ASSESSMENT OF LEVEL OF ADHERENCE TO ANTI RETROVIRAL THERAPY AMONG ADULT HIV INFECTED PATIENTS IN MEKELLE HOSPITAL, NORTHERN ETHIOPIA.

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ABSTRACT

Background: HIV/AIDS is one of the most destructive epidemics the world has ever witnessed. Non-adherence to the proposed antiretroviral regimen is considered to be one of the greatest dangers to the response to treatment on an individual level and the dissemination of resistant viruses on the community level. However a significant proportion of HIV-infected patients do not reach high levels of adherence. The objective of this study is to assess the Level of adherence and associated factors among HIV/AIDS patients receiving HAART in Mekelle Hospital, Northern Ethiopia. Methods: A cross sectional study was carried out from January 1, 2013 to July 30, 2013 among 382 adult PLWHA (>=18 years) attending ART clinic at Mekelle Hospital. Data was collected by a combination of structured questionnaire and document review. The data was entered and cleaned using Epi-Info; transported to SPSS 16.0 version for final analysis. Bivariate and multivariate analyses were performed to identify factors associated with adherence. Results: The rate of self reported adherence in the study based on the Schedule, indicator of the dose and time measurement 7 days preceding data collection was (78.3%). Females were more adhered than males (185/87.7%). Alcohol users have poor adherence than non alcohol users with 70.5% and 82.2% level of adherence respectively. Sex and educational status of the study participants were significantly associated with level of adherence with AOR (95% CI) of 3.81(2.18, 6.69) and 2.60(1.43, 4.71) respectively. Conclusion: The level adherence (78.3%) is still very low considering the WHO recommendation of 95%. Sex and educational status of the study participants were significantly associated with level of adherence. More focus should be given to males and individuals with low educational status to improve level of adherence and to assure the efficacy of HAART in prolonging the life of PLWHA.

KEYWORDS: Adherence, PLWHA, Mekelle Hospital, HIV/AIDS.

INTRODUCTION

HIV/AIDS is one of the most destructive epidemics the world has ever witnessed. In 2007 an estimated 33.2 million people were living with HIV worldwide, while 2.5 million of these people were children under 15 years old.¹ The number of people living with HIV worldwide continued to grow. Sub-Saharan Africa remains the region most heavily affected by HIV. In 2008, sub-Saharan Africa accounted for 67% of HIV infections worldwide, 68% of new HIV infections among adults. The region also accounted for 72% of the world’s AIDS-related deaths in 2008.² Ethiopia is home to approximately 800,000 patients with HIV/AIDS and the prevalence of HIV/AIDS in the general population is estimated to be 1.5%. In the past 8 years, decentralization and scale-up of the HIV care programme has occurred and by the end of 2011, 249,174 adult patients (86% of eligible patients) were on Highly Active Anti-retroviral Therapy (HAART).³ In Ethiopia, the antiretroviral treatment program started with a fee-based ART program in 2003 then decentralized and free ART program in the Country was lunched since 2005.⁴

Adherence to medication is a dynamic behavior affected by factors related to treatment regimen complexity, patient-related variables, patient–healthcare provider relationships and the quality of healthcare services.⁵ Non-adherence to the proposed antiretroviral regimen is considered to be one of the greatest dangers to the response to treatment on an individual level and the dissemination of resistant viruses on the community level.⁶ Very high levels of adherence (> 95%) are required for HAART to be effective for long term and to prevent the emergence of resistant viral strains.⁷ An adherent patient is defined as one who takes > 95% of the prescribed doses.⁸ However a significant proportion of HIV-infected patients do not reach high levels of adherence. The principal reasons reported for skipping
doses are running out of medication/drug, being away from home, being busy with other things, simply forgetting, having no food to take with the medication, fear of side effect and feeling sick or ill at that time.\(^{[10]}\)

Little is known about the rate and predictors of adherence in Ethiopia. In line with the above facts, about 720 patients were lost from their treatment since started the program in the study area and also reasons for treatment interruption were not investigated. It is known that development of successful interventions to improve treatment adherence requires understandings of those factors influencing patient’s medication taking by performing periodic assessment of level of HAART adherence. Predictors of adherence of Adult on HAART not yet well documented. This study will be helpful to fill the information gap and provide empirical evidence for program planners, decision makers and HAART program implementers at different levels. Therefore, identifying the level and predictors of adherence of adults on HAART will be helpful in planning, implementing and monitoring programs on HAART.

2. METHOD AND MATERIAL

2.1. Study Area and Period

The study was conducted in Mekelle city, Mekelle Hospital, which is located in northern Ethiopia. Mekelle zone is found 783 km north of the capital city Addis Ababa. A total of 289,587 people with 65,815 households are living in the city (source: Mekelle city plan and finance office, 2012). Mekelle Hospital is one of the referral hospitals of Tigray regional state found in Mekelle city, capital of Tigray regional state. About 17 professionals and adherence workers have been working in the ART clinic. The hospital gives different curative and preventive services for Mekelle residents and referred patients from other Districts, as well as the neighboring regions of Afar and Amhara. It provides HIV/AIDS related services such as HIV counseling and testing (HCT), TB/HIV collaborative activities, Prevention of Mother to Child Transmission (PMTCT), exposed care, opportunistic infection and Anti-retroviral (ARV) prophylaxis and treatment. In the Hospital, fee based HAART program has been introduced in 2003 and the free HAART program started in March 2005. A total of 7,350 HIV infected individuals have been enrolled since HAART started in the hospital. About 5,854 are ever started HAART in the hospital. The major justification to consider this hospital as study area was, more than 25% People Living With HIV/AIDS (PLWHA) under HAART in the Region are attending at this hospital, and it is also the earliest hospital since HAART program has been started in the region. The study was conducted from January 1/ 2015 to July 30/ 2015.

2.2. Study Design

Facility based Cross-Sectional study was used among PLWHA who have ever started HAART to assess level of adherence and associated factors to HAART.

2.3. Sample Size Determination and Sampling Technique

2.3.1. Sample Size Determination

The sample size was calculated by using single population proportion formula with 95% confidence interval, 50% level of adherence and margin of error 5%. The calculation resulted in a sample size of 347. Ten percent (10% = 35) of the total sample size were added for any non-response of the study subjects during the study period. The actual sample size of the study was 382.

2.3.2. Sampling Technique

Study participants were selected using simple random sampling technique from the HAART unique number of those currently on HAART in the ART clinic (taking HAART).

2.4. Data Collection Tools and Procedures

Data was collected using structured questionnaire and document review which include the following variables such as socio-demographic characteristics; Knowledge of patients towards treatment and health care system; patients self-report to treatment adherence in terms of time and dose and patient’s adherence to schedule. By considering the illiterate study participants, the questionnaire was administered face to face by data collectors. For the knowledge part, standard questions were prepared and asked for the study participants and their level of knowledge was determined based on predetermined cut of points. Treatment adherence was measured by the combination of self report, pill count and pharmacy refill records.

2.5. Data Quality Control and Management

An intensive one-day training session was given for all data collectors and supervisors before data collection. Before commencement of the actual study, the study tools and instruments were pre-tested in Mekelle health center in 5% of the total sample size and necessary modifications were incorporated to the questionnaire. Proper information about the study was provided to each participant and the interview was conducted in private room to create an atmosphere of empathy and confidence within a secure environment. Data collectors were selected from health workers particularly; Nurses who were previously trained and working on HAART in other health facilities (to minimize bias). The overall activity was controlled by the principal investigator of the study and proper designing of the data collection materials and continues supervision during data collection was performed. All completed questionnaires were examined for completeness and consistency during data management, storage and analysis.

2.6. Data Analysis

Data was coded, entered in to EPI-info and cleaned before data processing. Data was summarized and analyzed using SPSS 16.0 computer statistical soft ware. Descriptive and association test was made between the
dependent and independent variables, Bivariate and multivariate logistic regression with 95% Confidence Interval (CI) was used. Independent variables found significant at P-value<0.05 were entered to multiple logistic regressions to identify independent predictors of adherence after controlling for possible confounding variables. Odds ratios (OR) with their 95% CI were calculated and data is presented by tables and graphs. All the tests were considered significant at p<0.05 level.

2.7. Ethical Consideration
An ethical approval was obtained from the ethical review committee of Adigrat University College of medicine and health sciences research and community service office. Official Support letter was obtained from Adigrat University, Tigray regional health bureau and Mekelle Hospital for conducting the study. All participants were informed about the purpose and significance of the study to get their consent. Written informed consent was obtained from each study participant selected for the study.

2.8. Operational Definitions
Treatment adherence: defined as the ability of taking medications as prescribed.

Lack of adherence: level below 95% adherence (absolute level of adherence).

Missed dose: any antiretroviral medication missed to take by the patients as prescribed or taking late from the recommended time.

High adherence /optimal adherence: adherence levels that would be expected to enable successful treatment response that is at least 95% achievement of adherence.

 Seriously sick person: a person who is not able to walk without help and or not able to respond to questionnaire.

Stable mental condition: patient who doesn’t manifest active mental illness.

PLWHA: people who disclose their HIV sero-status.

STOP: If the patient and the clinician discussed and decided to stop treatment for different reasons.

LOST: If the patient has missed an appointment (not picked up drugs) for at least one month.

DEAD: If the facility has been notified that the patient has died.

Table 1.WHO cut off points with regard to level of Adherence.

| Adherence in % | Missed doses of 60 doses |
|----------------|-------------------------|
| G (Good) >95%  | <3 doses                |
| F (Fair) 85-94%| 4-9 doses               |
| P (poor) <85%  | >9 doses                |

3. RESULT AND DISCUSSION
3.1. Result
3.1.1 Socio-demographic characteristics and clinical markers of study participants
A total of 382, from3,650 eligible individuals, adult PLWHA have been participated in the study giving a response rate of 100%. All selected individuals were voluntary to participate in the study. Proper information regarding the benefit and confidentiality of the study was delivered to each participant. Out of the 382 PLWHA the largest number, 153 (40.1%), were in the age group 35-44 years. The mean (SD) age of the study participants was 37.4(8.29) ranging from 19 to 65 years and the number of female participants were 211(55.2%). The majority of the study participants were Tigray ethnic group [369(96.6%)] and Urban inhabitants [356(93.2%)]. Majority of the study participants were Orthodox religion followers [363(95.0%)]; 182(47.6) of the study participants were married or have partners, 22.8% were widowed, 24.8% were divorced and 5.5% were single. Around 180(47.1%) had attend elementary school. One hundred eleven (29.1%) were daily laborers. Around half, 188(49.2), live with their family/partner. Almost more than half, 201(52.6%), have monthly income of 500 and less Ethiopian birr and the median income of the participants was 500 Ethiopian birr (26 USD) ranged from 100 to 10,000 Ethiopian birr. Most respondents (97%) were detected as being HIV positive more than 2year ago. According to self report the most common mode of HIV transmission was through sexual intercourse with their partner or Husband (42.2%) (Table2).

Table 2 Socio-demographic and economic characteristics of the study participants, Mekelle Hospital, Mekelle zone, Northern Ethiopia, 2015(n=382).

| Variable | Frequency | Total- N(%) |
|----------|-----------|-------------|
|          | Male - N(%) | Female - N(%) | |
| Sex      | 171(44.8)  | 211(55.2)   | 382(100) |
| Age      |           |             |         |
| 18-24    | 2(0.5)     | 5(1.3)      | 7(1.8)  |
| 25-34    | 49(12.8)   | 89(23.3)    | 138(36.1) |
| 35-44    | 81(21.3)   | 72(18.8)    | 153(40.1) |
| >=45     | 39(10.2)   | 45(11.8)    | 84(20)  |
| Occupation |           |             |         |
The baseline CD4 count (at the start of HAART) of most of the study participants (73.6%) were less than 200 cells/ul of blood. After enrolled in to HAART, only 15.2% study participants have CD4 count of less than 200 cells/ul. This indicates greater improvement in CD4 count among individuals taking HAART. Almost all of the study participants, (97.4%), were on first line regimen, of these AZT based AZT,3TC, NVP (42.4%) and TDF based TDF,3TC,NVP (45.0%). D4t based were 10%. Only 2.6% study participants were on second line regimen due to drug resistance and/or some health problems. Only 8.2% of the study participants were enrolled on HAART for 6-24months; whereas 48.4% enrolled for 2-4years period. The rest 43.4% were under HAART for more than 4 years.

More than three-fourth (77.7%) of the study participants have never been treated for TB. Only 4.7% individuals were treated for TB in the last month. Only 17.6% were currently on TB treatment. Almost half (44.5%) of the study participants have no knowledge on importance of adherence. Around 44.2% individuals have clinical appointments of every month. More than half of the individuals, (58.4%), have no missed dose and in one fourth of the study participants (25.9%), one and above missed dose. The main reason for missed dose was for getting. Around 68.3% study participants were currently on treatment for opportunistic infection (OI); 6.3% were treated in the past three months and only 25.4% individuals never treated for OI. The distance from residence to clinic for most of the study participants (82.7%) was within the range of 10km. Considering patient-provider relationship, 33.2% had very good relationship; 45.5% had good relationship; and 21.3% were felt they had poor relation with their clinicians and with the HAART unit (Table 3).

3.1.2 Disclosure status, Social support status and Stigma related pill taking
Considering the disclosure status of the study participants, 65.4% disclose their HIV positive status to their family members only and 34.6% of the individuals never disclose their HIV positive status. Around three-fourth (73.8%) do not get family and social support. Almost more than half of the participants (52.5%) have stigma related pill taking. The source of information on availability of HAART treatment given was mass media (24.1%) and Health providers (75.9%) (Table 3).

### Table 3 Clinical markers of the study participants comparing male and female Level of adherence, Mekelle Hospital, Mekelle zone, Northern Ethiopia, 2015(n=382).

| Variable                        | Sex                      | Total- N(%) |
|--------------------------------|--------------------------|-------------|
| CD4 Count Baseline              | Male- N(%)               | Female- N(%)|                     |
| <=200                           | 132(34.6)                | 149(39)     | 281(73.6)           |
| 201-499                         | 39(10.2)                 | 60(15.7)    | 99(25.9)            |
| >=500                           | 0(0.0)                   | 2(0.5)      | 2(0.5)              |
### 3.1.3 Level of adherence among the respondents

Self reported dose /treatment adherence among the respondents was 78.3% (percent of participants achieving >95% adherence). A higher percentage of females than males had a level of adherence above 95%, i.e., 81% versus 74.9%, respectively. More adherence was observed in the middle aged study participants i.e. individuals at the lower and upper age extremities were less adhered. Considering the occupation of the study participants, merchants and daily laborers were lower in level of adherence with 75.3% and 72.1% respectively. Lower adherence was observed in urban inhabitants with level of adherence 78.1% and 80.8% respectively. Level of adherence was affected by the average monthly income of the study participants. Study participants who have more annual income (>=1000EBR) were less adhered than those with low annual income with 77.2% level of adherence. Study participants who live alone were less in adherence (74.8%) and those who live with their children were more in level of adherence (85.4%). Study participants who have a distance of =<10km were more adhered than those who have >10km with level of adherence 80.4% and 74.2% respectively.

Indicated reasons for missed appointment were forgetting 31.4%, too busy 11.5%, far distance 3.4% and felt sick 1%. The major reasons given for missing drugs/dose were forgetting, being busy with other things, feeling of sickness and the rest reasons included simply far from home, due to many pills, going to holy water, running out of drug and out of town.

### 3.1.4 Factors associated with level of adherence

Different factors were assessed for their association with level of adherence using bivariate logistic regression. On bivariate logistic regression sex of the study participants, educational status and alcohol use were found to be associated with adherence at p value less than 0.05. But on multivariate logistic regression only sex and educational status of the study participants were associated with adherence. Females were 3.2(1.89, 5.39) times more likely to be adhered than males. Study participants who can read and write were 2.6(1.09, 3.2) times more likely to be adhered than those who can’t read and write (Table4).
Table 4: Final logistic regression model that predictor Level of adherence dose time, Mekelle Hospital, Mekelle zone, Northern Ethiopia, 2015 (n=382).

| Variable                  | Adherence |          | p-value | Oddis ratio |                     | P value |
|---------------------------|-----------|----------|---------|-------------|----------------------|---------|
|                           | Yes       | No       |         | COR(95% CI) | AOR(95% CI)          |         |
|                           | N(%)      | N(%)     |         |             |                      |         |
| Sex                       |           |          |         |             |                      |         |
| Male                      | 118(69.0) | 53(31.0) | 1.00    | 3.09(1.89,5.39)* | 3.81(2.18,6.69)*     | 0.00    |
| Female                    | 185(87.7) | 26(12.3) | 0.000   |             |                      |         |
| Age                       |           |          |         |             |                      |         |
| 18-24                     | 5(71.4)   | 2(28.6)  |         |             |                      |         |
| 25-34                     | 113(81.9) | 25(18.1) | 0.84    | 1.20(0.22,6.65) |                     |         |
| 35-44                     | 120(79.5) | 31(20.5) | 0.22    | 0.66(0.34,1.28) |                     |         |
| >=45                      | 63(75.0)  | 21(25.0) | 0.43    | 0.78(0.41,1.46) |                     |         |
| Occupation                |           |          |         |             |                      |         |
| Employed                  | 65(89.0)  | 8(11.0)  |         |             |                      |         |
| Merchant                   | 155(73.5) | 56(26.5) | 0.24    | 0.41(0.09,1.81) |                     |         |
| Housewife                 | 24(85.7)  | 4(14.3)  | 0.78    | 1.20(0.32,4.540 |                     |         |
| Have no job               | 49(86.0)  | 8(14.0)  | 0.49    | 0.56(0.11,2.95) |                     |         |
| Others                    | 10(76.9)  | 3(23.1)  | 0.42    | 0.54(0.12,2.42) |                     |         |
| Marital status            |           |          |         |             |                      |         |
| Married                   | 147(80.8) | 35(19.2) |         |             |                      |         |
| Single                    | 17(81.0)  | 4(19.0)  | 0.37    | 0.758(0.414,1.39 |                     |         |
| Widowed                   | 69(79.3)  | 18(20.7) | 0.63    | 0.749(0.228,2.46) |                    |         |
| Divorced                  | 70(76.1)  | 22(23.9) | 0.61    | 0.830(0.410,1.68) |                    |         |
| Educational status        |           |          |         |             |                      |         |
| Unable to read and write  | 66(71.0)  | 27(29.0) |         |             |                      |         |
| Able to read and write    | 237(82.0) | 52(18.0) | 0.023   | 1.87(1.09,3.2)* | 2.60(1.43,4.71)*     | 0.002   |
| Residence of patient      |           |          |         |             |                      |         |
| Rural                     | 21(80.8.5)| 5(19.2)  |         |             |                      |         |
| Urban                     | 282(79.2) | 74(20.8) | 0.85    | 0.91(0.33,2.49) |                     |         |
| Average monthly income    |           |          |         |             |                      |         |
| =<500                     | 162(80.6) | 39(19.4) |         |             |                      |         |
| 501-999                   | 36(80.0)  | 9(20.0)  | 0.45    | 0.82(0.48,1.39) |                     |         |
| >=1000                    | 105(77.2) | 31(22.8) | 0.70    | 0.85(0.37,1.95) |                     |         |
| Living with               |           |          |         |             |                      |         |
| Alone                     | 101(77.1) | 30(22.9) |         |             |                      |         |
| Family/partner            | 150(79.8) | 38(20.2) | 0.43    | 1.44(0.58,3.58) |                     |         |
| Parent                    | 18(81.8)  | 4(18.2)  | 0.65    | 1.23(0.51,2.99) |                     |         |
| Children                  | 34(82.9)  | 7(17.1)  | 0.91    | 1.10(0.28,4.18) |                     |         |
| Alcohol use (self report) |           |          |         |             |                      |         |
| Yes                       | 67(70.5)  | 28(29.5) |         |             |                      |         |
| No                        | 236(82.2) | 51(17.8) | 0.016   | 1.93(1.13,3.30)* | 1.69(0.96,2.95)      | 0.07    |

*the variable shows an association with adherence at p value <0.05.

Study participants who can read and write were more likely to be adhered than individuals who can’t read and write. Around 82% of educated individuals were adhered. But only 71% of individuals among those who can’t read and write were adhered (Fig. 2).

Figure 1: Association of sex with adherence, Mekelle Hospital, Mekelle zone, Northern Ethiopia, 2015 (n=382).
Study participants who can read and write were 2.6(1.09, 3.2) times more likely to be adhered than those who can’t read and write (Figure 2).

Figure 2: Association of educational status with adherence, Mekelle Hospital, Mekelle zone, Northern Ethiopia, 2015(n=382).

3.2. DISCUSSION

The level of adherence that we found from this study was 78.3%. Considering the WHO recommendation of 95%, this result is still low. The level of adherence was comparable with those reported in Addis Ababa (81.2% and 82.8%) and South West Ethiopia (79.3%). This may suggest that adherence in regional setting is slightly lower than central settings. Some studies in resource-rich settings have documented less than 50% of patients taking all their antiretroviral medications on time and according to dietary instructions. This was much lower than our report confirming that patients in developing countries can achieve good adherence despite limited resources.

Study conducted in South West Ethiopia indicated that level of adherence was 98.8%, which is higher than that we found.

In our study, we found that females were more adhered than males. Study done in South Western Ethiopia also indicated that females were more adhered than males. The resulting higher rate of increase in the medication adherence for females than males might be attributed to females believes in self efficacy in whatever they do in order to succeed. This may also be due to the fact that males used stimulants and other social drugs which will affect adherence negatively than females. But study conducted in South and Central Ethiopia and Togo indicated that males were more adhered than females. Study conducted in Kenya also found that sex was not significantly associated with level of adherence.

We found an association between educational status and level of adherence. Educated participants have more adherence than individuals with lower educational status. This could be due to the reason that educated people typically engage in healthier behavior patterns. Similarly study done in Kenya found that educational status was significantly associated with level of adherence. Study conducted in South Africa found that low educational status was not a predictor of adherence for patients with fully subsidized therapy and concluded that adherence in developing countries has been found to be at least as good as adherence in developed countries.

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Alcohol consumption was significantly associated with adherence only in binary logistic regression. In our study we found that there was no difference in adherence with respect to difference in distance from the health facility. This could be due to the reason that most of the study participants, 82.7%, came from less than 10km or they live in the city. So distance could not be the reason for non-adherence. But, study conducted in Southern Ethiopia indicated that the odds of adherence among those who came from short distance was higher than among those who came from long distance.
3.3. Limitation of the Study
As the study design was cross sectional, no causal inferences can be made about any significant associations that are found. To some extent, over or under estimation of adherence during self report was another limitation. The other limitation is that respondents might respond ideally rather than what they practically exercise. The study was conducted in a single site.

4. CONCLUSION
The level adherence we found, 78.3%, is still very low considering the WHO recommendation of 95%. Sex and educational status of the study participants were significantly associated with level of adherence with AOR (95% CI) of 3.81(2.18,6.69) and 2.60(1.43,4.71) respectively. Females were 3.81 times more adhered than males. Educational status was also significant predictor of adherence in our study. Study participants who are able to read and write were 2.6 times more adhered than those who are unable to read and write. So, more focus should be given to males and individuals with low educational status to improve level of adherence and to assure the efficacy of HAART in prolonging the life of PLWHA. Adherence is a process, not a single event and adherence support must, therefore, be integrated into regular clinical follow up. Investigation of factors related with long-term adherence would require longer follow-up than the present study.

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Authors’ contribution
GG and HG designed the study, analyzed the data, drafted the manuscript and critically reviewed the article. All authors read and approved the final manuscript.

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