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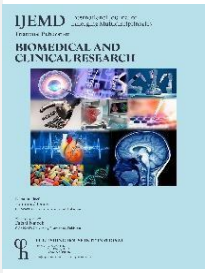

# The Impact of Antiretroviral Therapy on Birth Outcomes: A Retrospective Cohort Study

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## Abstract

**Objective:** This study aimed to evaluate the impact of highly active antiretroviral therapy (HAART) on pregnancy outcomes at a major tertiary hospital in Abuja, Nigeria.

**Design:** A cohort study was conducted.

**Methods**: HIV-infected pregnant women who initiated HAART during pregnancy for the prevention of mother-to-child transmission (pMTCT) were recruited, alongside a randomly selected group of HIV-uninfected pregnant women.

**Results:** A total of 489 pregnant women participated, including 237 HIV-infected and 252 HIV-uninfected women. HAART initiation during pregnancy was significantly associated with higher mean birth weights ($p = 0.0007$). While there were 30 cases of low birth weight in the HIV-infected group compared to 21 in the HIV-uninfected group, HAART was not significantly associated with low birth weight (OR 1.59, $p = 0.1182$). There were 6 stillbirths in the HIV-infected group and 5 in the uninfected group, with no significant association between HIV status and stillbirth (OR 1.28, $p = 0.6836$). However, 29 preterm deliveries occurred in the HIV-infected group compared to 8 in the uninfected group, showing a strong association between HIV infection and preterm deliveries despite HAART initiation (OR 4.25, $p = 0.0002$).

**Conclusion:** HIV-infected women receiving HAART during pregnancy have a significantly reduced risk of low birth weight but face an increased risk of preterm delivery.

**Keywords:** HAART, pregnancy outcomes, birth weight, stillbirth, preterm delivery

# Introduction

Pregnancy in women living with HIV presents specific challenges, particularly in the context of antiretroviral therapy (ART), which has emerged as a cornerstone in the prevention of mother-to-child transmission (pMTCT) of HIV. The global health community is dedicated to eliminating new pediatric HIV infections and improving maternal and child health outcomes through ART. A significant portion of this effort is aligned with the United Nations Programme on HIV/AIDS (UNAIDS) 95-95-95 goals aimed at ending the HIV/AIDS pandemic by 2030 [1].

Despite the lack of an effective HIV vaccine, ART has been instrumental in reducing HIV transmission, including perinatal, blood transfusion, and sexual transmission [2,3]. ART's role in the prevention of mother-to-child transmission is substantial, reducing the risk of transmission by over 96% when taken consistently with good adherence [4]. This intervention targets the significant burden that HIV poses on pregnant women and their unborn children.

HIV infection during pregnancy is associated with adverse outcomes such as high rates of prematurity and low birth weight, increasing the global burden of HIV in children under the age of five. The effectiveness of maternal zidovudine (ZDV) monotherapy, introduced in 1994, demonstrated a significant reduction in vertical transmission rates—from 25.5% without ZDV to 8.3% with it [5]. This milestone spurred the advancement of pMTCT programs, HIV treatment, and awareness efforts.

Despite global progress in ART, there remains limited research on the impact of this therapy on birth weight and prematurity within the Nigerian context. Nigeria carries a substantial burden of HIV, and as Africa's most populous nation, it faces unique challenges in managing HIV during pregnancy, which are closely tied to cultural, socioeconomic, and healthcare system constraints [6].

Understanding the effects of highly active antiretroviral therapy (HAART) on birth outcomes is vital for healthcare providers and policymakers in shaping national guidelines and programs. Improving maternal and child health outcomes aligns with public health priorities and the Sustainable Development Goals (SDGs) focused on health and well-being [4.7]. Therefore, this study contributes to the ongoing discourse on pregnancy outcomes in Nigeria, where the burden of HIV is high.

## Study context

This research was conducted at the University of Abuja Teaching Hospital (UATH), Nigeria, focusing on HIV-infected women receiving HAART under the pMTCT program which was initially funded by the US government's President’s Emergency Plan for AIDS Relief (PEPFAR). We assessed pregnancy outcomes such as birth weight, preterm deliveries, and stillbirths, comparing them to historical data from the pre-HAART era to evaluate the effects of HAART on these outcomes.

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The HAART for pMTCT program at UATH was initiated in 2006, and this study's findings provide valuable insights into the interplay between HAART and maternal-child health in an HIV-prevalent setting. The outcomes of this research will guide evidence-based practices and policies to optimize care for HIV-infected pregnant women and their infants.

## Objectives

1. To assess the impact of HAART on pregnancy outcomes at the University of Abuja Teaching Hospital, Nigeria.

2. To compare pregnancy outcomes in HIV-infected women before and after the initiation of HAART.

3. To provide recommendations for policy based on the study findings.

## Methods

### Study Design

This historical cohort study assessed pregnancy outcomes using standard diagnostic criteria. HIV-positive pregnant women receiving HAART were compared with HIV-negative controls from the same clinic. And these were matched for Age, Parity and gestational age.

### Data Collection

Data were collected from delivery records at an antenatal clinic serving middle and lower socioeconomic classes. Women were offered voluntary HIV testing during antenatal booking. HIV-positive women who consented to pMTCT services were referred for baseline assessments. Those with low viral loads (<1000 copies/ml) at 36 weeks gestation were allowed spontaneous vaginal births, while those with high viral loads (>1000 copies/ml) were counseled for elective Caesarean sections. Exclusions: Women with confounding characteristics such as multiple gestation or chronic diseases were excluded from the study.

### Data Analysis

Data were entered into Excel, cross-checked for accuracy, and transferred to Stata 10 for analysis. Descriptive statistics were computed for both groups, and Kruskal-Wallis and T-tests were used for continuous variables. The Mantel-Haenszel chi-square test assessed

the impact of maternal HIV status on pregnancy outcomes at 0.05 or less level of statistical significance.

## Results

### Participants

The records of 237 HIV-infected and 252 HIV-uninfected pregnant women were analyzed. The mean maternal age of HIV-infected women was 28.20 years (95% CI, 27.70-28.71) compared to 28.32 years (95% CI, 27.74-28.90) for HIV-uninfected women, with no significant difference in maternal age (p=0.9017) or parity (p=0.4022).

Birth Weight

The mean birth weight for babies of HIV-infected women was 2.96 kg (95% CI, 2.88-3.04) compared to 3.14 kg (95% CI, 3.08-3.21) for HIV-uninfected women. There was a significant difference between the two groups (p=0.0007).

Low Birth Weight (LBWt)

The prevalence of LBWt among HIV-infected women was 12.66% (95% CI, 8.34-16.92) compared to 8.33% (95% CI, 4.90-11.77) among HIV-uninfected women, but this difference was not statistically significant (p=0.1183).

Preterm Deliveries

The incidence of preterm deliveries among HIV-infected women was 12.24% (95% CI, 8.03-16.44) compared to 3.18% (95% CI, 1.00-5.35) among HIV-uninfected women, and this difference was significant (p=0.0001).

Stillbirth Rate

The stillbirth rate among HIV-infected women was 2.53% (95% CI, 0.52-4.55) compared to 1.98% (95% CI, 0.25-3.71) among HIV-uninfected women, but the difference was not statistically significant (p=0.6840).

Odds Ratios

The odds of low birth weight were 1.59 times higher in HIV-infected women compared to uninfected women (p=0.1182). The odds of stillbirth were 1.28 times higher

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(p=0.6836), and the odds of preterm delivery were 4.25 times higher in HIV-infected women (p=0.0002).

**Table 1:** Descriptive Statistics of Maternal Characteristics by Maternal HIV Status

| **Variable** | HIV infected on HAART<br>**N= 237** | HIV uninfected<br>**N=252** |
|---|---|---|
| **Maternal age** | | |
| Mean | 8.20 (95% CI, 27.70 - 28.71) | 28.32 (95% CI, 27.74 - 28.89) |
| Median | 28 | 28 |
| Minimum | 19 | 18 |
| Maximum | 42 | 41 |
| Range | 23 | 23 |
| Skewness | 0.312539 | 0.383905 |
| **Parity** | | |
| Median | 1 | 1 |
| Minimum | 0 | 0 |
| Maximum | 4 | 4 |
| Range | 4 | 4 |
| Skewness | 0.357965 | 0.386121 |

**Table2:** Descriptive Statistics of Pregnancy Outcome by Maternal HIV Status

| **Variable** | HIV infected on HAART | HIV uninfected |
|---|---|---|

| | N= 237 | N=252 |
|---|---|---|
| **Birth weight(kg)** | | |
| Mean | 2.96 (95%CI, 2.88 ±3.04) | 3.14 (95%CI, 3.08 ± 3.21) |
| Median | 3.00 | 3.14 |
| Minimum | 0.95 | 1.00 |
| Maximum | 4.60 | 4.90 |
| Range | 3.65 | 3.90 |
| Skewness | -0.6253 | -0.4661 |
| **Low birth weight** | 30 | 21 |
| | 12.65% (95% CI, 8.34 ±16.92) | 8.33% (95% CI, 4.90 ±11.77) |
| **Preterm** | 29 | 8 |
| | 12.24% (95%CI, 8.03±16.44) | 3.17% (95%CI, 1.00-5.35) |
| **Still birth** | 6 | 5 |
| | 2.53% (95%CI, 0.52%± 4.55 | 1.98%(95% CI, 0.25-3.71) |

**Table 3:** Analytical Statistics of Maternal characteristics by Maternal HIV Status

| **Variable** | HIV infected on HAART | HIV uninfected N= 252 | Difference | 95% CI interval | P-Value |
|---|---|---|---|---|---|
| **Mat. Age** | | | | | |

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| | | | | | |
|---|---|---|---|---|---|
| **(years)** | | | | | |
| Mean | 28.20 | 28.32 | 0.12 | -0.65-0.88 | P=0.7690 |
| **Parity** | | | | | |
| Mean | 1.62 | 1.52 | -0.10 | -0.34-0.14 | P=0.4099 |

**Table 4:** Analytical Statistics of Pregnancy Outcome by Maternal HIV Status

| **Variable** | HIV infected on HAART N=237 | HIV uninfected N= 252 | Difference | 95% CI interval | P-Value |
|---|---|---|---|---|---|
| Birth wt.(kg) | | | | | |
| Mean | 2.96 | 3.14 | 0.18 | 0.08-0.28 | ****0.0007**** |
| Low birth wt.(kg) | 12.66% | 8.33% | -4.33% | -9.80%-1.11% | 0.1183 |
| Preterm | 12.24% | 3.17% | -9.06% | -13.70%-4.42% | ****0.0001**** |
| Still birth | 2.53% | 1.98% | -0.55% | -3.19%-2.09% | 0.06840 |

**Table5:** Measures of Effect of Maternal HIV Status on Pregnancy Outcome

| **Variable** | HIV infected on | HIV uninfected | Odd Ratio | 95% CI interval | P-Value |
|---|---|---|---|---|---|

| | HAART N=237 | N= 252 | | | |
|---|---|---|---|---|---|
| Birth Weight | | | | | |
| Low | 30 | 21 | 1.59 | 0.88-2.88 | 0.1182 |
| Normal | 207 | 231 | | | |
| **Birth type** | | | | | |
| Still births | 6 | 5 | 1.28 | 0.38-4.27 | 0.6836 |
| Live births | 231 | 247 | | | |
| **Maturity** | | | | | |
| Preterm | 29 | 8 | 4.25 | 1.88-9.63 | **0.0002** |
| Term | 208 | 244 | | | |

## Discussion

This study analyzed records from 237 HIV-infected and 252 HIV-uninfected pregnant women, with findings comparable to other studies in sub-Saharan Africa (SSA), particularly Nigeria. Similar studies in Lagos, Malawi, and Ibadan also analyzed comparable cohorts, though sample sizes and inclusion criteria varied. The mean maternal age for HIV-infected women was 28.20 years (95% CI, 27.70-28.71) and 28.32 years (95% CI, 27.74-28.90) for HIV-uninfected women. There was no significant difference in mean maternal age (p=0.9017) or mean parity (p=0.4022). These results align with studies in Lagos and Enugu, which also found no significant differences between HIV-infected and uninfected women regarding maternal age and parity.

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However, a study in Ibadan found higher mean maternal age and parity among HIV-infected women, possibly due to socio-cultural factors [19, 23, 25].

The mean birth weight for babies of HIV-infected women was 2.96 kg (95% CI, 2.88-3.04) compared to 3.14 kg (95% CI, 3.08-3.21) for HIV-uninfected women, with a significant difference (p=0.0007). Similarly, research in Lagos reported lower mean birth weights for infants of HIV-infected women. This aligns with broader research suggesting maternal HIV infection, even with HAART, impacts fetal growth [19, 26].The possible reason could be that some antiretroviral drugs (e.g., protease inhibitors) have been associated with adverse pregnancy outcomes also, HIV-related anorexia, altered metabolism, and micro-nutrient deficiencies contribute to suboptimal fetal nutrition.

The incidence of low birth weight (LBWt) among HIV-infected women was 12.66% (95% CI, 8.34-16.92), compared to 8.33% (95% CI, 4.90-11.77) among HIV-uninfected women, though this difference was not statistically significant (p=0.1183). Other studies in Enugu and Kano also found higher incidences of LBWt among HIV-infected women, though the results were not always statistically significant [20, 23].

The incidence of preterm deliveries (PTD) was 12.24% (95% CI, 8.03-16.44) among HIV-infected women and 3.18% (95% CI, 1.00-5.35) among HIV-uninfected women, with a significant difference (p=0.0001). Studies from Southwestern China also reported higher preterm delivery rates among HIV-infected women, consistent with global research that HIV increases the risk of preterm birth [20]. This is because poor placental perfusion could contribute to preterm delivery.

The stillbirth (SB) rate was 2.53% (95% CI, 0.52-4.55) for HIV-infected women and 1.98% (95% CI, 0.25-3.71) for HIV-uninfected women, with no statistically significant difference (p=0.6840). Studies from Enugu and Kano found similar SB rates among HIV-infected women, mirroring our findings.

Regarding odds ratios, the incidence of low birth weight was 1.59 times higher in HIV-infected women than in uninfected women (p=0.1182). The odds of stillbirth were 1.28 times higher for HIV-infected women (p=0.6836), while the odds of preterm delivery were 4.25 times higher in this study. These findings align with studies from SSA, Malawi, Zambia, and Tanzania, which found higher risks of LBWt, SB, and PTD among HIV-infected women [21-23]. However, regional variations are likely due to differences in healthcare systems, PMTCT program effectiveness, and socio-cultural factors, as noted

in studies from Uganda [23]. The varied efficacy of different HAART regimens over time, as PMTCT programs have evolved, may also explain the differing birth outcomes seen in this study, as highlighted by .[25, 26]. Some of the possible reasons to support the finding is the fact that the timing of ART initiation during pregnancy matters. Early initiation is crucial for optimal fetal development. Different ART regimens may have varying effects on birth outcomes.

## Limitations of this study

This study was conducted at a single center, so the results cannot be generalized across SSA. The lack of CD4 count determination may have introduced a potential confounder. Moreover, using two different sampling techniques for subject recruitment may have introduced selection bias.

## Conclusion

Our study emphasizes the need for targeted interventions addressing the specific needs of HIV-infected pregnant women. While HAART remains crucial for managing HIV and preventing mother-to-child transmission, it is associated with adverse pregnancy outcomes such as lower birth weight and increased preterm deliveries. Continuous monitoring, early interventions, and tailored healthcare services are essential for improving maternal and infant outcomes.

## Recommendation

Further research through large, multi-center, prospective cohort studies across SSA is needed to generalize these findings. Investigating the negative impact of HAART on pregnancy outcomes versus its benefits in preventing mother-to-child transmission of HIV will inform future policy decisions.

## Competing Interests

All the authors declare no competing interests. When our work is published, the information provided in the submission system should be used as the source of truth.

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