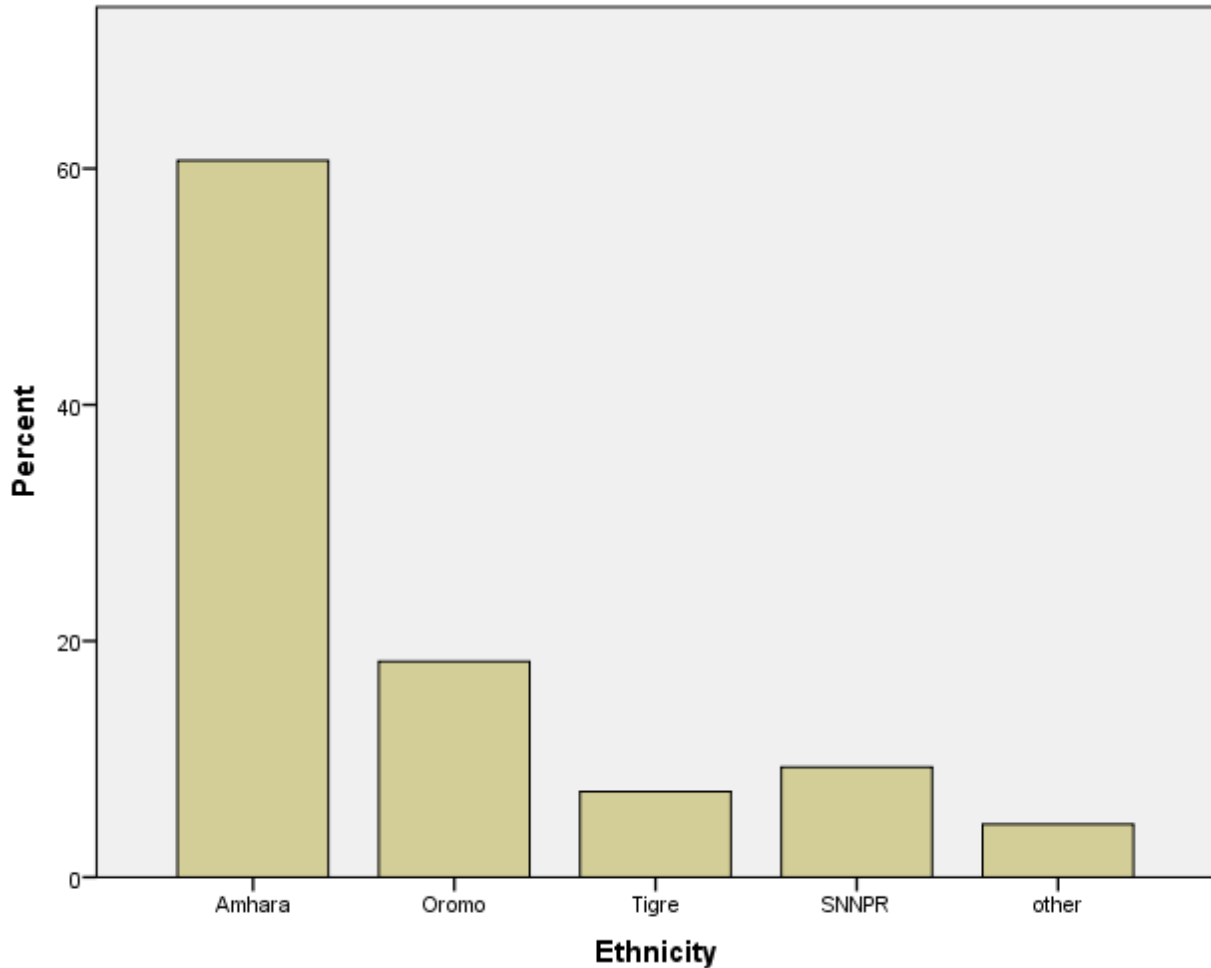
**Figure 4.6 Distribution of study participants, by religion (N=290)**

Figure 4.6 depicts the religion of the study participants. Out of the 290 study participants, 78.3% (n=227) were Orthodox Christians, 10.3% (n=30) were Protestants, 9.3% (n=27) were Muslims, 1.7% (n=5) were Catholics, and only 0.3% (n=1) had no religion.

The bivariate analysis in this study showed no statistically significant association between the religion of study participants and their combined adherence to ART ( $P=0.183$ ). This was consistent with other studies (De & Dalui 2012:251; Erah & Arute 2008:14), which indicated that religion was not associated with adherence to ART. However, a longitudinal study by Bonolo et al (2005:S9) reported that not participating in any religious activities was associated with non adherence.

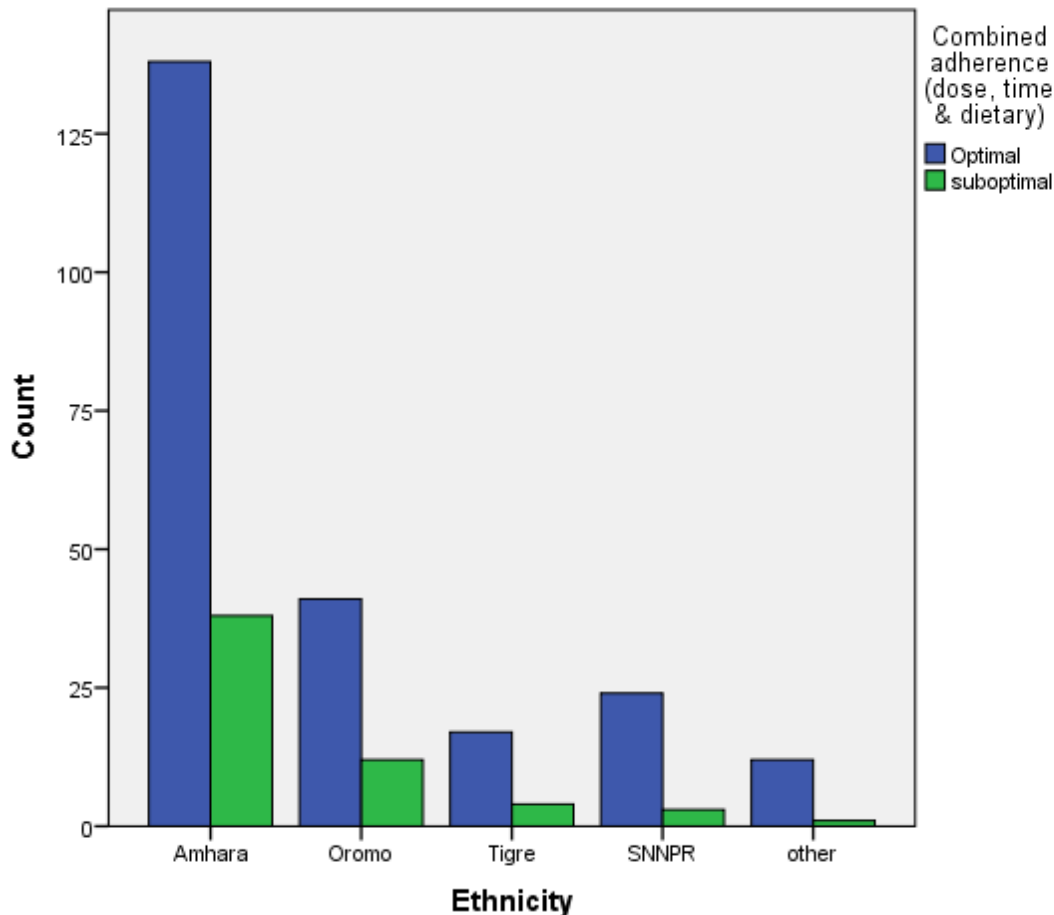
#### 4.3.1.7 Distribution of the study participants, by ethnicity

The study participants were asked to provide information about their ethnicity and the result was illustrated in the following figure.



**Figure 4.7 Distribution of study participants, by ethnicity (N=290)**

Figure 4.7 depicts the ethnic status of study participants. As can be seen, 60.7% (n=176) were Amhara, 18.3% (n=53) were Oromo, 9.3% (n=27) were Gurage, and the rest 4.4% (n=13) were categorized in other ethnic groups.



**Figure 4.8 Ethnicity of study participants and their combined adherence to ART (N=290)**

Among the 156 participants from the Amhara ethnic group, 78.4% (n=138) had optimal adherence and 21.6% (n=38) had suboptimal adherence. Out of the 53 Oromo participants, 77.4% (n=41) and 22.6% (n=12) reported optimal and suboptimal adherence, respectively. Among the 21 Tigre participants, 81.0% (n=17) had optimal adherence and 19.0% (n=4) had suboptimal adherence. Out of the 27 participants from the SNNPR, 88.9% (n=24) reported optimal adherence and 11.1% (n=3) had suboptimal adherence. Out of the 13 participants categorised under 'others', 92.3% (n=12) and 7.7% (n=1) had optimal and suboptimal adherence to ART, respectively.

In this study, the bivariate analysis showed no statistically significant association between the ethnicity of the study participants and their level of adherence (Fisher's Exact test=0.616). However, some studies in developed countries indicated association between

non adherence and ethnicity. In a study conducted in the United States, Blacks and Hispanics were found to be less adherent than Whites (Beer et al 2012:218).

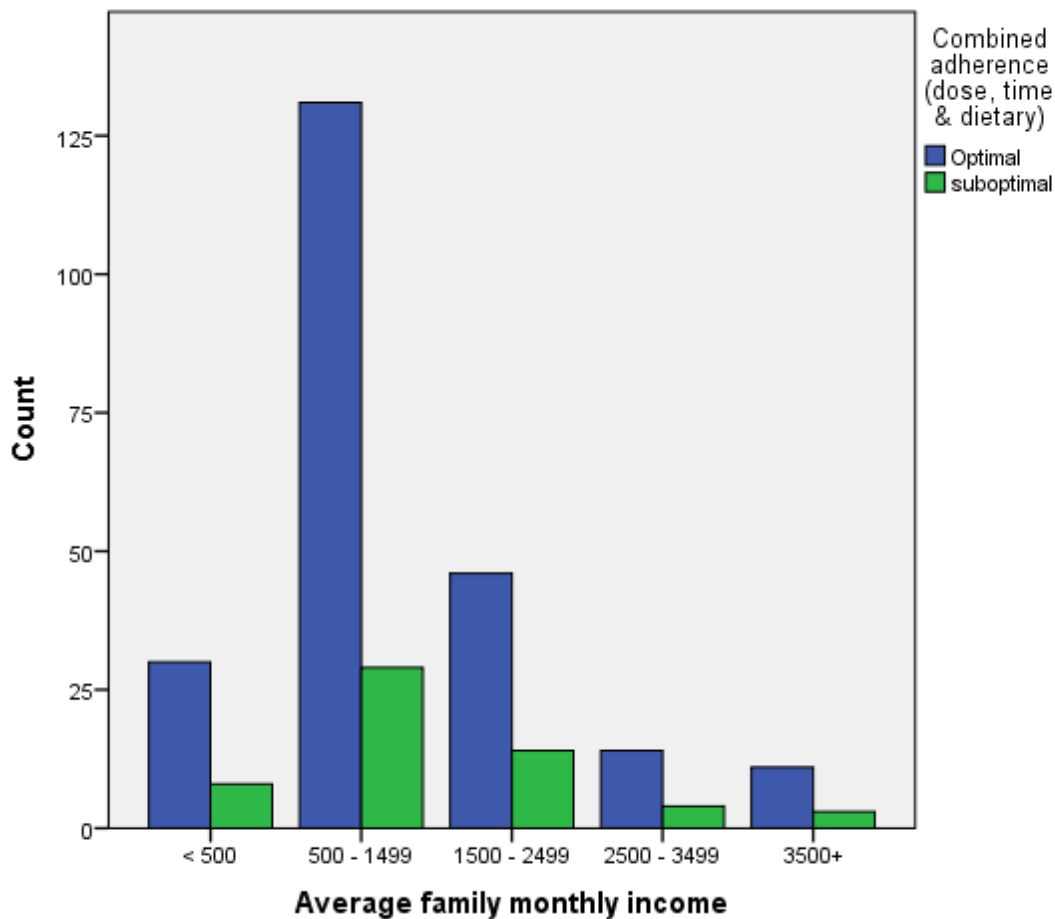
#### **4.3.1.8 Distribution of study participants, by average family monthly income**

**Table 4.5 Distribution of study participants, by average family income (N=290)**

Average family income (ETB)	Frequency	Percent
< 500	38	13.1
500 – 1499	160	55.2
1500 – 2499	60	20.7
2500 – 3499	18	6.2
3500+	14	4.8
Total	290	100.0

Table 4.5 depicts that among the 290 study participants, 55.2% (n=160) earned an average monthly family income between 500 and 1499 ETB, 20.7% (n=60) earned in the range of 1500-2499 ETB, 13.1% (n=38) earned less than 500 ETB, and only 4.8% (n=14) earned more than 3500 ETB. This showed that the majority of the study participants (68.0%) had an average monthly family income of less than 1500 ETB, which is too low to lead a reasonably decent life in the Ethiopian context.





**Figure 4.9 Average family income of study participants and their adherence to ART (N=290)**

Figure 4.9 depicts the average monthly family income of the study participants with respect to their adherence behaviour. It indicated that, among the 38 participants who got less than 500 ETB/month, 78.9% (n=30) had optimal adherence and 21.1% (n=8) had suboptimal adherence. Out of the 160 participants who got 500-1499 ETB per month, 81.9% (n=131) reported optimal adherence and 18.1% (n=29) had suboptimal adherence. Among the 60 participants who got 1500-2499 ETB per month, 76.7% (n=46) had optimal adherence and 23.3% (n=14) had suboptimal adherence. Out of the 18 participants who got 2500-3499 ETB per month, 77.8% (n=14) had optimal adherence and 22.2% (n=4) had suboptimal adherence. Among the 14 participants who got more than 3500 ETB per month, 78.6% (n=11) and 21.4% (n=3) had optimal and suboptimal adherence, respectively.

In this study, there was no statistically significant association found between average monthly family income and level of adherence to ART (Fisher's Exact test= 0.893). This

was in line with the study conducted by Caulbeck et al (2009: [S.a]), which showed individual or family income was not associated with adherence. Similarly, another study undertaken by Sarna et al (2008:32) also showed that adherence was not associated with economic status. However, the current finding is inconsistent with that of a study done in southwest Ethiopia, which observed that average family income was significantly associated with adherence to ART (Tiyou et al 2010: 4).

#### 4.3.2 Information regarding clinical condition of study participants

This section summarized the findings of the study on attributes related to the clinical condition of the study participants.

##### 4.3.2.1 Duration of time since diagnosed with HIV infection

The study participants were asked about the duration of time since they were diagnosed to have HIV infection. The result was depicted in the following figure.

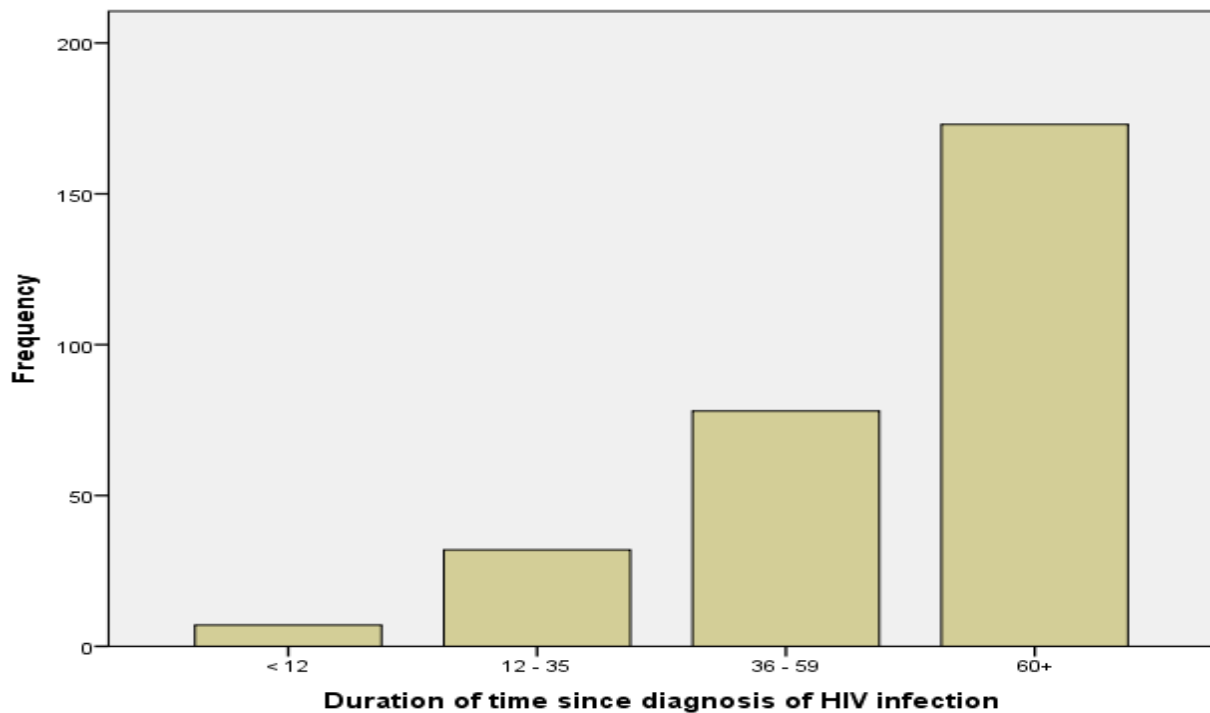


Figure 4.10 Distribution of study participants, by duration of time since HIV diagnosis (in months) (N=290)

Figure 4.10 shows that out of the total 290 study participants 2.4% (n=7) were diagnosed with HIV infection before 12 months, 11.0% (n=32) were diagnosed between 12 and 35 months before, 26.9% (n=78) were diagnosed between 36 and 59 months before, and 59.7% (n=173) were diagnosed 60 or more months before. The mean of duration of time that elapsed since the participants were diagnosed with HIV infection was 61.4 months and the range was 8 to 120 months. Thus, the majority of the study participants knew about their HIV status for a relatively long period of time.

The bivariate analysis of this study showed no statistical significant association between the duration of time of HIV diagnosis and combined adherence to ART ( $t = - 1.146$ ,  $P = 0.253$ ). This result was supported by studies conducted by Lal et al (2010:181) and Sarna et al (2008:32), which indicated that the length of time since the diagnosis of HIV infection was not associated with adherence to ART. On the contrary, Silva et al (2009:136) found out that the longer time that elapsed since HIV diagnosis, the greater the risk of non adherence.

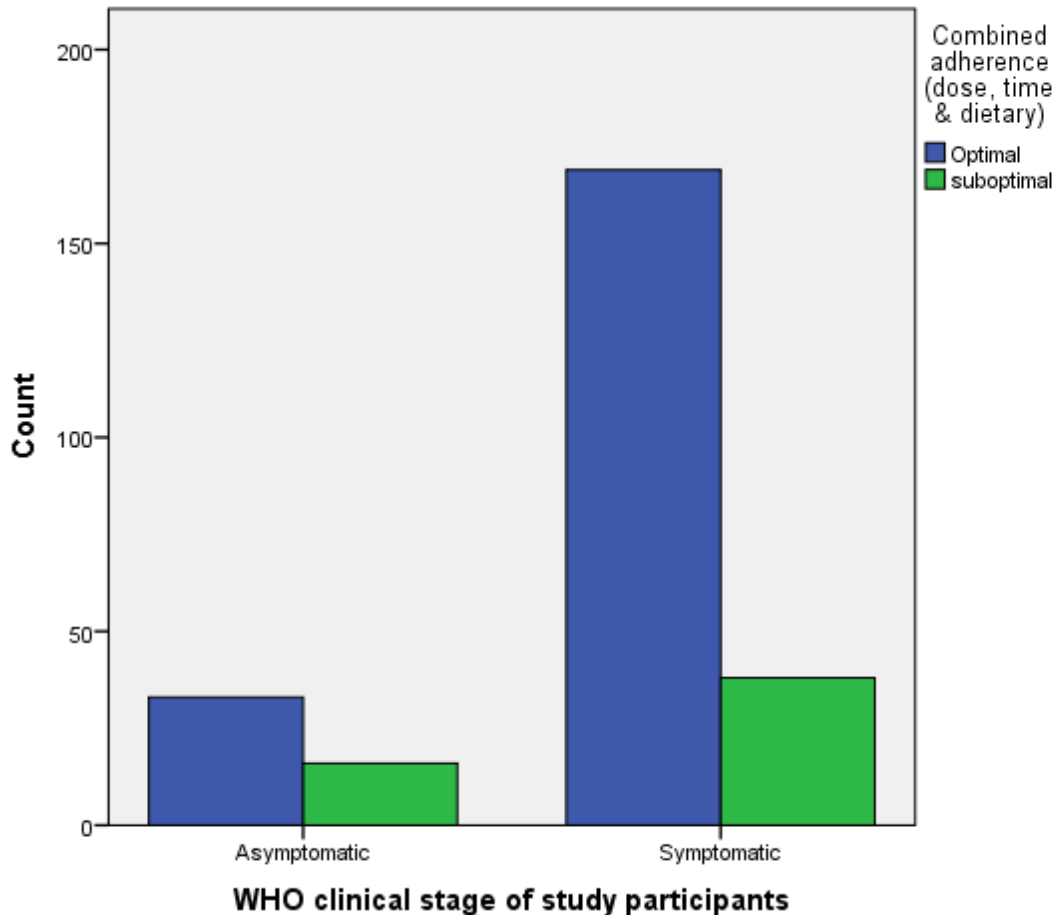
#### **4.3.2.2 WHO clinical stage of study participants at the time of ART initiation**

The WHO clinical stage of the study participants at the start of antiretroviral therapy was illustrated in the following table.

**Table 4.6 WHO clinical stage of study participants at the time of ART initiation (N=290)**

WHO clinical stage	Frequency	Percent
I	47	16.2
II	83	28.6
III	92	31.7
IV	32	11.0
Unknown	36	12.4
Total	290	100.0

Table 4.6 showed that, out of a total of 290 study participants, 16.2% (n=47) had stage I, 28.6% (n=83) stage II, 31.7% (n=92) stage III, and 11.0% (n=32) stage IV HIV disease before they started antiretroviral therapy. In other words, the majority of the study participants were symptomatic at the time of starting antiretroviral treatment.



**Figure 4.11 WHO clinical stage of study participants and their adherence to ART (N=290)**

Figure 4.11 depicts WHO clinical stages of the study participants, dichotomized into asymptomatic and symptomatic, in relation to their adherence to antiretroviral treatment. The result showed that, among a total of 49 study participants who were asymptomatic at the time of ART initiation, 67.3% (n=33) had optimal adherence and 32.7% (n=16) had suboptimal adherence. Out of the 207 study participants who were symptomatic, 81.6% (n=169) and 18.4% (n=38) demonstrated optimal and suboptimal adherence, respectively.

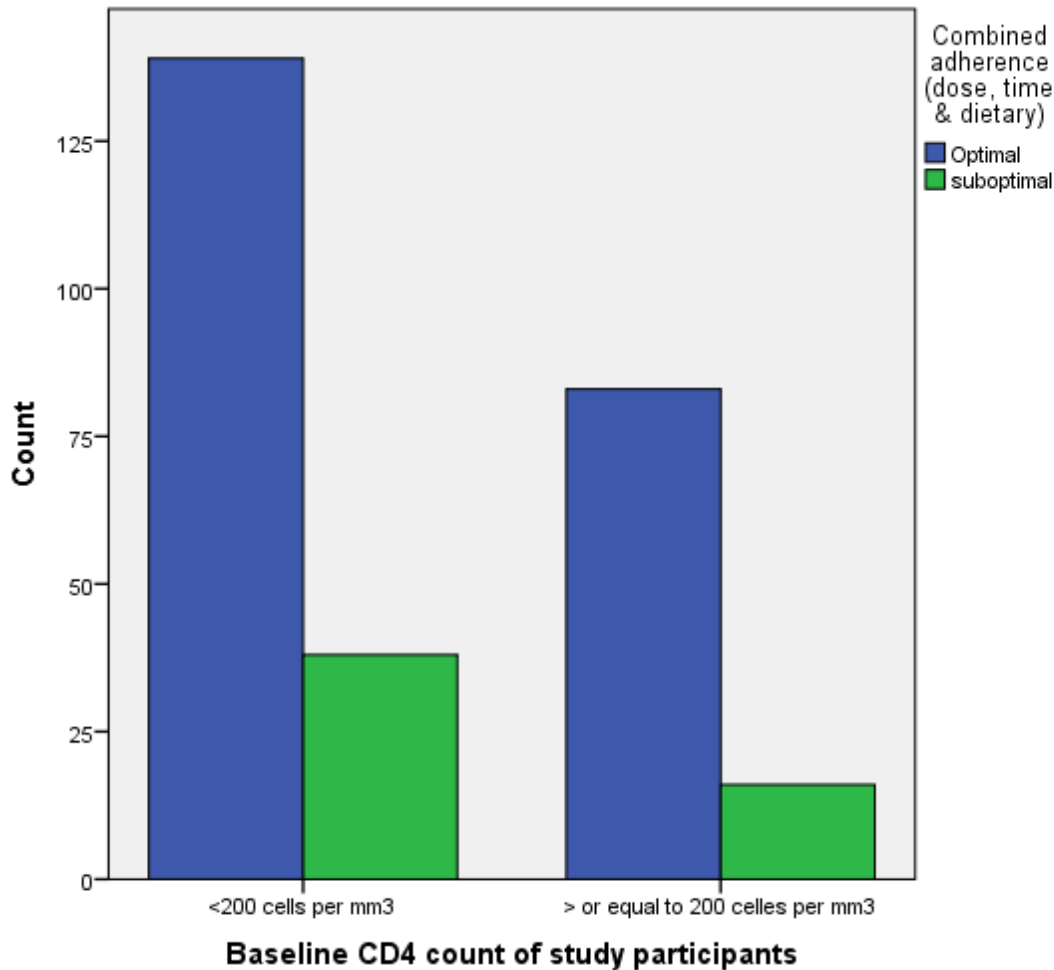
In this study, a statistically significant association was found between WHO clinical stage before initiation of antiretroviral therapy and combined adherence to ART ( $P=0.027$ ). This finding was supported by other similar studies conducted in resource-limited countries. A study conducted in Ethiopia revealed that WHO clinical stage was an independent predictor of adherence (Tiyou et al 2010:4). Similarly, Campos et al (2010:293) demonstrated those patients with asymptomatic clinical stage were more likely to have poor adherence. Despite the findings of the above studies, a study conducted in Zambia (Chi et al 2009:751) emphasized that WHO clinical stage was not predictive of non adherence.

#### **4.3.2.3 Baseline CD4 count of the study participants at the time of ART initiation**

**Table 4.7 Baseline CD4 count of study participants at the time of ART initiation (N=290)**

<b>CD4 count at baseline</b>	<b>Frequency</b>	<b>Percent</b>
<200 c/mm <sup>3</sup>	177	64.1
200 - 350c/mm <sup>3</sup>	87	31.5
>350c/mm <sup>3</sup>	12	4.3
Unknown	14	4.8
Total	290	100.0

As depicted in Table 4.7, the current study revealed that, out of the total 290 participants, 64.1% (n=177) had a baseline CD4 count of below 200 c/mm<sup>3</sup>, 31.5% (n=87) had a CD4 count between 200 and 350 c/mm<sup>3</sup>, 4.3% (n=12) had a CD4 count of greater than 350 c/mm<sup>3</sup>, and the other 4.8% (n=14) did not know their CD4 status at the time of ART initiation. This indicated that the majority of the study participants had a low level of immunological status at the beginning of their antiretroviral treatment. The fact that a significant number of the participants were symptomatic at the time of ART initiation may be associated with the low CD4 status before starting treatment.



**Figure 4.12 Baseline CD4 count and adherence to antiretroviral therapy (N=276)**

Figure 4.12 depicts the relationship between baseline CD4 count and adherence to antiretroviral therapy. It indicated that, among 177 study participants with a baseline CD4 count of less than 200 cells/mm<sup>3</sup>, 78.5% (n=139) had optimal adherence and 21.5% (n=38) had suboptimal adherence. And, out of the 99 participants with a baseline CD4 count of 200 cells/mm<sup>3</sup> and above, 83.8% (n=83) and 16.2% (n=16) had optimal and suboptimal adherence, respectively.

In this study, there was no statistically significant association found between baseline CD4 count and adherence to ART (P=0.286). This finding was in agreement with other studies (Fumaz et al 2008:799; Erah & Arute 2008:149), which revealed the absence of statistical difference between adherence of patients and their CD4 count. However, there were other contradictory findings in some studies which demonstrated a significant association between CD4 count of patients and adherence to ART (Beer et al 2012:216; Campos et al

2010:293). Another study (Sarna et al 2008:32) also indicated patients with a baseline CD4 count of 200 cells per mm<sup>3</sup> and above tended to have increased the risk of non adherence.

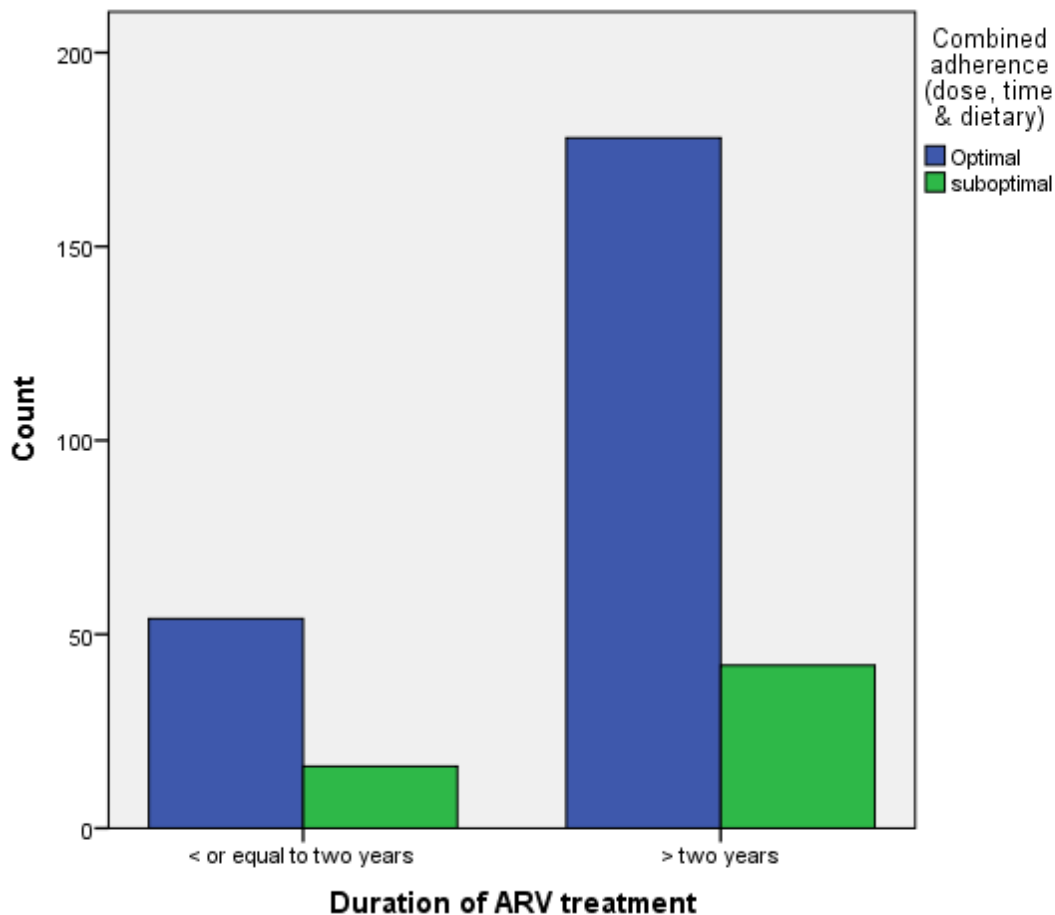
#### **4.3.2.4 Duration of antiretroviral therapy**

The study participants were asked about the length of time that had elapsed since they started antiretroviral treatment, and the result was displayed in the following table.

**Table 4.8 Distribution of study participants by duration of antiretroviral therapy (N=290)**

Duration of ART	Frequency	Percent
3 - 6 months	12	4.1
7 – 12 months	21	7.2
1-2 years	37	12.8
>2 years	220	75.9
Total	290	100

Table 4.8 shows, that out of the total 290 participants, 75.9% (n=220) had been on antiretroviral therapy for more than two years, while 12.8% (n=37) of the participants had received treatment for 1-2 years. It was also evident that 7.2% (n=21) of the participants had been on treatment for 7-12 months while the remaining 4.1% (n=12) had been taking antiretroviral therapy for 3-6 months. Thus, it can be said that the majority of the study participants had been treated for a relatively long period with antiretroviral therapy.



**Figure 4.13 Duration of ARV treatment and adherence to ART (N=290)**

Figure 4.13 shows that, among 70 participants who took antiretroviral treatment for two years or below, 77.1% (n=54) had optimal adherence and 22.9% (n=16) had suboptimal adherence to ART. Among the 220 study participants who took ART for more than two years, 80.9% (n=178) and 19.1% (n=42) reported optimal and suboptimal adherence, respectively.

In this study, there was no a statistically significant association found between duration of treatment and adherence to antiretroviral therapy ( $P=0.493$ ). This result was supported by Aragonés et al (2011:19), which showed lack of a significant association between number of years on ART and adherence. Consistently, Fumaz et al (2008:799) also revealed that length of time on treatment was not associated with level of adherence. However, other studies reported conflicting findings. Lal et al (2010:181), for instance, showed that duration of time on HAART was significantly associated with adherence. Venkatesh et al (2010:799)



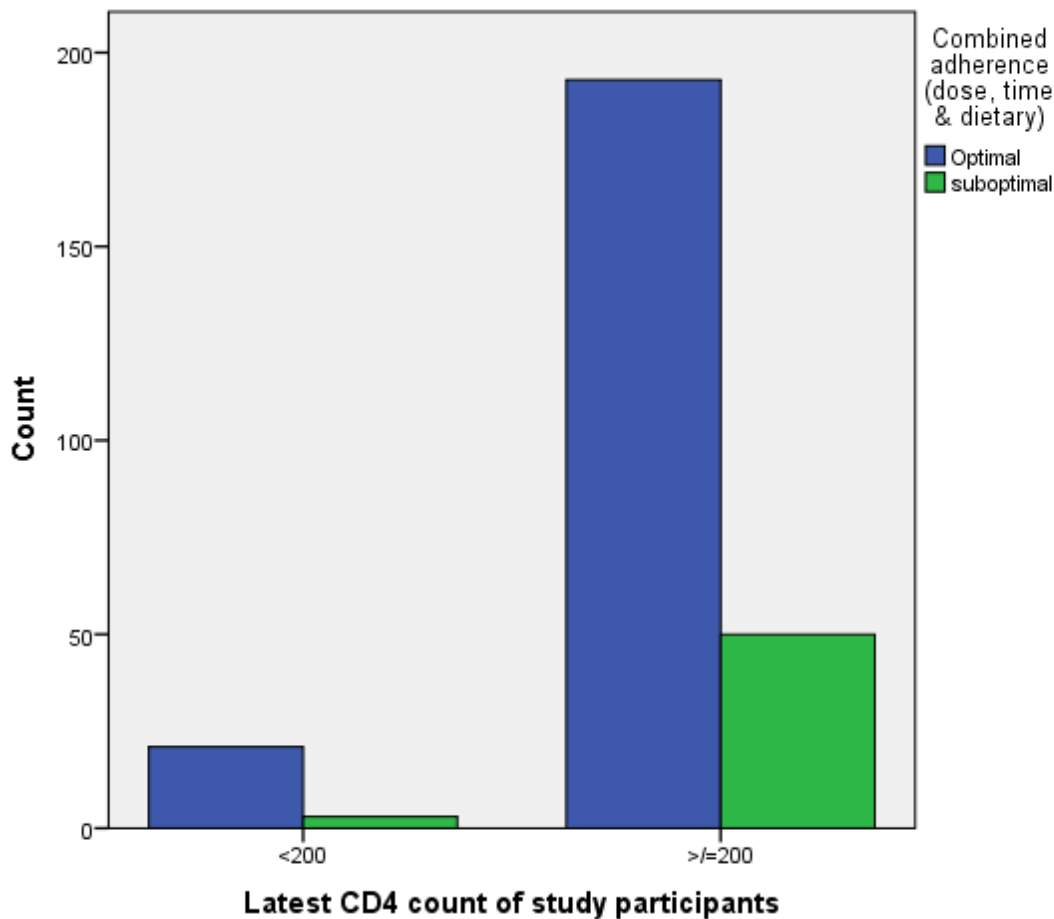
also reported that participants who had experienced HAART for greater than 24 months were more likely to be less adherent than participants who had been on HAART for less than 24 months. However, in a systematic review of studies, it was found that taking ART for more than two years was positively associated with adherence in high income countries (Gari et al 2013:7).

#### ***4.3.2.5 Latest CD4 count of the study participants who had been on treatment for a minimum of 6 months***

**Table 4.9 Latest CD4 count of study participants (N=267)**

Latest CD4 count	Frequency	Percent
<200 c/mm <sup>3</sup>	24	9.0
200 - 350c/mm <sup>3</sup>	133	49.8
>350c/mm <sup>3</sup>	110	41.2
Total	267	100.0

The latest CD4 status of the participants who had been receiving ART for a minimum of six months was assessed, and Table 4.9 revealed that 41.2% (n=110) had a CD4 count of greater than 350 c/mm<sup>3</sup>, 49.8% (n=133) had a CD4 count between 200 and 350 c/mm<sup>3</sup>, and 9.0% (n=24) had a CD4 count of below 200 c/mm<sup>3</sup>. The remaining 23 participants did not know their CD4 status. This finding indicated that the majority of the participants (83.8%) had a CD4 count of 200 c/mm<sup>3</sup> or more. Of these, 41.2% (n=110) had a CD4 count of above 350 c/mm<sup>3</sup>, which may be explained by the significant number of study participants having been taking antiretroviral treatment for more than two years.



**Figure 4.14 Latest CD4 count and adherence to ART (N=267)**

Figure 4.14 depicts the relationship between the latest CD4 count of study participants and their adherence to ART. It indicated that, out of 24 study participants with a CD4 count of below 200 cells/mm<sup>3</sup>, 87.5% (n=21) had optimal adherence and 12.5% (n=3) had suboptimal adherence. Among the 243 participants with a CD4 count of 200 cells/mm<sup>3</sup> and above, 79.4% (n=193) and 20.6% (n=50) demonstrated optimal and suboptimal adherence to antiretroviral treatment, respectively.

In this study, adherence to antiretroviral therapy was not found to be significantly associated with the latest CD4 count (Fisher's Exact test=0.431). This was in agreement with Fumaz et al (2008:799), which showed no difference in CD4 count of patients with different levels of adherence. But, Venkatesh et al (201:799) indicated that participants with current CD4 count greater than or equal to 500 cells/mm<sup>3</sup> were over two times more likely to be non adherent compared to participants with lower CD4 cell counts.

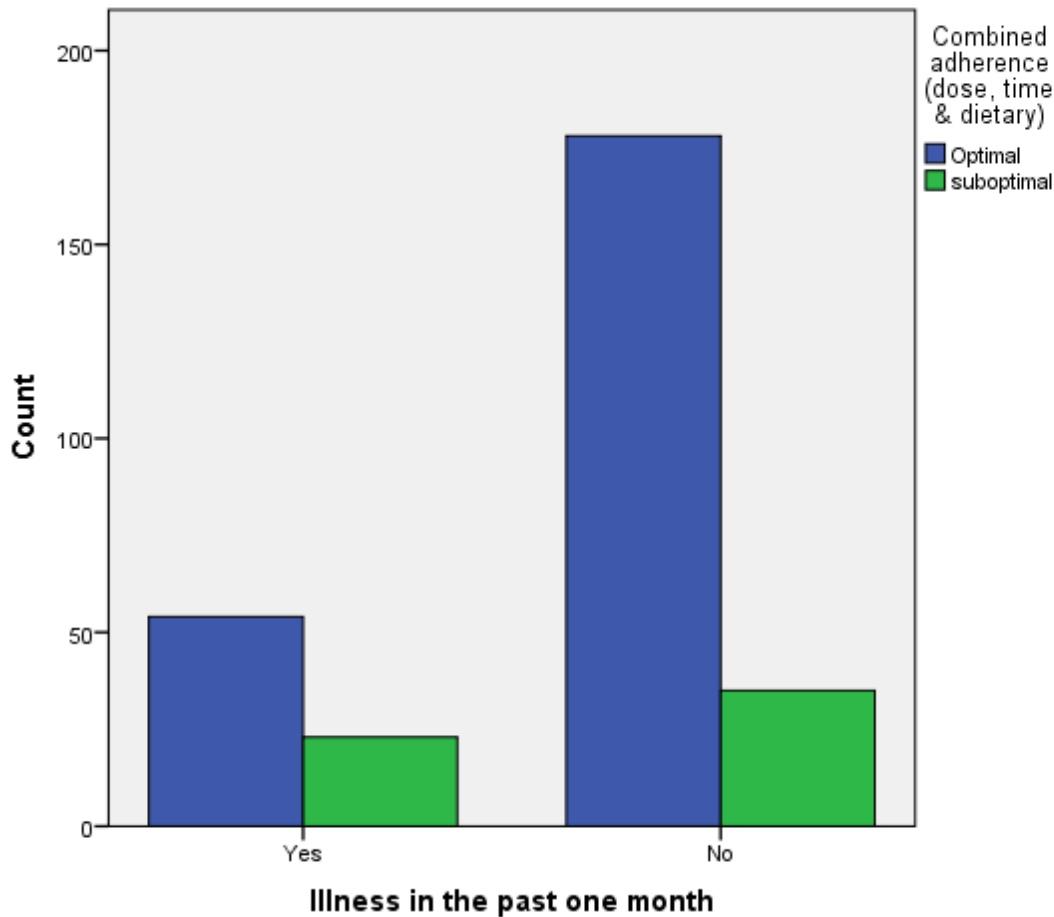
#### **4.3.2.6 Illness of the study participants during the past one month**

The study participants were asked whether they had been ill during the past one month, and the result was depicted in the following table.

**Table 4.10 Description of illness of study participants in the past one month (N=290)**

<b>Illness in the past one month</b>	<b>Frequency</b>	<b>Percent</b>
Yes	77	26.6
No	213	73.4
Total	290	100.0

Table 4.10 shows that, among 290 study participants, only 26.6% (n=77) suffered from illness during the past one month. The remaining 73.4% (n=213) did not complain of illness during the past one month. Majority of the study participants did not suffered from illness in the past one month which may be explained by progressive improvement in clinical condition of the patients with the use of antiretroviral therapy for long time.



**Figure 4.15 Illness in the past one month and adherence to ART (N=290)**

Figure 4.15 depicts the relationship between illness of study participants in the past one month and adherence to ART. It reveals that, among 77 study participants who reported illness in the past one month, 70.1% (n=54) had optimal adherence and 29.9% (n=23) had suboptimal adherence. On the other hand, among 213 study participants who were healthy in the past one month, 83.6% (n=178) and 16.4% (n=35) reported optimal and suboptimal adherence to ART, respectively.

In this study, there was a statistically significant association between adherence to ART and illness in the past one month ( $P=0.012$ ). This was consistent with Markos et al (2008:177), which documented presence of symptoms in the past month was associated with non adherence.

**4.3.2.7 Description of the seriousness of the illness by the study participants who were sick in the past one month**

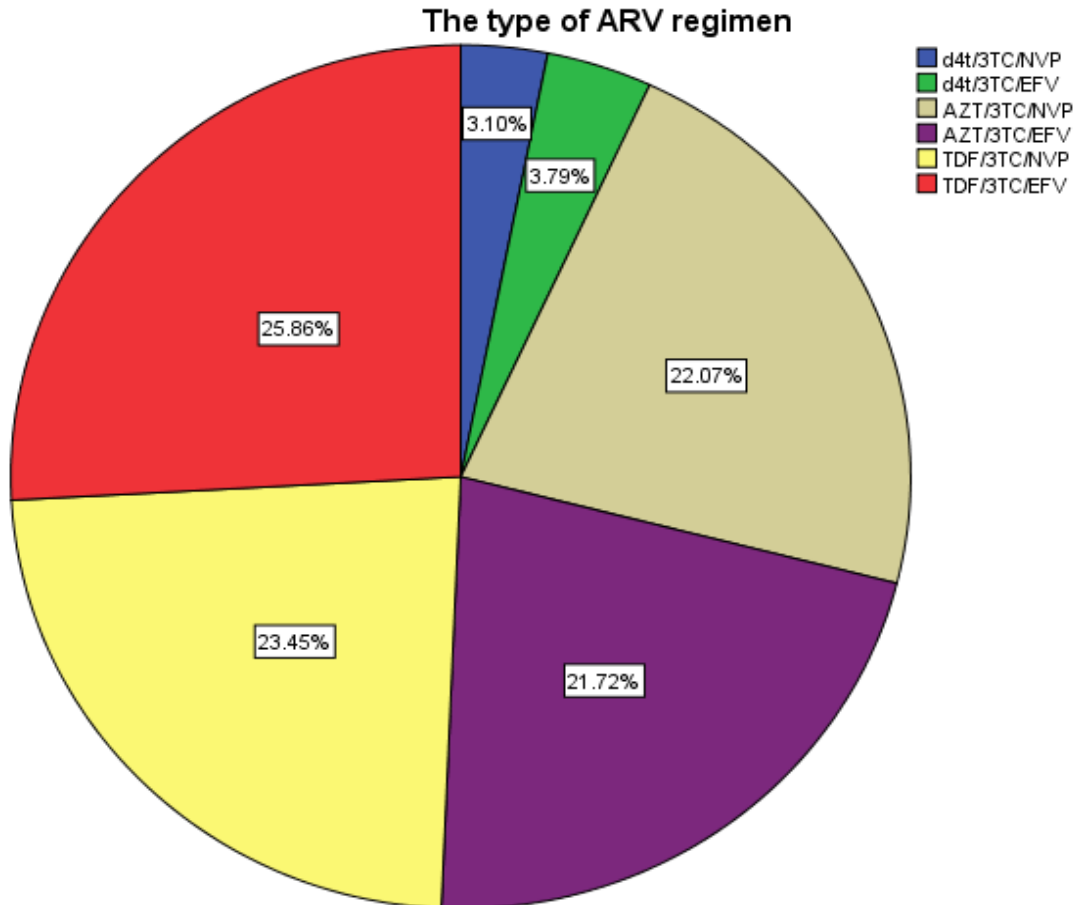
**Table 4.11 Seriousness of illness among the study participants who were sick in the past one month (N=77)**

Seriousness of illness	Frequency	Percent
Mild	43	55.8
Moderate	31	40.3
Severe	3	3.9
Total	77	100.0

Table 4.11 shows the seriousness of illness among the study participants who complained of illness in the past one month. Among the 77 participants who were ill in the past one month, 55.8% described their illness as mild, 40.3% as moderate, and 3.9% as severe. As mentioned earlier, the majority of the participants either did not complain of illness in the past month or reported the illness to be mild though they were sick. This may be related to the fact that most of the participants had been taking antiretroviral therapy for more than two years, which may have improved their immunity and clinical condition.

### 4.3.3 Responses related to questions on the type of current ARV regimen and level of adherence

#### 4.3.3.1 The type of ARV regimen taken by the study participants



**Figure 4.16 Pie chart showing the type of ARV drug regimen (N=290)**

As indicated in Figure 4.16, all of the study participants were taking first line ARV regimen. The study revealed that, out of the 290 study participants, 25.9% (n=75) were on TDF/3TC/EFV, 23.4% (n=68) on TDF/3TC/NVP, 22.1% (n=64) on AZT/3TC/NVP, 21.7% (n=63) on AZT/3TC/EFV, 3.8% (n=11) on D4T/3TC/EFV, and 3.1% (n=9) on D4T/3TC/NVP. This revealed that the majority of the respondents were receiving the preferred first line ARV regimen (either TDF- or AZT-based), which is currently recommended by the national treatment guideline.

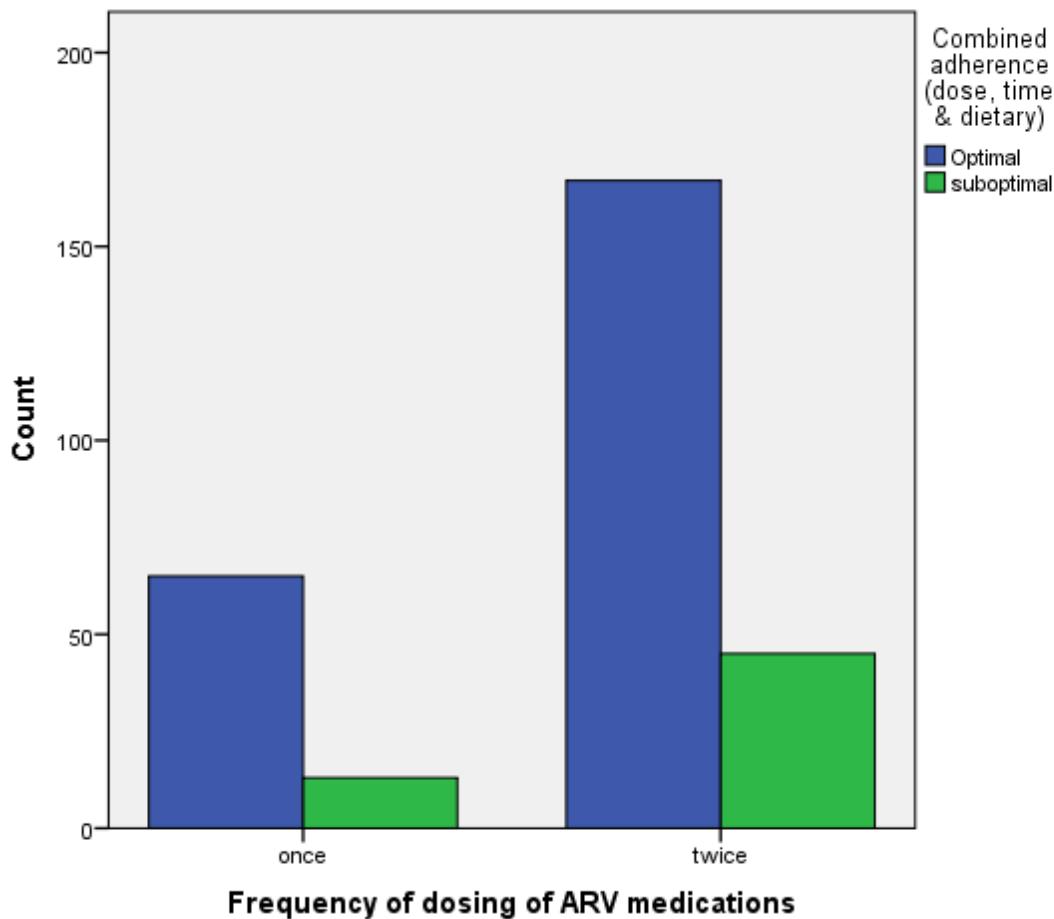
In this study, there was no statistically significant difference in the type of ARV regimen taken between those participants who had optimal adherence and those with suboptimal adherence ( $P=0.682$ ). This suggested that the level of adherence of the study participants was not influenced by the type of ARV regimen that the patients were taking. This finding was supported by Fumaz et al (2008:799), which showed no statistically significant difference in antiretroviral drug use and adherence to ART. Contrary to the current finding, a study done in India among HIV positive mothers demonstrated a statistically significant relationship between Efavirenz based regimen and poor adherence to ART (De & Dalui 2012:251).

#### **4.3.3.2 Frequency of daily use of ARV medications**

**Table 4.12 Frequency of daily use of ARV medications (N=290)**

Frequency of daily dose	Frequency	Percent
Once	78	26.9
Twice	212	73.1
Total	290	100.0

Table 4.12 shows that, out of the 290 study participants, 73.1% ( $n=212$ ) took a twice-daily regimen and the remaining 26.9% ( $n=78$ ) took a once-daily regimen. This indicated that almost all the study participants were receiving a simplified regimen in the form of fixed dose combinations. The ARV drugs taken by study participants were available in dual FDC (TDF/3TC, D4T/3TC and AZT/3TC) as well as in triple FDC (D4T/3TC/NVP and AZT/3TC/NVP).



**Figure 4.17 Frequency of dosing of ARV medications and adherence to ART (N=290)**

Figure 4.17 depicts the dosing frequency of ARV medications in relation to combination adherence to antiretroviral therapy. It indicated that, of the 78 participants who took a once-daily ARV regimen, 83.3% (n=65) had optimal adherence and 16.7% (n=13) had suboptimal adherence. Among the 212 participants who took a twice-daily ARV regimen, 78.8% (n=167) and 21.2% (n=45) reported optimal and suboptimal adherence, respectively.

The bivariate analysis in this study found no statistically significant association between dosing frequency of ARV medications and combined adherence to ART (P=0.389). This result was supported by Fumaz et al (2008:176), who reported no statistically significant difference in adherence of patients receiving once-daily and twice-daily ARV regimens. De and Dalui (2012:251) also indicated that the frequency of taking drugs daily was not associated with lower adherence. However, in situations where ARV medications are taken



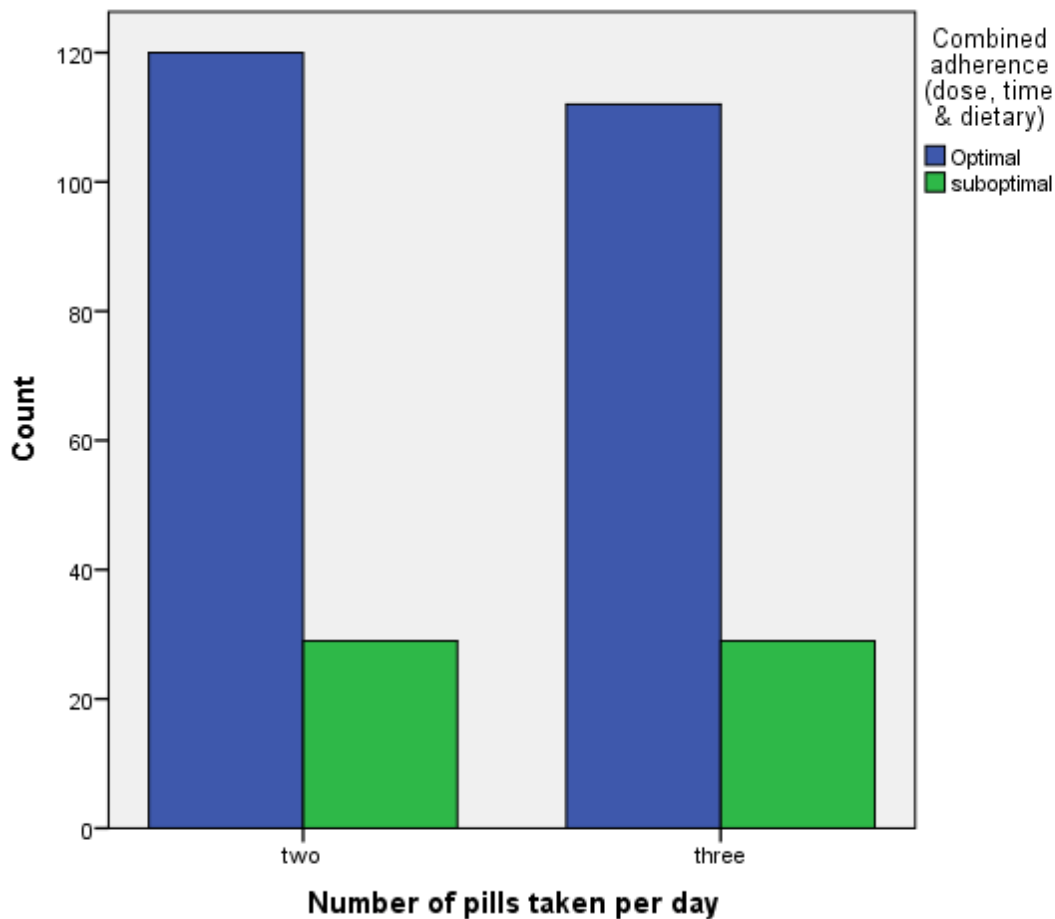
more than twice in a day, studies suggested an association between increased frequency of dosing and poor adherence (De & Dalui 2012:251).

#### **4.3.3.3 Number of pills of ARV drugs taken daily by the study participants**

**Table 4.13 Total number of ARV pills taken daily by study participants (N=290)**

Number of pills taken per day	Frequency	Percent
Two	149	51.4
Three	141	48.6
Total	290	100

Table 4.13 depicts the number of ARV pills taken per day by the study participants. It showed that 51.4% (n=149) took two pills per day and the remaining 48.6% (n=141) took three pills per day. The formulation of the currently available first line ARV drugs consisted of two or three ARV drugs in fixed dose combinations, which contributed to the relative reduction of number of pills to be taken daily. Thus, the majority of the participants received two ARV pills daily.



**Figure 4.18 Number of ARV pills taken per day and adherence to ART (N=290)**

As indicated in Figure 4.18, among 149 participants who took two ARV pills in a day, 80.5% (n=120) had optimal adherence and 19.5% (n=29) had suboptimal adherence. Out of 141 study participants who took three ARV pills per day, 79.4% (n=112) had optimal adherence and 20.6% (n=29) had suboptimal adherence.

In this study, there was no statistically significant association between the number of ARV pills taken per day and adherence to ART ( $P=0.841$ ). This finding is in agreement with another study which suggested that adherence did not differ between once- or twice-daily regimens (Fumaz et al 2008:799). However, a study conducted in India demonstrated taking four or more pills in a day was significantly associated with non adherence (Sarna et al 2008:32).

#### 4.3.3.4 Adherence level of the study participants

In this study adherence level of the study participants was assessed by using a self report method. The participants were asked to report on the number of missed ARV doses, how closely they followed their medication schedules, and dietary instructions agreed with health care providers in the past three days. The results of the level of adherence of the study participants based on three days' recall to dose, schedule, and dietary instructions are depicted in Table 4.14.

**Table 4.14 Distribution of participants, by adherence category in the past three days (N=290)**

Category	Optimal		Suboptimal		Total	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
Dose adherence	256	88.3	34	11.7	290	100.0
Schedule adherence	237	81.7	53	18.3	290	100.0
Dietary adherence	197	82.8	41	17.2	238	100.0
Combined adherence	232	80.0	58	20.0	290	100.0

Self report dose adherence was measured by asking participants the number of missed doses of ARV pills in the past three days. Missing at least one dose of ARV pills in the past three days resulted in adherence level of less than 95%. Table 4.14 shows that the majority (88.3% (n=256)) of participants reported no missed doses of prescribed ARV pills in the past three days, which resulted in an optimal adherence of  $\geq 95\%$ . The remaining 11.7% (n=34) of the participants reported missing at least one dose of their HIV medications, which meant that they had a suboptimal dose adherence of less than 95%. This adherence rate is found to be relatively higher than those reported in Ethiopia by Markos et al (2008:176) and Amberbir et al (2008:[S.a]). But it is lower than the adherence rate of 95% reported by Tiyou et al (2008:3-4). A similar finding was reported by Beer et al (2012:216).

With respect to schedule adherence, among the 290 study participants, the majority (82.4%) reported to have closely followed their ARV medications to the specific schedule in the past three days. This shows that a remarkable percentage of the participants took their medications at appropriate times according to the schedules agreed with the provider. The

result was found to be slightly higher than those in other similar studies in the country (Markos et al 2008:176; Tiyou et al 2008:3-4).

In this study, out of the 290 study participants, 82.0% (n=238) reported that they received special instructions in taking their HIV medications, and the remaining 18.0% (n=52) did not have such instructions. Out of the 238 participants who had special instructions related to dietary requirements from clinicians, 82.8% (n=197) reported to have followed the instructions all of the time in the past three days and they reported good adherence to instructions. However, the remaining 17.2% (n=41) of the participants did not often follow the instructions from clinicians in the past three days, which suggested that they had poor adherence to dietary instructions.

In this study the overall level of combined adherence to antiretroviral therapy in the past three days was measured taking dose adherence, schedule adherence, and dietary instruction adherence into account. The result showed that, out of the 290 study participants, a combined optimal adherence rate of 80.0% (n=232) was reported. This means the participants fulfilled an optimal adherence criteria of taking  $\geq 95\%$  of the prescribed ARV pills at the specified time schedule, and always conformed to the agreed dietary instructions. And, the non adherence rate was 20.0%.

The level of combined adherence in this study seems to be relatively higher than that of a study conducted in South West Ethiopia (Tiyou et al 2008:3-4) and other studies in Africa (e.g. Jean-Baptiste 2008:15). However, the finding of this study is found to be comparable to the findings of other studies conducted in Ethiopia, Zambia, Nigeria, Uganda and Tanzania (Abaase et al 2018:[S.a]; Amberbir et al 2008 [S.a]; Balikuddembe et al 2012:3; Ekama et al 2012:3; Nozaki et al 2011:832; Tessema et al 2010:5), as well as to the adherence level reported in the meta-analyses of studies in Sub-Saharan countries (Mills et al 2006a:682).

#### **4.3.3.5 Response of the study participants on missing doses of ARV medication in the past 7 days**

**Table 4.15 Missed doses of ART in the past 7 days (N=290)**

Missed dose in the past 7 days	Frequency	Percent
Yes	45	15.5
No	245	84.5
Total	290	100

As depicted in Table 4.15, the research finding on the adherence status of the study participants in the past week revealed that 84.5% (n=245) had not missed any of their ARV medications, and only 15.5% (n=45) had missed their pills in the past 7 days. Thus, the majority of the respondents reported optimal adherence during the week before the interview.

#### **4.3.3.6 Response of the study participants on missing doses of ARV medication in the past one month**

**Table 4.16 Missed doses of ARV medication by study participants in the past one month (N=290)**

Missed doses in the past one month	Frequency	Percent
Yes	51	17.6
No	239	82.4
Total	290	100

Similarly, the study participants were asked on their adherence behaviour in the past one month. The finding depicted in Table 4.16 demonstrates that 82.4% (n=239) of the participants had not missed doses of any of their ARV medications, while 17.6% (n=51) of the study participants had missed doses of their ARV pills. Again, the majority of the study participants reported having taken their prescribed antiretroviral pills properly.

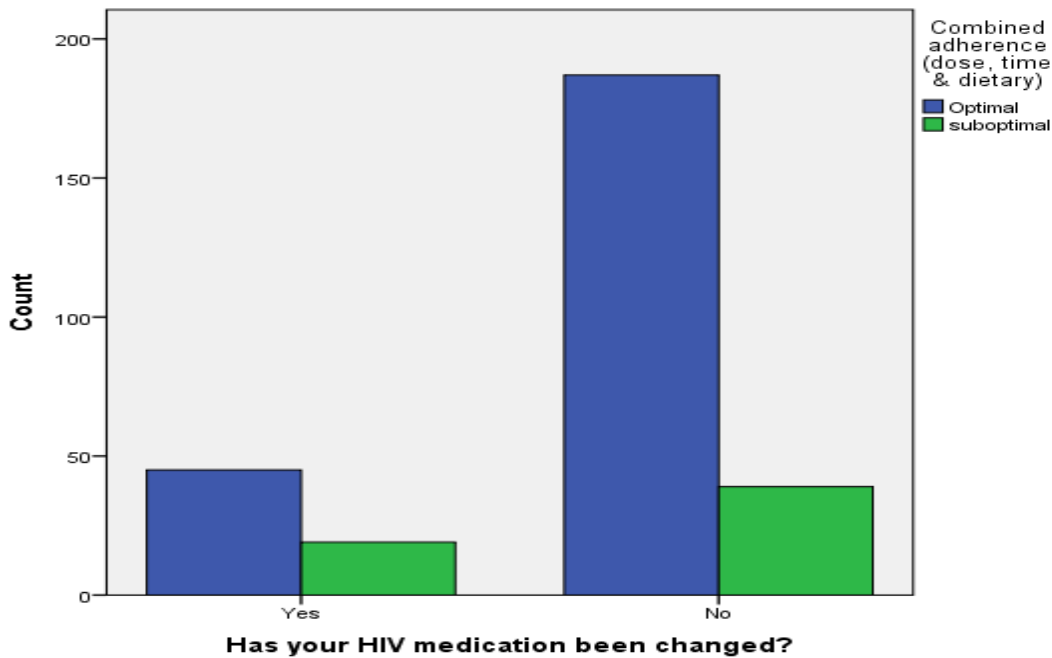
#### 4.3.3.7 Change of ARV medication

The study participants were asked about a change of ARV medication from the initial regimen, and the result is depicted in the following table.

**Table 4.17 Distribution of study participants, by change of ARV medication (N=290)**

Change of ARV medication	Frequency	Percent
Yes	64	22.1
No	226	77.9
Total	290	100

Table 4.17 shows that, out of the total 290 study participants, 77.9% (n=226) had never changed their ARV regimen, while 22.1% (n=64) reported having changed their ARV medications for different reasons. Thus, the majority of the study participants have been put on the same regimen since the initiation of the antiretroviral treatment.



**Figure 4.19 Change of ARV medications and combined adherence to ART (N=290)**

The relationship between change of ARV medication and combined adherence to ART is depicted in Figure 4.19. The result indicates that, out of 64 study participants who had had a change in ARV medication, 70.3% (n=45) reported optimal adherence and 29.7% (n=19)

reported suboptimal adherence. Out of the 226 participants who did not change their ARV medication, 82.7% (n=187) had optimal adherence and 17.3% (n=39) had suboptimal adherence.

The bivariate analysis in this study revealed a statistically significant association between change of HIV medication and combined adherence to ART ( $P=0.028$ ). The study finding pointed out that those participants who had changed their HIV medication tended to have suboptimal adherence as compared to those who had not changed ARV medication. This is supported by a study conducted in Brazil (Bonolo et al 2005:S9), which revealed that switching ARV regimen was significantly associated with non adherence.

#### ***4.3.3.8 Reasons for missing ARV medications in the past one month by the study participants***

The study participants who missed doses of their ARV medications in the past one month were asked about the reasons for missing their medication. In this study, the result showed that 17.6% (N=51) participants missed their ARV medication in the past one month. The reasons for missing ARV drugs cited by these study participants are depicted in the following table.

**Table 4.18 Reasons for missing doses of ARV medications in the past one month**

Responses	Frequency	Percent
Forgetting	20	35.1
Being busy with other things	10	17.5
Running out of pills	6	10.5
Not wanting others to see them taking their medication	5	8.8
Feeling depressed	5	8.8
Having too many pills to take	2	3.5
Feeling good	2	3.5
Feeling sick or ill	2	3.5
Feeling like the drug was harmful	1	1.8
Wanting to avoid side effects	1	1.8
Being away from home	1	1.8
Lack of transportation	1	1.8
Shortage of food	1	1.8
Total	57	100.0

The most common reason mentioned by the study participants for missing their HIV medications in the past one month was forgetfulness (35.1%). This was followed by being busy with other things (17.5%), running out of pills (10.5%), feeling depressed (8.8%), and not wanting others to see them taking their medications (8.8%). This finding is supported by many other similar studies conducted in resource-limited settings. Forgetfulness and being busy with other things were frequently identified reasons which were consistently observed in various studies (Jean-Baptiste 2008:16; Markos et al 2008:176; Sullivan et al 2007:3; Tiyou et al 2010:4; Wang et al 2009:759; Wasti et al 2012:73-75; Watt et al 2010:384). Some studies also suggested that running out of pills was a reason for missing ARV medications (Wasti et al 2012:75; Tiyou et al 2010:4).



#### 4.3.4 Knowledge about HIV disease and antiretroviral therapy

The study participants were asked to respond to items related to knowledge of the HIV disease and antiretroviral therapy based on a five-point Likert scale ranging from 'strongly disagree' to 'strongly agree'.

##### 4.3.4.1 *You know how each of your current HIV medications is supposed to be taken.*

**Table 4.19 Response of study participants to the statement that they knew about how their current HIV medications are supposed to be taken (N=290)**

Response	Frequency	Percent
Somewhat disagree	3	1.0
Neither agree nor disagree	42	14.5
Somewhat agree	99	34.1
Strongly agree	146	50.4
Total	290	100.0

The study participants were asked to state to what extent they agreed or disagreed to the statement that they knew how their HIV medications were supposed to be taken. Table 4.19 indicates that 50.4 % (n=146) of them strongly agreed, 34.1% (n=99) somewhat agreed, 14.5% (n=42) neither agreed nor disagreed, and 1% (n=3) somewhat disagreed to the statement. This illustrates that the majority (84.5%) of the study participants agreed that they had adequate knowledge on how their HIV medications were supposed to be taken. This shows that participants had information about how to take their HIV medication from health care providers at the time of ART initiation and during follow-up visits. This is important for the participants to properly adhere to their medications as prescribed.

#### 4.3.4.2 *You know what to do if you miss a dose of any of your HIV medications.*

**Table 4.20 Response of study participants on knowledge about what to do if a dose of HIV medication is missed (N=290)**

Response	Frequency	Percent
Somewhat disagree	6	2.0
Neither agree nor disagree	26	9.0
Somewhat agree	78	26.9
Strongly agree	180	62.1
Total	290	100.0

Table 4.20 illustrates that, out of the 290 study participants, 62.1% (n=180) strongly agreed, 26.9% (n=78) somewhat agreed, 9.0% (n=26) neither agreed nor disagreed, and 2.0% (n=6) somewhat disagreed to the statement of knowledge on what to do if patients missed any of their medication. Thus, the majority (89.0%) knew what to do if they missed their medication. This may indicate that patients are prepared to act appropriately in different circumstances where doses of HIV medication might be missed.

#### 4.3.4.3 *Skipping a few of your HIV medications from time to time would not really hurt your health.*

**Table 4.21 Response of study participants on whether skipping HIV medications would not hurt the health of patients (N=290)**

Response	Frequency	Percent
Strongly agree	3	1.0
Somewhat agree	21	7.2
Neither agree nor disagree	28	9.7
Somewhat disagree	70	24.1
Strongly disagree	168	57.9
Total	290	100.0

Table 4.21 shows that the majority of the respondents (57.9%) strongly disagreed and 24.1% (n=70) somewhat disagreed to the statement that skipping a few of the ARV medications would not really hurt the health of the participants. The rest (9.7%, 7.2% and 1.0%) neither agreed nor disagreed, somewhat, agreed and strongly agreed to the statement, respectively. This suggests that the majority of the study participants were not likely to take the risk of skipping doses of ARV medications as they acknowledged the consequences of missing drugs on their health.

#### **4.3.4.4 You know what the possible side effects of each of your HIV medications are.**

**Table 4.22 Response of study participants on knowledge about the possible side effects of ARV medications (N=290)**

Response	Frequency	Percent
Strongly disagree	2	0.7
Somewhat disagree	7	2.4
Neither agree nor disagree	56	19.3
Somewhat agree	93	32.1
Strongly agree	132	45.5
Total	290	100.0

The respondents were also asked if they knew the side effects of each of their ARV medications. As indicated in Table 4.22, the majority of the participants (45.5%) strongly agreed, and 32.1% (n=93) somewhat agreed, while 19.3% (n=56) neither agreed nor disagreed to the statement that they had knowledge of the possible side effects of their medications. The remaining 3.1% (n=9) of the participants did not have knowledge of the side effects of their ARV medications. This indicates that the majority of the study participants had appropriate counselling regarding possible adverse events related to HIV medications from health care providers while visiting the clinics.

**4.3.4.5 As long as you are feeling healthy, missing your HIV medications from time to time is OK.**

**Table 4.23 Response of study participants to the statement that missing HIV medications is OK as long as they are feeling healthy (N=290)**

Response	Frequency	Percent
Strongly agree	4	1.4
Somewhat agree	37	12.8
Neither agree nor disagree	24	8.3
Somewhat disagree	99	34.1
Strongly disagree	126	43.4
Total	290	100.0

The responses of the participants to the statement that missing HIV medications from time to time was OK as long as they felt healthy is depicted in Table 4.23. The majority of the respondents strongly disagreed 43.4% (n=126), and 34.1% (n=99) somewhat disagreed to that statement. This may indicate that most of the participants knew an HIV medication is a lifelong treatment and should not be interrupted even if the patient is clinically stable and well. In contrast, the other 14.2% (n=41) of the participants agreed to the statement, which suggests that these patients might not properly adhere to their medication during their course of treatment.

**4.3.4.6 You understand how your HIV medications work in your body to fight HIV.**

**Table 4.24 Response of study participants on their knowledge about how HIV medications work in their body to fight HIV (N=290)**

Response	Frequency	Percent
Strongly disagree	1	0.3
Somewhat disagree	4	1.4
Neither agree nor disagree	31	10.7
Somewhat agree	111	38.3
Strongly agree	143	49.3
Total	290	100.0

Table 4.24 shows the response of the participants on whether they understood how HIV medications work in their body to fight HIV infection. Among the 290 participants, 49.3% (n=143) strongly agreed, and 38.3% (n=111) somewhat agreed to the statement. This may indicate that most of the patients get enough information in relation to the way that HIV medications work to effectively control or suppress the HIV virus in the body.

**4.3.4.7 If you don't take your HIV medications as prescribed, these medications may not work for you in the future.**

**Table 4.25 Response of study participants to the statement that HIV medications may not work for the future if they did not take them as prescribed (N=290)**

Response	Frequency	Percent
Somewhat disagree	3	1.0
Neither agree nor disagree	29	10.0
Somewhat agree	94	32.4
Strongly agree	164	56.6
Total	290	100.0

As depicted in Table 4.25, out of the 290 study participants, 56.6% (n=164) strongly agreed and 32.4% (n=94) somewhat agreed to the statement that if patients did not take HIV medications as prescribed, these medications may not work in the future. This suggests that the majority of the participants were informed that unless the medications are taken as prescribed, the drugs will tend to fail in the future.

#### **4.3.4.8 Antiretroviral medications eradicate HIV from your body.**

**Table 4.26 Response of study participants on whether they believe antiretroviral medications eradicate HIV from their body (N=290)**

Response	Frequency	Percent
Strongly agree	1	0.3
Somewhat agree	4	1.4
Neither agree nor disagree	33	11.4
Somewhat disagree	87	30.0
Strongly disagree	165	56.9
Total	290	100.0

As depicted in Table 4.26, the result shows that the majority of the study participants (56.9%) strongly disagreed and 30.0% (n=87) somewhat disagreed that antiretroviral medications eradicate HIV from the body. Thus, this indicates that most of the participants were aware that HIV infection is not yet curable with the currently available antiretroviral medications. However, the remaining 38 (13.1%) participants believed or were in doubt that antiretroviral medications eradicate HIV from the body. This misinformation or misconception may adversely affect adherence behaviour of the patients.

**4.3.4.9 You believe that if you take your HIV medications as prescribed, you will live longer.**

**Table 4.27 Response of study participants as to whether they believe that if they take HIV medications as prescribed, they will live longer (N=290)**

Response	Frequency	Percent
Somewhat disagree	1	0.3
Neither agree nor disagree	21	7.2
Somewhat agree	78	26.9
Strongly agree	190	65.5
Total	290	100.0

As can be seen from Table 4.27, the majority of the study participants (92.4%) believed that they could live longer if they took their HIV medications as prescribed. This may be a positive reinforcement for the patients to better adhere to their medications to save their lives. The remaining 7.5% (n=22) of participants did not believe they would live longer by taking their HIV medications as prescribed.

**4.3.4.10 You know how your HIV medications interact with substances such as alcohol and 'khat'.**

**Table 4.28 Knowledge on interaction of HIV medications with substances such as alcohol and 'khat' (N=290)**

Response	Frequency	Percent
Somewhat disagree	2	0.7
Neither agree nor disagree	13	4.5
Somewhat agree	81	27.9
Strongly agree	194	66.9
Total	290	100.0

Table 4.28 depicts the responses of the participants regarding their knowledge on the interaction of HIV medications with substances such as alcohol and 'khat'. The majority of the participants (66.9%) strongly agreed and 27.9% (n=81) somewhat agreed to that statement, indicating that the majority were knowledgeable about the interaction of HIV medications with the substances. The remaining 5.2% (n=15) did not know the consequences of the interaction of HIV medications with substances such as alcohol and 'Khat'. This suggests that awareness creation work in this aspect could bring about a positive behavioural change to such people.

On the composite scale measurement the average score of study participants on knowledge about HIV disease and antiretroviral therapy was found to be 43.72, ranging from a minimum score of 10 to a maximum score of 50 representing 'strongly disagree' and 'strongly agree'. This shows that the majority of the study participants tend to have good knowledge on HIV disease and antiretroviral treatment.

In this study, there was a statistically significant association between having adequate knowledge about HIV disease and antiretroviral therapy, and combined adherence to ART ( $t = 4.270$ ,  $P=0.000$ ). This meant that participants who had adequate knowledge on aspects related to HIV disease and antiretroviral therapy had a better level of adherence as compared to those who had not. This finding is consistent with various studies conducted in developing and developed nations. A study conducted in southern Ethiopia documented that knowledge about adherence to ART was associated with adherence (Markos et al 2008:176). Amico et al (2009:74) also indicated that better adherence was associated with greater knowledge about one's ARV regimen. Lal et al (2010:3) demonstrated significant association between having information about the importance of adherence and adherence to ART. It was found that those who reported not having been told about the importance of HAART were 9.2 times more likely to be non adherent compared to those who reported having been told about its importance ( $P < 0.001$ ). Similarly, in a systematic review of studies, Gari et al (2013:7) reported higher level of treatment information and believing in the benefits of ARVs were associated with adherence to ART in high income countries (Gari et al 2013:7). Having information about the possible side effects of antiretroviral drugs also had influence on the adherence of patients. Evidence emphasized that having complaints of the side effects of antiretroviral medications was significantly associated with



poor adherence (Achappa et al 2013:222; De & Dalui 2012:251). This had implication on the importance of providing adequate information to patients about the adverse effects of their HIV medications. In contrast, Sarna et al (2008:32) indicated that knowledge of ART was not found to be associated with non adherence. Another study (Markos et al 2008:176) also reported that knowledge of patients about the benefit of ART was not associated with adherence.

This finding has a paramount importance in the provision of clinical care and antiretroviral therapy to HIV infected individuals, emphasizing on the role of health care providers to counsel and educate patients to positively influence their adherence behaviour. The education sessions need to address issues related to the nature of HIV disease and antiretroviral therapy, including how HIV medications should be taken, the importance of ART and adherence, how long HIV medications need to be taken, the possible adverse effects of antiretroviral therapy, and their interaction with substances such as alcohol.

#### **4.3.5 Responses to questions related to disclosure and social support**

The study participants were also asked questions related to disclosure and social support. The next section presented the findings on items related to disclosure and social support as follows.

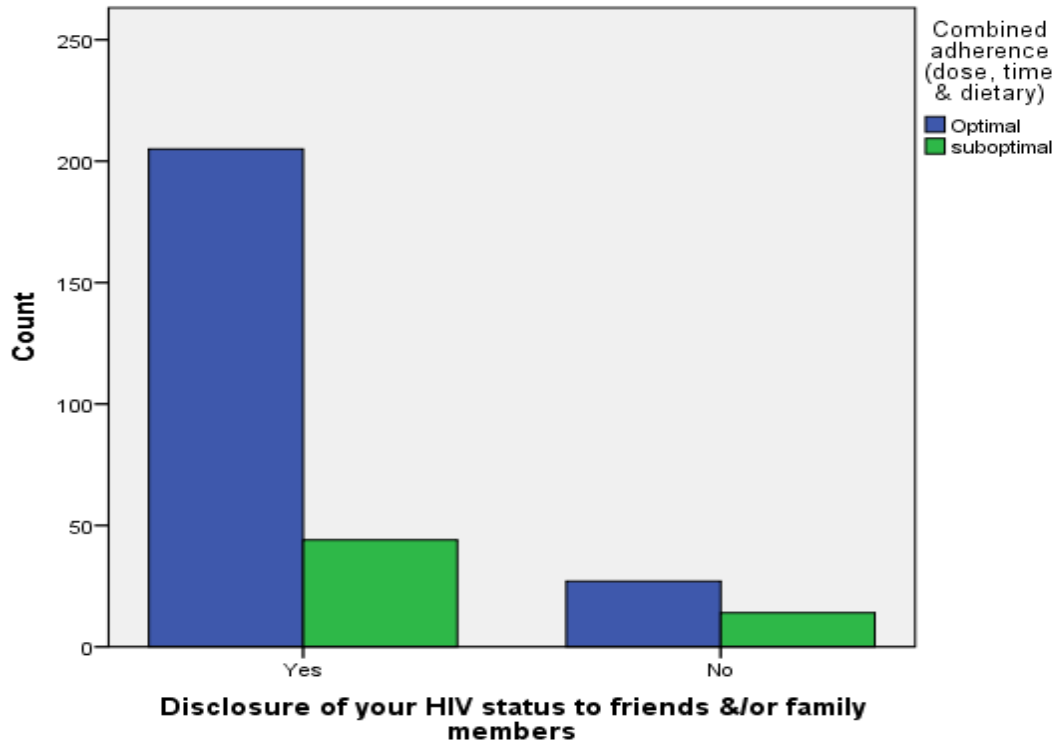
##### ***4.3.5.1 Disclosure of one's HIV status to friends and/or family members***

The study participants were asked whether they disclosed their HIV status to their friends and/or family members or not, and the result is depicted in the following table.

**Table 4.29 Disclosure of one's HIV status to friends and/or family members (N=290)**

<b>Response</b>	<b>Frequency</b>	<b>Percent</b>
Yes	249	85.9
No	41	14.1
Total	290	100.0

As indicated in Table 4.29, out of 290 study participants, 85.9% (n=249) disclosed their HIV status to their friends and/or family members, while the remaining 14.1% (n=41) did not disclose their HIV status to any individual close to them.



**Figure 4.20 Disclosure of HIV status to friends and/or family members and adherence to ART (N=290)**

Figure 4.20 depicts that, among 249 participants who disclosed their HIV status to their friends and/or family members, 82.3% (n=205) had optimal adherence and 17.7% had suboptimal adherence. On the other hand, among the 41 study participants who did not disclose their HIV status to anyone, 65.9% (n=27) and 34.1% (n=14) had optimal and suboptimal adherence, respectively.

In this study, a statistically significant association was found between disclosure of one's HIV status to a friend and/or family members and his/her adherence behaviour ( $P=0.015$ ). This result is supported by Birbeck et al (2009:672), who revealed that disclosure of one's HIV status to his/her spouse was associated with good adherence. Another study (Wasti et al 2012:75) also indicated that fear of disclosure of HIV status to the community was found to be one of the socio-cultural factors preventing adherence to antiretroviral therapy.

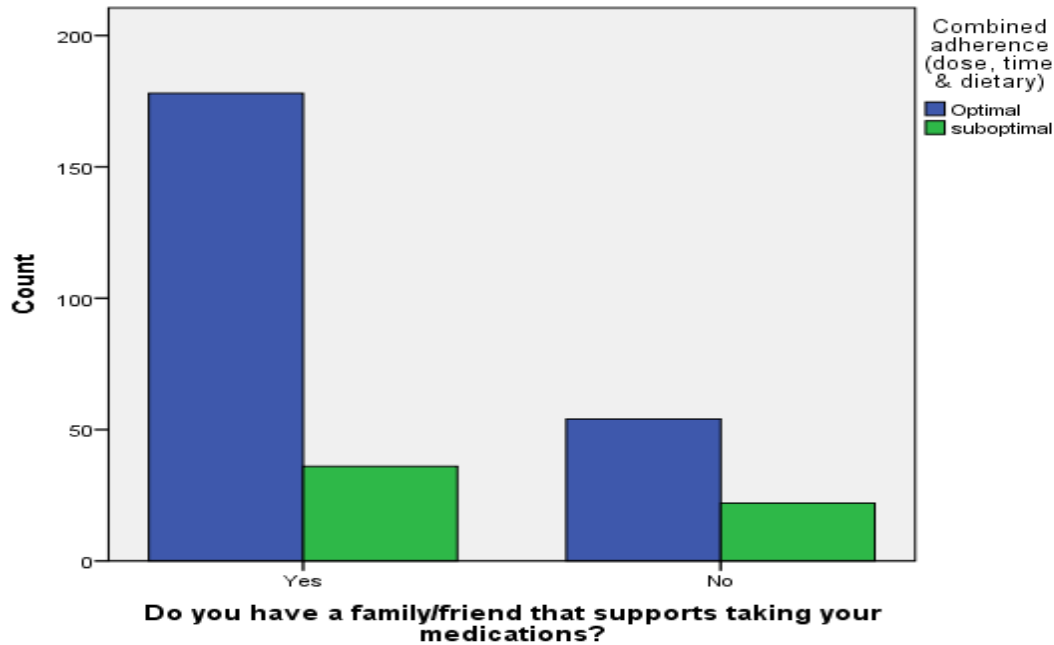
Patients may not want to disclose their HIV status due to fear of social stigma. Also, fear of social stigma in turn was found to be associated with non adherence (Achappa et al 2013:222).

**4.3.5.2 Do you have family members and/ or friends that support you in taking your medications?**

**Table 4.30 Support provided to study participants on taking HIV medications from family members and/or friends (N=290)**

Response	Frequency	Percent
Yes	214	73.8
No	76	26.2
Total	290	100.0

As depicted in Table 4.30, among the 290 respondents, 73.8% (n=214) claimed they had either a friend and/or a family member that supported them in taking their ARV medications. However, the remaining 26.2% (n=76) did not have support from their families and/or friends in taking their antiretroviral medications. This indicates that the majority of the study participants got support from close friends and/or family members to properly take their medication.



**Figure 4.21 Support from family and/or friend in taking HIV medications and adherence to ART (N=290)**

As indicated in Figure 4.21, out of the 214 study participants who had support from a family member and/or friend in taking their medications, 83.2% (n=178) had optimal adherence and 16.8% (n=36) had suboptimal adherence. However, among the 76 participants who did not have the support, 71.1% (n=54) had optimal adherence and 28.9% (n=22) had suboptimal adherence.

In this study, there was a statistically significant association found between availability of support in taking HIV medications from a family and/or friend and adherence to ART ( $P=0.023$ ). This shows that participants who had support from their friends and/or family members tend to have better adherence than those without support. This result is in agreement with a study conducted in Ethiopia (Amberbir et al 2008: [S.a]), which reported that adherence was more common in patients having social support. Other studies also demonstrated similar results in which availability of support from friends and relatives was associated with good adherence (Aragonés et al 2011:19; Jean-Baptiste 2008:19; Nozaki et al 2011:834; Protopopescu 2009:602; Tiyou et al 2010:4). However, Sarna et al (2008:32) did not find association between social support and adherence to HIV medications.

**4.3.5.3 How often do your friends and/or family members help you remember to take your medication?**

**Table 4.31 Help from friends and/or family members to remember to take HIV medications (N=214)**

Response	Frequency	Percent
Sometimes	72	33.6
Most of the time	114	53.3
Always	28	13.0
Total	214	100.0

Table 4.31 shows that, out of a total of 214 study participants who had friends and/or family member to support them, 33.6% (n=72) sometimes got help from them to remember to take HIV medications, 53.3% (n=114) got help most of the time, and 13.0% (n=28) always got help. Although the majority of the study participants almost regularly received support from their friends and/or relatives to remember to take their HIV medications, some of them lacked frequent support, which might contribute to the lower level of adherence for such patients.

**4.3.5.4 How satisfied are you with the overall support you get from your friends and/or family members?**

**Table 4.32 Satisfaction of the study participants with the overall support from friends and/or family members (N=234)**

Response	Frequency	Percent
Very dissatisfied	2	0.9
Somewhat dissatisfied	13	5.6
Neither satisfied nor dissatisfied	64	27.4
Satisfied	31	13.2
Very satisfied	124	53.0
Total	234	100.0

Table 4.32 indicates that, out of the 234 study participants, 0.9% (n=2) were very dissatisfied, 5.6% (n=13) were somewhat dissatisfied, 27.4% (n=64) were neither satisfied nor dissatisfied, 13.2% (n=31) were satisfied, and 53.0% (n=124) were very satisfied with the overall support from their friends and/or relatives. A significant proportion of the study participants did not seem to be satisfied with the support of their close friends and relatives. This may be related to the finding that the frequency of support some patients got in remembering to take HIV medications was relatively low.

The bivariate analysis in this study showed no statistically significant association between satisfaction with the overall support of study participants from their friends and/or relatives and their combined adherence to ART (P=0.222). This finding is not supported by other similar studies. A study conducted in Ethiopia (Markos et al 2008:176) reported that satisfaction with social support was associated with adherence. Similarly, a study in Vietnam suggested significant association between low satisfaction of received support and poor adherence to ART (Do et al 2013:5).

#### **4.3.5.5 Do you use any method to remind you to take your ARV medication?**

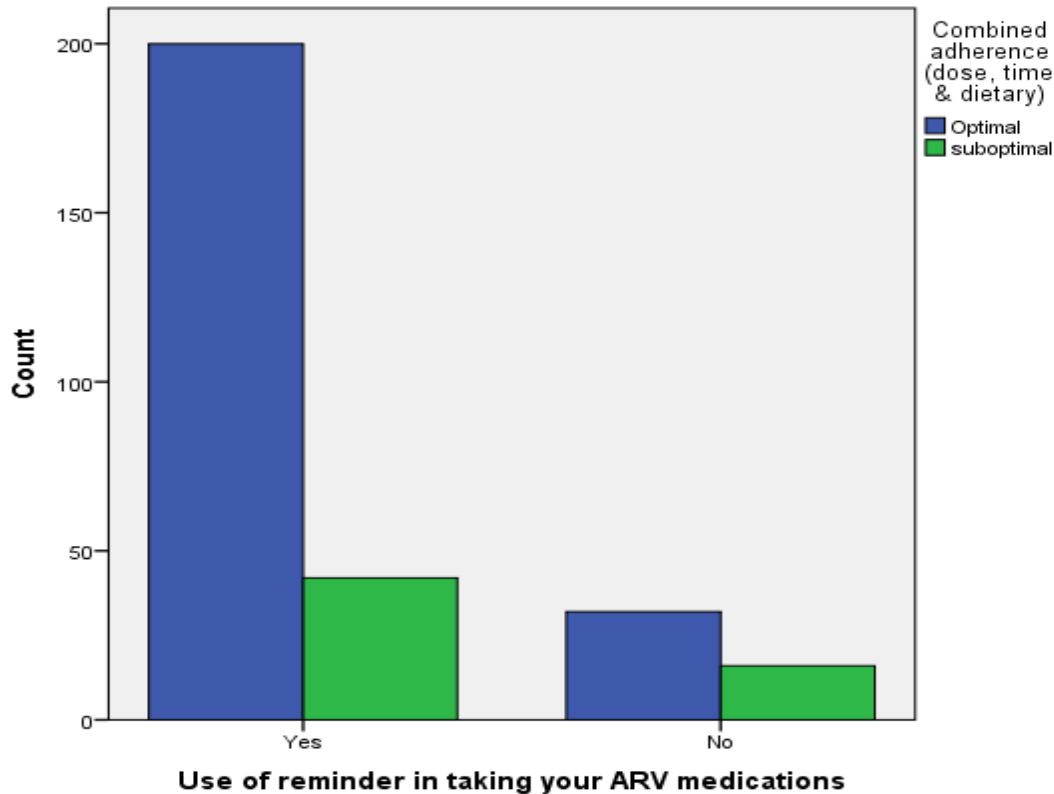
The study participants were also asked if they used reminders to take their HIV medications.

**Table 4.33 Use of reminders to take ARV medications (N=290)**

Response	Frequency	Percent
Yes	242	83.4
No	48	16.6
Total	290	100.0

As shown in Table 4.33, among 290 participants, 83.4% (n=242) claimed that they used reminders to help them to take their ARV medications properly while the remaining 16.6% (n=48) did not use reminders. The majority of the study participants used reminders to correctly take their HIV medications as prescribed, which helped them not to miss doses of ARV pills. Most of the time, patients may engage in various routine activities and may

forget to take their pills appropriately. This is supported by the finding that forgetfulness was mentioned as the most common reason for the study participants to miss their ARV pills in the past one month.



**Figure 4.22 Use of reminders to take HIV medication and adherence to ART (N=290)**

Figure 4.22 reveals that, out of 242 study participants who used reminders to take their HIV medication, 82.6% (n=200) had optimal adherence and 17.4% (n=42) had suboptimal adherence. Out of the 48 participants who did not use reminders, 66.7% (n=32) reported optimal adherence and the remaining 33.3% (n=16) had suboptimal adherence.

The bivariate analysis in this study showed a statistically significant association between use of reminders to take HIV medications and adherence to ART (P=0.011). This is supported by Nozaki et al (2011:834), which reported that using reminders to take HIV medications was associated with better adherence. Similarly, Amberbir et al (2008: [S.a]) also indicated that use of memory aids was an independent predictor of adherence to antiretroviral therapy.

#### 4.3.6 Aspects of patient-provider relationship

Different aspects of the patient-provider relationship were assessed on a five-point Likert scale, in which responses ranged from 'strongly disagree' to 'strongly agree'.

##### ***4.3.6.1 The health care providers give you appropriate information about taking your medications.***

**Table 4.34 Response of study participants on provision of appropriate information in taking HIV medications by health care providers (N=290)**

Response	Frequency	Percent
Strongly disagree	3	1.0
Somewhat disagree	11	3.8
Neither agree nor disagree	38	13.1
Somewhat agree	97	33.4
Strongly agree	141	48.6
Total	290	100.0

Table 4.34 shows that, among the 290 study participants, 48.6% (n=141) strongly agreed and 33.4% (n=97) somewhat agreed to the statement that they get appropriate information about taking their medications from the health care providers. The majority of the study participants reported that they received appropriate information about their medication from the health care providers. This was directly linked with the finding that the majority of the participants confirmed having adequate knowledge on aspects related to their HIV medications. This may in turn serve to alert the patients to properly take their medications as prescribed by the health care providers. Of the remaining participants, 13.1% (n=38) remained neutral, 3.8% (n=11) somewhat agreed, and 1.0% (n=3) strongly disagree to the statement.



**4.3.6.2 It is easy for you to discuss problems related to your medication with the health care providers.**

**Table 4.35 Response of study participants on whether it is easy for them to discuss problems related to HIV medications with their health care providers (N=290)**

Response	Frequency	Percent
Strongly disagree	3	1.0
Somewhat disagree	7	2.4
Neither agree nor disagree	32	11.0
Somewhat agree	80	27.6
Strongly agree	168	57.9
Total	290	100.0

Table 4.35 reveals that, out of the 290 participants, 57.9% (n=168) and 27.6% (n=80) strongly agreed and somewhat agreed, respectively, to the statement that the patients were at ease to discuss their problems related to HIV medications with their health care providers. This indicates that the majority of the participants were comfortable to discuss their problems with health care providers, which can greatly influence adherence behaviour of the patients. It is vital for the patients to approach their health care providers openly to talk about their health- and medication-related problems without fear and discomfort. This may also be a reflection of the positive attitude of health care providers towards their patients, treating them with respect and giving them adequate time to talk about their problems.

**4.3.6.3 The health care providers understand the problems you may have in taking your ARV medications.**

**Table 4.36 Response of study participants on whether health care providers understand the problems that patients have in taking HIV medications (N=290)**

Response	Frequency	Percent
Strongly disagree	5	1.7
Somewhat disagree	7	2.4
Neither agree nor disagree	31	10.7
Somewhat agree	89	30.7
Strongly agree	158	54.5
Total	290	100.0

Table 4.36 shows that, out of 290 study participants, 54.5% (n=158) strongly agreed and 30.7% (n=89) somewhat agreed to the statement that health care providers understand the problems that patients may encounter in taking their HIV medications. This may indicate the health care providers seem to be ready to help their patients with the problems they may face. This result is supported by the finding with respect to feeling easy to discuss problems with health care providers.

**4.3.6.4 The health care providers often help you in solving the problems you may have in taking medications.**

**Table 4.37 Support from the health care providers in solving problems related to taking HIV medications (N=290)**

Response	Frequency	Percent
Strongly disagree	5	1.7
Somewhat disagree	13	4.5
Neither agree nor disagree	31	10.7
Somewhat agree	88	30.3
Strongly agree	153	52.8
Total	290	100.0

Table 4.37 shows that, out of the 290 participants, 52.8% (n=153) strongly agreed and 30.3% (n=88) somewhat agreed to the statement that they often get help from health care providers in solving problems related to taking their medications. Of the remaining participants, 10.7% were neutral, 4.5% somewhat disagreed, and 1.7%, strongly agreed to the statement. This result was related to the above findings that indicated positive attitudes of the study participants about the interaction with their health care providers.

**4.3.6.5 You are satisfied with the overall care and support you get from the health care providers.**

The overall satisfaction of the participants on the care and support provided by health care providers was assessed and the findings are presented in the following table.

**Table 4.38 Response of study participants on their satisfaction with the overall care and support provided by health care providers (N=290)**

Response	Frequency	Percent
Strongly disagree	4	1.4
Somewhat disagree	18	6.2
Neither agree nor disagree	20	6.9
Somewhat agree	92	31.7
Strongly agree	156	53.8
Total	290	100.0

As indicated in Table 4.38, among the 290 participants, 53.8% (n=156) and 31.7% (n=92) were fully satisfied and somewhat satisfied with the overall care and support provided by the health care providers. However, only 6.9% (n=20) were neutral and 7.6% (n=22) were not satisfied with the overall care and support provided.

The result on the composite scale of measurement of aspects related to the patient-provider relationship revealed an average score of 21.56, which ranged from 5 to 25, representing extreme results. This denotes that the majority of the study participants tend to have a positive interpretation of the aspects of patient-provider relationship.

In this study, a statistically significant association was found between perception of study participants on aspects of patient-provider relationship and adherence to antiretroviral treatment ( $t = 2.551$ ,  $P=0.011$ ). Participants who had a positive view on the items related to patient-provider relationship were found to demonstrate better adherence as compared to those with a negative view. Aspects of patient-provider relationship in this study emphasized on the provision of appropriate information about HIV medications, interactions between patients and health care providers while discussing problems related to HIV medication, and the perceived satisfaction with overall support of health care providers. This finding is in agreement with Watt et al (2010:384), which found that perceived quality of patient-provider interaction was associated with adherence to ART. Other studies also demonstrated supportive evidence for the influence of aspects of patient-provider relationship on adherence. A study conducted in Vietnam (Do et al 2013:5)

reported that negatively perceived quality of information was significantly associated with suboptimal adherence to ART. In addition, De and Dalui (2012:251) indicated a significant association between bad attitude of health care personnel and poor adherence to ART.

#### **4.3.7 Aspects of clinical care setting**

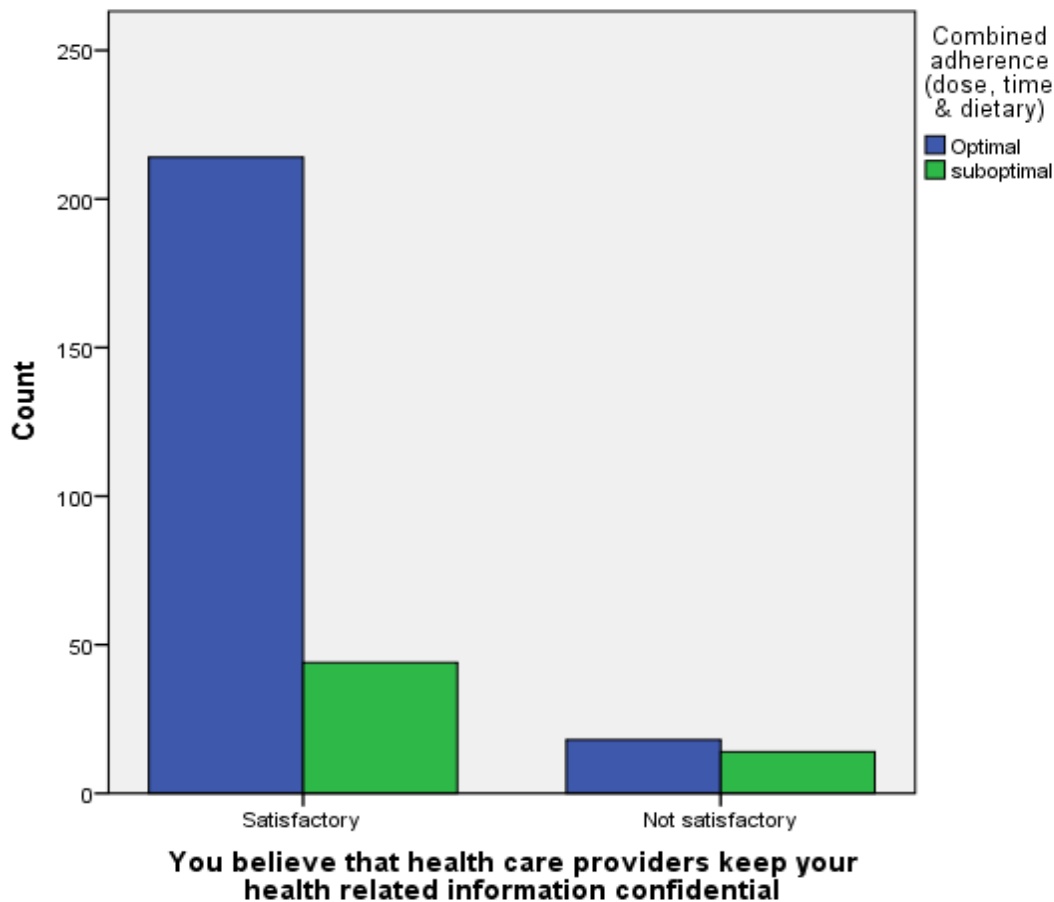
Different aspects of the clinical care setting were also assessed using a five-point Likert scale with response ranging from 'strongly disagree' to 'strongly agree'.

##### ***4.3.7.1 You believe that health care providers keep your health-related information confidential.***

**Table 4.39 Response of study participants to whether they believed health care providers kept their health-related information confidential (N=290)**

Response	Frequency	Percent
Somewhat disagree	7	2.4
Neither agree nor disagree	27	9.3
Somewhat agree	63	21.7
Strongly agree	193	66.6
Total	290	100

As shown in Table 4.39, out of the 290 participants, 88.3% (n=256) believed that the health care providers kept patients' health-related information confidential. This may indicate that patients have trust in their health care providers and protect them against social stigma and discrimination by keeping their information confidential, and this may encourage patients to freely discuss health-related issues with health care providers.



**Figure 4.23 Perception of study participants on confidentiality of health-related information and adherence to ART (N=290)**

As shown in Figure 4.23, among the 258 participants who believed their health-related information was kept confidential by health care providers, 82.9% (n=214) had optimal adherence and 17.1% (n=44) had suboptimal adherence. However, out of the 32 participants who did not believe information was kept confidential, 56.2% (n=18) and 43.8% (n=14) reported optimal and suboptimal adherence, respectively.

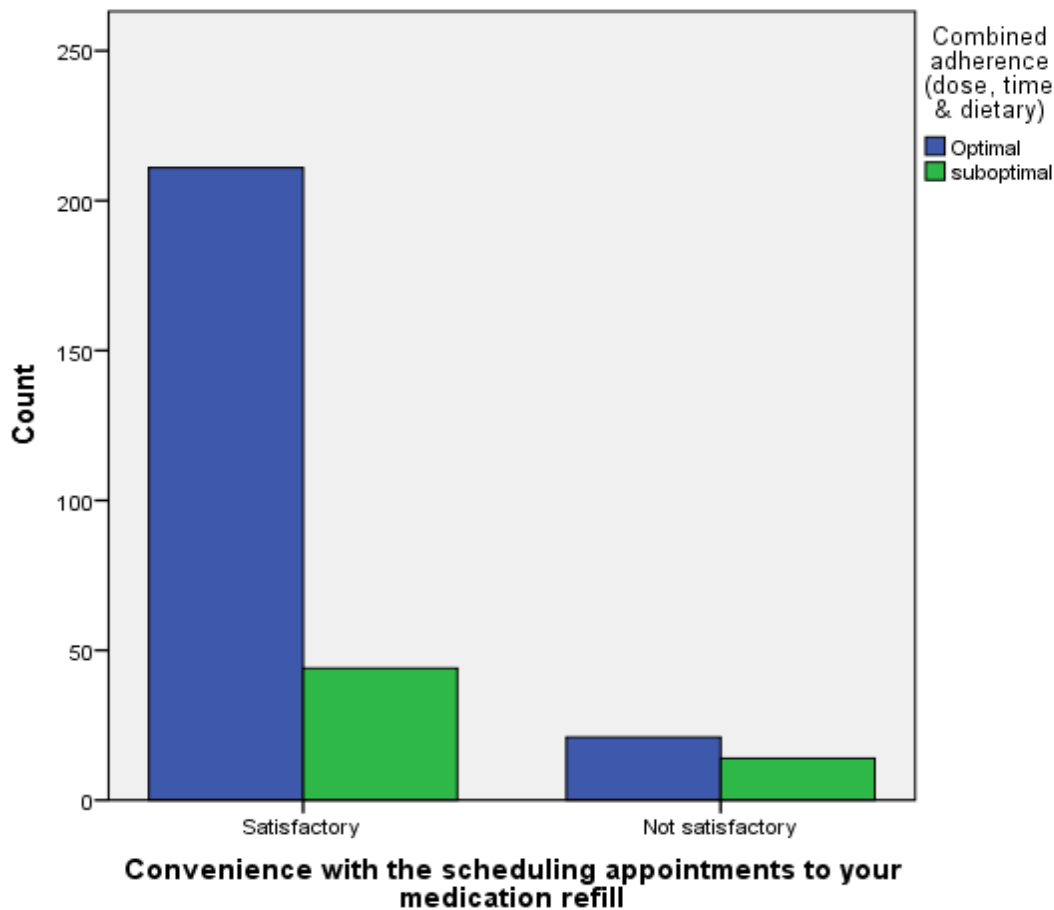
In this study, there was a statistically significant association between perception of study participants on confidentiality of their health-related information and adherence to antiretroviral therapy ( $P=0.000$ ). This is supported by Machtinger and Bangsberg (2006), which stated adherence of patients to their HIV medications, was influenced by perceived confidentiality of patients' clinical status.

**4.3.7.2 Appointment schedules to your medication refill are convenient to you.**

**Table 4.40 Response of study participants on the convenience of appointment schedules to HIV medication refill (N=290)**

Response	Frequency	Percent
Somewhat disagree	9	3.1
Neither agree nor disagree	26	9.0
Somewhat agree	62	21.3
Strongly agree	193	66.6
Total	290	100.0

As can be seen in Table 4.40, out of the 290 study participants, 66.6% (n=193) strongly agreed and 21.3% (n=62) somewhat agreed that appointment schedules to their medication refills were convenient. But 9.0% (n=26) remained neutral while 3.1% (n=9) somewhat disagreed to the statement. Thus, the majority of the study participants were happy about their appointment schedules. This could create an opportunity for the patients to collect their medications in time, and patients could avert the risk of interrupting their medications.



**Figure 4.24 Convenience with scheduling appointments to medication refill and adherence to ART (N=290)**

As depicted in Figure 4.24, among the 255 participants who were happy with appointment schedules to medication refill, 82.7% (n=211) had optimal adherence and 17.3% (n=44) had suboptimal adherence. On the other hand, out of the 35 participants who were not happy with the appointment schedules, 60.0% (n=21) and 40.0% (n=14) reported optimal and suboptimal adherence, respectively.

The bivariate analysis in this study found a statistically significant association between convenience with the appointment schedules to HIV medication refill and adherence to antiretroviral therapy (P=0.002). This result is in agreement with a study conducted in Eastern Africa (Chalker et al 2010: [S.a]), which indicated attendance of clinic within 3 days of appointment was significantly associated with self-report adherence.

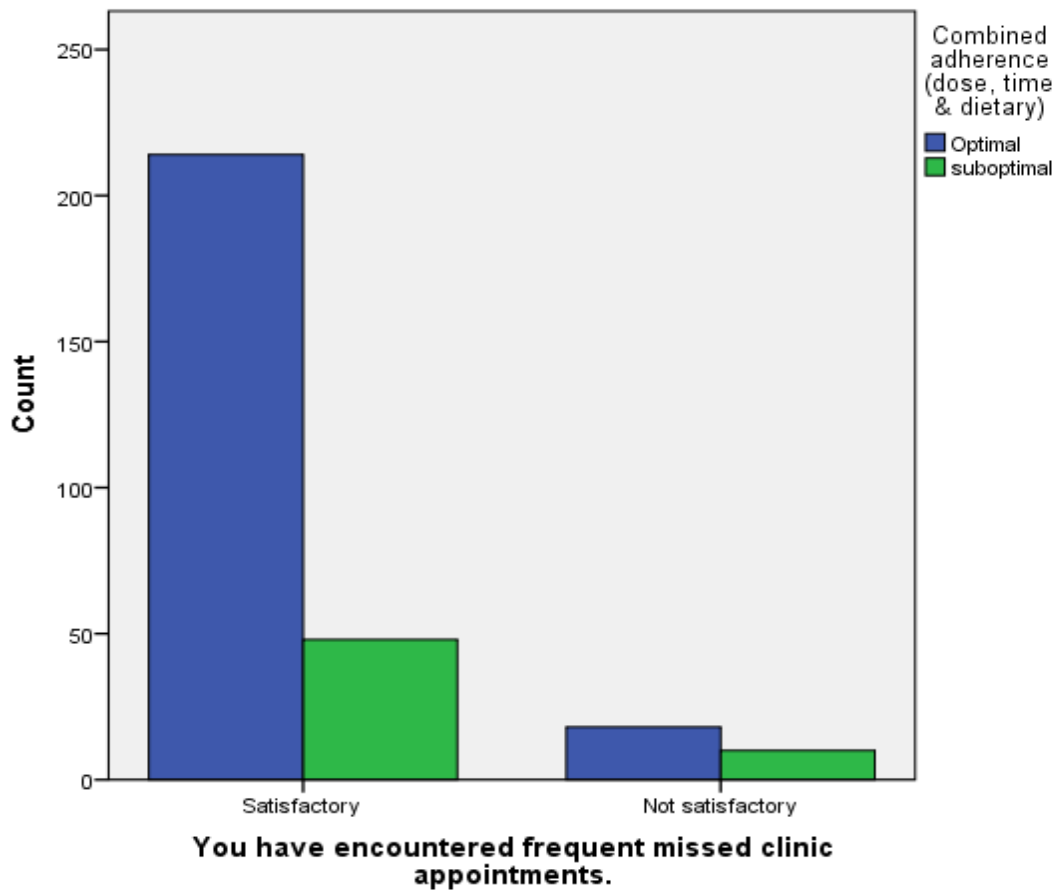


#### 4.3.7.3 You have frequently missed clinic appointments.

**Table 4.41 Response of study participants to whether they have frequently missed clinic appointments (N=290)**

Response	Frequency	Percent
Somewhat agree	5	1.7
Neither agree nor disagree	23	7.9
Somewhat disagree	51	17.6
Strongly disagree	211	72.8
Total	290	100.0

As presented in Table 4.41, out of the 290 respondents, 90.4% (n=262) reported that they had not frequently missed clinic appointments. This may be related to the finding that most of the patients had convenient schedules for their medication refill and had a good understanding of the need for timely refill of their HIV medications.



**Figure 4.25 Encounter of frequently missed clinic appointments and adherence to ART (N=290)**

Figure 4.25 indicates that, among the 262 participants who had frequently missed clinic appointments, 81.7% (n=214) reported optimal adherence and 18.3% (n=48) reported suboptimal adherence. And among the 28 study participants who had not frequently missed clinic appointments, 64.3% (n=18) and 35.7% (n=10) had optimal and suboptimal adherence, respectively.

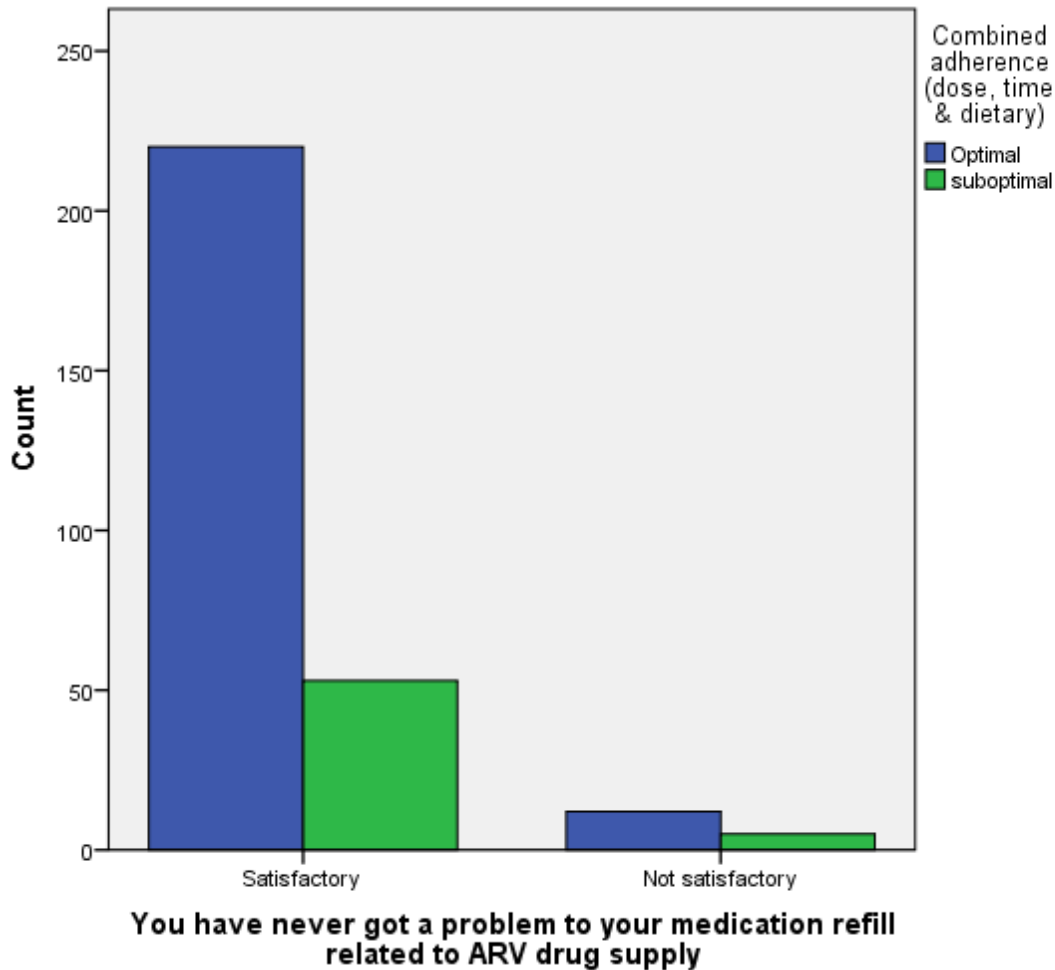
The bivariate analysis in this study revealed a significant association between frequent misses of clinic appointments and adherence to antiretroviral therapy ( $P=0.029$ ). This finding is consistent with that of Watt et al (2010:385), which demonstrated that ever missing of clinic appointments was significantly associated with poor adherence. Similarly, Claudbeck et al (2009: [S.a]) also showed the association of regular clinic follow-up with adherence to ART.

**4.3.7.4 You have never encountered problems with regard to ARV drug supply.**

**Table 4.42 Response of study participants to whether they have encountered problems related to ARV drug supply (N=290)**

Response	Frequency	Percent
Neither agree nor disagree	17	5.9
Somewhat agree	64	22.1
Strongly agree	209	72.1
Total	290	100.0

Table 4.42 depicts the response of study participants to whether they had problems with ARV drug supply. The research finding revealed that the majority of the respondents (94.2%) had not encountered problems in the refill of their medications related to ARV drugs. This can be explained by the provision of free antiretroviral therapy as well as the robust and uninterrupted ARV drug supply in the health facilities.



**Figure 4.26 Occurrence of problems to ARV drug supply and adherence to ART (N=290)**

Figure 4.26 reveals that, out of the 273 participants who never had problems with ARV drug supply, 80.6% (n=220) had optimal adherence and 19.4% (n=53) had suboptimal adherence. Among the 17 participants who had problems with refills of ARV drugs, 70.6% (n=12) and 29.4% (n=5) reported optimal and suboptimal adherence, respectively.

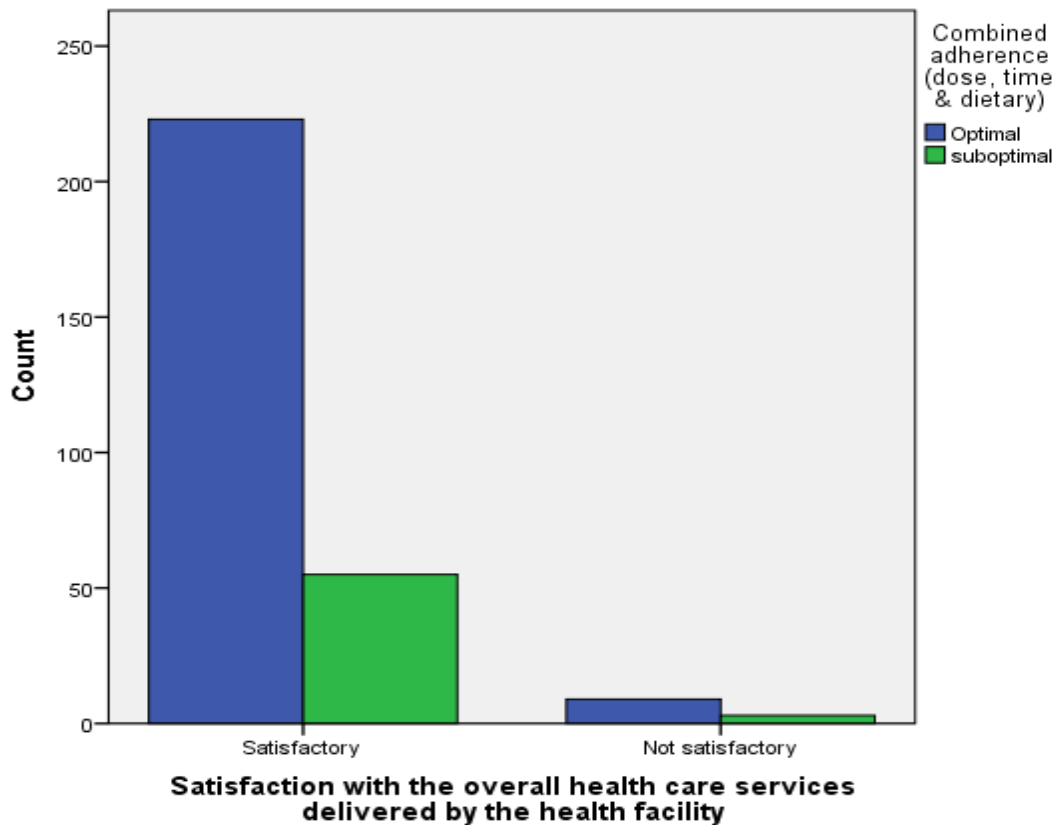
In this study, there was no statistically significant relationship between having problems with HIV medication refills and adherence to ART (P=0.317).

**4.3.7.5 You are highly satisfied with the overall health care services delivered by the health facilities.**

**Table 4.43 Response of study participants about satisfaction with the overall health care services delivered by health facilities (N=290)**

Response	Frequency	Percent
Strongly disagree	2	0.7
Somewhat disagree	1	0.3
Neither agree nor disagree	9	3.1
Somewhat agree	60	20.7
Strongly agree	218	75.2
Total	290	100.0

The study participants were also asked whether they were satisfied with the overall health care services delivered by the health facilities. Table 4.43 indicates that 75.2% (n=218) and 24.8% (n=60) strongly agreed and somewhat agreed to the statement. The remaining 4.2% (n=12) were not satisfied or were undecided about the overall health service delivery provided by the health facility. The majority of the study participants had a positive attitude towards the delivery of different health care services.



**Figure 4.27 Satisfaction with the overall health care services delivered by health facilities and adherence to ART (N=290)**

As presented in Figure 4.27, among the 278 participants who were satisfied with the overall health care service provided in the facilities, 80.2% (n=223) reported optimal adherence and 19.8% (n=55) had suboptimal adherence. Out of the 12 participants who were not satisfied with the overall health care service, 75.0% (n=9) and 25.0% (n=3) reported optimal and suboptimal adherence, respectively.

In this study, satisfaction with the overall health care services delivered by health facilities was not found to be significantly associated with adherence to ART (Fisher's Exact test=0.712). However, satisfaction with the past experience in the health care system was identified as an influencing factor in adherence to treatment (Machtinger & Bangsberg 2006).

### 4.3.8 Past and current use of alcohol and drug

#### 4.3.8.1 Ever use of alcohol

**Table 4.44 Ever use of alcohol by the study participants (N=290)**

Response	Frequency	Percent
Yes	72	24.8
No	218	75.2
Total	290	100.0

Table 4.44 shows that, out of the 290 study participants, 75.2% (n=218) had never taken alcoholic beverages in their life time, while the remaining 24.8% (n=72) had had experience in drinking alcohol. This indicates that the majority of the participants had never engaged in drinking alcohol. In this study, there was no statistically significant relationship between ever use of alcohol and adherence to ART ( $P=0.118$ ). However, Silva et al (2009:136) indicated past use of drugs was associated with risk of non adherence. Similarly, Sharma et al (2013:52) observed the association of alcohol addiction with non adherence to ART.

#### 4.3.8.2 Use of alcohol in the past one month

**Table 4.45 Use of alcohol by the study participants in the past one month (N=290)**

Response	Frequency	Percent
Yes	10	3.4
No	280	96.6
Total	290	100.0

With regard to the use of alcohol in the past one month, Table 4.45 shows that the majority of respondents (96.6%) did not drink alcohol in the past one month while only 3.4% (n=10) of them were found to have used alcohol in the past one month.

In this study, no statistically significant association was found between use of alcohol in the past one month and adherence to ART ( $P=0.108$ ). In contrast, several studies documented the association of use of alcohol in the past one month with the risk of non adherence (Achappa et al 2013:22; Bonolo et al 2005:S9; Do et al 2013:5).

#### **4.3.8.3 Ever use of cigarette**

**Table 4.46 Ever use of cigarette by the study participants (N=290)**

Response	Frequency	Percent
Yes	46	15.9
No	244	84.1
Total	290	100.0

Table 4.46 shows that, among the 290 participants, 84.1% ( $n=244$ ) had never ever smoked cigarettes, while only 15.9% ( $n=46$ ) had experienced cigarette smoking in their life time. In this study, ever use of cigarettes was not found to be significantly associated with adherence to ART ( $P=0.127$ ).

#### **4.3.8.4 Use of cigarettes in the past one month**

**Table 4.47 Use of cigarettes by the study participants in the past one month (N=290)**

Response	Frequency	Percent
Yes	9	3.1
No	281	96.9
Total	290	100.0

Table 4.47 reveals that, among 290 study participants, 96.9% ( $n=281$ ) had not smoked cigarettes in the past one month while only 3.1% ( $n=9$ ) reported smoking cigarettes in the past one month.



In this study, there was no statistically significant relationship between use of cigarettes in the past one month and adherence to ART ( $P=0.866$ ). In contrast, Bonolo et al (2005: S9) demonstrated association between current smoking and non adherence. Similarly, Sharma et al (2013:52) observed the association of smoking habit with non adherence to ART.

#### **4.3.8.5 Ever use of 'khat'**

**Table 4.48 Ever use of 'khat' by the study participants (N=290)**

Response	Frequency	Percent
Yes	47	16.2
No	243	83.8
Total	290	100.0

Table 4.48 shows that, of the 290 participants, 83.3% ( $n=243$ ) had ever chewed 'khat', while the remaining 16.2% ( $n=47$ ) had never used the stimulant. In this study, no association was found between ever use of 'khat' and adherence to antiretroviral therapy ( $P=0.3$ ).

#### **4.3.8.6 Use of 'khat' in the past one month**

**Table 4.49 Use of 'khat' in the past one month (N=290)**

Response	Frequency	Percent
Yes	12	4.1
No	278	95.9
Total	290	100.0

Table 4.49 depicts the use of 'khat' by the study participants in the past one month. Out of the 290 participants, 95.9% ( $n=278$ ) had not used 'khat' in the past one month while only 4.1% ( $n=12$ ) of them reported to have chewed 'khat' during the past one month. The result

indicates that a great proportion of participants had not been using 'khat', which may be related to better level of awareness in the interaction of the drug with HIV medications and the impeding risk of non adherence.

In this study, there was no statistically significant relationship demonstrated between use of 'khat' in the past one month and adherence to antiretroviral therapy ( $P=0.768$ ). Although there are a limited number of studies to compare this finding with, there are some that indicated the relationship between illicit drug use and poor adherence to ART. Fumaz et al (2008:799) indicated current substance use was associated with a lower level of adherence. Another study also suggested illicit drug use in the past one month was associated with suboptimal adherence (Do et al 2013:5).

#### **4.4 OVERVIEW OF THE RESEARCH FINDINGS**

The results of the study indicated that, among the 290 study participants, 88.3% ( $n=256$ ) reported no missed doses of prescribed ARV pills in the past three days, resulting in a self report optimal dose adherence of  $\geq 95\%$ . Moreover, 82.4% ( $n=230$ ) reported to have closely followed their ARV medications to the specific schedule in the past three days and 82.8% ( $n=197$ ) reported to have followed the instructions all of the time in the past three days.

In this study the overall level of combined adherence to antiretroviral therapy in the past three days was measured taking dose adherence, schedule adherence, and dietary instruction adherence into account. Thus, the combined optimal adherence rate was found to be 80.0%, fulfilling the optimal adherence criteria of taking  $\geq 95\%$  prescribed ARV pills at a specified time schedule, and always conforming to the agreed dietary instructions. And, the non adherence rate was 20.0%.

The most common reason mentioned by the study participants for missing their HIV medications in the past one month was forgetfulness (35.1%). This was followed by being busy with other things (17.5%), running out of pills (10.5%), feeling depressed (8.8%), and not wanting others to see them taking their medications (8.8%).

The bivariate analysis in this study found the following variables to be statistically associated with combined adherence to antiretroviral therapy significant at P value < 0.05: WHO clinical staging at initiation of ART, illness in the past one month, change of ARV medications, knowledge about HIV disease and antiretroviral treatment, disclosure of one's HIV status, availability of social support from friends and/or relatives, use of reminders in taking HIV medications, perception of patient-provider relationship, perceived confidentiality of health information, convenience of appointment schedules, and frequent missing of clinic appointments. No statistically significant association was demonstrated between socio-demographic variables and adherence in this study.

In multivariate logistic model, only WHO clinical stage, change of ARV medication, knowledge about HIV disease and ARV medication, and use of reminders in taking HIV medications remained statistically significant at P value < 0.05.

#### **4.5 CONCLUSION**

This chapter presented and described the results of the study in tables and graphs. The data were analysed to illustrate the characteristics of the study participants using descriptive statistics. Associations of independent factors with adherence to antiretroviral therapy were analysed using inferential statistics. The results of the study revealed the prevalence of adherence to ART by HIV infected adults. The study explored factors which were significantly associated with suboptimal adherence and interpreted the results in relation to other studies.

The following section, Chapter 5, presented the summary of the research findings, the limitations of the study, proposed recommendations, and conclusions.

## CHAPTER 5

### CONCLUSIONS AND RECOMMENDATIONS

#### 5.1 INTRODUCTION

This chapter presented the summary and interpretation of the research findings on the level of adherence and determinant factors affecting adherence to antiretroviral therapy in HIV infected adult patients. It also pointed out the contribution and limitations of the study. Finally, recommendations based on the research findings and the conclusions of the study are proposed.

#### 5.2 SUMMARY AND INTERPRETATION OF THE RESEARCH FINDINGS

The research findings were summarized and interpreted in light of the research objectives.

The objectives of the study were to:

- describe the level of adherence of HIV infected adult patients to antiretroviral therapy in Addis Ababa;
- explore the determinant factors that could affect patients' adherence to their antiretroviral therapy;
- identify the association of socio-demographic and other patient-related factors with the level of adherence; and
- recommend appropriate interventions with regard to the ways of improving adherence of patients based on the research findings.

##### 5.2.1 Adherence to antiretroviral therapy

It is well documented that the ultimate goal of antiretroviral treatment has been a significant reduction in the viral load of HIV and restoration of the immune function of the body, which later results in an improved quality of life (Beer et al 2012:123; Panel on antiretroviral guidelines... 2012:D1; Wasti et al 2012:71). However, adherence to treatment has been found a crucial and alterable factor that may determine whether patients get maximal

clinical benefit from antiretroviral therapy (Panel on antiretroviral guidelines... 2006:20; Matchtinger & Bangsberg 2006).

In this study the level of adherence to a dose of 95% and more, schedule, and instruction to dietary requirement in the past three days were found to be 88.3%, 81.7%, and 82.8%, respectively. The overall combined level of adherence to all indicators resulted in 80.0%. There is documented evidence that a high level of adherence (> 95%) will be required to have sustainable viral suppression and improvement in the clinical outcomes (Beer et al 2012:123; WHO 2006:78) and indeed a significant change in the quality of life of patients (Wang et al 2009:759). In comparison, the level of adherence in this study was found to be equivalent to the findings of other similar studies in Ethiopia, which reported overall adherence of 79.3% to 82.7% (Amberbir et al 2008 [S.a]; Tessema et al 2010:5). However, this was higher than the adherence report of 72.4% cited in Tiyou et al (2010:3-4). Furthermore, the findings of this study are comparable to different studies carried out in developing countries (Abaasa et al 2008:[S.a]; Balikuddembe et al 2012:3; Ekama et al 2012:3) as well as developed countries (Amico et al 2011:5; Sullivan et al 2007:3). This shows that a significant proportion of the study participants were able to demonstrate higher level of adherence to their HIV medications in this particular setting as compared to those in many other studies. This may be explained by the fact that the majority of the patients understood the importance of ART and adherence to it, which is usually addressed during adherence counselling sessions while patients get their HIV medication refills. However, the adherence rate may have been overestimated due to the use of the self report adherence measurement.

Although a higher level of adherence was reported in the study setting, 20% of the study participants were reported to have suboptimal combined adherence. Several studies suggested that poor adherence to HIV medications correlated with the emergence of drug resistance and subsequent treatment failure with increased morbidity and mortality (Beer at al 2012:216; Chi 2009:751-752; Enriquez & Mckinsey 2011:46; Goldman 2008:1032; Knobel 2009:366; San Lio et al 2008:1613; Vriesendorp et al 2007:1116). Therefore, these patients could be at a higher risk of developing drug resistance and treatment failure, which heralds the need to have a strategy that helps to address the foreseeable problems of the high risk patients towards better treatment follow-up and adherence.

Examining self report adherence to dose, schedule, and instruction may give a clearer and wider understanding of the overall level of adherence of patients. As it is widely claimed, self report adherence measure correlates with clinical outcomes and other objective measures. Nonetheless, it tends to result in a relatively higher adherence rate (Amico et al 2009:69; Reda & Biadgilign 2012:1-2; Steel et al 2007: 7). The self report combined adherence in this study is much higher than those reported by other studies based on more objective measures of adherence assessment (Chi et al 2009:748; Erah & Arute 2008:146-150; Goldman et al 2008:1032).

### **5.2.2 Factors affecting adherence to ART**

Adherence to antiretroviral treatment has been influenced by multiple factors associated with the patient, disease characteristics, patient-provider relationship, and drug-related and clinical settings (Enriquez & Mckinsey 2011:46; Machtinger & Bangsberg 2006). This study examined the association of such factors with adherence to antiretroviral therapy and identified the independent factors that were related to suboptimal adherence and those that were not. The discussions below substantiated this claim.

#### **5.2.2.1 Socio-demographic factors**

The study findings suggested that socio-demographic variables such as age, sex, educational status, religion, ethnicity, occupation and average family income were not associated with adherence to antiretroviral therapy. This is in agreement with different studies which documented the absence of statistically significant association between socio-demographic variables and adherence to ART (Aragonés et al 2011:19; Birbeck et al 2009:672; Cauldbeck et al 2009: [S.a]; Sarna et al 2008: 32). This indicates that it may be difficult to identify patients at risk of suboptimal adherence based on their demographic characteristics. However, some studies reported being female, being young, having low educational status, being unemployed, and having lower income to correlate with non adherence (Campos et al 2010:293-294; Hegazi et al 2010: 1342; Protopopescu et al 2009: 602; Sullivan et al 2007:3; Tiyou et al 2010:4; Venkatesh et al 2010:800; Wasti et al 2012:72).

### **5.2.2.2 Factors related to clinical condition**

The relationship between factors related to clinical condition of the study participants and suboptimal adherence was also examined. These factors include duration of time since HIV diagnosis, WHO clinical staging, baseline and current CD4 count, duration of antiretroviral therapy, change of ART medication, and experience of illness in the past one month.

The findings indicated that WHO clinical stage was significantly associated with adherence to antiretroviral therapy. Patients who were asymptomatic (32.7%) at the time of ART initiation were more likely to be non adherent as compared to symptomatic ones (18.4%). In the multivariate analysis, WHO clinical stage was also found to be an independent factor affecting adherence to ART. This can be explained by the fact that the symptomatic patients were committed and eager to get better with strict use of ART as prescribed by the health care providers. They might also have given due attention to ongoing education and counselling sessions provided by health care providers about taking HIV medications. This may not be the case especially for asymptomatic patients. In the study setting patients usually had proper adherence counselling sessions in preparation to initiate ART. Other studies also presented consistent findings where there was a difference in the level of adherence between asymptomatic and symptomatic individuals (Campos et al 2010:293; Tiyou et al 2010:4). In contrast, a study done by Chi et al (2009:751) emphasized that clinical staging did not affect adherence to ART.

The current findings also revealed illness in the past one month was statistically associated with adherence to ART. Those patients who had illness in the past one month were found at a greater risk of suboptimal adherence than those who were healthy. Markos et al (2008:177) also reported that having symptoms in the past one month was associated with non adherence. This could be associated with unpleasant experience of symptoms of illness, such as nausea and vomiting, and difficulty of having proper clinic follow-up. This suggests that health care providers should be cautious in evaluating and treating patients and should provide them with close support and counselling to help them adhere to their treatment. Besides, patients require more psychosocial support from families and/or friends especially when they get sick.

Other variables such as duration of time since HIV diagnosis, baseline and current CD4 count, and duration of treatment were not statistically associated with adherence in this study. Similar studies also documented consistent findings (Aragonés et al 2011:19; Fumaz et al 2008:799).

### **5.2.2.3 Treatment-related factors**

The study participants were taking first line antiretroviral drugs in line with the national guideline. The study finding indicated that the type of ARV regimen, the number of ARV pills per day, and the frequency of dosing were not associated with adherence to antiretroviral therapy. There was no difference in the adherence of patients taking once- or twice-daily regimens, and patients taking a total of two or three ARV pills per day. Although there was no association established in variables related to treatment with adherence in this study setting, the simplicity of currently available ARV medications has contributed to the reduction of the number of pills and the frequency of dosing. This may indirectly promote the adherence of patients to their treatment. However, previous studies documented that higher number of pills and more frequent dosing schedules had been associated with non adherence to treatment. Jean-Baptiste (2008:176) indicated that patients taking fixed-dose combination drugs tended to be more adherent than those taking multiple combined ARV drugs.

The study findings also noted that change of ARV medications was found to significantly affect adherence to ART. Those patients who had changed their HIV medications tended to report poor adherence than those who never changed their treatment. Consistent findings were reported by a study conducted in Brazil (Bonolo et al 2005:S9). This may be related to the tendency of patients to prefer their initial regimen, inadequate counselling and education on the changed regimen, and change in side effect profile of the changed regimen.



#### **5.2.2.4 Psychosocial factors**

A number of psychosocial factors have been cited to be consistently associated with adherence including psychological distress, active drug or alcohol use, social support, and knowledge and beliefs about HIV and its treatment (Machtinger & Bangsberg 2006). In this study the association of certain psychosocial factors with adherence to ART was also examined.

##### *Disclosure of HIV status:*

Disclosure of one's HIV status to either a friend and/or family members was found to be significantly associated with adherence to HIV medications in this study. Those patients who did not disclose their HIV status were at higher risk of suboptimal adherence. Birbeck et al (2009:672) showed that disclosure of HIV status to one's spouse was associated with better adherence. This finding was supported by other similar studies which reported the association of fear of disclosure and social stigma with non adherence (Nozaki et al 2011:834; Waite et al 2008:1369-70; Wasti et al 2012:75). It has been of paramount importance to disclose one's HIV status to supportive others from whom patients may get the necessary support to properly utilize health care services and appropriate treatment. This highlights the need for educating and encouraging patients to disclose their HIV status to supportive others as much as possible so that they can help them achieve the goal of their treatment. However, disclosure of one's HIV status may usually be difficult and complicated by the fear of social stigmatization and disruption in social networks. Studies indicated that a high level of social stigma concern by itself was found to be a significant independent predictor of medication non-adherence in the past four days (Waite et al 2008:1369).

##### *Social support:*

In addition to disclosure, the importance of social support was also emphasized. In this study, the presence of support from friends and/or relatives in taking HIV medication was found to be significantly associated with adherence to ART. Consistent findings were also documented in other similar studies in which social support was significantly associated with adherence (Amberbir et al 2008: [S.a]; Aragonés et al 2011:19; Nozaki et al 2011:834;

Tiyou et al 2010:4). Protopopescu et al (2009:602) also reported lack of support from a partner was significantly associated with non adherence. This reveals that social support from relatives and the community has been essential to deal with not only problems of patients in taking their HIV medications and treatment follow-up but also addressing multifaceted psycho-social needs of PLHIV. As it has been discussed earlier, this may be directly related to disclosing their HIV status to supportive others and discussing their medications. Thus, health care providers have to pay closer attention to helping patients disclose their HIV status and getting their friends and/or relatives to collaborate with them as part of the team in clinical care of the patients.

#### *Use of medication reminders:*

The other finding in this study was the significant association between use of reminders in taking HIC medications and adherence to antiretroviral therapy. Patients who used reminders in taking their HIV medications were more likely to have better adherence than those who did not. In agreement with this study, Amberbir et al (2008: [S.a]) revealed that patients who claimed to use memory aids were three times more likely to be adherent than those who did not. This suggests that patients should be encouraged to use reminders regularly so that they could take their medications strictly as prescribed by their physicians. The need to use reminders was also supported by the finding that forgetfulness was one of the major reasons stated by patients for missing their ARV pills.

#### *Substance abuse:*

The association of use of substances such as alcohol, cigarette, and 'khat' with adherence behaviour of patients was investigated in this study. No significant association was found between use of these substances in the past one month and adherence to antiretroviral therapy. It is reasonable to speculate that the majority of the study participants claimed not to have used these substances to create a positive impression. In any case, it would be quite important to address issues related to substance use in the ongoing counselling of patients as it may significantly help patients to take their HIV medications properly.

*Knowledge about HIV disease and antiretroviral therapy:*

The current study showed that knowledge about HIV disease and antiretroviral therapy was significantly associated with adherence to ART. Participants who had adequate knowledge about different aspects related to HIV disease and its treatment, reported better adherence than those who did not have adequate knowledge. Although the concept of knowledge seems to entail wider dimension, certain variables were incorporated to give insight into the level of knowledge of the study participants regarding HIV disease and ART. The assessment addressed important information about taking HIV medications, possible side effects of HIV medications, benefits of antiretroviral therapy, and importance of adherence. Consistent findings have been documented on the influence of knowledge about the benefits of one's HIV medications and importance of adherence on adherence behaviour of patients (Gari et al 2013:7; Lal et al 2010:3; Markos et al 2008:176), although Sarna et al (2008:32) reported a contradictory finding. In view of the common finding, patients should be well informed about their disease and the importance of taking HIV medications properly as prescribed. Besides, it would be vital to provide appropriate information about the benefits of ART and the importance of adherence in a simplified way so that patients can easily understand the concepts. This is necessary to tackle any possible misconceptions that may arise about HIV disease and antiretroviral treatment. The health care providers should give emphasis to the provision of structured and relevant information to patients about their disease before the initiation of ART and throughout the course of their treatment on a regular basis.

**5.2.2.5 Aspects of patient-provider relationship**

The association between the perception of the study participants on aspects of patient-provider relationship and adherence to antiretroviral therapy was examined. The majority of the study participants positively responded that they got appropriate information about taking HIV medications, that they could easily discuss their problems with health care providers, that health care providers understood their problems in taking their medication and often helped them to solve their problems, and that they were satisfied with the overall care and support provided by health care providers. It was found that perception on aspects related to patient-provider relationship was significantly associated with adherence

to ART. Those patients with a positive perception on items related to patient-provider relationship were more likely to have better adherence than those with a negative perception. This was supported by a study which illustrated that perceived quality of patient-provider relationship was associated with adherence (Watt et al 2012:384). This signifies that having a positive relationship with health care providers may lead to better adherence as patients could feel free to discuss various problems related to taking their medications without any fear and discomfort. Consequently, health care providers may develop specific measures to individual patients in addressing problems that may impact proper medication adherence. There is evidence that patients' overall satisfaction, willingness to involve patients in the decision making process, and positive relationship significantly affect adherence to HIV medications (Machtiger & Bangsberg 2006).

#### ***5.2.2.6 Aspects of clinical settings***

The influence of certain aspects of clinical setting on adherence has been documented in some studies. Sahay et al (2011:842) stated that having negative experiences with the health care system may be related to unplanned treatment interruption. The current study suggested that the extent to which patients believe their medical secrets are kept by health providers, the convenience of appointment schedules, and how frequently appointments to clinic visits were missed were significantly associated with adherence to antiretroviral therapy.

The study participants who believed health care providers kept health-related information of their patients confidential were more likely to have better adherence than those who did not. Patients seem to be sensitive to confidentiality of information about their health status, and sharing information recklessly may result in stigma and discrimination of patients. Thus, this may prevent patients from visiting clinics and taking their HIV medications regularly, and they may eventually become non adherent.

Another important finding in this study was that participants who had convenient appointment schedules to HIV medication refills were more adherent than those who did not. This finding was supported by Chalker et al (2010: [S.a]), which pointed out that regular attendance of patients (in the past three days of appointments) was associated with

adherence. This suggests that health care providers should thoroughly discuss with their patients before setting appropriate and convenient schedules for medication refills. Such patients require a suitable timing for their clinic follow-ups as they may often engage in various routine living activities including daily work and other emergency social events.

This study also revealed that patients who had frequently missed clinic appointments were more likely to have poor adherence as compared to those who had not missed clinic appointments. Similarly, some other studies also corroborated the association between missing clinic appointments and non adherence (Cauldbeck et al 2009: [S.a]; Watt et al 2010:385). Unless the patients appropriately follow their clinic visits for medication refills, they may run out of pills and this will result in non adherence. One of the reasons for missing clinic appointments could be having an inconvenient appointment schedule. Therefore, patients should get the opportunity to discuss and set their next visit with their health care providers. Additionally, allowing patients to play an active role in the management of their disease may promote their adherence to their medication. Even in certain circumstances where the patients face serious problems that may impede their clinic visit, they have to inform their health care providers in advance to make adjustments in their schedule and take adequate quantities of their HIV medications. Understanding patients as a whole should be emphasized.

### **5.2.3 Reasons for missing ARV pills**

Patients may often give various reasons for missing their HIV medications. This study revealed that forgetfulness (35.1%), being busy with other things (17.5%), and running out of pills (10.5%) were the most common reasons for patients to miss their ARV pills in the past one month. Consistent with this finding, a number of studies also mentioned the above reasons for missing one's ARV pills (Jean-Baptiste 2008:16; Markos et al 2008:176; Sullivan et al 2007:3; Tiyou et al 2010:4; Wang et al 2009:759; Wasti et al 2012:73-75; Watt et al 2010:384). It might be of importance to look into the influence of being busy with various activities and forgetfulness on proper adherence to treatment. This would emphasize the need for regular utilization of reminders by the patients to support optimal adherence to antiretroviral therapy. This also goes hand in hand with the earlier finding that reminders were an independent factor associated with adherence. On the other hand,

running out of pills may be interconnected with inconvenience of appointment schedules and missing clinic appointments. Thus, having an agreed upon and convenient appointment schedule may lessen the chance of missing clinic appointments and running out of pills.

### **5.3 CONCLUSIONS**

Generally, the level of adherence reported in this study was 80%, which is relatively high and supports the existing evidence that patients in resource-constrained settings could achieve better adherence. But, it also highlights the need to give attention to adherence of patients as 20% of the study participants reported suboptimal adherence. A number of factors that could affect adherence were analysed. Some of these factors, including WHO clinical stage, change of medication, and experience of illness in the past one month were associated with adherence of patients to ART. The other important factors related to optimal adherence include knowledge about HIV disease and antiretroviral therapy, disclosure of one's HIV status, social support, and use of reminders. Besides, perception of patient-provider relationship and clinical setting aspects such as perception on confidentiality of information, convenience with appointment schedules, and missing clinic appointments were found to be significantly associated with adherence to antiretroviral therapy. Forgetfulness, being busy with other things, and running out of medication pills were identified as the most common reasons for the patients to miss their HIV medications. Thus, appropriate recommendations are made in the subsequent section to address such multiple barriers across different dimensions.

### **5.4 RECOMMENDATIONS**

This study has come up with important findings on the level of adherence and identified factors affecting adherence of adult HIV infected patients to their antiretroviral therapy in Addis Ababa. Based on the findings of the study, the following recommendations have been made:

- Patients should have convenient clinic appointment schedules jointly set by the patient and health care providers so that they can get the necessary clinical evaluation and timely refills of their HIV medications. It would even be valuable to set up electronic-based appointment systems to better facilitate the follow-up of patients and to contact those patients who missed their clinic appointments as early as possible.
- Patients should be encouraged to disclose their HIV status at least to someone very close to them who would provide support not only in taking medication but also in other psychosocial needs of people living with HIV.
- While health care providers usually counsel and educate their patients before ART initiation and later on, special emphasis should be given to those patients who are asymptomatic, those who are sick while taking ART, and those who have changed their HIV regimen. To this effect, ongoing follow-up, intensive counselling, and support should be arranged to help them take their HIV medications properly.
- Health care providers should enhance their interpersonal interaction with their patients to appropriately deliver messages about the HIV disease and HIV medications, to build a trusting relationship and encourage patients to ask questions about their treatment and discuss challenges of taking ARV medications. This would give insights to the health care providers to develop a patient-specific follow-up and support to address issues affecting adherence. This should be supported by the preparation and dissemination of simplified IEC materials to the patients.
- The role of media spot messages about the HIV disease, antiretroviral therapy, the need for adherence should be intensified. This would give an opportunity to educate not only PLHIV but also the community at large, which may also help to reduce the possibility of stigma and discrimination.
- Peer education and adherence support group programmes should be further encouraged to help patients learn from one another about their life experiences, about breaking barriers of taking medications, and about dealing with common problems for treatment follow-up and adherence. Thus, adequate support from different levels of the health system would be required.

- Patients should be encouraged to use reminders as much as possible starting from their initiation to ART. Although it is possible to use various reminders including watches and the radio, in recent times applying innovative ways such as MEMS and mobile phone technologies (SMS text messages) in the study setting could be supportive to improve adherence of patients to ART as well as the ART program.
- The health care providers should regularly counsel and educate patients before initiation and during the course of antiretroviral therapy. The counselling sessions should emphasize on the nature of the HIV disease, characteristics of HIV medication, benefits of ART, the importance of adherence, the goal of the treatment, and the risks of non adherence to antiretroviral therapy. Patients should be encouraged to forward questions related to their health condition and HIV medications. However, this needs a concerted effort among the multidisciplinary team, including adherence counsellors.
- The management of the health facilities and health care providers should focus on maintaining confidentiality of patient-related information as much as possible. This should be supported with a code of conduct to help protect the rights of patients and promote optimal adherence to treatment.
- Further research should be conducted focusing on psycho-social issues including anxiety and depression among PLHIV. The association of adherence with clinical outcomes such as CD4 and viral load parameters as well as other factors should be explored using in-depth qualitative methods in various settings. It would also be necessary to carry out country-wide adherence studies, preferably with combined objective measures of adherence, to better understand the problem and develop effective adherence improvement strategies.

## **5.5 CONTRIBUTIONS OF THE STUDY**

Adherence to antiretroviral medications has been complex and multidimensional in nature. This study has documented valuable findings about the prevalence of adherence among HIV infected adult patients and factors that affect adherence of patients to antiretroviral treatment in Addis Ababa. This study explored amenable factors that may influence



adherence behaviour of patients on antiretroviral therapy in resource-limited setting. This is of importance in the design and development of targeted interventions to improve adherence of patients to achieve better clinical outcomes. It also pointed out important areas on which health care providers need to focus in their routine clinical practice to identify patients that are at risk of adherence early and provide them with appropriate counselling and educational support. It also provides some important information to policy makers, facility managers, and other partners in the development of ART and adherence-related policies and strategies. Thus, it can assist in drawing feasible and innovative adherence interventions and in achieving optimal adherence in the context of resource-constraint settings. Finally, it may also lay out a platform for other individuals who will be interested to work on various scientific endeavours in the field of HIV/AIDS treatment and adherence in the future.

## **5.6 LIMITATIONS OF THE STUDY**

This study was carried out in the face of some limitations. The research findings should be interpreted taking the following limitations into consideration.

- This study was conducted in only two health facilities in Addis Ababa city. This means the study findings cannot be generalized to other parts of the country. Thus, larger representative health facilities across the country should be involved to get a general picture of adherence prevalence in the country.
- The adherence of patients in this study was assessed with a self report method. Since there is no gold standard adherence measurement, self report has been a valid measure of adherence. However, self report measure has widely been known for its subjectivity and for overestimating adherence of patients. Besides, self report measure of adherence has been subjected to recall bias and social desirability bias.
- Another limitation which may reinforce social desirability bias is the fact that the study was conducted in health facility settings where patients may tend to provide positive responses on their adherence behaviour, patient-provider interaction, and aspects of clinic settings.

- While a cross-sectional study design was used to carry out this study, it was not possible to look into the dynamicity of the level of adherence across a period of time. It has been repeatedly mentioned that adherence has been a dynamic process and patients' adherence behaviour may change over time.

## **5.7 CONCLUDING REMARKS**

The level of adherence in the study setting was found to be 80.0%, which is higher than the findings reported in other studies in many other countries. The patients that reported to be non adherent should receive greater support with targeted adherence interventions. Adherence behaviour has been a challenging and complex phenomenon. It is dynamic by its nature and adherence behaviour of patients may vary overtime. This requires periodic evaluation of adherence of patients in order to develop appropriate adherence interventions in resource-limited settings. In several studies including this one, adherence was measured by a self report method due to its low cost and ease of administration. However, the tendency to overestimate adherence may obscure the actual circumstances in routine clinical practices. Thus, use of more objective measures, preferably in combination, has emerged as a better way of measuring adherence (Sahay et al 2011:837).

There have been multidimensional factors which may influence adherence behaviour of patients which could vary in different settings. Certain important factors affecting adherence of patients have been explored and identified in this study so that appropriate actions could be taken to resolve adherence problems.

Eventually, in order to better understand the nature of adherence and its associated factors, more quantitative and qualitative studies should be carried out in the context of resource-limited settings.

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**Annexure B: Application letter for permission to conduct the study**Date: 15/10/12

To: Addis Ababa city administration health bureau  
Addis Ababa

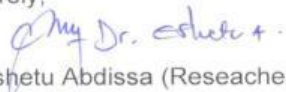
**Subject: Request for ethical approval to conduct a research**

I am writing to request ethical approval to conduct a research in Addis Ababa. I am MPH student in the University of South Africa. As part of the requirement to complete my master's degree in health studies, I would like to conduct a research on the level of adherence to antiretroviral therapy and its determinant factors among HIV infected adult patients in Addis Ababa.

People living with HIV receiving antiretroviral therapy may not adhere perfectly to their medications and various factors have been associated to influence their adherence behaviour. The purpose of this study will be to explore and describe the level of adherence and its determinant factors among HIV infected adult patients on antiretroviral therapy in Addis Ababa, Ethiopia. I hope the study will provide insights with regard to adherence of patients to antiretroviral therapy and understand the potential barriers to adherence. Moreover, it will provide valuable information with regard to patients' adherence and help to make recommendations for health care providers, health facilities and policy makers in enhancing the implementation of ART program and development of evidenced-based interventions to improve adherence to antiretroviral therapy.

I shall be very grateful if you grant me an approval to undertake this study in one of the health facilities in Addis Ababa. Should you have any queries, please do not hesitate to contact me.

Sincerely,



Dr. Eshetu Abdissa (Researcher)

Mob: +251 911 74 67 98

E-mail: [44928661@mylife.unisa.ac.za](mailto:44928661@mylife.unisa.ac.za)

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**Annexure C: Ethical clearance from Addis Ababa city administration health bureau**



Reference A.A.H.C/2193/22  
Date Nov 7, 2012

**To Bole 17 Health Center**

**Addis Ababa**

**Subject: Request to access Health Facilities to conduct approved research**


This letter is to support Dr Eshetu Abdissa to conduct research, which is entitled as “Determinant Factors Affecting Adherence To Antiretroviral Therapy Among HIV Infected Adult Patients In Addis Ababa ”.

The study proposal was duly reviewed and approved by Addis Ababa Health Bureau IRB, the principal investigator is informed with a copy of this letter to report any changes in the study procedures and submit an activity progress report to the Ethical Committee as required.

Therefore we request the Bole 17 Health Center staff to provide support to the Principal investigator.



With Regards

  
Dr Tadesse Ayalew

Head, Ethical Clearance committee

Cc: To Dr Eshetu Abdissa  
Addis Ababa  
Ethical Clearance Committee  
Addis Ababa

**Annexure D: Confidentiality pledge form signed by data collectors****CONFIDENTIALITY PLEDGE FORM**

I, the undersigned data collector have clearly understood the purpose of the study, and the basic ethical principles that are necessary during data collection. I will treat all the study participants with due respect while collecting the data. It is also my strict responsibility to maintain the confidentiality of the information provided by the study participants as much as possible and to keep the data collected in a restricted place and will not allow other individuals to get access to participants' information.

Name Sir Tseganesh Aydo

Date 28/02/13

Signature 

**CONFIDENTIALITY PLEDGE FORM**

I, the undersigned data collector have clearly understood the purpose of the study, and the basic ethical principles that are necessary during data collection. I will treat all the study participants with due respect while collecting the data. It is also my strict responsibility to maintain the confidentiality of the information provided by the study participants as much as possible and to keep the data collected in a restricted place and will not allow other individuals to get access to participants' information.

Name fikirte Belachew

Date 28/02/13

Signature 

**Annexure E: Informed consent form**

The purpose of this study will be to explore the level of adherence to antiretroviral therapy and its determinant factors among HIV infected adult patients. The study will benefit the participants from the recommendations that may result in improving adherence interventions based on the result. There will not be significant risks associated with participation in the study except minimal physical or psychological stress. Ethical approval has been obtained from the institutional review board of health studies department in UNISA and Addis Ababa regional health bureau. Permission to conduct the study was obtained from the health institution.

Participants were selected just by chance from computer based data and data will be collected by interviewing using a questionnaire. It will take you 20-30 minutes to complete the interview. You are allowed to ask questions at any time about the study. Your participation in the study will be voluntary; there is no obligation to participate. You have full right to withdraw from the study at any time if you feel uncomfortable or stressed.

The study data will be coded and it will not be linked to your names. The information you provide will be kept very confidential and it will not be shared to anyone without your permission.

I have understood this consent form and voluntarily consent to participate in the study.

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

Participant's signature: \_\_\_\_\_

Interviewer's signature: \_\_\_\_\_

**Annexure F: Proof of language edition**

Addis Ababa University  
College of Humanities, Language Studies, Journalism  
& Communication  
Department of Foreign Languages & Literature  
☎ (251) 1 239728 Fax N° (00251) 1 239729



Email: info@dfll.aau.edu.et

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☒ 1176

26 November 2013

**To Whom It May Concern**

This is to confirm that I have edited the language in the Master’s thesis entitled ‘Determinant Factors Affecting Adherence to Antiretroviral Therapy Among HIV-infected Adult Patients in Addis Ababa’ written by ABELTI ESHETU ABDISSA.

With regards,

Animaw Anteneh Kassa (PhD)  
Department of Foreign Languages and Literature  
Addis Ababa University



## Annexure G: Questionnaire

We would like to appreciate your willingness to participate in the study. The purpose of the study will be to explore the level of adherence to antiretroviral therapy and its determinant factors among HIV infected adult patients. You are kindly requested to provide genuine responses to the questions listed below. We need you to understand that all your responses are valuable and will be kept confidential. We need to have your patience as it will just take you about 20-30 minutes to respond to the questionnaire. Please do not hesitate to ask any question that may not be clear.

### 1. Demographic variables:

1.1. Age (in years): \_\_\_\_\_

1.2. Sex: 1= M                      2= F

1.3. Marital status:

1=Never married                      2=Married                      3=Divorced                      4=Widowed  
5=Separated

1.4. Literacy status:

1=Illiterate                      2=Read and write                      3=Grade 1-8                      4=Grade 9-12  
5=Tertiary (12+)

1.5. Occupation:

1=Unemployed                      2=Government employee                      3=Student                      4=Housewife                      5=driver  
6=Merchant                      7= Others, specify \_\_\_\_\_

1.6. Religion:

1=Orthodox                      2=Protestant                      3=Muslim                      4=Catholic                      5=others, specify \_\_\_\_\_

1.7. Ethnicity:

1=Amhara                      2=Oromo                      3=Tigre                      4=SNNPR                      5=Others, specify \_\_\_\_\_

1.8. Average family monthly income: \_\_\_\_\_



## 2. Information regarding the clinical condition of the patient

2.1. How long has it been since you are diagnosed with HIV infection? \_\_\_\_\_

2.2. What was the clinical stage of the patient at the time of ART initiation?

1                       2                       3                       4      5= Unknown

2.3. What was the baseline CD4 count at the time of ART initiation?

1= <200 c/mm<sup>3</sup>      2= 200 – 350c/mm<sup>3</sup>      3= >350c/mm<sup>3</sup>      4= Unknown

2.4. What is the latest CD4 count after at least 6 months of treatment?

1= <200 c/mm<sup>3</sup>              2= 200 – 350c/mm<sup>3</sup>      3= >350c/mm<sup>3</sup>      4=Unknown

2.5. How long have you been started on antiretroviral treatment?

1= 3 – 6 months      3= 7-12 months      4= 1-2 years      5= > 2 years

2.6. Were you sick in the past one month?      1=Yes      2=No

2.7. If yes, how serious was your illness?      1= Mild      2=Moderate      3=Severe

## 3. Questions related to the type of current ARV regimen and level of adherence

3.1. The type of current ARV regimen and frequency

Name of ARV regimen	No. of pills each time	
	Morning	Evening



3.9. People may miss taking their medications for various reasons. What were your reasons for missing any of your ART medications within the **past month**? (It is possible to give more than one response.)

1=being away from home

2=being busy with other things

3=simply forgot

4=having too many pills to take

5=wanted to avoid side effects

6=do not want others to notice taking medication

7=a change in daily routine

8=felt like the drug was harmful

9=felt sick or ill

10=felt depressed

11=ran out of pills

12=felt good

13=lack of transportation

14=shortage of food

15=others, specify \_\_\_\_\_

#### 4. Knowledge about HIV disease and antiretroviral therapy

Questions	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
4.1. You know how each of your current HIV medications is supposed to be taken.					
4.2. You know what to do if you miss a dose of any of your HIV medications.					
4.3. Skipping a few of your HIV medications from time to time would not really hurt your health.					
4.4. You know what the possible side effects of each of your HIV medications are.					
4.5. As long as you are feeling healthy, missing your HIV medications from time to time is OK.					
4.6. You understand how your HIV medications work in your body to fight HIV.					
4.7. If you don't take your HIV medications as prescribed, these kinds of medications may not work for you in the future.					
4.8. Antiretroviral medications eradicate HIV from your body.					
4.9. You believe that if you take your HIV medications as prescribed, you will live longer.					
4.10. You know how your HIV medications interact with substances such as alcohol and 'khat'.					

#### 5. The following questions ask about your social support.

5.1. Have you disclosed your HIV status to your friends &/or family members?

1=Yes

2=No

5.2. Do you have a family/friend that supports taking your medications?

1= Yes

2=No

If "no", please skip to question **no. 5.5 & 5.6.**

5.4. How satisfied are you with the support you get from your friends and/or family members?

1=very dissatisfied    2=somewhat dissatisfied    3=neither dissatisfied or satisfied  
4=somewhat satisfied    5=very satisfied

5.3. How often do your friends and/or family members help you remember to take your medication?

1=Never

2=Sometimes

3=Most of the time

4=Always

5.5. Do you use any method to remind taking your ARV medication? 1=Yes    2= No

## 6. Perception on patient provider relationship

Questions	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
6.1. The health care providers give you appropriate information about taking your medications.					
6.2. It is easy for you to discuss problems related to your medication with the health care providers.					
6.3. The health care providers understand the problems you may have taking your ARV medications.					
6.4. The health care providers often help you in solving the problems you may have taking medications.					
6.5. You are satisfied with the overall support you get from the health care providers.					

## 7. Clinical setting

Questions	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
7.1. You believe that health care providers keep your health related information confidential.					
7.2. You are convenient with the scheduling appointments to your medication refill.					
7.3 You have encountered frequent missed clinic appointments.					
7.4 You have never got a problem to your medication refill related to ARV drug supply.					
7.5 You are well satisfied with the overall health care services delivered by the health facility.					

**8. People have various health habits.** The following questions ask about your alcohol and drug use, past and current.

8.1. Have you ever had a drink containing alcohol?                      1= Yes                      2= No

    If yes, have you had a drink within the past 1 month?                      1= Yes                      2= No

8.2. Have you ever smoked cigarette?                      1= Yes                      2= No

    If yes, have you smoked within the past 1 month?                      1= Yes                      2= No

8.3. Have you ever chewed 'khat'?                      1= Yes                      2= No

    If yes, have you chewed it within the past 1 month?                      1=Yes                      2= No

----- THANK YOU! -----