

# High Rates of Viral Suppression in Pregnant Women Receiving Antiretroviral Therapy at Selected Government Health Facilities: A Retrospective Cohort Study

Zenebe Minda<sup>1\*</sup> and Lemessa Oljira<sup>2</sup>

<sup>1</sup>School of Public Health, Madda Walabu University, Ethiopia.

<sup>2</sup>School of Public Health, Haramaya University, Ethiopia.

## \*Correspondence:

Zenebe Minda, Madda Walabu University, Department of Public Health, P.O. Box 247, Robe, Ethiopia.

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## ABSTRACT

**Background:** The attainment of viral suppression (VS) has not only extended the life expectancy of HIV-infected pregnant women (HIPW) but also has significantly reduced the rate of HIV vertical transmission (VT). We to ascertain the rate of VS among HIPW at health facilities.

**Methods:** A retrospective cohort study was carried out from June 1, 2016, to May 31, 2024. Data were extracted via document review using a structured and pretested checklist.

**Results:** The overall VS rate was 392 (93.60%). Poor adherence to ART and a CD4 cell count of 350 or fewer were associated with a decreased likelihood of achieving VS. The odds of poor adherence to ART and a CD4 cell count of 350 or fewer were both 0.1 at 6 months after initiating ART (adjusted odds ratio [aOR] 0.1, 95% confidence interval [CI] 0.2-0.2) and (aOR 0.1, 95% CI 0.1-0.3), respectively. Employment increased the odds of VS in women by 4.1 times (aOR 4.1, 95% CI 1.1-14.9) at 6 months after ART initiation compared to being a housewife.

**Conclusion:** The VS rates observed in the study facilities are promising but remain significantly below the targets set for achieving epidemic control. Therefore, intensified efforts are crucial to attain the goal of HIV epidemic control.

## Keywords

Viral load, Suppression, HIV, Vertical Transmission, Pregnant Women.

## Abbreviations

VS: Viral suppressions, HIV: Human immunodeficiency virus, VT: Vertical transmission, HIPW: HIV-infected pregnant women, ART: Antiretroviral therapy, WHO: World Health Organization, OIs: Opportunistic infections, HFSUH: Hiwot Fana Specialized University Hospital, DCRH: Dil Chora Referral Hospital, MWU-GRH: Madda Walabu University Goba Referral Hospital.

## Background

Viral suppressions (VS) during pregnancy, labor, delivery, and breastfeeding via antiretroviral therapy (ART) is a crucial intervention that has significantly decreased vertical human immunodeficiency virus (HIV) transmission, contributing to the global effort to eliminate new HIV infections [1,2]. Achieving HIV viral suppression is vital not only for improving individual health but also for reducing the risk of vertical HIV transmission to below 5% in resource-limited settings [3-6]. Pregnant women infected with HIV who have a suppressed viral load can attain a 1–2% risk of vertical transmission. Nonetheless, there are instances where women with a suppressed viral load still transmit

the virus to their baby [7,8]. The successful eradication of HIV vertical transmission necessitates a multifaceted strategy. Given that vertical transmission of HIV largely hinges on the viral load, it entails the reduction of this load through the administration of maternal ART during pregnancy, labor, delivery, and throughout breastfeeding, following established guidelines and the World Health Organization's (WHO) B+ approach [9]. Several risk factors contribute to HIV perinatal transmission, with maternal viral load being a crucial one [10,11]. Pregnant women with HIV require regular viral load testing to measure the virus quantity in their blood, reported as virus copies per milliliter [12]. Elevated maternal viremia levels are linked to a higher risk of vertical HIV transmission [13]. Suboptimal suppression of viral load may result in an increased risk of vertical HIV transmission, including the transmission of resistant HIV strains [14,15]. Even with advancements in HIV treatment, a significant number of newborns are still at risk of acquiring HIV, making its elimination a challenging and urgent national health concern [16-18]. Despite the importance of ART in managing HIV, there is limited knowledge about the extent of viral suppression in women on ART during pregnancy, childbirth, and breastfeeding. These factors are crucial in preventing mother-to-child transmission of HIV. No prior studies have addressed this issue in the study settings. Consequently, this study focuses on evaluating the viral load suppression in HIV-positive pregnant women at selected governmental health facilities.

## Methods

### Study Setting

The research was carried out in 3 selected government hospitals of the Ethiopian where VT was prevalent- specifically in Hiwot Fana Specialized University Hospital (HFSUH), Dil Chora Referral Hospital (DCRH), and Madda Walabu University Goba Referral Hospital (MWU-GRH), located at a distance of 525, 515 and 450 Km away from Addis Ababa, the capital city of Ethiopia respectively. These hospitals are situated in the East and South East of the country, serves for more than 5.2, 3 and 2 million people, respectively.

### Study Design and Period

A retrospective cohort study was conducted in a facility from June 1, 2016, to May 31, 2024.

### Source and Study Population

The source population comprised all HIV-positive pregnant women under follow-up at the ART clinics of 3 purposively selected hospitals, while the study population included those who had at least one viral load test result six months after initiating ART during the study period.

### Sample Size Determination and Sampling Technique

The sample size was calculated using the single proportion formula.

$$N = (Z_{\alpha/2})^2 P(1-p) / d^2$$

Where, N= sample size,  $Z_{\alpha/2}$  = confidence interval (CI) level at 95% (CI = 1.96); P= the proportion of viral suppression among HIV-

infected pregnant women based on a previous study conducted 90.9% [19] and d= precision (margin of error) =0.03.

The sample size was calculated as follows:

$$N = (1.96)^2 \cdot 0.91(0.09) / (0.03)^2 = 349.$$

The minimum calculated sample size was 349. After adding 20% of the non-respondents the sample size was calculated as follows:

$$20/100 \times 349 = 70$$

$$70 + 349 = 419$$

Consequently, the study required a sample size of 419 HIV-infected pregnant women to assess the level of viral suppression. This total sample size (n=419) was distributed proportionally across six health facilities. In hospitals, all eligible records were sequentially selected until the necessary sample size was reached. If a record was missing information or was incomplete, it was replaced with the next available record until the required sample size was achieved.

### Data Collection Procedure

Various literatures were consulted to develop a tool for measuring viral suppression. This tool was subsequently structured, pretested, and utilized to assess HIV-infected pregnant women undergoing ART follow-up via document review.

### Data Processing and Analysis

The Excel data were verified for consistency and completeness before being exported to SPSS version 20 for analysis. Frequency distributions described the study participants, and a chi-square test compared the viral suppression rates across different participant categories. Associations between viral suppression and independent variables (age, residence, marital status, occupation, ART initiation time, CD4 count, WHO clinical stage, opportunistic infections, and adherence) were assessed using the backward likelihood ratio method in multivariable logistic regression. Significant associations between the dependent and independent variables were determined using the adjusted odds ratio (AOR) with a 95% confidence interval. A p-value of less than 0.05 was considered indicative of a significant association. The final results were presented in tables, figures, and narrative descriptions.

### Data Quality Assurance

Data quality was assured at all stages of the data collection process. Prior to data collection, experts verified the tool's validity. Data collectors received training to ensure a uniform understanding, as directed by the investigator. Throughout the data collection, collectors were reminded of the study's purpose and significance to encourage the gathering of high-quality data. Intensive supervision was maintained during this period. The investigator reviewed the data daily for completeness and consistency, taking appropriate corrective measures when needed.

### Operational Definitions

Suppressed viral load is defined as an HIV plasma viral load of less than 1000 copies/ml based on a single viral load measurement [20,21].

Results

Baseline Sociodemographic Characteristics of the participants

A review of 419 medical charts of HIV-infected pregnant women in ART follow-up clinics was conducted from June 1, 2016, to May 31, 2024. The participants' mean age was 28.70 ± 5.64 years. A significant number of participants were married (350, 83.50%) and had started ART before their current pregnancy (351, 83.80%), with 252 (60.10%) being housewives by occupation (Table 1).

Table 1: Baseline Sociodemographic Characteristics of Study Participants.

| Variable                 | Frequency (n) | Percent (%) |
|--------------------------|---------------|-------------|
| Maternal age (years)     |               |             |
| 15-24                    | 89            | 21.2        |
| 25-34                    | 270           | 64.4        |
| ≥35                      | 60            | 14.3        |
| Marital status           |               |             |
| Married                  | 350           | 83.5        |
| Single                   | 21            | 5.0         |
| Divorced                 | 36            | 8.6         |
| Widowed                  | 12            | 2.9         |
| Occupation               |               |             |
| Housewife                | 252           | 60.1        |
| Employee                 | 47            | 11.2        |
| Merchant                 | 74            | 17.7        |
| Daily labourer           | 46            | 11.0        |
| When did ART started?    |               |             |
| Befor current pregnancy  | 351           | 83.8        |
| During current pregnancy | 68            | 16.2        |

Clinical Characteristics of HIV-Infected Pregnant Women

The majority of the women had a baseline CD4 cell count greater than 350 (329, 78.50%). In terms of WHO clinical stages, 398 (95.00%) of the participants were classified as stage I, and a significant number did not have any opportunistic infections (376, 89.70%) at the start. With respect to ART, 383 (91.40%) showed good adherence to their initial ART regimen by the end of the follow-up period (refer to Table 2).

Table 2: Clinical Characteristics of Study Participants.

| Variable                       | Frequency (n) | Percent (%) |
|--------------------------------|---------------|-------------|
| Baseline CD4 count (cells/mm3) |               |             |
| >350                           | 329           | 78.5        |
| ≤350                           | 90            | 21.5        |
| Baseline WHO clinical stage    |               |             |
| Stage I                        | 398           | 95.0        |
| Stage ≥II                      | 21            | 5.0         |
| Opportunistic infection        |               |             |
| No                             | 376           | 89.7        |
| Yes                            | 43            | 10.2        |
| Adherence to ARV drug          |               |             |
| Good                           | 383           | 91.4        |
| Poor                           | 36            | 8.6         |

HIV Viral Suppression Status of the Participants

By the end of the follow-up period, the majority of participants, 392 (93.60%), had achieved viral suppression. Among those who

achieved viral suppression, women with a baseline CD4 count greater than 350 cells/mm<sup>3</sup> had a significantly higher suppression rate compared to those with a CD4 count less than 350 cells/mm<sup>3</sup> (97.26% vs 80.00%, respectively;  $\chi^2 = 34.939$ ,  $P < .001$ ). Additionally, there was a notable difference in suppression rates between pregnant women with good adherence to ART and those with poor adherence (96.34% vs 63.89%, respectively;  $\chi^2 = 57.498$ ,  $P < .001$ ) as shown in Table 3.

Table 3: Viral Suppression Rate Difference Between Different Categories of Study Participants.

| Variables                                   | Suppressed (%) | UnSuppressed (%) | Suppression Rate (%) | P value  |
|---------------------------------------------|----------------|------------------|----------------------|----------|
| Maternal age (years)                        |                |                  |                      |          |
| 15-24                                       | 82 (20.90)     | 7 (25.90)        | 92.13                | .809     |
| 25-34                                       | 254 (64.90)    | 16 (59.30)       | 94.07                |          |
| ≥35                                         | 56 (14.20)     | 4 (18.80)        | 93.33                |          |
| Marital status                              |                |                  |                      |          |
| Married                                     | 327 (83.50)    | 23 (85.20)       | 93.43                | .393     |
| Single                                      | 20 (5.10)      | 1 (3.70)         | 95.24                |          |
| Divorced                                    | 35 (8.90)      | 1 (3.70)         | 97.22                |          |
| Widowed                                     | 10 (2.50)      | 2 (7.40)         | 83.33                |          |
| Occupation                                  |                |                  |                      |          |
| Housewife                                   | 237 (60.30)    | 15 (55.60)       | 94.05                | .202     |
| Employee                                    | 41 (10.40)     | 6 (22.20)        | 87.23                |          |
| Merchant                                    | 69 (17.80)     | 5 (18.50)        | 93.24                |          |
| Daily labourer                              | 45 (11.50)     | 1 (3.70)         | 97.83                |          |
| When did ART started?                       |                |                  |                      |          |
| Befor current pregnancy                     | 330 (84.00)    | 21 (77.80)       | 94.02                | .383     |
| During current pregnancy                    | 62 (16.00)     | 6 (22.20)        | 91.18                |          |
| Baseline CD4 count (cells/mm <sup>3</sup> ) |                |                  |                      |          |
| >350                                        | 320 (81.70)    | 9 (33.30)        | 97.26                | .000*    |
| ≤350                                        | 72 (18.30)     | 18 (66.70)       | 80.00                | (34.939) |
| Baseline WHO clinical stage                 |                |                  |                      |          |
| Stage I                                     | 374 (95.40)    | 24 (88.90)       | 93.97                | .133     |
| Stage >II                                   | 18 (4.60)      | 3 (11.10)        | 85.71                |          |
| Opportunistic infection                     |                |                  |                      |          |
| No                                          | 354 (90.30)    | 22 (81.50)       | 94.15                | .144     |
| Yes                                         | 38 (9.70)      | 5 (18.50)        | 88.37                |          |
| Adherence to ARV drug                       |                |                  |                      |          |
| Good                                        | 369 (94.10)    | 14 (51.90)       | 96.34                | .000*    |
| Poor                                        | 23 (5.90)      | 13 (48.10)       | 63.89                | (57.498) |

\*Statically significant (P < .05).

Factors Associated with Viral Suppression

From logistic regression, both bivariate and multivariable analyses showed that adherence to ART, CD4 count, and occupation were statistically significant factors associated with viral suppression (VS) at 6 months post-ART initiation (Table 4). Poor adherence to ART and a CD4 cell count of 350 or fewer were linked with a lower likelihood of achieving VS compared to their counterparts in the multivariate analysis. The odds of poor adherence to ART and a CD4 cell count of 350 or fewer were both 0.1 at 6 months post-ART initiation (aOR 0.1, 95% CI 0.2-0.2) and (aOR 0.1,

95% CI 0.1-0.3), respectively. Being employed increased the odds of VS in women by 4.1 times (aOR 4.1, 95% CI 1.1-14.9) at 6 months post-ART initiation compared to being a housewife.

**Table 4:** Bivariable and Multivariable analysis of the Factors Associated with Viral Suppression 6 Weeks After Start of ART.

| Variables                                        | Bivariate analysis |          |         | Multivariable analysis |                  |         |
|--------------------------------------------------|--------------------|----------|---------|------------------------|------------------|---------|
|                                                  | cOR                | 95% CI   | P-value | aOR                    | 95% CI           | P-value |
| <b>Maternal age (years)</b>                      |                    |          |         |                        |                  |         |
| 15-24                                            | 1.2                | 0.3–4.3  | 0.8     | 2.0                    | 0.4–9.5          | 0.4     |
| 25-34                                            | 0.9                | 0.3–2.7  | 0.8     | 0.7                    | 0.2–2.6          | 0.6     |
| ≥35                                              | Ref                |          |         |                        |                  |         |
| <b>Marital status</b>                            |                    |          |         |                        |                  |         |
| Married                                          | Ref                |          |         |                        |                  |         |
| Single                                           | 0.7                | 0.1–5.5  | 0.7     | 0.3                    | 0.3–3.1          | 0.3     |
| Divorced                                         | 0.4                | 0.1–3.1  | 0.4     | 0.3                    | 0.1–7.6          | 0.5     |
| Widowed                                          | 2.8                | 0.6–13.8 | 0.2     | 0.7                    | 0.2–3.4          | 0.2     |
| <b>Occupation</b>                                |                    |          |         |                        |                  |         |
| Housewife                                        | Ref                |          |         |                        |                  |         |
| Employee                                         | 2.3                | 0.8–6.3  | 0.1     | 4.1                    | 1.1–14.9         | 0.03*   |
| Merchant                                         | 1.1                | 0.4–3.3  | 0.8     | 1.3                    | 0.3–4.8          | 0.7     |
| Daily labourer                                   | 0.4                | 0.1–2.7  | 0.3     | 0.3                    | 0.3–3.3          | 0.3     |
| <b>ART started</b>                               |                    |          |         |                        |                  |         |
| Before pregnancy                                 | Ref                |          |         |                        |                  |         |
| During pregnancy                                 | 0.7                | 0.3–1.7  | 0.4     | 0.9                    | 0.3–3.0          | 0.8     |
| <b>Baseline CD4 count (cells/mm<sup>3</sup>)</b> |                    |          |         |                        |                  |         |
| >350                                             | Ref                |          |         |                        |                  |         |
| ≤350                                             | 0.1                | 0.1–0.3  | 0.000*  | 0.1                    | 0.1–0.3          | 0.000*  |
| <b>Baseline WHO clinical stage</b>               |                    |          |         |                        |                  |         |
| Stage I                                          | Ref                |          |         |                        |                  |         |
| Stage ≥II                                        | 0.4                | 0.1–1.4  | 0.2     | 0.3                    | 0.1–1.4          | 0.1     |
| <b>Opportunistic infection</b>                   |                    |          |         |                        |                  |         |
| No                                               | Ref                |          |         |                        |                  |         |
| Yes                                              | 0.5                | 0.2–1.3  | 0.2     | 2.2                    | 0.6–8.2          | 0.2     |
| <b>Adherence to ARV drug</b>                     |                    |          |         |                        |                  |         |
| Good                                             | Ref                |          |         |                        |                  |         |
| Poor                                             | 0.1                | 0.0–0.2  | 0.000*  | 0.1                    | 0.02–0.2<br>.000 | 0.000*  |

Key: cOR: Crude Odds Ratio, aOR: Adjusted Odds Ratio, Ref: Reference category.

## Discussion

Viral suppression among HIV-infected pregnant women varies by location due to various factors, and the current study evaluated this in selected facilities. According to the study, 392 women (93.6%) achieved viral suppression at least six months after initiating ART. This suppression rate aligns with studies from North West Ethiopia, Kenya, and Malawi, which reported rates of 92.4%, 93%, and 90.1%, respectively [18,22,23]. However, it exceeds the rates found in studies from Cambodia and the Democratic Republic of Congo, which were 76% and 67%, respectively [24,25]. The elevated results in the current study may be attributed to a combination of HIV prevention interventions, such as testing and treatment, pre-exposure prophylaxis, screening, and management of opportunistic infections, along with the provision of ART in the study areas. These measures have likely contributed to a relatively

high rate of viral suppression among pregnant women, enabling improved follow-up during pregnancy for targeted prevention of viral transmission to fetuses. Additionally, the higher results could stem from a better understanding among women of the significance of viral suppression. Conversely, the viral load suppression rate in this study is marginally lower than the 98% reported by the federal HIV/AIDS prevention and control office [26]. This discrepancy may stem from inadequate reporting across various health facilities and the effectiveness of implemented interventions. Additionally, it may be associated with the lower CD4 counts in women and their suboptimal adherence to ART, impacting their comprehension of viral load suppression's significance. Many participants in this study exhibited low CD4 counts and poor adherence to ART.

The study's findings suggest a correlation between CD4 count and viral suppression. Women with a CD4 cell count greater than 350 were more likely to attain viral suppression compared to those with 350 or fewer CD4 cells. This enhanced suppression may be attributed to increased CD4 cell count due to ART, the women's perception of their improving health, and the conviction that greater suppression would lead to further improvement.

Research in Malawi has shown that poor adherence to ART is linked to low rates of viral suppression and adversely affects the vertical transmission of HIV [27]. Consequently, additional efforts are necessary in the study area to attain the desired viral load suppression in women receiving PMTCT care, which is crucial for preventing new pediatric HIV infections. Hence, health facilities, including hospitals and health centers, should prioritize identifying women with suboptimal adherence to ART to achieve viral suppression and ultimately eradicate HIV infection.

Being employed increased the odds of viral load suppression in pregnant women on ART in Ethiopia.

Various studies have shown that employment is significantly associated with higher rates of viral suppression [18]. This may be because employment offers better access to healthcare resources, enhances adherence to treatment, and leads to improved health outcomes. Such benefits are vital for reducing the risk of mother-to-child transmission of HIV, thereby improving the health of both mother and child. Consequently, this underscores the importance of providing support to housewives.

## Limitation of the Study

This study boasts several strengths and also presents certain limitations. To our knowledge, it is the first in this field to investigate the rate of viral load suppression. A robust analytical method was employed to determine the factors associated with it. However, a limitation was that not all the intended participants were included due to incomplete data, particularly concerning viral load suppression. The primary limitation was the inability to evaluate numerous risk factors that affect the viral load suppression rate, which are crucial for the overall rate in various studies. Additionally, the study's participants were recruited from public health facilities, potentially limiting the applicability of the

results to women who attend private facilities.

## Conclusion

This study highlights the high VS rate among HIV-infected pregnant women, emphasizing the critical role of adherence to ART and CD4 cell count in achieving successful treatment outcomes. Poor ART adherence and a CD4 count of  $\leq 350$  were significantly associated with lower odds of VS at six months post-ART initiation. Conversely, employment status positively influenced VS, with employed women having significantly higher odds of achieving VS compared to housewives. These findings underscore the need for targeted interventions to enhance ART adherence and support vulnerable groups, ensuring improved virological outcomes in HIV-infected pregnant women.

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