



ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF PUBLIC HEALTH

MAGNITUDE OF ANTERETROVIRAL THERAPY ADHERENCE AND ASSOCIATED FACTORS AMONG HEALTH CENTERS IN AKAKI KALITY SUBCITY, AA, ETHIOPIA.

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DECLARATION

I, the undersigned, declare that the thesis is my original work, has not been presented for degrees in any other University and all source of materials used for the thesis have been duly acknowledged.

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Table of content

Table of contents.....	!
List of tables.....	!!
List of figures.....	!!!
Abstract.....	!!!!
1. Introduction.....	1
1.1 Background of the study.....	1
1.2 Statements of the problem.....	2
1.3 Significance of the study.....	3
2. Literature review	4
2.1 Global situation of ART adherence.....	4
2.2 Africa situation of ART adherence.....	5
2.3 Ethiopian situation of ART adherence.....	6
2.4 summary.....	7
3. Objective.....	8
3.1 General objective.....	8
3.2 Specific objective.....	8
4. Methodology.....	9
4.1 Study design.....	9
4.2 Study area and setting.....	9
4.3 Source population.....	9
4.4 study population and subject.....	10

4.5 Exclusion and inclusion criteria.....	10
4.5.1 Exclusion criteria.....	10
4.5.2 Inclusion criteria.....	10
4.6 Sample size determination.....	10
4.7 Sampling procedure.....	12
4.8 Operational definition.....	13
4.9 Data analysis.....	13
4.10 Variable of the study.....	13
4.10.1 Dependent variable.....	13
4.10.2 Independent variable.....	14
4.11 Dissemination of the result.....	15
4.12 Ethical consideration.....	15
5. Result	16
6.1 Discussion.....	23
6.2 Strength and limitation.....	27
6.3 conclusion.....	28
6.4 recommendation.....	29
7. Reference.....	30
8. Annex 1(Determinant of adherence).....	34
9. Annex2 (information sheet and consent form).....	35
10. Annex 3(Questionnaires Amharic and English version).....	37
11. Annex 4(assurance of principal investigator).....	43

List of abbreviation

AACTG - adult AIDS clinical trial group

AAU- Addis Ababa University

AKSCHB-Akaki kaliti sub city health bureau

ART- Anti retroviral Therapy

AIDS-Acquired immunodeficiency syndrome

AZT- Zidovudine

3TC-Lamivudine

DCH-Department of community health

D4T- stavudine

EFV-Efavirenz

HIV- Human Immune deficiency virus

HAART- highly active antiretroviral therapy

MEMS- Medication Event Monitoring System

NVP-Neverapine

List of tables

Table 1: Basic socio demographic and psychosocial variables of the cross sectional survey

Table 2: Treatment, Clinical, and Health Care System related variables of the cross Sectional survey

Table3: Patient Adherence by Self-report

Table 4: Univariate and Multivariate Logistic Regression analysis: variables associated with adherence

List of figures

Figure 1 conceptual framework

Figure 2 sampling procedure

Figure 3 coded ARV regimen

Figure 4 Pie chart showing the proportion of client's reasons for non-adherence of PLWHA involved in the study

Abstract

Background The number of people living with HIV worldwide continued to grow in 2012, reaching an estimated 34million .Sub-Saharan Africa remains the region most heavily affected by HIV, In Ethiopia, the ART program started with a fee-based in 2003 then decentralized and free ART program in the Country was lunched since 2005. Non-adherence to the proposed antiretroviral regimen is considered to be one of the greatest dangers to the response to treatment.

Objective The main objective of this study is to determine the antiretroviral treatment adherence and its associated factors among patients living with HIV/AIDS on combination antiretroviral therapy.

Methodology: This is an institutional based cross sectional study. The study was conducted in Akaki kality sub city (Addis Ababa) from May to July. The study participants were selected by using systemic random sampling technique. Data was collected in three health center that is giving ART service. Of Total of 2698 client 633 client whom currently on ART follow up was sample study. Data was coded and entered in to Epi-info version 3.5.1and exported to SPSS version 20 for analysis. Descriptive statistics was used to generate proportion and odd ratio and confidence interval were calculated to assess the strength of associations of factors with adherence. logistic regression analysis was used to adjust or control the effect of different factor.

Results: 88% percent of patients were adherent by self report in the month before the assessment. 12% percent of patients were non adherent by self report The major reasons reported for non-adherence were, Twenty one percent of patients asserted that they missed their doses due to being away from home or having simply forgotten; while 19.7% listed run out of medication as the primary reason for treatment non-adherence. Other barriers to treatment included: being sick (15.8%), being busy (11.8%), went holly water (9.2%), being depressed (7.9%), self problem in taking medication (6.6%), being sleep (5.3%), work load (3.9%), confusion about dosage direction (3.9%) , fear of disclosure (2.6%), too many pills (1.3%), toxicity of the drug (1.3%), taking a drug remind me of my HIV (1.3%), people told the medicine is not good (1.3%) .

Associated factors of adherence in the multivariate analysis controlling for independent variable were: not being depressed, education, having social support and being closer to home from institution during follow up.

Conclusions The adherence rates found in this study are comparable to those of other studies in developing countries but these rates are still low for good clinical outcomes. Since adherence is a dynamic process and patient's behavior can change over time, there is also a need to have a follow up design, which would yield a more valid average measure of adherence as well as its determinants than a cross-sectional self-reported adherence assessment. Programs and clinical efforts to improve medication taking in the study setups should strive to manage depression with a multidisciplinary approach, Educational programme should be developed focusing on the people living with HIV-Aids.

INTRODUCTION

1.1 BACKGROUND

. The number of people living with HIV worldwide continued to grow in 2012 reaching an estimated 34 million. Sub-Saharan Africa remains the region most heavily affected by HIV. In 2011, sub-Saharan Africa accounted for 67% of HIV infections worldwide and 68% of new HIV infections among adults. The region also accounted for 72% of the world's AIDS-related deaths in 2011. World Health Organization (WHO) recommendations on the use of antiretroviral therapy in resource-limited settings recognize the critical role of adherence in order to achieve clinical and programmatic success (1).

Ethiopia's initial response to the epidemic had primary focus on prevention with little attention to treatment. With the introduction of antiretroviral therapy (ART) in resource-limited settings in early 2000's, Ethiopia was among the first few African countries to introduce ART in 2003, in selected health facilities following the issuance of the National antiretroviral drugs (ARVs) supply and use Policy in 2002. The Ethiopian free ART scheme was launched in 2005(2).

HAART (highly active antiretroviral therapy) results in improved survival, clinical, immunological and virological response. Adherence to HAART is one of very important factors which determine treatment success and occurrence of viral resistance (4). Numerous report have documented that the key to the success of new HAART is the ability and willingness of HIV positive individuals to adhere to complex ARV (antiretroviral) regimen and at least 95% adherence is required for ARV regimen to be fully effective and to avoid the emergency of resistance strain of virus (5).As a matter of fact attaining high level of adherence is a serious concern today in the world (1).

1.2 STATEMENTS OF THE PROBLEM

non-adherence to the proposed antiretroviral regimen is considered to be one of the greatest dangers to the response to treatment on an individual level and the dissemination of resistant viruses on the community level [3].

As a treatment of HIV infection with antiretroviral medications become reality in developing countries, adherence to antiretroviral treatment regimens also become a bigger issue that's needs to be addressed in this setting. Perfect adherence of at least 95% is needed for patient on antiretroviral therapy to keep the viral load at undetectable level as far as possible and to maintain the functionality of the the immune system. Several regimen related issues still need to be overcome to achieve optimal adherence.

Adherence plays an important role in the effectiveness of ART because individuals who demonstrate lower levels of adherence are at greater risk for increased levels of morbidity, treatment failure, and the development of drug resistant forms of HIV. Viral suppression may still occur with lower levels of mean adherence, from 54% - 100%, to potent regimens. When viral load rises, risk of transmission increases and the quality and longevity of life decreases (6, 7).

Introducing ART to sub-Saharan Africa was a topic of hot debate just a few years ago. Concerns about adherence and subsequent development of drug resistance, poor infrastructure, logistic and human capacity, and cost-effectiveness were the major issues. In Ethiopia, non-adherence to the proposed antiretroviral regimen is considered to be one of the greatest dangers to the response to treatment on an individual level and the dissemination of resistant viruses on the community level [7].

At present there are many health centers that provide ART service. The experience in implementing ART service identified the following major factors as bottlenecks to adherence treatment such as: Poor infrastructure, Patient and physician relationship, drug side effect, depression, long waiting time ,stigma, alcoholism, severity of illness ,lack of support, pill burden, poor patient information and knowledge and poverty.(5)

1.3 RATIONALE OF THE STUDY

Adherence is dynamic process and little is known about the rate and predictors of adherence in Ethiopia. Although ART program were decentralized to health centers little is known about the rate and factors affect adherence.

In addition to population in akaki kality sub city population, long distance heavy truck car drivers and HIV positive client from different area whom believe on using holly water (that is located in kality and mojo area) in order to cure HIV/AIDS are also ART customers of those health centers.

In this study it is attempted to indicate magnitude of adherence of PLWHA (people living with HIV/AIDS) to ARV and associated factors of adherence to PLWHA in the study area, so as to make lessons for future undertakings at national level.

It is expected that the findings generated from this study will contribute to knowledge and understanding of non-adherence to ARVs and be useful in developing interventions that will be undertaken to address ARV adherence. The data collected will be used by organizations involved in this area to deal with the problems associated with non-adherence.

2. LITERATURE REVIEW.

In people with HIV infections and prescribed a combination of ARVs treatment adherence levels of > 95% are required to maintain virologic suppression. An innovative and culturally sound strategy for enhancing adherence to ART is highly recommended because of the lifelong nature of the therapy. However, actual adherence rates are often far lower; most studies show that 40% to 60% of patients are < 90% adherent. Adherence also tends to decrease over time and in a number of studies patients offers a range of reasons for non-adherence.(8)

There are several known methods to achieve readiness to initiate antiretroviral therapy and maintain patient adherence. One of the method is to negotiate a plan or regimens that the patient understand and to which the patient is committed, taking time to ensure readiness for the first prescription, use of memory aids such as written schedules, pill boxes and medication organizers (8).

There are predictors of good adherence as well, such as availability of emotional and practical life support, the ability of the patients to fit the medications into their daily routine (8).In clinical practice non adherence to medication is wide spread among patients with chronic disease and shift to combination therapies for treating HIV infected individual has increased adherence challenges for both patients and health care providers (9).

2.1 Situation of antiretroviral therapy adherence

Globally

The use of antiretroviral in the USA has decreased AIDS related morbidity and mortality by up to 90% and significantly affected the trajectory of the epidemic. A prospective study conducted by American family physician to examine factors affecting adherence to HIV medication regimen the average adherence to the medication regimen was 71percent of all prescribed doses (10).

Research conducted in India Bangalore suggests ARV is treatment of choice & adherence is important factor in treatment failure and development of resistance. The study also revealed adherence rate was 60.4%. Of 39.6% who had missed a medication, approximately 50% had missed a medication in the last week& 40% had because they run out of medication. Missed medications means not taking a prescribed medication on any day as prescribed by the physician. Of the patients who had run out of tablets all lived more than 250 km from the clinic.

This may imply that there is a lack of availability of medicines in some geographical areas. It is difficult to understand why medication adherence should be less in this sample although it may have something to do with the criteria for measuring medication adherence. According to the study only those with 100% medication adherence were considered as adherent whereas in other studies the level of medication adherence is calculated and a level above 95% is taken to be adherent i.e. missing one medication in twenty is acceptable(9).

An operational research was conducted in Thailand, where eighty-eight adults and children Started triple drug antiretroviral treatment. Most have advanced disease in the first six months of treatment almost all patients saw an improvement in their CD4 cell count. Seven patients in the study developed serious drug side effects, requiring a change in Treatment. However, milder Side effect (E.g. nausea, diarrhea, headache, muscle pain) often improved within two to four weeks of initiating antiretroviral treatment. Adherence was improved by educating patients about side effect, and developing a Plan to help patients cope with side effects (11).

A research conducted in Peru, barriers of adherence were simply forgot(36%)stigma(23%) financial constraint(13%)& others(28%) like lack trust in medical provider, felt hopelessness & antiretroviral therapy causes unwanted effect(12) .

Adherence situation In Africa

A qualitative study in South Africa suggested, barriers to ART adherence were individual factors like alcohol use, being away from home, fear of stigma, use of traditional medicine, lack of belief in the existence of HIV, old age and illiteracy .The key facilitators were social support, belief in the value of treatment, belief in the importance of one's own life to the survival of one's family, and the ability to fit ART into daily life schedules (13).

A Study in Tanzania revealed the majority of patient had basic understanding of adherence. Misconception about taking medication after alcohol use. Barrier to adherence were use of alcohol, unavailability of food, stigma, disclosure concern and clinic dispensing too few pills (14).

A Study in Kenya reported, non-adherence rate was 18%. The main reason for therapy was being busy and forgetting. Seventy two (18%) respondents were non-adherence based on CASE adherence method, while 74 (18%) reported missing at least one dose of therapy per week (< 95% adherence) . Adherence to HAART among respondents differed significantly at p-value < 0.05 by age (p = 0.017), difficulty fitting therapy in own daily schedule (p = 0.006), social support (p =0.015), period on therapy (p = 0.002), self report missed therapy (p = 0.001), proximity to clinic where respondents refilled (p = 0.003) and time spent at clinic per visit (p =0.000) by multivariate analysis (15).

A Study in Mozambique also revealed that economic barrier, poor relation and conflict with health worker staff are also some of barrier of adherence (16).

The majority of the studies investigating the relationship between adherence and family or social support found that lack of support was an important risk factor for non-adherence (17, 18, 19, 20, 21, 22, and 23)

The Ethiopian situation

A study conducted in Jimma suggests that adherence rate were 72.4% based on self-report. Reason for non adherence was run out of medication (27%), being away from home (21.2%) and being busy (21%) . Patients who got family support were 2 times [2.12(1.25-3.59)] more likely to adhere than those who didn't get family support as an independent predictor of overall adherence (24).

A study in North West Ethiopia reported, level of non-adherence were 17.3% and non-readiness to HAART were 13.9%. main reason for non-adherence are drug side effect(31%) and other health problem 21.8% and major reason for non-readiness to HAART are anxiety(44.3%) and hopelessness 27.1%(25).

A study conducted in Addis Ababa reported, knowledge concerning ART adherence was found to be 81.2% but knowledge concerning benefit and eligibility of ART was found to be 44.5% and 45.1% respectively. Reasons given for non-adherence were being busy 33.9%, being away from home 27.5%, felt sleep (16%), felt depressed (4.6%), stigma 4.6%. associated factors of adherence in the multivariate analysis controlling for independent variable were: having regular follow-up, not being depressed, having no side effects, fitting a regimen to the daily routine, being satisfied with the relationship with health care providers, and the perception that doctors were capable and had access to assistance and reliable pharmacy. (26).

A study conducted in two military hospitals (Debrezeit and Addis Ababa) the average adherence rate to ARV medication was 82.8% of all prescribed doses. Keeping clinical appointment, using Memory aids and educational levels were associated with increased adherence (27).

In general, adherence rate in this study is 88%, which is higher than adherence rates in developed country but lower than that of optimum adherence level(>95%) to maintain virologic level. Associated factor were being away from home, run out of medication, being sick, being busy, , being depressed, self problem in taking medication, being slept, work load, confusion about dosage direction, fear of disclosure, too many pills, toxicity of the drug, taking a drug remind me of my HIV, people told the medicine is not good. But most of the study was done with small sample size. Since adherence is dynamic process and patient’s behavior can change over time previous studies were mainly done only in hospitals but health centers that are giving ART service were not included in the previous study.

Conceptual framework

Conceptual framework on the assessment of adherence on ART among PLWHA.

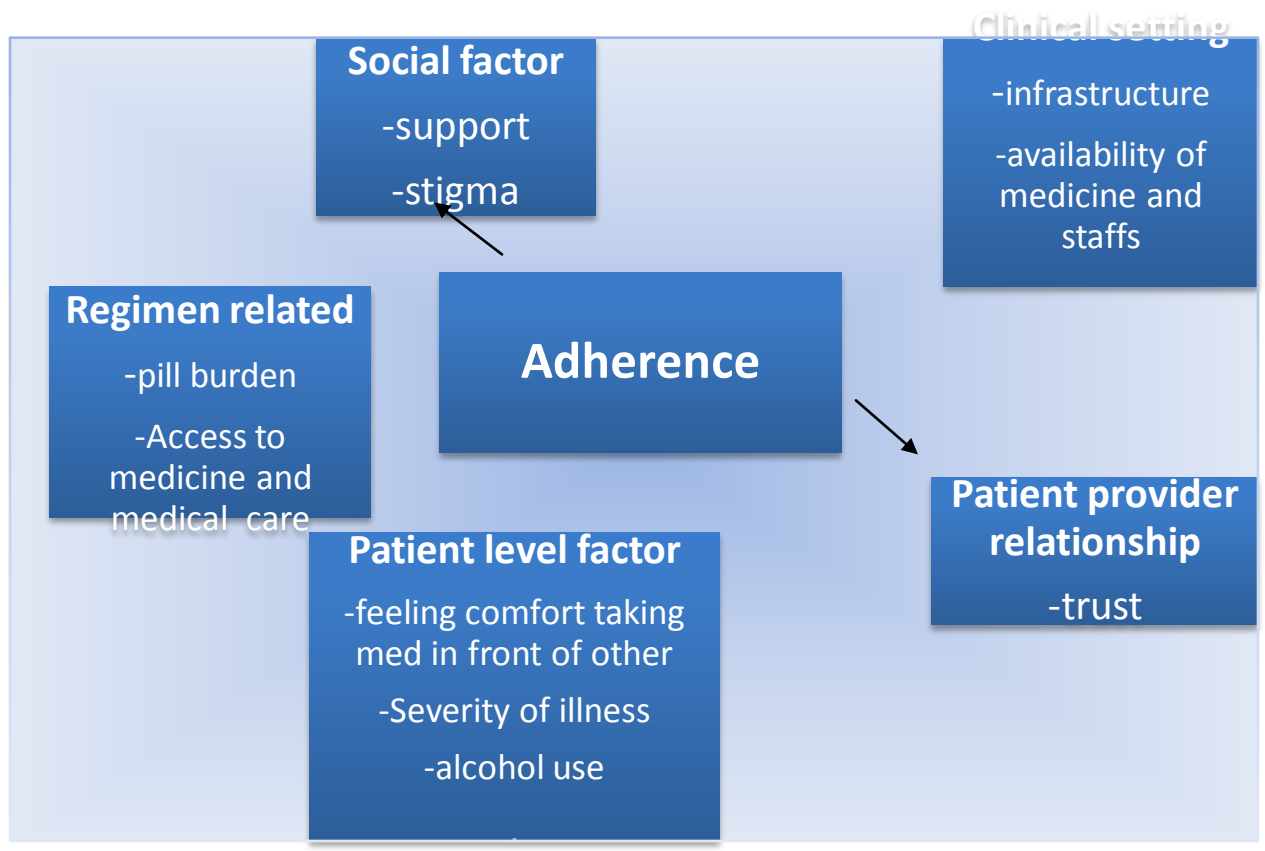


Figure 1 conceptual framework

3. OBJECTIVE

3.1 GENERAL OBJECTIVE

The main objective of this study is to determine the Magnitude of antiretroviral treatment adherence and its associated factors among patients living with HIV/AIDS on combination antiretroviral therapy in Akaki Kality sub city.

3.2 Specific objective is to:

- Determine the current ART adherence rate among PLWHA on ART in Akaki Kality sub city.
- Identify the factors associated with ARV adherence in Akaki Kality sub city.

METHODOLOGY

1. STUDY DESIGN

A cross sectional study was conducted in health centers found in akaki kality sub city from May to July 2013.

2. STUDY AREA AND SETTING

The study was conducted at antiretroviral therapy units in **Akakikality sub city** (Addis Ababa) particularly the ART Unit in Kality health center, Akaki health center and Saris health center from March 2013 to May 2013. Health centers are the only health facility in the sub city that are giving ART service. Akaki kality sub city is one of the sub city found on Addis Ababa with total population of 181,202.

Kality health center serves most of the patients on ART follow up. There were 1073 Patients on ART follow-up in health center ART unit. The ART-unit is known as ‘‘Room No 29’’ by all the Staff and clients visiting the health center. Three health officer and one BSc Nurse were assigned in the unit.

In Akaki health center there were 1000 Patients on ART follow-up in ART unit. One health officer and two Bsc nurse were assigned in the unit

In Saris health center there were 625 Patients on ART follow-up in ART unit. One health officer and two Bsc nurse were assigned in the unit

In addition to population in akaki kality sub city population, long distance heavy truck car drivers and HIV positive client from different area whom believe on using holly water (that is located in kality and mojo area) are also ART clients of those health centers.

3. SOURCE POPULATION

People living with HIV/ AIDS (PLWHA) who were on combination ARV treatment and on follow up in Akaki Kality health centers.

4. STUDY POPULATION

The study population constituted all PLWHA on combination ARV therapy and on follow up in health centers in akaki kality sub city ART-Units.

5. EXCLUSION AND INCLUSION CRITERIA

Inclusion criteria

Those aged at least 18 years, who gave informed consent and were free of neurocognitive impairments.

Exclusion criteria

HIV positive individual on HAART who were unable to hear, unconscious, mentally disabled and newly started ART and took less than 6 month were excluded from the source population.

6. SAMPLE SIZE DETERMINATION

Sample size of the study was determined based on the finding on a study done in jimma, south west Ethiopia. According to the finding magnitude of antiretroviral treatment adherence were 72.4%. Run out of medication (27%) was the most commonly reported associated factor of ART adherence mentioned (23). So sample size is calculated by the formula given below:

$$n = \frac{(z_{\alpha/2})^2 P(1-p)}{d^2}$$

Where: -n= sample size

$Z_{\alpha/2}$ = critical value of 95% confidence level of certainty (1.96)

d= precision (marginal error) =0.05

P=proportion (prevalence)

For specific objective one

Magnitude of ART adherence were 72.4% with 95% confidence level (1.96) sample size calculated as follows

$$n = \frac{(1.96)^2 * 0.724(1-0.724)}{(0.05)^2} = 306$$

Additional 10% non-respondent rate will consider: $n' = 306 + (306 * 0.1) = 336$

For specific objective two:

Sample size was determined by using Epi-info version 7, sample size and power for cross sectional study. Confidence interval (confidence level, CI or $1-\alpha$) =95%

Power ($1-\alpha$) =80% highest associated factor from the study were run out of medication which is 27% and calculated as follows

Ratio (exposed to unexposed) =1:1

% outcome in unexposed group 27%

%outcome in exposed group 17%

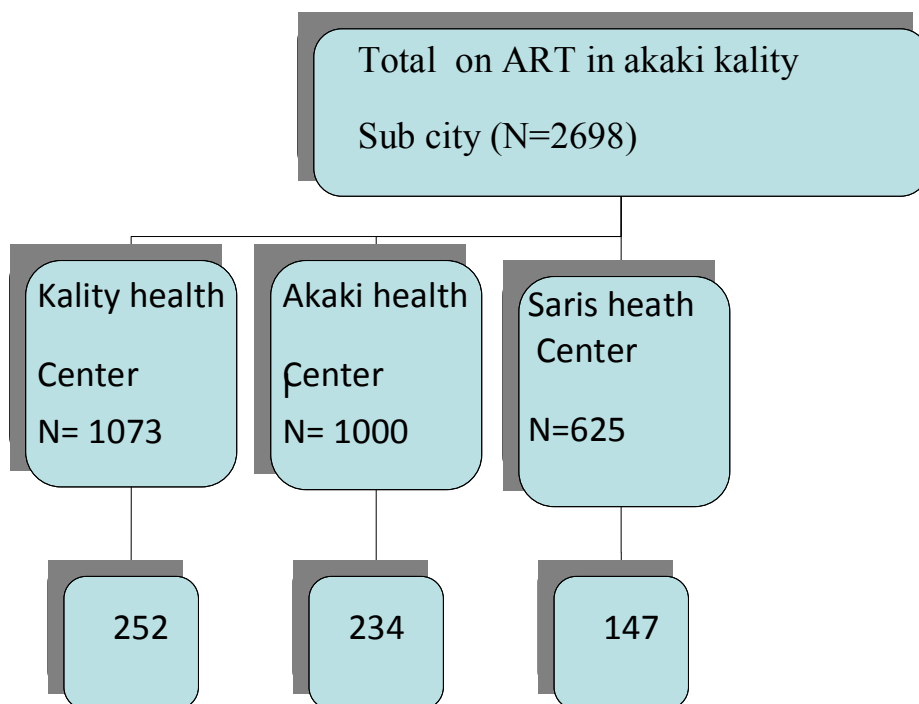
Additional 10% non-respondent rate

N=633

The sample size with the highest number of study participants (633) was included in the study.

7 SAMPLING PROCEDURE

From Probability sampling methods systematic random sampling technique was used to select study subjects from all selected health center. Sample for each health center was divided proportionally based on the number of clients in their ART clinics who are currently on ART follow up.



Total 633 clients currently on HAART in ART clinics of the selected health center

Figure 2 sampling procedure of the study

8. Data collection procedures

Standardized tool with minor modification were used to collect information. Firstly, the questioner was customized for this study in English language and then translated to Amharic language by translator. For the survey HIV infected patient who are on ART followed in ART unit at selected health centers from March, 2013 for the subsequent two month was invited and asked whether they agreed to participate in the questionnaire based interview.

Clients were recruited by their caregivers at the ART unit and asked to contact the study nurse in her/his office. Data were collected in a separate room to avoid introduction of bias during interview.

9. Data quality control

The training manuals were developed to provide a half days training before the data collection for the five data collectors who are degree Nurses/Health officers who had trained compressive ART. The data collectors were from health centers. The data collectors for each health centers were not from the same health center. Training was provided on sampling procedure, inclusion criteria, ethical consideration, and data collection procedure including how to approach study participants to get reliable results. And the supervisor who is MPH holder supervises the data collectors and collect filled questionnaire and checked for completeness on daily bases.

10. OPERATIONAL DEFINITION

ADHERENCE- the extent to which a patient continues the agreed-up on mode of treatment or intervention as prescribed. The definition is based on number of dose missed in specified time period, self- report and an appointment missed.

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

ART-Units-A unit in health center responsible for counseling, investigating, and treating HIV infected persons with antiretroviral drugs

Combination Therapy-Treatment of HIV infected people with three or more antiretroviral drug

HAART-It is a combination therapy, known as highly active antiretroviral therapy.

MEMS-Medication Event Monitoring System-it is a pill bottle cap containing a microchip that records each instance of bottle opening.

Resistance- reduction in a pathogen's sensitivity to a particular drug-resistance is thought to result usually from a genetic mutation.

11. Data processing and analysis

Data was coded and entered in to Epi-info version 3.5.1 and exported to SPSS version 20 for analysis. Descriptive statistics was used to generate proportion and odd ratio and confidence interval were calculated to assess the strength of associations of factors with adherence. Logistic regression analysis was used to adjust or control the effect of different

factor. only variables that were significantly associated on bivariate analyses were entered in the multiple logistic regression models. $P < 0.05$ was considered statistically significant. The results were reported as adjusted odd ratios (AOR) and 95% confidence intervals.

12. Variables of the study

12.1 Response (**dependent**) variable

The response variable is **adherence**

12.2 Independent variables

Age

Religion

Support

Distance

Occupation

Work load

Educational level

Belief in efficacy of medication

Drug side effect

Substance abuse

Run out of medication

Alcoholism

Depression

Patient and physician relation ship

Keeping clinical appointment

Feeling comfortable in taking medication in front of others+

Severity of symptoms or illness

13. Dissemination of Result

The final result of this study will be disseminated to Addis Ababa University, FMOH, AACAHB with respective health centers and other governmental and non-governmental organizations that are concerned with the study findings. The finding of this study will be published in relevant scientific and popular journal as appropriate.

14. Ethical Consideration

Ethical clearance was obtained from AAU, school of public health; informed consent was obtained from each study subject prior to the interview after the purpose and process of the study was explained to respondents. Confidentiality of the information was assured and Privacy of the respondent was maintained.

Results

Sociodemographic and psychosocial variables

A total of 633 clients were invited who came to the ART units for follow-ups to the structured interview questionnaires of the survey after giving informed verbal consent. This is 100% response rate.

The study participants ranged in age from 18 years to 72 years (median 33 years). Thirty percent (185) male and seventy percent (448) female subjects participated in the study. Eight-eight percent belong to Amhara and Oromo ethnic group i.e. 48% and 40.8% respectively. Eight three percent of the participants were Orthodox, followed by protestant (7.6%), Muslim (7.4%) and catholic (1.6%). 45.3%of the patients interviewed were married. Twenty six percent were illiterate, 25% elementary and 40.8% were diploma and above. Sixty three percent were employed and work active with 15% reporting to have less than 500 birr per month income, 58.6% income between 500 and 1000 birr. Thirteen percent reported active substance use, among the active substance users 59.3% drunk alcohol, 24.4%chewed chat and 15.1%Smoked cigarettes while on HAART.

Some 22% lived alone while the rest 75.5% lived with someone close. (table1) 53.1% have social support either from family, peers and friends and 46.9%Percent claimed to have no social support and. (77.6%) had disclosed their sero status to their partners and other close relatives.

Based on the Beck's depression inventory, 16.3 % were found to be depressed having score of > 14.

Table1: Basic socio demographic and psychosocial variables of the cross sectional survey at akaki kality health centers, A.A, 2013. (26)

<u>Variable</u>	<u>frequency</u>	<u>(%)</u>
Sex(n=633)		
Female	448	70.8
Male	185	29.2
Age(n=633)		
18-24	51	8.1
25-45	475	75
>45	107	16.9
Marital Status (n=633)		
Married	287	45.3
Single	127	20.1
Separated	87	12.7
Widow	132	20.9
Education(n=633)		
Illiterate	164	25.9
Elementary	158	25
Secondary	229	36.2
Diploma and above	29	4.6

Income (Birr) (n=633)		
<500	95	15
501-999	371	58.6
>1000	167	26.4
Work/Employment(n=633)		
Work active/Employed	400	63.2
Unemployed	221	34.9
Active Substance Use(n=633)		
Yes	84	13.3
No	549	86.7
Depression (n=633)		
Yes	103	16.3
No	530	83.7
Disclosure of sero status(n=633)		
Yes	491	77.6
No	142	22.4
Perceived Self Efficacy(n=633)		
Yes/No Doubt	286	45.2
No	346	54.7
Not Sure	1	0.1
Distance from facility(n=633)		
≤50km	462	73
>50km	171	27

Treatment, Clinical, and Health Care System related variables

Among the participants 44.8% had an adverse reaction to one or more of the ARVs they were prescribed, The rest (55.2%) claimed no adverse reaction.

Among the numerous adverse events mentioned, skin rash and itching accounted for 22.8%, nausea for 20.4%, vomiting for 16.8%, headache 16.5%, GI intolerance 10.9%, anemia 4.9%, depression 4.9%

When they had the problem 74.2% consulted their doctors immediately, 17.1% discontinued treatment till their date of appointment 7.3% discontinued all their drugs totally.

Thirty-two percent of the respondent were taking AZT+3TC+NVP, 18% on AZT+3TC+EFV, 14.7% on TDF+3TC+EFV, 13.6% on TDF+3TC+EFV and 9.8% on D4T+3TC+EFV were on ART drug regimen (figure 3). 7.6% of the respondent have previous history of hospital admission.

Only 10.6% respondent have history of <6 month duration on HAART, the rest (89.4%) have history of >6 month duration on HAART.

The proportion of participants having good knowledge on issues concerning importance of ART adherence was found to be low (45.8%) and 86.1% have committed and convinced before start ART.

Fifty four percent had no discomfort when taking their drugs in front of others, though 45.2% had some discomfort and the rest not sure.

Of types of memory aids 66.4%use watch bell, 4.6%pill box, 3.6% written schedule and rest 25.6% use nothing in order to take medication.

Ninety five percent the regimen was convenient and easy to fit to their daily routine, but 4.6% found it inconvenient and difficult to fit to their daily routine.

Most of the patients interviewed (97.6%) stated they had an excellent relationship with health care professionals and (94.2%) felt they had good open discussion and agreement with their doctors. 96.1 % of the patient claimed that their doctors were capable and they trusted them. Ninety five percent and 94.6 % were satisfied by the benefit they obtained from the ARV drugs and by their ART unit appointment and confidentiality respectively.

52.9%, 30.5% and 16.6%of participant visiting the ART unit every month, 2 months and 3months respectively.

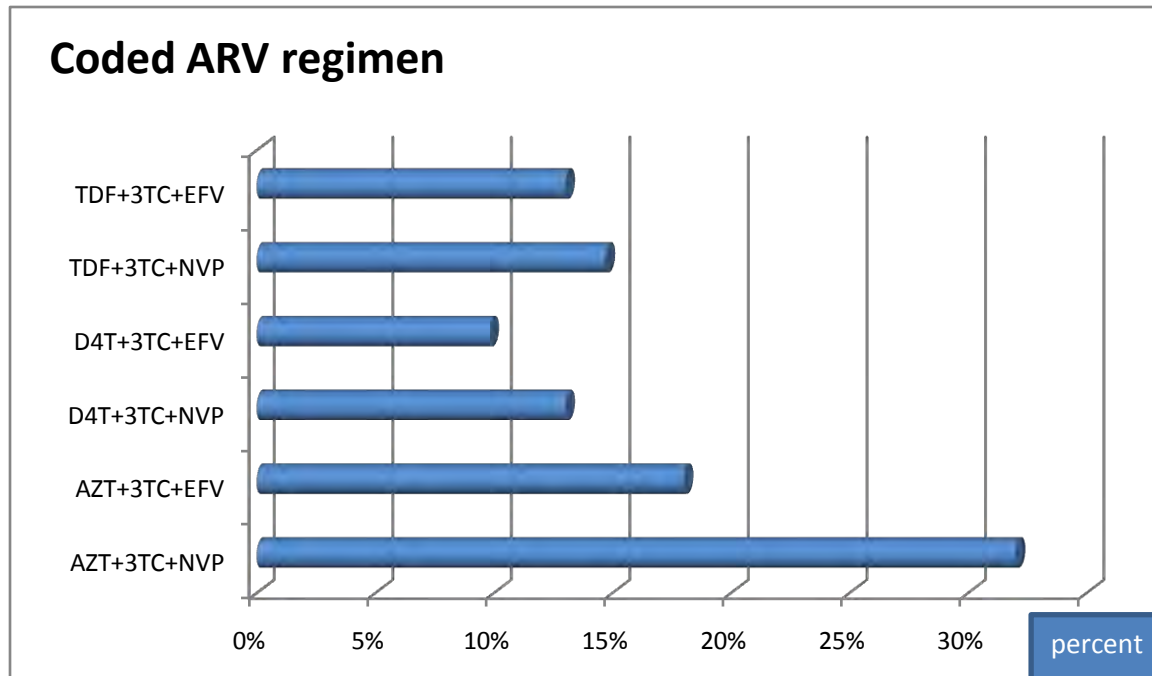
Eighty one percent of participants faced no problem so far to obtain the professional assistance they need from the health units, 75.2% also assured they had access to reliable pharmacies any time they want. At the time of survey 68.9% had at least one child under their care.

Table 2: Treatment, Clinical, and Health Care System related variables of the cross Sectional survey at akaki kaliti centers, A.A, 2013. (27)

Health Care issues	frequency	(%)
Treatment Duration (months)(n=633)		
1-6	67	10.6
7-12	149	23.5
13-24	76	12
25-36	117	18.5
>36	224	35.4
Perceived Satisfaction by the relationship with the *HCP (n=633)		
Yes	618	97.6
No	15	2.4
Perceived Access to reliable pharmacy(n=633)		
Yes	476	75.2
No	157	24.8
Not sure		

* HCP-Health Care Providers

Figure 3- Distribution of coded ARVs regimen prescribed for the participants in akaki kality health centers, 2013.



Patient reported rate of adherence and the reasons for non adherence.

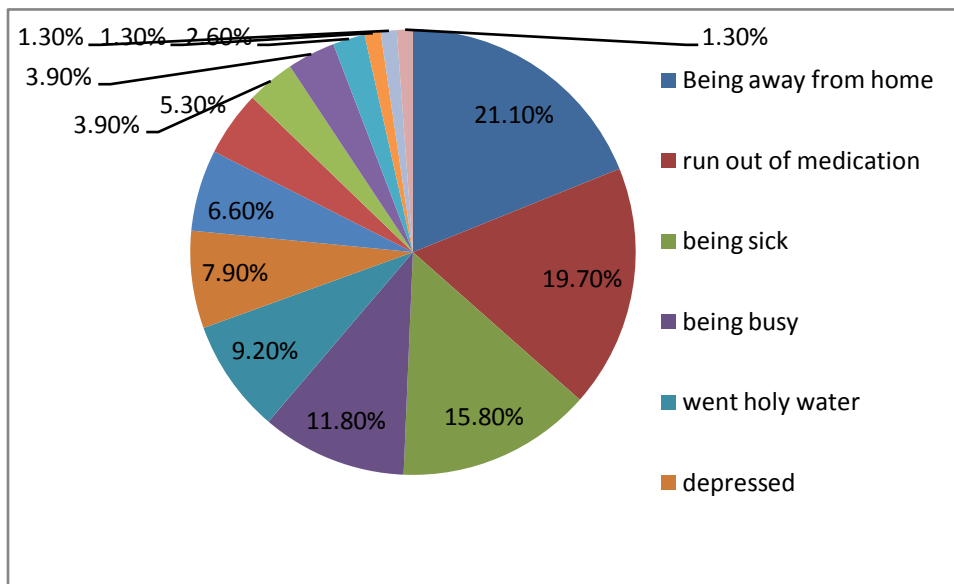
Adherence assessments to ARV therapy are summarized in Table 3- eighty eight percent of patients were adherent by self report in the week before the assessment, based on the definition outlined in the methods above and the rest 12% were non adherent.

The reasons cited by the patients for dose skipping while on treatment or their barriers to adherence were many. Twenty one percent of patients asserted that they missed their doses due to being away from home or having simply forgotten; while 19.7% listed run out of medication as the primary reason for treatment non-adherence. Other barriers to treatment included: being sick (15.8%), being busy (11.8%), went holly water (9.2%), being depressed (7.9%), self problem in taking medication (6.6%), being sleep (5.3%), work load (3.9%), confusion about dosage direction (3.9%), fear of disclosure (2.6%), too many pills (1.3%), toxicity of the drug (1.3%), taking a drug remind me of my HIV (1.3%), people told the medicine is not good (1.3%) (Fig 4).

Table3: Distribution of participants on Adherence by Self-report in akaki kality health centers, 2013.

	Adherent No	(%)	Non-adherentNo	(%)	Total
Previous day	621	86.9	10	13.1	633
Past 3 days	620	85.5	11	14.5	633
Past 7 days	578	91.3	55	72.4	633

Figure4 –Distribution of participants on reasons for missed doses.



Variables associated with adherence: Univariate and Multivariate Logistic Regression Analysis.

Non adherence was commoner among those; who were depressed, distant from health facility, those illiterate and poor social supports.

The odds of non adherence among illiterate was 0.12 as high as those who attended tertiary education level.

The odds of non-adherence among those didn't have social support is 0.56 as high as among those who have social support.

The odds of non-adherence among those their residency far is 0.46 as high as among Those who have come from a distance ≤ 50 KM.

The odds of non-adherence among respondent who have depression was 0.48 as high as among non depressed.

Table 4 shows the crude ORs for variables identified as correlates of adherence, which were statistically significant in the univariate binary logistic regression analysis.

Those who were depressed, distant from health facility, illiterate and poor social supports were statistically significant with adherence in univariate analysis. All the other variables included under socio demography, individual, health status/clinical and environmental/system related variables were not found to be significantly associated with adherence at $P < 0.05$.

Significantly associated variables with ARV adherence in the univariate binary logistic regression analysis at $P < 0.05$ were also reevaluated again separately with adherence as a Dependent variable and controlling for the effect of socio demographic variables (age, sex, Religion, ethnicity, marital status, educational status, employment, income, and living Situation). All the variables found to be associated with adherence on the univariate analysis remained significantly associated with adherence on the multivariate analysis (Table 4).

In the univariate logistic regression analysis poor HAART adherence practice was common among respondents who were illiterate [OR = 0.157, CI = 0.033, 0.737, $P = 0.019$], who were far from health facility [OR = 0.575, CI = 0.313, 0.957, $p = 0.05$], who were no social support [OR = 0.578, CI = 0.321, 0.961, $P = 0.05$], who have depression [OR = 0.490, CI = 0.280, 0.859, $P = 0.013$].

After adjustments for multivariate analysis model, a total of 4 variables that were associated in the univariate model were also remained significantly associated.

As shown below in table –4, in the final adjusted multivariate model, independent predictors of poor HAART adherence were the participants who had illiterate [OR = 0.111, CI = 0.023, 0.532, $P = 0.009$], who were far from health facility [OR = 0.467, CI = 0.244, 0.892, $p = 0.021$], who were no social support [OR = 0.560, CI = 0.328, 0.956, $P = 0.034$], who have depression [OR = 0.481, CI = 0.260, 0.890, $P = 0.02$].

Table4: Univariate and Multivariate Logistic Regression analysis: variables associated with adherence

<u>Variables</u>	HAARTAdherence		Adjusted OR	P value
	YES	NO		
Depression yes	83	20	1.00	
No	474	56	0.481 (0.260, 0.890)	
distance <50	400	62	1.00	
>50	157	14	0.467 (0.244, 0.892)	
support yes	293	43	1.00	
No	264	33	0.560 (0.328, 0.956)	
Education illiterate	124	40	0.111 (0.023, 0.532)	
Read and write	36	17	0.070 (0.013, .364)	
Elementary	149	9	0.600 (0.113, 3.169)	
Secondary	221	8	0.763	
Diploma and above	27	2	1.00	

Discussion

This study found an overall prevalence of HAART adherence by self report, 557(88%) of the sample taken _ 95% of their prescribed ARV doses in the past one month duration from the day before interview.

The result of the present study revealed that the average adherence rate to antiretroviral medication was lower than study done in south west Ethiopia which is 95% adherent with >95% of prescribed dose (24) and considerably lower than the 90 to 95 percent adherence rate required to prevent treatment failure and to prevent viral resistance (29).which is comparable to adherence in other HIV medication studies but greater than the finding of a study conducted by American Academy of Family Physician (28).

Average non adherence rate was 12% which is less than estimated of average rate of non adherent to antiretroviral therapy (29).

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 (38), 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 (38).

In this study, HAART adherence was assessed through patient's self-report method. Although, Self-reporting method considered overestimating medication adherence rate (32), 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 (32), and this method has Frequently been employed in antiretroviral research due to its practicality, low cost, Readiness to obtain the desired information, and to identify patients at risk for non-adherence (39).

In this study, variety of barriers to treatment adherence were reported from the respondents: of the total participants for(21%) of them being away from home or having simply forgotten, (19.7%) of respondent being run out of medication,(15.8%)of respondent being sick (11.8%) of respondent being busy, (9.2%) of respondent went holly water ,(7.9%)of respondent being depressed ,(6.6%)of respondent self problem in taking medication,(5.3%)of respondent being slept,(3.9%)of respondent work load,(3.9%)of respondent confusion about dosage

direction(2.6%) of respondent fear of disclosure,(1.3%)of respondent too many pills,(1.3%)of respondent toxicity of the drug,(1.3%)of respondent taking a drug remind me of my HIV,(1.3%)people told the medicine is not good.

23

The reasons patients cited for missing ARV doses in our study were almost identical to what is found by many others. among participants in the adult AIDS clinical trial group (AACTG) study (36), 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%) . almost the same percentage (64%) cited forgetting in a study by researchers at John Hopkins University (37).

In the final adjusted multivariate analysis of this study, a better adherence to HAART was observed among the respondents who had — no feelings of depression in the last one month, their residence is not far from health facility, those who attended higher educational level and who have good social support.

Social support was significantly associated with adherence in our study, social Support in general may enhance adherence, either directly (through encouragement, reassurance, reinforcements, systemic cues, bolstering of competence, and motivation) or indirectly (by buffering the effect of those variables that might interfere with adherence, e.g. life's stresses, anxiety, and depression).Social support must also be conceptualized in terms of not merely availability but also its perceived adequacy, support may not be considered helpful unless the individual perceives it as being supportive.

Our data suggested that those who have good social support have more adherent than who doesn't have social support.

Depression, which is related one way or the other with social support as mentioned above, was found to be significantly associated with adherence. Depression has been shown to be associated with devaluation of self-worth, lack of mastery of one's environment, and unhealthy self-caring behaviors, including inability to transform information into effective self-care strategies (33).

In a previous study of HIV infected patients, depression was significantly associated with non adherence With Zidovudine therapy (34). The lack of fighting spirit, loss of motivation, and Hopelessness was identified as characteristics of the patients at risk of non-adherence with therapy.

Distance in this study also significantly associated with adherence. The odds of adherence among those who came from a distance of >50Km was about 0.46 times lower to adhere than that among those who came from greater than 50Km. Distance may have an effect on the timing of appointments for patients. Patients from far away may not have frequent and regular follow up, probably due to transport and time costs. Lack of frequent follow up may lead to obtaining less

information about adherence. This suggests that patients would benefit if ART services were available in more institutions located closer to Beneficiaries' homes.

Education is found to be associated with increased adherence, as educational level increase the more likely to be increased adherence. There was statistically significant difference in higher education level when comparison was made among illiterate [OR= 0.111 CI=0.023, 0.532,p=0.006] .

24

In agreement with these findings, some studies also suggest that adherence to HAART tends to increase with participants who: free of depression (34), those their residency is near health facility, who have good social support and who attended higher educational level. This agrees with the results from recent study done in the Southern region (Yrigalme Hospital) & at Addis Ababa civil hospitals & the study done at Oromia region (Adama & Jimma Hospital) indicated greater part of the variable mention above in this study had showed association with adherence(26,27).

Study done in bishoftu hospital, east shoa also suggests that improved adherence to HAART was observed among the respondents, who had adequate social support & satisfied with the social support they got, satisfied with the health care system, accessible distance of ART unit setting with regards to distance, had no children under their care & dependability, no history of active substances use, minimal /manageable or no adverse influence of ART education & good knowledge about ART eligibility (39).

However, the characteristics, such as self-efficacy of treatment, history of active substances use, which have ARV drug side effect, good knowledge about ART eligibility, free access to pharmacy service at any time, Perceived Satisfaction by the relationship with the health care provider were not shown any significant relationship with HAART adherence in this study; inconsistently with results of other studies (39).

Strength and limitation of these study

Strength

- The presence of a locally validated Beck's Depression Inventory and social support assessment tool has enabled us to assess depression and social support in a more valid way.
- Data collected by currently practicing ART clinician.
- Multivariate analysis made to control the effect of confounder.

These study have the following **limitation** that must be acknowledged

- First a ~~gold~~ "gold standard" for assessment of adherence does not exist, in this study generally adherence was measured using self-report; studies suggest self-report tends to overestimate adherence. Nevertheless, structured self-report has been reliably associated with both objective measures of adherence and viral load.
- Another limitation of our study is that combination methods like FGD that will strengthen the study weren't used due to non willingness of participant because of stigma.
- Finally, since our study was performed only in one sub city in Addis Ababa the generalizability of our findings may be limited.

Conclusion

The finding of this study shows a better adherence rate than most. Although the adherence rates found in this study are comparable to those of other studies in developing countries these rates are still low for good clinical outcomes. . so we believe there is a tremendous need to strengthen the existing qualities and keeping in mind the associated factors identified in our study, adherence has to be improved and monitored using multifaceted and repetitive interventions. .

The most important factors associated with increased adherence are educational level, social support, distance and depression.

However determinants like side effects, treatment –fit” to daily routine, satisfaction with relationship with health care providers, patient’s perception of their doctor’s capacity found to consistently associated with adherence in many studies were not found to be significantly associated with adherence in our study

The reasons for missing pills were being away from home, run out of medication, being sick, being busy, went holly water, being depressed, self problem in taking medication, being slept, work load, confusion about dosage direction, fear of disclosure, too many pills, toxicity of the drug, taking a drug remind me of my HIV, people told the medicine is not good.

It was concluded that most patients need modification to improve their Adherence to ARV treatment in order to achieve sustainable suppression of viral Replication and to prevent treatment failure.

Hence, the following recommendations have been made based on the finding of the study so as to give a clue about the possible direction to follow and focus to alleviate the existing problems of adherence.

RECOMMENDATION

- Educational programme should be developed focusing on the people living with HIV-Aids. The education programme should be patient's centered education approaches that ensure a good understanding of the treatment of antiretroviral by the patient on the help of memory aids and keeping clinical appointment.
- Detect and manage depression among patients on ART with a multidisciplinary approach.
- Emphasis should be given for income generating activities and social supports that helps to remember the patients for medication taking.

- Patients would benefit if ART services were available in more institutions located closer to beneficiaries' homes (Expand ART service to all health center).
- Further study on adherence and adherence measurement should be carried out to fill the gap of adherence measurement.

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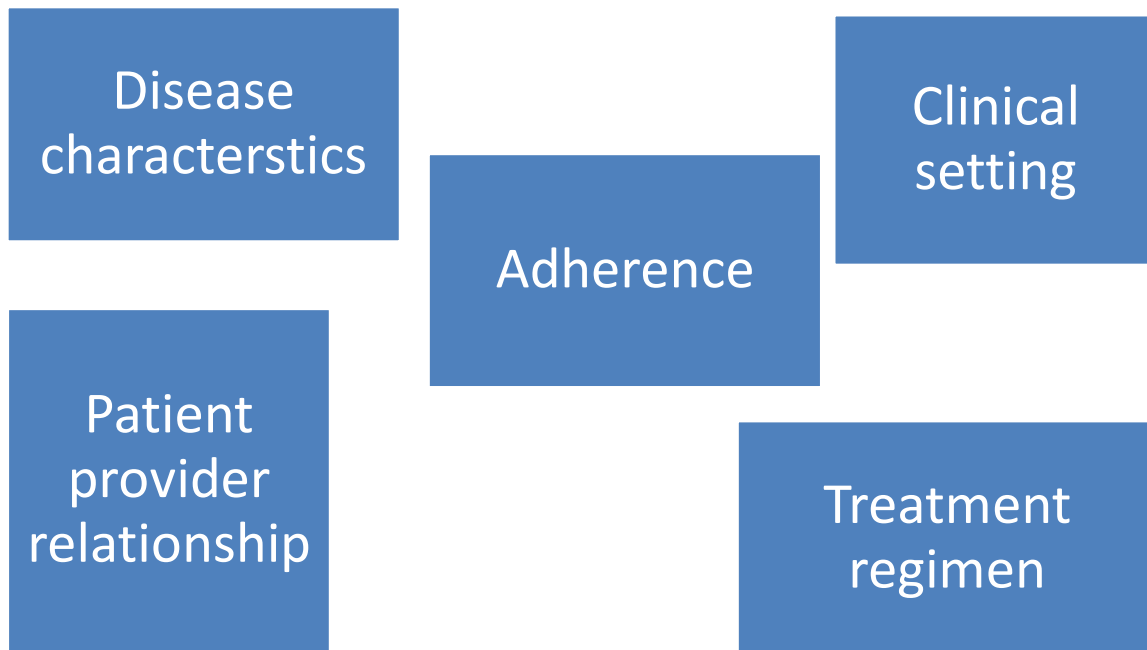
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ANEX- 1

Determinants of antiretroviral therapy adherence



- Patient variable**
- **Socio demographic**
- **Psychosocial factors**

Annex 2 Information Sheet and Consent Form

Information Sheet and Consent form for study participant on Magnitude of antiretroviral therapy adherence and associated factor. Name of organization- Addis Ababa university/SPH

Name of Principal investigator- Anwar sabir

Name of Sponsor – Self Sponsor

Introduction

This information sheet and consent form is prepared by the principal investigator to clarify the study that you are asked to take part. So you invite to see this form carefully before you decide to participate or not. If there is any unclarity you welcome.

Purpose

The main purpose of this research is to asses Magnitude of antiretroviral therapy adherence and associated factor . This finding help us to identify the associated factors of antiretroviral therapy adherence that is important to limit the development antiretroviral treatment drug resistance.

Procedure

If you are willing to participate in my project, you need to understand and sign the consent form. Then you will be interviewed by the data collector we will not ask you personal questions.

Risk/Discomfort

There Is no any risk/anticipated harm which will happen on you due to your participation but you may feel discomfort owing to your wasted time but it is not as such long.

Benefit or Incentive

By your participation, you may not get direct benefit/incentive but you can improve your and other health by this research findings.

Confidentiality

The information that we will gather from this research will be kept confidential, and used only for research purpose. We use a code number in the questionnaire, you need not to tell your name because we want to assess an average finding but not individual.

Right to refuse or withdrawal

Your participation in this research is fully based on your willingness and you have also a right to refuse some question you are not willing to answer. You have also a full right to withdraw from this study at any time you want.

Person to contact

If you have any question you can contact:-

Principal investigator – Anwar Sabir

Cell phone: 0913374242

E-mail: kanwarsabir@ymail.com

If you are agreed to participate, please sign below

Signature

Signature of principal investigator

Date

date

Annex -3 Questionnaires (English and Amharic version)

Questionnaire for the Cross- Sectional assessment

Introduction

I am -----working as data collector in this study that assess what is magnitude of antiretroviral adherence and associated factor in the ART unit in ----- health center.

The study is run by AAU, DCH. On this questionnaire your name will not be written and I am going to ask some questions that touch personal life and secretes; 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 understand better how patients are adhering to the antiretroviral on use and what barriers they have for their non-adherence, in order to develop good strategies and solve the problems for the future. We would greatly appreciate your truthful and keen participation in responding to this questionnaire.

Identification Number-----

Date of Interview-----

Interviewer Name-----

Supervisor-----

Section I: Socio demographic characteristics

No	Questions	Coding categories	Code
101	Sex	1.Male 2.Female	
102	Age(in year)		
103	Ethnic group	1. Amhara 2. Oromo 3.Tigre 4.Gurage 5.Other specify-----	
104	Marital status	1.Single 2.Married 3. Divorced 4. Separated 5.Widowed	
105	Religion	1.Orthodox 2.Catholic 3.Protestant 4.Muslim 5.Other specify-----	
106	Education	1.Illiterate 3.Secondary 2.Elementary 4.Diploma and above 5.Other specify-----	
107	Monthly income(birr)	1. < 500 2. 500-1000 3.1000and above 4.Unstated	
108	Employment	1.work active 2.Unemployed 3.Pensioner 4.Student	
109	Active substance use	1.yes 2.No	
110	What substance you Use	1.Khat 2.Cigarette 3.Alcohol 4.Other specify-----	
111	Whom do you live with	1.Live alone 2.My family 3.my parents 4.Unstable 5 No answer	

Section 2 Health problem (depression) encounter within last 4 weeks

No	Health problem(depression) symptom encounter In the last 4 week	Yes	No
1	Do you often have headache?	1	2
2	Is your appetite is poor?	1	2
3	Do you slept badly?	1	2
4	Are you easily frightened?	1	2
5	Do your hands shake?	1	2
6	Do you feel nervous, tens or worried?	1	2
7	Is your digestion poor?	1	2
8	Do you have trouble thinking?	1	2
9	Do you un happy?	1	2
10	Do you cry more than usual?	1	2
11	Do you find it difficult to enjoy your daily activities?	1	2

12	Do you find it difficulty in decision making in day to day life?	1	2
13	Is your daily work suffering?	1	2
14	Are unable to play a useful part in life?	1	2
15	Have you lost interest in things?	1	2
16	Do you feel that you are the worthless person?	1	2
17	Has the thought of ending your life been on your mind?	1	2
18	Do you feel tired all the time?	1	2
19	Do you have uncomfortable feeling in your stomach?	1	2
20	Are you easily tired?	1	2

Section 3 Character of drug regimen/treatment

No	Questions	Answer	Code
301	Do you know the types of medication You are taking?	1. Yes 2. No 3.don't know	
302	After you have been started medication what clinical benefit you get?	1.Weight gain 2.Reduction of fever 3.Reduction of hospitalization 4.Reduction in frequency of diarrhea 5.Reduction of morbidity 6.all 7.Don,t know	
303	Did you have any side effect when u take medication	1.Yes 2.no 3.Don,t know	
304	If yes question 403 which of the following symptom did you feel more than one answer is possible	1.nausea 2. Vomiting 3.headache 4.anemia 5GI intolerance 6.depression 7.rash 8.diarhoea 9.other	
305	What measure did you take when you developed side effect?	1.emmideatly stopped taking pills 2.withheld until the date of appointment 3.imidiately I was reported to clinician 4.Droped out permanently 5.Don,t know	
306	Can you mention the name the drug you are	1.-----	

	taking?1. Name 2.Dose, 3.frequency, 4.totally pills daily 5. With meal 6.empty stomach 7.don,tknow	2.----- 3.----- 4.----- 5.----- 6.----- 7.-----	
307	Do you have history admission during last one year after initiation of ART	1.yes 2.no	

Section 4 patient level factor

No	Question	Answer	Code
401	Are you committed and convinced before start ART?	1.Yes 2.No 3.Don,t know	
402	How long have been on HAART?	1.1-6 Month 4.25-36m 2.7-12 month 5.>36 3.13-24 month	
403	What was your CD4 count?	1. Initial----- 2. Recent-----	
404	Have you disclosed your HIV status to your family/relative?	1.Yes 2.No	
405	Do you know importance of adherence before you start ART?	1.Yes 2.No	
406	Do you feel comfortable when you are taking ART in front of other?	1.Yes 2.No 3.Don,t know	
407	What types of schedules do you use for memory aids in order to take medication?	1.Pill boxes 2.Writen schedule 3Don,t have any memorial aid 4.Watch bell 5.Other---	
408	Do you have any emotional and practical support?	1.Yes 2.No 3.Don,t know	
409	If yes to question 504,who support You?	1.Family 2.Friends 3Peer 4.Community 5.Other	
410	What type of support did you get from your supporter?	1.Fanancial support 2.Care and emotion 3.Food and care	

		4.Remedies of medication 5.Other	
411	What pattern of emotional life do you have?	1.Unstable emotional life 2.Stable emotional life 3.other 4.Don,t know	
412	Does medication schedule fit your daily routine?	1.Yes 2.No	
413	If question 508 is no, mention any of inability	1. 2. 3. 4.	

Section 5 Patient providers 'relationship

501	Are you satisfied with the clinician service	1.Yes 2.No 3. Not sure	
502	Do you feel the health care providers treating you are capable	1. Yes 2. No 3. Not sure	
503	Do you have open communication with physician treating you	1.Yes 2.No 3.Not sure	
504	How frequent do you visit your doctor	1.Every month 2.Every 2 month 3. Every 3month 4.Other specify	
505	Do you obtain the education or assistant You need during your visits.	1.Yes 2.No 3Not sure	

Section 6 health care system and clinical setting

601	Do you have access to reliable pharmacy any time you want	1.Yes 2.No 3.Not sure	
602	Are you satisfied with the changes/ Improvements you obtain for your Treatment	1.Yes 2.No 3.Not sure	
603	At present do you have a child under your care	1.Yes 2.No	
604	Child tested for HIV	1.Yes,positive 2.Yes,negative 3.Not tested	

605	Are you satisfied in the scheduling Appointments and confidentiality of the treatment unit	1.Yes 2.No 3.Not sure	
606	Distance from facility	1.<50km 2.>50km	

Adherence assessment and reason for skipping

I. Patient Interview

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

Today, number of doses skipped _____

Yesterday, number of doses skipped _____

In the past three days, number of doses kipped _____

In the past one month, number of doses skipped _____

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 _____

III. Reasons for skipping the doses

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 away 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 reminds me 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

16 .Fasting/went holly water

