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**Level of Adherence and Associated Factors to Option B+ PMTCT
among HIV Positive Pregnant Women in Hadiya Zone, Southern
Ethiopia**

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Level of Adherence and Associated Factors to Option B+ PMTCT among HIV Positive Pregnant Women in Hadiya Zone, Southern Ethiopia

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ABSTRACT

Background: Option B+ is a test and treat strategy in which HIV+ pregnant women are initiated on antiretroviral therapy regardless of their immunologic status & clinical status and are maintained on treatment for life in an attempt to avert mother to child transmission of HIV and improve the survival of mothers, newborns and children. Adherence is the single most important modifiable factor to achieve the above outcome. Non-adherence to PMTCT drugs increases the risk of treatment failure, maternal HIV disease progression, and the potential development of drug-resistant virus. The study aimed to identify the level of adherence to the Option B+ PMTCT programme and factors associated with adherence among HIV positive pregnant women in the Hadiya zone, southern Ethiopia, 2016.

Methods: A facility based cross-sectional study was conducted among 215 HIV-positive pregnant women in 2016. Data were collected using a structured interviewer-administered questionnaire. Data were entered into Epi-Data Statistical software version 3.1, and exported to SPSS version 21 for analysis. Descriptive statistics such as frequencies, proportions, and means were carried out. Multiple logistic regressions were used to estimate the effect sizes of factors associated with adherence to Option B+ PMTCT drugs.

Results: The adherence level of respondents to option B+ PMTCT drugs was 83.7% (95 % CI: 78.3, 88.6). Mothers who were counseled on the side effects of ARV medications had 7.2 times higher odds (aOR 7.2, 95% CI 2.2, 22.8) of adhering to Option B+ PMTCT care and support as compared to those who were not counseled properly. Disclosing their HIV status to their partner was also positively associated with good adherence (aOR 3.09, 95% CI 1.04, 9.1). HIV positive pregnant women with good partner involvement in PMTCT care and support had 72% more likely to be adherent to option B+ PMTCT as compared to low (aOR 0.28; 95% CI: 0.06, 0.12).

Conclusion: The adherence level of mothers towards PMTCT care and support was 83.7%. Proper counseling on the side effects of PMTCT drugs, care and support, HIV status disclosure to partners and Male partner involvement were significant predictors of adherence to PMTCT.

Keywords: *Adherence, Option B+ PMTCT, Hadiya zone.*

Abbreviations: PMTCT ----Prevention of Mother-to-Child Transmission of HIV, aOR --- Adjusted Odds Ratio, CI ----- Confidence Interval, HIV---Human Immunodeficiency Virus

INTRODUCTION

The acquired immune deficiency syndrome (AIDS) epidemic is one of the most destructive epidemics that the world has ever faced [1]. Since the start of the epidemic, around 78 million people have become infected with HIV and 39 million people have died of AIDS-related illnesses globally & among these 20.6 million from Sub-Saharan Africa and 4.5 million in Ethiopia [2].

The World Health Organization (WHO) has started to implement different strategies for the optimization of PMTCT care and support: Option A & Option B. As well as these two options, a third approach is now being used Option B+ which is not completely new, but rather is a more feasible alternative to WHO's proposed option B and With this option, all pregnant women living with HIV are offered life-long ART, regardless of their CD4 count [3].

The advantage of Option B+ will include simplification for both the mother-infant pair and the provider, which are likely to facilitate higher retention rates and improved clinical benefits, which will decrease the transmission of HIV to infants. Added benefit of Option B+ beyond the clinical benefit will include improved maternal health and reduce the risk of HIV transmission to HIV negative male sexual partners [3,4].

In 2013, the Ethiopian government adopted Option B+ to substantially increase provision of antiretroviral treatment to pregnant women living with HIV and aims to eliminate new HIV infections in children and keep their mothers alive & the mother and her child are followed up as a pair for up to 18-24 months [5].

The success of HAART, like any medication, is dependent on both the intrinsic properties of the drugs and the individual's ability to take the medication as prescribed which explained by adherence [6]. Adherence has been defined as the extent to which a person's behavior taking medication, following a diet, or making healthy lifestyle changes corresponds with agreed upon recommendations from a health-care provider [7]

There are different methods for assessing adherence. They include direct methods such as biologic markers and body fluid assays, or indirect methods such as self-report/interview, pill counts, pharmacy records, computerized medication caps, and viral load monitoring. While a combination of these methods may be employed, patients self-report is the most widely used given its ease of implementation and use of already existing resources. Studies have also indicated that self-reports correlate well with both viral load and clinical outcomes [8].

Adherence is the backbone of antiretroviral therapy. Studies of the antiretroviral therapy (ART) showed that almost perfect adherence; greater than 95% was required to obtain maximal effectiveness [9]. Sustaining consistent and nearly perfect adherence is required to optimize the outcomes of ART, such as minimized drug resistance, slowed disease progression, decreased hospitalization and delayed death and general health, longevity, and, quality of life [10].

The success of ART is compromised by failure to maintain optimal levels of adherence over the long term and inadequate adherence is the major cause for sub-therapeutic drug levels and drug resistance that is transmissible to un-infected or infected others. Thus, adherence to therapy has become central and a major concern which requires continuous attention to prevent or delay resistance [11].

Non-adherence to PMTCT drugs increases the risk of treatment failure, MTCT, maternal HIV disease progression, and the potential development of drug-resistant virus [12,13].

Though several studies in Ethiopia have identified the factors associated with non-adherence to antiretroviral therapy among HIV-positive adults, only one from literature search studied antiretroviral adherence issues in HIV-positive pregnant option B+ women [14].

Reports have also shown that the availability of a limited number of regimens and the use of fixed dose combinations in option B+ support adherence. It can also limit unnecessary regimen switching and selective drug taking [15]. Moreover, ART preparation at the first visit, the barriers related to the retention and adherence and the public health implications of reduced adherence to Option B+ in resource-limited settings are not well known and need to be fully understood and investigated. So the aim of this study is to identify the level of adherence to the Option B+ PMTCT programme and factors associated with adherence among women on Option B+ in the Hadiya zone, southern Ethiopia.

Materials and Methods

Study Area and setting

The study was conducted in Hadiya Zone, which is established in 1985 EFY with an area of 3542.66sqkm which is 3% of the total area of southern nations nationalities and peoples region (SNNPR). According to the report of zonal health bureau, the total population in 2008 is approximately 1,547,848 (which is 9% of the SNNRP population with the population density of 92 people per square kilometer. The zone is located south west of Ethiopia, 230km far from the Addis Ababa and 194km far from Hawasa, the regional capital. The zone is bordered by Gurage zone in the north, Silte zone in the east, kembeta & Alaba in the south & Yam special woreda & Omo River in the west. In the zone there are 10 woredas, 01 town and 329 kebeles with 303 peasant association & 26 sub cities. The study was conducted at public hospitals & health centers where option B+ PMTCT services were available. The zone is served by 3 hospitals & 62 health center, 3 hospitals & 22 health centers are providing integrated maternal, neonatal, and child health (MNCH)/option B+PMTCT services to HIV-positive women, free of charge[16].The study recruited pregnant HIV-positive women in the zone who were attending the health institutions for PMTCT care and support during the study period.

Study period

Study was conducted from Mar15-Apr 30/2016,this is due to resource limitation

Study design

A facility based cross-sectional study design was used. Since HIV positive women are on the follow up and easy to study on adherence.

Population

Source Population

All pregnant HIV positive women who were attending the health institutions for PMTCT care and support during the study period. This is for the purpose of generalization.

Study Population

Selected pregnant HIV positive women who fulfill the inclusion criteria & who were attending the health institutions for PMTCT care and support during the study period. Since it is not feasible to study all pregnant HIV positive women coming to institution during study period.

Sample size determination

First, the sample size was determined by using a single population proportion with the assumption of a 95% confidence level, 5% margin of error, and the expected level of adherence to option B+ Tigray region, northern Ethiopia (87%) [14] to compensate for non-response, a 15% contingency for the calculated sample is considered in advance. Accordingly, the total sample size was

$$n1 = \frac{(Z_{\alpha/2})^2 P(1-P)}{d^2} = \frac{(1.96)^2 0.87(1-0.87)}{(0.05)^2} = 174$$

Sample size calculation for associated factors

Second, the sample size was determined by using a double population proportion Using Epi Info version 7.1 and based on the study done in Tigray region; the main predictors affecting the adherence were proper counseling on the side effects of PMTCT drugs and HIV status disclosure to their partners.

Sample size calculation for proper counseling

p1 = proportion of adherence among clients who were counseled on ART Side effect (92.2%)

p2 = proportion of adherence among clients who were not properly counseled on ART Side effect (69%)

Z β = 80%, (power = 0.84), Z α $\frac{1}{2}$ = 1.96 at 95% CI

Using Epi Info version 7.1, the final sample size calculated is **n2=90**

Sample size calculation for HIV disclosure to their partners

p1 = proportion of adherence among HIV status disclosed clients (90.6 %)

p2 = proportion of adherence among none disclosed clients (75%)

Z β = 80%, (power = 0.84), Z α $\frac{1}{2}$ = 1.96 at 95% CI

Using Epi Info version 7.1, the final sample size calculated is **n3=182**

The largest sample size, 182 was taken.

For a response rate of 85%, n_f = 182/0.85 = 215, where n_f = the final sample size.

Sampling procedure

Twenty five health facilities were giving option B+ PMTCT care & support. 10 health facilities out of 25 health facilities were selected using a random sampling method. A specific sample size was allocated to each facility using proportion-to-size allocation. Thus, 67, 26, 17, 34, 30, 7, 15, 5, 6, 8 study participants from Nigist Eleni Mohammad Metesabiya Hospital, Shone Hospital, Gibe Hospital, Hosanna HC, Geja HC, Morsito HC, Kosha HC, Ginbichu HC, Qorga HC, and lissana HC were taken respectively. Within each health facility, women were selected by using consecutive sampling. In total, 215 women were interviewed.

Inclusion & Exclusion criteria

Inclusion criteria

Women who were enrolled in the Option B+ PMTCT programme at the time of the study and who had been on ART for more than 2 months. This due to reduce recall bias and selection bias on the recruitment for the study.

Exclusion criteria

Women who started ART before pregnancies were excluded from the study. Because ,their are already adhered to the option B+ services and they are liable to bias

Study variables

Dependent variables

Adherence level

Independent variables:

- Moderating Factors
 - Socio demographic and economic characteristics of women
Age, Place of residence, Religion, Education status, Occupational status, Household income, Distance
 - Access to health information
 - Access to medical care
- Adherence Information
 - Knowledge of the mother regarding Option B+ PMTCT
- Adherence motivation
 - Attitude of the mother towards Option B+ PMTCT
 - Male partner involvements in Option B+ PMTCT activities
- Adherence Behavioral Skills & engaging in a series of coordinated behaviors

Type of ART drug, partner support, place of ARV medication, use of reminders, missing of ARVs, disclosure status, attending ANC visit, counseling, CD4+ cell count, WHO clinical stage.

Data collection procedures

Data were collected using a structured interviewer-administered questionnaire. The questions included were based on the Information–Motivation and Behavioral Skills (IMB) model. The questionnaire constituted questions that provide information on socio-demographic and economic characteristics of respondents, clinical characteristics, male partner factors, knowledge and attitude of mothers towards option B+ PMTCT drugs.

A self-report from a multi-method tool to measure ART adherence in the resource-constrained settings and a pharmacy adherence policy to support adherence to ART were used.¹⁷

Measurements

Adherence: the level of adherence was measured using four adherence measurement questions adapted from the experience in South Africa, which were designed to measure adherence in the resource-constrained setting.¹⁷ The tool comprises four questions:

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 troubles in 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?

The adherence level of a woman was considered as to have good if she responded ‘No’ to four of the questions. However, if she responded at least one ‘Yes’ to the questions, she was considered to have poor adherence level.

Knowledge: the knowledge of the women on Option B+ PMTCT was measured from the total number of correct answers to six knowledge questions, with a minimum score of 0 and maximum of 6. The knowledge of the women on the Option B+ PMTCT programme was considered ‘high’, ‘moderate’, and ‘low’ if they answer >80%, 60–79%, and <60% of the knowledge questions, respectively.¹⁸

Attitude: the attitude of mothers towards the Option B+ PMTCT programme was defined as ‘positive’ if the score of the attitude questions is above the median and as ‘negative’ if the score is below the median.

Male involvement: Regarding male involvement, the composite measure of male partner involvement in the Option B+ PMTCT programme was measured from the total number of correct answers to 10 questions that focus on the male partner’s support of his wife, with a minimum score of 0 and maximum of 10. Involvement will be considered ‘good’ for those who scored >7, ‘moderate’ for those who scored 4–6, and ‘low’ for those who scored <3 to the questions on male partner support.¹⁸

Operational definitions

Adherence behavioral skill: in this study refers to the actions and activities that the women were engaged after having had well informed & motivated to act on the clinical characteristics of the illness as noted in the conceptual model of the study.

OptionB+ women: all Pregnant HIV positive women who were taking lifelong triple ARV (TDF + 3TC +EFV) in the health institutions for PMTCT regardless of *CD4 count*, WHO clinical stage or gestational age.

Data processing and analysis

Data were entered into Epi-Data Statistical software version 3.1, and exported to SPSS version 21 for analysis. Descriptive statistics such as frequencies, proportions, and means were carried out. Binary logistic regression was used to measure the strength of association between independent and dependent variable using odds ratio and 95% of confidence interval. Independent variables which show significant association with dependent variable were candidates for multiple logistic analyses using p-value (less than 0.25) as a cutoff point to see presence of statistical significance. Multiple logistic regression analysis was carried out to identify factors associated with adherence and P value <0.05 was considered as significant. Then outputs were presented using tables and graphs. Finally, the results were compared with available findings indifferent literatures.

Data quality assurance

The questions were prepared in English and then translated into the local language (Hadiyisa) and then translated back to English to assure the consistency of the questions. The questionnaire was pre-tested on 11 HIV-positive option B+ women in Shurmo HC, Fonko HC, Jawe HC and Achamo HC before the actual data collection to ensure the appropriateness of the content with regard to the questions, language, and organization. The data collectors who were from the same facility but not from PMTCT unit were trained (10 clinical nurses) and two public health officers (supervisors) for one day on the objective, data collection tools, and interview techniques. The supervisors used to check the questionnaires for completeness.

RESULTS

Sociodemographic and economic characteristics of the study participants

A total of 202 HIV positive pregnant mothers were included in the study making the response rate to 94%. i.e. 13 women did not participate in the study for different reasons. The mean age of the respondents was 29.4 years with standard deviation of 4.3. The majority were urban residents (53%) and Orthodox Christians (46%). 55.4% did not have a job – they were limited to indoor activities. Regarding educational status, 58 (28.7%) women were illiterate. With regard to the length of the journey to reach the health facilities for PMTCT services, 58.4% of the women used to walk for less than 1 hour. 93.6% of the respondents earned a monthly income of less than 1000 Ethiopian Birr. Friends, health personnel, Kebele meeting, neighbors and Radio/TV were the source of information for 33.2, 98, 24.3, 21.8 and 34.7 percent of the women respectively (see Table 1).

Table1. Sociodemographic and economic characteristics of women under Option B+ PMTCT care and support in health facilities of Hadiya zone, Southern Ethiopia (n=202), 2016

Variables	Number (N = 202)	Percentage
Age, years		
20-24	23	11.4
25-29	95	47
30-34	56	27.7
35-39	28	13.9
Place of residence		
Urban	107	53
Rural	95	47
Religion		
Orthodox	93	46
Muslim	37	18.3
Catholic	7	3.5
Protestant	65	32.2
Ethnicity of the mother		
Hadiya	102	50.5
Kembata	23	11.4
Gurage	27	13.4
Silte	16	7.9
Amhara	23	11.4
Others	11	5.4
Educational status		
No education	58	28.7
primary(1-8)	89	44.1
secondary(9-12) or beyond	55	25.2
Occupational status		
house wife	112	55.4
Business	34	16.8
Salaried	6	3.0
daily laborer	50	24.8
Average time taken in hours to reach to your PMTCT site		
less than 1 hour	118	58.4
greater or equal to 1 hour	84	41.6
house hold earning estimated in birr per month		
<700	132	65.3
≥700	70	34.7

Clinical characteristics of the study participants

At the start of ART, 123(60.9%) of the respondents were in WHO clinical stage 1. The majority of respondents started New HAART regimen (tenofovir, lamivudine, and efavirenz; TDF–3TC–EFV) immediately after testing for HIV. Concerning the CD4 count, 131 (64.9%) of the respondents had a CD4 count of at least 500 cells/mm³. Nearly 53.5% of the women had received their ARV medication at PMTCT centers and the remaining women had received treatment at ART clinics even if in areas where there were separate clinics for PMTCT care and support. Regarding adherence counseling, 91.6% of the respondents were counseled about disclosure while they received the drugs. Almost 41.1% of the women had attended antenatal care (ANC) at least two times and 89.6% of ANC attendant had not missed any of the visits(See Table 2 below)

Table2. Clinical characteristics by level of adherence among women under Option B+ in public health facilities of Hadiya zone, Southern Ethiopia (n=202),2016

Variables	Adherence level	
	Adherent n (%)	Non adherent n (%)
WHO category at admission		
Stage 1	110(89.4)	13(10.6%)
Stage 2,3&4	59(83%)	12(17%)
Type of the regimen		
New HAART regimen (TDF- 3TC- EVF)	160(84.7%)	29(15.3)
Non TDF- 3TC- EVF HAART regimen	9(69.2%)	4(30.8%)
CD4 count at admission (cells/mm3)		
less than 200	7(58.3%)	5(41.7%)
200- 249	6(66.7%)	3(33.3%)
350- 499	38(76.0%)	12(24.0%)
greater or equal to 500	118(90.1%)	13(9.9)
Where the mother is receiving her ARV medication		
At PMTCT center	93(86.1%)	15(13.9%)
At ART clinic	76(80.9%)	18(19.1%)
Counseled on side effects		
Yes	159(88.8%)	20(11.2%)
No	10(43.5%)	13(56.5%)
ANC visits		
One	19(73.1%)	7(26.9%)

Two	71(85.5%)	12(14.5%)	
Three	61(83.6%)	12(16.4%)	
Four	14(90.0%)	6(10.0%)	
Gestational age during the study (weeks)			
less or equal to 12	13(78.9%)	6(21.1%)	
13-28	62(84.9%)	11(15.1%)	
greater than 28	92(83.6%)	18(16.4%)	
HIV disclosure to partner			
Yes	144(92.9%)	11(7.1)	
No	25(53.2%)	22(46.8%)	
The time the women is disclosing her HIV/AIDS status to her partner			
Before	65(87.8%)	9(12.2%)	
After	77(90.6%)	6(9.40)	
How the women has disclosed her HIV/AIDS status to her			
her own decision	10(55.5%)	8(44.5%)	
by health professional support	76(91.6%)	7(8.4%)	
MSG (Mother Support Group)	50(89.2%)	6(11.8%)	
Receipt of partner support			
Yes	131(94.9%)	7(5.1%)	
No	14(75.0%)	6(25.0%)	
Any strategy the women is using to remember taking ARV medication			
Yes	67(93.1%)	5(6.9)	
No	102(78.5%)	28(21.5%)	

Knowledge, attitude and Male partner involvement

Knowledge

Majority of the respondents, (94.6%), perceived that HIV infected pregnant women can transmit HIV to her unborn baby. In addition, they believe that it is possible to reduce the risk HIV transmission to the baby if she takes PMTCT drugs. More than half of the women (54%) were aware that missing ARV drugs has negative effects on prevention of HIV transmission from mother to child. On the other hand, 92.1% of the respondents believed that good adherence could reduce the risk of opportunistic infections.

In summary, the composite measure of knowledge among HIV positive pregnant women showed that 59.9% (121), 21.3% (43) and 18.8% (38) had higher, moderate and lower knowledge on Option B+ PMTCT, respectively (see Table 3 below).

Table 3. Knowledge questions and responses regarding Option B+ PMTCT among HIV positive pregnant mothers in Public of Hadiya zone, Southern Ethiopia (n=202), 2016

Characteristics	True n (%)	False n (%)
Condom use can prevent HIV transmission during sex with an HIV infected partner.	125(61.9)	77(38.1)
Sero positive women can transmit HIV to their babies during pregnancy.	191(94.6)	11(5.4)
HIV positive women can reduce the risk of HIV transmission to their babies if they take PMTCT drugs.	193(95.5)	9(4.5)
Missing to take some drugs of PMTCT has no effect on the effectiveness of PMTCT care and support.	93(46)	109(54)
Adhering to ARV drugs can reduce the risk of opportunistic infections	186(92.1)	16(7.9)
Male partners' support during PMTCT care does not have any effect on mothers to adhere to PMTCT drugs	59(29.2)	143(70.8)

Attitude

The composite measure of attitude among HIV positive pregnant women showed that 191(94.6%) and 11(5.4%) of the respondents had positive and negative attitude towards Option B+ PMTCT care and support respectively (see Table below)

Table 4. Attitude questions and responses regarding Option B+ PMTCT among HIV positive pregnant mothers in Public facilities of Hadiya zone, Southern Ethiopia (n=202), 2016

Variable	Agree n (%)	Disagree n (%)
It is tiresome to take PMTCT drugs every day	46(22.8)	156(77.2)
Taking PMTCT drugs benefits not only to the mother but also to the babies.	191(94.6)	11(5.4)
Starting ART treatment earlier can help to improve quality of life and survival of the mother	197(97.5)	5(2.5)
Involving male partner in care and support increases effectiveness of PMTCT services	184(91.1)	18(8.9)
I don't like to give birth taking PMTCT drugs	58(28.7)	144(71.3)
I don't recommend to have sex without condom regardless of the HIV status of partner	173(85.6)	29(14.4)

Male partner involvement

Regarding to male partner involvement in PMTCT care and support, 150(74.5%) of their partners participated in decision making. Half of the women discussed on use of condom with their partner and only 20(9.9%) of the women had visited their option B+ PMTCT site with their partner. As an indicator to the partners support, 18.8%, 48% and 61.4% of them knew the name of the ARV, dosage and frequency of regimen, respectively. Over seventy five percent (75.2%) of the women also received financial support from their partner. In addition, 114(51.3%) used to discuss with their wives on the advantage of ANC and 129(63.9%) knew and remind the appointment date for ANC and 40(19.8%) of the partners had accompanied their wives to ANC.

In summary the composite measure of male involvement in PMTCT services showed that 73 (36.1%) of respondents had lower male involvement on PMTCT care and support; yet, 40 (19.8%) and 89(44.1%) had higher and moderate male involvement, respectively (see fig 3 below)

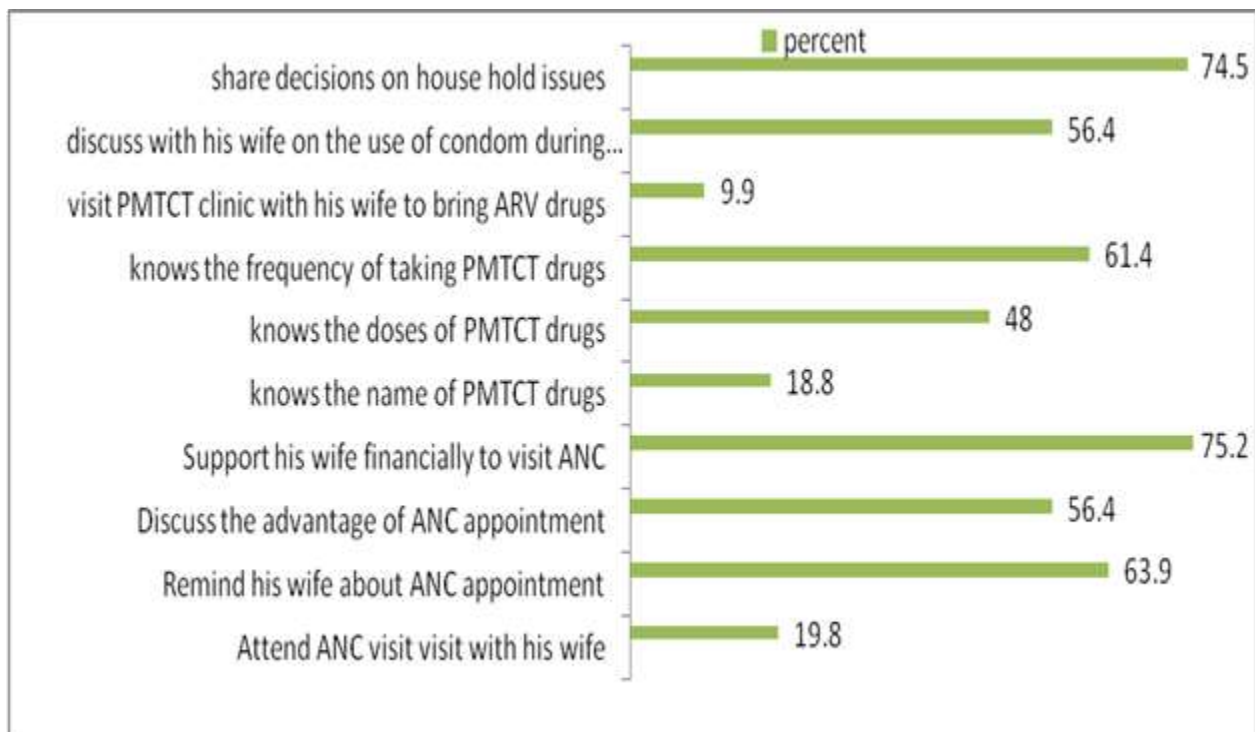


Figure 3: Percentage respondents who had male involvement to adherence of HIV positive pregnant women to option B+ PMTCT care and support in Hadiya zone, 2016.

Adherence to Option B+ PMTCT drugs

Overall, 83.7% (95 % CI: 78.3, 88.6) of the respondents were adherent to Option B+ PMTCT drugs. The frequently mentioned reasons to non-adherence were inability to remember the time for taking drugs. This study showed that 33 (16.3%) of the respondents were non-adherent to Option B+ PMTCT care and support. Out of these non-adherent respondents, 26(78.8%) of them

had missed their ARV medication within the last three days prior to the study. Among the reasons to miss their Option B+ PMTCT ARVs, forgetting to take medications (53.8%) was the dominant obstacle for adherence followed by the fear of side effects (23.1), non disclosure (15.4) and travelled away (7.7).

Table 5. Reasons to non-adherence to Option B+ PMTCT among HIV positive pregnant women in Public facilities of Hadiya zone, Southern Ethiopia, 2016

Reason for non adherence	Frequency	Percent
Difficult to remember	27	46.6
Feeling better	5	8.6
Missing the medication	26	44.8

Factors associated with adherence to Option B+ PMTCT drugs

The results of the multivariable logistic regression analysis showed that mothers who were counseled on the side effects of ARV medications had 7.2 times higher odds (aOR 7.2, 95% CI 2.2,22.8) of adhering to Option B+ PMTCT care and support as compared to those who were not counseled properly. Disclosing their HIV status to their partner was also positively associated with good adherence (aOR 3.09, 95% CI 1.04, 9.1). HIV positive pregnant women with good partner involvement in PMTCT care and support had 72% more likely to be adherent to PMTCT (aOR=0.28; 95% CI: 0.06 and 0.12).(see Table 6 below)

Table 6. Binary and Multiple logistic regression analysis of predictors of adherence to Option B+ PMTCT among HIV positive pregnant women in Public facilities of Hadiya zone, Southern Ethiopia,2016

Characteristics	Adherence		Crude OR (95% CI)	Adjusted OR (95% CI)
	Adhered # (%)	Non-Adhered # (%)		
WHO clinical Stage				
Stage1	110(89.4)	13(10.6)	2.86(1.33, 6.17)	0.17(0.02,1.25)
Stage 2 or 3 or 4	59(74.7)	20(25.3)	1	
Type of regimen				
New regimen	160(84.6)	29(15.4)	2.45(0.7, 8.49)	1.87(0.30,11.51)
Non new regimen	9(69.2)	4(30.8)	1	
CD4 count (cells/mm3)				
>500	118(90.0)	13(10.0)	3.56(1.64, 7.7)	1.19(0.23,6.18)
<500	51(71.8)	20(28.2)	1	
Counseled on side effect				

Yes	159(94.1)	10(5.9)	10.33(4.01,26.63)	7.2 (2.2,22.8)*
No	20(60.6)	13(39.4)	1	
Counseled on HIV Status disclosure				
Yes	161(87.0)	24(13.0)	7.54(2.65,21.44)	0.55(0.07,4.07)
No	8(47.1)	9(52.9)	1	
HIV Status disclosure				
yes	144(92.9)	11(7.1)	11.52(4.97,26.66)	3.09 (1.04, 9.1)*
No	25(53.2)	22(46.8)	1	
Knowledge on Option B+ PMTCT				
High	109(90.1)	12(7.9)	0.44(0.15,1.21)	0.34(0.11,1.03)
Moderate	35(81.4)	8(8.6)	0.21(0.08,0.51)	0.54(0.15,1.96)
Low	25(65.8)	13(34.2)	1	
Male partner involvement				
High	80(89.9)	9(10.1)	2.4(0.37,0.46)	0.28 (0.06,0.12)*
Moderate	29(72.5)	11(27.5)	1.6(0.08,0.16)	0.08(0.01,0.42)
Low	45(61.6)	28(38.2)	1	

Discussion and conclusion

The overall level of adherence to Option B+ PMTCT care and support was 83.7% (95 % CI: 78.3, 88.6). The main factors affecting adherence for the women included in this study were proper counseling on the side effects of the drugs during PMTCT drug provision, disclosing their HIV status to their partner and HIV positive pregnant women with good partner involvement in PMTCT care and support.

In this study, 83.7% (95 % CI: 78.3, 88.6) of the HIV-positive pregnant women were adherent to Option B+ PMTCT care and support. These results is consistent with the study done in Tigray, Ethiopia where 87.1% (95 % CI: 82.6, 90.7) of the respondents were adherent to option B+ PMTCT [14]. This may be due to rapid expansion and scale up of option B+ program at national level. This percentage is slightly lower than that reported from a study conducted in Bwaila Hospital, Malawi (91%) [19]. The discrepancy in the results may be attributable to the quality of data used for assessing the level of adherence. In the Malawi study, the researchers used the pill count from the electronic medical record system; in this study the method is self report and may account for the difference in adherence level.

When compared to studies done in other countries of Sub-Saharan Africa, the adherence level in this study is slightly higher than those reported from Nnewi in Nigeria (78.3%), Lagos in Nigeria (80.6%), and Kisumu in Kenya (82%), but lower than that reported from western Kenya (89%) [20,21]. This may reflect differences in the PMTCT option used, as most of these studies focused on Option A PMTCT; Option A is a different strategy for PMTCT care and support to Option B+. This difference could have had an effect on the adherence level, as the latter may be considered a simplified option. However, the finding in this study shows a lower adherence level as compared

to that reported in a study carried out in Addis Ababa, Ethiopia [22]. This discrepancy may have resulted from differences in awareness, educational level of the women, and better access to infrastructure and better partner involvement in PMTCT care and support in Addis Ababa than in this study.

In this study 76.7% (95% CI: 70.3, 82.2) of the respondents had disclosed their HIV status to their partner. Statistically, disclosure status was significantly associated with adherence to Option B+ PMTCT care and support. These results are consistent with the study done in Tigray, Ethiopia where 77.2% of the respondents had disclosed their HIV status to their partner and statistically, disclosure status was significantly associated with adherence to Option B+ PMTCT care and support [14]. But lower than in a study done in Addis Ababa, Ethiopia and Tanzania [22,23]. This difference may be due to the better awareness and educational level of the women. Studies done in Nnewi in Nigeria, Lagos in Nigeria, and Ghana show that 88.3%, 86.5%, and 85.5% respectively, of the women had disclosed their HIV status to their partner and statistically, disclosure status was significantly associated with adherence to Option B+ PMTCT care and support [20, 21,24]. These percentages are slightly higher when compared to this study (76.7%). However, they are consistent with those of studies done in Addis Ababa and Tanzania [22,23]. Disclosure of HIV status to their partner, the partner's involvement in HIV PMTCT, and counseling on ARV drugs had no significant association with adherence in the study done in Addis Ababa [25]. Generally, HIV status disclosure is considered important in motivating the partner for VCT, reducing risky sexual behavior, increasing partner support & diminishing the transmission of HIV infection in HIV-negative male sexual partners (discordant couple), which is one of the additional benefits of Option B+ over options A and B [4].

In this study 19.8% of the women had received higher male involvement on PMTCT care and support and statistically, male partner's involvement was significantly associated with adherence to Option B+ PMTCT care and support. This percentage is slightly lower than that reported from a study conducted in Tigray, Ethiopia where 25% of the women had received higher male involvement [14]. This difference may be due to the better awareness of the women as well as her partner. The partner's involvement in option B+ PMTCT had no significant association with adherence in the study done in Tigray, Ethiopia [14].

Unlike to study in Nigeria [21], male involvement in PMTCT care and support in this study was higher. This could be attributable to the integrated community interventions including PMTCT services in Ethiopia through the aid of Health Extension Program. Male partner involvement was associated with adherence to PMTCT and this was consistent with a study done in Tanzania which indicates that women who disclosed their HIV status were significantly more adherent to prophylaxis in the pre-delivery period than women who did not [23]. This association shows that male partners who get involved in PMTCT care and support could have better understanding and awareness towards the treatment. Hence, women who get psychological and financial support would be more adherent to PMTCT. This finding implies that stakeholders should also focus on male partners to optimize the benefits of Option B+ PMTCT care and support.

Proper counseling on the side effects of ARV drugs was found to be a significant predictor of good adherence to Option B+ PMTCT. This association is consistent with the study done in Tigray, Ethiopia [14]. Even though there are no other studies showing this relationship, this association is reasonable since women experiencing side effects of the ARV drugs are less likely to trust the

treatment and adhere to it [25]. Another study showed that women experiencing milder side effects such as skin rash or skin discolorations, fatigue, headache, and fever were more likely to adhere to Option B+ PMTCT drugs than those experiencing more severe side effects such as metabolic effects (central nervous system (CNS) toxicity, severe hepatic necrosis, and renal toxicity) [26]. This is consistent with this study, in which the study participants who were counseled about their medication effect were more likely to adhere to Option B+ PMTCT care and support. This appears plausible since one of the drug regimens of Option B+ (TDF–3TC–EFV) has the potential to induce side effects of CNS toxicity like headache, strange dreams, and confusion; this is particularly due to efavirenz. The missed opportunity to counsel on the potential side effects of this regimen may have a negative impact on the mother's satisfaction with the medication.

This study showed that the majority of respondents (94.6%) perceived that MTCT of HIV/AIDS was possible and that 88.3% of the respondents were aware that it was possible to reduce the risk of infection in the baby if they took PMTCT drugs effectively. This is in agreement with the study conducted in Ghana [24].

A number of participants in the studies carried out in Nnewi, Nigeria (63.8%), Lagos, Nigeria (57.6%), and Addis Ababa health centers (20.8%) showed that the main reason reported by the non-adherent respondents for missing their drugs was forgetfulness [20,21,22]. This study also showed a similar finding, forgetting when to take the ARV drugs was the most frequently mentioned reason for non-adherence (51.9%).

As the study used cross-sectional design, it did not allow the researcher to establish a causal relationship between significantly associated variables and treatment adherence, as both variables were measured at the same time.

Since the study is also a cross-sectional study, it addresses the adherence during only the three days prior to the time when the study took place. But one should consider is that adherence behavior might vary among different patients at different times and on different days. Adherence is a dynamic process that changes over time with changing beliefs, attitudes, emotions, and daily and larger life events.

“Gold standard” for assessment of adherence does not exist, in this study adherence was measured using self-report; studies suggest that self-reported adherence measurements are known to increase adherence rates [17]. This is due to Social desirability (projection of a positive image)

The adherence level of mothers towards PMTCT care and support was 83.7%. Although this represents reasonably a good adherence level, it still indicates that a significant number of the women 33(16.7%) were poorly adherent to option B+ PMTCT drugs. This poses a serious threat because when ARV medications are taken intermittently, they develop an increasing inability to combat the HIV virus therefore, negates the efficacy of the ART regimen in the future. This obviously poses an enormous threat to the overall health status of individuals and of the community as a whole because the selection of ARV drugs that are available to patients in developing countries like Ethiopia, are very limited indeed. Health care professionals who administer ARV therefore need to take urgent action in order to improve the level of poor adherence among those who were non adherent to ARV medications.

Proper counseling on the side effects of PMTCT drugs, care and support, HIV status disclosure to partners and Male partner involvement were significant predictors of adherence to PMTCT. The result has positive implication in the prevention of HIV transmission which could be applied in HIV control interventions in similar settings. The findings revealed the need for on-going informational, educational and communication interventions to address the knowledge, motivation and adherence behavioral skills of patients in order to improve the current levels of ART adherence behavior.

RECOMMENDATION

For health facilities

The health professionals should periodically assess patient's medication adherence at every visit and intervene accordingly.

Encouraging the women to come along with a treatment supporter (partners) for the counseling sessions would help in educating the partners appropriately and improving adherence in the long run.

For FMOH, Regional health bureau and zonal health departments

Currently existing Information, Education and Communication (IEC) interventions on HIV/AIDS should be strengthened at individual and community levels in order to reduce non disclosure and increase partner support.

For researchers

Since Option B+ continues life-long, there may be change in adherence over the course of treatment, including in the lactating period. So feature research should focus on lactating women.

It is important to state that self-report used to measure adherence is not the gold standard for adherence measurement. It is advisable for the feature researcher to use multiple tools.

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Declarations

competing interest; Authors declare that no competing interest

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Ethical consideration

Ethical clearance was obtained from the Ethical Review Committee of Jimma University, College of health Sciences. Letters of permission were obtained from Hadiya Zone health department, woreda health office and from each respective health facilities. Informed consent was obtained from each study participant. All the information obtained from each study participant was coded and confidentiality was kept.

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