Assessment of Antiretroviral therapy Initiation among pregnant Women under Option B+ Approach; Viral Load and CD4 Count Outcomes in selected Hospitals of West Zone Oromia, Ethiopia: Quantitative Prospective Cohort Study Design

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Research article

Keywords: ART Initiation Pregnant Women Option B +, Viral Load, CD4 Count

Posted Date: May 29th, 2019

DOI: <https://doi.org/10.21203/rs.2.9662/v1>

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Abstract

Abstract Background: Antiretroviral therapy (ART) is effective for elimination of mother-to-child transmission (eMTCT) of human immunodeficiency virus (HIV) infection, reducing infant mortality and ensuring maternal virologic suppression. While pregnant women require lifelong ART immediately they test HIV positive (“test and treat”) under Option B+ programs, eMTCT programs face challenges and information on the relationship between the time to ART initiation following HIV testing and treatment outcomes is limited in Ethiopia **Methods:** A quantitative prospective cohort design was employed to conduct the study. Five randomly selected Hospitals providing Option B+ services with routine viral load assessment by Oromia regional Laboratory (ORL) from January 2016 to January 2017 was randomly selected. Bivariate and multivariable analyses were conducted to determine factors affecting the time to ART initiation following an HIV test and logistic regression used to determine the correlation between time and treatment outcomes. **Results:** The study results produced and evidence of a mean VL (copies/ml) of 197.27 copies/ml. Respondents that were on ART for a shorter period ≤ 37 months had the least proportion of women 31% were suppressed with VL<1000 copies/ml compared to those on ART for >38 months (58.7%) were suppressed. The median (IQR) CD4 count change or difference among women that had initial and last CD4 was 581 cells/ μ l and mean of current CD4 count 629.17cells/ml³ and more than 85.3% had increase CD4 count. Therefore, in this study identified that factors associated with viral load response were poor /fair adherence missing doses in the past month, missing appointments, baseline CD4 and maternal months on ART were statistically significant among HIV positive pregnant women that initiated lifelong ART on option B+ in Ethiopia. **Conclusion:** The study results demonstrated that HIV positive pregnant women Study results indicate that majority of the respondents 89.7% were suppressed of which 80.3% were undetectable (VL= 0 copies /ml³ and 85.3% had increased CD4 count and 10.3% were not suppressed (VL >1000 copies/ml). Therefore, strategies aimed at improving adherence among women on option B+ are to ensure that these women achieve adequate immunological outcomes. **Keywords:** ART Initiation Pregnant Women Option B +, Viral Load, CD4 Count

Background

Moreover, antiretroviral therapy (ART) coverage is much lower (20%) in developing settings like Asia, Pacific, Eastern, and Northern Africa as compared to over 90% in Eastern and Central Europe and Caribbean (1). Findings of studies in other African countries like Zimbabwe, Tanzania, and Malawi suggest that while Option B+ is expensive, it is cost effective in terms of averting infant infections (2).another study suggested that Option B+ improves the women’ and infants’ health outcomes(3).

Despite the rollout of interventions such as the Option B+ program, suggest that the HIV prevalence among women and new HIV pediatric infections remain disproportionately high especially in Sub-Saharan Africa. This is further aggravated by weak health systems which hinder the initiation and follow up of women initiating on lifelong ART. For example, low uptake of antenatal care (ANC) services, stigma and lack of disclosure negatively impact PMTCT programs (4). In Zambia reports that HIV-infected women attending PMTC programs present to care late in pregnancy and many are lost to follow up by six

months postpartum (5). Similarly, a systematic review conducted among 44 studies in Sub-Saharan Africa assessing barriers and facilitating factors of ART in PMTCT reveals that inadequate knowledge on HIV, ART and vertical transmission; lower maternal education level, stigma, poor staff-client interactions, service accessibility, and non-facility deliveries are among the barriers or factors

Option B+ includes the period from pregnancy to lactation which therefore targets both pregnant and lactating women. In this study, however, the focus will be on pregnant women that initiated ART and received option B+ services for at least 12 months. Therefore, the research statement for this study is “What is the correlation between the time to antiretroviral therapy initiation following an HIV test and treatment outcomes among HIV pregnant women that initiated ART on Option B+ for at least 12 months in healthcare facilities of Ethiopia”?

Methods

Study setting and design

The research design for this study quantitative prospective cohort descriptive design was conducted from January 2017 to March 2017, at ART clinics of governmental hospitals in West Shoa zone, Oromia Regional State, Ethiopia. Ambo town which is the capital of the zone is located 112kilometers to the west of Addis Ababa the capital of the country. According to information from the zonal health office, the total population in the zone is estimated to be 2,381,079 of which 1,214,350 of them are female. Currently, the health system of the zone consists of 6 hospitals, 90 health centers and 447 health posts with 98% of potential health service coverage.

There are different governmental and non-governmental organizations working on HIV/AIDS in the zone. There are 5 hospitals namely Ambo hospital, Enchini Primary Hospital, Gedo Hospital, Gindaberet Hospital, Guder Primary Hospital and 21 health centers are ART sites currently, there 8,439 clients on ART in West Shewa zone (Data from west Shewa zone health office, November 2016).

For the study, three public hospitals (Ambo General Hospital; 3000 clients, Gedo Hospital; 485 clients, Enchini Primary Hospital; 976 client) and were selected based on the load of the clients served in the facilities that conduct routine viral load assessment for patients on option B+ PMTCT by Oromia regional laboratory during January 2016 to January 2017. HIV positive pregnant women that initiated ART received option B+ services for 12 months and had viral load assessment will be targeted in these health facilities during the study. All Sampled pregnant HIV positive women that initiated ART under Option B+ services for at least 12 months from selected healthcare facilities in West Shoa zone.

The selection criterion was included HIV positive pregnant women that initiated ART and received Option B+ services for at least 12 months with viral load assessment selected from 3 Hospital in West Shoa Zone of Oromia region that conducted viral load assessment for patients on ART by Oromia regional laboratory during January 2017 to March 2017.

Sample size determination and Sampling procedure

The required sample size was determined using Statecalc program of the EPI INFO version 7.1.0 statistical package with a 50% rate of viral suppression based on limited data with a precision of $\pm 5\%$ and Confidence limits as % of 95. By considering correction formula, since the total population was less than 10000 which as was 1860, the final sample size was 318. The final size with a non-response rate of 5% was 334. All hospitals found in West Shoa Zone of Oromia region that providing ART services was identified and randomly selected by computer generated methods to be included in the study. The number of study respondents was be allocated proportionally for the five Health centers, based on their total number of ART clients' positive pregnant women who initiated ART under option B+ for at least 12 months to participate in the study.

Operational definitions

Treatment outcomes in the study this concept were included desired results following therapy or treatment outcomes among pregnant women that initiated ART under Option B+ programs for at least 12 months in Ethiopia which was

- CD4 count
- viral suppression (among women)

Data collection tools and procedures

The data collection tool will include a structured questionnaire (translated) and chart or medical records abstraction tool adopted from similar surveys and modified for the study. Questions in the chart abstraction were adopted from the HIV care card used for clinical management of clients receiving HIV care and treatment. Data on both the questionnaires and abstraction forms were collected by trained research assistants and data abstractors. At the completion of abstraction at the health facilities, tools were checked for completeness and completed tools were collected by the team leaders and stored in safe and locked cabinets accessed only by the researcher.

Data management and Analysis

The returned questionnaires were checked for completeness, cleaned manually, coded and entered into EPI INFO 7.1.0 version and then transferred to SPSS windows version 20.0 for further analysis. Frequencies mean and standard deviation was used to summarize descriptive statistics of the data and text, tables and graphs were used for data presentation. Bivariate analysis was used primarily to check which variables have an association with the dependent variable individually. Variables which are found to have an association with the dependent variables were then entered into Multiple Logistic regression for controlling the possible effect of confounders and finally, the variables which have significant

association was identified on the basis of AOR, with 95%CI and p-value to fit into the final regression model.

Results

The respondents' mean age was 30.78 years (n=319) with a standard deviation (SD) of ± 6.56 years.

Their age ranged from 18 to 50 years; 77.4 % of them were ≤ 35 years

In Table1 out of 319 respondents that completed information about their marital status, 233(73.0) respondents reported that they were married and 24(7.5%) were divorced/Separated

In table1, Orthodox and Protestants had the highest proportion of 48.6 and 45.8% and ethnicity the majority 246(77.1%) were Oromo followed by Amhara 46(14.4%).

Of the respondents, 116(36.4%) were not attained formal education and 18(5.6) achieved were diploma and above (see table 1)

Clinical Characteristics of respondents

Clinical characteristics included time to ART from HIV diagnosis, the WHO clinical stage at ART start, CD4 count at ART, time on ART, missed appointments, missed doses in the past month, adherence to ART, type of ART regimen and counseling sessions. These are exhibited in Table 2.

Out of 319 respondents that had WHO stage at ART start documented, 35.7% (n=114) were staged as WHO stage 1 and 45.6% (n=146) as stage 2. The results of the respondents' WHO clinical stage at ART start is exhibited in table 1. Out of the 319 respondents, 196 had their CD4 counts at ART start as exhibited in table one had less than (≤ 350 cells/ μL) were 61.4% at baseline and 85.3% respondents (n= 271) had > 350 cells/ μL during data collection on current recent CD4 counts.

The mean CD4 at ART start was 349.68 cells/ μL and IQR (1- 1012). Out of the 319 respondents that had current CD4 count > 350 cells/ μL 272(85.3%) while initiated ART with CD4 cell counts ≤ 350 cells/ μL were 61.4%.

The majority of the respondents were initiated on the recommended ART regimen for option B+ with 65% (n=207) TDF+3TC+EFV.

Other respondents were initiated on AZT+3TC+EFV 3.8 % (n=12). None of the respondents were initiated on 2nd line regimen.

Time to ART from HIV test

In the study, all the 319 (100%) respondents were assessed for time to ART following HIV testing. The mean time in months among the 31.7% (n=101) women that delayed (did not start on the same day)

initiating ART following an HIV test. The results of the respondents' time to ART start following HIV testing are exhibited in figure 1

Viral suppression

The study results produced an evidence of a mean VL (copies/ml) of 197.27 copies/ml.

The study results indicate that majority of the respondents 89.7% were suppressed of which 80.3% were undetectable (VL= 0 copies /ml³. When dichotomized, 89.7% (n=286) HIV pregnant women were suppressed with VL <1000 copies/ml versus 10.3% (n=33) that were not suppressed (VL >1000 copies/ml).

Respondents that were on ART for a shorter period ≤ 37 months had the least proportion of women 31% were suppressed with VL<1000 copies/ml compared to those on ART for >38 months (58.7%) were suppressed.

CD4 count response

The median (IQR) CD4 count change or difference among women that had initial and last CD4 was 581 cells/ μ l and mean CD4 count 629.17cells/ml³. Out of the total 319 respondents that were assessed for CD4 response, more than 85.3% had increase CD4 count. Among the women that had decreased or no change in CD4, only five individual had no CD4 count change (difference between the initial and last CD4 count was zero).

Predictors of viral suppression at multivariable level

Variables that had p value <0.2 as well as the primary independent variable (WHO clinical stage 2 95% CI; 0.316 to 2.036, p=0.008) compared to WHO stage 1; women that missed doses in the past month 95% CI; 0.047-1.077, p=0.033) versus those that did not miss; women that missed an appointment 95% CI; 0.002 - 0.280, p=0.047), at ART start CD4 95% CI 2.6 to 8.23 , P= 0.021, maternal months on ART, 38- 70 months (P=0.037), >71 months (p=0.032) and adherence(p=0.0306) were associated with viral suppression with p values >0.05.

Out of 319 respondents included in the final model (p<0.05), factors that were independently associated with increased HIV viral load copies/ml included women that poor /fair adherence to ART drugs compared to those that good (coef. -1.390, 95% CI; -2.059 to -0.721, p<0.001). For each additional increase in time to ART from HIV testing in months, HIV VL copies/ml increased by 0.018 copies/ml (95% Confidence interval (CI) 0.002 to 0.035, p=0.03). Therefore, in this study, missing doses in the past month, missing appointments, baseline CD4 and maternal months on ART were statistically significant.

Predictors of CD4 count response at multivariate level

Out of 319 respondents included in the final model ($p=0.001$), increased gestational age at ART start, maternal age in years and adherence on medication were independently associated with CD4 response or immunological outcomes among HIV pregnant women initiated on lifelong ART on option B+. Improved CD4 response was associated with increased gestational age at ART start (coef. 106.508, 95% CI; 25.238 to 186.472, $p=0.011$). Alternatively, decreasing CD4 count was associated with increased age (coef. -11.156, 95% CI; -21.183 to -1.128, $p=0.029$) and fair/poor adherence to medication (coef. -121.931, 95% CI; -227.86 to -16.001, $p=0.024$). Variables that were not independently associated with CD4 response included time to ART following HIV testing, missed doses in the past month and parity.

Discussion

Time on ART is an important predictor of treatment outcomes among women who initiate ART under option B+. Most importantly, the initial period during ART initiation is associated with poor outcomes like reduced viral suppression. The proportion of suppressed respondents with VL <1000copies/ml was lowest 31% among those on ART for <37 compared to those on ART for 38-70 months 58.7%) and majority of the respondents 89.7% were suppressed of which 80.3% were undetectable (VL= 0 copies /ml³). Detectable VL or none suppression is highest among women that enroll on option B+ with ≤ 4 months of ART (7). The results of this study emphasized the need to intensify support for HIV pregnant women on option B+ during the early months of ART initiation.

Most of the respondents in the study at the start of ART presented with high CD4 count with a median of 349.68 cells/ μ L and IQR (1-1012) and less advanced WHO Treatment stage with 96.9% ($n=309$) staged as WHO stage 1 and 3.1% ($n=10$) as stage 2, report that 70.5% of breastfeeding and pregnant women on option B+ in Northeast Ethiopia initiate ART with WHO clinical stage 1 and 6.6% with stage 2 (8). In Haiti, 92% of women have clinical stage 1 or 2 among the 68% of option B+ clients (8). This study 11.6% were WHO stage 3 and 6.9 % were stage 4. In Malawi (10) report that 80.2% ($n=5991$) women on option B+ have WHO clinical stage1, 3.9% ($n=1,294$) WHO stage 2, 10.2% ($n=2,765$) WHO stage 3 and 2.9% ($n=214$) with stage 4 and other study done by Kamuyango et al, more women in the pre-option B+ cohort have WHO stage 3 or 4 at the time of ART initiation compared to those on option B+ (11.9% versus 1.1%, $p<0.001$) (11).

In this study, 61.4% ($n=196$) respondents had CD4 counts <350 cell/ μ L at baseline which implied that there were women on option B+ that initiated ART with a low CD4 count and recent last six month CD4 count indicated that only 14.7% ($n=47$) were less than 350 cell/ μ L this leads to improved immune recovery. Women on option B+ that initiate ART with low CD4 count at ART start, therefore, would benefit from getting a baseline CD4 cell count.

Concerning VL suppression, the study results revealed a median viral load (copies/ml) of 3.62 copies/ml with IQR (3.00-12.01copies/ml) compared to a median viral load (copies/ml) of 4.3 (2.0–5.7; 3.8–4.7) among women that are ART naïve and experienced (Aziz et al 2013: 1538). The difference in the median VL according to Aziz et al (2013:1538) and the study could be explained by the difference in study

respondents. The study consisted of ART naïve pregnant women while the study had both naïve and ART-experienced participants and ARV-naïve pregnant women are more likely to achieve viral loads <1000 copies/ml compared to those who are ARV-experienced (4).

The study results also indicated that majority of the women 89.7% (n=286) HIV pregnant women have suppressed with VL <1000 copies/ml compared to 10.3% (n=33) that were not suppressed (VL >1000 copies/ml). The high viral suppression rates were comparable to another study conducted in Uganda with 96% (67/70) pregnant and lactating women on option B+ suppressed at 6 months, 93.1% (174/187) at 12 months and 95.8% (479/500) at 24 months with suppression VL<1,000 copies/ml (12) and also report a viral suppression rate (VL<1,000 copies/ml) of 90% (n=448) among pregnant and breastfeeding women enrolled on option B+ in 13 large health facilities in Malawi(10).

In this study, decreased CD4 count or immunologic failure was associated with fair/poor adherence to medication (coef. -121.931, 95% CI; -227.86 to -16.001, p=0.024) which was similar with the log of change of CD4 cell count among patients with fair adherence is 2.9% less than patients with good adherence [ARR = 0.0290133, 95% CI (0.00974, 0.043931); p<0.001] and the log of change of CD4 cell count among patients with poor adherence at visiting time is 5.7% less than those of good adherent patients [ARR = 0.0573, 95% CI (0.0214, 0.0706); p <0.001](13). In this study, all patients had access to free ART and laboratory tests including VL assessment and CD4 count measurement (13).

In Uganda, poor maternal adherence to ART is independently associated with infant HIV infection (adjusted hazard ratio [aHR] 1.88, 95% CI 1.30-2.73), p<0.001) among women on option B+ (14)

Alternatively in a systematic and meta-analysis study in low and middle-income countries report that adherence is higher during pregnancy (75.7%, 95% CI 71.5–79.7%) compared to the postpartum (53.0%, 95% 32.8% to 72.7%) (p=0.005) period (15). These differences could be caused by the different regimen used in the two studies. Moreover, a regimen with reduced pill burden, easier dosing, and better tolerability may also enhance ART adherence among pregnant women (16). Various PMTCT programmes use different methods for measuring adherence. However, common measures include self and proxy reports, pill counts, pharmacy refills, electronic drug monitoring, virologic markers (CD4 counts, viral loads) and blood draws for drug concentrations. On the other hand report a higher proportion of 87.1% (95% CI 82.6–90.7%) among HIV-positive pregnant women on option B+ with adequate adherence in Tigray, northern Ethiopia reports a similar percentage of 95.9% (306) among women on option B+ with good adherence compared to 12.1% (n=23) with poor adherence in Amhara region, North East Ethiopia(17). A much higher proportion of pregnant and breastfeeding women on option B+ (91.4%) have good adherence to ART ($\geq 95\%$ adherence) (MSPH 2015:10). Ensuring adequate adherence to ART among women who initiate lifelong ART on option B+ is essential for an improved immunological response. This would consequently contribute to the reduction of MTCT. Strategies targeting to address issues that hinder adherence among HIV positive pregnant women on ART are essential for improved immunological outcomes.

Most studies indicated similar findings in which older individuals are more likely to have immunological failure compared to those that are younger. In Ethiopia, report that immunological treatment failure is

associated with old age (18). Furthermore, in North-West Ethiopia, each unit increase in years is associated with a 3.3% cell/mm³ decrease in the log of change of CD4 cell count (0.0098, 0.0899); p=0.0264] (13). Patients with lower CD4 cell count at ART initiation and more advanced age (> 40 vs <40 years) demonstrate a decline in CD4 cell count from baseline to 12, 24, and 36 months of follow-up (14)

Findings in seven countries in Sub-Saharan Africa and Thailand suggest that lower CD4 cell increase is independently associated with male sex, older age and lower CD4 cell count at ART initiation (Toro et al 2010:515). According to He et al (2016:[2]), age (aHR=0.77, 95% CI 0.61–0.97), baseline CD4+ count (aHR=1.60, 95% CI 1.37–1.86), initial regimens, changes in regimen (aHR=0.58, 95%CI 0.49–0.69) and inclusion of a cotrimoxazole prophylaxis (aHR=0.66, 95%CI 0.51–0.85) are associated with CD4+ T cell count recovery. In North West Ethiopia, higher baseline CD4 count, younger age, working functional status, and time on treatment contribute positively to the increase of the CD4 cell count (Gezie 2016:[1]). In Abidjan, immunological failure is three times higher in patients ≥15 years of age that had baseline CD4 cell count of ≥200/mm³ (19).

While the study results did not elicit any statistically significant results between time to ART start following HIV testing and immunologic response, the results indicated that delay in initiating ART following HIV testing among pregnant women on option B+ is associated with decreasing CD4 count response (coef -0.225; 95% CI-3.503 to 3.013; p=0.882) which is in agreement with some studies which suggest that delayed ART initiation is associated with poor treatment outcomes.

On the contrary, suggest that immunological treatment failure is associated with lower baseline CD4 count and higher educational status (18). According to conducted in Addis Ababa showed that women with lower CD4 count before ART initiation <200 cells/mm³ are 0.023 times less likely to achieve good immunological outcome compared to those with CD4 count ≥200 cells/mm³ (AOR=0.023, 95% CI= (0.003 – 0.190), p=0.000 among women who start HAART before or during pregnancy in a Hospital in Addis Ababa.

Conclusions

The mean CD4 at ART start was 349.68 cells/μL and IQR (1- 1012). Out of the 319 respondents that had current CD4 count > 350 cells/μL 272(85.3%) while initiated ART with CD4 cell counts ≤ 350 cells/μL were 61.4%. The median (IQR) CD4 count change or difference among women that had initial and last CD4 was 581 cells/μL and mean CD4 count 629.17cells/ml³ and more than 85.3% had to increase CD4 count.

Study results indicate that majority of the respondents 89.7% were suppressed of which 80.3% were undetectable (VL= 0 copies /ml³ and majority of them 85.3% had increase CD4 count. When dichotomized, 89.7% (n=286) HIV pregnant women were suppressed with VL <1000 copies/ml versus 10.3% (n=33) that were not suppressed (VL >1000 copies/ml).

Therefore, in this study identified that factors associated with viral load response were poor /fair adherence missing doses in the past month, missing appointments, baseline CD4 and maternal months on ART were statistically significant. WHO stage, missed doses in the past month, CD4 counts, maternal months on ART and adherence were associated with viral suppression and missing doses in the past month, missing appointments, baseline CD4 and maternal months on ART were statistically significant.

The results also illustrated that delayed ART initiation following HIV testing among HIV positive pregnant women would result in increased viral copies. Improved CD4 response was associated with increased gestational age at ART start. Alternatively, decreasing CD4 count was associated with increased age and fair/poor adherence to medication. The significant results included factors that hindered the process of ART initiation and compliance to medication such as minimal male participation during PMTCT; missing clinic appointments due to traveling away from home or taking a trip and work-related issues; missing doses due to traveling away from home, forgetting and lack of food.

The results of this study were also guided policy and current protocol modification in the area of Option B+ implementation especially in low-resource countries that face challenges due to weak health systems and to contextualize it.

Analyzing the relationship between factors that influence ART initiation and treatment outcomes among these women through empirical processes was provide awareness, guidance, and suggestions on viable approaches or strategies that health providers can employ to support women and their infants during ART initiation.

FMOH would be better to decentralize ART care and laboratory services to zonal level to increases access to health facilities

Trained peer support groups established to support women that enroll on lifelong ART.

Improved partner participation and support to women enrolled in option B+ programmes.

Male partners support the women to initiate and adhere to lifelong ART

Therefore, strategies aimed at improving adherence among women on option B+ are to ensure that these women achieve adequate immunological outcomes.

Prospective studies that aim at further understanding the factors associated with treatment outcomes like viral change, LTFU and immunological outcomes among women who initiate on lifelong ART including the outcomes among children is beneficial in developing strategies to further support women on option B+.

Abbreviations

ANC	Antenatal care
ART	Antiretroviral therapy
AZT	Zidovudine
DNA	Deoxyribonucleic Acid
EFV	Efavirenz
eMTCT	Elimination of Mother-to-child transmission
HBM	Health Belief Model
HIV	Human immunodeficiency virus
MoH	Ministry of Health
MTCT	Mother-to-child transmission
NNRTI	non-nucleoside reverse transcriptase inhibitor
NVP	Nevirapine
PCR	Polymerase chain reaction
PMTCT	Prevention of Mother-to-child transmission
TDF	TenofovirDisoproxilFumarate
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization
3TC	Lamivudine

Declarations

Acknowledgments

We are grateful to the Department of Nursing and medical staffs for their constructive comments and continuous encouragement starting from topic selection to the development of this research proposal. We also want to acknowledge Ambo University, College of medicine and health sciences for giving us this opportunity. We are grateful for all Mothers attending Prevention of Mother to Child Transmission in West Shoa Zone Health Facilities, Data collectors and supervisor for their valuable contribution and support. Last not list to West zone Health office.

Funding

This study was supported by the Ambo University, College of medicine and health sciences research and community service. The funder had no role in the design, data collection, analysis and interpretation of

results in this study.

Availability of data and material

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' Contributions

Dereje Bayissa Demissie, Gizachew Abdissa Bulto, Wagi Tosisa Mekuria and Fikru Negassa Dufera conceptualized the study, designed the study instrument and conducted the data analysis and wrote the first draft and final draft of the manuscript. DBD Approved the research proposal with some revisions, participated in data analysis, revised subsequent drafts of the paper and involved in critical review of the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study have been performed in accordance with the Declaration of Helsinki and approved by Ambo University. Formal letter of cooperation was written to respective hospitals /health centers by Ambo University. The right to refuse was respected and information collected from this research project was kept confidential and the collected information was stored in a file, without the name of the study participant.

Consent for publication: Ambo University and Authors agreed for publication in reputable journal. (Agreement Ref number: CMHS-R219/2019)

Competing interests

The author(s) declare that they have no competing interests including financial or funding.

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References

1. *Global Report: UNAIDS Report on the global epidemic. 2013. United Nations programme on HIV/AIDS (accessed 30 August 2016).*
2. Gopalappa, C, Stover, J, Shaffer, N & Mahy, M. 2014. The costs and benefits of Option B for the prevention of mother-to-child transmission of HIV. *AIDS* 28(1):S5-S14.
3. Fasawe, O, Avila, C, Shaffer, N, Schouten, E, Chimbwandira, F, Hoos, D, Nakakeeto, O & De Lay, P. 2013. Cost-effectiveness analysis of Option B+ for HIV prevention and treatment for women and children in Malawi. *PLoS One* 8(3):1-10.
4. Aizire, J, Fowler, MG & Coovadia, HM. 2013. Operational issues and barriers to implementation of prevention of mother-to-child transmission of HIV (PMTCT) interventions in Sub-Saharan Africa. *Curr HIV Res* 11(2):144-159.
5. Scott, CA, Iyer, HS, Bwalya, DL, Bweupe, M, Rosen, SB, Scott, N & Larson, BA. 2013. Uptake, outcomes, and costs of Antenatal, well-baby, and prevention of Mother-to-child transmission of HIV services under routine care conditions in Zambia. *PLoS One* 8(8):1-11.
6. Gourlay, A, Birdthistle, I, Mburu, G, Iorpenda, K & Wringe, A. 2013. Barriers and facilitating factors to the uptake of antiretroviral drugs for prevention of mother-to-child transmission of HIV in Sub-Saharan Africa: a systematic review. *J Int AIDS Soc* 16(1):1-21.
7. Gill, MM, Hoffman, HJ, Bobrow, EA, Mugwaneza, P, Ndatimana, D, Ndayisaba, GF, Baribwira, C, Guay, L & Asiimwe, A. 2016. Detectable Viral Load in Late Pregnancy among Women in the Rwanda Option B+ PMTCT Program: Enrollment Results from the Kabeho Study. *PLoS One* 11(12): [1-14].
8. Mitiku, I, Arefayne, M, Mesfin, Y & Gizaw, M. 2016. Factors associated with loss to follow-up among women in Option B+ PMTCT programme in northeast Ethiopia: a retrospective cohort study. *Journal of the International AIDS Society* 19(1): [1-8].
9. Myrttil, M. 2016. ART attrition across health facilities implementing Option B+ in Haiti. Doctoral dissertation. University of Washington. Washington.
10. Haas, AD, Tenthani, L, Msukwa, MT, Tal, K., Jahn, A, Gadabu, OJ, Spoerri, A, Chimbwandira, F, van Oosterhout, JJ & Keiser, O. 2016. Retention in care during the first 3 years of antiretroviral therapy for women in Malawi's option B+ programme: an observational cohort study. *The Lancet HIV* 3(4):e175-e182.
11. Kamuyango, AA, Hirschhorn, LR, Wang, W, Jansen, P & Hoffman, RM. 2014. One-year outcomes of women started on antiretroviral therapy during pregnancy before and after the implementation of option B+ in Malawi: a retrospective chart review. *World Journal of AIDS* 4(3):332-337.
12. Ayanga, RA, Namukwaya, Z, Lugolobi, EN, Nabweteme Mugerwa, JN, Afrika, SA, Kakande, A, Kanya, S, Byamugisha, J, Musoke, P & Nolan, M. 2015. Virological response among HIV-infected pregnant

and lactating women initiated on Option B + attending the PMTCT program at Mulago National Hospital, Kampala, Uganda. International AIDS Society (Accessed 29 October 2017)

13. Seyoum, A & Temesgen, Z. 2017. Joint longitudinal data analysis in detecting determinants of CD4 cell count change and adherence to highly active antiretroviral therapy at Felege Hiwot Teaching and Specialized Hospital, North-west Ethiopia (Amhara Region). *AIDS Research and Therapy* 14(1): [1-13].
14. Maskew, M, Brennan, AT, Westreich, D, McNamara, L, MacPhail, AP & Fox, MP. 2013. Gender differences in mortality and CD4 count response among virally suppressed HIV-positive patients. *Journal of Women's Health* 22(2): [1-9] (accessed 28 June 2017).
15. Ngarina, M, Tarimo, EAM, Naburi, H, Kilewo, C, Mwanyika-Sando, M, Chalamilla, G, iberfeld, G & Ekstrom, AM. 2014. Women's preferences regarding infant or maternal antiretroviral prophylaxis for prevention of mother-to-child transmission of HIV during breastfeeding and their view on Option B+ in Dares Salaam, Tanzania. *PloS One* 9(1):1-11.
16. Nachega, JB, Mugavero, MJ, Zeier, M, Vitória, M & Gallant, JE. 2011. Treatment simplification in HIV-infected adults as a strategy to prevent toxicity, improve adherence, quality of life and decrease healthcare costs. *Patient Preference and Adherence* 5: 357-367.
17. Tsegaye, D. 2016. Level of adherence and associated factors to option B+ PMTCT programme among pregnant & lactating mothers in selected government health facilities of south Wollo zone, Amhara region, North East Ethiopia, 2016. Doctoral dissertation. Addis Ababa University College of Health Sciences. Addis Ababa.
18. Teshome, W & Assefa, A. 2014. Predictors of immunological failure of antiretroviral therapy among HIV infected patients in Ethiopia: a matched case-control study. *PloS One* 9(12): [1-13].
19. Abrogoua, DP, Kablan, BJ, Kamenan, BAT, Aulagner, G, N'Guessan, K & Zohoré, C. 2012. Assessment of the impact of adherence and other predictors during HAART on various CD4 cell responses in resource-limited settings. *Patient preference and adherence* 6:227-237
20. Ijigu, GM, Gemed, DH & Angamo, MT. 2015. Maternal immunologic and clinical response to antiretroviral therapy initiation before or during pregnancy in HIV-1 infected women and associated factors in Southwest Ethiopia. *Gulhane Medical Journal* 57(2):152-159.

Tables

Table 1: Sociodemographic characteristics of HIV+VE pregnant women initiated ART under Option B+ in selected health facilities of West Zone Oromia, Ethiopia 2017

Variable	Category	Frequency (%)
Age	Age in years (n=319) Mean 30.78 (SD) (6.56)	
	<= 26	99(31.0)
	27 - 30	62(19.4)
	31 - 35	86(27.0)
	36+	72(22.6)
Marital status :	Single	41(12.9)
	Married	233(73.0)
	Widow/widowed	21(6.6)
	Divorced/Separated	24(7.5)
Religion	Orthodox	155(48.6)
	Protestant	146(45.8)
	Muslim	18(5.6)
Ethnicity	Oromo	246(77.1)
	Amhara	46(14.4)
	Tigray	14(4.4)
	Gurage	13(4.1)
Education	Illiterate	116(36.4)
	Read and Write	62(19.4)
	1-8th grade	93(29.2)
	9- 10th grade	30(9.4)
	Diploma and above	18(5.6)
Employment	Gov't	31(9.7)
	Merchant	53(16.6)
	Private	47(14.7)
	Housewife	123(38.6)
	Farmers	65(20.4)
Residence	Urban	193(60.5)
	Rural	126(39.5)

Table 2: Respondents' clinical characteristics HIV+VE pregnant women initiated ART under Option B+ in selected health facilities of West Zone Oromia, Ethiopia 2017

Variable		Frequency (%)
Time to ART from HIV testing	Same day (0 day)	218(68.3)
	Delay 1 thru 8 days)	101(31.7)
WHO Clinical stage at ART start	Clinical Stage 1	114(35.7)
	Clinical Stage 2.	146(45.8)
	Clinical Stage 3	37(11.6)
	Clinical Stage 4	22(6.9)
WHO Treatment stage (WHO- T)	T-Stage 1	309(96.9)
	T-Stage 2	10(3.1)
CD4 at ART start/ BaselineCD4	Median CD4 (IQR) 349.68 cells/ μ L (1-1012)	
	Respondent that had CD4 count at Baseline	
	≤ 350 cells/ μ L	196(61.4)
	> 350 cells/ μ L	123(38.6)
Current CD4	Median CD4 (IQR) 629.17 cells/ μ L (1-1012)	
	≤ 350 cells/ μ L	47(14.7)
	> 350 cells/ μ L	272(85.3)
Mean of Time on ART in months was 57.7	Ranges from 6 month to 151 months On ART	
	≤ 37 months	108 (33.9)
	38 - 70 months	108(33.9)
	71+ months	103(32.2)
Clinical Adherence	Schedule	309(96.9)
	Unscheduled	10(3.1)
Adherence to medication	Good	306(95.9)
	Poor/ Fair	13(4.1)
ART Regimen	TDF+3TC+EFV-1e	207(64.9)
	AZT+3TC+NVP-1c	93(29.2)
	TDF+3TC+NVP-1f	7(2.2)
	Azt+3tc+EFV-1d	12(3.8)
ART regimen of the mother on	Yes	315(98.7)
	No	4(1.3)
Maternal PMTCT intervention during a recent pregnancy		
Newly diagnosed and started on ART during a recent pregnancy	Yes	87(27.3)
	Know HIV +ve on ART	232(72.7)

Variable		Frequency (%)
Of Newly diagnosed and started on ART during a recent pregnancy		
ANC		67(21)
Labour @Delivery		15(4.7)
Post-Partum(FP,EPI,U5yrOPD)		6(1.9)

Table 3: Predictors of viral suppression at multivariable with viral suppression of HIV+VE pregnant women initiated ART under Option B+ in selected health facilities of West Zone Oromia, Ethiopia 2017

Variable	95% CI	P-value
Adherence to ART		
Good	(reference)	
Fair/Poor	-2.059 to -0.721	0.000
Time to ART	0.002 to 0.035	0.030
Adherence to ART		
Good	(reference)	
Fair/Poor	-0.062 to 0.872	0.043
Missed Doses		
Yes	(reference)	
No	0.04 to 0.280	0.02

Table 4: Association between independent factors and CD4 response of HIV+VE pregnant women initiated ART under Option B+ in selected health facilities of West Zone Oromia, Ethiopia 2017

Variable	Coef.	95% CI	P-value
Gestation age	106.508	25.238 to 186.472	0.011
Age	-11.156	-21.183 to -1.128	0.029
Fair/poor adherence	-121.931	-227.86 to -16.001	0.024

Figures

**EMPLOYMENT STATUS AMONG HIV+VE PREGNANT WOMEN
INITIATED ON OPTION B+ IN 8 HEALTH FACILITIES IN WEST
ZONE OROMIA, ETHIOPIA**

Figure 1

Time to ART Initiation HIV testing HIV+VE pregnant women initiated ART under Option B+ in selected health facilities of West Zone Oromia, Ethiopia 2017