Addis Ababa University

College of Health Science

School of Public Health

Assessment of Anti-Retroviral Therapy Adherence and its Determinants among HIV-Positive Mentally Ill Patients Attending Outpatient Department at Amanuel Mental Specialized Hospital, and St. Paul Hospital Millennium Medical College

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List of Acronyms

AIDS	AcquiredImmunodeficiency Syndrome
AMSH	Amanuel Mental Specialized Hospital
ART	Anti-Retroviral therapy
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency virus
MDD	Major Depressive Disorder
MI	Mental Illness
NGOs	Non-Governmental Organizations
PLWHA	People Living With HIV/AIDS
SPHMMC	St. Paul Hospital Millennium Medical College
UNAIDS	Joint United Nations Program on HIV / AIDS
WHO	World Health Organization
YLD's	Years of Life Lost Due To Disability

Abstract

Background: *HIV is an infectious disease that affects people without any boundary and health status. While mental disorders could predispose individuals to different communicable diseases including HIV, people who already encountered HIV could sustain depression and mental disorders where adherence to antiretroviral therapy (ART) could be hampered. Despite this fact, there is a paucity of information in this area.*

Objective: *the aim of the study is to asses ART adherence and its determinants among HIV positive mentally ill patients attending outpatient department at Amanuel Mental Specialized Hospital and St. Paul Hospital Millennium Medical College.*

Method :*a quantitative cross-sectional study was undertaken among 416 HIV positive mentally ill patients attending outpatient services at antiretroviral therapy units of Amanuel Mental Specialized Hospital and St. Paul Hospital Millennium Medical College. The data was collected using structured questionnaire and analyzed using SPSS 21.*

Result: *A total of 416 were interviewed. The principal reasons reported for skipping doses in this study were being busy, falling asleep, and running out of medication and religious beliefs. The overall self-reported ART dose adherence among the mentally ill was only 57.2%. Adherence was independently associated with being employed (OR 0.505, 95% CI 0.321-0.797)**,** running out of drugs (OR 0.031, 95% CI 0.003-0.276), being busy (OR 0.015, 95% CI 0.003-0.064), falling asleep (OR 0.032 95% CI 0.004-0.281) and Depression wasn't significantly associated with ART adherence.*

Conclusion: *the self-reported adherence level was low in the study area. The study showed that mentally ill patients are more influenced by personal and emotional reasons than the other factors like, medication related, patient-provider relationship, and health care delivery system.*

Key words: *ART Adherence, HIV positive, mentally ill*

1. Introduction

1.1 Background

The world has committed to ending the AIDS epidemic by 2030 in order to achieve this, UNAIDS recommends a Fast-Track approach: substantially increasing and front-loading investment to overcome one of the greatest public health challenges in this generation. In just 2014 and 2015 the number of people living with HIV on antiretroviral therapy has increased by about a third, reaching 17.0 million people. Since the first global treatment target was set in 2003, annual AIDS-related deaths have decreased by 43%. In the world's most affected region, eastern and southern Africa, the number of people on treatment has more than doubled since 2010, reaching nearly 10.3 million people. AIDS-related deaths in the region have decreased by 36% since 2010. But new cases of 2.1 million were recorded worldwide adding up to a total of 36.7 million people living with HIV. Scale-up of antiretroviral therapy is on a Fast-Track trajectory that has surpassed expectations. Global coverage of antiretroviral therapy reached 46% at the end of 2015(1).

Good adherence to anti-retroviral therapy is necessary to achieve the best virological response, lower the risk that drug resistance will develop, and reduce morbidity and mortality. These benefits critically depend on patients achieving and maintaining high levels of medication adherence (2). To avoid the emergence of the resistant strains of the virus, World Health Organization (WHO) recommends at least 95% of adherence to ART (3). Even though importance of ART adherence has been recognized and promoted, many of the reported adherence rates are below the recommendation. the magnitude of adherence among the patients in Soweto, South Africa, was 88% (4); twenty percent of the participants in a community setting in Atlanta missed at least one dose of ART(5). In Ethiopia, the magnitude of adherence was 81.2% in three hospitals in Addis Ababa (6). There has been a concern about the capability of patients in resource-limited settings to adhere to ART, especially in the African context (2).

The burden of mental health problems is increasing globally(7). Mental disorders are widely recognized as a major contributor (14%) to the global burden of disease worldwide(8). It is an

integral part of general health(9). However, it is considered that over 450 million people worldwide suffer from some form of mental disorders(10). Nearly 25% of individuals, in both developed and developing countries like Ethiopia develop one or more mental or behavioral disorders at some stage in their life(11). This makes them concern to the society due to the loss of productivity due to their disability, increased health care cost and burdening the society, their families and the government as well(12).

In South Africa neuropsychiatric disorders comes second after HIV/AIDS in years of life lost due to disability (YLD's)(13). "In low income countries, depression and malaria represents almost similar problems (3.2% versus 4% of the total disease burden), but the funds being invested to combat depression are only a very small fraction of those allotted to fight malaria" (8)

In addition, mental disorders are associated with risk factors for communicable and non-communicable diseases like heart disease, cancer, diabetes, HIV infections and maternal and child health(14). Conversely, health conditions increase the risk for mental disorders, e.g. HIV/AIDS and heart disease are associated with depression(14). A study done in South Africa found that 44% of people living with HIV/AIDS have a diagnosable mental health condition compared with 17% in the general population(15).

Mental illnesses occur with chronic mental conditions in many patients, causing significant role impairment, work loss and work cutback. "They also worsen prognosis for heart disease, stroke, diabetes, HIV/AIDS, cancer and other chronic illnesses."(16). Major depressive disorder (MDD) among individuals living with HIV is a significant public health problem(17). And ART non-adherence is one factor(18). Depression or psychiatric morbidity is common predictor of non-adherence(19) . ART adherence is now widely recognized as a critical health promotion behavior for HIV positive individuals on therapy(20), where adherence to HIV treatment regimen is defined as taking pills in all the prescribed doses at the right time, in the right doses and in the right way(21).

On this study of ART adherence and its determinants among HIV positive mentally ill patients attending outpatient service, information on the patients' adherence status and the challenges they face on doing so or the factors that affect their adherence to their medications will be

provided. The current study will assess ART adherence and its determinants among HIV positive mentally ill patients attending outpatient department at Amanuel Mental Specialized Hospital (AMSH) and St. Paul Hospital Millennium Medical College (SPHMMC) from January 2018– March 2018.

1.2 Statement of the Problem

HIV-positive individuals have high rates of depression(22). And in developing contexts, there is evidence that depression is a risk factor for non-adherence to ART(23).

According to WHO, mental illness is present at any point in time in the world(24)and estimated that it contributes 8.1% to the global burden of disease(25).According to the report by WHO, In the United States of America HIV infection Prevalence rates in mentally ill inpatients and outpatients have been reported to be between 5% and 23%(26).While in African psychiatric population the HIV prevalence data is few, one study in 2000 carried out at Weskoppies Hospital, South Africa showed only 9% prevalence among 200 new admissions. In the same hospital another study in 2012 showed 11% prevalence increment(27).

In Ethiopia mental illness is the leading non-communicable disorder(28).The average prevalence of mental disorders in Ethiopia is 18% and 15% for adult and children respectively(29). A study showed that it contributes to over 12% of the burden of disease(30), consistent with this, a study in 2006 indicated that the health problem associated with mental disorder in Ethiopia is as high as 20%(31).In a study done at Yirgalem Hospital, the adherence level for patients who missed ARV treatment drug doses was 88.7%(32). If a patient is not optimally adherent to ART, the possibility of the failure of the treatment along with deterioration in the health status of the patient and the development of a multidrug resistance to antiretroviral drugs that can be transmitted to others, is undeniably high.

A relationship between stress, depression and immune response such that HIV infection is likely and it may progress more rapidly in individuals with these symptoms(33). HIV infection and MI co-morbidity appear to be detrimental for medication adherence(34). Depressive symptoms among HIV positive persons have long been linked to poor medication adherence(35) at the same time a study has showed that HIV positive individuals with co-morbid bipolar disorder have significantly worse adherence to their antiretroviral medication compared to those without

the disorder(36). Mental illness being present in almost half of HIV positive patients(37) a study on similar topic showed that many patients with serious mental illness are able to adhere very well to antiretroviral regimens, yet a substantial proportion displayed poor adherence(38).

In general there has been studies done on ART adherence among HIV positive patients, there also has been studies done on medications adherence of mentally ill patients with their respective medications, while mentally ill patients are prone to challenges on staying adherent to their medication there has been a contradict on significant relationship between mental illness and medication adherence on different studies as well as a limited Information regarding ART adherence and its determinants among HIV positive mentally ill patients in Ethiopia. This study assessed ART adherence and its determinants among HIV positive mentally ill patients attending outpatient department at AMSH and SPHMMC.

1.3 Significance of the Study

It is crucial for patients living with HIV to be adherent on their ART medications. Influenced by various factors, it might be challenging for HIV positive mentally ill patients to be compliant on their routine medications. ART adherence and mental illness is a concern in the whole world but predominates in poor countries such as Ethiopia. Hence the study result will show the existing ART adherence and its determinants among HIV positive mentally ill patients attending outpatient department at AMSH and SPHMMC by assessing their level of adherence and determinants, it will Provide data to give insight to the health system, policy makers, and other stakeholders who are concerned about ART adherence and mental health in improving the adherence level by promoting adherence so that the patients and the community at large may benefit, and it may add to literature of ART adherence among HIV positive mentally ill patients.

2. Literature Review

2.1 Global burden of HIV/AIDS problem

The human immune deficiency virus/Acquired Immune deficiency syndrome (HIV/AIDS) is one of the most destructive epidemics and a major threat to the world population affecting over all social, economic, and political wellbeing as well as individual health (39).

There were an estimated 34 million people living with HIV/AIDS (PLWHA) in 2011(39).The majority,97% of them were from low and middle income countries(40).Sub Saharan African is the most affected region contributing more than 69% of the total(39).In Ethiopia there were about 789,900 people living with HIV/AIDS in 2013(41).According to the 2011 Ministry of health report, about 333,453 PLWHA were on ART in Ethiopia (6).

2.2 ART Status in Ethiopia

Free Anti retro viral treatment(ART) service was launched in Ethiopia in January 2005 and hospitals began providing free ART in March 2005.The government focused on accelerated access to ART in June 2006 .This accelerated access, especially in health centers, was not accompanied by an equally rapid rise in ART uptake as expected(42).

Even though it doesn't cure, antiretroviral therapy (ART) has remained the only available option in reducing HIV/AIDS related morbidity and mortality. It has long been found to be effective in reducing viral load and transmission, improving immune function, and quality of life of PLWHA(43). However, successful long term treatment of HIV requires strict adherence to the ART regimen(44).

Inadequate adherence increases the risk of drug resistance and treatment failure. Therefore, optimal adherence is highly essential for sustainable success to ART(45). Taking greater than 95% of prescribed doses is recommended for optimal virology suppression and to minimize the rate of greater than 50% is associated with less than 95% adherence rate(46).

2.3 Definition of adherence

Adherence to medication, also known as compliance with medication is the extent to which patient follows medical instruction(47). This however does not mean that patient is only a passive receiver of medical advice and not an active contributor in the treatment process. In the treatment of patients with HIV infection it is essential to achieve more than 95 % adherence to ART in order to suppress viral replication and avoid the emergence of resistance(48). Achieving such high rates of adherence is often very challenging in such patients, because their regimens include multiple drugs that may have complex dosing schedules and may cause food interactions and adverse effects resulting in poor tolerability. In addition, life style factors and issues in the patient-provider relationship may make adherence difficult(48). Considering these issues, a practical definition of adherence in the context of ART can be stated as the extent to which a person's behavior in taking medication, following dietary specifications and/or executing lifestyle changes corresponds to the agreed recommendations from a health care provider. In case of mentally ill patients this can be related both to the care givers and the mentally ill patient's behavior and agreement recommendations is required from both the mentally ill patient and care giver.

2.4 Magnitude of adherence to ART

Worldwide, regardless of the illness or treatment many people do not take their medications correctly(49). A study in Brazil showed that the cumulative incidence of non-adherence to be 36.9%(50). Adherence among patients in Soweto, South Africa was 88%, in Cape Town; 63% of patients maintained adherence levels of 90%(18). Consistent factors for poor adherence include, stress, substance use, regimen complexity, and depression. Patients who do not have social support are less likely to continue their treatment with optimal requirement(51).On aggregate, non-adherence to ART is estimated at between 50-80% in different social and cultural settings(44).

Long-term adherence interventions are needed for durable effect, particularly in chronic diseases such as HIV. Antiretroviral therapy lowers viral load only when treatment regimen is fully adhered. Human immune deficiency virus (HIV) poses a unique challenge due to its rapid replication and mutation rates hence very high levels of adherence (greater than 95%) are

required to achieve long-term suppression of viral load(29). A study conducted in the antiretroviral therapy unit of Jimma University Specialized Hospital on predictors of ART adherence among HIV infected patients Self-reported dose adherence in the study area was 94.3%. The rate considering the combined indicator (dose, time and food) was 75.7 %(32).

2.5 Mental illness and HIV/AIDS

According to the WHO report by secretariat on HV/AIDS and mental health, "Mental health and HIV/AIDS are closely interlinked; mental health problems, including substance-use disorders, are associated with increased risk of HIV infection and AIDS and interfere with their treatment, and conversely some mental disorders occur as a direct result of HIV infection." This has resulted in higher mental illness prevalence among HIV infected individuals than the general population. HIV infection not only has psychological impact but also has direct effects on the central nervous system causing neuropsychiatric complications(26).

Acquired immune deficiency syndrome (AIDS) is one of the most destructive epidemics the world has ever witnessed. At present an estimated 33.4 million people are living with HIV worldwide, nearly two-thirds of these live in sub-Saharan Africa(52). On top of the economic and related challenges people living in developing world go through each day having a lifelong treatment and care requiring disease makes life even harder for the HIV positive patients adding up to the stress the disease itself brings upon them.

Mental disorders can be classified into primary including: schizophrenia, schizoaffective disorder or secondary such as psychosis caused by a medical condition such as HIV infection disorders(22). Most studies associate depression with HIV positive patients' related mental illness. HIV-positive individuals are at a twofold(53) to five fold(54)great risk for depression than are HIV-negative individuals.

2.6 ART Adherence and mentally ill patients

Severe depression and trauma are experienced by many HIV positive patients(55) resulting on adequate ART adherence of HIV positive individuals with mental disorder to be less likely(56).Due to the mediating role of non-adherence to antiretroviral therapy (ART), relatively worse health outcomes in HIV patients and depressive symptoms are associated(57). A study done in Madrid, Spain showed that the degree of adherence to antiretroviral therapy is influenced by Socio-demographic and psychological factors(58). Similar study done on common mental health problem and ART adherence stated "Depression, anxiety disorders, and disorders related to substance abuse were identified as key role-players influencing ART adherence"(59)

Decreased adherence to ART may be the result of feelings of hopelessness and a depressed mood that are associated with the difficulty individuals have in coping with the burden of HIV/AIDS and a co-morbid mental illness(60)..A meta-analysis done on depression treatment on enhancing ART adherence concluded that "Across 29 studies of 12,243 persons living with HIV/AIDS, treatment of depression and psychological distress improved antiretroviral adherence"(61). Another recent meta-analysis across 95 samples found depressive symptoms being significantly related to ART non-adherence(62).A study showed that AIDS-infected individuals are 30 % more adherent to HAART in a given month if they used antidepressants in the prior month(63) implying HIV positive psychiatric patients adherence to their ART medication can also be influenced by whether they are taking their antidepressants or not.

There exists different view among different studies with respect to mental illness and ART adherence, a meta-analysis of 29 studies concluded that improvements in adherence to antiretroviral therapy is associated with treatment of depressive symptoms and alleviation of psychological distress(61). To support this, another study done in Africa on youth suggested that among factors related to ART adherence mental health should also be considered(64). While another study done in United States resulted in discontinuation of HAART in the first and second years of treatment in psychiatric patients is less likely (76).

2.7 Factors influencing adherence to ART

The factors influencing adherence can be divided in to three main groups(50).

1. Patient and family/care giver related factors

Family plays a crucial role in any kind of treatment in children. For example younger children are often given medications by their parent or other family member(51). Major issues related to family or caregiver that influences adherence include: presence of anxiety, depression, active substance abuse, the presence of HIV infection in another family member, fear of disclosure of HIV positivity of the family, family disruptions. If the caregiver himself/herself is infected then he/she is struggling with his/her own illness, psychosocial factors, medication regimens and most often financial burden due to expenses incurred on his/her own therapy, child's therapy and associated cost of medical treatment(48).

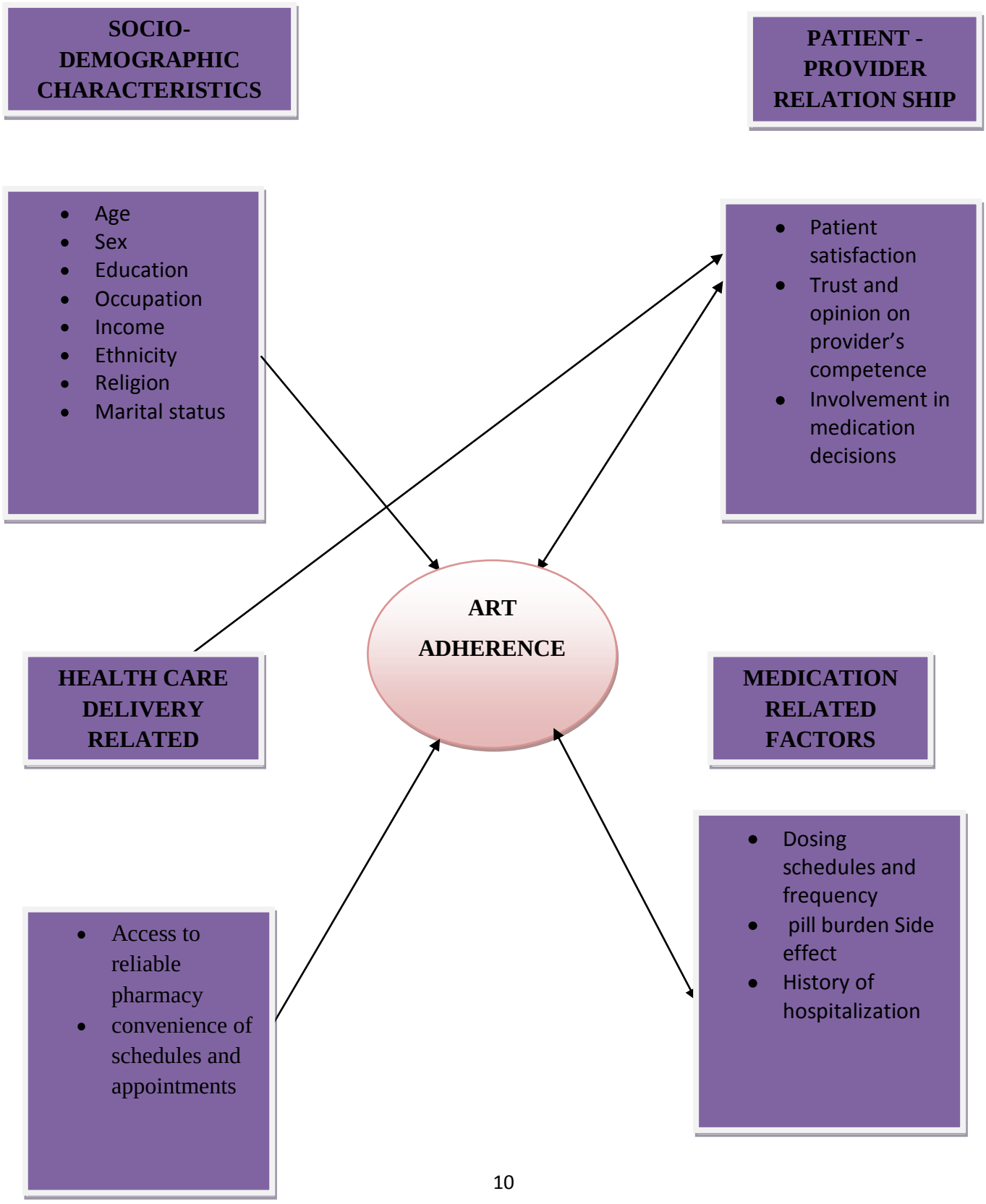
2. Medication related factors

Characteristics of the commercially available formulations, such as taste, palatability, size of pills, availability of liquid formulations, storage requirements (e.g. refrigeration for liquid formulations), adverse effects (e.g. metabolic complications) can significantly affect adherence. Further, pharmacokinetic and or Pharmaco-dynamics properties of the drugs such as need for daily administration, dietary restriction, drug interactions, frequency of dosing, dosage and therefore pill burden also influence adherence to therapy(50).

3. Health care delivery system related factors

Factors not directly related to patient or drugs can also influence adherence. For example limited availability and accessibility of ART at healthcare facilities for diagnosis and treatment of HIV especially in developing countries, high cost of ART and other health services, presence of experienced health care providers, patient provider relationship, availability of counseling services and social, economic or psychological support for people living in developing countries can influence adherence positively or negatively (47).

2.8 Conceptual Framework



3. Objective

3.1 General objectives

To assess ART adherence and its determinants among HIV positive mentally ill patients attending outpatient department at AMSH and SPHMMC 2018.

3.2 Specific objectives

- ✓ To asses level of ART adherence among HIV positive mentally ill patients attending outpatient department at AMSH and SPHMMC 2018.
- ✓ To determine factors associated with ART adherence among HIV positive mentally ill patients attending outpatient department at AMSH and SPHMMC 2018.

4 Methodology

4.1 Study Setting

The study was conducted at Amanuel Mental Specialized Hospital and St. Paul Hospital Millennium Medical College. AMSH was established in 1930, to serve as a general hospital for the native Ethiopians during the short Italian regime. The structure of the hospital was not initially made to serve as a mental health hospital and it was only after 1956 E.C that the Hospital was designed to mental health treatment hospital. After 1997 E.C, the hospital has been recognized as a specialized mental hospital. This Hospital is the first of its kind situated in Addis Ketema sub city, Addis Ababa, the capital city of Ethiopia. The hospital service focuses on improving mental health of its clients. In addition the hospital has antiretroviral treatment (ART) clinic which is staffed by one general practitioner and two nurses. St. Paul's Hospital was established by Emperor Haile Selassie I in 1969 with the help of the German Evangelical Church with the intent to helping the poor who could not afford to pay medical expenses. The hospital's first location was around the regional bus terminal which is commonly referred to as Atobs Tera. It was inaugurated in July 1947 and furnished with 250 beds. Among the different departments in the hospital above 4,000 patients are served on the ART clinic and it also hasa psychiatric department which gives service to more than 1,000 outpatients.

4.2 Study period

This study was conducted from January 2018 to March 2018 at AMSH and SPHMMC.

4.3 Study Design

A cross sectional study was undertaken.

4.4 Source and Study population

The source population included all the HIV positive mentally ill patients treated in outpatient department of AMSH, and SPHMMC ART clinic. The study population consisted of all HIV positive mentally ill patients treated in outpatient department of AMSH and SPHMMC ART clinic at the study period.

4.5 Inclusion and Exclusion Criteria

4.5.1 Inclusion Criteria

- HIV positive mentally ill patients aged 18 years and above on ART follow up
- HIV positive patients with mental disorder on medications for mental illness
- HIV positive mentally ill patients currently on Antiretroviral regimen

4.6 Sample size determination

Estimation of single population proportion formula was used. $N = P (1- P) \times (Z\alpha/2)^2/d^2$ where P is the anticipated adherence proportion; for the purpose of this study to get maximum sample size, 50% is taken as anticipated adherence proportion. If p =0.5, d is the precision required on either side of the proportion (d = 0.05), and confidence interval is 95% (the cut- off value of the normal distribution z = 1.96), n1 = sample size, $n1 = p (1- p) \times (z \alpha/2)^2/d^2$

$n1= 0.5(1- 0.5) (1.96)^2/.05^2$

n1 = 384 (sample size)

Ten percent (10%) of the sample was added to recompense for the anticipated non-response, loss to follow up and losses to death. The actual size of the cohort needed for the study will then be 422.

4.7 Sampling procedure

All patients that fulfill the inclusion criteria were selected, and using simple random sampling from within the sample proportionally from the average of 624 and 200 HIV positive mentally ill patients at AMSH and SPHMMC respectively a sample of 320 and 102 were selected using lottery method. Each of the selected participant's clinical follow up record was selected from the database of the unit.

Sample source	AMSH	SPHMMC
Total population	624	200
Sample allocation	(624/824) x 422	(200/824) x 422
	= 320	= 102

4.8 Variables

4.8.1 Dependent variables:

Adherence to ART

4.8.2 Independent variables:

- **Socio-Demographic Characteristics**
  - age, sex, education, occupation, income, ethnicity, religion and marital status
- **Patient Provider Relationship Variables**
  - satisfaction with the providers, trust and competence, involvement in medication decisions
- **Medication Related Variables**
  - dosing schedules and frequency, pill burden, side effect, history of hospitalization
- **Health Care Delivery System Related Variables**
  - access to reliable pharmacy, convenience of schedules and appointments

4.9 Data collection instrument

Data was collected from both patient's medical record and structured questionnaire. Demographic data of patients and adherence on follow up was gathered. The structured questionnaire was used to assess the level of adherence, medication related, patient-provider relationship and the health care delivery system related factors.

Interviewer administered questionnaire was used to gather data from HIV positive mentally ill patients. The structured questionnaire is adopted from WHO guideline and previous study done in Ethiopia(65).

Data on drug adherence was collected using patient self-report sequentially about the number of doses skipped on the past seven days, to minimize the recall bias for the 7 days adherence assessment was used. For those who have a history of missed doses, reasons for skipping a dose was asked.

4.10 Data Collection technique and procedure

Three counselors each in the study area conducted the data collection. Appropriate training was given to the interviewers and supervisor by the principal investigator.

Data was collected through face-to-face interview with the study subjects in the counseling room, and the recorded patient profiles were reviewed, each individual participated in an average of 30 minute interview.

4.11 Data Quality Assurance

To assure quality of the data a structured standard questionnaire was used. Pretest was carried out on 21 individuals (5% of sample size) on similar subjects, which were not included in the study. Modifications and adjustments were made on questions and their responses based on lessons from the pretest. And data collectors were trained to familiarize them with the data abstraction format and to be sensitive to the patients' emotion while interviewing. The completeness of the data collected was supervised by the principal investigator and by assigning supervisors assigned at each hospital.

4.12 Data Entry and Analysis Procedure

Data was entered into Epi info version 7.2.0.1for cleaning and exported to the Statistical Package for the Social Sciences (SPSS version 21.0) computer software for analysis.

The primary outcome variable was adherence with therapy, defined as patient self-report of whether any antiretroviral medication had been skipped the previous seven days. Self-reported adherence to all antiretroviral agents was summarized as the ratio of the average daily number of antiretroviral medications adhered to correctly according to the standard instructions over the total number of antiretroviral medication prescribed per day. The results were then expressed as a percentage, and patients aggregated into two group consisting of those adherent (took ≥95% antiretroviral correctly) and non-adherent (took <95% antiretroviral correctly)(65).

The analysis consisted of basic summaries of patient characteristics, Univariate and bivariate analysis of the relation between dose skipping and various factors. Descriptive statistics (frequencies, tables, percentages, means, and standard deviation) was used to generate proportion and using bivariate analysis p- values ($p<0.05$) was used to decide whether observed difference would be statically significant or not. Multiple variable analysis was also employed to identify the independent predictors for adherence to check for confounding factors, P-values< 0.2 were used to decide whether observed difference would be statically significant or not.

4.13 Operational Definition

Mentally ill patients attending outpatient department: those mentally ill patients who are clinically accepted as they can manage to take their medication on their own and put on follow up.

Co-morbidity: the mental illness that occur together with being HIV positive.

4.14 Ethical Considerations

Ethical clearance was obtained from the Ethics Review Committee of the School of Public Health, Addis Ababa University as well as Amanuel Mental Specialized Hospital and St. Paul Hospital Millennium Medial College ethical review committee.

The data collector nurse informed participants that participation is entirely voluntary, they will have the right to refuse or withdraw, and their treatment will not be influenced whether they take part in the study or not. No harm is expected on the patients as a result of the study, but if the patients experience psychological sensitivity they will be linked to the counselors at the end of the interview. Data collectors were used from the nurses counseling in each ART clinic of the hospitals' to increase trust. Confidentiality of the information was assured and privacy of the respondent was maintained.

4.15 Dissemination plan

The findings of this study will be disseminated through presentation, publication, and distribution to relevant bodies. During the formal final presentation of the research report, all concerned bodies including the hospital medical directors, health professionals working in the ART unit, the academic community and students will be invited to attend.

5 Results

5.1 Socio -Demographic Characteristics of the Study Participants.

A total of 416 study participants participated in this study making a response rate of 98.6%. Most of them were female 319 (76.7 %). Their mean age was 44years SD (±9). The minimum age was 21 and the Maximum was 78 years old with a median of 43years, and most 343 (82.5%) were urban residents. Concerning marital status majority 122 (29.3%) were married, followed by 102 (24.5%) widowed, 78 (18.8%) never married and 18 (4.3%) separated, majority 157 (37.7%) can read and write, 120 (28.8%) were illiterate,56 (13.5%) had finished elementary, 52 (12.5%) secondary, and 31 (7.5%) 12+, majority 305 (75.3%) earn ≤500birr regarding monthly income, where268 (64.4%) were unemployed (Table 1).

Table 1 Socio-Demographic characteristics of HIV positive mentally ill patients attending outpatient department in AMSH and SPHMMC, Addis Ababa, Ethiopia 2018

Category	Frequency	%
Sex		
Male	97	23.3
Female	319	76.7
Age		
18-24	6	1.4
25-40	152	36.5
41-60	248	59.6
>60	10	2.4
Residence		
Urban	343	82.5
Rural	73	17.5
Marital Status		
Never married	78	18.8
Married	122	29.3
Divorced	96	23.1
Separated	18	4.3
Widowed	102	24.5
Religion		

Orthodox Christian	245	58.9
Muslim	108	26.0
Protestant	60	14.4
Others	3	0.7
Educational Status		
Illiterate	120	28.8
Read and write	157	37.7
Elementary (1-8)	56	13.5
Secondary (9-12)	52	12.5
12+	31	7.5
Monthly income		
<= 500	305	75.3
>= 501	109	26.2
Occupation		
Employed	148	35.6
Unemployed	268	64.4
Living with		
Alone	50	12.0
Family	349	83.9
Parents	17	4.1

5.2 Medication Related Factors

Among the participants 296 (71.2%) didn't know the type of medication they use. While all of them took their medication twice a day, those taking two pills a day were the majority, 326 (78.4%).Regarding side effect of medication235(56.5%) had encountered medication side effect. From the 74 (17.8%) hospitalized after drug initiation 53 (12.7%) were hospitalized only once, where 58 (14%) were admitted for less than ten days. Among those who reported to have side effects, 84 (21.4%) of the responses were nightmare followed by83 (21.2%) fatigue/weakness and82(20.9%)had headache, and 31 (7.9%) nausea. Among 235 who have experienced side effect of the medication 116 (27.9%) didn't take any action, 58 (13.9%) withheld until the date of appointment on measures taken for encountered side effect of medication (Table 2).

Table 2 Medication uptake and related factors among HIV positive mentally ill patients attending outpatient department of AMSH and SPHMMC, Addis Ababa, Ethiopia 2018

Category	Frequency	%
keeping medication schedule		
Always	393	94.5
Most of the time	16	3.8
Rarely	7	1.7
Ever given special instruction		
Yes	148	35.6
No	268	64.4
Keeping special instruction over last four days (n-148)		
Always	132	31.7
Most of the time	8	1.9
Rarely	8	1.9
No response	268	64.5
Ever hospitalized after drug initiation		
Yes	74	17.8
No	342	82.2

5.3 Patient-Provider Relationship

Almost all414 (99.5%) were informed on the need for adherence by the health care providers. And 409 (98.3) were satisfied with the clinician's service. Concerning involvement in decision making majority 289 (69.5%) expressed of being involved, 400 (96.2%) responded of getting education or assistance during their visit (Table 3).

Table 3 Experience and Perception of HIV positive mentally ill patients attending outpatient department in AMSH and SPHMMC towards health professionals, Addis Ababa, Ethiopia 2018

Category	Frequency	%
Confidence on Care provider capability		
Yes	414	99.5
No	2	0.5
Relationship with clinician		
Trust on clinicians	407	97.8
Neglect	6	1.4
Ignorant	3	0.7
Has frank relationship with clinicians		
Yes	414	99.5
No	2	0.5
Got information on treatment risk and benefit facts		
Yes	404	97.1
No	12	2.9

5.4 Health Care Delivery System Related Factors

Majority 409 (98.3%) had reliable pharmacy access,405 (97.4%) were satisfied with the improvement from treatment. Regarding appointment schedule and confidentiality 402 (96.6%) were satisfied. On follow up frequency 56.5% (n=235) had a follow up every 3 month, followed by 176 (42.3%) every 2 month. 403 (96.9%) had an ongoing care whenever needed.

5.5 ART medication adherence measurement

Among 416 participants Majority 238 (57.2%) were adherent, while178 (42.8%) weren't adherent to their ART medication (Fig 1).

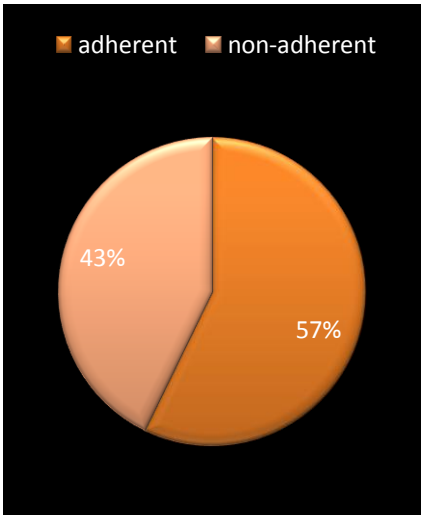


Figure 1 ART adherence among HIV positive mentally ill patients attending outpatient department in AMSH and SPHMMC, Addis Ababa, Ethiopia 2018

Majority 259 (62.3%) didn't miss taking their medication on weekends. Among 238 who claimed to be adherent, the reason to take their medication regularly, 79 (19%) was to stay alive followed by 75 (18%) to be healthy, 44 (10.6%) using reminders and the rest, 24 (5.8%) and 16 (3.8%) were for accounted for my family and keeping clinician's instruction respectively.

Regarding the reason for missing dose majority 49 (21.5%) of the responses were by being busy, followed by being away from home and religious beliefs 45 (19.7%), falling asleep 14 (6.1%) (Fig 2).

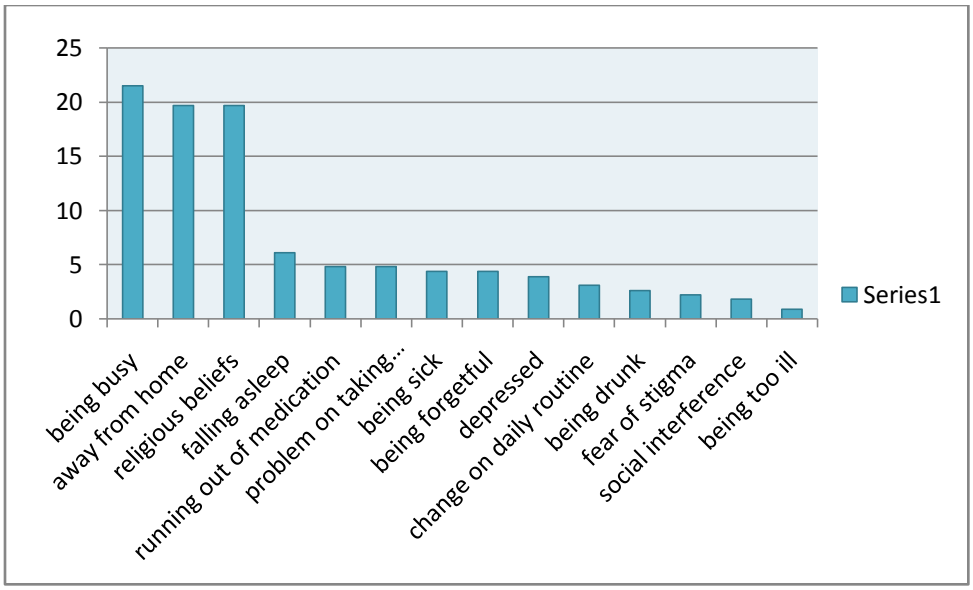


Figure 2 barriers for adherence among HIV positive mentally ill patients attending outpatient department in AMSH and SPHMMC, Addis Ababa, Ethiopia 2018

5.6 Socio Demographic Factors Associated with ART Adherence.

In bivariate analysis, among the Socio demographic variables ,marital status, monthly income, and occupation and ART adherence were significantly associated ($p< 0.05$) the rest weren't associated with ART adherence.

Marital status was significantly associated with ART adherence, singles were 48.1% less likely to be adherent **COR0.519 (95% CI 0.302-0.0891)**, Monthly income was statistically significant with ART adherence, those earning ≤ 500 birr were about 2 times more likely to be adherent **COR1.870 (95% CI 1.202-2.908),** occupation was statistically significant with ART adherence, those employed were 48.8% less likely to be adherent **COR 0.512 (95% CI 0.340-0.769)**(Table 4)**.**

Table 4 Socio Demographic Factors Associated with ART adherence among HIV positive mentally ill patients in AMSH and SPHMMC, Addis Ababa, Ethiopia 2018

Variables	ART Adherence		P	COR (95%CI)
	Yes freq (%)	No freq (%)		
Sex				
Male	55 (13.2)	42 (10.1)	0.973	0.973 (0.615-1.540)
Female	183 (44.0)	136 (32.7)		1
Age				
18-24	3 (0.7)	3 (0.7)	0.223	0.250 (0.027-2.319)
25-40	90 (21.6)	62 (14.9)	0.209	0.363 (0.075-1.767)
41-60	137 (32.9)	111 (26.7)	0.142	0.309 (0.64-1.482)
>60	8 (1.9)	2 (0.5)		1
Residence				
Urban	194 (46.6)	149 (35.8)	0.561	0.858 (0.513-1.436)
Rural	44 (10.6)	29 (7.0)		1
Marital status				
Never married	52 (12.5%)	26 (6.3%)		1
Single	110 (26.4%)	106 (25.5%)	0.017	**0.519 (0.302-0.0891)**
Married	76 (18.3%)	46 (11.1%)	0.530	0.826 (0.455-1.500)
Educational Status				
Illiterate	77 (18.5%)	43 (10.3%)	0.531	1.293 (0.578-2.893)
Read and write	84 (20.2%)	73 (17.5%)	0.642	0.831 (0.381-1.812)
Elementary	28 (6.7%)	28 (6.7%)	0.471	0.722 (0.298-1.750)
Secondary	31 (7.5%)	21 (5.0%)	0.889	1.066 (0.432-2.631)
12+	18 (4.3%)	13 (3.1%)		1
Monthly income				
<= 500	187(45.2%)	118 (28.5%)	0.005	**1.870 (1.202-2.908)**
>= 501	50(12.1%)	59 (14.3%)		1
Occupation				
Employed	69 (16.6%)	79 (19.0%)	0.001	**0.512 (0.340-0.769)**
Unemployed	169 (40.6%)	99 (23.8%)		1

5.7 Factors related to medication, patient- provider relationships and health care delivery system with ART Adherence

There was no statistically significant association found between medication related factors and ART adherence; between patient-provider relationship and ART adherence and between health care delivery system related factors and ART adherence (Table 5).

Table 5 Factors related to medication, patient- provider relationships and health care delivery system with ART Adherence

Variables	ART Adherence		P	COR (95%CI)
	Yes freq (%)	No freq (%)		
Total number of pills taken daily				
One pill	18 (4.3)	12 (2.9)	0.534	0.750 (0.303-1.857)
Two pills	180 (43.3)	146 (35.1)	0.102	0.616 (0.345-1.100)
Three pills	40 (9.6)	20 (4.8)		1
Encountered medication Side effect				
Yes	134 (32.2)	101 (24.3)	0.929	0.982 (0.664-1.453)
No	104 (25.0)	77 (18.5)		1
Relationship with clinician				
Trust each other	233 (56.0)	174 (41.8)	0.744	0.670 (0.060-7.443)
Neglect	3 (0.7)	3 (0.7)	0.638	0.500 (0.028-8.952)
Ignorant	2 (0.5)	1 (0.2)		1
Got information on treatment risk and benefit facts				
Yes	230 (55.3)	174 (41.8)	0.505	0.661 (0.196-2.230)
No	8 (1.9)	4 (1.0)		1
Follow up frequency				
Every 3 month	132 (31.7)	103 (24.8)		1
Every 2 month	106 (25.5)	70 (16.8)	0.410	1.182 (0.795-1.757)
Monthly	0 (0.0)	5 (1.2)	0.999	0.000

5.8 ART adherence measurement

In bivariate analysis those with P<0.05 were taken as statistically significant. Among reasons for non-adherence**,** being busy was associated significantly with ART adherence, those who were busy to take their medication were 97.6% less likely to be adherent **COR0.024 (95% CI 0.006-0.99),** falling asleep was statistically significant with ART adherence, those who missed dose by falling asleep were 46% less likely to be adherent **COR 0.54 (95%CI 0.007-0.413),** running out of medication was also statistically significant with ART adherence, those who missed dose by running out of medication were 92.9% less likely to be adherent **COR 0.071 (95% CI 0.009-0.559),** and religious beliefs was the other statistically significant with ART adherence, those with religious belief (going to holy water) were 98.7% less likely to be adherent **COR 0.013 (95% CI 0.002-0.094)** (Table 6).

Table 6 Barriers for adherence Associated with ART Adherence among HIV positive mentally ill patients attending outpatient department in AMSH and SPHMMC, Addis Ababa, Ethiopia, 2018

Variables	ART Adherence		P	COR (95%CI)
	Yes freq (%)	No freq (%)		
Being busy				
Yes	2 (0.5)	47 (11.3)	0.000	**0.024 (0.006-0.99)**
No	236 (56.7)	131 (31.5)		1
Away from home				
Yes	0 (0.0)	45 (10.8)	0.997	0.00 (0.00)
No	238 (57.2)	133 (32.0)		1
Falling asleep				
Yes	1 (0.2)	13 (3.1)	0.005	**0.54 (0.007-0.413)**
No	237 (57.0)	165 (39.7)		1
Depressed/overwhelmed				
Yes	0 (0.0)	9 (2.2)	0.999	0.000 (0.00)
No	238 (57.2)	169 (40.6)		1
Running out of medication				
Yes	1 (0.2)	10 (2.4)	0.012	**0.071 (0.009-0.559)**
No	237 (57.0)	168 (40.4)		1

5.9 Independent predictors of ART adherence

In order to control confounding factors a multiple variable analysis was used. Those P-values less than 0.2 in bivariate analysis were included in multiple variable analysis. Among socio demographic variables, occupation was significant in explaining ART adherence, furthermore among barriers for adherence being busy, falling asleep, running out of medication and religious beliefs were independent predictors of ART adherence.

Occupation was significantly associated with ART adherence controlling other factors, employed were 64.8% less likely to be adherent, **AOR0.352 (95% CI 0.152-0.813)**

Among the barriers for adherence being busy, falling asleep, running out of medication, and religious beliefs were significantly associated with ART adherence. By controlling the effect of all other relevant factors the result indicated that those who forgot to take their medication by being busy were 98.5% less likely to be adherent,**AOR0.015 (0.003-0.064),** falling asleep accounted for 96.8% less likely to be adherent, **AOR 0.032 (0.004-0.281),** running out of medication resulted on 96.9% less likely to be adherent,**AOR0.031 (0.003-0.276)**, and with religious belief (going to holy water), those who had religious beliefs were 99.5% less likely to be adherent,**AOR0.005 (0.001-0.40)(**Table 7).

Table 7 multiple variable logistic regression model to identify independent predictors of ART adherence among HIV positive mentally ill patients attending outpatient department at AMSH and SPHMMC, Addis Ababa, Ethiopia 2018

Variables	ART Adherence		COR(95% CI)	P	AOR(95% CI)
	Yes freq (%)	No freq (%)			
Age					
18-24	3 (0.7)	3 (0.7)	0.250 (0.027-2.319)		
25-40	90 (21.6)	62 (14.9)	0.363 (0.075-1.767)		
41-60	137 (32.9)	111 (26.7)	0.309 (0.64-1.482)		
>60	8 (1.9)	2 (0.5)	1		
Marital status					
Never married	52 (12.5)	26 (6.3)	1		

Single	110 (26.4)	106 (25.5)	**0.519 (0.3021-0.891)**		
Married	76 (18.3)	46 (11.1)	0.826 (0.455-1.500)		
Educational Status					
Illiterate	77 (18.5)	43 (10.3)	1.293 (0.578-2.893)		
Read and write	84 (20.2)	73 (17.5)	0.831 (0.381-1.812)		
Elementary (1-8)	28 (6.7)	28 (6.7)	0.722 (0.298-1.750)		
Secondary (9-12)	31 (7.5)	21 (5.0)	1,066 (0.432-2.631)		
12+	18 (4.3)	13 (3.1)	1		
Occupation					
Employed	69 (16.6)	79 (19.0)	**0.512 (0.340-0.769)**	0.015	**0.352 (0.152-0.813)**
Unemployed	169 (40.6)	99 (23.8)	1		1
Total number of pills taken daily					
One pill	18 (4.3)	12 (2.9)	0.750 (0.303-1.857)		
Two pills	180 (43.3)	146 (35.1)	0.616 (0.345-1.100)		
Three pills	40 (9.6)	20 (4.8)	1		
Special instruction while taking medication					
Yes	78 (18.8)	70 (16.8)	0.752 (0.502-1.127)		
No	160 (38.5)	108 (26.0)	1		
Hospitalized after drug initiation					
Yes	36 (8.7)	38 (9.1)	0.657 (0.397-1.087)		
No	202 (48.6)	140 (33.7)	1		
Being busy					
Yes	2 (0.5)	47 (11.3)	**0.024 (0.006-0.99)**	0.000	**0.015 (0.004-0.064)**
No	236 (56.7)	131 (31.5)	1		1
Falling asleep					
Yes	1 (0.2)	13 (3.1)	**0.54 (0.007-0.413)**	0.002	**0.032(0.004-0.281)**
No	237 (57.0)	165 (39.7)	1		1
Running out of medication					
Yes	1 (0.2)	10 (2.4)	**0.071 (0.009-0.559)**	0.002	**0.031 (0.003-0.276)**
No	237 (57.0)	168 (40.4)	1		1
Religious beliefs					
Yes	1 (0.2)	44 (10.6)	**0.013 (0.002-0.094)**	0.000	**0.005 (0.001-0.040)**
No	237 (57.0)	134 (32.3)	1		1

6 Discussion

In this study, we found that the level of ART adherence among HIV positive mentally ill patients on follow up is low and the reasons are more related to personal and emotional basis than other factors like, medication related, patient provider relationship and health service delivery system.

The level of adherence and factors associated with ART adherence of HIV positive mentally ill patients attending outpatient department at AMSH and SPHMMC were examined. Non-adherence usually means skipping one dose of medicine. Based on the self-report questionnaire, in line with other studies conducted in southwest regional hospitals of Cameroon(66)the study results indicated that more than half of the PLWHA had good adherence to ART defined as ≥95%. Inconsistent with other studies (2, 32) Nevertheless, almost 42.8% of respondents reported poor ART adherence. This is a concern given poor adherence severely compromises effectiveness and is linked with the likelihood of the drug resistance. In this study the low adherence level could be due to the patients being mentally ill require extra care and attention than the other HIV positive patients without mental illness.

Adherence to ART in this study was associated with socio-demographic characteristics, and barriers for adherence. In the final model, the variables occupation, being busy, falling asleep, running out of medication, and religious beliefs played a significant role in predicting adherence to ART.

Occupation showed a significant association with ART adherence where employed were 64.8% less likely to be adherent than the unemployed, this could be as a result of being busy which was a major reason for the patients not adhere to their regimen. And also many of them had low income even being employed, which could also add up dissatisfaction and result in an emotional stress on them.

The principal reasons reported for skipping doses were similar to other studies despite the mental health status of our study population(6, 65). The most important reasons raised by the participants were being busy, falling asleep, running out of medication, and religious beliefs. The fact that they reported being busy may be related to low paying and busy schedule which predisposes patients to forget their medication. The medications they take for mental illness

could also contribute to falling asleep. In addition, their mental health status could contribute to forgetting to fill their medication regimen which predisposes to running out of medication. This study shows that patients have a range of reasons for failing to adhere to their antiretroviral regimens. These reasons should be assessed for an individual patient and appropriate adherence-enhancing intervention should be undertaken. In this case, adherence counseling might incorporate strategies to avoid misunderstood religious beliefs by working with religious leaders on raising the followers understanding.

In this study depression wasn't significantly associated with ART adherence. Inconsistently with other studies conducted in southwest Ethiopia, southwest regional hospitals of Cameroon(66, 67)this could be as the result of as the patients being on antipsychotic medication the depression might be controlled.

7 Limitation of the study

Although the study has high response rate 98.6%, its limitation could be since it was conducted only on two hospitals the findings may not be generalizable to other settings. There is no gold standard for measuring adherence and our measurement of adherence is only based on patients' report of missed doses. And with their being mentally ill it might be subjected to recall bias.

8 Conclusion and recommendation

8.1 Conclusion

The study showed that the level of ART adherence among HIV positive mentally ill patients on follow up at AMSH and SPHMMC is low. The determinants showed that for mentally ill patients the challenge to stay adherent to their regimen is more of personal and emotional reasons rather than factors like medication related, patient-provider relationship, and health care delivery system. Therefore they should be given a special care separately from PLWHA with no mental illness, and their needs a work to be done in collaboration with religious institutions.

8.2 Recommendation

1. The hospitals should provide a separate health care delivery system, counseling means for mentally ill patients living with HIV from the PLWHA without mental illness.
2. A proper documentation of HIV positive mentally ill patients' information in the hospital
3. There need a collaborative work to be done with religious institutions on raising awareness.
4. Further research should be done on HIV positive patients with a known mental illness.

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ANNEXES

Annex 1. Information sheet (English version)

Greetings! My name is _____. I am here on behalf of Adiyam Mulushoa, student of Public Health at Addis Ababa University. She is conducting a research on ART adherence and its determinants among HIV positive mentally ill patients attending outpatient department at AMSH and SPHMMC for the partial fulfillment of second degree. Your honest answer to these questions will help us better understand the level of patients' adherence to their antiretroviral drugs on use and the determinants for their adherence, in order to develop good strategies and solve the problems for the future. You are chosen to participate in this study. The choice is made randomly. Before you decide whether to participate or not in this study, I would like to explain to you the objective of the study, any risks, benefits, procedure and what is expected from you.

Objective of the study: the study will assess ART adherence and its determinants among HIV positive mentally ill patients on follow up.

Procedure: The study involves a face-to-face interview with the data collector who will be asking you several questions using a structured questionnaire. After you sign the consent form, the Data collector will then ask you the relevant questions and your response will be written on the questionnaire. The interview will take about 30 minutes.

Benefit of the study: There is no direct benefit to study participants, but the result of the study will be disseminated to concerned bodies including AMSH and SPHMMC, Addis Ababa Health Bureau, Addis Ababa University, Ministry of Health and other concerned bodies working on ART adherence and mental health.

Risk (harm) of the study: There is no harm on participating in this study but part of your time (average of 30 minutes) will be consumed to answer the questions.

Rights of participants: completely free to take part or not in this study. If you decide that you do not want to be part of the study, this will not be held against you and you will not be

disadvantaged in any way. You are also free to withdraw from the study at any time if you feel that you cannot proceed. You can ask any question which is not clear for you.

Confidentiality: All information you give me will be strictly confidential and will be kept in a safe and secure place. Your name will not appear anywhere on the questionnaire to ensure anonymity. Only the principal investigator will know the details and will discard it after completing analysis. I would greatly appreciate your truthful and keen participation in responding to this questionnaire.

Do I have your permission to continue? (Circle)

1 = Yes 2 = No (End the interview)

Starting Time: [__|__: __|__]

Thank you.

Identification Number_____

Date of Interview_____

Interviewer Name_____

Supervisor_____

Annex 2. Informed consent (English version)

The objective, benefits, harms, procedures and confidentially of the study has been read and explained to me in the language I comprehend. I further understand that, taking part in this study and withdraw from participating in any time without having reason is purely voluntary.

I agree to participate in this study.

Participant:

Sign (signature or thumb print).....Date.....

For further information you can contact the primary investigator with the following address:

Name: Adiyam Mulushoa

Phone No. 0910024757

Email: adimule1@gmail.com

Annex 3. Questioner (English version)

Questioner for the assessment of ART adherence and its determinants among HIV positive mentally ill patients attending outpatient department at Amanuel Mental Specialized Hospital and St. Paul Hospital Millennium Medical college, Addis Ababa 2018

Section I Socio-demographic Information			
SN	**Questions and Filters**	**Response & Coding Categories**	*Skip*
101	Sex of the respondent	1. Male 2.Female	
102	Age (In complete years)	_____	
103	Where is your permanent residence?	1. Urban 2. Rural	
104	What is your ethnic group?	1. Oromo 2. Amhara 3. Tigirie 4. Other	
105	Current marital status	1. Single 2. Married 3. Divorced 4. Separated 5. Widowed	
106	Religion	1. Orthodox Christian 2. Muslim 3. Protestant 4. Others	
108	If yes, what is the average monthly income you get by yourself?	_____ Birr/month	
109	What is your major occupation currently? (Whatever you do to earn money)?	1. Employed 2. Unemployed	
110	Whom do you live with	1. Live alone 2. My family 3. My parents	

Section II- Medication related variables			
SN	**Questions and filters**	**Response and coding categories**	**Skip**
201	Do you know the types of medication you are taking?	1.Yes 2. No ——→	Go to Q203
202	Can you mention the frequency and total pills you take daily of the drugs you are taking?	1. Frequency_____ 2. Total pills daily_____	
203	How closely did you follow your specific schedule?	1.Allways 2.Most of the time 3.Rarely	
204	Does any of your anti-HIV medications have special instructions, such as "take with food" or "on an empty stomach" or "with plenty of fluids?"	1.yes 2.No ——→	Go to Q206
205	If Yes to Q203, how often did you follow those special instructions over the last four days?	1.Allways 2.Most of the time 3.Rarely	
206	Did you have any adverse effect (side effect) when you take medication (after ART initiation)?	1.Yes 2.No ——→	Go to Q209
207	If yes to Question 206, which of the following symptoms did you feel? ***[More than one answer is possible]***	1.Nausea 2.Vomiting 3.Headache 4.Fatigue/weakness 5.back pain 6.Stomach upset 7.Depression 8.Skin Rash 9.Diarrhea 10. Things taste strange 11. nightmare	
208	What measures did you take when you developed side effect?	1.Immediately stopped taking pills 2.Withheld until the date of appointment 3.Immediately reported to clinician 4. Dropped out permanently 5. I didn't took any measures	
209	Have you ever been hospitalized after you have been started on ART?	1. Yes. 2. No. ——→	Go to Q301
210	Please tell me how many times have you been hospitalized after you have been starting ART?	_____ Times.	
211	How many days you have been admitted to hospital for management and follow up?	I have been in hospital for ____days.	

Section III- Patient - Providers Relationship variables		
SN	**Questions and filters**	**Response and coding categories**
301	Have you been informed about the need for adherence before you started ART?	1. Yes 2. No
302	Are you satisfied with the clinicians' service?	1.Yes 2.No
303	Do you feel the health care providers treating you are capable?	1.Yes 2. No
304	What types of interaction (relationships) do you have with clinician?	1. Trust on clinician 2. Neglect 3. Ignorant
305	Do you have open communication with health care provider treating you?	1.Yes 2. No
306	Does your doctor explain facts about the benefits and risks of your treatment?	1.Yes 2. No
307	Does your care taker/doctor involve you in decision about your treatment?	1.Yes 2. No
308	Do you obtain the education or assistant you need during your visits?	1.Yes 2.No

Section IV- Health care system delivery related variables			
SN	**Questions and filters**	**Response and coding categories**	**Skip**
401	Do you have access to reliable pharmacy any time you want?	1.Yes 2.No	

402	Are you satisfied by the changes/ improvements you obtain for your treatment (e.g. in the pharmacy, laboratory, counseling etc…)	1.Yes 2.No	
403	Are you satisfied in the scheduling appointments and confidentiality of the treatment unit	1.Yes 2.No	
404	How frequent is your follow up?	1. Every 3 month 2. Every 2 month 3. Monthly	
405	Do you get ongoing care whenever you need?	1.Yes 2.No	

Section V-Adherence Assessment Interview Questionnaire

(Instructions for interviewer: You should read the following statement as it is, as it may help the PLWHA to feel more comfortable to admit that she/he has forgotten to take her/his medication correctly.)

Now I'm going to ask some questions about your HIV medications. When taking your daily ARV medications you may have many tablets, which you might have to take many times in a day. Thus it is normal that you might forget to take your medications, or to do so as directed by your doctor and that you may have your own reasons for doing so. Please answer the following questions honestly so that the hospital staff will be able to help you to ensure that you take your ARV medications correctly in the future.

SN	*Questions and filters*	*Response and coding categories*	*Skip*
501	How many pills did you miss in the past seven days, number of doses skipped?		
502	If you have not missed any doses, what made you take your medications regularly?	_____	
503	Some people forget to take their pills on the weekend days. Did you miss any of your medication last Saturday or Sunday?	1. Yes 2. No	
504	What is the reason for skipping your dose? **[Multipile responses are possible. After respondent answers, probe by asking for any others]**	1.I was too busy with other things 2. I was away from home. 3. There was a change in my daily routine. 4.I felt asleep. 5.I felt depressed or overwhelmed. 6.I had problem taking medication on time 7.I felt sick or ill at that time 8. I run out of medication. 9.I had too many pills to take. 10.I felt the drug is too toxic/ harmful and want to avoid side effects. 11. Stigma, disclosure or privacy issues. 12. Taking the drugs is a reminder of my HIV status. 13.I was confused about the dosage directions at that time. 14.I did not think the drug is doing anything to improve my	

		health. 15. People told me the medicine is no good. 16.Simply forget 17.Social situation interfered 18.Felt good 19.Were high or drunk 20.Felt it interfere with sex life 21.Unable to get food and drink 22.Religious belief/'going to holy water' 23.Trying traditional medicine for OIs 24.Transportation problem 25.Other illness (Co-morbidity) 26.Too ill to attend clinic to collect the drugs	

Is there anything you would like to add or ask me?

Thank you for participating in this interview!

Annex 3. Information sheet (Amharic version)

ክፍለአንድ፡- የጥናትማብራሪያ (መረጃ) ቅፅ

ጤናይስጥልኝ!ስሜ_____ይባላል፡፡እዚህ የተገኘሁት በአዲስ አበባ ዩኒቨርስቲ የህብረተሰብ ጤና ተማሪ በሆነችው አድያም ሙሉሸዋ ምትክ ነው፡፡ ተማሪዋ የሴቶችደቨ ቫይረስ በደማቸው ውስጥ የሚገኝ የስእምር ህሙማን ላይ ያረ ሴቶችደቨ ቫይረስ መድኃኒት አጠቃቀማቸው እና ወሳኝ የሆኑ ነገሮች ላይ የሁስተኛ ዲግሪ ማሚያ ጥናት በማካሄድ ላይ ትገኛለች፡፡ ይህም ያረ ሴቶችደቨ ቫይረስ መድኃኒት አጠቃቀማቸው እና ወሳኝ የሆኑ ነገሮች ምን እንደሆኑ ማወቁ ጠቃሚና ተግባራዊ ሲሆኑ የሚችሉ የመፍትሔ እርምጃዎችን ለመውሰድ ለስሚያስችል ነው፡፡ እርስዎ በዚህ ጥናት ላይ እንዲሳተፉ ተመርጠዋል፡፡ ምርጫው የተካሄደው በግምታዊ አመራረጥ ነው፡፡ በጥናቱ ውስጥ ለመሳተፍ ወይም ላለመሳተፍ ከመወሰንዎ በፊት የጥናቱን ዓላማ፣ማንኛውም ችግሮች፣ጥቅማጥቅሞች፣ሒደትና ከእርስዎ የሚጠበቀውምን እንደሆነ ልገልፅለዎት እወዳለሁ፡፡

የጥናቱአላማ፡-የሴቶችደቨ ቫይረስ በደማቸው ውስጥ የሚገኝ የስእምር ህሙማን ላይ የያረ ሴቶችደቨ ቫይረስ መድኃኒት አጠቃቀማቸው እና ወሳኝ የሆኑ ነገሮችን ማጥናት ነው፡፡

የጥናቱሒደት፡-ጥናቱ የሚከናወነው ፊት ለፊት በሚደረግ ቃለ-መጠይቅ ሲሆን ቃለ መጠይቅ አድራጊውም ጥያቄዎችን ከመረቀት እያየ የሚጠይቅዎት ይሆናል፡፡ እርስዎ እንደፈቀዱ በጥናቱ ለመሳተፍ መስማማትዎን በስምምነት ፎረሙ ላይ ከፈረሙ በኋላ ቃለመጠይቅ አድራጊው ከመጠይቁ ላይ ጥያቄዎችን ተራ በተራ እያነሳ በመጠየቅ የሚሰጧቸውን ምላሾች በመጠይቁ ላይ የሚፅፍ ይሆናል፡፡ ቃለ-መጠይቁ ሰላሳ ደቂቃዎች ያህል ሊወስድ ይችላል፡፡

የጥናቱ ጥቅማጥቅም፡-

በጥናቱ በመሳተፍዎ የሚያገኙት ቀጥተኛ ጥቅማጥቅም የለም፡፡ ሆኖም ግን የጥናቱ ውጤት በያረ ሴቶችደቨ እና በስእምር ህመም ላይ ለሚሰረ ተቋማት ማስተም አማኑኤል እና ቅድስዩሙስ ሆስፒታል፣ ለአዲስ አበባ ጤና ቢሮ፣ ለአዲስ አበባ ዩኒቨርስቲ እና ሌሎች የጤና ጥበቃ ሚኒስቴርና መንግስታዊ ያልሆኑ ድርጅቶች የሚያርስ ሲሆን ይህም በያረ ሴቶችደቨ መድኃኒት እና የስእምር ህመም ላይ ጠቃሚ እርምጃዎችን እንዲወስዱ ያግዛቸዋል፡፡

የጥናቱ ጉዳት፡-

በዚህ ጥናት ላይ በመሳተፍዎ ምንም አይነት ጉዳት የለም፡፡ ሆኖም ግን ጥያቄዎችን ለመመለስ 30 ደቂቃ ያህል ልንወስድብዎት እንችላለን፡፡

የተሳታፊዎች መብት፡-

በዚህ ጥናት ውስጥ ለመሳተፍ ወይም ላለመሳተፍ ሙሉ ነፃነት አለዎት። የጥናቱ አካል ለመሆን ካልፈለጉ በእርስዎ ላይ ምንም የሚያመጣው ጉዳት የሌለ ከመሆኑም በላይ ምንም አይነት ጥቅም የሚያሳጣዎም አይደለም። በጥናቱ ላይ መቀጠል የማይችሉበት ነገር ከገጠመዎት በየትኛውም ሰዓት አቋርጠው መውጣት ይችላሉ። እንደዚሁም ግልጽ ያልሆነልዎት ነገር ካለ በየትኛውም ሰዓት መጠየቅ ይችላሉ።

ምስጢራዊነት፡-

ለእኔ የሚሰጡኝ መረጃዎች ሁሉ በጥብቅ ምስጢር የሚጠበቁ ሲሆን በተጨማሪም በአስተማማኝና ደህንነቱ በተጠበቀ ስፍራ ይቀመጣሉ። ደህንነትም ለማረጋገጥ ሲባል ስምዎትም ሆነ ሌላ መለያዎ በየትኛውም የመጠይቁ ክፍል ላይ አይሰፍርም። ዋነኛው የጥናቱ አጥኚ ብቻ ዝርዝር መረጃዎችን የምታውቅ ሲሆን ጥናቱ እንዳበቃም የሚሰረዝ ይሆናል።

በዚህ ጥናት ላይ ለመካተት ፈቃድዎ ነው?

1. አዎ (ወይ ስምምነት ሰነዱ ማለቁ)
2. አይ (አመሰግኖ መሰናበት)

Annex 4: informed consent (Amharic version)

ክፍል ሁለት፡ የስምምነት ቅፅ

የጥናቱ ዓላማ፣ ጥቅማጥቅም፣ ጉዳቶች፣ ሒደቶችና ሚስጥራዊነት በሚገባኝ ቋንቋ ተነቦልኝ ተረድቻለሁ። በተጨማሪም በጥናቱ መሳተፍ ሆነ ከጥናቱ በለስፈለገኝ ሰዓት መውጣት ሙሉ በሙሉ በእኔ ፈቃደኝነት ላይ የተመሰረተ መሆኑን ተረድቻለሁ።

በዚህ ጥናት ላይ ለመሳተፍ ተስማምቻለሁ።

ተሳታፊ፡

ፊርማ (ፊርማ ወይም የጣት አሻራ) _____ቀን_____

ለበለጠ መረጃ ወይም ማብራርያ ከፈለጉ የዚህ ጥናት ባለቤት በሚከተለው አድራሻ ማግኘት ይችላሉ።

ስም፡ አድያም ሙሉሸዋ

ስ.ቁጥር፡0946727808

ኢ.ሜይል፡adimule1@gmail.com

ለቁና ትብብርም በጣም አመሰግናለሁ!

Annex 5. Questioner (Amharic version)

የማህበራዊስናየስነ-ህዝብሁኔታ			
ተራ.ቁ	ጥያቄ	መልስ	ደህፍ
101	ጸታ	1. ወንድ 2. ሴት	
102	እድሜ		
103	መኖሪያ	1. ከተማ 2. ገጠር	
104	ብሔር	1. ኦሮሞ 2. አማራ 3. ትግሬ 4. ሌላ	
105	የጋብቻ ሁኔታ	1. ያላገባ 2. ያገባ 3. አግብቶየፈታ 4. የተለያየ 5.የትዳር አጋር ከዚህ አለም በሞት የተለየ	
106	ሀይማኖት	1. ኦርቶዶክስ ክርስቲያን 2. ሙስሊም 3. ፕሮቴስታንት 4. ሌላ	
107	የትምህርት ደረጃ	1. ማንበብ እና መጻፍ የማይችል 2.ማንበብና መጻፍ የሚችል 3.አንደና ደረጃ 4. ሁስተና ደረጃ 5. 12+	

108	ወርሃዊገቢ		
109	የስራ ሁኔታ	1. ቅጥረኛ 2.ስራ የሌለው	
110	ከማን ጋር ትኖራለህ	1. ብቻዬን 2. ከቤተሰቤ ጋር 3. ከጓደኞቼ ጋር	

ከመድኃኒት ጋር ተያያዝ ጉዳዮች			
ተራ.ቁ	**ጥያቄ**	**መልስ**	**ዝለፋ**
201	የምትወስዳቸውን የመድሃኒት አይነቶች ታውቃለህ/ለች	1.አውቃለሁ 2.አላውቅም ⟶	ወደ ጥ.ቁ 203
202	የምትወስዳቸውን መድሃኒቶች ጊዜ፣ አመቃላይ ብዛት በቀን መጥቀስ ትችላለህ	1.ጊዜ 2.አመቃላይየኪኒንብዛትበቀንውስጥ	
203	እንዴት ባለ ቅርበት የፀረ ኤችጓይ ቪመድሀኒት ፕሮገራምህን /ሽን ትከታተላለህ /ያለሽ	1.ሁልጊዜ 2.አብዛኛውንጊዜ 3.አልፎአልፎ	
204	የትኛውም የፀረ ኤች አይቪ መድሃኒትህ /ሽ የተሰየ ትእዛዝ አለው አንደ ከምግብ ጋር ይመሰድ ወይም በባይ ሆድ ወይም ከብዙ ፈሳሽ ጋር የሚል	1.አለው 2.የለውም ⟶	ወደ ጥ.ቁ 206
205	በጥያቄ ቁ.204 አለው ብለው ከመለሱ ባለፉት 4 ቀናት ውስጥ ምን ያክል ጊዜ ይህን ትዕዛዝ በትክክል ተከታትለከዋል /ሽዋል	1.ሁልጊዜ2.አብዛኛውን ጊዜ 3.አልፎ አልፎ	
206	መድሀኒቱን በምትወስድበት /ጂበት ጊዜ የትኛውም አይነት የመድሀኒት ጎንዮሽ አጋጥሞሀል/ሻል	1.አጋጥሞኛል 2.አላጋጠመኝም ⟶	ወደ ጥ.ቁ 209

207	በጥያቄ ቁ.204 ስለሙ ብለሙ ከመለሱ ምን አደነት ስማችች ከሚለተሉት ውስጥ ስግኙተል/ሻል	1.ማቅለሽለሽ 2.ማስመለስ 3.ፊስምታት 4.ድካም/ስቅምማጣት 5.የጀርባ ህመም 6.የሆድመቆጣት 7.ድብርት 8.የቅዳማሳስክ 9.ማስቀመጥ 10.ያልተለመደጣእም 11. ቅሾት	
208	የመድሀኒት ጎንዮሽ ባጋጠመህ ጊዜ ምን ስደረክ/ግሽ	1.ወድያው መድሃኒቱን መውሰድ ስቅምኩ 2.እስክ ቀጠሮ ድረስ ስቅምኩ 3.ወድያው ለዘኪም ስሳወኩ 4. ሙሉ በሙሉ ስቀረጥኩ 5. ምንም ስላደረኩም	
209	የፀረ ኤችሳደቪ መድሀኒት ከጀመርክ በሓላ ሆስፒታል ተኝተህ ታውቃለህ /ቂያለሽ	1.ስውቃለሁ 2.ስላውቅም ⟶	ወደጥ.ቁ 301
210	ስንት ጊዜ ሆስፒታል ተኝተሀል /ሻል	_____ጊዜ	
211	ስንት ቀን ሆስፒታል ቆይተሀል /ሻል	_____ ቀን	

በታካሚና ስገልግሎት ሰጪ መካከል ያስ ግንኙነት			
ተራ.ቁ	**ጥያቄ**	**መልስ**	**ያልፉ**
301	በታካሚና ስገልግሎት ሰጪ መካከል ባስ ግንኙነት ስለመድሃኒት በስግባቡ ተነግሮሃል /ሻል	1.ተነግሮኛል 2.ስልተነገረኝም	
302	በሃኪሞቹ ስገልግሎት እርካታ ስለህ	1.ስለኝ 2.የለኝም	
303	የህክምና ስገልግሎት የሚሰጡህ ባለሞያዎች ብቃት ስላቸው ብለህ/ ሽ ተተማመናለህ /ኛለሽ	1.ስተማመናለሁ 2.ስልተማመንም	

304	ከሃኪምህ ጋር ምን አይነት ግንኙነት አለህ/ሽ	1.አምነዋለሁ 2.ንቁ አተዋወለሁ 3.ችላአላለሁ	
305	የህክምና አገልግሎት ከሚሰጥህ/ሽ ባለሞያ ጋር በግለፅ ትነጋገራላቹ	1.አንነጋገራለን 2.አንነጋገርም	
306	ሃኪምህ ለስ ህክምናህ አውነተኛ ጥቅምና ጉዳት ይገልፅልሃል /ሻል	1.ይገልፅልኛል 2.አይገልፅልኝም	
307	ሃኪምህ /የህክምና አገልግሎት የሚሰጥህ ባለሞያ ለለህክምና አገልግሎትህ ሳይ ውሳኔ እንድ ትወስን/ኝ ያካትትሀል/ ሻል	1.ያካትተኛል 2.አያካትተኝም	
308	በቀጠርህ ሳይ የምተፈልገውን ትምህርትና እገዛ ታገኛለህ /ሽ	1.አገኛለሁ 2.አላገኝም	

የጤና አጠባበቅ አገልግሎት አሰጣጥ			
ተራ.ቁ	**ጥያቄ**	**መልስ**	**ይሰፈ**
401	በፈለከው ጊዜ አስተማማኝ መድሀኒት ቤት ታገኛለህ/ሽ	1.አገኛለሁ 2.አላገኝም	
402	በህክምናህ ሳይ ባገኘከው /ሽው የጤና ለውጥ አርካታ አለህ/ ሽ ለምሳሌ በፋሪማሲው ፣በላብራቶሪው፣ በምክር አሰጣጡ	1.አለኝ 2.የለኝም	
403	በቀጠሮ አሰጣጡ ሳይ እና በህክምናው አስተማማኝነት ሳይ አርካታ አለህ	1.አለኝ 2.የለኝም	
404	በየስንት ጊዜ ነው ክትትልህ/ሽ	1.በየ 3 ወር 2.በየ 2 ወር 3.በየወሩ	
405	ቀጣይነት ያለው እንክብካቤ በሊድክ ቁጥር ታገኛለህ	1.አገኛለሁ 2.አላገኝም	

ክፍል 4፡ የአግባቢዊ መድኃኒት አጠቃቀድ መመዘኛ ቃለ መጠይቅ

(ቃለ መጠይቁን ለሚያካሂደው ጠያቂ መመሪያ ፡ከዚህ በታች ያለውን ጽሁፍ እንዳለ ደነበብሳቸው ከሌችለደ ቪሌድስ ጋር የሚኖረ የለእምር ህሙማኑ በነጻነት መድኃኒታቸውን በትክክል እንዳልወሰዱ እንዲያምኑ ስለሚያግዛቸው

አሁን ስለ ጸረ ሌችለደቪ መድኃኒት አጠቃቀሞ አንዳንድ ጥያቄዎችን አጠይቅዎታለሁ፡፡ የየለስት ጸረ ሌችለደቪ መድኃኒችትን ሲወስዱ በቀን ውስጥ ሲወስዱ የሚገቡ ብዙ ክኒኖች ሲኖርት ደችሳል፡፡ በዚህም ምክንያት መድኃኒችችን ሀኪሙ እንዳዘዘው ለመውሰድ ሲረሱ ደችሳሉ፡፡ለዚህም የራስዎት የግል ምክንያት ሲኖረዎት ደችሳል፡ ፡

እባክዎትን ለቀጣዮቹ ጥያቄዎች በታማኝነት ደመልሱ፡፡ ምክኒያቱም የሆስፒታሉ ህክምና ሰራተኞች ለመደፌቱ መድኃኒችትን በትክክል እንዲወስዱ እንዲያግዝዎት ስለሚረዳቸው፡፡

ተ.ቁ	*ጥያቄ*	*መልስ*	*ስለፍ*
501	ባለፉት ሰባት (7) ቀናት ውስጥ ምን ያክል ኪኒን ሳደወስዱ ቀረ?		
502	ምንም ሳደረሱ መድኃኒችትን ከወሰዱ ለዚህ ምክኒያቱ ምንድን ነው?		
503	እርስዎ ያለፈው ቀዳሚ ወደም እሁድ መድኃኒችትን መውሰድ ረስተዋል?	1. አዎ 2. አልረሳሁም 3.አደታወቅም	
504	መድኃኒችችን ለመውሰድ የረሱበ ትምክንያት ምንድን ነው? (ከአንድ በላደ መልስ መመለስ ደቻላል ተጠያቂው መልስ ከመለሰ በኃላ ሌላ ምክንያት ካለ ማመጣጣት)	1. በሌላ ስራ ተጠምጂ ነበረ 2.ከቤ ርቄ ነበር 3. ከተለመደው አወሳሰድ የተቀየረ ነበር 4. እንቅልፍ ወስዶኝ 5. ድብርት ደዞኝ/ስሜታዊ ሆኜ ነበር 6. በሰዓቱ የመውሰድ ችግር አለብኝ 7.በሰዓቱ አሞኝ ነበር 8. መድኃኒቴ አልቅብኝ ነበር 9. ብዙ መድኃኒት የምወስደው ነበረኝ 10. መድኃኒቱ መርዛማ ነው ብዬ ስላሰብኩ/ የጎንዮሽ ጉዳቱን ስማስቀረት 11. መገለል እንዳደደርስብኝ ብዬ ስራሴን ላለማጋለጥ 12. መድኃኒቱን መውሰዴ የሌችለደ ቪ ታማሚ መሆኔን ለለሚያስታውሰኝ 13. አወሳሰዱ ግልጽ ስላልነበረልኝ 14.መድሃኒቱ ለጤናዬ መሻሻል ምንም እገዛ አለው ብዬ ስላላመንኩ 15. ሰዎች መድኃኒቱ ጥሩ አደደለም ስላሉኝ	

		16.እንዲሁ ፈስቼው 17.ማህበራዊ ኑሮዬ ጣልቃ ገብቶ ብኝ 18.ጤንነት ተሰምቶኝ 19.ሰክፌ ስለነበር 20. ከዘታዊ ግንኙነት ህጸጠቴ ጋር ስለተጋጨብኝ 21.ምግብ እና መጠጥ ማግኘት ስላልቻልኩ 22.ሀጸማኖታዊ ስለተሳሰቦች መኖር (መበል መዒድ) 23.ባህላዊ መድኃኒትን ለተዛማጅ በሽታዎች መጠቀም 24.የትራንስፖርት ችግር 25.ሴሎች በሽታዎች 26.መድኃኒት ዒጂ ለማምጣት በጣም ታምሟ ስለነበር ቀረሁ	

መጨመር የሚፈልጉት ጠጸም ሲጠጸቁኝ የሚፈልጉት ነገር ካለ

በዚህ ቃለ መጠጸቅ በመሳተፌት አመሰግናለሁ!

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