ADHERENCE TO ANTIRETROVIRAL THERAPY IN CURRENTLY CHANGED TREATMENT GUIDELINE ON PEOPLE LIVING WITH HIV/AIDS AT BISHOFITU HOSPITAL, EAST SHOA, 2011. ETHIOPA.

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List of abbreviations

AIDS- Acquired immunodeficiency syndrome.

ART- Anti retroviral Therapy

ART Unit- A unit in a hospital responsible for counseling, investigating, and treating HIV-infected persons with antiretroviral drugs.

ARV - Antiretroviral drugs/ substance used to kill or inhibit the replication of a retrovirus such as HIV.

HAART - Highly active antiretroviral therapy: the name given to treatment regimens meant to aggressively suppress viral replication and progress of HIV disease. The current HAART regimen is a fixed dose combined to single drugs.

HIV- Human Immune deficiency virus

IVDU- Intra Venous Drug Use

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

MOH - Ministry of Health

PLWHA - People living with HIV and/or manifestations of AIDS

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Abstract

Background:

Adherence to antiretroviral therapy (ART) is crucial to ensure viral suppression, decrease the risk of disease progression and drug resistance. Non-adherence to ART, likewise, is common in all groups of treated individuals & lack of strict adherence to ART is considered to be one of the key challenges to AIDS care worldwide.

Objective:

To assess adherence to ART on currently changed guideline and factors associated with it among People Living with HIV/AIDS (PLWHA) attending ART unit at Bishofitu Hospital.

Method:

A cross sectional survey of 317 clients attending for ART at Bishofitu Hospital was carried out using both quantitative & qualitative design method. Using a structured and pre-tested questionnaire, data on drug adherence and other variables was collected through in-depth interview, peer educators FGD, patient's self report (interview), pill count and by reviewing their clinical records. The nurse & ART Clinician who are working in the ART unit were involved in data collection after being trained. Ethical clearance was obtained from concerned bodies and consent was sought from the study subjects. Adherence is defined as the number of doses taken divided by the number of doses prescribed over a given period. It is considered as good if the patient took ≥ 95% of the prescribed doses correctly. Odds ratio was done to determine the strength of association for different variables.

Major Findings

The overall prevalence of HAART adherence was found to be, 398(95.4%) in this study. The highest proportion, 61 % of patients missed or delayed their doses due to simply forgetting & 47.4% due to being away from home & 29.4% being too busy. Independent positive predictors of HAART non adherence reported in this study comprise:-the participants who had: PLWHA's residency far from Bishofitu hospital (>47 KM.), depression feelings , ART eligibility knowledge, medication adverse effect, history active substance uses, no adequate social support & one or two children under their care in the final adjusted multivariate analysis.

Conclusions & Recommendations:

The prevalence of ART adherence among clients using currently changed single combined fixed dose in this study was found higher than most studies done in developed countries & even much higher than the findings of other studies in Ethiopia. From these, we can infer that single & simplified ART has reduced the pill burden & helped the clients to take it at ease & this has increased the level of adherence behavior of clients, therefore continuous effort should be made to increase clients' awareness to maintain the best level of adherence outcomes.

1. Introduction

HIV prevention aims to prevent the transmission of HIV and re infection. HIV/AIDS-related treatment aims to improve the quality of life of people living with HIV/AIDS. HIV prevention and HIV/AIDS-related treatment support each other in many ways (1). The ultimate goal of HAART is to reduce viral load to an undetectable level. These powerful therapeutic agents have been associated with undesirable side effects that have made the regimens difficult to tolerate. Most of the drugs may cause nausea, vomiting, and diarrhea, and the regimens include a high pill burden. (1)

In countries with broad access to effective antiretroviral therapy (ART), the clinical benefits have been dramatic. Far fewer people are progressing to AIDS, hospital AIDS wards have practically emptied, and the age-adjusted death rate from HIV/AIDS has declined by more than 70%.(54R) Adherence to ART has emerged as both the major determinant and the Achilles' heel of this success.(2, 3,4)

Antiretroviral adherence is the second strongest predictor of progression to AIDS and death, after CD4 count. Incomplete adherence to ART, however, is common in all groups of treated individuals. The average rate of adherence to ART is approximately 70%, despite the fact that long-term viral suppression requires near-perfect adherence. Study shows typical adherence rates for medications prescribed over long periods of time are approximately 50-75%.Adherence is perceived as a significant barrier to the delivery of ART in Sub-Saharan Africa (5). Studies done in other countries suggested the average rates of non-adherence with Antiretroviral therapy (ARV) range from 50% to 70% in different settings, and the risks associated with non adherence are extensive at both individual and societal levels.(5,6, 7,)

Bishofitu Hospital is one of the regional ART providing institutions among governmental hospital found in oromia regional state with a total population 120,800. Bishofitu hospital is the leading to implement BPR to improve the quality of the service & simplify service accessibility & delivery ART service free of charge.

To my search, there are no studies performed in oromia hospital on a simplified HAART regimen (a fixed dose antiretroviral drugs combined in to a single) based on currently changed WHO treatment guidelines, therefore the objective of this study is to determine the trend of ART adherence as to the current treatment guideline & factors associated with it in a setting, is represented by Bishofitu hospital.

2. Literature Review

An estimated 33.2 million people worldwide were living with HIV, 2.5 million became newly infected and 2.1 million lost their lives to AIDS at the end of 2007 (8). Sub-Saharan Africa remains the worst affected region in the world. A little more than one-tenth of the world's population lives in sub-Saharan Africa, which is home to almost 68% of all people living with HIV (9). The HIV/AIDS epidemic in Ethiopia continues to pose a threat to the lives of its people. It is estimated that 977,394 people live with the virus resulting in 71,902 HIV related deaths in 2007 (9). The national prevalence of HIV in 2007 is estimated to be 2.1% (9)

HIV prevention aims to prevent the transmission of HIV and reinfection. HIV/AIDS-related treatment aims to improve the quality of life of people living with HIV/AIDS. HIV prevention and HIV/AIDS-related treatment support each other in many ways (1). These powerful therapeutic agents have been associated with undesirable side effects that have made the regimens difficult to tolerate. Most of the drugs may cause nausea, vomiting, and diarrhea, and the regimens include a high pill burden. (1)

Antiretroviral adherence among HIV-infected patients has become critical in the treatment of HIV. **(**10**)** Unfortunately, measurement of antiretroviral adherence is limited by the lack of a "gold standard," thus making evaluation of adherence an imperfect science (10,11). The most frequently applied methodology in the measurement of adherence is patient self-report. In addition to potential overestimation of actual adherence, self-reported adherence is limited in that data may only reflect short-term or mean adherence. (10,11)

Improvements in the survival of HIV-infected adults have been attributed to various factors, including earlier diagnosis of HIV disease, greater access to medical care, and development of therapeutic strategies to limit replication of HIV (11) .Nevertheless, it is increasingly clear that the therapeutic benefits of highly active antiretroviral therapy (HAART) are strongly dependent on stringent patient adherence to these regimens. Most study noted that adherence to HAART must exceed 95% to limit viral replication effectively. (11)

The same authors reported that among the patients evaluated in their study, patients with less than 80% medication adherence had an 87% virologic failure rate, whereas patients with medication adherenceranging from 80% to 90% reported a virologic failure rate of 47% Patients with an adherence rate more than 95% had a 10% virologic failure rate(12) Another study suggested that with decreased adherence clearly associated with increased HIV viral load. (13)

During the last decade, access to HIV care in Sub-Saharan Africa has been improved by reduction in the cost of ART and by the implementation of WHO guidelines promoting scaling-up by task

shifting for clinical decision-making to less specialized health-care workers (14) However, the challenge to achieve high adherence to ART is particularly acute in Sub-Saharan Africa as the high rates of HIV/AIDS lead to greater absolute numbers of affected individuals than in other low-income regions. Although long-term good ART adherence has been observed in certain settings of public sectors in Africa (Nachega, data presented at 16th Conference on Retroviruses and Opportunistic Infections 2009), the magnitude of this challenge in Sub-Saharan Africa remains large (15).and there is growing evidence for high rates of patients loss to follow-up (16,17). a recent review reported that ART programmes in Africa retain only about 60% of their patients after two years on ART. (18)

Little is known about rates of adherence and factors that influence adherence to ART in Africa. A cross-sectional study of 1-month adherence among patients in Soweto, South Africa was >95% for 88%, 90–95% for 9% and, <90% for 3% (19). In a prospective study done in Cape Town to monitor adherence and evaluate factors predicting poor adherence revealed 63% of patient's maintained adherence of 90% to the prescribed tablets. Adherence was significantly associated with the reduction in viral load .(20)

In Ethiopia recently, two studies were performed in Addis Ababa in three civil hospitals and two defense hospitals. The levels of adherence >95% reported were 81.2% in the preceding institutions and 82.8% in the latter institutions (21) . In the study done at two hospital of oromia region state , it was found 83.0 % & in the study performed at southern region (Yirgalem hospital) the adherence rate was found 74.2%%. (22)

In the Addis Ababa studies the major reasons reported for non-adherence were being too busy with other things or simply forgetting (33.9%), and being away from home (27.5%) (21). Absence of depression and drug side effects, treatment fitting to daily routine, satisfaction of relationship with health care providers, patients' perceptions of their doctors' capacities, perceived access to support from their ART unit, and reliable pharmacies for ARV, was all significantly associated with ART combination therapy adherence (21). Keeping clinical appointments, using memory aids and educational levels were associated with increased adherence level in the Military Defense Hospital ART unit clients .(21)

Most frequently cited reasons for non-adherence are; simple forgetting, being away from home, being busy, or experiencing a change in daily routine. Additional barriers to adherence include psychiatric disorders, such as depression or substance use, uncertainty about the effectiveness of treatment and the consequences of poor adherence, regimen complexity, and treatment side effects . (22)

Low levels of adherence may adversely affect patient outcomes and result in rapid rebound of plasma viremia, development of resistant strains of HIV, more rapid immune deterioration, and quicker progression to AIDS and death. (23)

Adherence to antiretroviral therapy (ART) is crucial to ensure viral suppression, decrease the risk of disease progression and drug resistance. However, it is difficult to measure accurately, which is reflected in the number of conflicting reports available on the response to ART in people living with HIV/AIDS (PLHIV). Optimistic reports may have over-emphasized selective publication of positive results , or have been biased towards highly motivated patients with early access to limited therapy . Given these methodological difficulties, it is not surprising that a bewildering number of factors have been reported to influence adherence: age; gender; monthly income; level of education; travel time from home to clinic; baseline CD4 cell count; CDC HIV clinical stage before starting ART, type of ART regimen, presence of early ART side-effects and disclosure of HIV status to at least one relative (24)

Despite the critical need for strong HIV treatment adherence, research indicates that many patients have difficulty realizing this goal. A meta-analysis of 59 studies conducted in North America and Africa reported that only 55% of North American patients demonstrated high levels of ART adherence (Mills et al., 2006). The percentage of African patients who achieved high adherence was more favorable (77%), but this proportion could decline over time as patients initiating therapy encounter the challenges of maintaining long-term adherence, and as treatment availability in these nations expands beyond those with early access to ART. (25)

Pill counts often are used by investigators as a more objective means of evaluating medication adherence behavior. This method requires that patients return medications to the study center or clinician for assessment. Several studies have noted patients engaging in “pill dumping” as a means of preventing acknowledgment of poor adherence behavior. (26) Physician and other health care provider estimates of patient medication behavior also have proven to predict actual patient adherence poorly. (27)

In a study of 45 patients, Bangsberg et al. noted that 13% of patients were not following their regimens as prescribed. Whereas provider adherence estimate explained only 26% of the variation in pill count adherence, patient report explained 72% (28). Studies have shown that medication adherence among patients aged 60 years or older ranges from 26% to 68%. Although some studies find that age is positively associated with adherence (29) , most of the literature has shown that it is not age specifically that relates to adherence but the factors commonly related to aging (e.g., polypharmacy, cognitive and physical limitations, social isolation, and access to affordable services) that are often predictive of adherence. (29)

Although few specific antiretroviral adherence studies have been conducted in older patients with HIV, several socio-behavioral factors have been related to antiretroviral adherence behavior among HIV-infected adults, including active alcohol or drug use (30,31,32)

Depression and decreased adherence, particularly in relation to unstable housing. Unstable housing also has been reported as an independent predictor of decreased adherence, although one study of a cohort of 132 homeless male subjects noted that of the 22% taking PIs, 80% of these individuals reported taking more than 90% of their prescribed doses . (33)

Other studies also have reported racial and ethnic variations in antiretroviral adherence. Singh et al. (27) reported that nonwhite patients were less likely to be adherent compared with white patients. Gender also has been associated with antiretroviral adherence, because male gender seems to be related to decreased adherence This pattern holds true for black men, who have been shown in several studies to be less likely to adhere to antiretroviral. (34)

Other studies noted factors that have been associated with decreased adherence include the following: lower levels of education, anxiety, pain, pill burden, lack of convenient access to medication, side effects, and dissatisfaction with the health care system. (34)

As noted conducted qualitative interviews with 49 older adults (aged 50–67 years) to determine the main factors relating to non adherence, among the factors listed by patients were side effects, busy schedules, fatigue, and stigmatization of HIV. The authors concluded that age-related issues, including complex regimens and visual and cognitive impairment, were not major factors regarding non-adherence with these patients. (35) Regarding interventions, no single approach to improve adherence behavior is considered penultimate. (36)

The importance of a simplified HAART regimen cannot be overstated. Although it may seem intuitive that higher pill burdens may be associated with decreased adherence, this premise has not proven to be the case in various studies. (37) Study noted that among 100 patients interviewed, the primary cause for decreased adherence was difficulty in remembering, followed by inconvenient dosing around meals. (36) Several researchers have used various mechanical devices to improve antiretroviral adherence. Mechanical assistance can be provided through use of written schedules, pillboxes, alarm clocks, pagers, and other reminders. (38)

Treatment adherence across diseases has been the focus of research for the past 4 decades, but interest in studying adherence has intensified during the era of combined antiretroviral therapy. (39) The limitations of existing adherence measures have hindered progress in adherence research in HIV and other diseases. (39) Optimizing adherence measurement in clinical and research settings is crucial for several reasons. (39)Antiretroviral adherence is crucially important in resource-limited settings, where second-line medication options are limited or virtually nonexistent and suboptimal adherence must be identified before the development of resistance. (40)

Commonly used methods for measuring adherence include indirect measures, such as self-reports, electronic drug monitoring (EDM), pill counts, and pharmacy refill records, and direct measures, including detection of drugs or drug metabolites in plasma. (40) Most commonly, respondents are asked to report the number of doses they missed during a specified recall period or to estimate their overall percent adherence on a visual analogue scale. Response tasks may also include qualitative estimates of overall adherence, reporting the number of days of perfect adherence in the prior week, recalling when the respondent last missed a dose, or determining the number (or proportion) of doses (or pills) missed (or taken) over a specified recall period. Substantial variation also exists in the relevant time frame, with recall periods including the past 1, 3, 7, or 30 days. (41)

Some data suggest that self reported adherence is inaccurate even among patients who report missing doses, however, and should thus not be considered 100% specific for poor adherence. (41)Several interview techniques may lessen the ceiling effect associated with self-reported adherence. (41)

Some researchers suggest that if the viral load is not detectable in the blood because the person is taking HIV treatment (taken as a viral load less than 50 copies/ml in most assays) then the person may not be infectious , This paper addressed the possible impact of treatment as prevention on couples who have different HIV status i.e. one person is HIV +ve and one person HIV –ve. The recommendation was that the potential benefits of treatment as prevention should be discussed with the couple by their health care worker in order for the couple to make an informed decision about whether it would be necessary for them to continue using condoms. (42)

Researchers at the WHO have taken the knowledge that successful treatment reduces the risk of infection and modelled the potential impact at a population level in a high prevalence country with a generalized epidemic – in this case, South Africa. The estimated impact of treatment on new HIV infections (incidence) is based on the assumption that at least 90% of people in that country have an annual HIV test and those who test HIV +ve start antiretroviral treatment immediately. (43)

In countries with broad access to effective antiretroviral therapy (ART), the clinical benefits have been dramatic. Far fewer people are progressing to AIDS, hospital AIDS wards have practically emptied, and the age-adjusted death rate from HIV/AIDS has declined by more than 70%.(24,40) Adherence to ART has emerged as both the major determinant and the Achilles' heel of this success. (2,3,4,)

Antiretroviral adherence is the second strongest predictor of progression to AIDS and death, after CD4 count.(24,40) Incomplete adherence to ART, however, is common in all groups of treated individuals. The average rate of adherence to ART is approximately 70%, despite the fact that long-term viral suppression requires near-perfect adherence. (6,7)

Study shows typical adherence rates for medications prescribed over long periods of time are approximately 50-75%. (5)

Non-adherence to ART, likewise, is common in all groups of treated individuals. The average rate of adherence varies by the method used to assess it and the group studied, but appears to be approximately 70%. For example, in a prospective study, 140 individuals in a public hospital HIV clinic were followed for 1 year after initiation of ART. The investigators assessed adherence using 3 methods: a computer chip embedded in a specially designed pill-bottle cap to record the time and duration of each bottle opening (microelectronic monitoring system [MEMS], or MEMS caps), pill count, and self-report.(24)They calculated a composite adherence rate including all 3 measures that demonstrated a mean adherence rate of 71%. Only 6% of the patients took >=95% of their medications, the optimal level for durable virologic and clinical success. (44)

Studies of different groups of HIV-positive individuals in the United States generally show similar, suboptimal rates of adherence. (45) While it is difficult to compare studies using different measures of adherence, mean adherence was suboptimal in the following disparate groups of HIV-positive individuals: in a large multicenter clinical trial (85% adherence by self-report), among patients from a veterans and university hospital (75% by MEMS), among the marginally housed (89% by self-report, 73% by pill count, 67% by MEMS),among those with serious mental illness (66% by MEMS), among predominately minority women (64% by MEMS),and among 2 different groups of inner-city residents with a history of injection drug use 80% by pill count, 53.5% by MEMS in one group,and 78% by self-report, 53% by MEMS in the other group. (45)

Studies from Canada and developed countries in Latin America and Europe demonstrate similar rates of suboptimal adherence. (45) In general, 10% of patients report missing at least 1 antiretroviral dose on any given day and 33% report missing at least 1 dose within the past month. (45) Rates of adherence also are known to decline over time.It can be concluded that most patients taking ART, regardless of their background or life situation, will encounter difficulties with adherence. (45)

For most patients, near-perfect (>95%) adherence is necessary to achieve full and durable viral suppression (45) In practice, this degree of adherence requires a patient on a twice-daily regimen not to miss or substantially delay more than 3 doses of antiretroviral medications per month. This degree of adherence is far greater than that commonly associated with other chronic diseases and is quite difficult for most patients to maintain over the course of a lifelong illness. (45)

Adherence was estimated using pharmacy refill data in 886 treatment-naive individuals in British Columbia followed prospectively for a median of 19 months after starting ART. Of the 502 individuals at the 95-100% adherence rate, 84% achieved plasma viral loads <500 copies/mL, whereas only 64% of the 64 people at the 90% to <95% adherence rate achieved this level of suppression ($p = 0.001$) . (46)

The primary goal of treatment with ART is to prevent HIV-related morbidity and mortality. Many studies have shown a strong correlation between adherence and clinical outcomes and/or laboratory markers (notably CD4 count). Non-adherence has been found to diminish the immunological benefit of ART and increase AIDS-related morbidity, mortality, and hospitalizations. (46)

Adherence clearly has been associated with CD4 count in a number of settings. In a prospective cohort study of 1,095 patients enrolled in 2 randomized multicenter trials of initial and salvage ART, participants who reported adherence levels of 100%, 80-99%, and 0-79% had CD4 increases of 179, 159, and 53 cells/μL, respectively, from baseline to month 12 ($p < 0.001$).In the VA/university cohort study cited above, those with >=95% adherence had a mean increase in CD4 count of 83 cells/μL while those with adherence of <95% had a mean increase of 6 cells/μL.A prospective study of 173 HIV-positive patients for 2 to 6 months grouped participants by self-reported adherence rates. Patients reporting 95-99% adherence at 6 months had an increase in CD4 count from baseline of 59 cells/μL while those with adherence <80% showed a net loss from baseline of 8 cells/μL. (47)

The relationship between adherence and mortality was further defined in a population-based analysis of 1,282 ART-naive HIV-positive individuals in British Columbia who started triple-combination therapy between August 1996 and December 1999.Adherence was estimated by dividing the number of months of medications dispensed by the number of months of follow-up. In a multivariate model, 2 factors--each 100-cell decrement in baseline CD4 count and <75% adherence to ART--were each associated with increased mortality with a risk ratio of 1.31 (95% CI: 1.16-1.49; $p < 0.001$) and 2.90 (95% CI: 1.93-4.36; $p < 0.001$), respectively. After adjusting for all other factors, those participants who obtained <75% of their antiretroviral medication were 2.97 times more likely to die (95% CI: 1.33-6.62; $p = 0.008$). (48)

In a cohort study of 1,219 HIV-infected patients who began ART during the period 1990 to 1999 at a single hospital in Barcelona, Spain, adherence was assessed by self-report and pharmacy refill data.(14)Patients were considered non-adherent if they took <90% of prescribed ART. The initial regimen consisted of mono therapy in 23.7% of cases, 2 drugs in 30.5%, and 3 drugs in 45.8%. In multivariate analysis, the only modifiable variables that significantly affected mortality were treatment type (mono therapy: relative hazard [RH] = 9.76; 95% CI: 4.56-20.90; 2-drug therapy: RH = 9.12; 95% CI: 4.23-19.64) and adherence (non-adherence: RH = 3.87; 95% CI: 1.77-8.46). (49)

Non-adherence has also been associated with increased rate of hospitalization (54) and longer hospital stays. (34)

Non-adherence to ART has been clearly implicated in the development of antiretroviral-resistant virus. Initial views, based upon experience with tuberculosis, suggested that patients with low levels of adherence might be at greatest risk for developing drug-resistant infection. Recent data suggests

that the relationship between adherence and resistance is more complicated and likely varies by antiretroviral class. (37)

A cross-sectional study compared 32 patients experiencing virologic failure on their initial regimen of single PI-containing ART with 36 similar patients whose viral loads remained fully suppressed. (50)

A large study of patients from Europe and Israel confirmed that the transmission of drug-resistant virus is not unique to North America. The CATCH study evaluated more than 1,600 recently infected individuals and found that 9.6% of them had genotypic resistance to 1 or more antiretroviral medication. (51)

A simple visual method of assessing adherence recently has been found to be equivalent to the more commonly used verbal self-report. The Visual Analogue Scale (VAS) asks subjects to indicate a point on a line that shows their best guess about how much of each drug they have taken in the past 3 or 4 weeks. For example, 0% means they have taken no drug, 50% means they have taken half their drugs, and 100% means they have taken every single dose. (51)

It also has been recognized that individual adherence behavior can vary during a given period and usually deteriorates over time. A single adherence assessment provides only a snapshot of adherence behavior. It is therefore important to reassess adherence periodically, and if problems have been identified, as frequently as each visit. Adherence assessments now commonly ask about adherence over more recent periods of time (eg, past 3 days and/or past 7 days) and over longer periods (eg, past 1 month). (52)

3. Rationale & significance of the study

There are several concerns about antiretroviral regimens adherence. The drugs can have serious side-effects, regimens can be complicated, requiring patients to take several pills at various times during the day & if patients miss doses, drug resistance can develop. Much has been done to wards Interventions to improve adherence include starting when patients are ready, treating substance abuse and depression before initiating ART, simplifying the regimen, and tailoring it to the patient's lifestyle, management of drug side effects, increasing support, using skill building exercises, using reminders, motivation and education, minimizing the pill burden, trusting relationship with health care provider, patient education and convenient access to medications and refills, frequent visit to the provider, avoiding dietary restriction and providing medications free of charge. (54,55)

The current guidelines for adults and adolescents which were stated on October 6, 2005 has made treatment regimens greatly simplified in recent year & bring forth a fixed dose antiretroviral drugs combined in to a single to improve adherence & avoid resistance (56) . Even though; the guidelines were revised it was not implemented as per the current guidelines in Ethiopia & many ART providing unit were using the previous one or the three drug combination is commonly known as a triple cocktail till recent time . But currently almost all have started using it.

Why Should We Measure Adherence? 1. Adherence changes over time because people get better, Side effects of drugs , "Treatment fatigue" (57) & clients may look for alternative treatment like traditional medicine ,etc. Therefore, periodical research evaluation of ART adherence is crucial & alarming to set a new strategy for ART treatment adherence behaviour.

Researchers recommended more research should be undertaken to improve current treatments includes decreasing side effects of current drugs, further simplifying drug regimens to improve adherence, and determining the best sequence of regimens to manage drug resistance. Therefore , a study that assess adherence to ART (for early adherence measuring predicts future adherence.)in accordance with currently changed treatment guidelines(WHO) has a great importance to access information on the challenges & obstacles faced by ART users & service provider as a base line information:-

- For monitoring & evaluation of treatment adherence behavior.
- To improve adherence in similar ART unit or settings in the future.

4. Objectives

4.1 General objective:

To evaluate adherence to ART among people living with HIV/ADIS in accordance with currently changed treatment guidelines at Bishofitu Hospital of south West oromia.

4.2 Specific objective:

1. To assess adherence to antiretroviral therapy based on current treatment guidelines.
2. To assess the relationship between ART adherence& its determinants.

5. Methodology

5.1 Study area and study periods

The study was conducted from February to March 2009 at ART unit of Bishofitu Hospital in oromia regional state. Among governmental hospital found in oromia regional state three nearby hospital to Addis Ababa, namely Adama, Bishofitu & Ambo hospital are taken to be selected as the study area based ART client load(case load), geographical accessibility & provision of ART service in well organized manner because of time factors & financial constraints. Of which Bishofitu hospital was selected as study area by lottery system of simple random sampling methods.

5.2 Study design

A cross sectional survey design using both quantitative & qualitative method was carried out, to approach the respondents & to bring forth information as per the constructed variables of the study objectives.

5.3 Population Sources

All people Living with HIV/ADIS eligible for HHART & being treated with antiretroviral therapy in oromia regional state.

5.4 Study Population

All people Living with HIV/ADIS eligible for HHART & being treated with antiretroviral therapy in the study setting. (Bishofitu Hospital)

5.5 Inclusion criteria

All the study population both male & female who fulfilled the below criteria;

1. Taking fixed dose multiple combined ATR to a single drug
2. ≥18 years of age
3. Give verbal informed consent voluntarily
4. Admitted to the study hospital for Antiretroviral drug or take the drug as out patient
5. Not critically sick

5.6 Exclusion Criteria

1. All ART clients who are un able to hear, unconscious & mental disabled.

5.7 Sample size & sampling method

Study shows typical adherence rates for medications prescribed over long periods of time are approximately 50-75% (5) .Based on this assumption the sample size is determined by assuming stabilized adherence prevalence rate 50%, giving any out come to be within 5% degree of freedom / marginal error & 95% confidence interval of certainty (alpha=0.05) to obtain the highest possible sample size . Based on this, the actual sample size is computed using one-sample population proportion formula.

Where ;

n=sample size

[Zα/2] = critical value 1.96

P= assume stabilized adherence prevalence rate 50%

Thus the sample size is

$$n = \frac{(1.96)^2 \times (0.5(1-0.5)}{(0.05)^2}$$

$$= 384$$

Non-response rate 10% = 38+384= 422 (Total Sample size), n= 422

5.8 Sampling Procedure/techniques

With regards to sampling techniques , a total of 1725 PLWHA sampling unit is on HAART & follow up at ART unit of Bishofitu Hospital at a time of proposal writing/planning ,all other to be enrolled being eligible for ART till the study periods (February to March 2009) was registered & included in the sampling frame . Finally , using the systematic random sampling system of those coming for follow up of ART ever 4th ART clients was involved in the study .Data collection time was from February 1,2009 to March,2009.

For the qualitative one, the selection of the participants for FGD with peer educator & defaulter tracer & in-depth interview was carried out using purposive sampling. The socio demographic profile of FGD & the in-depth interview was coded after data collection.

5.9.1 Measurements

5.9.2 Questionnaire design

The questionnaire format was taken from the study done at oromia regional state (58),study done in Southern Nations and Nationalities Peoples Region (22) and some additional questions will be added from other studies & other sources down loaded from internet . The purpose of making this is to use standard questionnaire to ensure validity of the study.

5.10 Variables of the study

The following variables are selected and were measured;

Independent variable

- Demographic variables

Age, sex, religion, marital status and ethnic groups

- Socio-economic variables

Occupation, educational status, monthly income

- Factors related to health service ,social care & support
- Factors related to active substance use of drugs ,chat & alcohol
- Factors related to drug side effect, feeling of depression & CD4 count
- Factors related to benefits & importance adherence
- Factors related to belief in efficacy of medication
- Perceived severity of non adherence
- Satisfaction on HAART & service

Dependent variable

- Behavior out come
- Practice of adherence & non-adherence to HAART

5.11 Data collection and management (Quality)

Items concerning information on the questionnaire should be completed by interviewer and should be related to the respondent's answer. The questionnaire was translated to Amharic language then back to English to ensure the consistency of the questionnaire. The questionnaire was pre-tested on the a sample population of 20 clients using a treatment of HAART at BIshofitu hospital in order to make all the data collectors understand each question in a similar way and collect the intended information plus to fish out questionnaire needs to be amended.

Three registered nurses working at ART unit was selected & involved in data collection & they was offered three day training before engaging to the activities .The interview was conducted in a place where the interviewee feels free & alone with the respondent. The respondent's right not to participate in the study was respected for those who are found to refuse.

In the same manner one supervisor was selected (ART clinician if possible) & highlighted/trained about the study to ensure the completeness & quality of information during data collection.

There was spot checking of the data collector's to give timely correction at mark. The filled questionnaire was received by supervisor & the principal investigator at daily base after a thorough Check ups to manage problem encountered. FGD was carried out with peer educator & defaulter tracer . With regards to in-depth interview ten 10(ten) study subjects with homogenous back ground was considered & the study subject was limited during data analysis process by checking for redundant information and saturation of ideas produced from the interviewees. There was note taking & daily data analysis by the principal investigator & it was recorded with tape recorder to transcribe it word by word. At a time of data processing also, data was entered into a computer, & 10% of the data entered was cross-checked for consistency.

5.12 Data collection Method

Every other patient who comes for ART service during the data collection time was interviewed by trained enumerator. At the same time their clinical records was looked for. Data collection was done from February to March 2009. Patients were interviewed for the following variables; socio demography, health and illness, knowledge and attitude to the regimen, relation with health care professionals, HIV/ADIS related disease occurrence while taking ART and opinion of the health delivery system. Record review was also carried out and; CD4 lymphocyte count, adverse reactions to ARV and the duration of ART was recorded from the clinical chart. Data on drug adherence was collected using patient self report about the number of doses skipped on the previous day, the past three days and the past seven days. Patients

were told to bring their drug holding strips/boxes and these were checked for proper use of the drugs. For in-depth interviewing, the sessions was carried out by the principal investigator

5.13 Data analysis

The raw data collected was entered in to EPI-Info version 3.2.2 & SPSS version 11/17 software package & analyzed. The result/summary of data was presented using table, figure & graph. Descriptive statistics was used to generate proportion & P-value was used to make a decision whether observed difference was statistically significant or not. Furthermore factors affecting adherence to HAART will be analyzed / comparison of PLWHA who is adherent (≥ 95 %) and non – adherent (t < 95%) to take their 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 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. value** 0.05 were considered significant. A score above 14 in the Beck's depression inventory is considered as having depression, while below 14 indicates no depression. Knowledge related to adherence is calculated as having good knowledge if the respondents answer all the questions correctly.

5.14 Operational Definition

1. Antiretroviral treatment adherence practice – PLWHA on highly active antiretroviral therapy reportedly taken 95% of the prescribed ARV medication as their agreement with health care provider.

2. Antiretroviral treatment adherence status of individual study subject – is taking ≥ 95% of the prescribed doses which is calculated by dividing the total number of the percentage doses taken by the total number of doses prescribed for the past seven days .the total ARVs that the individual reportedly taken divided by the total number of ARVs prescribed for him/he

3. Prevalence of Antiretroviral treatment adherence in the past seven days –percentage of the number of study subject who have reportedly taken ≥ 95% of their prescribed ARVs divided by the total respondents of the study in the past seven days from a day before an interview.

4. Fixed dose combinations : are multiple antiretroviral drugs combined into a single pill.

5. Knowledge related to adherence is calculated as having good knowledge if the respondents answer all the questions correctly.

5.15Ethical Consideration

The proposal was evaluated by IRB (institution of Review Board) for topic & Methodology relevance .Ethical clearance for proposal was obtained from the Research and Publications school of public Health, AAU Medical Faculty & Oromia Regional Health Bureau (ORHB), the Zonal Health Desk and the Medical Director of Bisofitu Hospital. Before applying the questionnaire permission was obtained from each study subject. The information was gathered on informed consent/voluntary bases after obtaining permission from each respondent& the respondent is autonomous to answer the entire question, to jump or interrupt in the middle & the right not to answer is also respected. The name of the respondents was not recorded, collected data was not used for other function & purpose of the study was explained, confidentially requiring their personal feeling was kept. The findings of the study would be disseminated to relevant body.

6. Result of the study

6.1. Result of the cross sectional survey

I.) Socio demographic characteristic

Four hundred & twenty two eligible respondents (non-respondent rate included) were selected from Bishofitu hospital to be the part of the study. Of these, five refused to participate in the study & thus the response rate was found to be 98.8 %. A total of 264(63.1%) of female & 153(36.9%) of male participated in the study. Of the respondents 308(76.6%) of the participants range between 25-45 years of age, 61(15.2%) is in the age range >45 years of age & 33(8.2%) of the participants range between 18-24 years of age. The mean age of the respondents was 35.34, the median age was 33 years of age & the standard deviation was found to be 9.96. The mean age for male respondents were found to be 38.4 years & the mean age for female respondents were 33.6 years One hundred ninety (45.9%) of the participants were married, 99(23.9%) were single & 125 (30.2%) were others (separated, divorced & widowed).

As to the educational status 335(80.3%) ever attended school; of these majority proportion 163(39.1%) of the participants was attended elementary school & 110(26.4%) was attended secondary school, 82(19.7%) was illiterate, the remaining participants were read & write & attended diploma. A total of 130(85%) of male respondents ever attended school & 203(77.5%) of female respondents ever attended school. The largest proportion 201(49.5%) of the participants had in-come less than 500 ETB & 153(37.7%) of the participants was unable to describe their in-come in ETB & the remaining a few participants 24(5.9%) & 28(6.9%) had in come between 501-999 & >1000 ETB respectively. Socio demographic data is summarized in Table.1. Below.

Of the sample, 201(49.3%) of the study subject participants were employed & work actively & 158(38.7%) of the participants claimed that currently they did not have work & they are unemployed. As to depression measure, based on Beck's depression inventory (*BDI>14), 47(23.9%) of the participants was found depressed. 406(98.8%) of the respondents reported that ART utilization would benefit them & 5(1.2%) of the participant claimed that ART would not benefit them. 344(96.4%) of the respondents claimed that they had disclosed their sero-status & 13(3.6) reported they did not disclosed.

From the total sample ,391(96.8%) of the respondents reported that they do believe in self-efficacy (no doubt) of the regimens , 9(2.2%) & 4(1.%) reported that they do believe but doubtful & do not believe in the self-efficacy of the regimens respectively. 396(96.8%) of the respondents reported that they had no history of substance uses & 13(3.2%) of the respondents claimed that they had history of substance uses.(see Table.3.)

Table 1: Basic socio demographic and psychosocial characteristics of PLWHA involved in the study Bishofitu hospital, East Shoa, Ethiopia, 2011.

Variables	Number	Percent (%)
Sex –		
-Male	153	36.9
- Female	264	63.1
Age-		
-18-24	33	8.2
- 25-45	308	76.6
- >45	61	15.2
Marital status-		
-Single	99	23.9
- Married	190	45.9
- Others*	125	30.2
Education-		
Illiterate	82	19.7
Read & write	43	10.3
Elementary	163	39.1
Secondary	110	26.4
Diploma and above	19	4.6
Income (Birr)-		
<500	201	49.5
501-999	24	5.9
>1000	28	6.9
Unstated*	153	37.7
Work/Employment-		
Work active/Employed	201	49.3
Unemployed	158	38.7
Others*	49	12
Depression (*BDI>14)		
Yes	47	23.9
No	150	76.1

Belief ARV Benefits		
Yes	406	98.8
No	5	1.2
Disclosure of Sero-status		
Yes	344	96.4
No	13	3.6
Perceived Self Efficacy		
Yes/No Doubt	391	96.8
Yes but Doubtful	9	2.2
Not Sure	4	1.0
Substances use		
Yes	13	3.2
No	396	96.8

*Represents respondents who were separated, divorced & widowed & those who have not stated their income & those who were prisoner & students.

II) Service Environment & Satisfaction

A total of 353(91.5%) of the respondents reported that they were satisfied with the social support & care they obtained & 33(8.5%) of the participants claimed that the social support & care they obtained were insufficient. 363(91%) of the participants reported that they had got satisfied from the value/respect from others & only 36(9%) claimed that they were not satisfied with the value/respect they got from others.

Of the total sample, 327(80.7%) of the respondents claimed that they had access to reliable pharmacy & 78(19.3%) reported that they had no access to reliable pharmacy. Nearly all 404(98.8%) of the participants reported that they were satisfied by the services they received from their clinician & 5(1.2%) claimed they were not satisfied the service they received from their clinician. 396(96.3%) of the respondents claimed that they had open communication with their clinician & satisfied & 7(1.7%) claimed they were dissatisfied & had no open communication with their clinician.

Nearly the largest proportion 253(63.3%) of the respondents claimed encountered no side effect on utilizing single fixed dose & 147(36.8%) claimed they had encountered side effect. 387(95.8%) of the participants reported that they had no history of admission to hospital in the last one month's & 17(4.2%) of the respondents reported that they had history of admission to hospital in the one months. (See Table.2.Below).

Table.2. Basic socio environmental factors of PLWHA involved in the study Bishofitu hospital, East Shoa, Ethiopia, 2011.

Variable	Frequency	Percent (%)
Social support and satisfaction		
Yes, satisfied	353	91.5
No, not satisfied	33	8.5
Value/respect from others		
Yes, satisfied	363	91
No, not satisfied	36	9
Access to reliable pharmacy		
Yes	327	80.7
No	78	19.3
Satisfaction with Clinician service		
Yes, satisfied	404	98.8
No, not satisfied	5	1.2
Satisfaction on open communication with HCP		
Yes, satisfied	396	98.3
No, not satisfied	7	1.7

Encountered side effect with current regimens (Fixed Dose) Yes, Encountered No, Not Encountered	 147 253	 36.8 63.3
Admission to hospital last one month Yes, Admitted No, Not admitted	 17 387	 4.2 95.8

II.) Knowledge about ART Drugs

The treatment duration of 344(92.2%) respondents ranges between 1-6 months & the remaining ranges between 7-37 months. With regards to ART benefit knowledge, 218(52.3%) of the participants were found to be satisfactory (Answer all {4} ART knowledge question correctly) & 199(47.7%) of the participants were found to be unsatisfactory (miss at least one of four ART knowledge question). Knowledge about the eligibility of ART was found unsatisfactory (Miss at least one of the three Question) for 354(84.9%) participants & satisfactory (Answer the three Question correctly) for 63(15.1%) of the participants. Knowledge about ART adherence was found to be unsatisfactory (Miss at least one of the three adherence Question) for 340(81.5%) participants & satisfactory (Answer the three adherence Question correctly) for 77(18.1%) participants. (See Table .3. Below)

Of the total sample, 315(77%) of the respondents reported that treatment schedule of fixed single dose fit their daily routine than previous & 25(6.2%) of the respondents claimed that the treatment did not fit their daily routine. Nearly all of the respondents reported that they took their medication on specified time but in case they delay, 117(86.7%) reported that they would delay < 30 minutes & 18(13.3%) claimed that they would delay for 30-90 minutes.

Nearly all uses memory aids to take their medication, the largest proportion 377(93.3%) were using watch bell & the remaining were using written schedule & pill box. 369 (90.7%) 0f the respondents reported that they got information from health personnel & 29(7.1%) of the respondents claimed that the source of information about ART was media & & the remaining reported they got information from other source.

Table 3: Treatment, Clinical, and Health Care System related variables of PLWHA involved in the study, Bishofitu Hospital, East Shoa, Ethiopia, 2011.

Variable	Frequency	Percent (%)
Treatment Duration (months)		
1-6	344	92.2
7-12	24	6.4
13-24	3	0.8
25-37	2	0.5
ART Benefit knowledge		
Good	218	52.3
Unsatisfactory	199	47.7
ART Eligibility knowledge		
Good	63	15.1
Unsatisfactory	354	84.9
ART Adherence knowledge		
Good	77	18.5
Unsatisfactory	340	81.5
Treatment schedule of fixed single dose fit your daily routine than previous		
Yes	315	77.8
No	25	6.2
Not sure	65	16.0
Number of minutes delayed		
<30	117	86.7
30-89	18	13.3
≥90	-	-
Methods of memory aid		
Pill boxes	11	2.7
Written schedules	14	3.5
Watch bell	377	93.3
Do not have	2	0.5

III.) Adherence Practice

On the assessments made, adherence practice was measured during the past seven days, three days & during the previous day before the days of interview by using self-report & pill count methods. Based on the survey, ART adherence during past three days showed that, 398(95.4%) of the participants reported that they adhered (took ≥ 95% of the prescribed HAART) to their treatment & 19(4.6%) of the respondents claimed they did not adhere (took < 95 % of the prescribed HAART) to their treatment. The result showed that during the past seven days, 397(95.2%) of the participants had taken ≥ 95% of the prescribed HAART (adhere to their treatment). (See Table 4. Below.)

Table 4: Patient Adherence by Self-report and pill count of PLWHA involved in the study, Bishofitu Hospital, East Shoa, Ethiopia, 2011.

Variable	Number	Percent (%)
ART adherence During previous day		
Adherent (>95%)	398	95.4
Non-adherent (<95%)	19	4.6
ART adherence During Past three days		
Adherent (>95%)	398	95.4
Non-adherent (<95%)	19	4.6
ART adherence During Past Seven days		
Adherent (>95%)	397	95.2
Non-adherent (<95%)	20	4.8

IV.) Reasons for non-adherence (see Table 4.)

Figure 1. Pie chart showing the proportion of client's reasons for non-adherence of PLWHA involved in the study, Bishofitu Hospital, East Shoa, Ethiopia, 2011.

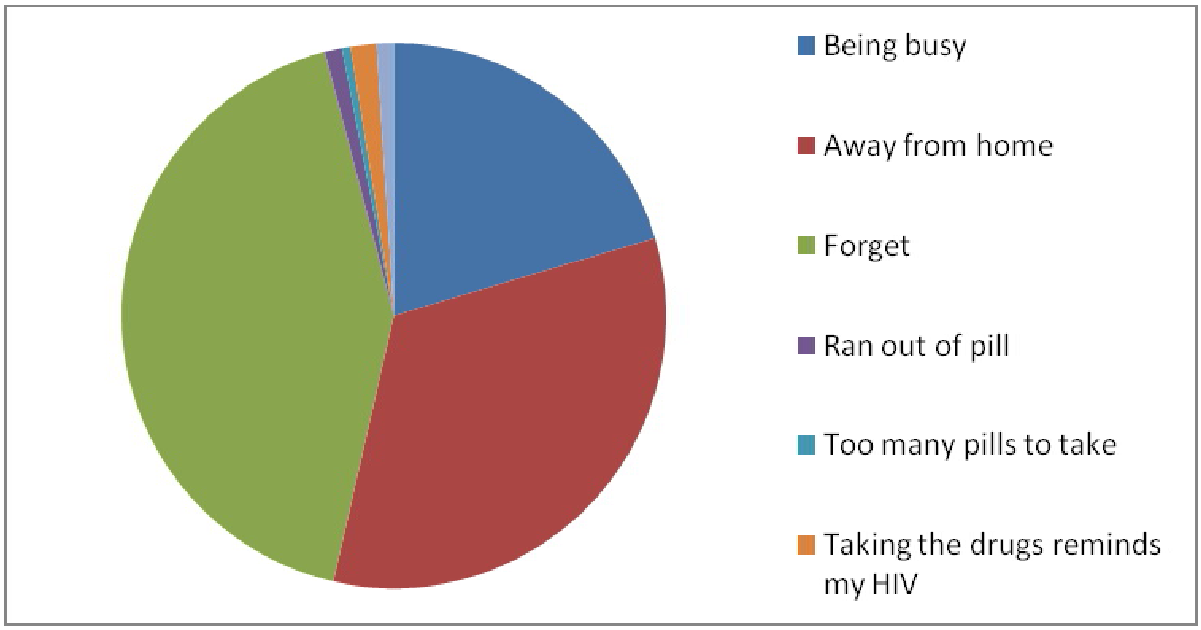


Table: 5 Reasons for missing doses/non-adherence among the study participants, Bishofitu Hospital, East Shoa, Ethiopia, 2011.

Reasons	Number	Percent (%)
Being too busy	40	29.4
Being away from home	65	47.4
Felt asleep	1	0.7
Simply forget	83	61.0
Want to avoid side effect	10	7.5
Change in daily routine	1	0.7

Felt depressed	2	1.5
Didn't want other to notice me	-	0
Felt sick	2	1.5
Had problem of taking medication	-	0
Ran out of pill	2	1.5
Too many pills to take	1	0.7
Taking the drugs reminds my HIV	3	2.2
Thought the drugs are doing nothing to improve my health	-	0

V.) Factors/ variable associated with adherence

Distance from Bishofitu hospital, medication adverse effect, satisfaction with social support & active substance use & caring for children has association with adherence in univariate analysis. The odds of non adherence among those who have medication adverse effect symptoms is 1.481 times higher than among those who have do not adverse effect. The odds of non-adherence among those have do not have adequate social support is 4.697 higher than among those who have adequate social support. The odds of non-adherence among those their residency far is 4.909 higher than among those who have come from a distance less than 45 KM.

The odds of non-adherence among those who do practice substance use are 1.043 higher than among those who do not practice substance use. The odds of non adherence among those who had children under their care are 1.449 times higher than among those who have do not have children under their care. (See Table .6.Below)

Table 6: Association of variables with adherence among the study participants, Bishofitu Hospital, East Shoa, Ethiopia, 2011.

Variables	HAART Adherent		Crude OR, 95% CI for Exp (B)	Adjusted OR, 95% CI for Exp (B)
	Yes	No		
Medication adverse effect Yes No	10	126	1.481, (0.622, 3.527),	1.075, (0.308, 3.749)
	12	224	1	1
Knowledge on ART benefit Unsatisfactory Good	158	10	0.465, (0.165, 1.306),	0.588, (0.176, 1.965)
	204	6	1	1
Knowledge on ART eligibility Unsatisfactory Good	17	304	1.261,(0.346, 4.569)	2.190,(0.303, 15.851)
	6	55	1	1
Knowledge on Adherence Unsatisfactory Good	18	291	0.841,(0.302, 2.345)	0.921, (0.194, 4.367)
	5	68	1	1
Satisfaction with social Support Yes No	310	11	4.697, (1.390,15.869)	11.833, (1.518,92.219)
	24	4	1	1
Schedule fitting daily routine Yes No	87	1	4.745(0.618,36.442)	0.961, (0.938,0.985)
	275	15	1	1
Depression No	4	129	1.364, (0.148, 12.535)	0.977, (0.951, 1.003)

Yes	1	44	1	1
Caring for children Yes	271	11	1.449, (0.490, 4.288)	5.000,(0.535,46.719)
No	85	5	1	1
Active Substance use Yes	1	10	1.633, (0.200, 13.369)	1.192,(1.022, 1.391)
No	21	343	1	1
Believe on efficacy of ART Yes	22	340	1.229, (0157., 9.613)	0.966, (0.946,0.986)
No	1	19	1	1
Distance from ART Unit <45km	324	11	4.909 (1.600,15.066)	17.286(3.555-84.050)
≥ ≥45 KM	30	5	1	1

6.2. The in-depth interview result (Qualitative)

Table.7. Basic socio Demographic characteristics of the PLWHA respondents participated in the in-depth interview at Bishofitu Hospital, 2011.

Respondent	Sex	Age	Marital Status	Educational Status	Religion	Monthly In-come	Working Status	Duration On ART
Respondent, 1	M	34	Married	12	Muslim	700ETB*	Working	6 Mon.*
Respondent,2	M	27	Married	12 + 1	Christian	800ETB	Working	23 Mon.
Respondent,3	M	31	Single	7	Muslim	Unknown	Working	12 Mon.
Respondent,4	F	26	Single	10	Christian	300ETB	Working	7 Mon.
Respondent,5	F	41	Widowed	Literate	Christian	Unknown	Working	30 Mon.
Respondent,6	F	29	Married	12 + 2	Christian	1200ETB	Working	7 Mon.
Respondent,7	M	35	Single	10	Christian	600ETB	Working	24 Mon.
Respondent,8	F	35	Single	9	Christian	500ETB	Working	6 Mon.
Respondent,9	M	28	Single	12	Christian	Unknown	Working	6 Mon.
Respondent,10	M	29	Single	12	Christian	700ETB	Working	14 Mon.

* Mon –represents Month & *ETB represents Ethiopia birr.

A total of 10 individual were participated in the in-depth interview meeting, of these 6 study subjects were male & the remaining were female. The age of the participants range from 27 to 41 years with mean age of 31.5 years old. Seven were single, two was married & one was widowed. The educational status of the participants range from grade 7 to 12+2 except one respondent can read & write. Eight were Christian & two was Muslim. All the participants were working actively & earn

monthly in-come which ranges from 300 ETB to 1200 ETB except two of the respondents were unable to describe their monthly in-come. Duration on utilizing ART of the participants ranges from 6 to 30 months with average duration of 13.5 months on ART. (See Above in Table – 7)

Thematic Area focused on & identified in the in-depth interview:_

1.) Factors the influence ART adherence practice

2.) Improvement in health status (Change in quality of life)

3.) Knowledge & Psychological factors.

1.) Factors that influence ART adherence practice

The question raised under these thematic areas were to describe the daily routine when taking fixed dose combined ARV to a single drugs whether they experienced any problem , like side effects ,access, dosage schedule ,medication interaction , convenience of treatment location, consultation on treatment, interaction with other medication & relation of the clients with the health care provider. With regards to whether the treatment schedule fit their daily routine than previous all except three participants stated that the treatment schedule does fit their daily routine & does take the prescribed medication in a specified time. One of the service users said that "when I took the drugs the drugs are too many that they irritate my stomach & I immediately started vomiting, he also stated that I'm a daily laborer I don't have adequate & appropriate in-come to buy food in order to take the drugs after having foods, for these reasons I don't have fixed or specified time to take the drugs to fit daily routine.

The other women respondent said that "I have not given any orientation when to take whether there is specified or fixed time to take, how long to take & how much dose to take in a profound way by the health care provider that I took the drug as I like to take & when I remember to take at the beginning of the therapy & near to stop taking drugs. As I started I'm near to die because of the drugs adverse influence & admitted to hospitals. Even the pills are too many to take at regular time & I fade up to take it. But currently she said that the pills burden is reduced to only one drug that it is very convenient & suitable to take & the side effects are also manageable & small." The other women respondent said that "the hospital is very far from my residency site I mostly miss the appointment of pharmacy refill for I lack money for transportation & sometimes also when I come for refill they told me to come another time for refill for the drugs stoke run out. Even if there is adequate supplies the health personnel was not around to give us drugs & we are made to wait longer. Even the health personnel were not friendly to orient us about the medication to fit the

schedule with my daily routine. She also complained drug side effect like vomiting, headaches, diarrhea, loss of appetite, heartburn .etc….

Four out of ten of the respondents claimed that hospital setting is far from their residency home & they encountered difficulties in accessing the drugs refill & sometimes they miss or come after appointment time passed. When they are asked about after how long of diagnosis they decided to start ART early all except one of them stated utilizing ART by their own decision but majority of them don't exactly remember after how long of diagnosis they started ART.

When they are asked about having access any time they want advice or support for their problem. Majority of the respondents said "we were not given time to discuss our problem with our Doctors for they are busy & there are a lots of PLWHA on treatment to be seen by them." Majority of them also responded "they got treatment support from families, friends, relatives & some Local NGO's." Eight out of ten respondents claimed that the support were not adequate they suffered economical burden to support themselves & their families.

2.) Improvement in health status(Change in quality of life because of combined ART)

The question raised under these thematic areas was whether taking fixed dose combined ART to a single drugs change the quality of their life. Nine out of ten claimed that fixed dose combined ART to a single drugs had dramatic improvement in their health status. One of 34 years male old respondents tell that " before I started the fixed dose combined ART to a single drugs I was in ill health almost on a bed for 2 weeks in a months' time. He also said I cannot walk out for work to win daily bread. Almost two of my sons dropped of schools because I am unable to cover their school fees. My life dream & vision had been collapsed & I was desperate in life & wish to die. Even I had poor appetite & started to have opportunistic infection. But within three months after initiation of ART I had got to gain weight, my general healthy had been recovered & all opportunistic infection stopped. I got out of bed & started working to win daily bread & started to generate in-come. My attitude has been changed for life & my dream come true to raise my sons for I hoped to live longer."

Next participant female respondent also explained that " Before I started fixed dose combined ART to a single drugs my general healthy has come deteriorating, had weight loss, unable to feed , very weak & spent most of my time on bed. I had developed rash all over face & bodies, had night sweating & persistent diarrhea. I am totally paralyzed & I cannot do anything. But after ART initiation my body started functioning & I became strong to work & I also got out of bed & able to help myself. Even the rash disappeared, the night sweating & diarrhea stopped. Finally she said I have regained hope for life."

Other respondents also claimed that we were at a grief & almost approached to death before we started fixed dose combined ART to a single drugs. We were having different type of opportunistic

infection, we can't generate in-come, we are helpless & hopeless even we had been admitted to hospital three to five times in 6 months time. But after initiation of fixed dose combined ART to a single drugs we have got dramatic improvement in our health condition & we all got out of bed & like others we were able to do & live quality life as other people live. They all claimed that we have got time to live long & educate their children at schooling & also said we are able to live longer to fulfill life dream & vision."

3.) Knowledge & Psychological factors.

The question raised under these thematic areas was from whom/where they heard or obtained information about ART & their understanding of the treatment plan. Majority of the respondent do not have adequate knowledge & awareness about the importance & benefit of ART before they initiate to utilize ART & at the beginning a few weeks after initiation of ART. Five out of ten were not even aware of ART before & heard about ART from health professionals at a time they visited health institutions to know their sero-status for HIV at VCT center , four of them heard about ART after they were admitted to hospital & diagnosed as HIV/AIDS patients & one of the ten respondents heard about ART from Media before he undergoes VCT. Two of the respondents said that "at the beginning I do not know the importance & benefit of ART & I even thought that one may take the drugs for one or two years & stop the drugs when he got relieved from the disease or opportunistic infection. I also thought that ART do not cure HIV/ADIS. Before I started taking the drugs I don't have confidence on the self efficacy of the medication. But after four month my understanding about the treatment increased even I have benefited from the ART & started taking by fixing dose & time for treatment compliance. "

The other respondents also explained that "before the initiation of ART I don't have the knowledge & awareness about ART & for I see many debilitated & bed reddened AIDS patients die immediately with one to two weeks after starting to take drugs & I think in my heart that the drugs are given to kill HIV/ADIS patients for they are burden for the family & community. But my attitude about the medication changed after one of my friends living with HIV/ADIS who were weak, admitted to hospital & expected to die within a few days, get dramatic improvement in his health after five months of taking ART."

The next other respondents also said that "in the beginning I know that all HIV positive & reached to HIV/ADIS stage can take ART & it will probably help them if they take the medication with 'Holy water' otherwise it will not work for them. He also describe that it is also good to take the medication with substance like herbal it will facilitate the efficacy of the drug to speed up cure from HIV/AIDS. But know 27 months since I started ART I understand that all positive will not take ART & there is criteria to start to use the drugs.

6.3 The peer educator FGD result (Qualitative)

Table.8. Basic socio Demographic characteristics of the PLWHA peer educators participated in Focus group discussion at Bishofitu Hospital, 2011.

FGD* Member	Responsibility	Sex	Age	Marital Status	Educational Status	Religion	Duration On ART
Participant,1	Peer Educator	M	48	Married	12	Christian	24 Month
Participant,2	Peer Educator	M	35	Married	10	Christian	12 Month
Participant,3	Peer Educator	M	30	Married	7	Christian	34 Month
Participant,4	Peer Educator	M	27	Single	12	Christian	15 Month
Participant,5	Peer Educator	M	34	Single	12	Christian	20 Month
Participant,6	Peer Educator	M	41	Widow	6	Christian	14 Month
Participant,7	Peer Educator	M	38	Married	10	Christian	36 Month
Participant,8	Peer Educator	M	36	Married	12	Christian	18 Month

FGD* - represents Focus Group Discussion.

A total of 8 peer educators were participated in the in FGD Session, all of study subjects were male. The age of the participants range from 27 to 48 years with mean age of 28.5 years old. Five were married, two was single & one was widowed. The educational status of the peer educator participants range from grade 7 to 12. All were Christian in religion. Duration on utilizing ART of the peer educator participants ranges from 12 to 36 months with average duration of 17.5 months on ART. FGD for men was handled separately for a total of 2 hours session to keep homogeneity & mange biases & the other session was not held because of limited number of (2) female peer educators availability. (See Above in Table – 8)

Thematic Areas identified for FGD with peer Educators

1.) Reasons for lost to follow-up & poor treatment adherence

2.) Clients reaction to the new fixed dose combined to a single drugs & complaints/drugs adverse influence

3.) Quality of life after treatment initiation

4.) Suggested comments to improve treatment adherence.

1.) Reasons for lost to follow-up & poor treatment adherence

Under these thematic areas the question raised & forwarded to the group is to describe from their experience the major reasons for lost to follow-up & poor treatment adherence. The FGD members described some " Six of the eight raised that majority of the clients suffered from economical problem & the ART center is very far from their residence & they lack money for transportation. Even peer educator gave example, three people we encountered to discuss with them why they disappeared from follow-up , three of them claimed that our residence is far from ART center we do not have money to pay for transportation & we do not have money to buy food for survival. Some lacks knowledge about how long to take the treatment disappeared from follow- up when they got recovered from opportunistic infection & after sometimes they presented to hospital with their condition worsen & deteriorated physically."

The peer educators also commented "some of the clients violate the advice given to them by health personnel & take the medication as they want without fixed time adherence & dose adherence & some uses substance like alcohol, chat & smoke cigarette." Fellow peer educators also said that "many of the clients who disappeared from the follow up had low perception about the importance & benefit of the treatment & look for other option like 'herbalist, holy water & prayer', they stop the treatment & get lost." The other two out of eight peer educators claimed that "when we ask them why do you get lost from follow-up, some client complain of the health personnel are unfriendly, they do not give us appropriate & adequate instruction & orientation & the made us wait longer when we come treatment refill."

But all peer educators claimed that “we are doing our best, counseling them & teaching them not disappeared from the follow-up & adhere to their prescribed medication.”

2.) Clients reaction to the new fixed dose combined to a single drugs & complaints/drugs adverse influence.

Under these thematic areas the question raised & forwarded to the group is to describe from their experience clients reaction to the new fixed dose combined to a single drugs & complaints on drugs adverse influence. All of the peer educators claimed that “ many clients complained side effects of the treatment before the treatment is changed to single fixed dose , they tell we take too many drugs we take three pills morning & afternoon with other additional medication & we are fed-up to take the drugs, the peer educator mentioned some of the adverse influence the client complain of, are rush all over the bodies , diarrhea , vomiting , night mare etc….even some clients stopped treatment because of the side effects & for some their Doctors change the treatment for the them.” All the peer educators claimed that “ but now after the treatment is changed to a single fixed dose the client take one pill morning & one pill afternoon & they are free from pill burden & the client claimed that the medication is so simple & suitable to take & there adverse influence are very minimal & small , they said we take it happily.’’

The peer educators claimed that “ even some of the client take only one pill per day , it becomes so easy take the drugs that , the peer educators claimed currently lost to follow-up is very few , it is not as many as before when the medication is multiple. Peer educators also said that currently there is no problem of adherence , it is only few because of their own reasons ,otherwise; many adhere to their treatment.” we are also doing our best to educate them about the adverse influence is at the initiation of the treatment & later it is manageable.

3.) Quality of life after treatment initiation

Under these thematic areas the question raised & forwarded to the group is to describe from their experience things they observe about the client’s quality of life after treatment initiation & adherence. All of the peer educators claimed in one accord “ those client who take their medication on daily basis as per the instruction & orientation given to them by health personnel & adhere to

their treatment get dramatic improvement in their healthy & get free from opportunistic infection." Peer educator also claimed that " many returned to their daily routine works & started to work. Many are also living longer without being admitted to hospital & we testify that the treatment completely changed the life of PLWHA & inspire hope & realistic life goals."

4.) Suggested comments to improve treatment adherence.

Under this thematic areas the question raised & forwarded to the group is to give comment & suggestion from their experience how to improve treatment adherence. All of the peer educators claimed that "many of the clients have very low knowledge & awareness about the perceived benefits of ART & adherence, therefore; it is good to provide the client with multiple education & encounters to raise their knowledge. Peer educators also suggested peer educators defaulter tracing also good way to bring back those clients lost to follow-up & many of the clients do not disclose their sero-status to their family & they lack treatment support groups to stick to the treatment,therefore; it is good to counsel the client to disclose their sero-status & get treatment support groups to adhere to their treatment."

Peer educators also claimed that " many of the clients do not have treatment reminder, therefore; it is good to educate them to have treatment reminder signal when to take the drugs & education about the discipline of treatment not take with other substance like alcohol, chat etc… & many of the clients are economically not strong it is also good to provide them addresses that works on care & support to obtain help in order to adhere to their treatment."

7. Discussion

In this study the overall adherence was measured using self-report & pill count, 95.4% of the participants were adhered ≥ 95% to their prescribed antiretroviral therapy during the past three days before the days of interview.

The adherence level in this study is much higher than the findings of other studies conducted in most developing countries including Ethiopia. Even if, Study shows typical adherence rates for medications prescribed over long periods of time are approximately 50-75%. (5)

The adherence rate is also much higher in this study than the value reported In Addis Ababa, Southern region & Oromia, for recently conducted research in Ethiopia also confirm that the levels of adherence >95% reported were 81.2% in three civil hospitals and 82.8% in defense hospitals of Addis Ababa (21). In the study done at two hospital of Oromia (Jimma & Adama) region was found 83.0 % & in the study performed at southern region (Yirgalem hospital) the adherence rate was found 74.2%%. (22).

In this study the adherence level is higher; However, Data from other Africa countries indicated that the challenge to achieve high adherence to ART is particularly acute in Sub-Saharan Africa as the high rates of HIV/AIDS lead to greater absolute numbers of affected individuals than in other low-income regions. Although long-term good ART adherence has been observed in certain settings of public sectors in Africa (Nachega, data presented at 16th Conference on Retroviruses and Opportunistic Infections 2009), the magnitude of this challenge in Sub-Saharan Africa remains large (15). and there is growing evidence for high rates of patients loss to follow-up (16,17). a recent review reported that ART programmers in Africa retain only about 60% of their patients after two years on ART.

Supplementary data also showed that A cross-sectional study of 1-month adherence among patients in Soweto, South Africa was >95% for 88%, 90–95% for 9% and, <90% for 3% (19). In a prospective study done in Cape Town to monitor adherence and evaluate factors predicting poor adherence revealed 63% of patient's maintained adherence of 90% to the prescribed tablets.. Although it may seem intuitive that higher pill burdens may be associated with decreased adherence, this premise has not proven to be the case in various studies (37). And the value of adherence in this study is still a bit higher than studies done in most Africa countries. The current guidelines for adults and adolescents which were stated on October 6, 2005 has made treatment regimens greatly simplified in recent year & bring forth a fixed dose antiretroviral drugs combined in to a single to improve adherence & avoid resistance (56). From this, we can infer that adherence in those client using a fixed dose combined to a single drugs currently is better than those client previously using combined dose (cocktail type) Antiretroviral therapy, for pill burdens may be associated with

decreased adherence (37). In line with these findings, subjects participated in the in-depth interview & peer educator's FGD reported that the currently changed single combined fixed dose has reduced the regimens side effect & the side effect is minimal & manageable. They claimed that single combined fixed dose is suitable & simple to take & has now reduced the pill burden that led us to treatment fatigue & decreased adherence.

In this study the level of adherence was measured using self report & pill count. Most data suggested that commonly used methods for measuring adherence include indirect measures, such as self-reports, electronic drug monitoring (EDM), pill counts, and pharmacy refill records, and direct measures, including detection of drugs or drug metabolites in plasma. (40) Most commonly, respondents are asked to report the number of doses they missed during a specified recall period or to estimate their overall percent adherence on a visual analogue scale. Response tasks may also include qualitative estimates of overall adherence, reporting the number of days of perfect adherence in the prior week, recalling when the respondent last missed a dose, or determining the number (or proportion) of doses (or pills) missed (or taken) over a specified recall period. Substantial variation also exists in the relevant time frame, with recall periods including the past 1, 3, 7, or 30 days. (41)

Data showed that the most frequently applied methodology in the measurement of adherence is patient self-report. In addition to potential overestimation of actual adherence, self-reported adherence is limited in that data may only reflect short-term or mean adherence. (10,11) In this study the level of adherence is evaluated using self report & pill count the findings was found nearly the same & this is made to reduce the threat of Self reporting might overestimate the rate of adherence to medication. For furthermore, Pill counts often are used by investigators as a more objective means of evaluating medication adherence behavior (22).

In this study, diversity of obstacle to treatment adherence were reported from the respondents; 40(29.4%) Being too busy, 65(47%) Being away from home, 83(61%) Simply forget, 10(7.5%) Want to avoid side effect & 2(2.5%) run out of pills. In line with these findings, subjects participated in this study of the in-depth interview & peer educator's FGD reported the same reasons for barriers of treatment adherence. This is almost the same with other studies conducted in Ethiopia, which is most frequently cited reasons for non adherence are; simple forgetting, being away from home, being busy, or experiencing a change in daily routine (22).

In this study it was found that distance from Bishofitu hospital, medication adverse influence, presence of one or two children under PLWHA using ART, active substance use among PLWHA practicing it, satisfaction with social support & ART knowledge eligibility are significantly associated with non adherence behavior both in the univariate & multivariate analysis, with a slight increment of the OR in the multivariate analysis. Which 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(21,22). In harmony with this study, other studies noted factors that have been associated with decreased adherence include the following: lower levels of education, anxiety, pain, pill burden, lack of convenient access to medication, medication side effects, active substance uses, distance of residence, dissatisfaction with social support & the health care system. (34)

In the final adjusted multivariate analysis of this study, we can infer 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. In agreement with these findings, study subject involved in the in-depth interview & peer Educators' FGD noted that good adherence was observed among clients who had better perceived benefit & self-efficacy of ART, accessing ART at ease & their residence is not distant from ART center, did not drink alcohol & chew chat & had adequate treatment support & financial support.

This study did not indicated depression, self-efficacy of treatment, adherence knowledge & knowledge about the benefit of ART have association with adherence both in the bivariate & multivariate analysis. This is probable because of a very small proportion of the participant were able to answer all the inquiry of ART benefit & adherence knowledge (15%) correctly without missing even one inquiry & a very low proportion clients (23.3%) of 197 valid study subject which is very small sample had scored above 14 on the Beck depression inventory. Even though this study did not indicated, data suggested that additional barriers to adherence include psychiatric disorders, such as depression or substance use, uncertainty about the effectiveness of treatment and the consequences of poor adherence, regimen complexity, and treatment side effects(22). Other studies suggest that depression and decreased adherence, particularly in relation to unstable housing also has been reported as an independent predictor of decreased adherence, although one study of a cohort of 132 homeless male subjects noted that of the 22% taking PIs, 80% of these individuals reported taking more than 90% of their prescribed doses. (33)

Data suggested that the primary goal of treatment with ART is to prevent HIV-related morbidity and mortality. Many studies have shown a strong correlation between adherence and clinical outcomes and/or laboratory markers (notably CD4 count). Non-adherence has been found to diminish the immunological benefit of ART and increase AIDS-related morbidity, mortality, and hospitalizations. (46) In line with these findings, subjects participated in this study of the in-depth interview & peer educator's FGD reported the opportunity to access ART had made them to have improved healthy status & minimize occurrence of opportunistic infection & helped them to engage actively to their work & maintain realistic goal in life.

From this we can infer that, Interventions recommended in other studies may directly or indirectly help to improve adherence for patients in this study & much has to be done to wards Interventions to improve adherence include starting when patients are ready, treating substance abuse and depression before initiating ART, simplifying the regimen, and tailoring it to the patient's lifestyle, management of drug side effects, increasing support, using skill building exercises, using reminders, motivation and education, minimizing the pill burden, trusting relationship with health care provider, patient education and convenient access to medications and refills, frequent visit to the provider, avoiding dietary restriction and providing medications free of charge. (54,55)

8. Strength & limitation of the study

- ✓ Strength :_
  - ➢ Measuring tools per tested & modification made
  - ➢ Data collected by currently practicing ART clinician
  - ➢ In-depth plus peer educator FGD conducted to complement the quantitative studies
  - ➢ Pill count & client self report is used to evaluate adherence rate
  - ➢ Multivariate analysis made to control the effect of confounder
- ✓ Limitation of the study
  - ➢ Some variables that every time predict adherence did not indicate the same findings as others
  - ➢ Only single session of FGD was under taken because of a limited number of (2) female peer educator availability.
  - ➢ There might be recall biases missed doses or delayed doses
  - ➢ Some participants may not bring their pill for pill count.

9. Conclusion & Recommendation

The prevalence of ART adherence among clients using currently changed single combined fixed dose this study was 95.4%. This level of adherence is higher than most studies done in developed countries & even much higher than the findings of other studies in Ethiopia.

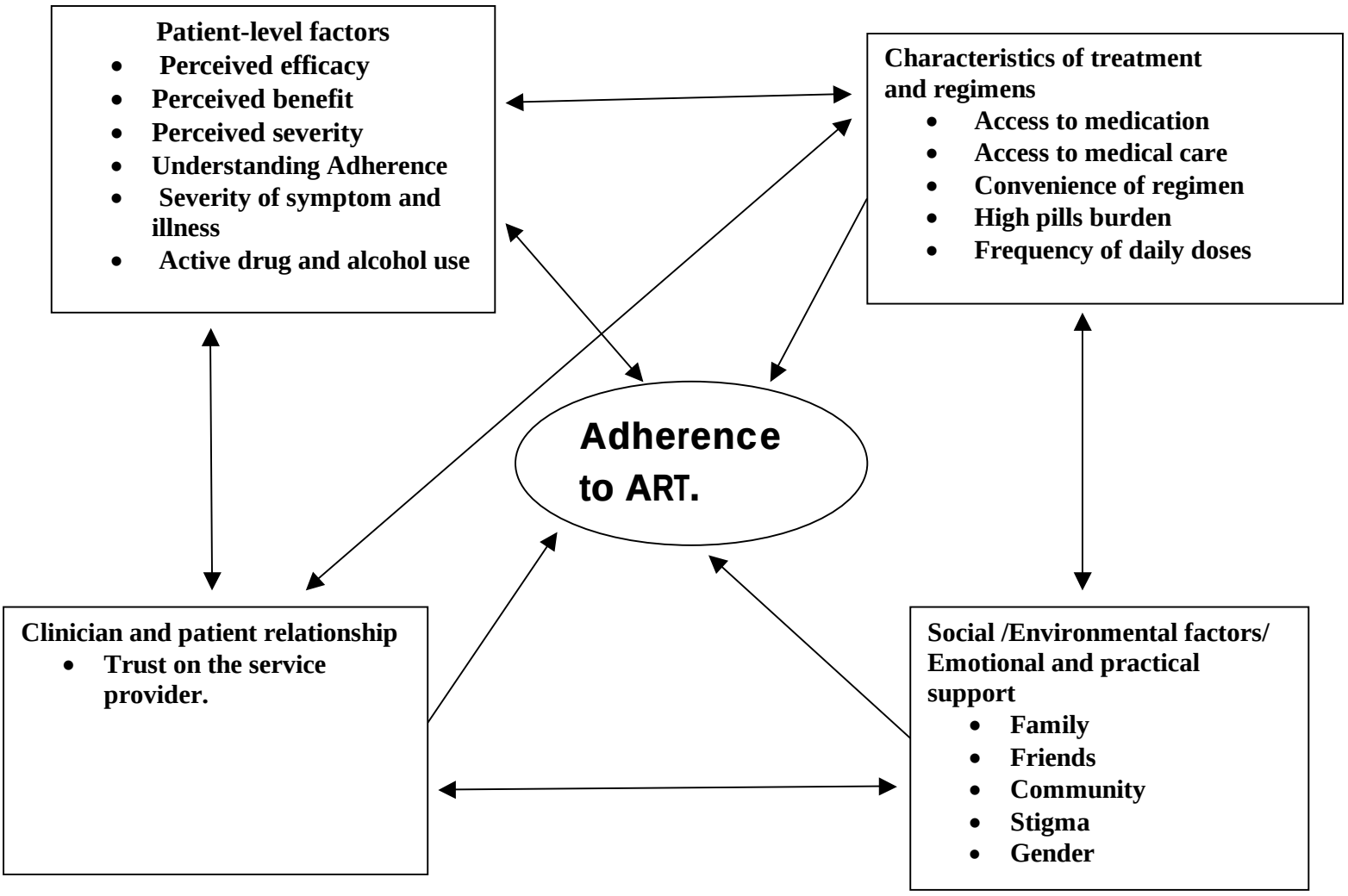
Distance from Bishofitu hospital, medication adverse effect, satisfaction with health service providers, satisfaction with social support & active substance use & caring for children has association with non adherence in bivariate & multivariate analysis. These factors were the consistent factors determining adherence to ART.

Based on the finding of this study we recommended the following interventions; -

- More & more researches should continually be conducted to simplify ART regimen likewise single combined fixed dose
- Strategies should be designed to decentralize ART service to make the service accessible

Annex:-II Conceptual Framework

Assumed conceptual framework on the assessment of adherence on ART among PLWHA.
Figure 1. Below.



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Annex –IV Questionnaire

Part .1. **AAU, MF, DCH**

Questionnaire for In-Depth Interview Guide **Adherence to ART**

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

o From whom /where did you heard /obtain the information about ARV

o After how long of diagnosis you decide to start ARV

o What were the factors which influence your decision making?

o Describe your understanding of your treatment plan

o Describe your daily routine when taking fixed dose combined ARV to a single drugs , Have you experienced any problems –like side- effects, access, interaction with other medications, dosing schedules?

o Whom do you consult in case of treatment problems?

o Do you have access any time you want advice /support for your problems

o How do you describe your relationship with health care providers?

o How convenient is the treatment unit location /services for you, and

o Did taking combination ARV treatment change the quality of your life, if so, in what ways?

Part .2. FOCUS GROUP DISCUSSION :- TOPIC GUIDE

1. At this moment ,we would like you to introduce yourself to the rest of the groups .

Let's start with the research team

- Name
- Education
- Work experience

2. Ice breaking Question /warming up

To show concern about the peer educator & defaulter tracer , start by asking them how they cope with life ,their jobs ,health ,etc.

Next we would like to hear about your experience or knowledge about ATR Adherence .

2.1 what do you think is major reason for lost to follow up & poor treatment Adherence ?

probes: A) Would you explain further ?

B) would you give us example ?

C) Is there anything else?

2.2 What do you think is the major complaint/drug adverse effect on using the previous combination ARV treatment ?

probes: A) Would you explain further ?

B) would you give us example ?

C) Is there anything else?

2.3 What are the clients reaction to the new fixed dose combined to a single drugs ?

probes: A) Would you explain further ?

B) would you give us example ?

C) Is there anything else ?

2.4 What did you observe about the client's quality of life after treatment initiation & adherence

probes: A) Would you explain further ?

B) would you give us example ?

C) Is there anything else ?

2.5 What do you suggest to improve ART treatment adherence ?

probes: A) Would you explain further ?

B) would you give us example ?

C) Is there anything else ?

Part .3.

AAU, MF, DCH

Questionnaire for Cross- Sectional Survey of

Adherence to ART

Introduction : Information sheet & consent form that certify respondents agreements before interview.

I am ----------working as a data collector in this study that assess antiretroviral adherence and its related factors in the ART unit at Bishofitu hospital.

The study is run by AAU, DCH, in collaboration with----------.

On this questionnaire your name will not be written, all your answers will be kept completely confidential.

The answers you give will be used to plan ways to help other people who must take pills on a difficult Schedule. Please do the best you can to answer all the questions. You do not have to answer, if you do not wish to answer a question, even you may end this interview any time you want to. Do you agree to participate in this study? _____. Thank you for helping in this important study.

Date of Interview_____ Hospital ID_____

Study ID _____

Interviewer Name----------

Supervisor----------

Section I: Socio demographic characteristics

No	Questions	Coding Categories	Code
101	Sex of respondent	1. Male 2. Female	
102	Age in years		
103	Ethnic groups	1. Amhara 2. Oromo 3. Tiger 4. Other specify_____	
104	Marital status	1. Unmarried 2. Married 3. Divorced 4. Separated 5. Widowed	
105	Religions	1. Orthodox 2. Catholic 3. Protestant 4. Muslim 5. Other specify_____	
106	Literacy	1. Illiterate 2. Read & write 3. Elementary4. High school 5. Diploma or above	
107	Monthly income (in birr)	1. 200-250 2.251-500 3. 501-999 4. 1000 & above 5. Variable	
108	Working situation	1. Work active 2. Unemployed (Jobless) 3. Pensioner 4. Student 5. other specify_____	

109	Do you have history of Active ubstance use ?	1. Yes 2. No	
110	If yes to Question 109, which substance do you use?	1. Kcatt 2. Cigarette 3.Alcohol 4.IV drugs 5. other	

Section II: Social support and Psychological variables

No	Questions	Coding categories	Code
201	With whom do you live?	1.Live alone 2.My family 3.My parents 4.unstable	
202	Do you have any emotional & practical support ?	1.Yes 2.No	
203	If yes to Question 202, who support you ?	1. Family 2.Friends 3.Peer 4. Community 5.Other	
204	What kind of support or care do you get from the above people,	1. Material / financial 2. Information / advice 3. Other specify	
205	Are you satisfied with their help	1. Yes 2. No	
206	Are you valued for your skills or abilities by others?	1. Yes 2. No	
207	Are you satisfied with the way people value for your skills or abilities	1. Yes 2. No	
208	Are you confident enough in the ability to adhere to ARV medication in the future?	1. Yes 2. No	

209	Do you know the consequence of non-adherence?	1. Yes 2. No	
200	if yes to question , mention some of them	_____	
211	Do you have any doubts about HCP	1. None 2. Some 3. Many	
112	Do you think ART benefits you	1. Yes 2. No	
213	Have you ever thought about your susceptibility to have the consequence of none adherence for incase of missing/skipping any ART doses?	1. Yes 2. No	

Section III Beck Depression Inventory

No.	Question	Coding categories				
		(0)strongly Disagree	(1)Disagree	(2)Don't know	(3)Agree	(4)Agree strongly
301	You have been sad & feeling low.					
302	You have been nervous & irritable.					
303	You have been feeling bad.					

304	You have been having problem with your day to day activities					
305	You have been debilitated & sick .					
306	You have heated your self					
307	You have thought to harm your self					
308	You have no appetite at all any more					
309	You haven't had a good sleep at all anymore.					
310	You have lost interest in sex completely					

Section IV: Health Status

No	**Questions**	**Coding categories**	**Co de**
401	When did you hear about ARV	1. Before my illness, 2. After my illness 3. During my illness 4. Recently	

402	From where did you get the information about ARV	1.HealthcareProfessionals 2.MassMedia 3. Others specify_____	
403	Are you committed /convinced before starting ART ?	1.Yes 2. No	
404	Were you aware of the benefit of ART	1. Yes 2. No	
405	After you had started ART, what clinical benefit did you get ?	1.Improved quality of life 2.Weight gain 3.Reduced fever 4.Reduction of hospitalization 5.Reduce frequency of diarrhea 6.No benefit at all.	
406	Do you know the importance of adherence before you start ART	1. Yes 2. No	
407	How long have you been on ART	_____	
408	What benefits does it give you	_____	
409	What was your CD4 count (write the date)	Initial_____ Recent_____	
410	Have you disclosed you HIV status to your family and relatives	1.Yes 2.No	
411	.If yes to the above question, to whom?	1.wife 2.family members 3.friends 4.others specify	
410	Have you had any symptoms in the past four weeks/1 months while on ART	1. Yes 2. No	
411	If yes to question 410 , which one was very serious ?	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 & chest pain 8.Chest pain & dyspnea	
412	Do you have history of admission during the last one month ?	1.Yes 2.No	
413	Do you have history of admission during the last one years ?	1.Yes 2.No	
414	How long have you been admitted to hospital for management & follow up for the last one years ?	1.I have been in hospital for ___ days .2.I have been admitted ___ times in a year.	

Section V: knowledge and Attitudes towards the regimen

No	**Question**	**Coding categories**	**Code**
501	When taking ART, AIDS will be delayed	1. Yes 2. No	
502	When taking ART, an HIV- infected person will be cured from AIDS	1. Yes 2. No	
503	When taking ART, it can happen that one may get sick from the Rx itself.	1. Yes 2. No	
504	When taking, ART, the person will ive longer than when is not	1. Yes 2. No	
505	All HIV - infected persons can take ART	1. Yes 2. No	

	ART		
506	Only when the body's defense system extremely low (very low WBC) is a person should take ART	1. Yes 2. No	
507	When one takes ART, it has to be taken at specific time	1. Yes 2. No	
508	When one takes ART, the daily doses should not be escaped	1. Yes 2. No	
509	You need to take pills the rest of your life to delay AIDS	1. Yes 2. No	
510	Were you convinced before stating ART?	1.Yes 2.No3.Not sure	
511	Are you taking a fixed dose combined to a **single drugs currently** ?	1.Yes 2.No	
512	Do you believe in Self Efficacy of the regimens ?	1. Yes/No Doubt 2. Yes but Doubtful 3. No 4. Not Sure	
513	What do you suggest about a fixed dose combined to a **single drugs** ?		
514	Do you feel comfortable when taking ART in front of others than before ?	1.Yes 2.No3.Not sure	
515	Does the Rx schedule fit you daily Routine than the previous	1.Yes 2.No3.Not sure	
516	Do you take your dose in a specified ime per day ?	1.Yes 2.no	
517	If No to question ,516 how much ninutes do you delays from the	1.<30minutes 2.30-89 minutes 3.≥90 minutes	

	pecified minutes?	minutes 3.≥90 minutes	
518	What types of schedules do you use the memory aids in order to take medication ?	1.pill box 2.written schedules 3.watch bell 4.Don't have	
519	Have you ever had any side effect to ART after the current regimens ? 1.Yes 2.No	1. Yes 2. No	
520	Specify the side effect	1.nausea and vomiting 2.headach 3. anemia 4.GIintolerance 5. depression 6.rash 7. other specify-_____	
521	What did you do when you had side effect?	1.Immediately report to clinician 2.Immediately stopped taking pill 3.With held until the date of appointment 4.Dropped out permanently	
522	Are you taking any other medication now with your ARV	1.Yes 2.No	
523	What is the drug		
524	What is/are the most likely way you become infected with HIV	1.sexual intercourse 2.shared needle 3. Blood transfusion 4.Dont know 5.Other specify	

Section VI: Patient Providers Relationship

No	Question	Coding category	Code
601	Are you satisfied with the clinicians service	1.Yes 2.No 3.Not sure	
602	Do you feel the health care providers treating you are capable	1.Yes 2.No 3.Not sure	
603	Do you have open communication with *HCP treating you	1.Yes 2.No 3.Not sure	
604	How frequent do you visit your doctor	1.every month 2.every 2 month 3.every 3 month 4.Variable	
605	Do you obtain the education or assistant you need during your visits	1.Yes 2.No 3.Not sure	

HCP

Section VII: Health care system and Clinical Setting

No	Question	Coding category	Code
701	How far is your residence from the ART unit you are attending	1.<45KM 2.>45 KM 3.Not sure	
702	Do you have access to reliable pharmacy any time you want	1.Yes 2.No 3.Not sure	

703	At present do you have a child under your care?	1.Yes 2.No 3.Not sure	
704	Are you satisfied by the improvements you obtain for your treatment	1.Yes 2.No3.Not sure	
705	Are you satisfied in the scheduling appointments of the treatment unit	1.Yes 2.No3.Not sure	
706	Are you satisfied in the confidentiality of the treatment unit	1.Yes 2.No 3.Not sure	

Section VIII: Adherence assessment & Reasons for skipping doses

I. Adherence Assessment

Patient Interview

Ask questions about number of doses skipped & unmet restrictions, i.e. like

food required with drug, time schedule, with empty stomach . . . etc

Name of the ARV drugs that the patient is taking _____

ARV drugs frequency/administration /number of daily doses_____

Number of doses skipped; Yesterday, _____

In the past three days, _____

In the past seven days, _____

How closely did you follow specific schedule in the past 7 days?

1. Never 2. Sometimes. 3. About half of the time

4. Most of the time 5. All of the time.

How often did you follow special instruction?

1. Never 2. Sometimes 3. About half of the time

4. Most of the time 5. All of the time.

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 _____

II. Reasons for skipping the doses

NB: More than on answers is possible

No	Reasons for skipping doses	Tick
1	being away from home	
2	were too busy	
3	simply forgot	
4	too many pills to take	
5	wanted to avoid side effects	
6	did not want others to notice me taking the medication	
7	had a change in daily routine	
8	felt like the drug was harmful	
9	felt asleep	
10	felt sick	
11	felt depressed/overwhelmed	
12	had problem of taking meal at specified time (meals, empty stomached…)	
13	ran out of pills	
14	felt good	
15	taking medication reminded my HIV	
16	Confused about the dosage	
17	I thought the medication had no value	
18	People told me the medicine is not good	