

Adherence to Option B⁺ and Associated Factors Among Pregnant Women on PMTCT Services at Public Health Facilities of East Shawa Zone, Oromia, Ethiopia

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Abstract

Background: Anti-retroviral therapy has made a significant reduction in morbidity and mortality related to HIV/AIDS. However, it cannot be fully realized without addressing barriers related to retention in care and medication adherence.

Methods and materials: A descriptive cross-sectional study design was implemented to select pregnant women on option B⁺ anti-retroviral treatment (ART). The collected data was cleaned and entered into Epidata version 3.1 and exported to SPSS Version 21 for analysis. Multiple logistic regression models were used to indicate the association between variables.

Results: The overall drug adherence of pregnant women on ART medications was 82.6%. The study showed that participants educational status, AOR 4.54 (95% CI; 1.72-11.95), participants status disclosure 2.61 (95% CI; 1.01-6.71), social and financial support to the participants AOR 2.76 (95% CI; 1.17-6.51), counseling on the benefit AOR 2.9 (95% CI; 1.27-6.63), were all positively and significantly associated with adherence to option B⁺ treatment while experience of drug side effect AOR 0.24 (95% CI; 0.1-0.6), and fear of stigma and discrimination AOR 15.79 (95% CI; 4.64-53.67), was negatively associated with adherence to option B⁺ treatment.

Conclusion: Educational status, counseling on health benefit of treatment for the fetus and the mothers, social and financial support favors adherence, fear of stigma and discrimination and drug side effects effect negatively affect adherence to option B⁺. The study recommends collaborative work among patients, healthcare professionals, and the public to enhance ART adherence.

Keywords: HIV; ART; Option B⁺; Adherence; Pregnant women; Ethiopia

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Introduction

Since the start of the epidemic, about 78 million people have become infected with HIV while 35 million people have died from AIDS-related illnesses [1]. In 2013 there were 35 million people living with HIV. Sub-Saharan Africa shared about 24.7 million of the world HIV positive people and 58% of them were women [2]. In 2015, 77% (69-86%) of pregnant women living with HIV had access to antiretroviral medicines to prevent transmission of HIV to their babies [1]. Anti-retroviral therapy has made a significant reduction in morbidity and mortality related to HIV/AIDS [3]. Since 2010, new infection of HIV was declined by

50% due to applications of Option A, Option B, and Option B⁺ protocols [4].

According to option A, pregnant women start ART prophylaxis as early as 14 weeks of gestation and as soon as possible thereafter during pregnancy and labor, and the infant continuing to take prophylaxis throughout breastfeeding. Under option B, the women start ARV during pregnancy and continuing to take it throughout breastfeeding. On the other hand, the third approach, option B⁺, recommend the use of lifelong ARV drugs for all pregnant women regardless of their CD42 count [5,6]. Option B⁺ was first conceived and implemented in Malawi in 2011 [7]. In

2013, Ethiopian government launched implementation of option B⁺ with aims to eliminate new HIV infection to children in 2015 and to keep the mother alive [8]. Since its implementation, the number of women on ART is increasing in Ethiopia [9].

Even though ART decrease morbidity and mortality related to HIV/AIDS, it cannot be fully realized without addressing barriers related to retention in care and medication adherence [3]. Non-adherence to HAART is associated with an increased tendency to vertical transmission of HIV, the progression of mothers HIV to AIDS, raised a number of orphaned children, economic impact and potential development of drug-resistant virus [10-13]. So retention in care is a determinant factor to bring desired effect [14]. There are several anticipated fear related option B⁺ adherences; Option B⁺ doesn't consider the CD4 status and recommends all pregnant including women who feel healthy to initiate lifelong ART which can affect their adherence [15]. Moreover, option B⁺ recommends initiation of lifelong ART without considering gestational age which increases the probability of non-adherence due to long-time exposure to treatment [16].

Though several studies assessed ART adherence levels and factors affecting adherence in different regions of Ethiopia, to the best of investigator's knowledge there is no study conducted on Option B⁺ ART adherence issues among HIV positive pregnant women in Oromia regional state. So, this study is aimed to assess the level of ART adherence and factors affecting it among pregnant women on option B⁺ PMTCT program in East Shawa zone of Oromia regional state, Ethiopia.

Materials and Methods

Study area and study period

This study was conducted in public health facilities (hospitals and health centers) of East Shawa zone, one of the twenty-zones in Oromia regional state. The zone has four public hospitals (Adama Referral Hospital, Bishoftu General Hospital, Welenchit district hospital and Batu district Hospital) and seventy health centers. All of the public hospitals and sixty-one of the health centers in this zone provide PMTCT services. The study was conducted in all the four public hospitals and eighteen health centers. The study was conducted from January to March 2017.

Study design

A health facility based cross-sectional study design was implemented to assess the level of adherence to option B⁺ treatment and associated factors among pregnant women on PMTCT follow up at selected public health facilities of East Shawa zone.

Population

The source population was all pregnant women on PMTCT follow up at public health facilities of East Shawa Zone. The study population was pregnant women on PMTCT follow up at the selected public health facilities of East Shawa Zone.

Inclusion and exclusion criteria

Inclusion criteria: Pregnant women who were on PMTCT follow

up for at least one month at the selected public health facilities of East Shawa zone were included in the study.

Exclusion criteria: Pregnant women who were on PMTCT follow up but who was critically ill and unable to communicate during data collection period were excluded from the study.

Sample size

Sample size (n) was determined based on a single population proportion formula with the following assumptions; the level of confidence (α) was taken to be 0.05 ($Z(1-\alpha/2)=1.96$); the margin of error was taken as 0.05. For the first specific objective, based on the study conducted at public hospitals of Tigray regional state, the levels of option B⁺ ART adherence was 87.1% [17]. For a second specific objective, based on a study conducted in Addis Ababa HIV disclosure status was 77.2% [18]. Accordingly, the calculated sample size was 172 and 304 respectively with 5% consideration for non-responses. Finally, the maximum sample size was taken (304).

Sampling procedure

Public Healthcare facilities in East Shawa zone that which provides ART services were classified as public hospitals and health centers. All of the public hospitals in the zone were included in the study. Since the zone has sixty-one public health centers that provide option B⁺ PMTCT services, it was economically difficult to include all of them. As a result, each health center was considered as similar to their administration and quality of service they provide. Finally, 30% of the health centers were randomly selected by simple random sampling technique to get an adequate sample for the study. A specific sample size was allocated to each health facility using proportion-to-size allocation. To select 304 pregnant women, the first women in each public health facilities were randomly selected by simple random sampling technique.

Data collection and instruments

To collect data from pregnant women; the interviewer-administered questionnaire was used. There was one data collector for each selected health facilities. The qualification of data collectors was a Bachelor of Science in Nursing. They were recruited based on their competence and data collection experience. In addition, they were not working at the selected public health facilities in which the study was conducted. Moreover, one supervisor for each hospital and one supervisor for every three health facilities were recruited. They provided with training on the data collection method by principal investigator before data collection go-ahead.

Measurements

There is no standard tool to measure the level of adherence. But this study applied adherence measurement questions adapted from South Africa experiences, which was designed to measure adherence in the resource-constrained setting to collect data for outcome variables [19]. Another study conducted in Tigray regional state, Ethiopia, has also used the same tool to measure the level of adherence in the study area [17].

Ethical considerations

Ethical clearance was secured from Research Ethics Committee (REC) of the School of Public Health as mandated by Addis Ababa University. Letter of permission was obtained from Oromia Regional Health Bureau, zonal health, and district officials. Informed consent was obtained from all pregnant women prior to proceeding data collection from them. This was done after the clear description of the objectives of the study and of its procedures. Then, each respondent was asked to check whether the information provided for the purpose of the study has been adequately understood or not. Confidentiality of the information obtained from each participant was maintained.

Data entry, processing, and statistical analysis

Data were checked for completeness, inconsistencies, cleaned, coded. The collected data was entered into EpiData 3.1 (EpiData Association, Odense, Denmark) and then exported to SPSS version 21.0 for statistical analysis.

Descriptive statistics were used to summarize the data. Bivariate logistic regression was used to find an association of each independent variable with the dependent variable. Variable with P-value of <0.25 were considered for multivariate logistic regression to control the effect of the confounders. Then, the significance level was set at P<0.05.

Operational definitions

Good adherence: A woman was considered good adherence if she responded ‘No’ to all (four) questions prepared to assess the adherence level. These questions are:

- 1) Do you sometimes find it difficult to remember to take your medication?
- 2) When you feel better, do you sometimes take a break from your medication?
- 3) Many patients have trouble with taking their ARV doses as prescribed; did you miss any ARV doses in the last 3 days?
- 4) Sometimes if you feel worse when you take the medicine, do you stop taking it? [17,19].

Poor adherence: A woman was considered as poor adherence if she responded ‘Yes’ to at least one of the above questions [17,19].

Results

Socio-demographic characteristics of respondents

A total of 304 respondents were planned to be interviewed. However, about 293 pregnant women on option B+ ART drug at public health facilities in East Shawa Zone were interviewed regarding their ART drugs adherence. The overall response rate was 96.4%.

Concerning the age category of respondents 95 (32.4%) of them belong to the age group of 30 to 34 while 85 (29%) of them belong to the age group 25-29. The mean age ± SD of

the participants was 29.2 ± 4.6. Two hundred and twenty-five (76.8%) of the respondents were urban residents. Majority of the study participants were Ethiopian orthodox Christianity followers which accounted for 202 (68.9%) of the respondents followed by protestant 55 (18.8%). Concerning the educational status, one hundred and fifty-three (52.2%) of the respondents have a primary education while 83 (28.3%) of them can’t read and write (**Table 1**).

Two hundred and forty-nine (85%) participants were married, and 27 (9.2%) of the respondents divorced while widowed constituted 10 (3.6%) of the respondents. Regarding their occupation, more than half 161 (54.9%) of the respondents were housewives. Three-fourths of the respondents 223 (76.1%) were living with their husbands/partners while 25 (8.5%) of them live alone at the time of the study.

ART adherence level and health care system related characteristics of respondents

Majority of the respondents 184 (62.8%) were attending their ART follow up at health centers. Two hundred and twenty-

Table 1 Socio-demographic characteristics of pregnant women on option B+ ART drugs at East Shawa Zone, Oromia, Ethiopia January to March 2017.

| Variables | Categories | Frequency | Percentage |
|-----------------------|----------------------|-----------|------------|
| Residence | Urban | 225 | 76.8 |
| | Rural | 68 | 23.2 |
| Religion | Muslim | 32 | 10.9 |
| | Christian Orthodox | 202 | 68.9 |
| | Protestant | 55 | 18.8 |
| | Others ¹ | 4 | 1.4 |
| Marital status | Married | 242 | 82.6 |
| | Divorced | 27 | 9.2 |
| | Widowed | 17 | 5.8 |
| | Others ² | 7 | 2.4 |
| Age | <25 | 62 | 21.2 |
| | 25-29 | 85 | 29 |
| | 30-34 | 95 | 32.4 |
| | ≥35 | 51 | 17.4 |
| Educational Status | Can’t read and write | 83 | 28.3 |
| | Primary (1-8) | 153 | 52.2 |
| | Secondary and above | 57 | 19.5 |
| Occupational status | Own work | 70 | 23.9 |
| | House Wife | 161 | 54.9 |
| | Private employee | 43 | 14.7 |
| | Government employee | 9 | 3.1 |
| | Others ³ | 9 | 3.1 |
| Monthly income | <650 | 58 | 19.8 |
| | 650-1400 | 134 | 45.7 |
| | >1400 | 101 | 34.5 |
| Person they live with | Partner | 223 | 76.1 |
| | Extended family | 45 | 15.4 |
| | Alone | 25 | 8.5 |

¹Waqefata, Adventist and Catholic

²Cohabitant, separated

³Farmers, Commercial Sex Workers

six (77.1%) of the study participants spent less than an hour walking on foot to reach healthcare facilities for their follow up. Regarding time of their HIV status diagnosis, the majority of the study participants 180 (61.4%) knew their HIV status before being pregnant. More than half of the respondents, 158 (53.9), started their ART drugs during the second trimester (13-28 weeks) of their current pregnancy.

Concerning pregnancy type, 213 (72.7%) of the participants had intended pregnancy. With regard to disclosure status, 249 (83.3%) of the respondents disclosed their HIV status to their husbands/partners and/or family and/or friends and/or other significant persons. Majority of the respondents 204 (69.6%) received financial and social support from partner, family, relatives, governmental or non-governmental organizations meanwhile 173 (59%) of the respondents participated in HIV positive mother to mother discussion about ART adherence. Sixty-five (22.2%) participant developed ART side effect during the current pregnancy. The overall adherence level to antiretroviral medication was 82.6%, which was achieved by 552 study participants (Table 2).

Predictors of option B+ ART adherences using bivariate and multivariate logistic regression

FEducational status was significantly associated with adherence

status. Women who had the educational status at primary school level were 4.5 more likely to have good adherence than those who were unable to read and write, [AOR 4.54 (95% CI; 1.72-11.95)]. The analysis also leveled that Antiretroviral drug adherence was strongly associated with drug side effect. Accordingly, women who developed drug side effect during current pregnancy were 76% less likely to have good adherence than their counterparts, [AOR 0.24 (95% CI; 0.1-0.6)] (Table 3).

Respondents who were counseled on health benefit of treatment for mother and fetus were nearly three times more likely to be adherent than those who were not counseled, [AOR 2.9 (95% CI; 1.27-6.63)]. Moreover, ART adherence has a strong association with fear of stigma and discrimination. Those who didn't report fear of stigma and discrimination were about sixteen times more likely to have good adherence than those who reported fear of stigma and discrimination in the current pregnancy, [AOR 15.79 (95% CI; 4.64-53.67)].

The study also showed that respondents who received social and financial support from partner, family, friends, relatives, government or non-governmental organizations were 2.76 times more likely to have good adherence than those who didn't receive support, [AOR 2.76 (95%CI; 1.17-6.51)]. Furthermore, respondents who had a poor relationship with health care

Table 2 HIV, ART, and health care system related characteristics of pregnant women on option B+ ART drugs at East Shawa Zone, Oromia, Ethiopia January to March 2017.

| Variables | Categories | Frequency | Percentage |
|--|---------------------------------|-----------|------------|
| Types of health care facilities | Health Center | 184 | 62.8 |
| | Hospital | 109 | 37.2 |
| Time need by patient to reach healthcare facilities | <1 Hour | 226 | 77.1 |
| | ≥ 1 Hours | 67 | 22.9 |
| Gestational age at the time of ART initiation | ≤ 12 Weeks | 105 | 35.8 |
| | 13-28 Weeks | 158 | 53.9 |
| | ≥ 28 Weeks | 30 | 10.2 |
| Time of diagnosis for their HIV status | Before being pregnant | 180 | 61.4 |
| | After being pregnant | 113 | 38.6 |
| Pregnancy type | Intended | 213 | 72.7 |
| | Unintended | 80 | 27.3 |
| HIV disclosure status | Disclosed | 249 | 83.3 |
| | Not Disclosed | 49 | 16.7 |
| Frequency of counseling on ART adherence by healthcare provider | Always | 198 | 67.6 |
| | Some times | 73 | 24.9 |
| | At initiation of treatment only | 22 | 7.5 |
| Developed ART drug side the effect of current pregnancy | Yes | 65 | 22.2 |
| | No | 228 | 77.8 |
| Any social and financial support | Yes | 204 | 69.6 |
| | No | 89 | 30.4 |
| Participated in HIV positive mother to mother discussion about ART adherence | Yes | 173 | 59 |
| | No | 120 | 41 |
| Relationship with healthcare provider | Good | 264 | 90.1 |
| | Poor | 29 | 9.9 |
| Reported fear of stigma and discrimination during current pregnancy | Yes | 51 | 17.4 |
| | No | 242 | 82.6 |
| Level of ART Adherence | Good | 242 | 82.6 |
| | Poor | 51 | 17.4 |

Table 3 Bivariate and multivariate analysis result for factors associated with ART drug adherence among option B+ pregnant women in public health facilities of East Shawa Zone, Ethiopia, 2017.

| Variables | Categories | Adherence Status | | COR 95% CI | AOR95% CI |
|---|----------------------|------------------|------|-------------------|-----------------------|
| | | Good | Poor | | |
| Marital Status | Married | 204 | 38 | 1.84 (0.89-3.77) | 2.3 (0.41-12.96) |
| | Unmarried | 38 | 13 | 1 | 1 |
| Educational Status | Can't read and write | 56 | 27 | 1 | 1 |
| | Primary (1-8) | 138 | 15 | 4.43 (2.19-8.26) | 4.54 (1.72-11.95)** |
| | Secondary and above | 48 | 9 | 2.57 (1.10-6.00) | 2.79 (0.87-8.92) |
| Economic Status | <650 | 45 | 13 | 1 | 1 |
| | 650-1400 | 118 | 16 | 2.13 (0.94-4.78) | 1.7 (0.58-4.95) |
| | >1400 | 79 | 22 | 1.04 (0.48-2.26) | 1.1 (0.38-3.17) |
| Person they live with | Partner | 191 | 32 | 4.69 (1.96-11.24) | 6.1 (1.22-30.4)* |
| | Extended family | 37 | 8 | 3.63 (1.21-10.90) | 4.98 (0.81-30.68)* |
| | Alone | 14 | 11 | 1 | 1 |
| Type of health care facility | Hospital | 96 | 13 | 1.92 (0.97-3.79) | 1.21 (0.50-2.95) |
| | Health Center | 146 | 38 | 1 | 1 |
| Place of residence | Urban | 190 | 35 | 1.67 (0.86-3.25) | 2.17 (0.59-8.00) |
| | Rural | 52 | 16 | 1 | 1 |
| Time needed to reach health facility | <1 hour | 191 | 35 | 1.71 (0.88-3.33) | 1.14 (0.31-4.26) |
| | ≥ 1 hours | 51 | 16 | 1 | 1 |
| HIV status disclosure | Disclosed | 211 | 37 | 2.57 (0.125-5.30) | 2.61 (1.01-6.71)* |
| | Not Disclosed | 31 | 14 | 1 | 1 |
| Fear of stigma and discrimination | Yes | 38 | 13 | 1 | 1 |
| | No | 234 | 8 | 10 (3.89-25.75) | 15.79 (4.64-53.67)*** |
| Relationship with health care provider | Good | 224 | 40 | 1 | 1 |
| | Poor | 18 | 11 | 0.29 (0.13-0.66) | 0.22 (0.08-0.62)** |
| Social and financial support from others | Yes | 188 | 23 | 4.24 (2.26-7.95) | 2.76 (1.17-6.51)* |
| | No | 54 | 28 | 1 | 1 |
| Any side effect during current pregnancy | Yes | 48 | 17 | 0.49 (0.25-0.96) | 0.24 (0.1-0.6)* |
| | No | 194 | 34 | 1 | 1 |
| Counseled on health benefit of treatment for mother and fetus | Yes | 173 | 24 | 2.82 (1.52-5.23) | 2.9 (1.27-6.63)* |
| | No | 69 | 27 | 1 | 1 |

Note : *represents P<0.05, **P ≤ 0.01, ***P ≤ 0.001

providers were 78% less likely to be good adherent than those who reported having a good relationship, [AOR 0.22 (95% CI; 0.08-0.62)] (Table 3).

Discussion

In this study, good adherence was achieved by 242 respondents, which accounts 82.2% of the study participant. This level of adherence is similar to the study conducted in Chongwe district of Zambia (82.5%) and Kisumu, Kenya (82%) [20,21]. On the hand the overall adherence level of this study is less than the result reported by the study conducted in Tigray regional state of Ethiopia (87.1%), South Wollo Zone of Amhara regional state of Ethiopia (87.9%), the study in Western Kenya (89%), the study conducted in Bwaila Hospital, Malawi [16,22,23]. The study conducted in Tigray regional state of Ethiopia used similar tool with our study to assess the level of adherence. However, the discrepancy might be due to; the study conducted in Tigray regional state used data from public hospitals only, but our study used hospitals and health centers. The women on follow

up at primary health care facilities are less adherent to ART medications than those on follow up at hospitals [24].

In this study, educational status was strongly associated with ART adherence. The respondent who had the educational status at primary school level were 4.5 times more likely to have good adherence than those unable to read and write, AOR 4.54 (95% CI; 1.72-11.95). Similarly, educational status was strongly associated with adherence status in the previous study by Kristen in Tanzania, Boateng in Ghana and Ayuo in Western Kenya [16,25,26]. This might be due to better educated have access to information and are more likely to make better-informed decisions.

The study conducted in Zambia reported that; women attended follow up at referral health facilities were more likely to be poor adherent than those on follow up at rural health centers (20). In contrary, a study conducted in Addis Ababa, Ethiopia, shows that the women on follow up at primary health care facilities are less likely to continue their follow up than those on follow up at hospitals [25]. However, in this study type of health care facilities has no statistically significant association with ART drug

adherence both in bivariate and multivariate analysis, COR 1.92 (95%CI; 0.97-3.79) vs. AOR 1.21 (95% CI; 0.50-2.95).

Social and financial support from partner, family, friends, governmental and non-governmental organization were associated with medication adherence. Those received supports were 2.76 times more likely to have good adherence than those didn't have support from others, AOR 2.76 (1.17-6.51). This study finding is in line with the result reported by the study conducted in Nigeria [27]. This might be due to the usual benefit of social and financial support for moral encouragement and healthcare assistance through transportation and reminders [3].

Women lived with a partner were six times more likely to be adherent than those lived alone, AOR 6.1 (95% CI; 1.22-30.4). Moreover, those who lived with extended family were nearly five times more likely to be adherent to their ART drug than those lived alone with AOR of 4.98 (95% CI; 0.81-30.68). The study in Ukraine agree with our finding; poor adherence during pregnancy was more commonly reported among women living with their extended family and women not living with a partner [28]. HIV status disclosure to partner, family, friend, and significant others had a statistically significant association with ART adherence [25,27,28-30]. Our study agreed with these studies. Respondents who disclosed their HIV status to others were 2.6 times more likely to have good adherence than those who didn't disclose their status, AOR 2.61 (95% CI; 1.01-6.71).

Good relationships with their health care provider enabled patients to have better information about the importance of adhering to their ART medications [31-33]. Similarly, in our study, the respondent who reported a poor relationship with health care provider were 78% less likely to be good adherent than their counterparts, AOR 0.22 (95% CI; 0.08-0.62).

Adherence to option B⁺ was strongly associated with drug side effect. The respondents who self-reported experience of drug side effect in current pregnancy was 76% less likely to have good adherence than who didn't develop drug side effect, AOR 0.24 (95% CI; 0.1-0.6). The previous study in Ukraine also reported similar finding on association of drug side effect and ART adherence [28]. Moreover, fear of stigma and discrimination determine the adherence status in our study. Those who didn't

report fear of stigma and discrimination were nearly 16 times more likely to have good adherence than those reported it. Our finding is consistent with previous studies conducted in India, Tanzania, and Nigeria [27,34,35].

Proper counseling on health benefit of the ART treatment for mother and fetus were significantly associated with medication adherence. Our study shows that; women who counseled on health benefit of treatment for mother and fetus were 2.9 times more likely to be good adherent than their counterparts, AOR 2.9 (95% CI; 1.27-6.63).

The major limitation of this study was considered as a method by which adherence was evaluated, based on self-report, thus the adherence estimate might be affected by some recall bias which might have a tendency to overestimate adherence level. However, the investigators believe as this effect was minimized by data quality control strategies like frequent supervision of data collectors and informing the respondents about the aim of the study and the role of their participation in detail.

Conclusion and Recommendations

Majority of the respondents were adherent to their ART drug regimen. However, nearly one-fifth of the respondents did not adhere to their drugs. The finding of this study depicts that fear of stigma and discrimination and drug side effects effect negatively affect ART drug adherence of pregnant women while appropriate counseling on health benefit of ART for fetus and mothers, social and financial support, patient-health care provider relationship, disclosure status and educational status positively affect ART adherence. Based on the result of the present study, investigators recommend collaborative work between the patient, family, healthcare provider, a governmental and non-governmental organization to enhance ART medication adherence during pregnancy.

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