

## HIV Mother-to-Child Transmission: Pregnancy Outcomes and Serological Status of Newborns of HIV-Positive Mothers Monitored in the Kati Hospital Cohort

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### ABSTRACT

**Objectives:** This study investigates the residual risk of mother-to-child transmission (MTCT) of HIV among women living with HIV who are on sustained antiretroviral therapy.

**Methodology:** This retrospective observational cohort study analysed the medical records of HIV-positive women receiving highly active antiretroviral therapy (HAART), who were followed between 2019 January 1 and December 31, at Kati University Hospital in the Koulikoro region of Mali.

**Results:** Among the 996 people living with HIV (PLHIV) included in the cohort, 480 were women (48.19%). Of these, 52 (10.8%) became pregnant, with 30 pregnancies occurring during the study period. 21 (70%) had an undetectable viral load and CD4 cell counts were below 350/mm<sup>3</sup> in 5 cases. By the end of pregnancy, 29 women delivered live new-borns, including 2 infants with low birth weight (2/29; 7%), 3 cases of prematurity and one neonatal death was recorded. After 2 years, 3 children (10.34%) were infected by HIV and one child had died. All children infected by HIV were from mothers with virological failure and had not received appropriate prophylaxis.

**Conclusion:** This study demonstrates that the goal of eliminating mother-to-child transmission of HIV was not achieved in this hospital.

### Keywords

HIV Mother-to-child transmission, Under ART, Kati.

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## Introduction

Even today, HIV remains a public health issue, particularly in countries with limited resources. According to UNAIDS, 38.4 million [33.9 million–43.8 million] people are estimated to be living with HIV in 2021. Of these, 36.7 million are adults (aged 15 and older) and 1.7 million are children (aged 0–14) [1].

Since the beginning of the epidemic, there has been a trend towards the feminisation of HIV. In fact, women and girls were more numerous, accounting for 54% of all people living with HIV in 2021. Of the approximately 1.5 million people newly infected with HIV in 2021, women and girls will account for 49% [1]. In addition, worldwide, AIDS remained the leading cause of mortality among women aged 15 to 44. Since the start of the epidemic, there has been a trend towards the feminisation of HIV. Indeed, women and girls were more numerous with 54% of all people living with HIV in 2021. Of the approximately 1.5 million people newly infected with HIV in 2021, women and girls will account for 49% [1]. In addition, worldwide, AIDS remained the leading cause of death among women aged 15 to 44 [1].

Apart from strict compliance with prevention measures in HIV-infected women, the risk of mother-to-child transmission (MTCT) remains high. In the absence of any intervention, the risk of MTCT *in utero* and during childbirth is 15–30%, and the risk is increased to 20–45% in breast-fed children. Without early detection and ARV treatment, half of all children infected with HIV at birth will not survive to their second birthday, and only 1 child in 5 will survive to the age of 5 [2].

In line with international commitments to end the HIV epidemic by 2030, and to meet the imperative of eliminating mother-to-child transmission of HIV, Mali launched a programme to prevent mother-to-child transmission of HIV (PMTCT) in 2001. The country subsequently drew up a PMTCT operational plan for 2018–2019, the overall objective of which was to reduce PMTCT to 8% by the end of 2030 [3].

Tangible progress has been made in the provision of services, with the number of PMTCT sites increasing from 1 in 2001 to 338 in 2011 and 1,211 in 2021 [4]. Despite these important achievements, there is still insufficient coverage of the national territory, making antenatal consultations and continuous monitoring of women and their children difficult.

In Mali, the mother-to-child HIV transmission rate was around 9.6% in 2015 compared with 4.7% in 2017 (PTME Survey Report 2017). Every year, around 1,600 new HIV infections in children (<15 years) are recorded in Mali (Joint mission report, 2018) [5].

Mali is seeking to eliminate mother-to-child transmission of HIV. Assuming that HIV transmission from mother to child in HIV-positive women on antiretroviral treatment and regularly monitored in a cohort is zero, we initiated this study. The general objective was to study the risk of MTCT of HIV. More specifically,

the aim was: i) to *determine the pregnancy outcome of women on HAART in the hospital cohort*, and ii) to *determine the rate of mother-to-child transmission of HIV at Kati Hospital*, iii) to *determine the factors associated with transmission of HIV from mother to child*.

## Patients and Methods

### Study design and area

Our study took place in the prefecture (cercle) of Kati, in the Koulikoro region. Kati is located to the north-east of Bamako, the capital of Mali. It has an estimated population of 254,765 in 2021. Recruitment took place in the HIV Care Unit of the Medical Department of the Kati Hospital, known as the Centre Hospitalier Universitaire (University Hospital Center) Professor Bocar Sidi Sall.

### Study Type and period

This was a retrospective observational cohort study including the records of 996 PLHIV followed up in the active file. The period indicated for pregnancies was between 1 January and 31 December 2019. This corresponded to the recruitment period for a doctoral thesis in medicine.

### Study population

The study population consisted of PLHIV followed up in the medical department cohort at Kati University Hospital. Due to the specific nature of the study, women's files were selected.

### Inclusion criteria

Women included were those who had been on antiretroviral treatment for at least 6 months and who had become pregnant during the survey period. In collaboration with the gynaecology-obstetrics and paediatrics teams, information on the course of pregnancy and childbirth and the outcome of the children was completed.

### HIV care

All women were receiving antiretroviral treatment. For HIV-1, the preferred first-line regimen was Tenofovir-disoproxil-fumarate (TDF)-lamivudine (3TC)-Efavirenz (EFZ). The second-line regimen was Zidovudine (ZDV)-3TC-Lopinavir/ritonavir (Lp/r). For HIV-2 and HIV-1+2, the preferred first-line regimen was: TDF+3TC+Lp/r. These treatment regimens were in effect in the country.

Newborns received antiretroviral prophylaxis and cotrimoxazole, depending on the feeding option. Breastfed newborns received Nevirapine (NVP) syrup at a dose of 2 mg/kg/day, starting immediately after delivery and continuing for six weeks. Newborns receiving formula were given AZT syrup at a dose of 2 mg/kg twice daily, starting immediately after delivery and continuing for six weeks. Adjustments were made for follow-up according to the child's weight.

## Data collect

A structured questionnaire has been elaborated. The sampling approach was exhaustive targeting all cases meeting our inclusion criteria listed above. Quality control of the data collected was carried out for each record in real time.

A database was created in Excel for data entry. Verifications were carried out on 100% of the entries. The analysis was performed using SPSS version 12.0.

## Variables studied

The variables of interest studied are sociodemographic data (age, residence, occupation, marital status, and level of education), obstetric data (gestational age, abortion, pregnancy outcome, and mode of delivery), immunological-virological data on the mother (recent viral load and CD4 count, HBV co-infection), therapeutic data (HAART for mother and child, treatment adherence in the mother), clinical (signs/symptoms during pregnancy) and data relating to newborns (outcome: alive or deceased, clinical parameters and seroconversion).

## Operational definitions of certain terms

*Pregnancy history:* This is the number of confirmed pregnancies.

*First-time mother:* a woman who became pregnant for the first time

*Low Pregnancy Parity:* a woman who was in her second or third pregnancy.

*Multi parity:* Refers to a pregnant woman who has had several pregnancies and is multiparous: who has given birth several times or who has given birth to more than one baby during the same delivery.

*Low birth weight:* Newborns weighing less than 2,500 grams are considered low weight (or small birth weight).

The viral load was considered undetectable when it was < 1000 copies/mm<sup>3</sup>.

## Ethical clearance

As part of this study, administrative authorisation was obtained. Verbal consent was also requested and obtained from all women. Confidentiality of information was guaranteed, with only staff directly involved in care being informed of the women's HIV status. All questionnaires were kept in a cabinet to which only the attending physician and the doctoral student in medicine had access.

## Results

### Global Results

A total of 996 PLHIV are currently registered at the Kati University Hospital (Figure 1), 480 of whom are female (48.2%). Among these women, 52 became pregnant while on antiretroviral triple therapy (10.8% of women), including 30 during the period of our study.

## Sociodemographic characteristics

The average age of the women was 30 ± 15, with a predominance of women aged 25–34 (53.34%). They were married (in 80% of cases) and resided in Kati for 86.7% of cases. The majority had attended school, with 20% having completed primary education, 46.66% secondary education, and 10% higher education. We note that most women (63.34%) were unemployed (housewives). Details are provided in Table 1.

**Table 1:** Sample Description.

Variables	Number	Percentage
<b>Age</b>		
Average age =30 years ± 15		
15-24 years	8	26,66%
25-34 years	16	53,34%
35 years et plus	6	20,0%
<b>Marital status</b>		
Married	24	80%
Single	6	20%
<b>Residence</b>		
Kati	26	86,7%
Out of Kati	4	13,3%
<b>Instruction</b>		
Primary	6	20%
Secondary	14	46,66%
Superior	3	10%
Not schooled	7	23,34%
<b>Occupation</b>		
Housewife	19	63,34%
Public service worker	7	23,33%
Retailer	4	13,33%

## Obstetrical Data

Most of women (60%) had few pregnancies (women in their second or third pregnancy), followed by women with multiple pregnancies (more than three pregnancies) with 30% of cases. More than 83.34% had at least one abortion. At the end of the follow-up period, 90% of pregnancies had reached full term and three women had given birth before the end of their pregnancy (prematurity). Vaginal delivery was the main mode of delivery (83.34%), but two women gave birth by caesarean section (Table 2).

**Table 2:** Description of women according to gynaecological and obstetric variables.

Variables	Number	Percentage
<b>Pregnancy status</b>		
First-time pregnancy	3	10%
Low pregnancy parity	18	60%
Multi pregnancy parity	9	30%
<b>Abortion history</b>		
Yes	25	83,34%
No	5	16,66%
<b>Pregnancy evolution</b>		
Full-term pregnancy	27	90%
Premature pregnancy	3	10%

<b>Delivery mode</b>		
Through the lower route	28	83,34%
By high route	2	6,66%

### Immunovirological and therapeutic variables

HIV-1 was the most prevalent serotype, accounting for 93% of cases (Figure 1).

An HIV viral load dating back less than 6 months was available for 28/30 women. It was undetectable (less than 1,000 copies/mm<sup>3</sup>) in 70% (21/30) and above the threshold of 1,000 copies/mm<sup>3</sup> in 7 women, or 23.33%. Although all women were on ART, the CD4 T-cell count was below 200 cells/mm<sup>3</sup> in two patients and between 200 and 399 CD4 T-cell in three women. Systematic screening for HBs antigen (HBsAg) revealed one case of HIV/HBV co-infection. All women were treated with ARVs, with 63.34% receiving first-line therapy 2 nucleoside reverse transcriptase inhibitors and 1 non-nucleoside reverse transcriptase inhibitor (2 NRTIs + 1 NNRTI). Treatment adherence was considered good in most cases (Table 3).

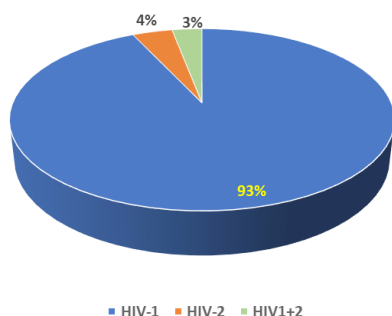


Figure 1: Breakdown by HIV serotype.

Table 3: Immunological, virological and therapeutic data.

<b>Immunological, virological and therapeutic characteristics</b>		<b>Number</b>	<b>Percentage</b>
<b>Viral load</b>	* Undetectable	21	70%
	≥ 1000 copies/mm <sup>3</sup>	7	23,33%
	Not done	2	6,67%
<b>Lymphocytes CD4 rate</b>	Not done	9	30%
	< 200/ mm <sup>3</sup>	2	6,67%
	200-399/ mm <sup>3</sup>	3	10%
<b>VHB co-porting</b>	≥ 400 /mm <sup>3</sup>	16	53,33%
	Yes	1	3,33%
	No	29	86,67%
<b>ARV Diagram</b>	2 INTI* + 1 INNTI*	19	63,34%
	2 INTI* + 1 *IP/r	11	36,66%
<b>Adherence to ART</b>	Good	26	86,66%
	Bad	4	13,34%

INTI\*: Nucleotide/nucleoside reverse transcriptase inhibitors + 1 INNTI\*: Non-nucleotide/nucleoside reverse transcriptase inhibitors; \*PI/r: Protease inhibitor/ritonavir.

### Signs/symptoms

Most symptoms have been recorded during the first trimester. Sympathetic disorders (nausea and vomiting), probably related to pregnancy, were the most common. Urinary tract infections were noted fairly frequently during all three trimesters (Table 4).

Table 4: Distribution according to symptoms related to the trimesters of pregnancy.

<b>Signs/symptoms</b>	<b>First quarter</b>	<b>Second quarter</b>	<b>Third quarter</b>
Fever	6	2	3
Oral candidiasis	11	9	12
Diarrhea	8	1	0
Urinary infection	19	11	15
Nausea	25	7	2
Vomiting	22	4	2
Headache	17	6	12
Vertigo	4	1	0
Oedema of the lower limbs	0	3	7

### Newborn data

About 29 women (96.67%) gave birth to live babies, and one case of stillbirth has been recorded. Newborns weighing less than 2,500 grams are considered low birth weight (or small for gestational age). This applied to two newborns in our series. In 66.96% (20/29) of cases, the newborns were breastfed, four mothers (13.79%) opted for formula feeding and five (19.25%) for mixed feeding (Table 5).

Table 5: Child parameters.

<b>Variables related to newborn</b>		<b>Number</b>	<b>Percentage</b>
<b>Condition of the newborn baby</b>	Live birth	29	96,67%
	Stillborn	1	3,33%
<b>Newborn weight</b>	< 2500 g	2	6,66%
	2500-3500 g	22	73,34%
	> 3500 g	6	20%
<b>Food supply type</b>	Maternal	20	66,96%
	Artificial	4	13,79%
	Mixed	5	19,25%
<b>Becoming at age 2</b>	HIV-positive	3	10%
	HIV-negative	26	86,67%
	Deceased	1	3,33%

At two years of age, three cases of mother-to-child transmission of HIV were reported, representing 10% of children. 86.67% were HIV-negative and one child died before reaching two years of age. These cases of seroconversion were observed in women whose treatment had failed.

### Discussion

The primary goal of Highly Active Antiretroviral Therapy (HAART) is to achieve an undetectable viral load (VL). This period

of viral suppression represents the optimal window for conception, offering the lowest risk of mother-to-child transmission (MTCT) of HIV. The threshold for undetectability is set at 1000 copies/μL of blood. In our cohort, 10.6% of women receiving HAART became pregnant, including 30 participants in our study. Among these, seven (7/30; 23.33%) had a VL ≥1000 copies/μL, despite good adherence being reported in 86.66% (26/30) and poor adherence in 13.34% (4/30).

According to literature, virological suppression is generally achieved with adherence levels of at least 95% - a higher threshold than what was observed in our study [6,7]. In our context, adherence was assessed using pill counts and prescription refill tracking, both of which have limited reliability. Suboptimal adherence may also explain the switch to second-line therapy after first-line treatment failure in six women, as evidenced by their low CD4 counts.

The main barriers to adherence identified were forgetfulness and difficulty accessing treatment centres, primarily due to financial constraints. At the CHU du Point G in Bamako, forgetfulness (47.5%) and poor access to healthcare facilities (34.6%) were the most frequently reported reasons for non-adherence [8]. In Gabon, the use of concurrent medications was associated with lower adherence [9]. In Kinshasa, barriers such as consultation fees, HAART side effects, and patient perceptions including forgetfulness were also documented [10]. Although HIV-related care (screening, initiation, and follow-up tests) is free of charge, delays in performing required tests do occur.

In our study, most women were paucigravida (60%) or multigravida (30%) and were already aware of their HIV-positive status. Improved health and the routinization of care may sometimes result in a certain level of complacency.

At the end of pregnancy, 96.7% of women gave birth to live infants, with one stillbirth reported. Among the live births, two (2/30; 6.66%) had low birth weight (< 2500 g). This proportion is lower than the 25.75% prevalence of low birth weight recorded in 2013 at the Maternity Unit of the Reference Centre in Commune IV, Bamako [11], and comparable to the 7.8% observed among infants born to HIV-positive mothers not receiving HAART in four African countries [12]. The association between HIV and low birth weight is well established, though multifactorial in nature.

Despite a 52% reduction in new paediatric HIV infections since 2010 [1], MTCT still accounts for over 90% of HIV infections in infants and young children and more than 10% of global HIV infections [13,14]. Without HAART, the risk of vertical transmission ranges from 15–30% during pregnancy and delivery, with an additional 10–20% risk associated with prolonged breastfeeding [15]. Suppression of maternal VL to undetectable levels (<50 copies/mL) through highly active antiretroviral therapy (HAART) remains the most effective strategy and is the standard of care in most high-income countries, where MTCT rates have fallen to 1–2% [15].

In our study, we recorded three cases of HIV transmission to infants, corresponding to an MTCT rate of 10%. Reproductive health is typically addressed at ART initiation and reinforced throughout follow-up. However, this focus may be lost after transfer to the obstetric team, with some women expressing a lack of confidence in new providers and fear of HIV status disclosure. Strengthened communication and collaboration between teams is thus recommended.

In Lubumbashi (in DRC), Tshikwey Ngwey, et al. [16] reported an MTCT rate of 12.7% (20/157) across 12 health facilities. In Senegal, Diouf, et al. [17] reported no MTCT cases among 42 exposed children two months after weaning. Several risk factors for MTCT have been identified. In Ethiopia, the rate of HIV positivity among exposed infants was only 3.8% [18].

In our setting, maternal clinical stage (AIDS stage II), poor HAART adherence, and lack of infant ARV prophylaxis were predictive of MTCT. In Ethiopia, additional significant predictors included poor infant prophylaxis adherence, absence of paternal treatment, infant age at HAART initiation >6 weeks, maternal enrolment in PMTCT during or after delivery, and advanced maternal WHO clinical stage. Furthermore, an additional risk of 10–20% is associated with prolonged breastfeeding and failure to adhere to recommended precautions [16].

Breastfeeding was practiced by 66.97% of mothers, largely due to financial constraints and concerns about explaining the decision not to breastfeed. Some (5/29; 19.25%) initially opted for formula feeding but were later unable to afford it, resulting in early introduction of complementary feeding.

## Conclusion

Despite tangible progress in reducing MTCT of HIV in Mali, the country has not yet reached the goal of elimination. The national strategy for elimination focuses on ARV treatment and reproductive health education for HIV-positive women. Despite these efforts, the rate of mother-to-child transmission of HIV remains high among women on HAART who are regularly monitored in Kati. Further research is needed to identify the determinants of MTCT in the locality, to formulate recommendations for achieving the goal of eliminating MTCT, and to train staff.

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