

# **ADHERENCE TO ANTIRETROVIRAL THERAPY: A CROSS-SECTIONAL STUDY OF ADULTS IN ETHIOPIA**

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## **ABSTRACT**

Antiretroviral medications have improved the management of the Human Immunodeficiency Virus infection. However, their effectiveness in suppressing the replication of the human immunodeficiency virus is hampered by adherence levels below 95%.

This study examined the influences on the use of antiretroviral therapy among adults in Ethiopia. The study is a quantitative, cross-sectional, institution-based study with descriptive and analytic components. A total of 338 patients were systematically selected. These patients were interviewed about their experiences of taking ART using a structured interview schedule.

Data were sorted, coded and entered into the computer using the Statistical Package for Social Sciences (SPSS) version 16.0. Data presentations include charts, graphs and frequency tables. Patients were grouped according to their ability to adhere to treatment, based on a score derived from adherence assessment for seven days preceding the interviews.

A multivariate regression model was used to determine predictors of non-adherence. Non-adherence was common among participants aged 18 to 30 years, with limited education, who were unmarried and had low-incomes. Forgetfulness and doubts about confidentiality influenced non-adherence, especially among single young females.

**KEYWORDS:** adherence to antiretroviral therapy, antiretroviral therapy (ART), HIV/AIDS in Ethiopia, non-adherence to antiretroviral therapy

## **INTRODUCTION AND BACKGROUND INFORMATION**

Patient adherence is a dynamic phenomenon broadly affected by patient, medication, disease, provider and system factors. Poor antiretroviral therapy (ART) adherence has

been associated with a number of factors in the United States of America (USA) and western Europe, including treatment side-effects, complex regimens, lack of social support, mental illness, active substance use, stigma, low levels of literacy, poverty issues (such as transportation problems, food insecurity), asymptomatic status of the patient prior to initiation of treatment, poor understanding of the ART regimen, inadequate pharmacy services and a lack of confidence or trust in healthcare service providers (Tusiime et al., 2008:209; Rachlis et al., 2011:11; Ingersoll & Cohen, 2008:216).

Ethiopia initiated a fee-based antiretroviral therapy (ART) programme in July 2003, in Addis Ababa. This programme was later implemented throughout the country because of its success. Facilities providing ART service grew from three in 2004 to 481 in June 2009 (136 hospitals and 345 health centres) (HIV/AIDS Prevention and Control Office [HAPCO] 2008–2009:37). According to the United Nations Programme of HIV/AIDS (UNAIDS 2010:98), the adult treatment coverage need ranges from 52% to 65%. These figures illustrate the magnitude of the task to provide prevention, care and treatment and support services for those who need them as well as indicate the need to develop strategies to maximise long-term ART adherence. This is a multidimensional problem influenced by multiple interrelated factors which could be addressed by adopting a multidisciplinary approach (El-Sadr et al., 2010:5). This takes into account the patient, the treatment regimen, the ART providers and the environment (Tusiime et al., 2008:38).

Reportedly adherence to anti-hypertensive medications varies from 26% to 51% (WHO, 2003). Patients' adherence to anti-depressive medications has been found to be 40%–70% while ART adherence rates of 37%–83% were observed in one cohort of patients (WHO, 2006:4). However, according to Paterson et al. (2000:23.), adherence to protease inhibitor therapy of 95% or greater is required to optimise virological outcomes for human immuno-deficiency virus (HIV) positive persons. Negash and Ehlers (2013:4) reported that out of 335 patients, 26.5% (n=94) were non-adherent in Addis Ababa, Ethiopia, implying that these patients might not derive the maximum benefit from ARVs and might develop ARV-resistant strains of HIV.

### **Definitions of key concepts**

**Antiretroviral drugs (ARVs)** are drugs that can slow down the progress of HIV and thus slow down the damage to one's immune system. They slow down the replication rate of HIV (Gay et al., 2011:263).

**Antiretroviral therapy** is a combination of three or more antiretroviral drugs that are used to suppress the HIV virus and stop the progression of HIV disease (WHO, 2008:16).

**Adherence to antiretroviral therapy (ART)** implies 95% compliance of persons living with HIV to be involved in choosing, starting, managing and maintaining a given ART regimen to control HIV replication and improve the immune function. It means taking the correct doses of drugs at the correct time and in the correct way (such as with the right type of food or fluid) and adhering to the treatment plan. It also means keeping the drugs safely (Amberbir et al., 2008:265; Horizons, 2004:16).

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

## **PROBLEM STATEMENT**

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

## **PURPOSE OF THE STUDY**

The purpose of this study is to investigate the factors that influence adherence to ART levels at one hospital in Addis Ababa, Ethiopia.

## **OBJECTIVES OF THE STUDY**

The objectives of the study were to:

- examine the proportion of ART adherence among the study participants;
- identify factors that influence adherence.

## **RESEARCH METHODOLOGY**

This is a quantitative, cross-sectional, institution-based study with descriptive and analytic components (Stommel & Wills, 2004:3). The study was conducted at a district hospital, located in the western part of Ethiopia, and the south western part of Oromiyya region. This is a referral hospital in the east Wollega zone with a catchment population of 2.8 million people in 2011 (Central Statistics Agency, 2012:233).

## **Population and sample**

The population in this study consisted of all ART patients. Inclusion criteria were that respondents had to be 18 years or older and should have been on ART for a minimum of 12 months at the time of the interview.

## ***Sampling procedure***

Systematic sampling was applied when choosing respondents for structured interviews. Systematic sampling relates to the selection of respondents, from a population list or “sampling frame”, in a predetermined manner commencing from a randomly selected starting point. Every fourth person, adhering to the inclusion criteria and who was willing to be interviewed, was selected. A total of 338 respondents were selected.

## ***Data collection process***

Data were collected by the principal investigator and four research assistants who were registered nurses trained on basic ART. The research assistants were not employees of the study hospital. This approach to data collection was adopted to minimise respondent bias. All research assistants were trained on data collection to ensure consistency in the process. Data were collected for six weeks from June to August 2011. A sample of all data (5% collected by the research assistants) was validated by the principal investigator for completeness.

## **Data analysis**

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

## **ETHICAL CONSIDERATIONS**

The ethical protection of respondents was maintained throughout this study. Before the study began, ethical clearance was obtained from the Higher Degrees Committee of the Department of Health Studies at the University of South Africa. Institutional consent was obtained from the medical director’s office of the participating hospital.

Informed verbal consent of respondents was sought, obtained and recorded in writing. The objectives of the study were discussed with each respondent. The respondents were told that no incentives would be paid. The study had no risks and they had the right to discontinue the interview at any time. The cellphone number of the principal investigator was given to the respondents in case they had any queries. To ensure autonomy in this

study, a written statement explaining the purpose of the study and procedure for data collection was developed. This was done to ensure consistency in information provided to all potential participants. Respondents were also told that participation in the study was voluntary and that they had the right to withdraw from the study at any time during the course of the study, without incurring any negative consequences whatsoever.

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

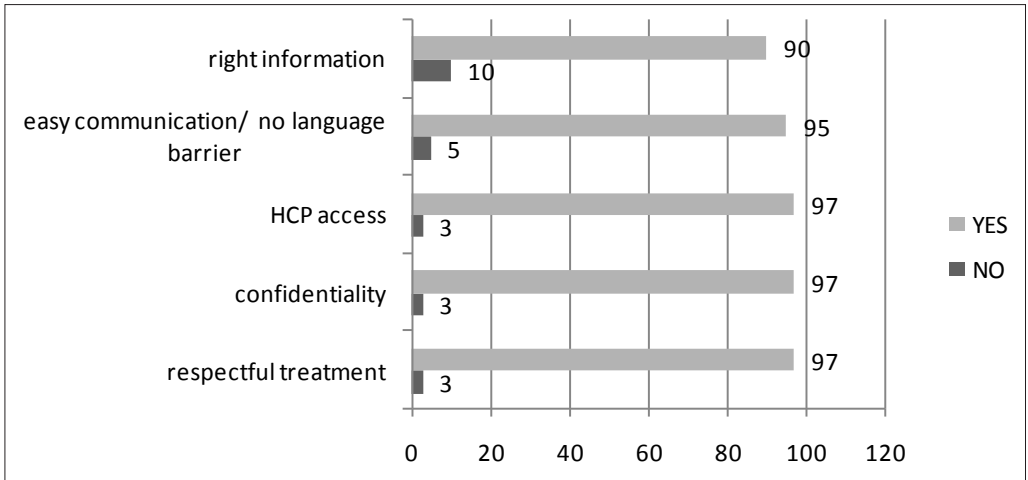
The standardised questionnaire was pre-tested on a population with similar characteristics to the study respondents. It was then amended to address suggestions made. The statistician determined the Cronbach's alpha to be 0.625, which indicated the accuracy of the questionnaire. By using strong inclusion and exclusion criteria and using random selection of study respondents from the study population, and making the sample population representative of the study population, selection bias was minimised in this study. All variables were measured in the same way with all the respondents. Since it is a cross-sectional study, data collectors knew little about the respondents which also helped to prevent information bias.

## **FINDINGS**

A total of 338 adults aged between 18 and 51 years participated in the study. Of these, 85% (n=289) were aged 20 to 40 years of age; 62% (n=208) were females and 38% (n=128) were males. All the respondents were on ART at the time of the interview and of these, 86% (n=290) had been hospitalised during the past year prior to the interview.

## **HEALTH CARE FACILITIES' AND PROVIDERS' INFLUENCE ON ART ADHERENCE**

These factors are displayed in Figure 1.



**Figure 1: Health care facility and providers’ influence on ART adherence**

Ninety percent (n=304) of the respondents reported that their healthcare providers supplied the correct information on which they could base their decisions. A higher percentage (95%; n=355) had no problem with communication and generally the respondents were satisfied with the role of healthcare providers in influencing ART adherence.

**PSYCHOSOCIAL FACTORS**

Various psychosocial factors (family support and illness factors) were associated with ART adherence and non-adherence. Of the respondents, 16% (n=62) reported that they had been treated for a psychiatric illness in the past; 10% (n=38) reportedly had suffered from depression; and 2% (n=7) reported active substance use while on ART. Some 75% (n=291) claimed to have no one to talk to while the rest 25% (n=97) reportedly had someone close to talk to while depressed; 84% (n=326) had disclosed their status to family members and 13% reported that they were receiving help from their family. Major findings of the study were categorised under variables associated with adherence and non-adherence. Table 1 shows the crude odd ratios and captures some reasons for missing ART.

**REASONS FOR MISSING ANTIRETROVIRAL DRUGS**

All 338 participants were asked to choose from 13 reasons for missing ARVs listed in the questionnaire. They were requested to choose all reasons relevant to them and the findings are depicted in table 1.

**Table 1: Reasons for missing antiretroviral drugs**

No.	Reason for missing ART	Proportion	Percentage %
1.	Simply forgot	16/338	21.9
2.	Too busy	16/338	21.9
3.	Away from home	13/338	17.8
4.	Ran out of pills	8/38	10.9
5.	Avoiding being seen swallowing pills	5/338	6.8
6.	A change in daily routine	5/338	6.8
7.	Fear of side effects	2/338	2.8
8.	Too many pills	2/338	2.8
9.	Felt sick	2/338	2.8
10.	Felt depressed and overwhelmed	1/338	1.4
11.	Unable to comply with dietary instructions	1/338	1.4
12.	Fell asleep	1/338	1.4
13.	Too many times to swallow pills	1/338	1.4

## **FACTORS PREDICTING ADHERENCE AMONG RESPONDENTS**

Univariate and multivariate binary logistic regression analyses were conducted to identify correlations between factors associated with ART adherence or non-adherence. All variables were dichotomised to fit the model and they were screened to identify participants' variables by using univariate analysis at a p-value of 0.25. Variables associated with adherence on the univariate analysis remained significantly associated with adherence on the multivariate analysis as shown in Table 2. Table 2 shows the crude ORs for variables identified as correlates of adherence, which were statistically significant in the univariate binary logistic regression analysis.

**Table 2: Factors predicting adherence among respondents**

Characteristics	Did you miss one or more doses over the last seven days?		Crude odds ratio (COR = 95%)	Adjusted odds ratio (AOR=95%)
	No	Yes		
Age in years 18–30 31 and older	107 210	12 9	2.6(1.06-6,40)* 1	3.45 (1.11-10)* 1
Level of education No education 7 years of formal education or more	74 242	13 8	5.31(2.12-13.31)*** 1	5.06(1.64-15.60)** 1
Marital status Not married Married	174 142	17 4	3.46(1.14 10.53)*** 1	2.37 (1.65-8.60)* 1
Water supply Pipe Other	273 42	13 7	0.28 (0.09-0.84)* 1	0.37 (0.05-0.92)* 1
Electricity Available Unavailable	290 42	16 5	0.28 (0.09-0.84)* 1	0.33 (0.08-0.98)* 1
Healthcare providers Accessible Inaccessible	311 6	17 4	0.06 (0.01-0.22)*** 1	0.11 (0.01-0.99)* 1
Maintenance of confidentiality Confidentiality maintained by healthcare providers Confidentiality not maintained	311 6	17 4	0.08 (0.02-0.31)*** 1	0.033(0.03-0.58)** 1
Language barrier with HCP Present Absent	12 307	4 7	6.02 (1.75-20.64)** 1	2.76 (1.61-12.44)** 1
Psychiatric illness Treated for such illnesses Not treated for such illnesses	44 267	8 13	3.73 (1.46-9.52)** 1	3.56 (1.16-10.93)* 1

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



Participants also reported on their rate of adherence. More than 90% of respondents reportedly never missed a single dose of ARVs during the week preceding the assessment as shown in Table 3.

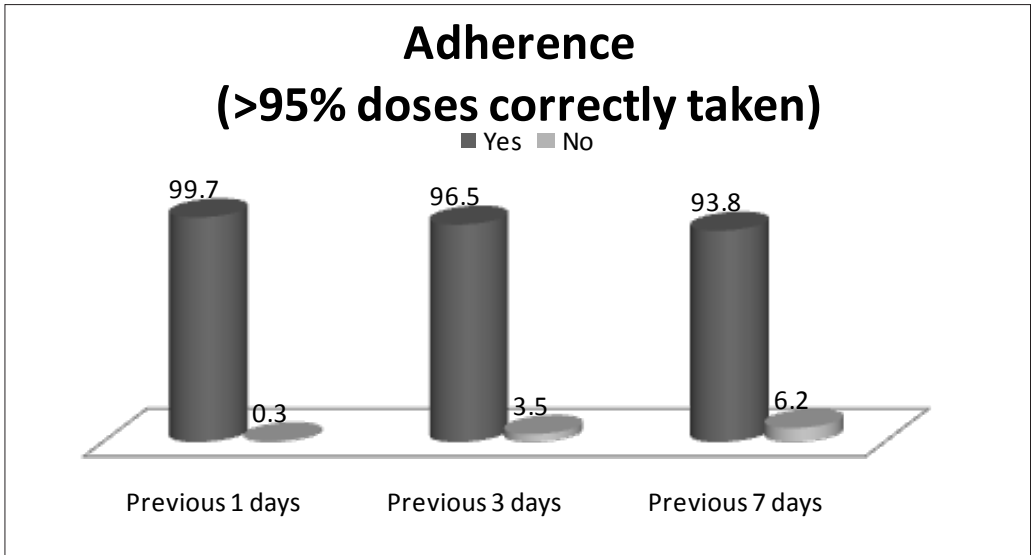
## SELF-REPORTED ADHERENCE

Adherence assessments to ART are summarised in Table 3. About 93.8% of the participants claimed never to have missed a single dose of medication in the week before the assessment and hence, based on their self-reporting, were found to be adherent, based on the definition outlined above. The one-day and three-day adherence rate was 99.7% and 96.5% respectively.

**Table 3: Self-reported adherence among respondents**

	<b>Adherence (&gt;95% doses correctly taken)</b>	
	<b>Yes</b>	<b>No</b>
Previous 1 day	338 (99.7%)	1 (0.3%)
Previous 3 days	328 (96.5%)	12 (3.5%)
Previous 7 days	319 (93.8%)	21 (6.2%)

The study found that non-adherence was common among respondents aged 18 to 30 years, with little education, unmarried and with minimal basic amenities such as water and electricity. These findings are similar to those of previous studies (Gay et al., 2011: 207; Ray et al., 2010:125). All the other variables included under socio-demographic, patient/provider relationship and family support were not found to be significantly associated with adherence at  $p < 0.25$ .



**Figure 2: Self-reported adherence score**

All the variables found to be associated with adherence on the univariate analysis remained significantly associated with adherence on the multivariate analysis as shown in Table 2.

## DISCUSSION

Many factors pertaining to ART adherence identified in this study were consistent with literature from both developed and developing countries. Females in this study aged between 18 and 30 years, with little education and with poor housing infrastructure were significantly associated with non-adherence. This was a unique finding as demographic factors are generally not consistently associated with adherence to ART (Fong et al., 2003:135).

Education levels and income are the two most studied livelihood factors and the latter demonstrated a significant association with ART adherence. Education level was a determinant factor for self-efficacy, which is defined as a conviction that one can successfully execute a specific behaviour such as ART adherence (Barclay et al., 2007:49). Conflicting evidence may be found about the association between socio-demographic factors and adherence behaviour; when an association is found, the direction is towards lower levels of adherence with younger age, being single and lower income, which might be complicated by other factors (Tuisiime et al., 2008:28).

ART adherence was estimated by self-reports using structured interview questions that could be subject to over-estimation as patients tended to overstate their ART adherence. Other measures of adherence, such as pill counts, pharmacy records, electronic devices or therapeutic drug monitoring were not available for the study. Measuring ART adherence using patients' self-reports could be easily replicated in most resource-limited settings including Ethiopia (Amberbir et al., 2008:265).

In the current study, 93.8% (n=363) of patients were adherent with >95% prescribed doses. This study found a better adherence level than previously reported in Ethiopia (Awel, 2008:40; Tadios & Davey, 2006:237) apart from a study by Amberbir et al. (2008:265). It is comparable with, or higher than, those reported in other African countries, excluding Rwanda (Musiime et al., 2011:279).

A perceived lack of confidentiality reportedly posed a barrier to ART adherence, consistent with a study reporting that poor self-reported access to medical care was strongly associated with stigma (Sayles et al., 2009:1107). In this study, 21.9% (n=16) of patients did not disclose their HIV status to their family members. Although family support was not significantly associated with adherence in the study, social support might enhance adherence, either directly in the form of reminders, financial help, and emotional backing, or indirectly by buffering the effect of those variables that might interfere with adherence. Examples of these variables include substance use, stress, anxiety, and depression (Tiyou et al., 2010:39).

A large-scale meta-analysis of both quantitative and qualitative studies from developing and developed nations reported reasons for non-adherence. Outcomes of this analysis indicated important barriers to adherence to be similar across multiple settings and countries, and identified that fear of disclosure, forgetfulness, a lack of understanding of treatment benefits, complicated regimens, and being away from one's medications were consistent barriers to adherence (Sayles et al., 2009:1108). More important to poor settings were issues of access, including financial constraints and an interruption of access to medicines (Mills et al., 2006:680).

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

## **CONCLUSION**

The study has examined factors that influence patients' adherence to ART. It is noted from this study that simple forgetfulness is a critical reason for patients' non-adherence to ART. It is evident from the study that female patients between the ages of 18 to 30 tend to forget to take their ART more than other age groups. It is critical to state that this age group is generally worried about healthcare workers not keeping their medical information confidential. In fact, this is another factor that seems to contribute hugely to the ART non-adherence of this population. Taking into account the magnitude of factors that could influence people's adherence to treatment, more work is still needed in this area.

## **RECOMMENDATIONS**

Based on the results of this study the healthcare system needs to improve patients' confidence, trust, and satisfaction with healthcare providers. The respondents had indicated that lack of confidentiality is a barrier to ART adherence and hence the healthcare system should strive to improve perceived confidentiality for patients.

Sustainable strategies are also needed to assist patients to remember their medications. A number of strategies to improve on the ability to remember to take one's ART have been proposed and instituted. Such strategies include electronic reminders, filling caps and counselling, and all of them seem not to have worked or not to be sustainable especially to patients who do not have any income (Awel, 2008:20). The study therefore recommends that further research should be done that would look into finding strategies that would improve patients' memories for taking their ARTs.

## **LIMITATIONS**

The study used a cross-sectional design; it did not allow the researchers to establish a causal relationship between significantly associated variables and treatment adherence, as both variables were measured at the same time. The "gold standard" for assessment of adherence does not exist. In this study adherence was measured using self-reports, which might tend to over-estimate levels of adherence. Social desirability (the projection of a positive image) could have induced an over-estimation of adherence, but the principal investigator tried to minimise that by explaining to each patient that it was not always easy to adhere to medical treatments in general (Joubert & Ehrlich, 2007:163). The patients were also informed that their answers would not interfere with the care they received. Furthermore, structured self-reports have been reliably associated with both objective measures of adherence and viral load. The other limitation of the study was that it did not segregate patients into cohorts of treatment (at least yearly cohort batches) according to the date of initiation of ART to see issues specific to every cohort. For example, forgetfulness to take pills, which was given by the majority of the respondents

as a reason for missing pills, might be a problem for beginners until a certain period of time, which could improve later.

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