Virology Journal

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Human Immunodeficiency Virus (HIV) viral load suppression status and associated factors among pregnant women receiving Highly Active Antiretroviral Therapy (HAART) in Ethiopia

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Abstract

Background Mothers with an undetectable viral load pose no risk of transmitting the Human Immunodeficiency Virus (HIV) to their fetuses. However, there is limited information on the HIV viral suppression status (≤ 1000 RNA copies/mL) among pregnant mothers at the national level. This study aimed to assess the HIV viral load suppression status among pregnant women and identify factors associated with unsuppressed maternal viral levels (> 1000 RNA copies/mL).

Methods We conducted a cross-sectional study using secondary data from the national HIV viral load data repository. The study included all pregnant women who initiated antiretroviral therapy (ART) and underwent routine HIV viral load testing. Data were collected from July 2022 to June 2023 (2015 Ethiopian Fiscal Year (EFY)). Analysis was performed using STATA v.17, with descriptive statistics (frequency, percentage, mean, and standard deviation) calculated. A mixed-effects logistic regression model was used to quantify the strength of associations between variables and HIV viral load status (suppressed vs. unsuppressed), expressed through odds ratios.Variables showing a significant association with the outcome ($p < 0.02$) were selected for further analysis using multiple logistic regression models.

Results The analysis included a total of 13,000 mothers with complete data from viral load tests conducted on pregnant women. The HIV viral suppression rate among these women before delivery was 96.8%. Among those with suppressed results, 96.5% had an undetectable HIV viral load. Multiple binary logistic regression analysis indicated that individuals aged 19–29 had 3.17 times higher odds (AOR 3.17, 95% CI 1.17–5.17, $p = 0.002$) of having an unsuppressed viral load compared to those under 19. Additionally, individuals with poor adherence to treatment had 12.6 times higher odds of experiencing unsuppressed viral loads (AOR 12.64, 95% CI 10.74–14.54, $p = 0.001$). However, no significant association was found between the timing of viral load testing and unsuppressed maternal HIV viral load.

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Conclusion The findings indicate that while the overall rates of HIV viral suppression among pregnant women are high, specific demographic factors such as age and treatment adherence play crucial roles in achieving undetectable viral loads. The data suggests a need for targeted interventions focusing on mothers age from 19 to 30 years and strategies to improve adherence to treatment regimens to enhance outcomes further.The results have significant implications for policy and clinical practices aimed at improving health outcomes for mothers and newborns affected by HIV/AIDS.

Keywords HIV, Viral suppression, Pregnant women, Ethiopia

Introduction

Human Immunodeficiency Virus, HIV, is a viral infection that attacks the body's immune system. It weakens the immune system by targeting white blood cells, making it easier for the person to get sick with various diseases. The most advanced stage of HIV is called AIDS (acquired immunodeficiency syndrome) [1]. Globally, there were 1.2 million [940,000–1.5 million] pregnant women with HIV in 2022, of which an estimated 82% [64–98%] received antiretroviral therapy (ART) to prevent mother-to-child transmission [2, 3]. Mother-to-child transmission of HIV (MTCT) can occur during pregnancy, labour, delivery, or breastfeeding. In the absence of intervention, the rate of transmission of HIV from a mother living with HIV to her child during pregnancy, labour, delivery or breastfeeding ranges from 15 to 45% [4]. However, with access to (ART), the risk of transmission can be significantly reduced [4]. Programmes for preventing the transmission of HIV during pregnancy, birth and breastfeeding have averted an estimated 3.4 million infections in children (aged 0–14 years) since 2000 [3]. Achieving retention in care and preventing new HIV infections are ongoing priorities to eliminate MTCT [5]. According to the 2013 Ethiopian Fiscal Year (EFY) and health-related indicator survey, out of a total of 3,268,599 pregnant, labouring, and lactating women, 90% (2,955,504) were screened for HIV. Among those tested, 16,586 were found to be positive. Of the HIV-positive mothers, 79% (13,064) were initiated on the HIV treatment [6].

A meta-analysis conducted in Ethiopia reported an overall HIV prevalence of 5.74% among pregnant women, with regional variations observed. Higher prevalence rates were noted in the Amhara region compared to Addis Ababa, Oromia, and the Southern Nations, Nationalities, and Peoples' (SNNP) region [7].

A study conducted in the Amhara region of Northwest Ethiopia reported a viral non-suppression rate of 9.1% among pregnant women. Factors associated with higher viral suppression rates included earlier WHO clinical stages (I and II), good adherence to ART, and routine testing. No significant differences were observed based on age, type of drug regimen, breastfeeding status, or specific treatment combinations [8].

The national guidelines recommend that, for all pregnant women, regardless of the timing of ART initiation, it is advised to conduct viral load testing at 34–36 weeks of gestation or, at the latest, during delivery. This helps

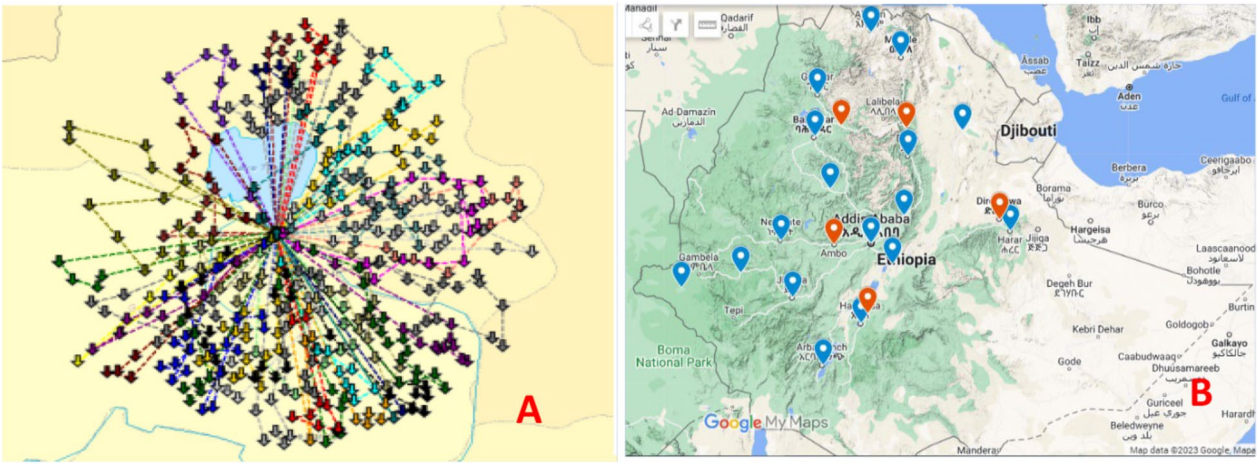

Fig. 1 Specimen referral network showing the linkage between ART sites and HIV viral load testing sites. **A** showed number of referring facilities, **B** number of HIV viral load testing facilities

identify women at risk of treatment failure and infants at a higher risk of perinatal transmission. If the viral load is greater than 1000 copies/mL, the treatment monitoring algorithm (Fig. 1) should be followed, and enhanced postnatal prophylaxis should be provided to the infant. Additionally, if available, consider conducting infant nucleic acid testing at birth [9]. In addition, for pregnant women who were already receiving ART before conception, it is recommended to conduct a viral load test at the first antenatal care visit or when they first present. This helps identify women at an increased risk of in-utero transmission. For pregnant women who start ART during pregnancy, conduct a viral load test three months after ART initiation to ensure rapid viral suppression.

The available data strongly indicates that when a mother with HIV adheres to antiretroviral therapy and maintains a suppressed viral load ($\leq$1000 copies/mL) throughout pregnancy, childbirth, and breastfeeding, the likelihood of transmitting the virus to her child can drop to less than 1% [6–8]. Furthermore, if the mother's viral load is undetectable before and during pregnancy and delivery due to antiretroviral therapy, there is no risk of transmitting HIV to the infant during pregnancy. On the contrary, the risk of vertical transmission increases significantly when the mother's viral load is not suppressed [10]. WHO guidance indicates that a pregnant mother living with HIV whose viral load is suppressed within four weeks of delivery is at low risk of transmitting HIV to their infant and recommends breastfeeding for women taking antiretroviral therapy [11].

Ethiopia is striving to eliminate mother-to-child transmission of HIV by 2025, with a key target of achieving a 98% viral suppression rate among expectant mothers living with HIV by that year [12]. The rationale of the of the study, maintaining HIV viral load suppression immediately before delivery is one of the prevention strategy for mather to child transmission of HIV. However, the information on the suppression status of pregnant mother is primarily limited at facility and regional levels. Therefore, the study aims to determine the national-level HIV viral suppression status among pregnant women and identify the factors contributing to unsuppressed viral load.

Methods

Study design, setting and population

A cross-sectional study design was employed, utilizing secondary data from the national HIV Viral load repository from July 2022 to June 2023. Of the 2856 health facilities providing PMTCT services in the country as of 2023, data from all facilities with PMTCT sites that met the inclusion criteria were included in this study. These facilities provide counseling services, initiation of treatment, and monitoring HIV viral load per the national guideline. In addition, they collect blood samples and refer the samples to the nearest HIV Viral load testing site for regular HIV treatment monitoring (Fig. 1).

In the 2023, there are more than 26 functional HIV Viral load testing sites that they collect specimen from their nearby facilities, analyze them, and return the results to the refereeing facilities. Relevant client information was entered into a data base regularly which is directly synchronized with the national server at Ethiopian Public Health Institute (EPHI). The source population for this study includes all pregnant women living with HIV/AIDS receiving HAART in Ethiopia. However, the study population are all pregnant women living with HIV/AIDS who have started HAART and undergone for HIV viral load testing during the study period.

Inclusion and exclusion criteria

Inclusion criteria All pregnant women living with HIV/AIDS who had been on HAART for a minimum of three months and underwent HIV viral load testing before delivery during the study period.

Exclusion criteria Pregnant women who have been on HAART for less than three months, those with incomplete demographic or clinical information, and those whose viral load results have not been recorded in the system were excluded from the study.

Study procedures

A census or a complete enumeration approach was used to include all women who had been tested for HIV viral load prior labour during the study period. A data extraction tool was developed based on the key indicators monitored by Ministry of Health (MOH) utilizing both paper-based and/or electronic medical records and viral load testing records. The tool was used to gather the most recent secondary (retrospective) data on the outcome variable (viral suppression) and independent factors including age, sex, treatment regimen type, and adherence status. Similarly, the recent HIV viral load result before delivery within the study period was filtered and exported into the Excel format and then encoded into STATA V.17 for further analysis. One data collector was recruited based on the experience of managing the national databases. Orientation was given to the data collector regarding the objective of the study, ethical issues, data extraction procedure and quality of data. The investigator continuously checked the quality of the data throughout the data abstraction period.

Statistical analysis

The data was extracted from a national database and then coded and analyzed using the STATA version 17.0.

Table 1 Clinical characteristics of pregnant women living with HIV, 2023

Variable	Category	Frequency	Percent (%)
ART Regimen	First Line	7468	96.19
	Second Line	171	2.20
	Third Line	125	1.61
Timing of VL testing	1st tested after 3 months during ANC visit*	2550	33.14
	2nd VL at 6 Month**	1352	17.41
	At 34–36 weeks ofgestation***	3839	49.45
	At the first ANC visit****	23	0.30
Adherence	Good	7504	96.65
	Poor	260	3.35

*Those pregnant women tested for HIV and know their results and initiated ART tested for HIV viral load after three months of initiating the ART

**HIV viral load test performed after six month of ART initiation during their ANC follow up. This is for pregnant women knew their HIV status during their ANC follow up and started ART

***Pregnant women knew their HIV status and started ART before ANC follow up. Therefore, during at 34–36 weeks of gestation, HIV viral load should be tested

****Pregnant women knew their HIV status and started ART before ANC follow up. Therefore, during their first ANC visit, HIV viral load should be tested

Descriptive statistics were analyzed to summarize the data. The chi-square test was employed to evaluate the association between the outcome variable and predictors. A mixed model for logistic regression was used. The odds ratio was calculated to quantify the strength of the associations. Variables that show a significant association with the outcome ($p < 0.02$ were selected for further analysis using multiple logistic regression models.

Results

Socio-demographic characteristics of study participants

A total of 7764 pregnant women who initiated HAART and were tested for viral load just before giving birth were included in this study. The median age of the participants was 35 years old, with interquantile range of 28 to 40. Among them, 52.2% (4056) were in the 30-40age group, followed by 25.9% in the 19–29 age group. The majority of viral load tests (72%) were conducted at five HIV VL testing laboratories in Addis Ababa, while Oromia accounted for 1324 tests (17%). A total of 93.3% of the viral load tests were performed using the Abbott m2000sp/m2000rt platform, known for its accuracy and reliability in detecting viral RNA, while the remaining 6.7% used the Roche COBAS® AmpliPrep/COBAS® TaqMan® (CAP/CTM) platform, which offers comparable sensitivity and specificity. Both platforms are widely used in clinical laboratories to ensure high-quality, reproducible results. Additionally, 99.8% of the specimens tested were plasma samples, the gold standard for viral load testing due to their superior sensitivity and reliability in detecting viral RNA, further enhancing the accuracy and consistency of the testing process.

Clinical characteristics of study participants

Among participants, 96.2% (7793 out of 7764) were treated with first-line ART regimen followed by 2.2% with the second line regimen and 1.63 with the third line regimen. Nearly half (49.4%) of all pregnant women were tested for viral load at 34–36 weeks of Gestation. Among those who were aware of their HIV status and initiated ART during their Antenatal care (ANC) follow-up, 2573 women (33.1%) were tested only once during the first ANC (after 3 months of ART initiation) during their ANC followup. Additionally, 1352 women (17.4%) pregnant women were tested for the second viral load after 6 months of ART initiation. Only 23 (0.3%) pregnant mothers, who had already started ART before conception, were tested for viral load during their first ANC visit till delivery. Overall, the majority of the study participants demonstrated good adherence to treatment, with 7259 women (97%) achieving this outcome.

Viral load suppression status

The study revealed shows that the rate of HIV viral suppression (defined as ≤ 1000 RNA copies/ml) among pregnant women was 96.8% with 95% CI 96.8–97.1%. This

Table 2 HIV Viral Load Suppression Status and Viral Quantity among Pregnant Women, 2023

Variable	Category	Frequency	Percent
Viral level	Undetectable	7247	96.5
	Suppressed Viral Load (< = 1000copies/ml)	7513	96.8
	Unsuppressed (> 1000 copies/ml)	251	3.23

indicates that only 3.2% of the participants had an unsuppressed (>1000 RNA copies/ml) HIV viral load result. Among those with suppressed viral load, 7247 participants (96.5%) had undetectable level of HIV RNA in their blood, which is below the detection limit of the testing instruments (Tables 1, 2).

The rates of viral suppression varied significantly by age group ($p=0.001$)., with rates of 93.9% for those aged 14–18 years, 95.7% for 19–29 years, 97.4% for 30–40 years, and 96.7% for those over 40 year. Additionally, the viral suppression rates varied significantly by treatment regimen ($p=0.016$). Among the 7468 pregnant women on first-line treatment, 7234 (96.9%) achieved viral suppression. Similarly, 93% of those on second-line treatment and 96% of those on third-line treatment also achieved viral suppression (Table 3).

Factors associated with unsuppressed HIV viral load

Binary logistic regression revealed statistically significant associations between maternal HIV unsuppressed status and factors such as age group, adherence, time of testing, and ART regimen ($p<0.02$) (Table 3).

The multiple binary logistic regression demonstrated that the odds of having an unsuppressed HIV viral load was 3.17 times (AOR 3.17, 95% CI 1.17–5.17, $p=0.002$) higher for individuals who belong to the age group of 19–29 years compared to those less than 19 years. In addition, the odds of developing unsuppressed viral load is 12.6 times higher in those having poor adherence AOR 12.64, 95%CI (10.74–14.54), $p=0.001$.

The odds of **viral unsuppression** for women on second-line treatment are approximately **0.014 times** the odds of viral unsuppression for women on first-line treatment AOR 0.014 (95% CI 0.003–0.071, $p=0.001$.

However, time for testing and ART regimen did not have a significant association with unsuppressed maternal HIV viral load (Table 3).

Discussions

The study revealed that a significant proportion of pregnant women undergoing antiretroviral therapy (ART) achieved HIV viral suppression, with only a small percentage exhibiting unsuppressed viral loads. Among those with suppressed viral loads, the majority had undetectable HIV RNA levels, indicating effective viral control. The findings suggest that younger women and those with poor adherence to ART are at a higher risk of failing to achieve viral suppression. Additionally, transitioning to second-line ART notably improved viral suppression rates, reducing the number of unsuppressed viral loads by approximately fourfold. In contrast, the timing of viral load testing did not significantly influence the outcomes.

Table 3 Binary and multiple logistic regression of factors associated with a suppressed viral load (> 1000 copies/ml of HIV RNA in the blood)

Variable	Viral load		Unadjusted OR	*P*-value	Adjusted OR	*P*-value
	Unsuppressed	Suppressed	(95% CI)		(95% CI)	
Age Group						
14–18	16	247	1		1	
19–29	87	1925	0.70 (0.40–1.21)	0.199	3.17 (1.17–5.17)	0.002**
30–40	101	3955	0.40 (0.23–0.94)	0.001*	1.99 (0.26–3.72)	0.025
>40	47	1386	0.52 (0.29–0.94)	0.030	3.12 (0.93–5.33)	0.005
ART Regimen						
First Line	234	7234	1		1	
Second Line	12	159	2.33 (1.28–4.26)	0.006*	0.014 (95% CI 0.003–0.071	0.001***
Third Line	5	120	1.29 (0.52–3.18)	0.583	2.43 (0.15–4.70)	0.037
Timing for testing						
1st test at ANC (only once during the first ANC)	74	2499	0.75 (0.57–1.00)	0.052	1.75 (0.20–3.30)	0.027
2nd VL at 6 Month	32	1320	0.62 (0.42–0.91)	0.015*	1.08 (– 0.65–2.82)	0.222
Until 34th–36th weeks of gestation	145	2694	1		1	
Adherence						
Good	5	7499	1		1	
Poor	246	14	10.18 (9.15–11.21)	0.000***	12.64 (10.74–14.54)	0.001***

***Shows *p*-value < 0.02 (Clinical Significance)

In this study, 96.8% (95% CI 96.6–97.1%) of pregnant women achieved overall HIV suppression, with their viral load falling below 1000 copies/mL. Specifically, 96.5% had undetectable HIV levels. Achieving undetectable viral load is crucial because individuals living with HIV who maintain suppressed levels do not transmit the virus to their sexual partners and have a minimal risk of vertical transmission to their children [11]. Studies have shown that the risk of HIV transmission is negligible when a person's viral load is below 1000 copies/mL [13].

Comparable findings were reported in similar studies, including a retrospective cross-sectional study in Zimbabwe, which reported a viral suppression rate of 87.7%, with 73% of participants having undetectable viral levels [14] In Ethiopia, a study in the Amhara region reported a suppression rate of 90.9% [8], and another study in Uganda found that 91.9% of pregnant women had suppressed viral loads [15]. These studies employed similar methods and sample sizes, producing results consistent with the current study.

However, the findings of this study differ slightly from a study conducted in South Africa, which reported a suppression rate of 77.6% and undetectable viral levels in 63.6% of pregnant women at the time of delivery [16]. Another study from South Africa in 2017 found that only 56.2% of pregnant women in the 15–49 age group attending antenatal care were virally suppressed [17]. Similarly, a hospital-based study in Cameroon from 2019 to 2021 showed that 67.6% of pregnant women had undetectable viral loads [18].

These differences may stem from the smaller sample sizes and facility-based designs of those studies, whereas this study included a larger sample representing a broader geographic area.

The binary logistic regression analysis demonstrated that women aged 19–29 years had 3.17 times higher odds of having an unsuppressed viral load compared to women younger than 19 years. Furthermore, transitioning from first-line to second-line ART significantly reduced the odds of unsuppressed viral loads, with a fourfold decrease in risk. This finding is consistent with studies from South Africa, where younger age and first-line ART were associated with increased odds of viral load unsuppression [19]. However, some studies from South Africa found that younger age (14–19 years) was less likely to be associated with viral suppression compared to older age groups [20]. These discrepancies could be due to differences in the inclusion of younger women in those studies.

The study found no significant association between unsuppressed viral load and the timing of viral load (VL) testing before delivery during ANC follow-up. This may be due to several factors. Firstly, viral suppression is influenced by various factors such as adherence to antiretroviral therapy (ART), the duration of treatment prior to pregnancy, and baseline viral load, rather than the specific timing of VL testing during pregnancy. Consistent and high adherence to ART likely ensures viral suppression regardless of when the VL test is performed during ANC visits. Secondly, variations in the timing of VL testing may not significantly impact the results if most women were already virally suppressed at the time of ANC enrollment due to prior ART initiation.

The study also found that poor adherence to ART was a significant factor for viral unsuppression, with individuals showing 12.6 times higher odds of unsuppressed viral loads. This finding is consistent with other studies, including a research project in Ghana that identified adherence as a critical determinant of viral suppression [21]. Similarly, a retrospective study in Uganda found that poor adherence was associated with a 4.553 times higher odds of unsuppressed viral loads compared to individuals with good adherence [22]. Interestingly, no significant difference was observed in viral suppression outcomes based on the timing of viral load testing. Despite this, regular monitoring is essential throughout pregnancy to promptly detect unsuppressed viral loads. Among the pregnancies studied, 27.7% of women were not virally suppressed by the end of pregnancy, highlighting the ongoing challenges in achieving and maintaining viral suppression in this population [23]. This underscores the importance of targeted prenatal care and HIV management in pregnant women, including decisions regarding delivery methods and gestational timing [24].

This study is one of the first at the national level to assess HIV viral load status and associated factors for unsuppressed viral load in pregnant women. With a large sample size that includes both rural and urban populations, the findings are more generalizable to the Ethiopian context. However, there are limitations, such as the use of secondary data, which may include inconsistencies and gaps in information. Additionally, important predictor variables were not captured in the national databases, which may limit the depth of our analysis.

Conclusion

This study highlights key factors associated with viral unsuppression in pregnant women on ART, including age, adherence, and treatment regimen. It underscores the importance of enhancing adherence to ART, particularly in younger women, and ensuring timely access to second-line treatments. Further research is needed to explore additional factors and refine strategies to improve viral suppression and reduce the risk of HIV transmission to both sexual partners and children.

Abbreviations

ACIPH	Addis Continental Institute of Public Health
ANC	Antenatal Care
AIDS	Acquired Immune-Deficiency Syndrome
ART	Antiretroviral Therapy
EFY	Ethiopian Fiscal Year
EPHI	Ethiopian Public Health Institute
FMOH	Federal Ministry of Health
HAART	Highly Active Anti-Retroviral Therapy
HIV	Human Immuno-Deficiency Virus
PMTCT	Prevention of Mother to Child Transmission
PLHIV	People living with Human Immunodeficiency Viruses
RNA	Ribonucleic Acid
TND	Target Not Detected
VL	Viral Load
WHO	World Health Organization

Acknowledgements
The authors are grateful to Addis Continental Institute of Public Health, and Ethiopian Public Health Institute for their support, coordination and providing access to data. We also gratefully acknowledge the authors, the clients, PMTCT facilities, and HIV viral load testing sites.

Author contributions
GH: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, writing original draft, Writing review & editing. AK: Data curation, Formal analysis, Investigation, Methodology, Writing—review & editing. KZ, AT, NN. BA, FG, DM, SA, AA, JB, GT & MH: Formal analysis, Methodology, Writing—review & editing. KY: Conceptualization, Formal analysis, Methodology, Supervision, Writing review & editing.

Funding
The author(s) declare no financial support was received from anywhere.

Availability of data and materials
The data that support the fndings of this study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
Ethical clearance and approval were obtained from the Institutional Ethical Review Boards of Addis Continental Institute of Public Health Ref. No: ACIPH-MPH/022/16 and Ethiopian Public Health Institute with protocol number EPHI-IRB-543-2023.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Received: 4 November 2024 Accepted: 11 February 2025
Published online: 25 February 2025

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