

Addis Ababa University School of Graduate Studies

Antiretroviral Treatment Adherence and Its Determinants among
People Living With HIV/AIDS on Highly Active Antiretroviral
Therapy at Two Hospitals in Oromiya Regional State, Ethiopia, 2006

BY

MIFTAH AWEL

A Thesis Submitted to the School of Graduate Studies of Addis Ababa
University in Partial Fulfillment of the Requirements for the Degree of
Masters in Public Health, DCH, AAU

July, 2007
Addis Ababa
Ethiopia

Assurance of principal investigator

The undersigned agrees to accept responsibility of the scientific ethical and technical conduct of the research project and for provision of required progress reports as per terms and condition of the Research publication office in effect at the time of grant is forwarded as the result this application.

Name of the investigator: Miftah Awel

Date _____ Signature _____

Approval of the primary Advisor

Name of the primary advisor Dr. Dr.Mesfn Addise (MPH, MD)

Date _____ **Signature** _____

ACKNOWLEDGEMENT

My sincere and deepest gratitude goes to my advisor and instructor Dr.Mesfn Addise from the DCH, MF, AAU for his unreserved assistance in giving me timely comments and relevant guidance throughout the study: i.e. From the beginning of the proposal to this level of this research paper.

I am very grateful and would like to extend my heartfelt thanks and appreciation to CDC-EPHA project for sponsoring this study financially and its commitment in providing budgetary support [which is a limitation mostly] for realization of post graduate research papers.

My appreciation and thanks also goes to my instructors and all the rest staffs of community health department for their unreserved knowledge, cooperation and assistances in the whole process of this research paper.

Lastly but not least, I would like to acknowledge the study participants for their full participation and genuine responses, and the data collectors, the supervisor as well as the staff members of Adamma and Jimma hospital art units for their visible responsibility and support shared during data collection period of this study.

.

TABLE OF CONTENTS

CONTENTS
PAGE

ACKNOWLEDGEMENT	I
TABLE OF CONTENTS	ii
LIST OF TABLES	Error! Bookmark not defined.
LIST OF FIGURES	V
LIST OF ABBREVIATIONS	VI
DEFINITION OF TERMINOLOGIES	vii
ABSTRACT	VIII
I. INTRODUCTION	1
1.1. Background Information	1
II. LITERATURE REVIEW	6
2.1- <i>Rationale & Significance of the Study</i>	10
2.2- <i>Operational Definitions</i>	10
2.3 - <i>Conceptual Framework</i>	11
II. OBJECTIVES	14
3.1- <i>General Objective</i>	14
3.2- <i>Specific Objectives</i>	14

IV. METHODOLOGY	15
4.1 - Study Area and period	15
4.2 - Study Design and variables	15
4.3 - Study Population	16
4.4 - Sample Size and Sampling Methods.....	16
4.5 - Data Collection Procedures and Instruments.....	17
4.6 - Statistical Analysis	19
4.7 - Ethical Considerations	19
4.8 – Strengths and Limitations of the Study	20
V. RESULTS OF THE STUDY	21
5.1 The in-depth interview results	21
5.2 The cross-sectional survey results.....	26
VI. DISCUSSION	40
VII. CONCLUSIONS AND RECOMMENDATIONS	43
VII. REFERENCES	45
ANNEXES	49
Annex - 1 English In-Depth Interview Guide.....	49
Annex - 3 Amharic Questionnaire for the Cross-sectional assessment.....	52
Annex – 4.1 Stepwise discriminant analysis results: the predictive model built, after the data was filtered for co-linearity.....	4

LIST OF TABLES

Table 1 Socio-demographic attributes of the respondents participated in the in-depth interview at Adamma and Jimma specialized hospitals, 2006.....	21
Table 2 Basic socio-demographic attributes of the cross-sectional survey at Jimma specialized and Adamma hospitals, 2006.....	27
Table 3 Socio-environmental factors of the cross-sectional survey at Jimma specialized and Adamma hospitals, 2006.	29
Table 4 Psychological factors of the cross-sectional survey at Jimma specialized and Adamma hospitals, 2006.	33
Table 5 HAART adherence Status by self-report of the cross-sectional survey at Jimma specialized and Adamma hospitals, 2006.....	34
Table 6 Results of the multivariate analysis: Variables associated with adherence to HAART in the final Adjusted model with their ORs of the cross-sectional survey at Jimma specialized and Adamma hospitals, 2006.....	39

LIST OF FIGURES

Figure 1 Conceptual model of influences on health behavior	1
Figure 2 Distribution of participants on sources of information about HAART	1
Figure 3 Distributions of the Participants on Reasons for Missed Doses	1
Figure 4 Distribution of coded ARVs prescribed for the participants	1

LIST OF ABBREVIATIONS

- **AAU** - Addis Ababa University
- **AIDS** - Acquired Immunodeficiency Syndrome
- **ART** - Antiretroviral Therapy
- **ARVs** - Antiretroviral Drugs/Medications
- **DCH** - Department Of Community Health
- **HAART** - Highly Active Antiretroviral Therapy
- **HBM** - Health Belief Model
- **HIV** - Human Immune Deficiency Virus
- **MoH** - Ministry of Health
- **PLWHA** - People Living With HIV/AIDS
- **PMTCT** - Prevention Of Mother To Child Transmission
- **TRA** - Theory of Reasoned Action
- **UNAIDS** - United Nations Program on HIV/AIDS
- **VCT** - Voluntary Counseling and Testing

DEFINITION OF TERMINOLOGIES

Adherence - the extent to which a client's behavior coincides with the prescribed regimen as agreed upon through a shared decision making process between the client and the health care provider.

ART - The treatment modalities that are used for treatment of HIV infection.

ARVs - Antiretroviral drugs used for the treatment of HIV infection.

Combination Therapy - combination of three or more ARVs to treat HIV infection.

Community factors - social networks and norms or standards that exist formally or informally among individuals, groups, and organizations.

Highly Active Antiretroviral Therapy (HAART) - triple drugs combination therapy (triple drugs as single medications) used for treatment of HIV infected people, and it is believed to be more effective/potent preparation but the great concern are treatment-resistant variants of HIV that rapidly develop in response to under dosing intermittent and irregular use of the regimens in HAART.

Individual/psychological factors - individual characteristics that influence behavior such as knowledge, attitudes, beliefs, and personality traits.

Normative Belief - when a person believes that important others or referents think he should or should not perform the behavior.

Self-efficacy - the confidence in one's ability to make the desired change.

Subjective Norms - it is a person's perception of social pressure put on to behave in some way. It is also functions of beliefs but different type of belief- Normative Belief.

ABSTRACT

Background information: today, HIV infection is a serious public health problem. However, the advent of highly active antiretroviral treatment (HAART) has dramatically improved the prognosis for HIV-positive patients, substantially reducing the rate of disease progression and death; but HAART Adherence is found to be critically important for the success of the therapy.

Objectives: the objective of this study was to determine the degree of antiretroviral treatment adherence and its associated factors in all people living with HIV/AIDS on highly active antiretroviral therapy (HAART) and follow up at ART - units of Adamma and Jimma specialized hospitals in Oromiya regional state from July to August 2006.

Methods: a cross sectional survey design, using both quantitative and qualitative methods, was used to conduct the study. A total of 459 people living with HIV/AIDS treated with highly active antiretroviral drugs invited to complete sets of variables using an interview and self-administered methods to elicit information on variables of demographic characteristics, ARV drugs, psychological & socio-environmental factors, and substance abuse, emotional distress, perceived social support, ART services & care providers respectively.

Of the total respondents, 265 [57.7%] and 194 [42.3%] were females and males respectively who participated in this study. A total of 300 [65.4%] respondents were in the age range of 26-35 years while, 94 [20.5%] were in the range of 18-25 years.

Adherence to antiretroviral therapy in the previous three days of the interview was measured by self-report. Initially, the percent of adherence was calculated for each drug by dividing the number of pills taken by the number of pills prescribed. Then, the percent of adherence to the antiretroviral regimen was estimated by the average of adherence to the drugs.

Patients who reported an intake of $\geq 95\%$ of the prescribed medication were considered to be adherent. Data was checked for multi-co-linearity and comparison of PLWHA who were adherent and non – adherent (taken $< 95\%$ of their doses of antiretroviral medications) groups was determined on important variables. The significance level was measured using 95% CIs of adjusted and crude odds ratios for which, $P \leq 0.05$ were considered significant.

Further, the independent predictors of adherence were also assessed using a sequence of two multivariate logistic regression models; so that the variables that had significant effect on adherence ($p < 0.05$), either in the crude or adjusted model were selected for inclusion in subsequent models.

Major findings: the overall prevalence of HAART adherence was found to be, 381[83.0%] in this study. Independent positive predictors of HAART adherence reported in this study include:- the participants who had: A perception about personal susceptibility to non-adherence threats [OR = 17.388, CI = 4.026, 75.096, p = 0.000], ability to adhere in future [OR = 7.212, CI = 3.465, 15.012, p = 0.000.], and an access to reliable pharmacy any time [OR = 7.908, CI = 3.296, 18.971, p = 0.000]; had no history of active substance use [OR = 0.387, CI = 0.195, 0.768, p = 0.007], positive beliefs on the efficacy of HAART[OR = 0.449, CI = 0.243, 0.829, p = 0.011], no ARVs side effects [OR = 0.455, CI = 0.224, 0.922, p = 0.029], had no depressed feelings in the last one month [OR = 2.16, CI = 1.32, 6.58, P = 0.001], were not using other drugs along with ARVs [OR = 2.478, CI = 1.121, 5.475, p = 0.025] and had no child under their responsibility [OR = 0.437, CI = 0.218, 0.874, p = 0.019] in the final adjusted multivariate model.

Conclusions & Recommendations: therefore, based on these facts, it is helpful to recommend the following efforts to maximize patient adherence:- regimen rehearsal and other assistances must begin before patients have their first prescription filled; selecting a simple and tolerable antiretroviral regimen that matches the patient's lifestyle; and supportive environment in which family, friends, the community and care providers come together to ensure that barriers to adherence are minimized were found that the most important step toward optimizing adherence.



I. INTRODUCTION

1.1. Background Information

HIV infection is a serious public health problem. According to estimates from the World Health Organization (WHO), there are more than 36 million infected people and 22 million had already died (1-3), & another 5.3 million people became newly infected with HIV, which means more than 15,000 people per day or 11 per minute world wide (2).

The Sub-Saharan African is one of the regions where over 2.2 million people died of AIDS, and around 3 million people became newly infected with HIV (1).

Though, the production of ART started since 1990; it was universally recognized that access to effective HIV/AIDS treatment and care till recently was highly inequitable (1-5); in response to these, WHO has set a target to have 3 million people on ART by the year 2005 (1). Provision of antiretroviral to the poor and marginalized segment of the population was the most controversial and feared act due to the number of impacts it could pose to the individual as well as to the whole of society (2-5).

Like in many other resource poor countries, in Ethiopia there are 1.5 million people living with HIV/AIDS including 200,000 children (1). Almost 22 years have passed since the emergence of the HIV/AIDS epidemic in Ethiopia but HIV- infected people in Ethiopia were not yet fully benefited from the use of ART. However, since the beginning of 2002, ART is more openly discussed in the public media, coinciding with the publication of the ART policy in Ethiopia and due to the efforts made by multilateral donors and non-governmental organizations to provide ART in limited settings (2, 3, 4).

Fully cognizant of competing demands of equal magnitude such as famine, malaria and tuberculosis and uncertainty of the program sustainability, the Government of Ethiopia elected to introduce the ART provision with the goal to prolong the lives, to restore the mental and physical functions and to improve the quality of life of PLWHA (2, 3, 4). On the same year, the Federal MOH and FHAPCO developed Guidelines on ARVs for use and implementation in Ethiopia, and then they began providing ART training to teams of health service providers.

According to the report, the MOH-FHAPCO update as of December, 2006 shown that a total of 96,937 PLWHA are ever enrolled on ART, 58,421 PLWHA are started ART and 46050 PLWHA are currently on ART; its service is given in a total of 192 health facilities (101 hospitals and 91 health centers) (3 - 5).

The experiences in implementing these projects identified the following major problems in adherence to treatment: insufficient training of staff, poor infrastructure, long waiting time, lack of trust, stigma, poor supply system, poor motivation of staff, cultural beliefs, pill burden, poor patient information and knowledge, the use of traditional medicine and poverty, and then the government has made some adjustments and initiatives on ART-service scale up programs since the beginning of 2005 (3, 4, 5).

The advent of highly active antiretroviral therapy has dramatically improved the prognosis for HIV-positive patients, substantially reducing the rate of disease progression and death (6-10).

Today several researchers have proven that the introduction of highly active antiretroviral therapy has transformed HIV infection into a chronic manageable disease, had a major impact on the quality of life and the prospects for an extended survival in HIV-infected persons; many of them have been able to go back to work and lead a full social life (10-12).

Antiretroviral therapy (ART) for the treatment of HIV disease, which specify the use of at least 3 different type of drugs (multiple individual drugs) taken once, twice, or 3 times a day (6, 7), which became a constant challenge for patients, especially in light of the treatment guidelines for HIV disease; treatment non-adherence was found to be mainly a response to the burdens of complicated drug regimens that disrupt one's daily routine (8). Moreover, HIV-infected patients who are already taking an extraordinary number of antiretroviral pills often have co-morbid conditions that require additional medications (9).

The new generations of HAART offer the potential for long-term suppression of HIV replication; however, the challenge now is to encourage and enable patients to take these medicines correctly, in order to achieve their maximum effect (12). Adherence to this antiretroviral therapy, however, is critically important for the success of the therapy. Some researchers suggest that near-perfect adherence, i.e., higher than $\geq 95\%$, is necessary to achieve suppression of HIV replication (HIV-RNA < 400 copies/ml) (8).

Inadequate viral suppression resulting from failure to adhere closely to treatment causes a worsening of immunological and clinical states and leads to emergence of drug-resistant HIV strains (8, 11, 13-16). Although, treatment regimens for HIV-AIDS are becoming less complex with the advent of HAART of twice-a-day and once-a-day dosing (17); researchers found that a variety of factors have a positive or negative effect on the degree of adherence, that may diminish the patient's ability or willingness to adhere to an antiretroviral regimen.

Several studies indicated that the key to the success of the new highly active antiretroviral therapies (HAART) is the ability and willingness of HIV-positive individuals to adhere to complex antiretroviral regimens (18), in order to prevent the consequences of poor adherence (19-23).

The authors further emphasized that adhering to HAART presents a great challenge - the task is daunting: treating a stigmatizing illness with a lifetime regimen, often of considerable complexity, and with medications likely to be accompanied by unpleasant side effects. When adherence problems are identified early, appropriate interventions need to be promptly undertaken in an atmosphere of teamwork, trust, and confidence.

They suggested that many of the new strategies for improving adherence to antiretroviral drugs seek to improve the patient's motivation, which can only be achieved by listening to the whole patient ('other issues that affect the patient, affect adherence), and the implementation of these strategies in the real world requires multidisciplinary efforts and counseling by trained professionals may be necessary in this context, and ultimately improve adherence (16, 17, 24, 25).

It is because adherence is strongly linked to a patient's beliefs and attachment to care: these may include issues related to the virus (viral burden and pre-therapy drug susceptibility), medications (restrictions of food and water, tolerability, pill size, and pill burden), problematic relationships with health care providers (communication breakdowns, ignorance of or insensitivity to cultural differences, and lack of experience in treating HIV infection), the health care system (language limitations, poor access to adjunctive services, and inadequate pharmacy hours), and psychosocial difficulties (family and earnings responsibilities and unreliable social networks)(10, 14-17)). In a number of studies: socio-demographic characteristics such as younger age (8, 18, 19), low income (21, 22), and low levels of schooling (22, 25) were found to have association with non-adherence.

Factors that negatively influence adherence to HAART therefore pose considerable threats to both individual and public health, because failure to adhere to treatment schedules is particularly troublesome with HAART because of HIV's ability to rapidly develop resistance to these drugs. Virus-resistant mutations can develop after only days of intermittent use of HAART (combination therapy) (8-10, 24, and 25). The necessity of attending to high level of adherence to HAART in patients undergoing HIV-AIDS treatment became increasingly pressing to developed countries as the HIV epidemic spreads to their impoverished areas and as antiretroviral treatments become increasingly available in developing countries, where several determinants of non-adherence were expected to occur dominantly (18).

Many researches so far reviewed on correlates of adherence have recommended use of various methods for a more comprehensive profile to characterize ART adherence in patients with HIV infection and a Continuous monitoring of adherence with a variety of assessment methods at variety of settings to determine the efficacy, the safety and the clinical implications of poor adherence (19-22).

On the other hand, when examining the predictors of adherence, some authors have suggested taking into account psychological factors such as stress, depression and coping skills since they have been shown to decrease adherence to the prescribed medication (21, 23, 24). Few studies have emphasized the patients', perception of their illness and medication, the availability of social support, patients', understanding of the rationale for treatment and the patient-doctor relationship (12).

Two small scale studies titled with evaluation of ART adherence at three hospitals in Addis Ababa (26) & at the Ministry of National Defense Force hospitals in Addis Ababa and Debreziet (27) were conducted both in 2005. These two studies used the same adherence definition (taken $\geq 95\%$ of the prescribed regimen accordingly), method (self-report method) to assess treatment adherence, and almost similar reports, 81.2% of treatment adherence in the past 7-days & 82.8 % of treatment adherence in the past 1-month respectively.

However, there are many limitations to the reported treatment adherence data to compare results and reach substantiated conclusions. These limitations include, most of the studies and research papers on this subject in general lack standardization of methods used in several studies; specifically these the above two studies lack uniformity on the time spans used to assess treatment adherence status, they did not use similar questions, data represented a small group of subjects and covered limited geographic areas.

Evaluating adherence has proven to be difficult; researchers usually find one or another method for evaluating adherence or a combination of methods more satisfying and applicable to their needs. Majority of the studies so far conducted lack uniformity in their results, making it difficult to achieve consensus on modifiable correlates and predictors on which intervention strategies should be designed to assist people undergoing HAART. This is because, currently there is no gold standard for measuring adherence (18,19); some methods of doing so include interviews with patients, manual counting of pills, counting of opened bottles and serum or urinary dosing of drug metabolites (20), and some have used a different criteria to define good adherence(12, 13).

Researchers recommended designing an innovative and culturally sound strategy, because of the life long nature of the highly active antiretroviral therapy (HAART) and standardizing treatment for resource-limiting countries: maintaining acceptable quality of care and deal with human resource constraints, for promoting adherence to ART and avoid resistance.

In response to these recommendations and drawbacks in majority of studies on adherence to HAART, suggest undertaking more study at variety of settings through use of different research designs and treatment adherence evaluation methods for a more comprehensive profile to characterize HAART adherence.

Impressive intervention efforts on HIV/AIDS care and support programs have been made to curb the spread of HIV epidemic in Ethiopia. One of the various measures, since not longer than three years duration, HIV - infected people in the rural areas and regional towns had a chance for use of HAART through service expansion initiatives. However, the importance of research is less considered, almost none published data on this issue is accessed in the study areas.

Therefore, the objective of this study was to determine degree of adherence to HAART and its associated factors among PLWHA on HAART. It is important that the awareness of these challenges and obstacles faced by clients can assist individualizing management approaches and design culturally sound intervention strategies that would help for improvement of treatment adherence.

II. LITERATURE REVIEW

Today, some 37.8 million people are living with HIV and there are 22 million deaths in the world since the first cases of AIDS were identified in 1981. This epidemic has a serious impact on households & communities, most studies indicated that the sub-Saharan African countries losing on average between 1% & 2% of their annual economic growth (1 - 3).

The impact of HIV/AIDS can be viewed in different areas as, on population & population structure, it results in a decrease in life expectancy with more deaths in ages of twenties & thirties. HIV/AIDS also drives the already determinate households of these countries to destitution due to losses of income & production of a household member, & increase in an extraordinary care needs & household expenditures for medical & related costs (2). In addition to the negative impacts of HIV/AIDS in the above mentioned sectors it is a significant obstacle to children achieving universal access to primary education by 2015 due to the loss & absenteeism of teachers and orphans & vulnerable children in school (2, 3).

To decrease these impacts of HIV/AIDS, different Programs have been formulated but most until recently neglected care and support for people living HIV, their families and their countries as an element. There are examples, however, of innovative community-based projects that responded to care and support needs early in the pandemic. Experiences in these projects have shown improvement in demand for HIV VCT services, and early management & prevention of infections disease (1, 2, 3). The ART and VCT among the other needs after being assessed by several studies in developing countries form the basis of the essential care elements (4, 5).

Combination antiretroviral therapy or highly active antiretroviral treatment (HAART) has given new hope to those infected with HIV, but the combination of at least three medications used in this therapy make this one of the most difficult of regimens to follow. Medications may need to be taken with or without food in multiple doses throughout the day, often in combination with other HIV-related medicines (6).

The consequences of not taking the drugs properly may be severe: resistance can develop rapidly, and the potential benefits of the treatment can be entirely lost. There is also the danger of cross resistance —resistance to one medication can result in the decreased effectiveness of many others, restricting future options (6). Many authors suggest that non-adherence tends to increase with the number of times medications must be taken per day (14, 16) and the number of different medications (21). Patients who are experiencing adverse effects are less likely to adhere than patients who are tolerating the medication (18, 19).

Some studies have investigated patient attitudes towards antiretroviral treatment. The perceived convenience of the antiretroviral regimen, or "fit" with routine and daily activities was associated with better adherence (13). Patients who were less sure of the link between non-adherence and the development of drug resistance were less adherent (17). Self-efficacy expectations of antiretroviral therapy may be a promising aspect of patient attitude towards treatment (19).

Cross-sectional studies (10, 14, 17, 24) have suggested that low levels of self-efficacy expectation to take medication as prescribed were associated with non-adherence to antiretroviral therapy. A prospective randomized two-arm controlled study showed that a specific educative intervention increased maintenance of high levels of adherence during one-year follow up. In this prospective study, perceived self-efficacy and effort to take medication were associated with a high-level adherence one year after beginning therapy (25 - 27).

A variety of factors have a positive or negative effect on the degree of adherence, while some have no predictive value whatever - Positive predictors: patient belief in HAART, physician experience, social supports, adherence to office visits; Negative predictors: includes: active injection/ drug use, active alcohol abuse (>14 drinks / wk), active psychiatric disease, cumulative impact of HIV infection, and Non-predictors: race, gender, disease stage, history of substance abuse (28).

What a patient understands about a specific regimen, including the reason for taking each medication and the intricacies of dosing schedules and administration requirements, can have a profound influence on adherence. On a broader level, patients' attitudes and cultural beliefs influence their trust in Western medicine. Their degree of skepticism about the medical establishment and the extent to which they believe myths about antiretroviral medications collectively influence their ability to adhere to treatment (26).

Suboptimal adherence may cause viral rebound, which is often associated with the emergence of drug resistance. In fact, in a recent study of 1647 plasma samples obtained from participants in the HIV Cost and Service Utilization Study, the estimated overall prevalence of drug resistance was 78%. Class-specific resistance prevalence was 70% for nucleoside reverse transcriptase inhibitors; 42% for PIs; and 31% for non-nucleoside reverse transcriptase inhibitors (29).

The long-term success of antiretroviral therapy and the avoidance of drug resistance depend on the care provider's comprehensive knowledge of the available treatment options, understanding of the factors associated with optimal adherence, and success in devising strategies to prevent and manage difficulties related to adherence(6).

Clinicians need to understand what each patient expects from antiretroviral medications and the degree to which he or she has confidence in their efficacy. Is the patient's motivation high enough to optimize his health? Personality type; existing stress and a patient's perception of stress; active substance abuse; other psychiatric conditions, such as depression; and the patient's level of cognitive functioning all affect adherence(6). The patient's relationship with the provider is crucial, particularly in the management of adverse drug reactions. Patients must believe that their clinicians are truly members of their team and are willing to work with them to manage toxicities and to change regimens if necessary. A patient's trust in his provider makes it easier to discuss issues when a medication is causing difficulties. In addition, adherence is enhanced when patients have friends or family members who can be relied on for help and support, as well as for providing reminders to take medication (6).

In one survey conducted by the Gay Men's Health Crisis, the majority (70% to 80%) of patients reported that body shape changes, nausea and vomiting, other GI side effects, such as diarrhea affected their willingness to take medications (30). The association between increasing regimen complexity and decreased adherence is well established in a variety of chronic disease conditions, including HIV infection (29).

The HIV Epidemiologic Research study found that although 75% of women in this cohort understood the dosing frequency and 80% understood food restrictions associated with their particular regimens, only 63% understood both issues (31). Not surprisingly, the percentage of patients with a correct understanding of dosing frequency decreased with increasing regimen complexity. These findings were independent of race/ethnicity, current or past injection drug use, and education. In another study, 80% or greater adherence was associated with twice-daily or less frequent dosing (13). These findings are further supported by those of Eisen and colleagues,(32) who showed that adherence improved from 59% to 83.6% when dosing was reduced from 3 times a day to once daily. A study by Eron and colleagues (33) found that there was no difference in adherence rates in patients who received either once-daily (90%) or twice-daily (87%). Adherence is also diminished as the actual number of pills taken daily is increased (34), when there are food or fluid restrictions, and when medications that require special storage conditions are used.

Any measure that improves a patient's social support or education about HIV and antiretroviral therapy is likely to improve adherence (9). Although written materials may be helpful for some patients, face-to-face counseling is preferable-even after patients have been taking their medications for a while, periodic reinforcement is necessary, because adherence tends to diminish with time, pill organizers and reminder devices help patients remember to take their medications & resulted in an overall adherence rate of more than 95% among users with cognitive impairment (35).

The number of doses is another important variable. Some studies support the hypothesis that the number of doses is more important than the number of drugs used (16, 18, 28), as a small number of medication sessions tends to fit more easily into the patient's daily routine (19, 24, 28-30). Nevertheless, other studies did not find this association, which suggests a need for more comprehensive studies concerning this issue (36-38). Efforts to maximize patient adherence must begin before patients have their first prescription filled. These early interventions reduce the risk of viral rebound and the emergence of drug resistance. Moreover, patients who maintain a high level of adherence have been shown to enjoy a better quality of life and to feel more optimistic about their future with HIV infection.

Conclusively, from these literatures reviewed, it is possible to understand the following facts in short: a variety of personal and systemic strategies can help optimize patient adherence; good patient-provider communication is essential when individualizing therapeutic regimens, to this end, it is important to provide patients with information that will help them anticipate, plan for, and deal effectively with medication related challenges.

Therefore, characterizing the status and pattern of HAART- adherence and even service in its targets would be great to plan intervention strategies that would help the PLWHA to maintain, promote, and to improve the gear towards successful HAART adherence practice contextually.

2.1-Rationale & Significance of the Study

The promises of revolutionary HIV-AIDS treatments also bring significant challenges. Today, in the fear of developing treatment-resistant variants of HIV that rapidly develop particularly in response to non – adherence to HAART; researchers recommended designing a need based strategy to standardize treatment for resource-limiting countries, for promoting adherence to HAART and avoid resistance. In response to these recommendations majority of studies suggest undertaking more studies.

Therefore, a study that determines the status of adherence to HAART and examines its related factors has great importance to access information on the challenges and obstacles faced by clients and service providers as base line information:-

- For monitoring and evaluation of treatment adherence behaviors.
- To develop innovative and culturally sound intervention strategies and to individualize management approaches that would help for improvement of treatment adherence.

2.2- Operational Definitions

1. Antiretroviral treatment adherence practice - people living with HIV/AIDS (PLWHA) on highly active antiretroviral therapy reportedly taken $\geq 95\%$ of their prescribed ARV medications as to their agreement with health care provider.
2. Antiretroviral treatment adherence status of individual study subject - the percentage of the total ARVs that the individual reportedly taken divided by the total number of ARVs prescribed for him/her.
3. Prevalence of Antiretroviral treatment adherence in the past three days - percentage of the total number of study subjects who have reportedly taken $\geq 95\%$ of their prescribed ARVs divided by total respondents of study in the past three days from a day before an interview.

2.3 - Conceptual Framework

There is no doubt that human behavior is complex and often beyond comprehension. If human behavior were simple to figure out, for that matter, there would be no great literature and working to change health-related behaviors would be very easy (39). However, individuals are unique and their behaviors are multidimensional. Individuals vary within groups and groups differ in significant ways from each other. At the same time, the quest to understand human behavior is not entirely elusive. Research has shed light on some of the “levers” that move human beings to act (40). Through behavior-change theories that most behavioral scientists have used to explain and influence health behaviors of both individuals and social groups -- Theory is important because it goes beyond trying to explain actions or inactions of specific individuals to provide a unified basis for understanding, predicting to the extent possible, and influencing human behavior in general (39).

The theories are divided into categories according to the desired locus of change. In reality, it is difficult to analyze individuals' behavior without considering the social context in which they live, or to analyze group behavior without appreciating differences among the individuals who compose that group. In an earlier day, the task of changing health-related behavior was thought to be simply a matter of sending health messages — a one-direction communication approach. Today, sound health promotion programs no longer rely on one-shot exhortations via booklets, posters, or media broadcasts. They encompass extensive research on relevant audiences; skill-building; multi -channeled education and advocacy using influential persons; policy development; community mobilization; and organizational, economic, and environmental change. This approach recognizes that human beings live in a dynamic “social ecology” as well as a physical one (39).

Therefore, based on review of literatures and empirical knowledge from disciplines of public health, a construct of health belief model, theory of reasoned action and theories of interpersonal ---one of them is -- social learning theory is used as the conceptual framework. The authors of these three theories focusing on individuals recognize that one person's behavior does not exist in a vacuum and is influenced by context. Their models relate a person's readiness and ability to undertake healthier behaviors to his or her characteristics: levels of knowledge, skills, perceptions, beliefs, values, motivation, levels of self-efficacy (“Can I do this?”) and self-esteem (“Do I deserve to be healthy?”), and the need for the approval of others (39). Hence, we assumed that these theories would fit within an ecological perspective -- the perspective that involves two key ideas and that can help guide health interventions:

First, health-related behaviors are affected by, and affect, multiple levels of influence: intrapersonal or individual factors, interpersonal factors, institutional or organizational factors, and community factors. The second key idea recognizes reciprocal causation between individuals and their environments: Behavior both influences and is influenced by the social environment in which it occurs (39).

The theories that fit within an ecological perspective include:-

Health Belief Model (HBM) - they theorized that people are afraid of getting serious illnesses, and that health related behaviors reflect a person's level of fear based on level of threat perceived, and a person's expected fear reduction potential of taking action. The Health Belief Model identifies four aspects of this assessment: perceived susceptibility to ill health (risk perception), perceived severity of ill health, perceived benefits of behavior change, and perceived barriers to taking action.

Theory of Reasoned Action (TRA) - it views a person's intention to perform or not a health behavior as immediate determinant of the action. Intention represents a person's motivation in the sense of his/her conscious plan or decision to exert effort or perform the behavior and it is a function of two basic determinants: Attitude & Subjective norms.

Theories of Interpersonal (TOIP) - interpersonal environments matter. Other people's behaviors, ideas, advice, assistance or lack of it, and emotional support play important influence includes those closest to an individual, such as family members, friends, and other peers, but the circle can expand to encompass coworkers, health professionals, and other people one identifies with or admires. The dynamic is reciprocal: People are both influenced by and influence others.

Social Learning Theory - in order to understand and change unhealthy behaviors, Social Learning Theory analyzes psychosocial influences arising from the interaction of individual factors, the social environment, and experience. While the physical and social environment shapes behavior, people are not passive in the process, since they in turn can change their environments—a reciprocal dynamic. The theory emphasizes behavioral capability: A person needs to know what to do and how to do it. Thus, clear instructions and sometimes training are needed, but still may not be enough. Social Learning Theory considers self-efficacy.

The assumed extended dynamism that exists between human behaviors and the environmental factors is shown in figure-1below

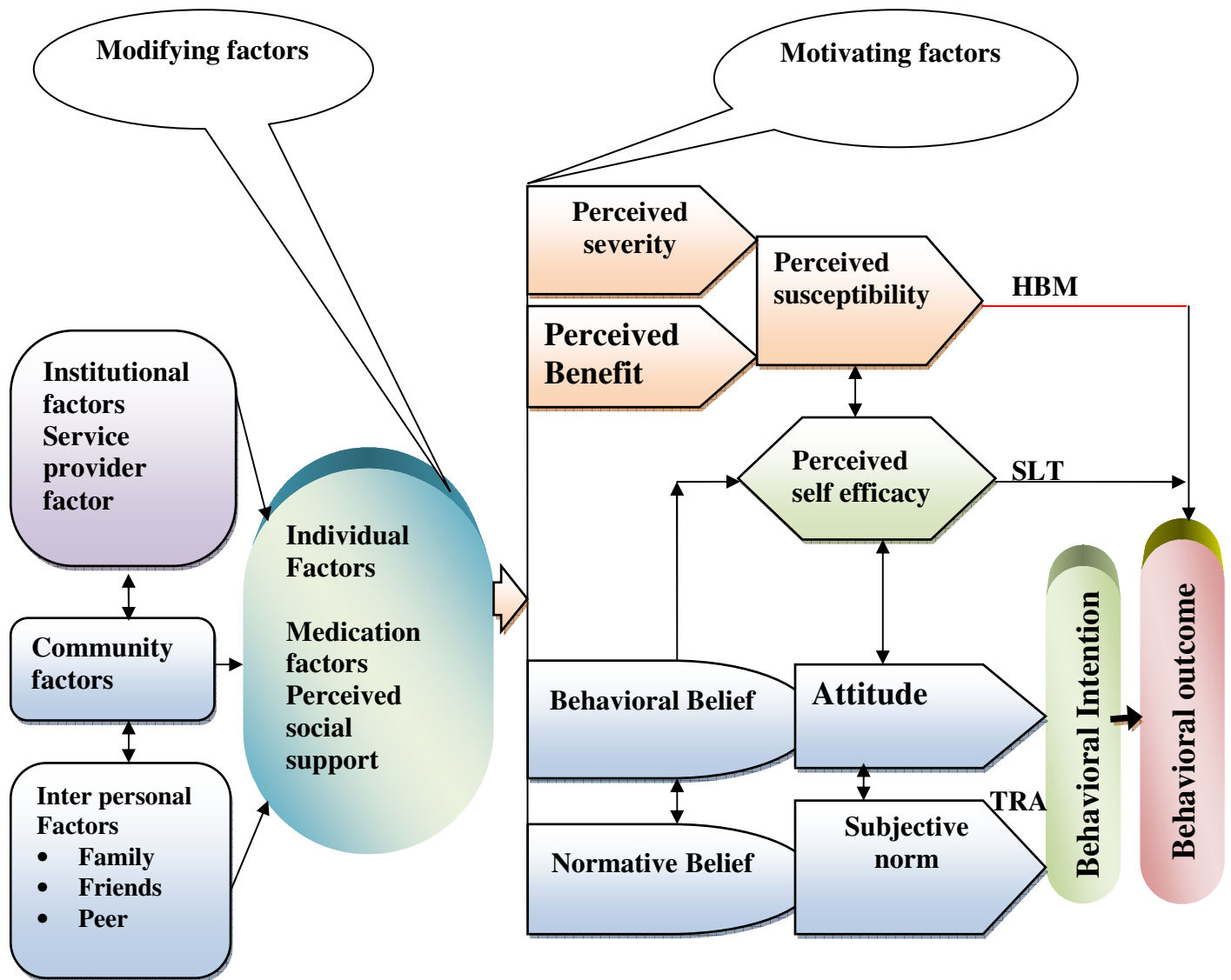


Figure 1 Conceptual model of influences on health behavior

III. OBJECTIVES

3.1- General Objective

To determine magnitude of antiretroviral treatment adherence and its associated factors in all people living with HIV/AIDS on highly active antiretroviral therapy (HAART) and follow up at ART - units of Adamma and Jimma specialized hospitals in Oromiya regional state, 2006.

3.2- Specific Objectives

- ❖ To determine degree of antiretroviral treatment adherence in all people living with HIV/AIDS on highly active antiretroviral therapy (HAART) and follow up at ART - units of Adamma and Jimma specialized hospitals.
- ❖ To identify associated factors of antiretroviral treatment adherence in all people living with HIV/AIDS on highly active antiretroviral therapy (HAART) and follow up at ART - units of Adamma and Jimma specialized hospitals.

IV. METHODOLOGY

4.1 - Study Area and period

The study was conducted from July to August 2006 at ART - units of Adamma and Jimma specialized hospitals in Oromiya regional state. The ART units of these health facilities were considered more preferably, because of their geographical accessibility and provision of ART service in well organized manner at a planning stage of this study.

4.2 - Study Design and variables

A cross-sectional survey design, using both quantitative & qualitative methods was used to approach participants and to elicit information on objectively constructed variables of the study. Sets of variables for which the participants were invited to complete include:-

❖ **Independent variables**

➤ **Modifying factors**

- *Social environment*: factors related to health service, social care and support.
- *Personal life style related factors*: factors related to use of active substance, use of other drugs/ treatments along ARVs.
- *Health status and clinical results*: side effects of ARVs, CD4 count, perceived feelings of depression.

➤ **Motivating factors**

- *Cognitive factors*: - Source of information about ARVs; knowledge about eligibility, benefits and adherence.
- *Psychological factors*: - Beliefs on efficacy of HAART, Self-efficacy to treatment adherence, Perceived susceptibility and perceived severity of non-adherence, Perceived benefit & satisfaction of HAART/its services.

❖ **Dependent variables** – outcome behaviors: practice of adherence and non-adherence to highly active antiretroviral therapy.

❖ **Socio-demographic characters** – age, sex, marital status, ethnicity, religion, monthly income, educational status and occupation.

4.3 - Study Population

Source Population – all people living with HIV/AIDS (PLWHA) treated or being treated with highly active antiretroviral therapy (HAART) in Oromiya regional state.

Study Population – all people living with HIV/AIDS, who were on highly active antiretroviral therapy and follow up at the study settings.

Inclusion Criteria – all the study population, both males and females who fulfilled the criteria, such as: ≥ 18 years of age (highly affected age group by HIV/AIDS currently), gave verbal informed consent voluntarily and not critically sick.

4.4 - Sample Size and Sampling Methods

To determine the sample size for the cross-sectional survey design, it was assumed that the precision to an acceptable approximation of the population was taken to be 95% (CI of 95%), taking a difference of no more than 5% from the actual figures in the source population. Since our current adherence rate or proportions of any related concepts on adherence to HAART was not known, a rate of 50% was preferred to obtain the largest possible sample size using the single population formulae. To compute for non-response rate, 10% of the total sample size [N = 384] was added for each site and then the total sample size was found to be 461. The sample size was calculated using the following formulae: -

$$N = \frac{Z (\chi^{1/2})^2 P (1-P)}{D^2}, N = 384$$

Where, N = sample size, Z ($\chi^{1/2}$) = 1.96, which is the upper percentile of the standard normal distribution, P= HAART adherence rate, which was assumed to be 50% and D= difference from the actual figures of source population, which was taken to be 5%.

As to the sampling methods, a total of 1430 PLWHA -- sampling units [462 at Adamma & 968 at Jimma specialized hospitals] who were on HAART and follow up within the study period [July - August 2006]] registered in the sampling frame. Finally, Using a systematic random sampling technique, 312 respondents from Jimma specialized hospital and 149 respondents from Adamma hospital were selected proportionally (N = 461). For the qualitative part, the selection of the participants was carried out using purposive sampling technique to reflect the diverse socio-demographic characteristics of the study population, i.e. all PLWHA on HAART and follow up at ART units of the study sites. Five respondents from each site, a total of 10 interviewees participated in the in-depth interview. Each in-depth interview session of both sites was conducted with the respondents who had a follow up within July 17 - 21 and July 24 – 28, 2006 at ART- units of Adamma and Jimma specialized hospitals respectively.

The size of participants for in-depth interview was not pre-determined but through the data analysis process in checking for redundant information and saturation of ideas/concepts forwarded from the interviewees on daily basis limited us their total number to be 10 (that was 5 from each site).

4.5 - Data Collection Procedures and Instruments

Data on the study variables were gathered through using structured questionnaire and checklist guided in-depth interview techniques. Initially, this data collection process was started with an individual in-depth interviewing technique - the entire in-depth interviewing sessions were carried out by the principal investigator in both sites sequentially. In undertaking the interview sessions, checklist as a tool was constructed on predetermined areas of emphasis that were organized from review of literature on adherence to HAART.

It was organized with the following sample questions include: “Describe your understanding of your treatment plan?” “Describe your daily routine when taking combination ARV?”, “From whom /where did you heard /obtained the information about ARV?”, “After how long of the diagnosis you decided to start ARV?”, “What were the factors which influenced your decision making?”[See annex- I].

After the subjects were asked for their voluntary participation, the principal investigator audio taped and took field notes in conducting the conversational individual in-depth interview with a total of 10 (five at each site) respondents. Each interview lasted between 35-40 minutes in a setting where there was no any interference.

Particularly, the data processing and analyzing procedures particularly to this part of the study began on the first day of interview. On a daily basis, data were processed, and patterns were identified as well as compared throughout the study & further scrutinized to discover recurrent patterns and saturation of ideas before the themes were identified and interpreted.

Then secondly, for the quantitative cross-sectional survey, a structured questionnaire was used record information on variables of the study. The questionnaire was developed by the investigator, modifying items available from standard questionnaires after discussion with experts in the field of specialty. There were 10 questions addressing the patient-doctor relationship, 26 regarding knowledge, attitude, self efficacy and beliefs about the illness as well as its treatment, and 9 regarding social support along with questions on socio-demographic characteristics. The questionnaire was translated from English to Amharic language and piloted on 20 individuals, then made some modification accordingly.

The definitive structured interviewer - administered questions were used to record data on variables such as: socio-demographic characteristics, perceived severity of non-adherence, perceived susceptibility for non-adherence, knowledge about the illness and beliefs about treatment.

It was introduced questions regarding the understanding of the prescribed regimen and difficulties in taking the different drugs as well as their causes. Interviewers proceeded to ask participants to think back about what they did in the last three days and recall the times they had taken each drug.

The structured self-administered questions were prepared on variables include: substance abuse, emotional distress, perceived social support, health service factors, client - doctor relationship and other treatments they currently taking that were not part of the antiretroviral therapy.

Clinical charts were inspected in order to validate some of the information and collect additional clinical information-when the respondent were not certain on the information they have given to interviewer such as CD4 cell count at enrollment & most recently, drug side effects, and names of the ARV drugs;

The structured interviewer administered questionnaire filled out with the help of one nurse as data collector and one public health expert [MPH graduate] as supervisor at each site from July, 15- August, 30 2006, after they had a one day introductory session with the instrument. The adherence assessment was performed for the past one month, three days and since the ART was initiated using patients self-report. However, treatment adherence during the past three days was preferred for its reliability to compare with different variables of the study in order to understand their influence.

In assessing treatment and adherence status, participants were interviewed to identify the HIV treatments they were currently taking and the doses taken in the past 3 days from the day before the interview. With regard to perceived barriers to treatment and reasons for non-adherence - the participants were asked to reflect back on the past one month recall to the best of their ability the times when they had missed a dose of their antiretroviral medications, and mark the circumstances that played a role in their not taking their medication at those times (because this has no any detailed procedures or steps that require memorization).

4.6 - Statistical Analysis

Data were analyzed using SPSS – 11-version statistical computer program, and summary of data presented with tables and figures. Adherence to antiretroviral therapy in the previous three days of the interview was measured by self-report. Initially, the percent of adherence was calculated for each drug by dividing the number of pills taken by the number of pills prescribed. Then, the percent of adherence to the antiretroviral regimen was estimated by the average of adherence to the drugs. Patients who reported an intake of 95% or more of the prescribed medication were considered to be adherent.

Comparison of PLWHA who were adherent (taken $\geq 95\%$ of their doses of antiretroviral medications) and non – adherent (taken $< 95\%$ of their doses of antiretroviral medications) was carried out on various variables, such as socio-demographic, psychological, socio - environmental and health service related factors of the stud; and their significance tests determined using univariate & multivariate logistic regressions.

The independent predictors of adherence were also assessed using a sequence of two multivariate logistic regression models; so that the variables that had significant effect on adherence ($p < 0.05$), either in the crude or adjusted model were selected for inclusion in subsequent models. The magnitude of the association between the different variables in relation to the adherence to treatment measured through, 95% confidence intervals (CIs) of adjusted and crude odds ratios (ORs) for which, $P \leq 0.05$ were considered significant.

4.7 - Ethical Considerations

The research plan was approved by the AAU, MF Ethical clearance-committee and official letter of co-operation written and handed to directors of Adamma and Jimma specialized hospitals.

Individuals were briefed on the aim of the study, as there was no budgeted fee to pay for their time/participation, their right to take part or not in the study at any time and verbal consent was obtained from each individual.

Finally, they asked to complete an anonymous survey and interview on variables of the study.

4.8 – Strengths and Limitations of the Study

In our study we used a combination of quantitative and qualitative methods, which helped us to cover wider concepts related to ARVs adherence in complementing one the other.

The use of a behavioral model construct as conceptual framework enabled us to address adherence influencing factors comprehensively during the study tool construction and also helped in data analysis as well as interpretation.

Additionally, getting the total response rate of 99% in this study were some of the reputable evidences that would be mentioned as its strengths. However, we feel that this study has several limitations that must be acknowledged such as: lack of a “gold standard” method for treatment adherence assessment, in this study adherence was measured using self-report, though many literatures reported the reliability of this method, there are also studies suggested that self-report tends to overestimate adherence; and also different concepts on definition of adherence to HAART.

Instead of giving as index of good adherence values above 80%, which is a threshold based on data from other chronic illnesses such as hypertension or diabetes. It was decided to define excellent adherence when $\geq 90\%$ of the pills prescribed in any regimen were taken in accordance with the prescribed regime. In agreement with the suggestions from recent HIV literature, and following the recommendations made by the International AIDS Society-USA Panel Guidelines, in which it is stated that ,less than excellent adherence may result in virus breakthrough and the emergence of drug-resistant strains.

The cross-sectional design of this study did not allow us to establish a causal relationship between significantly associated variables and treatment adherence, as both variables were measured at the same time.

Furthermore, using not critically sick participants of the study as inclusion criteria may reduce the chance of getting HAART non-adherent groups, because critically sick PLWHA could have a tendency to become non-adherent groups.

Finally, since, this study is an institutional based study in which institutions are tertiary referral centers with no defined catchment areas and open/ free access. It is likely that there is a selection process by which better-informed patients attend these hospitals and this may limit the generalizability of its findings.

V. RESULTS OF THE STUDY

5.1 The in-depth interview results

- Socio-demographic attributes of the participants

A total of 10 individual in-depth interviews [IDI] were carried out and the subjects, 4 men and 6 women ranging from 21 to 40 years of age, with an average age of 29.5 years were involved in the IDI- sessions of the study. Three single, four married and the rest were separated or widowed in marriage. All participants were actively engaged on activities of daily living and earn a monthly income that ranges from 200-1000 ETH. Birr, however, two of the participants were failed to know the exact amount of their monthly income. Their average time since ART treatment started was 11 months and they had an educational status that ranges from Grade 7 to Diploma (see below in table – 1).

Table 1 Socio-demographic attributes of the respondents participated in the in-depth interview at Adamma and Jimma specialized hospitals, 2006.

Respondents	Age	sex	Educational status	Marital status	Religion	Ethnicity	Income ETHB*	Work situation
R1	26	M	12+2	Married	Muslim	Amhara	800	working
R2	25	M	9	Single	Muslim	Oromo	200	working
R3	40	M	12	Married	Orthodox	Oromo	1200	working
R4	32	F	12	Widow	Muslim	Oromo	unknown	working
R5	20	F	7	Single	Muslim	Gurage	700	working
R6	26	F	12	Married	Protestant	Oromo	900	working
R7	31	F	10	Separated	Orthodox	Tigre	unknown	working
R8	30	F	12+2	Married	Orthodox	Oromo	1200	working
R9	36	F	12	Widow	Muslim	Amhara	>500	working
R10	21	M	11	Single	Protestant	Amhara	800	working

* Ethiopian birr

Major themes identified include: - A) Factors that modifies behavioral practice (socio-environmental factors, barriers and ARV drugs), B) Cognitive and Psychological factors. C) Quality of life.

A. Factors that modifies behavioral practice (socio-environmental factors, barriers and ARVs

The first question asked under this theme was to describe/ list some of the facts or instructions given to them at initiation of ART treatment. Except four participants the rest indicated that they had no proper and adequate instructions initially. One mother said that “I was confused and frustrated at the moment, let alone to remember the things they told us I do not know how I reacted and I was unstable for along time, for instance I do not know exactly for how long I should take the drugs, some say to be stopped after adequate weight gain etc.”The other male respondent indicated that the agreement of PLWHA to start the ARVs may not necessarily mean they have understood all the instructions shared during that time and emphasized the importance of timely as well as individualized care and support. The next respondent “a patient who is going to take drugs with disturbing side effects for a longer duration for a disease that is linked with cultural influences in the society should have timely or according to the patient condition and needs.” Female nurse and a male who have the same years of educational study responded on things that should be expected from the PLWHA before the initiation of the HAART “before the initiation of ARV drugs patient must know her/his sero-status and patient must know for how long, why, when and how they should take the prescribed pills, then patient will be committed to take the ARVs.

When they were asked about the requirements during therapy, all participants suggested that social support from a family, community, NGOs and others were important factor in assisting them to adhere to their drug regimen; and the patient also should avoid substances like chatt, alcohol and cigarette smoking.

Moreover, fifty percent of the respondents appreciated the adequacy as well as satisfaction from care and social support provided from governmental or NGO and community organizations. Seven of the ten respondents said they did not disclose their sero-status to their family members or to others who are close to them. They claimed fear of disturbing or losing the normal relationships they had with their families and within their communities as major reasons for not disclosing their sero-status. However, in contrast with past years in which there was widespread of discrimination and stigmatization against PLWHA, the participants reported much reduction in its magnitude. Except four participants, the remaining mentioned the obstacles/ difficulties that they had experienced in taking HAART. They identified side effects of ARV drugs and economical problems as having a significant effect on their lives.

Economical problems like for transportation whenever they need to consult on health problems in between and ARV drugs at date of appointments and to have appropriate diet that required for ARV treatment. Where as medication side effects such as head aches, GIT related health problems [vomiting, nausea, diarrhea, gastritis, loss of appetite], weakness and bad dreams /night mares were identified as having a significant impact on adherence.

Finally under this theme the questions raised were the length of time taken to reach to decision on initiation of ARVs and the factors which influenced their decision: nearly all respondents were initiated ART by their own decision after they had assistances from health professionals, but two respondents: male and female started ART by family decisions for their deteriorating health status, after six and four months since they knew the diagnosis respectively. Two widow mothers were started the ART also because of their deteriorating health status at the time they were admitted in a hospital for HIV/AIDS related health problems. The other four were started ARVs after two months because they worried about the life of their children for which no one was close to them. The other challenging factors to the participants were: the relationship that perceived to be lost in the family and with in the communities, their doubts about their self-efficacy to adhere to treatment, their doubts about ART efficacy and problem of acceptance they had when diagnosis was told.

B) Cognitive and Psychological factors

All except two mothers from both sites were heard about HIV/AIDS before they knew their sero-status. Majority of them were diagnosed with HIV, after they developed some HIV/ AIDS related problems or at the advanced stage of HIV progression. The knowledge they had doesn't imply them to under take VCT and then initiate ART early, it was for their deteriorating health status or because they had a health problem and then went to health personnel who suggested them to under take HIV test. After they had some time, almost all initiated antiretroviral therapy by their own decision, where as two were by family decisions.

One a 30 year female nurse working in NGO and three male participants were knew about ART, its benefits and its adherence; where as the remaining participants were lacking these facts before the diagnosis of HIV/AIDS. Six out of ten participants were confident enough to take ARVs in front of others and reported that they had no any unusual feelings in doing so. One third of the respondents was not sure on efficacy of ARV medications and were not sure even in their ability to adhere in future time.

The perceived reasons for their beliefs were described by one female” what we know and what we see of the PLWHA on ART are died in short duration since they started treatment, though at the beginning they had shown slight improvements such as weight gain and less frequency of diseases”.

The other woman indicated and it seemed to be deep rooted [it was claimed by all of them] “I heard and saw people who had significant improvements, even cured completely through use of holly-water; being /praying at holly places, I started ART because it is better from doing nothing and I wanted to try it with treatment first; otherwise, I have a plan to go there after some time”.

These participants who were not sure/ not confident enough to adhere in future claimed” one female respondent because of my plan mentioned above i.e. to use of holly water and go to “Gedamm”, Some of them said “it is very difficult to anticipate what is happening in future, because ART may not be free that makes difficult to continue the treatment for majority of us.”

Further they were asked on what they know about the benefits, eligibility and adherence of ART. The following are sample statements from the participants of both sites related to these questions indicating about its benefits by one male respondent “what we know that once you get HIV/AIDS; you die after one/ two years because of the virus in our body, however ART kills these viruses so that we can live longer”.

C. Quality of life

Though, four of the PLWHA participated in the study claimed to have no improvement; eight of the ten participants stated that they satisfied and achieved successful results since they initiated combination therapy; so that they viewed HAART as life enhancing and offered them a renewed quality of life.

These PLWHA who had no subjective improvement in quality of life: as one female respondent stated "generally, I do not feel well; I was admitted in the hospital four times because of chronic diarrhea, skin rash and repeated infection of GIT and lungs such as TB, Amoebiasis , Giardiasis ETC" since 6 months of ART was initiated.

The other male indicated "As I told you before I start ART my kilo was 58kg but after I began the treatment that had 3 month duration my kilo reduced to 49kg". The respondents who were satisfied from the responses described: a male respondent "I feel healthy, currently I have returned back to my previous work and I am working equally with these work mates who do not have the virus".

A female participant "before I start to take the drugs I was in bed for some five months and then people advised to go health center, I started the treatment 1 year back ;thus I began walking alone without any support, go to the toilet by myself, get out of bed, take medications my self".

Most of the respondents valued and emphasized the importance of people who are HIV positive admitting that they have the disease and accepting that ART would benefit them, so that they can move forward with their lives. They had positive outlooks on life and looked forward to make the best of their lives. One informant said about HIV and ART denial" denying HIV positive state and then failing to initiate ART is denying life."

The participants who experienced a positive response to treatment were also had good hope and positive self esteem to run activities of daily living in their future life. A woman who is also home based care provider talked about her experience as she visited those PLWHA who are not taking treatment in their homes "they are hopeless about life, they just give up and leave everything.

5.2 The cross-sectional survey results

I. Socio-demographic Characteristics

Four hundred and sixty one eligible respondents were selected for the study at Jimma specialized hospital and Adamma hospital. Among those subjects, 2 refused to participate and 459 participated in the study. A total of 265 [57.7%] females and 194 [42.3%] males were participated in this study. Of the respondents 300 [65.4%] were in the age range of 26-35 years, 94 [20.4%] in the range of 18-25 years, while the rest 65 [14.2%] were ≥ 36 years old. The mean [\pm SD] age of the study subjects was 33.24 [\pm 9.65] years with a median age of 31 years. From the respondents, 170 [37.0%] of the participants were married; and 202 [44.0%], 133[29%], 58[12.6%], 37[8.1%] and 29[6.3%] of them were Oromo, Amhara, Gurage, Gedeo and Tigre by ethnicity respectively. As to the religion of respondents, 265 [57.7%], 91[19.8%], 91[19.8%], 12[2.6%] were orthodox Protestant, Muslim and Catholic Christians respectively. The majority of the participants, 347 [75.6%] had 12 or less years of schooling.

Almost half of the sample, 230 [50.1%] had monthly income of ≤ 500.00 (ETB), 68[14.8%] of the participants reported that they had varied amount of monthly income depending on situations and the rest 52 [11.3%] of them confirmed that they do not have adequate information on the amount of their monthly income. As shown below in Table - 2, only 28 [6.1%] of the participants claimed to have no occupation currently where as the rest respondents reported that they have at least something to engage on in daily bases.

Table 2 Basic socio-demographic attributes of the cross-sectional survey at Jimma specialized and Adamma hospitals, 2006.

Variables	No	%
Educational Status of the Respondents		
Illiterate	61	13.3
Grade 1-6	50	10.9
Grade 7-12	297	64.7
Diploma and above	51	11.1
Marital Status of the Respondents		
Not married	148	32.2
Married	170	37.0
Divorced	58	12.6
Widowed	72	15.7
Separated(not confirmed legally)	11	2.4
Occupational Status of the Respondent		
Government employee	98	21.4
Employee of private institutions	103	22.4
House wife	59	12.8
Merchant	53	11.5
Farmer	37	8.1
Driver	31	6.8
Student	28	6.1
No occupation	28	6.1
Others*	22	4.8
Monthly income[ETH. birr]		
≤ 200	141	30.7
201-500	89	19.4
≥501	109	23.8
varied amount♣	68	14.8
do not know ¥	52	11.3

*--- Represents respondents who were Volunteers for providing home based care & support and females who were bar ladies.

♣__ Represents respondents who had no consistent monthly income

¥__ Represents respondents who didn't know the exact amount of monthly income of the family

II. Modifying factors

- **Socio-environmental factors**

A total of 150[32.7%] participants were living alone and 309[67.2%] were living with other people close to them. Nearly thirty five percent of the sample had social support and were satisfied with it, where as the rest were claimed to have inadequate social support and care.

A total of 260 [56.6%] respondents had at least one child and 199 [43.4%] of them had no child under their care. When asked about the serostatus of their last child, 68[26.2%] were seropositive, 84 [32.3%] were seronegative, and 108 [41.5%] were not known their serostatus.

The majority of the study subjects, 393[85.6%] had disclosed their HIV status and 66 [14.4%] were not disclosed to any one. The perceived reasons for these who don't want to disclose their serostatus include for 32 [48.5%] subjects was stigma & discrimination, for 24 [36.4%] was fear of family/parenthood relationships and for the other 10[15.1%] PLWHA was their state of healthy condition doesn't urged them to disclose.

Of the total sample, 169 [36.8%] were assured the adequacy and satisfaction with the respect or the Value they had from others, but 290 [63.2%] of the respondents were unsatisfied and claimed to have no respect from the other social groups in the community.

Though, 21 [4.6%] of the participants claimed to have no trust and had some doubts on competence/ capability of service providers, the rest, 438[95.4%] participants were assured their beliefs and trust on capability of service providers. From the total participants 443 [96.5%] reported that they satisfied by their ART unit appointment and confidentiality

A total of 430 [93.7%] participants had regular follow up: every month, 2 months or 3 months, where as only 29 [6.3%] of them had irregular visiting schedules to the ART unit. Of the total study subjects, 446[97.2%] reported that they had an excellent relationship with health care professionals and 437[95.4%] felt they had good open discussion with their care providers. A total, 435 [94.8%] of participants assured their access for professional assistance from the care providers and health units and 417[90.8%] of participants faced no problems to obtain an access of reliable pharmacies at any time.

Table 3 *Socio-environmental factors of the cross-sectional survey at Jimma specialized and Adamma hospitals, 2006.*

<i>Variables</i>	<i>N_o</i>	<i>%</i>
Social support and satisfaction		
Yes ,satisfied	158	34.4
No ,not satisfied	301	65.6
Value/respect from others		
Yes, satisfied	169	36.8
No, not satisfied	290	63.2
Access to reliable pharmacy		
Yes	417	90.8
No	42	9.2
Adequacy & satisfaction on the relationship with HCP		
Yes, satisfied	446	97.2
No, not satisfied	13	2.8
Adequacy & satisfaction on open communication with HCP		
Yes, satisfied	437	95.4
No, not satisfied	22	4.6
Adequacy & satisfaction on education and assistance		
Yes, satisfied	435	94.8
No, not satisfied	24	5.2
Satisfaction in scheduling appointments & confidentiality		
Yes, satisfied	443	96.5
No, not satisfied	16	3.5
Frequency of follow up /appointment time		
Every one month	134	29.2
Every two months	76	16.6
Every three months	220	47.9
Variable♣	29	6.3

♣ Respondents who had irregular visiting/ follow-up schedules to the ART unit, because of any personal problems.

- **Factors related to Personal life style**

At the time of interview, from August 1-30, 2006; a total of 132[28.8%] respondents were taking additional medicines with their ARVs and the rest 327 [71.2%] respondents were not using additional drugs.

A total of 323 (70.4%) respondents had no history of active substance use, and 136 [29.6%] of them were using active substances; of them 79 [58.1%] were chewing chatt, 27 [19.9%] were smoking cigarettes and 30 [22.0%] were used to drink alcoholic beverages at least on two days of the week while they were on HAART.

- **Health status and clinical results**

The proportion of participants who had depressed feelings during the past one month was 228[49.7 %] and those who had no feelings of depression were 231[50.3%].

Those subjects who had their CD4 count measured, the initial and most recent median CD4 counts were 127 (ranging 2 to 565) and 305 (ranging 1 to 990) /mm³ respectively. Of the total participants 400 [87.1%] subjects had CD4 count \leq 200 and 59[12.9%] were had CD4 count \geq 201 at the start of ART, where as with regarded to most recently measured CD4 count: a total of participants, 241(52.5%) had CD4 count \leq 200 and the rest 218 (47.5%) of them had CD4 count \geq 201.

- **ARV medication related factors**

Of the total participants 181 (39.4%) had no side effects of ARVs and the rest, 278 [60.6%] respondents had an adverse reaction to one or more of the ARVs; and almost for all of them it was developed in the first three weeks of enrollment to ARV treatments. Though, there was a problem to get full data; through the information available in patients' records and recall, of the numerous adverse events identified skin rash and other skin problems accounted for 47 [16.9%], GI problems [Nausea, vomiting and diarrhea] for 133 [47.8%], Tingling, headache, weakness and night mares/ bad dreams for 50 [18.0%], anemia/excessive menses for 22 [7.9%] and the combination of these mentioned side effects accounted for 26[9.4%]. Of these who had an adverse reaction, 208 [74.8%] subjects consulted their doctors immediately without interruption of the regimen, while 70 [25.2%] patients were stopped taking ARV drugs when they had the problem. The duration of HAART, for 296[64.5%], 112 [24.4%] and 51 [11.1%] of the participants was \leq 11 months, 1-2 years and \geq 3 years respectively.

III. Motivating factors

- **Factors related to Cognition / Knowledge about ARV drugs.**

The level of knowledge about the benefits, eligibility and adherence of ART [who have answered all questions correctly], knowledge about the benefits of ARVs were satisfactory for 390 (84.9%) and unsatisfactory for 69 (15.1%), knowledge about eligibility for HAART were satisfactory for 356 (77.6%) and unsatisfactory for 103 (22.4%), and knowledge about adherence of HAART were satisfactory for 431 [93.9 %] and unsatisfactory for 28 (6.1%) participants.

The source of information about HAART for 212[46.2%] was the health care professionals, 160[34.9%] participants mentioned mass media, whereas, 53[11.5%] and the rest 34 [7.4%] were heard from AIDS clubs and other sources [friends, family] respectively (see figure – 2 below). Before the diagnosis of HIV/AIDS, a total of 258 (56.2%) participants know about HIV/AIDS, where as, 201 (43.8%) of them don't know about HIV/AIDS; and also before the diagnosis of HIV/AIDS the level of knowledge about HAART were found to be, 205 [44.7%] of the participants had never heard, where as 254 [55.3%] of the subjects had some awareness.

SOURCES OF INFORMATION ABOUT HAART

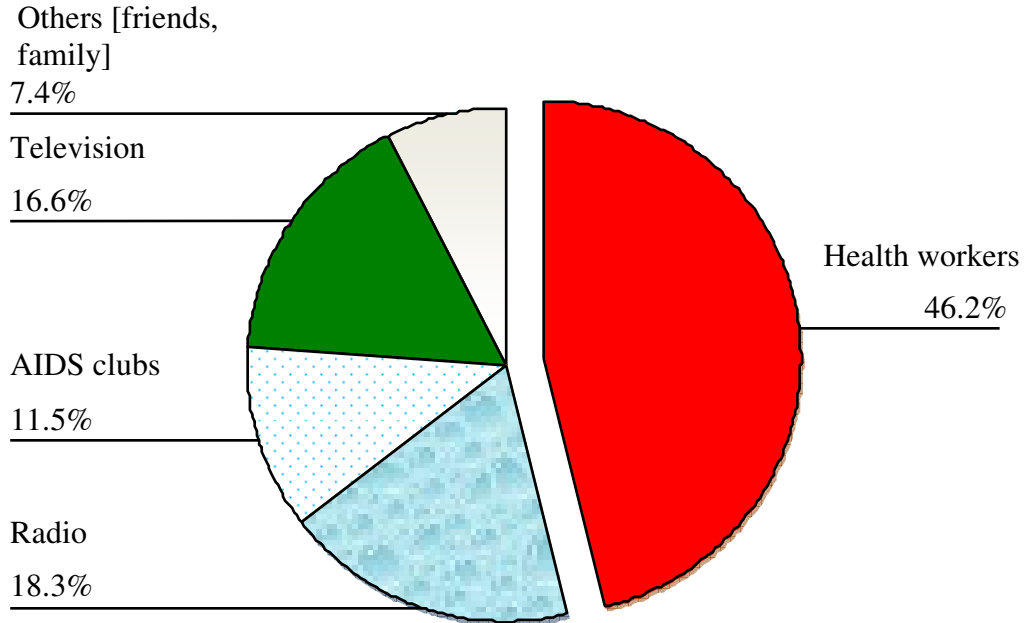


Figure 2 Distribution of participants on sources of information about HAART

- **Psychological factors**

The level of beliefs about therapy was unsatisfactory for 176 [38.3%] individuals that had some doubts about ARV drugs, where as 283 [61.7%] of the subjects believed that the ART would benefit them and self efficacy to adhere treatment even if obstacles such as ARVs treatment schedule dose not fit with routine activities was asked, 318 [69.30%] of them were confident enough to adhere, whereas 141[30.70%] respondents were not sure to adhere.

The participants were asked about their perception on severity and susceptibility for threats of non-adherence in case of missing the daily ARVs regimen for some reasons, 417 [90.8%] participants had high perception on its threats and 441 [96.1%] of them also perceived their high risk status for its threats. More than one third, 162[35.3%] of the participants were not sure in their ability [self-efficacy] to take ARVs in front of strangers or with presence of other people, where as, 297[64.7%] of them had no unusual feelings. Further they were asked about their future intention [ability] to adhere, 384 [83.7%] subjects had no doubts and were sure on their ability to adhere ART.

Only 28 [6.1%] of the subjects claimed to have no perceived improvement, otherwise the remaining, 431[93.9%] participants claimed to have perceived improvement, and also, 416[90.6%] participants satisfied, but 43[9.4%] were unsatisfied by the benefit they obtained from the ART medications. Of these subjects who were reported perceived changes and improvements, 294 [68.2%] of them had improvements in total quality of life & morbidity, 69[16.0%] were obtained an improvement in frequency of hospital admission & HIV/AIDS related morbidity [fever, diarrhea] and 68 [15.8%] of them had weight gain. Of the total subjects, for 358 [78.0%] participants the regimen was convenient and easy to fit but for 101 [22.0%] of them it was inconvenient and difficult to fit with their daily routine, and 186[%40.5%] of the respondents were not believed/convinced that as they had HIV in their blood stream to take ARVs.

Table 4 Psychological factors of the cross-sectional survey at Jimma specialized and Adamma hospitals, 2006.

<i>Variables</i>	<i>N_o</i>	<i>%</i>
Beliefs on the efficacy of HAART.		
Yes	283	61.7
No, have doubt	176	38.3
Perceived severity to non adherence		
High	417	90.8
Low	42	9.2
Perceived susceptibility to non adherence		
High	441	96.1
Low	18	3.9
Self efficacy to adhere ARVs in future		
Yes , I am sure	384	83.7
No , I am not sure	75	16.3
Believed/convincd that he/she being infected with HIV and needs ART		
YES	273	59.5
NO , I have not convinced	186	40.5

IV. Patient report on Adherence to HAART

- **HAART adherence practice**

The assessment of adherence to HAART in HIV positive patients during the past one month, the past three days and since the enrollment to ARVs therapy was measured using self report method. As shown in Table 6, according to cued recall for the previous three days, 78[17.0%] of the participants reportedly taken <95% of their antiretroviral medications[non-adhered], where as, 381 [83.0%] of them taken ≥95% of their prescribed ARV drugs[adhered] of the past three days duration. The average [±SD] number of doses missed in the past three days and one month duration was found to be 1.17[±0.37] and 1.24[±0.43] respectively. Almost all participants were on twice daily regimen, and also 409 [89.1%] of the sample were taking in absence of compulsory fasting where as, 50 [10.9%] were taking at least one daily dose in a compulsory fasting state. Of the total participants, 380 [82.8%] were reported that they used to memory aids, where as the rest were not using at all in order to remember their treatment schedules.

Table 5 HAART adherence Status by self-report of the cross-sectional survey at Jimma specialized and Adamma hospitals, 2006.

<i>Variables</i>	<i>N_o</i>	<i>%</i>
ART adherence during the past three days		
Adherents [took ≥95% of prescribed doses]	381	83.0
Non-adherents [took <95% of prescribed doses]	78	17.0
ART adherence during the past one month		
Adherents [took ≥95% of prescribed doses]	347	75.6
Non-adherents [took <95% of prescribed doses]	112	24.4
Ever skipped of the prescribed ARV regimens since your start of ARVs.		
Yes	157	34.2
No	302	65.8
Respondents taking ARVs with any restrictions?		
With food	409	89.1
With out food	50	10.9
Methods of memory aid		
Pill boxes	23	5.0
Written schedules	22	4.8
Watch bell	335	73.0
Do not have	79	17.2

A total of 302 [65.8%] participants were never missed a single dose of the ARV regimen & 157[34.2%] of them reportedly missed at least one dose of ARV regimen since their enrolment. The patients were also asked open ended and structured questions to mention reasons or barriers for skipped doses of the ARV drugs, as shown below in figure-3: the patients report on perceived reasons of missed regimens accounted for 34[21.7%] of them being too busy with other things or simply forgotten, for 28 [17.8%] of them being away from home for some social reasons, for 24 [15.3%] of them having problems in taking ARV medications at specific times because of change in daily routine, felt sleepy and presence of other people, for 45 [28.7%] individuals being too sick/weak at that time and for 26 [16.6%] participants also shortage of ARV medications at hand because of some public holidays or weekends that coincide with date of appointments were described as the primary barriers to treatment adherence.

REASONS OF SKIPPED ARV REGIMENS

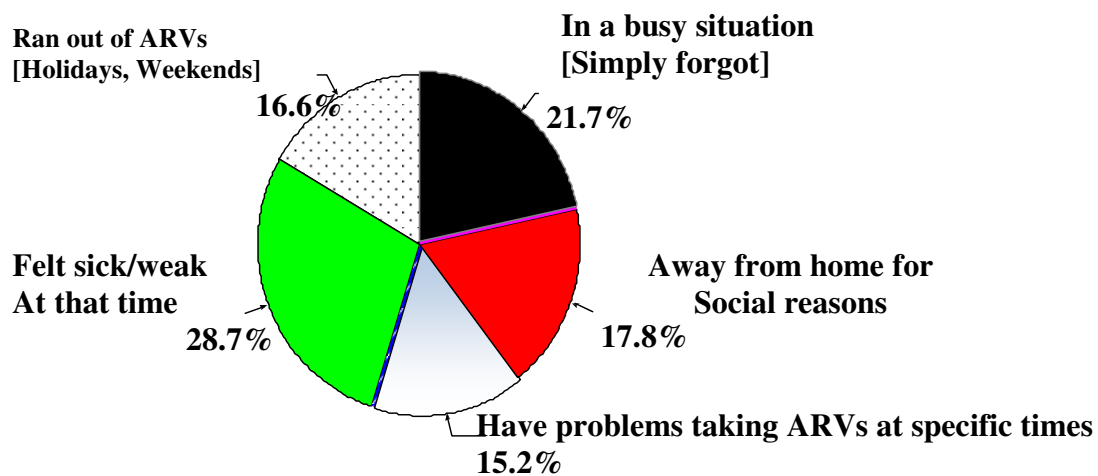


Figure 3 Distributions of the Participants on Reasons for Missed Doses

Though, the respondents were not able to recall the name of their coded ARVs regimens; through the information available in patients' records, all PLWHA were on first line ARVs regimen, 142[30.9%], 104[22.7%] and 89[19.4%] of the participants were taking 1a [30], 1a [40] and 1b [30] respectively [see figure-4].

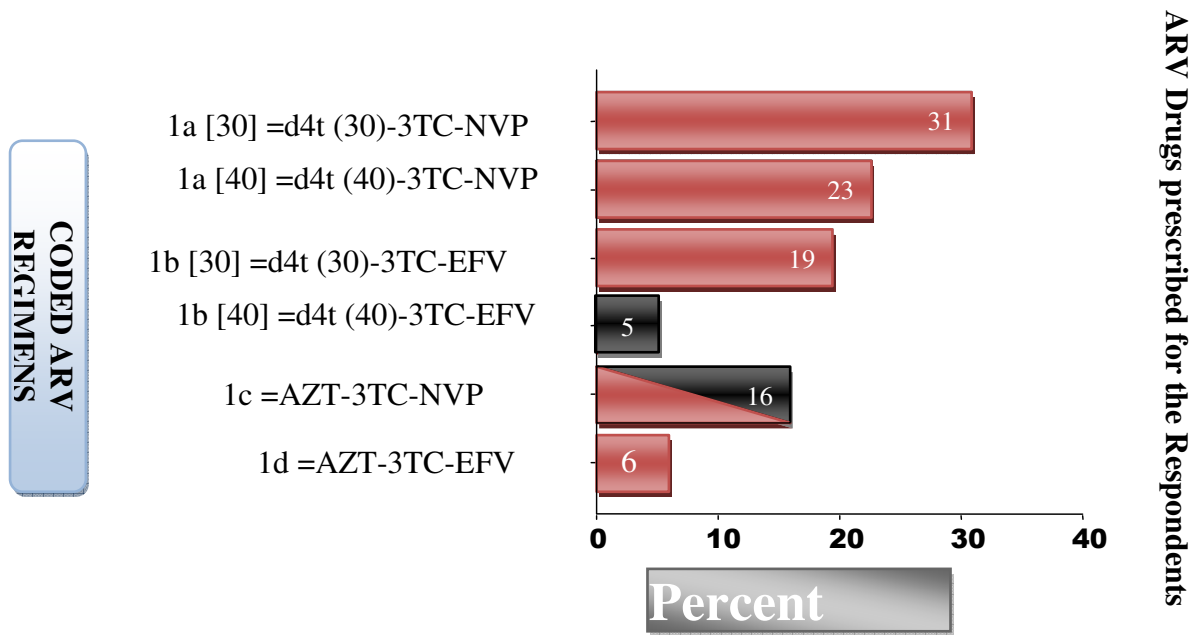


Figure 4 Distribution of coded ARVs prescribed for the participants

V. Factors Related to Treatment Adherence

As shown in the conceptual model of this study, many factors are influencing human health behaviors and made them more difficult to figure out and often beyond comprehension. Thus in addressing this multidimensionality; there would be too many variables for analysis which may result in multicollinearity among the predictors, so that this can lead to biased estimates and inflated standard errors.

Discriminant analysis method was used to filter the data for multicollinearity and build a predictive model of group membership based on the observed characteristics of each case.

As a criterion, Wilks' Lambda [F] statistics generated in the procedure was used to discriminate group memberships and to filter the variables for multi-co-linearity through selecting one variable from a group of variables that were correlated each other or had the same effect on HAART adherence. Therefore, after several steps of this procedure to discriminate a group membership between groups, it enabled to build a best predictive model of a group membership for 16 from a total of 40 cases in this study [see for the detail in annex - 4.1].

Thus, significance levels of predictor variables were determined using univariate and multivariate logistic regression models. The participants who were adherent [reportedly taken $\geq 95\%$ of the prescribed doses of ARVs] and non – adherent [reportedly taken $< 95\%$ of the prescribed doses of ARVs] in the previous three days of interview were compared on key socio-demographic, psychological, socio - environmental and health service related factors.

In the univariate logistic regression analysis, though, poor HAART adherence practice was common among respondents who were not married [OR = 0.620, CI = 0.457, 0.840, P = 0.002]; satisfactory adherence was commoner among participants who had a perception of non – adherence threats, [OR = 13.829, CI = 3.130, 61.095, p = 0.001], had an intention to adhere in future [OR = 7.462, CI = 3.533, 15.763, P = 0.000], had an access to pharmacy service at any time [OR = 9.904, CI = 3.981, 24.638, P = 0.000], had no history of Active Substance use [OR = 0.368, CI = 0.183, 0.742, P = 0.005], had no doubt on the efficacy of ARVs [OR = 0.372, CI = 0.201, 0.687, P = 0.002], had no adverse effects of ARVs [OR = 0.406, CI = 0.198, 0.834, P = 0.014], had no child under their responsibility [OR = 0.301, CI = 0.148, 0.609, P = 0.001], had no depressed feelings in the last one month [OR = 4.46, CI = 2.26, 9.83, P = 0.001], were not using other drugs along with ARVs [OR = 3.405, CI = 1.522, 7.617, P = 0.003], had a source of information about HAART from groups other than health personnel [OR = 0.467, CI = 0.279, 0.782, P = 0.004] and participants who were self efficient to take ARVs with the presence of others [OR = 2.108, CI = 1.026, 4.333, P = 0.042].

However, four of the characteristics, such as duration of HAART, a belief on presence of HIV in blood stream, utilization of methods as memory aid and belief on competency of health care providers were found to have no any significant relationship with HAART adherence in the univariate logistic model.

Independent predictors were also assessed using a sequence of two multivariate logistic regression models and the variables that had significant effect on adherence ($p < 0.05$), either in the crude or adjusted model were selected for inclusion in subsequent models.

Initially, a first adjusted multivariate model was set up with adjustments for variables, which were identified to have significant association with HAART adherence in the univariate regression model. At this level, after adjustments for initial multivariate analysis model, a total of 10 variables that were associated in the univariate model were also remained significantly associated, where as unlike to the results of the univariate model, however, 2 characteristics, include: source of information about ARVs initially and unusual feelings while taking ARVs in presence of others were failed to show any association with HAART adherence in the initial adjusted model.

Next, a second [a final] adjusted multivariate model was constructed by taking these variables that had a significant relationship with treatment adherence in the initial adjusted model ($p < 0.05$) into account. In final adjusted model the following 9 characteristics of the participants, which were associated in the initial adjusted multivariate model were also found to be a strong independent predictors of treatment adherence in this study.

As shown below in table – 7, in the final adjusted multivariate model, independent positive predictors of HAART adherence were the participants who had:- A perception about personal susceptibility to non-adherence threats [OR = 17.388, CI = 4.026, 75.096, $p = 0.000$], ability to adhere in future [OR = 7.212, CI = 3.465, 15.012, $p = 0.000$.], and an access to reliable pharmacy any time [OR = 7.908, CI = 3.296, 18.971, $p = 0.000$]; had no history of active substance use [OR = 0.387, CI = 0.195, 0.768, $p = 0.007$], positive beliefs on the efficacy of HAART [OR = 0.449, CI = 0.243, 0.829, $p = 0.011$], no ARVs side effects [OR = 0.455, CI = 0.224, 0.922, $p = 0.029$], had no depressed feelings in the last one month [OR = 2.16, CI = 1.32, 6.58, $P = 0.001$], were not using other drugs along with ARVs [OR = 2.478, CI = 1.121, 5.475, $p = 0.025$] and had no child under their responsibility [OR = 0.437, CI = 0.218, 0.874, $p = 0.019$]. Unlike the initial adjusted multivariate model, marital status of the respondents was not associated in the final adjusted multivariate model.

Table 6 Results of the multivariate analysis: Variables associated with adherence to HAART in the final Adjusted model with their ORs of the cross-sectional survey at Jimma specialized and Adamma hospitals, 2006

Variables	HAART adherence		Adjusted ORs & 95% CI for Exp(B)
	YES	NO	
Ever thought about your susceptibility to non-adherence threats?	379	65	17.388, [4.026, 75.096], p = 0.000
Yes			1
No	3	12	
Are you confident enough in the ability to adhere in future	337	47	7.212, [3.465, 15.012], p = 0.000.
Yes, I am sure			1
No, I am not sure	45	30	
Has history of Active Substance use?			
Yes	76	30	- 0.387, [0.195, 0.768], p = 0.007.
No	306	47	1
Do you have access to reliable pharmacy any time you want?	361	59	7.908, [3.296, 18.971], p = 0.000
Yes			1
No	21	18	
Has adverse effects of ARVs			
Yes	217	59	- 0.455, [0.224, 0.922], p = 0.029
No	165	18	1
Depressed feelings in the last one month [n = 308]			
Yes	110	32	- 2.16 [1.32, 6.58] P = 0.001
No	144	22	1
Any doubt on efficacy of ART			
YES , I have doubt	129	42	- 0.449, [0.243, 0.829], p = 0.011.
NO	253	35	1
Do not take any other drugs			
Yes	110	23	2.478, [1.121, 5.475], p = 0.025.
No	272	54	1
Do you have a child under your responsibility			
Yes	214	46	- 0.437, [0.218, 0.874], p = 0.019
No	168	31	1

VI. DISCUSSION

This study found an overall prevalence of HAART adherence by self report, 381[83.0%] of the sample taken $\geq 95\%$ of their prescribed ARV doses in the past three days duration from the day before interview.

The HAART adherence rate in this study found to be higher than the findings of other studies conducted in most developed countries in which they documented the HAART adherence rates that ranges from 40% to 70% (35, 40, 41); although, some of them used different criteria to define good adherence and adherence assessment methods [42-47].; but comparable HAART adherence rate was reported by, Yonas T. (26) in a recent cross sectional studies of ARV adherence among PLWHA reported that 81.2% of patients were adherent with taking $> 95\%$ prescribed doses in three hospitals of Addis Ababa,; and also the average adherence rate of 82.8% was reported by Ayallew M. (27) among PLWHA, in the ministry of national defense force hospitals of Addis Ababa and Debreziet.

Furthermore, all subjects participated in this study were on twice daily ARV regimens that can substantiate the high adherence rate found in this study; similarly the findings of some studies even at developed countries indicated that the association between increasing regimen complexity and the decreased adherence is well established in a variety of chronic disease conditions, including HIV infection. These findings were independent of race/ethnicity and education (41, 42, 44, and 46). In another study, 80% or greater adherence was associated with twice-daily or less frequent dosing (40).

Further supported by Eisen and colleagues (32), showed that the improvement of adherence from 59% to 83.6%, when dosing was reduced from 3 times a day to once daily. A study by Eron and colleagues (33), found that there was no difference in ART adherence rates in patients who received either once-daily (90%) or twice-daily (87%) for 48 weeks.

In addition to these facts, the data from other African settings indicated that patients of low socioeconomic status are able to achieve excellent rates of adherence with access to routine medical care, subsidized ARV therapy, and free laboratory monitoring. In a cohort study of ARV adherence among semi urban South African living in extreme poverty, Byakika-Tusiime & Orrell et al (47-49), found that lower socio economic status was not a predictor of adherence for patients with fully subsidized therapy. In fact, adherence levels were similar to or better than those found in industrialized countries. Similarly, high levels of adherence (78%) were reported by Laurent et al. in a resource-poor setting in Senegal and by Byakika-Tusiime & Orrell et al (66%) in 3 treatment centers in Kampala, Uganda (47-49).

In this study, HAART adherence was assessed through patient's self-report method. Although, self-reporting method considered overestimating medication adherence rate (43), some authors suggested that self-report has the potential to be one of the most accurate measures of behavioral adherence, because only the patient that can report actual behavior (43), and this method has frequently been employed in antiretroviral research (40), due to its practicality, low cost, readiness to obtain the desired information, and to identify patients at risk for non-adherence (6).

In the current study, variety of barriers to treatment adherence were reported from the respondents; of the total participants for 34[21.7%] of them being too busy with other things or simply forgotten, for 28 [17.8%] of them being away from home for some social reasons, for 24 [15.3%] of them having problems in taking ARV medications at specific times because of change in daily routine, felt sleepy and presence of other people, for 45 [28.7%] being too sick/weak at that time and for 26 [16.6%] participants also running out of ARV medications on week ends and holidays were factors claimed to have a significant impact on their HAART adherence. In line with these findings, subjects participated in in-depth interview of this study also reported the same reasons for their interruption of the ARV regimens. Similarly, many other authors reported that the existence of significant relationships between several factors, non-adherence to combination therapy can result from forgetting, lack of motivation, and intolerance of side effects (6, 26, 27, 40 – 43).

Consistently, among persons studied in one AIDS clinical trial, missed doses of antiretroviral agents were most likely to occur because of sleeping through a dose (36%), being away from home (32%), changing one's routine (27%), forgetting (43%), being too busy to take the dose (22%) and feeling sick (11%) (6, 40-43).

In the final adjusted multivariate analysis of this study, a better adherence to HAART was observed among the respondents, who had — no a child under their responsibility, no history of using active substances, no feelings of depression in the last one month, no adverse side-effects of ARV drugs and who were not taking other drugs along ARVs.

In agreement with these findings, Some studies also suggest that adherence to HAART tends to increase with participants who: free of depression (19, 20, 24), free of adverse effects (27,28), free of a stressful situations (17, 20), free of substance abuse (16, 17, 19, 25). Substance abuse also raises concerns about antiretroviral treatment owing to the cognitive and behavioral disturbances common in substance-abusing populations. Some researchers suggested that substance-abusing patients have a host of problems, including resistance to comply with instructions, potential drug interactions, and conditions of living in poverty, that present considerable challenges to medical management of HIV infection.(12, [13](#)).

Further more, according to the results of this study, characteristics of the participants such as positive self efficacy/ strong intention to adherence to combination therapy in future, beliefs on efficacy of HAART and free access to pharmacy service at any time were also independent predictors of HAART adherence in the final adjusted multivariate analysis.

The findings of the in-depth interview of this study also confirmed that the PLWHA who are on ART had positive outlooks on life and looked forward to make the best of their lives. One informant even stated about denial of HIV and ART as “denying HIV positive state and then failing to initiate ART is denying life.” The participants who experienced a positive response to treatment were also had good hope and positive self esteem to run activities of daily living in their future life.

Consistently, several research papers reported that factors as positive predictors- patient beliefs in efficacy of HAART and satisfaction with quality of care (9, 10). Some studies have investigated patient attitudes towards antiretroviral treatment. Self-efficacy expectations (29) of antiretroviral therapy may be a promising aspect of patient attitude towards treatment. Self-efficacy expectation was the variable most strongly associated with adherence in this study; this association was also reported in other studies (6, 38, and 40). Thus this makes theoretical sense that Bandore’s (40) social-learning theory hypothesis states self efficacy expectation is a more central determinant of adherence to health behaviors than outcome expectation. People act on their beliefs about what they can do as well as their beliefs about the likely effects of various actions. The potential motivating effects of the outcome expectations of a particular health behavior is partly governed by beliefs in personal capabilities.

However, the characteristics, such as duration of HAART, beliefs on presence/ acceptance of HIV- serostatus, utilization of methods as memory aid and belief on competency of health care providers in the univariate logistic model; source of information about ARVs initially and perception of unusual feelings while taking ARVs in presence of others in the first adjusted model; and marital status of the respondents in the final adjusted model were not shown any significant relationship with HAART adherence in this study; inconsistently with results of other studies. It may be the areas of the study that are tertiary referral health facilities located in towns, it is likely that there is a selection process by which better-informed patients attend these hospitals.

VII. CONCLUSIONS AND RECOMMENDATIONS

The objectives of this study were to assess magnitude of HAART adherence and identify its associated factors among PLWHA receiving HAART. This knowledge should provide an opportunity for the design of new strategies to improve adherence to HAART.

In the current study, more than four in twenty five PLWHA on HAART were non-adherent to their treatment regimen in the previous 3 days and they reported variety of factors such as being too busy with other things/simply forgotten, being away from home for some reasons, having problems in taking ARV medications at specific times, being too sick/weak at the time, their working conditions and shortage of ARVs to have significant influence on their treatment adherence.

We have also identified a number of independent predictors of treatment adherence to the ARV medications during the past three days at $p < 0.05$. In the final adjusted multivariate analysis of this study, a better adherence to HAART was observed among the respondents, who had — no a child under their responsibility, no history of using active substances, no feelings of depression in the last one month, no adverse side-effects of ARV drugs and who were not taking other drugs along ARVs. Additionally, characteristics of the participants such as positive self efficacy/ strong intention to adherence to combination therapy in future, beliefs on efficacy of HAART and free access to pharmacy service at any time were also independent predictors of HAART adherence in the final adjusted multivariate analysis.

However, the characteristics, such as duration of HAART, beliefs on presence/ acceptance of HIV- serostatus, utilization of methods as memory aid and belief on competency of health care providers in the univariate logistic model; source of information about ARVs initially and perception of unusual feelings while taking ARVs in presence of others in the first adjusted model; and marital status of the respondents in the final adjusted model were not shown any significant relationship with HAART adherence in this study; inconsistently with results of other studies. Since the study settings are tertiary referral hospitals with open/free access and no defined catchment area, which may affect the selection process to include better-informed PLWHA attending these hospitals that may affect the information collected on these variables.

However, this was suggested in many literatures that the improvement in the quality of patient's life and motivation for adhering to treatment is influenced by the behaviors of both patient and clinician, (26). If the objective of antiretroviral therapy is to prolong life, prevent disease progression and improve the quality of life, it is critical that patients are provided with as much education and support as possible, given the need for maximal long term adherence to currently available treatments.

Many of the strategies for improving adherence to antiretroviral drugs seek to improve patients' motivation, which can only be achieved by listening to the whole patient. So that, the implementation of these strategies in the real world requires multidisciplinary efforts and counseling by trained professionals may be necessary to provide guidance and be able to offer some assistance, treat depression, and ultimately improve adherence.

A cross-sectional design, in this study did not allowed us to establish a causal relationship between significantly associated variables and treatment adherence, as both variables were measured at the same time.

Therefore the awareness of factors that are negatively influencing adherence to treatment, among health professionals caring for HIV-positive patients needs to be increased in order to intervene appropriately. The task is daunting: treating a stigmatizing illness with a lifetime regimen, often of considerable complexity, and with medications likely to be accompanied by unpleasant side-effects that strongly influence HAART adherence practice. So that Patient resources to cope successfully with high-risk situations be identified, and those with low levels of self-efficacy may be supported by interventions in situations in which their ability to adhere is weak.

In any case, based on the results of this study it would be important to recommend that:

- ❖ To under take longitudinal & experimental studies in different settings, with Variety of assessment methods are needed to characterize & provide stronger evidence on HAART adherence and its determinants.
- ❖ Counseling by trained professionals & integration of medical, substance use, and mental health treatment.
- ❖ Improve patients' motivation, which can only be achieved by listening to the whole patient (other issues that affect the patient, affect adherence)
- ❖ Availability and continuity of providers over time.
- ❖ Use of a multidisciplinary team approach/peer support.
- ❖ Assess Readiness and determine the patient's goals.
- ❖ Proceed slowly and informatively in teaching.
- ❖ Get feedback, including the patient's beliefs and perceived barriers.
- ❖ A practice run without drugs & assess each patient as a unique individual.
- ❖ Help patients to develop an approach when adverse life events threaten to disrupt adherence.

VII. REFERENCES

- WHO. 3 million HIV/AIDS sufferers could receive ART by 2005, WHO press release 58, Geneva, 2002.
- MOH, Disease prevention and control department, AIDS in Ethiopia, 5th Edition, Addis Ababa, MOH, 2004
- The Federal Democratic Republic of Ethiopia. Policy on anti-retroviral drugs, supply and use. Addis Ababa, Ethiopia, July 2002.
- Antiretroviral therapy program for HIV- infected patients in Ethiopia. Protocol prepared by Ethiopian Health and Nutrition research institute, Black Lion Hospital, Police Hospital, and Armed Force General Hospital, 2002.
- The Federal Democratic Republic of Ethiopia. MOH press release on anti-retroviral drugs, supply and use. Addis Ababa, Ethiopia, September 2006
- Eric S. et al. Improving Adherence to Antiretroviral Therapy. Cliggott Publishing, Division. AIDS Read 13(2):81-90, 2003.
- Monforte A.A., Testa L., Adorni F., et al. Clinical outcome and predictive factors of failure of highly active antiretroviral therapy in antiretroviral-experienced patients in advanced stages of HIV-1 infection. AIDS 1998; 12:1631-7.
- Paterson D.L., Swindells S., Mohr J., et al. Adherence to protease inhibitor therapy and outcomes in patients with HIV infection. Ann Intern Med 2000; 133:21-30.
- Gifford AL, Bormann JB, Shively MJ, Wright BC, Richman DD & Bozzette SA (2000). Predictors of self-reported adherence and plasma HIV concentrations in patients on multidrug antiretroviral regimens. *Journal of Acquired Immune Deficiency Syndromes*, 23: 386-395.
- Zolopa AR, Shafer RW, Warford A, Montoya JG, Hsu P, Katzenstein D, Merigan TC & Efron B (1999). HIV-1 genotypic resistance patterns predict response to saquinavir-ritonavir therapy in patients in whom previous protease inhibitor therapy had failed. *Annals of Internal Medicine*, 131:813-821.
- Wainberg MA & Friedland G (1998). Public health implications of antiretroviral therapy and HIV drug resistance. *Journal of the American Medical Association*, 279: 1977-1983.
- Morse EV, Simon PM, Coburn M, Hyslop N, Greenspan D & Balson PM (1991). Determinants of subject compliance within an experimental anti-HIV drug protocol. *Social Science and Medicine*, 32: 1161-1167.
- Eldred LJ, Wu AW, Chaisson RE & Moore RD (1998). Adherence to antiretroviral and *Pneumocystis* prophylaxis in HIV disease. *Journal of Acquired Immune Deficiency Syndrome*, 18: 117-125.
- Mothashari F, Riley E, Selwyn PA & Altice F (1998). Acceptance and adherence with antiretroviral therapy among HIV-infected women in correctional facility. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*, 18: 341-348.

- Haubrich RH, Little SJ, Currier JS, Forthal DN, Kemper CA, Beall GN, Johnson D, Dube MP, Hwang JY & McCutchan JA (1999). The value of patient-reported adherence to antiretroviral therapy in predicting virologic and immunologic response. *AIDS*, 13: 1099-1107.
- Chesney MA, Ickovics JR, Chambers DB, Gifford AL, Neidig J, Zwickl B & Wu AW (2000). Self-reported adherence to antiretroviral medication among participants in HIV clinical trials; the AACTG Adherence Instruments. *AIDS Care*, 12: 255-266.
- Kastrissios H, Suarez JR, Katzenstein D, Girard P, Sheiner LB & Blaschke TF (1998). Characterizing patterns of drug-taking behavior with a multiple drug regimen in an AIDS clinical trial. *AIDS*, 12: 2295-2303.
- Gordillo V, Del Amo J, Soriano V & Gonzalez-Lahoz J (1999). Sociodemographic and psychological variables influencing adherence to ART. *AIDS*, 13: 1763-1769.
- Singh N, Squier C, Sivek C, Wagener M, Nguyen MH & Yu VL (1996). Determinants of compliance with antiretroviral therapy in patients with HIV, prospective assessment with implications for enhancing compliance. *AIDS Care*, 8: 261-269.
- Kleeberger CA, Phair JP, Strathdee AS, Detels R, Kingsley L & Jacobson LP (2001). Determinants of heterogeneous adherence to HIV-antiretroviral therapies in the Multicenter AIDS Cohort Study. *Journal of Acquired Immune Deficiency Syndromes*, 26: 82-92.
- Nemes MIB, Souza MM, Souza A, Grangeiro A, Souza RS & Lopes JF (2000). Prevalência da aderência e fatores associados. In: Ministério da Saúde do Brasil, Coordenação Nacional de DST AIDS (Editores), *Aderência ao Tratamento por Anti-Retrovirais em Serviços Públicos no Estado de São Paulo*. Ministério da Saúde do Brasil, Brasília, DF, Brazil, 65.
- Kalichman SC, Ramachandran B & Catz S (1999). Adherence to combination ART in HIV patients of low health literacy. *Journal of General Internal Medicine*, 14: 267-273.
- Catz SL, Kelly JA, Bogart LM, Benotsch EG & McAuliffe TL (2000). Patterns, correlates, and barriers to medication adherence among persons prescribed new treatments for HIV disease. *Health Psychology*, 19:124-133.
- Palella F, Delaney K, Moorman A, *et al.* Declining morbidity and mortality among patients with advanced HIV infection. *N Engl J Med* 1998, 338:853-860.
- Lange J. Issues for the future of antiretroviral therapy. *ART* 1997, 2 (suppl. 4):71-83.
- Yonas T., antiretroviral treatment adherence and its correlates among people living with HIV/AIDS on highly active antiretroviral therapy in Addis Ababa, Ethiopia; 2005.
- Ayalew M. Assessment of Adherence to Antiretroviral Therapy among HIV-infected persons in Addis Ababa and Debreziet at the ministry of national Defense force hospitals; Addis Ababa, Ethiopia, April 2005.
- Gebo KA, Keruly JC, Moore RD. Is illicit drug use a risk factor for non-adherence to antiretroviral therapy? In: Program and abstracts of the 8th Conference on Retroviruses and Opportunistic Infections; February 4-8, 2001; Chicago. Abstract 477.

- Richman DD, Bozzette S, Morton S, et al. The prevalence of antiretroviral drug resistance in the US. In: Program and abstracts of the 41st Interscience Conference on Antimicrobial Agents and Chemotherapy; December 16-19, 2001; Chicago. Abstract LB-17.
- Kasper TB, Arboleda. The impact of patient perceptions of body shape changes and metabolic abnormalities on ART. In: Program and abstracts of the XIIIth International AIDS Conference; July 9-14, 2000; Durban, South Africa. Abstract WePpB1380.
- Stone VE, Hogan JW, Schuman P, et al. Antiretroviral regimen complexity, self-reported adherence, and HIV patients' understanding of their regimens: survey of women in the HER study. *J Acquir Immune Defic Syndr*. 2001; 28:124-131
- Eisen SA, Miller DK, Woodward RS, et al. The effect of prescribed daily dose frequency on patient medication compliance. *Arch Intern Med*. 1990; 150: 1881-1884.
- Eron JJ, Berstein B, King M, et al. Once-daily vs twice-daily Kaletra (lopinavir/ritonavir) in antiretroviral-naive HIV+ patients: 48-week follow-up. In: Program and abstracts of the 8th Conference on Retroviruses and Opportunistic Infections; February 4-8, 2001; Chicago. Abstract 409-W.
- Bartlett JA, DeMasi R, Quinn J, et al. Overview of the effectiveness of triple combination therapy in antiretroviral-naive HIV-1 infected adults. *AIDS*. 2001; 15:1369-1377.
- Andrade A, Davis H, Celano S, et al. Intervention trial using a novel electronic device in HAART initiators: impact of cognitive dysfunction. In: Program and abstracts of the 8th Conference on Retroviruses and Opportunistic Infections; February 4-8, 2001; Chicago. Abstract 602.
- Muma R.D., Ross M.W., Parcel G.S., et al. Zidovudine adherence among individuals with HIV infection. *AIDS CARE* 1995; 7:439-47.
- Koop C.E. Assessing and enhancing compliance with antiretroviral therapy. *The nurse practitioner* 1997; 22:311-9.
- Erwin J. Adherence and its implications for antiretroviral therapy. *Int Antiviral News* 1998, 6: 12-14.
- National Cancer Institute, *Theory at a Glance: A Guide for Health Promotion*: (2003)
- Bandura A (1997). *Self-Efficacy: The Exercise of Control*. W.H. Freeman & Company, New York, NY, USA
- Gallant JE & Block DS (1998). Adherence to antiretroviral regimens in HIV-infected patients: results of a survey among physicians and patients. *Journal of the International Association of Physicians in AIDS Care*, 4:32-35.
- Basen-Engquist K (1992). Psychosocial predictors of "safer-sex" behaviors in young adults, *AIDS Education and Prevention*, 4:120-134.
- Kasen S, Vaughn RD & Walter HJ (1992). Self-efficacy for AIDS preventive behaviors among tenth grade students. *Health Education Quarterly*, 19:187-202.
- Mehta S, Moore RD, Graham NM. Potential factors affecting adherence with HIV therapy. *AIDS* 1997, 11:1665-1670.

- . Jong MD, De Boer RJ, De Wolf F, *et al.* Overshoot of HIV-1 viraemia after early discontinuation of antiretroviral treatment. *AIDS* 1997, 11:F79-F84.
- Fätkenheuer G, Theisen A, Rockstroh J, *et al.* Virological treatment failure of protease inhibitor therapy in an unselected cohort of HIV-infected patients. *AIDS* 1997, 11: F113-F116.
- Erlon, J.A & Mellors, P (1999). Adherence to combination therapy in persons living with HIV: balancing the hardships and the blessing. *Journal of the Association of Nurses in AIDS care*, 10 (4), 75-84
- Laurent C, Fatou N, Gueye NF, *et al.* Long-term follow-up of a cohort of patients under HAART in Senegal [abstract]. 10th conference on Retroviruses and Opportunistic Infections, Boston, February 2003.
- Byakika-Tusiime Orrell J, Oyugi JH, Tumwikirize WA, *et al.* Ability to purchase and secure stable therapy are significant predictors of non adherence to antiretroviral therapy in Kampala Uganda [abstract]. 10th conference on Retroviruses and Opportunistic Infections, Boston, February 2003.

ANNEXES

Annex - 1 English In-Depth Interview Guide

Introduction: Welcome to the interview

My Name is -----and I work for -----and I come from-----.

We are here to discuss the antiretroviral treatment adherence and its related factors. There is no right or wrong answers; all comments: both positive and negative, are most important. We would like to have many opinions and views. I would like this to be open interview, so feel free to express your opinion honestly & openly. I would like to confirm that all your comments are confidential and used for research purpose only. Your name will not be recorded to protect your confidentiality. Are you willing to participate in the interview? Y/N

Thank you for your willingness.

Questions & Instructions for the Interview

- From whom /where did you heard /obtain the information about ARV
- After how long of diagnosis you decide to start ARV
- What were the factors which influence your decision making?
- Describe your understanding of your treatment plan
- Describe your daily routine when taking combination ARV, Have you experienced any problems –like side- effects, access, interaction with other medications, dosing schedules?
- Whom do you consult in case of treatment problems?
- Do you have access any time you want advice /support for your problems
- How do you describe your relation ship with health care providers?
- How convenient is the treatment unit location /services for you, and
- Did taking combination ARV treatment change the quality of your life, if so, in what ways?

Annex – 2 English Questionnaire for the Cross-sectional assessment

Introduction: I am -----working as data collector in this study that assesses what the antiretroviral treatment adherence and its associated factors in the ART unit of -----hospital. This study is conducted by AAU, DCH, in collaboration with-----.On this questionnaire your name will not be written and I am going to ask some questions in line with your personal life related to the treatment. In which all your answers will be kept completely confidential you do not have to answer question that you do not want to answer; even you may end this interview any time you want too. However, your honest answer to these questions will help us to understand better how patients are adhering to the antiretroviral treatment and what barriers that prevent them from following the treatment as to the agreement. This finding will help to develop good strategies and solve the problems for the future. We greatly appreciate your truthful and keen participation in responding to this questionnaire. Identification Number-----Interviewer Name-----Supervisor-----Date of Interview-----

Section I: Socio-demographic characteristics

NO	Questions	Coding Categories
101	Sex of respondent	1. Male 2. Female
102	Age (In complete years)	-----
103	Ethnic group	1. Amhara 2. Oromo 3. Tigirie 4. Gurage 90. No Response 5. Other specify
104	Marital status	1. Unmarried 2. Married 3. Divorced 4. Separated 5. Widowed 90. No Response
105	Religion	1. Orthodox 2. Catholic 3. Protestant 4. Muslim 90. No Response 5. Other specify
106	Educational level	1. Illiterate 2. Grade 1 – 6 3. Grade 7 – 12 . Diploma and above 90. No response
107	Monthly income(Birr)	1. <150 2. 150–249 3. 50-249 4. 350 – 449 5. 450 – 549 6. 550 – 649 7. 650 – 749 8. > 850 90. No response
108	The current Occupational status	1. Government employee 2. Unemployed 3. Private employee 4. Student 5. Merchant 6. Other specify 90. No Response

NO	Questions	Coding Categories
201	Do you have history of Active Substance use?	1. Yes 2. No 80. Don't know 90. No response
202	If yes to Question 201, Which substance do you use?	1. Chatt 2. Cigarette 3. Alcohol 4. Other 5. Iv drugs 80. Do not know 90. No response
203	With whom do you live?	1. Live alone 2. My family 3. My parents 4. unstable 5. No Answer
204	Do you have any Emotional and practical support?	1. Yes 2. No 80. Don't know 90. No response
205	If yes to Question, 204 who Supports you?	1. Family 2. Friends 3. Peer 4. Community 5. Other 90 .No response 80. Do not know
206	What types of supports did you get from your supporter?	1. Material / financial 2. Information / advice 3. Other --- 80. Do not know 90. No response
207	Are you satisfied with their help?	1. Yes 2. No 90. No response 80. Do not know
208	Are you esteemed or valued for your skills/ abilities by other?	1. Yes 2. No 90. No response 80. Do not know
209	Are you satisfied with the way people hold you in esteem or value for your skills or abilities?	1. Yes 2. No 90. No response 80. Do not know
210	Are you confident enough in the ability to adhere to antiretroviral medication in future	1. Yes 2. No 90. No response 80. Do not know
211	Do You Know the consequences of non-adherence?	1. Yes 2. No 90. No response 80. Do not know
212	If yes to question, 211 mention some of them	-----
213	Do you know about the severity of the consequences to non-adherence?	1. Yes 2. No 90. No response 80. Do not know
214	Have you ever thought about your susceptibility to have the consequences of non-adherence for incase of missing/skipping any ART doses?	1. Yes 2. No 90. No response 80. Do not know

NO	QUESTIONS	CODING CATEGORIES				
		(0)strongly disagree	(1)disagree	(2)don't know	(3) agree	(4)agree strongly
301	you have been sad and feeling low					
302	you have been nervous and irritable					
303	You have been feeling bad					
304	you have been having problems with your day-to-day activities					
305	You have been feeling debilitated and sick					
306	You are taking the best pills for your disease					
307	Your laboratory exams/CD4counts are good when you adhere to ART					
308	Your health will be protected if you adhere to ART					
309	Your appearance will be good and healthy if you adhere to ART					
310	Your life will be prolonged if you adhere to ART					
311	<i>Of the symptoms you have mentioned which one was very serious? More than one answer is possible readout the options</i>	1. Candidiasis (Mouth sore) 2. Herpes simplex With muco- cutaneous ulcer 3. HIV-associated dementia 4. weight loss 5. Chronic diarrhea > 30 days 6. Fatigue & fever 7. Chronic cough, night sweating, fever 8. Chest pain, and fever Cough, dyspnea 80- Don't know 90- No Response				
312	Do you have history of admission during the last one month?	1. Yes. 2. No. 80. Don't know 90. No response				
313	Do you have history of admission during the last one year?	1. Yes. 2. No. 80. Don't know 90. No response				
314	How Frequent you have been admitted to hospital for management and follow up during the last one year?	1. I have been in hospital totally for __days. 2. I have been admitted ___ times with in the year?				

401	Are you taking your ART medication regularly with your ARV	1. Yes 2. No 80. Don't know 90. No response
402	When you continue on ART, you will be cured	1. Yes 2. No 80. Don't know 90. No response
414	When did you hear about ART	1. Before my illness, 2. After my illness 3. During my illness 4. Recently 5. Don't know 90. No response
403	When taking ART, it can happen that one may get sick from the treatment itself.	1. Yes 2. No 80. Don't know 90. No response
405	When taking ART, you can get HIV infected again (if you have not taken ART for a long time)	1. Yes 2. No 80. Don't know 90. No response
405	When one takes ART, has to be taken at specific time always	1. Yes 2. No 80. Don't know 90. No response
406	When you are on ART, the only way to stop you is to stop taking it	1. Yes 2. No 80. Don't know 90. No response
407	You need to take the medicines of adherence before you start ART	1. Yes 2. No 80. Don't know 90. No response
418	How long you have been on HAART	
419	what was your CD4 count	Initial _____ Recent _____
420	Have you disclosed you HIV status to your family and relatives	1. Yes 2. No 90. No response 80. Don't know
421	Are you committed/convicted before stating ART	1. Yes 2.No 90. No response 80. Don't know
422	After you have been started Antiretroviral therapy, what clinical benefit did you get?	1.Improved quality of life 2.Weight gain Reduced fever 3.Reduction of hospitalization 4.Reduced frequency of diarrhea 5.No benefit at all
423	Did you have any adverse effect (side effect) when you take ARVs?	1. Yes 2. No 80. Don't know 90. No response
424	If yes to Question 423, which of the following symptoms did you found? More than one answer is possible.	1. Nausea, Vomiting, GI intolerance 2. Headache, Anemia, Rash 3. Depression 6.Diarrhea 7.Others

425	What measures did you take when you developed side Effect?	1. Immediately stopped taking pills 2. With held until the date of appointment 3. Immediately I was reported to clinician 4. Dropped out permanently
426	What types of schedules do you use for memory aids in order to take medication?	1. Pill boxes 2. Written schedules 3. Don't have any memory aids 4. Watch bell 80. Do not know 90. No response

Section V: Patient Providers Relationship

NO	Questions	Coding Categories
501	Are you satisfied with the clinicians service	1. Yes 2.No 80.Don'tknow 90. No response
502	Do you feel the health care providers treating you are capable	1. Yes 2.No 80.Don'tknow 90.No response
503	Do you have open communication with HCP treating you	1. Yes 2.No 80.Don'tknow 90.No response
504	How frequent do you visit your doctor	1.every month 2.every 2 month 3.every 3 month 4.Variable
505	Do you obtain the education or assistant you need during your visit.	1. Yes 2.No 80.Don'tknow 90.No response

Section VI: Health care system and Clinical Setting

NO	Questions	Coding Categories
601	Do you have access to reliable pharmacy any time you want	1. Yes 2.No 80. Don't know 90. No response
602	Are you satisfied by the changes/ improvements you obtain for your treatment	1. Yes 2.No80. Don't know 90. No response
603	At present do you have a child under your care	1. Yes 2.No80. Don't know90. No response
604	Child tested for HIV	1. Yes, positive 2 .Yes, negative3. Not tested
605	Are you satisfied in the scheduling appointments and confidentiality of the treatment unit	1. Yes 2.No80. Don't know 90. No response

VII. Adherence assessment & Reasons for skipping doses

1. Patient Interview Ask questions about number of doses skipped & unmet restrictions, i.e. like food required with drug, time schedule with empty stomach etc

- o Name of the ARV drugs that the patient is taking 1.....2..... 3.....
- o ARV drugs frequency/administration /number of daily doses
- o Number of each pill per treatment session1.....2.....3.....
- o Number of each pill the patient took during the last 72 hours1.....2.....3...
- o Compulsory fasting..... Medication taken with a meal

II. Pill Count: For patients who brought their pills, count the pills remaining in the pill bottle

& calculate the difference between actual & exacted number of pills remaining. Number of pills remaining _____Number of pills dispensed last time ___Expected number of pills remaining Reasons for skipping the doses since the last one month (Including for the last 72 hours adherence history)

NB: More than on answers is possible

No	Tick	Reasons for skipping doses
1>	I was too busy with other things or simply forgot.
2>	I was a way from home.
3>	There was a change in my daily routine.
4>	I felt asleep.
5>	I felt depressed or overwhelmed.
6>	I had problem taking medication at specific times.
7>	I felt sick or ill at that time
8>	I ran out of medication.
9>	I had too many pills to take.
10>	I felt the drug is too toxic/ harmful and want to avoid side effects.
11>	I did not want other to notice me I am taking medicine.
12>	Taking the drugs is a reminder of my HIV.
13>	I was confused about the dosage directions at that time.
14>	I did not think the drug is doing anything to improve my health.
15>	People told me the medicine is no good

Annex - 3 Amharic Questionnaire for the Cross-sectional assessment

203 - Tdcu=Á: - u201 çÉ ,Á'f ÁVL: %}q}f 2SÊc-"uS<Á -"u<KA -}Ñu="<" aÒ ð" jw' ÁcÖ<-IM;1.)-ÁÝw|-M u²=IU [j;%KG< 2.)-Ó"um >ÁÁKU 3. >ÁÝw"U 4.%} Ökc< %}K"U

ÝfÇ' /òp' Á---	1 2 3 4	1.)-JuÉÖö- j;%KG<2.)- Ó"um>ÁAMU
ÝÖÁ™ <"/e^ vMÁ{x<-	1 2 3 4	3.U"U>LÁ[N<M"U
ÝMD<-	1 2 3 4	4.%}Ökc< %}K"U
Ýu?)cx<-	1 2 3 4	
ÝK?KA< c -<	1 2 3 4	

SÖÄp	SMe
204 uzÄ[c< SA'1"/ i"" %ÄÉT@ T^T>Á SÉH">- ð"AT>ÄeðMÓ/i S<K< KS<K< >U"lulM /iulM;	1.)A2. >LS"Ý<ufu99. >L"Ý<U
205 uzÄ[c< / ?< >Áy= / u ðÉT@ T^T>Á SÉH">+ uÓ?" vS<A ± LÄ Ø' x_ >KI;	1.)A 2. %}K"U99. >L"Ý<U
206 SEH">+' u ð²uf SSJÁ Scf S"<cÉ eS%MI/i ð ÖÖ- /i "Áe Ø' x_ >KI/i	1.)-ð ÖÖ- " Ø' x_ %}K"U 2.ð ÖÖ- " Ö" Ø' x_ >K"3.ðU>M>ÁSeK"U Ø' x_ >K"4.ðU>M>ÁSeK"U Ø' x_ Ö" %}K"U99. >L"Ý<U

SÖÄp	SMf%ø†"<	
	>-	%}KU
^e U f 2" f' 'u' -f; %}UÓw öLÖ„f k" dDM; KS)-f Ä†Ñ^K<; ukLK< ö" Hf ö" Hf ÁKA ðM; (ö" Hf ÄcT -ðM); ðf Ä" kÖk×M; weßf" ß" kf ÄcT -ðM; UÓw ÝuK< u%EL %}S" g" g' ,Ö' >Kxf; %}T>Áeu<f" Hdw uÓMí KT"p Ä†Ñ\ 'u'; Áe} " f >ÄcT -fU; %}N" eT@f Ý" fa"< u}K% G< @ ð ÄcT -ðM; S" " f c=ðMÑ< ,Ö' ÄÑØV ðM; "<X' @ u' Na< LÄ KSeÖf Ä†Ñ^K<; Y^ - f >e†Ö] ÄJ" x ðM; >eðLÑ"> " ÖnT> uJ' < " Na< LÄ KSÝ" f (S" Á%}f) Ä†Ñ^K<; öLÖf-uT"-> <U "Ñ" LÄ k" dDM; ^e - " aÖ u=e >É"Ñ" < ÁevK<; IÄ"; ' <aÁ' }uLg >un' >Ý}S wK" < Áeu< 'u'; É"U u>%Ñ>2?" < ÄcT -ðM; JÉ - " <eØ Ø' eT@f >ÄcT -fU; ukLK< É"U ÄcT -ðM;		

jðM fe f : u?i %}N" /%Éw' f/%SÝöf/SK;Á SÖÄp /u"" SSJÁ' Ý²=I ulk 21 ewew N]ð< ÄÑ—K< :: ð"Á"Ç"Æ ewew 4 N]ð< >K<f:: Ý4~ ewew "<eØ 1 ufjM eT@f-" %}T>ÑMç"<" N]ð uSU[Ø ulØ 2<JÁ jw UMj f ÁÉ"Ñ< :: K ð e ->Öv "K"< Ý"É N]ð ulÄ K=S' Ö< Ä<LK< : Mw ÁÉ"Ñ< ' %}2_ "<U ÚU[< vKð"< XU" f u% %}T>cT -} " eT@f " < TÖnKM ÁKxf ::

}.l.	SOÄp	SMe
4@1	uSÉSJA YGY=V Ö' c=N~< eK >?Äy= ?Ée Á<l 'u' ::eK >?Äy= ?Ée IÉT@	1. >'<nKG2 >L~<pU 99.SMe >KU::
4@2	T^2T>Á SÉH'>„ SŠ' < %cS<f :eK SÉH'>„ † %cS<f Á'f Y%>f' < ::	1. YS I@ST@ uòf 2. Y I@SUÿ< uG^L
4@3	SÉH'>„ † YSÉSa uòf eK Önt>†' < Á<l 'u'	3. ISU LÄ I@ÁK' < 4. up' u< 99. >Le I' < eU
4@4	SÉH'>„ † dÁs Ö< uc~> u I^22< SW[f S'cÉ u×U >eðLN> I'ÁJ'Á' <nK< ::%IÉT@	1. Ö?> vKS<Á -< 2. _C=Á2. K?y=> 4. Ö?>x
4@5	T^2T>Á SÉ I'>„ † KU' ÁIM N>?> }Öks< -----	3. Yü?>cxš 6. YÖÁ™Š7. Y?>Ée ;Kx 99. >Le I' < eU
4@6	%IÉT@ T^2T>Á SÉH'>„ † U' ÖkT@ >eN<-KAf	1. >- 2. >L' < pU 99. I' @' I1. >- 2. >L' < pU 99. I' @' I
4@7	SÉSJA c=S[SI %'uaf c=C= ö' IØ' e'f 'u' :: %SÉSJA -----%>c^ufk'----- up' u<	1. uÖpLL QÄ', uØ' jKÄBm2. jwÁf UÜ->KG<3. fY<df k'fM—M4. Jeü
4@8	%>e^ YK----- k'-----	I M S]—, k'dM::5. jPTØ k'fM—M:6. U>ÖnLÄ ui I' k'fM—M7. K?L --
409	uzÄ[<< }Öm SJ^m %>IÉT@ T^2T>Á SÉ I'>„ † I'ÁT>~>eAE KK?KA< TKfU KÖÁ™-/i /Ku?>cw >e I' < k^M::	1. >- 2. >Le I-Lu 3. uYðM

}.l.	SOÄp	SMe
5@1	%>IÉT@ T^2T>Á SÉ'>f c="eAE "A >?Ée Á[%>T>YÉuf øØ'f Ák'dM	1. I' < f 2. Ncf 99.99 I' @' I
5@2	%>IÉT@ T^2T>Á SÉG'>„ † c=ÖkU uyÄ[c< %>Á² c' < øèV ÁÉ">M	1. I' < f 2. Ncf 99. I' @' I
5@3	%>IÉT@ T^2T>Á c=ÖkS< 'Ç'É uSÉ I'>„ † Uj>Áf K=ISS<K=NAE Ä'LK<	1. I' < f 2. Ncf 99. I' @' I
5@4	I'TT>-> %>IÉT@ T^2T>Á SÉ I'>„ † c=ÖkS< YTAÖks<fÁMp [P U LK< N>?> Á^K<::	1. I' < f 2. Ocf 99. I' @' I
5@5	%>IÉT@ T^2T>Á SÉ I'>„ † e'ÖkU zÄ[c< Yc' < l' S<K<uS<K< ÄÖöM	1. I' < f 2. Ncf 99. I' @' I
5@6	T'—<U uzÄ[c< %>Á² c' < SÉ I'>„ † SÖkU Ä'LM	1. I' < f 2. Ncf 99. I' @' I
507	%c' < l' ui I' %SYLYM >pU u×U c=ÄjU w% " < %>T>ÄeðMÑ"	1. I' < f 2. Ncf 99. I' @' I
508	SÉ I'>„ † e'ÖkU uk' < eØ u' c' c' f' < S' < cÉ ÁKw"	1. I' < f 2. Ncf 99. I' @' I
509	SÉ I'>„ † e'ÖkU %>K' < SÉ I'>„ † øèV S^KM SJ' < %>KvT' < U::	1. I' < f 2. Ncf 99. I' @' I
510	>?Ée" KT^Ö%>f SÉH'>„ † K IÉT@ Mj S'cÉ >KvT' < ::	1. I' < f 2. Ncf 99. I' @' I
511	SÉH'>~> ufjijM KS' < cÉ SK< K<K< "c" < q' Ö' < " < %ÉS\fc< öf SÉH'>„ † c="eAE U"U SÚ'p >ÄcT-fU	1. >- 2. >ÄÄKU 99. I' @' I
512	%SÉH'>„ † >dcÉ c' f' Y I'Kf.) I'Kf I'penc?> Ö' ÄcTTM::	1. >- ÄcT—U 2. >Ä ÄcT—M 99. >L' Y<U
513	%>IÉT@ T^2T>Á SÉH'>„ † c=ÖkS< u'c< Uj' Áf %>Ä[< dÄÉ I'öj' >K	1. ÄeTTM 2. ÄeTU 99. >L' Y<U
514	dÄÉ =>öj~ %>Ä[< f SŠ' < -----%>dÄÉ =>öj~ UMj'f U' u'-----	1. >- 2. %>KU
515	KdÄÉ =>öj~ S'ö? < " < %>vK' < SÉH'>f T' u' :: -----	1. "Ç=Á' < SÉH'>~> >quY<2. I'eYKÖa k'@ >S[Ø]
516	u'p~ U' >Ä'f U' I' cAE	"Ç=Á' < < KÉY] >T'Y' < 4. SÉH'>~> uS<K] < Y' < uK?L Ñ
517	u>G<< c' f' Y IÉT@ T^2T>Á SÉH'>„ † ujÜT) KK?L uüi %>T>~>eAf SÉH'>f >K	ÉS'Y<99. >Le I' < eU
518		1. >- >K 2. >M'eÉU
519		
SOÄp		SMe
61	YT>ÄjVf HY=U Ö' "ÄU YK?KA< %>Ö?> vKS<Á< Ö' vKAf Ö' < f [ij]M::	1. [ij]KG< 2. >M[I'G<U 99. >L' Y<U/I' @' I
62	%>T>ÄjVf Ö?> vKS<Á< -< wI "†" < wK' < ÄU"K< u'c<e LÄ >S' @' >KAf	1. wI "†" < >S' @' >K' 2. wI "†" < >S' @' %>K'U3. wI >ÄÄ
63	YT>ÄjVf %>Ö?> vKS<Á< -< Ö' ÖMè %> " < ÄÄf SÓw'f >KAf	>S' @' %>K'U
64	kÖa -u>e'f N>?> < " < ukÖa -k' %>T>ðMÑ<f^m %>T>ÖÄ'f fU' f' ÉÖö ÁÑ—K<	1. >K' 2. %>K'U99. >L' Y<U
65		1. u>Ä' 2. u>G<Kf 3. u>fef 4. ÄKÁAM
		1. >- >Ñ—KG<2. >L' N'U99. >L' Y<U
SOÄp		SMe
7@1	uðKÑ<f N>?> Y I'k ö' Tc= SÉH'>f %>TÖ—f IÉM >KAf	1. >- 2. %>K'U99. SMe %>KU
7@2	uQiU^m u IÉT@ T^2T>Á SÉH'>„ † vN<f K' < Ø [ij]M	1. >- [ij]KG< 2. >M[I'G<U99. SMe %>KU
7@3	wG<< c' f' u I'f I'w'u? Y' ÁK I' M' >KAf	1. >- >K' 2. %>K'U99. SMe %>KU
704	MÐOE/ MÐ }S' U' M	1. >- p²+ö 2. >- ' @Ö+ö3. >M}S[SIU
7@5	ujfM" IjU" jökA kÖa >ÁÄ" T>eØ^öf [ij]M	1. [ij]SÁKG< 2. >M[I'G<U99. SMe %>KU >L' Y<U/

Annex – 4.1 Stepwise discriminant analysis results: the predictive model built, after the data was filtered for co-linearity.

variables	Tolerance	F to Remove	Wilks' Lambda
1. Perceived susceptibility to non-adherence threats?	0.938	35.286	0.771
2. Are you confident enough in the ability to adhere in future	0.919	34.823	0.770
3. Do you have access to reliable pharmacy any time you want?	0.922	28.187	0.760
4. Any doubt/lack of confidence on benefits of ART?	0.987	11.063	0.732
5. Did you have any adverse effects (side effects)?	0.926	4.730	0.722
6. Do you have history of Active Substance use?	0.914	10.166	0.731
7. At present do you have a child under your care?	0.811	12.077	0.734
8. Marital status of the respondent	0.797	11.308	0.733
9. Depressed feelings in the last one month	0.798	9.789	0.728
10. Are you taking any other medication now with your ARV?	0.807	8.773	0.729
11. What was your source of information about ART initially?	0.901	7.835	0.727
12. Unusual feelings on taking ARVs in - front of others people?	0.892	4.528	0.722
13. ART duration	0.940	2.333	0.711
14. DO you believed that you are infected HIV and needs	0.965	0.322	0.714
15. What types of methods do you use for memory aids	0.935	1.233	0.713
16. Do you think the HCP capable and trust them?	0.961	0.001	0.715