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EFFECTIVENESS OF POST-EXPOSURE ANTI-RETROVIRAL PROPHYLAXIS IN BABIES BORN TO HIV-POSITIVE MOTHERS AT GOA MEDICAL COLLEGE: A RETROSPECTIVE STUDY

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Post-exposure prophylaxis, HIV, Vertical transmission, Maternal adherence, Antiretroviral therapy

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ABSTRACT: Vertical transmission remains a major contributor to paediatric HIV infections despite significant advancements in antenatal care and the use of antiretroviral therapy (ART) and post-exposure prophylaxis (PEP). These measures have successfully reduced mother-to-child transmission rates, yet non-compliance with prescribed regimens continues to pose significant challenges. This retrospective study evaluates the effectiveness and safety of PEP in infants born to HIV-positive mothers at Goa Medical College from 2015 to 2022.A total of 97 infants born to HIV-positive mothers were included in the analysis. The study revealed a vertical transmission rate of 2.1%, with two infants testing positive for HIV. Both positive cases were associated with maternal non-compliance, either due to delayed initiation of ART or incomplete administration of PEP to the infant. No significant adverse effects of PEP were observed, indicating its safety and tolerability. The findings underscore the critical role of maternal adherence to ART and strict implementation of PEP protocols in preventing HIV transmission. Comprehensive counselling and robust support systems are essential to address compliance issues and optimize the efficacy of these interventions. Overall, this study reaffirms that PEP, when properly administered, is a safe and effective strategy for reducing vertical HIV transmission.

INTRODUCTION: Human Immunodeficiency Virus (HIV) remains one of the foremost global health challenges, particularly affecting paediatric populations through vertical transmission. Vertical transmission, also known as mother-to-child transmission (MTCT), encompasses a significant route of paediatric HIV infection and includes transmission during pregnancy, childbirth, and breastfeeding [1].

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Globally, an estimated 1.5 million children are living with HIV, with the vast majority acquiring the infection vertically [2]. Without intervention, the risk of vertical transmission ranges from 15% to 45%, influenced by maternal factors such as viral load, CD4 count, timing of antiretroviral therapy (ART) initiation, obstetric practices, and breastfeeding [3, 4].

However, significant advancements in antenatal care and the implementation of ART for pregnant women, alongside post-exposure prophylaxis (PEP) for infants, have markedly reduced MTCT rates [5]. According to the latest WHO guidelines, effective use of combination ART (cART) during pregnancy, coupled with infant PEP, can reduce transmission rates to below 5% [6].

India, with an estimated 2.4 million people living with HIV, has made notable progress in preventing MTCT through comprehensive Prevention of Parent-to-Child Transmission (PPTCT) programme under the National AIDS Control Programme (NACP) [7].

Despite these efforts, national MTCT rates remain around 9%, significantly higher than the global target, highlighting ongoing gaps in coverage, adherence, and service delivery [8]. Regional disparities, driven by socio-economic, cultural, and systemic healthcare factors further complicate implementation [9]. Post-exposure prophylaxis plays a critical role in this prevention cascade, offering immediate protection to infants exposed to HIV during delivery. PEP regimens typically include zidovudine monotherapy for infants at lower risk and combination regimens for those at higher risk [10]. While these strategies have reduced transmission, challenges remain, particularly regarding maternal ART adherence, timely PEP initiation, adverse neonatal effects, and continuity of care [10, 11].

In Goa, a state with a relatively high HIV prevalence, data on neonatal PEP effectiveness and safety remain sparse. Understanding local dynamics, including healthcare delivery practices, maternal adherence patterns, and infant clinical outcomes, is essential to enhance the regional effectiveness of existing PPTCT programs. This study aims to assess the effectiveness and safety of neonatal PEP among infants born to HIV-positive mothers at Goa Medical College, with the goal of informing policy, refining clinical protocols, and improving paediatric HIV outcomes.

MATERIALS AND METHODS:

Study Design and Setting: This retrospective cross-sectional study was conducted at the Prevention of Parent-to-Child Transmission (PPTCT) Centre, Goa Medical College, with the objective of assessing the effectiveness of post-exposure antiretroviral prophylaxis (PEP) in infants born to HIV-positive mothers. The study included 97 HIV-positive mothers who delivered between January 2015 and December 2022. Infant follow-up data were accessed from case records to evaluate HIV transmission rates and the impact of prophylactic interventions.

Ethical Considerations: Ethical approval for the study was obtained from the Institutional Ethics Committee (IEC) of Goa Medical College and the Goa State AIDS Control Society (GSACS). All patient data were anonymized during data extraction and analysis to ensure strict confidentiality.

Data Collection: Data were retrieved from hospital records and PPTCT registers. The following parameters were recorded:

- Maternal demographic characteristics.
- Antiretroviral therapy (ART) regimen during pregnancy.
- Mode of delivery.
- Infant feeding practices.
- Type and duration of postnatal antiretroviral prophylaxis.

Infant HIV status was evaluated at specific intervals:

- ❖ At 6 weeks using dried blood spot (DBS) testing.
- ❖ At 6 and12 months using HIV antibody tests.
- ❖ At 18 months for final serological confirmation.

Based on test results, infants were classified as either HIV-negative or HIV-positive.

Statistical Analysis: Data were compiled and analysed using Microsoft Excel. Descriptive statistics, including means and percentages, were used to summarize findings. The vertical transmission rate was calculated as the proportion of infants who tested HIV-positive by the end of the follow-up period.

RESULTS: Between January 2015 and December 2022, a total of 107 HIV-positive mothers delivered at Goa Medical College and Hospital. Of these, 10 infants were excluded from the final analysis due to incomplete records, including one infant who died of pneumonia and clinical sepsis in the Neonatal Intensive Care Unit (NICU). Thus, data from 97 infants were included in the final evaluation.

Among these 97 infants, two were confirmed HIV-positive, yielding a vertical transmission rate of 2.1%. Regarding maternal ART regimens, both HIV-positive infants were born to mothers receiving the Tenofovir-Lamivudine-Efavirenz (TLE) regimen.

TLE was also the most commonly prescribed regimen among the cohort, followed by the Tenofovir-Lamivudine-Dolutegravir (TLD) regimen. The distribution of maternal ART regimens is detailed in **Table 1**.

TABLE 1: MOTHER'S ART REGIMENAND HIV STATUSOF THEBABY

Mother's ART regimen	HIV status of the Baby		
Regimens	**+ve**	**-ve**	**Grand Total**
TL+ATV/r		2	2
TLD		25	25
TLE	2	67	69
TLN		1	1
ZLN		1	1
Grand Total	2	96	98

T-Tenofovir, L-Lamivudine, ATV/r-Atazanavir/ritonavir, D-Dolutegravir, E-Efavirenz,N-Nevirapine, Z-Zidovudine

Regarding the antiretroviral prophylaxis administered to infants, the first HIV-positive case was delivered via spontaneous vaginal delivery. Although prescribed a standard 6-week Nevirapine regimen, the infant received prophylaxis for only 10 days due to poor adherence.

The infant was on exclusive replacement feeding and tested positive for HIV at 6 weeks of age, underscoring the critical role of strict adherence to neonatal PEP protocols. The second HIV-positive infant was delivered *via* caesarean section and completed the full 6-week Nevirapine prophylaxis course. However, this infant was exclusively breastfed, and maternal adherence to ART was documented to be suboptimal.

The infant tested positive for HIV at 18 months, suggesting that inadequate maternal viral suppression during breastfeeding may have contributed to postnatal transmission. These cases highlight key risk factors like non-adherence to neonatal prophylaxis and maternal ART, affecting transmission outcomes as detailed in **Table 2**.

TABLE 2: PROPHYLACTIC (PX) ART REGIMEN ADMINISTERED TO THE BABY AND HIV STATUS

Px ART of Baby (Nevirapine- Nev) (Zidovudine- Zid)	HIV status at 6wks (DBS test*)		HIV status at 6 months (Ab Test)		HIV status at 12 months (Ab Test)		HIV status at 18 months (Confirmatory Ab Test)	
Nevirapine*6wks	-ve	85	-ve	85	-ve	84	-ve	84
	+ve	1	+ve	1	+ve	2	+ve	2
Nevirapine*12wks	-ve	3	-ve	3	-ve	3	-ve	3
	+ve	0	-ve	0	-ve	0	-ve	0
Zidovudine*6wks	-ve	1	-ve	1	-ve	1	-ve	1
	+ve	0	+ve	0	+ve	0	+ve	0
Zid+Nev*6wks	-ve	3	-ve	3	-ve	3	-ve	3
	+ve	0	+ve	0	+ve	0	+ve	0
Zid+Nev*12wks	-ve	5	-ve	5	-ve	5	-ve	5
	+ve	0	+ve	0	+ve	0	+ve	0

*DBS- Dried Blood Spot. At 6 weeks of age, only DBS test is done to determine HIV status of the baby. Whenever Antibody tests at 6, 12 or 18 months are found to be positive, the HIV status is confirmed with DBS. If DBS is positive, HIV status is considered positive. Ab-Antibody.

Among the study population, the majority of mothers (n = 62) delivered via caesarean section, while 35 underwent vaginal delivery. Notably, one case of vertical transmission was recorded in each delivery group, as illustrated in **Fig. 1**. Among feeding practices, of the two positive infants, one was exclusively breastfed (by a mother poorly adherent to ART), and one received exclusive replacement feeding but incomplete prophylaxis. Among the seven infants with mixed feeding practices, none tested HIV-positive as shown in **Table 3.**

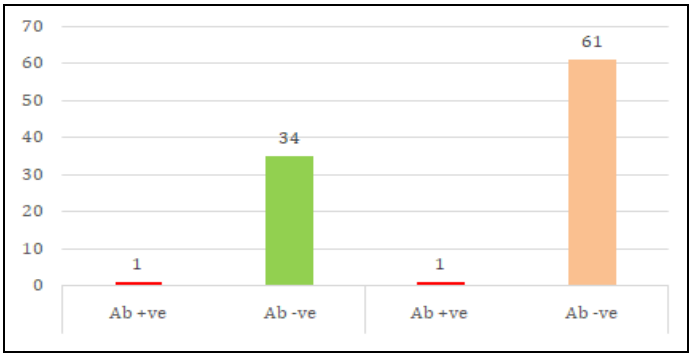

FIG. 1: HIV STATUS OF THE BABY AND MODE OF DELIVERY

TABLE 3: TYPE OF FEED AND HIV STATUS OF THE BABY

Type of feed	HIV status of Babies		
	Positive	Negative	Grand Total
Breastfeed	1	27	28
Exclusive replacement	1	62	63
Mixed		7	7
Grand Total	2	96	98

Overall, the findings demonstrate that standard prophylactic regimens effectively reduced vertical transmission rates at this centre to levels aligned with global targets (<5%) [11]. However, the identified cases highlight persistent challenges in adherence to both maternal ART and neonatal prophylaxis, underscoring the need for enhanced adherence support and robust monitoring strategies to ensure optimal paediatric outcomes 10.

DISCUSSION: In the absence of medical intervention, the risk of vertical transmission of HIV ranges from 15% to 45%, influenced by maternal and perinatal factors such as viral load, mode of delivery, breastfeeding practices, and timing of maternal infection [12]. A combined strategy comprising maternal combination antiretroviral therapy (cART) during pregnancy and delivery, followed by neonatal post-exposure prophylaxis (PEP), forms the cornerstone of prevention efforts. According to WHO guidelines, timely and appropriate implementation of these interventions can reduce the risk of mother-to-child transmission (MTCT) to below 5% [11].

The present study reported a vertical transmission rate of 2.1%, consistent with global targets, thereby reflecting the effectiveness of the integrated Prevention of Parent-to-Child Transmission (PPTCT) protocols implemented at Goa Medical College. Importantly, both cases of HIV transmission in this cohort were associated with non-adherence, either due to suboptimal maternal ART compliance or incomplete administration of neonatal PEP. These findings highlight that the observed transmission events were likely due to lapses in adherence and implementation, rather than the failure of the prophylactic regimen itself.

Comparable findings have been reported in both Indian and international studies. A study by Radhika et al. conducted in a tertiary care centre in Delhi reported a mother-to-child transmission (MTCT) rate of 2.5%, with poor adherence to maternal ART and irregular follow-up identified as major contributing factors [13]. Similarly, a cohort study from South Africa found that, despite universal access to ART, maternal non-compliance, particularly among breastfeeding populations, remained a principal driver of transmission [14]. In contrast, a multicentric evaluation by the INSPIRE collaboration in sub-Saharan Africa documented MTCT rates below 2% in settings with high adherence to both maternal ART and infant PEP, reinforcing the role of optimal implementation in significantly reducing perinatal HIV transmission [10].

In the U.S., around 5,000 women with HIV give birth annually, but effective interventions such as maternal and infant antiretroviral therapy and avoidance of breastfeeding have substantially reduced vertical transmission rates. Prompt postnatal prophylaxis for all HIV-exposed infants, especially within six hours of birth, is crucial and should be guided by maternal virologic status and

the infant's transmission risk [15]. A study by Lanbo Yang *et al* found that caesarean delivery rates were significantly higher in women living with HIV compared to those without, though this trend declined over time with the widespread use of combination antiretroviral therapy (cART) [16]. Antiretroviral therapy (ART) substantially reduces the risk of HIV transmission during breastfeeding, while ART proved effective, evidence remains limited regarding the comparative efficacy of different ART regimens and adjunct interventions such as high-dose vitamin A [17]. In the present study, although the relationship between mode of delivery and feeding practices with infant HIV status was explored, the number of positive cases was too small to establish any definitive conclusions.

Our findings underscore the critical importance of adherence counselling and continuous support for HIV-positive mothers. Comprehensive education on the necessity of strict adherence to antiretroviral therapy (ART), completion of infant post-exposure prophylaxis (PEP) regimens, and appropriate infant feeding practices should be systematically integrated into both antenatal and postnatal care protocols. Notably, the case in which neonatal PEP was discontinued after 10 days subsequently resulting in HIV seropositivity demonstrates the direct consequences of incomplete prophylactic intervention.

A study by Vundli Ramokolo *et al.* in HIV-exposed but uninfected children reported no significant adverse impact of in-utero antiretroviral exposure on postnatal growth up to 18 months, thereby supporting the universal initiation of ART in all pregnant women living with HIV [18]. Consistent with this evidence, no significant adverse events were observed in our study population, further demonstrating the safety and tolerability of neonatal PEP regimens. These findings align with existing literature supporting the safety profile of zidovudine and nevirapine-based prophylaxis in neonates [10]. Nonetheless, continued pharmacovigilance and routine laboratory monitoring remain essential to detect potential haematological or hepatic toxicity, particularly in cases requiring prolonged prophylactic therapy. Despite its strengths, this study has several limitations. As a single-centre, retrospective analysis, its findings are limited by a relatively small sample size and restricted generalizability. Furthermore, incomplete and inconsistent documentation impeded in-depth evaluation of certain critical variables, including the exact timing of maternal ART initiation, maternal viral load, and relevant socioeconomic determinants. The existing recording system also lacked the capacity for robust longitudinal tracking and integration of interdependent variables, which may have otherwise yielded additional insights into factors influencing PEP outcomes.

This study reaffirms that neonatal post-exposure prophylaxis (PEP), when implemented in accordance with WHO and NACO guidelines, is both effective and safe in preventing mother-to-child transmission (MTCT) of HIV. However, the success of such interventions is critically dependent on maternal adherence to antiretroviral therapy (ART) and the complete administration of neonatal PEP. To address implementation gaps, it is imperative to strengthen adherence support mechanisms, enhance medical record-keeping systems, and expand community-based follow-up services. Furthermore, exploring innovative strategies such as the use of long-acting antiretroviral agents may further improve HIV-free survival among exposed infants and should be prioritized in future antiretroviral drug development efforts [19].

CONCLUSION: In this study, conducted at Goa Medical College, we observed a vertical transmission rate of 2.1% among 97 infants born to HIV-positive mothers between 2015 and 2022. Both HIV-positive cases were linked to maternal non-compliance. One mother failed to adhere to her ART regimen, while the other did not ensure her infant received the full PEP course, ultimately resulting in the infants testing positive for HIV. These findings highlight that maternal non-adherence to prescribed therapies, rather than the failure of PEP itself, was the key determinant in these transmission cases. This emphasizes the critical need for proper counselling and education of HIV-positive mothers regarding adherence to ART, feeding practices, and the importance of completing the infant's PEP regimen. The study reaffirms that PEP is a safe and effective intervention for preventing HIV transmission.

No significant adverse events were reported, further supporting its tolerability. Ensuring strict adherence to ART and PEP protocols remains paramount in achieving the goal of eliminating vertical transmission of HIV.

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CONFLICT OF INTEREST: Nil

REFERENCES:

1. Global HIV & AIDS statistics -Fact sheet | UNAIDS [Internet]. [cited 2025 Apr 16]. Available from: https://www.unaids.org/en/resources/fact-sheet
2. Global HIV Programme [Internet]. [cited 2025 Apr 16]. Available from: https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/overview
3. Townsend CL, Byrne L, Cortina-Borja M, Thorne C, de Ruiter A and Lyall H: Earlier initiation of ART and further decline in mother-to-child HIV transmission rates, 2000-2011. AIDS 2014; 28(7): 1049–57.
4. Goga AE, Dinh T, Jackson DJ, Lombard CJ, Puren A and Sherman G: Population–level effectiveness of PMTCT Option A on early mother–to–child (MTCT) transmission of HIV in South Africa: implications for eliminating MTCT. Journal of Global Health 2016; 6(2): 020405.
5. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach [Internet]. [cited 2025 Apr 16]. Available from: https://www.who.int/publications/i/item/9789240031593
6. Global HIV Programme [Internet]. [cited 2025 Apr 16]. Available from: https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/prevention/mother-to-child-transmission-of-hiv
7. HIV/AIDS Data Hub for the Asia Pacific [Internet]. [cited 2025 Apr 19]. HIV/AIDS Data Hub for the Asia Pacific. Available from: https://www.aidsdatahub.org
8. Pandey A, Sahu D, Bakkali T, Reddy D, Venkatesh S and Kant S: Estimate of HIV prevalence and number of people living with HIV in India 2008–2009. BMJ Open. 2012; 2(5): 000926.
9. Guidelines for HIV post-exposure prophylaxis [Internet]. [cited 2025 Apr 19]. Available from: https://www.who.int/publications/i/item/9789240095137
10. Chi BH, Stringer JSA and Moodley D: Antiretroviral drug regimens to prevent mother-to-child transmission of HIV: a review of scientific, program, and policy advances for sub-Saharan Africa. Curr HIV/AIDS Rep 2013; 10(2): 124–33.
11. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach [Internet]. [cited 2025 Apr 19]. Available from: https://www.who.int/publications/i/item/9789240031593
12. Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021 [Internet]. [cited 2025 Apr 19]. Available from: https://www.who.int/publications/i/item/9789240027077
13. (PDF) Prevention of Parent to Child Transmission of HIV: Single Centre Experience of 14 years at Tertiary Care Hospital in Delhi, India. ResearchGate [Internet]. 2024 Oct 22 [cited 2025 Apr 19]; Available from: https://www.researchgate.net/publication/319478787_Prevention_of_Parent_to_Child_Transmission_of_HIV_Single_Centre_Experience_of_14_years_at_Tertiary_Care_Hospital_in_Delhi_India
14. Goga AE, Dinh TH, Jackson DJ, Lombard C, Delaney KP and Puren A: First population-level effectiveness evaluation of a national programme to prevent HIV transmission from mother to child, South Africa. J Epidemiol Community Health 2015; 69(3): 240–8.
15. Vijayan V, Naeem F and Veesenmeyer AF: Management of Infants Born to Mothers with HIV Infection. Am Fam Physician 2021; 104(1): 58–62.
16. Yang L, Cambou MC, Segura ER, de Melo MG, Santos BR and Dos Santos Varella IR: Cesarean delivery and risk of HIV vertical transmission in Southern Brazil, 2008-2018. AJOG Glob Rep 2023; 3(2): 100194.
17. Xu F, Xiong Y, Gu M, Wan L and Wang Y: Interventions to prevent mother-to-child transmission in breastfeeding mothers with HIV: a systematic review and meta-analysis of randomized controlled trials. Rev Inst Med Trop Sao Paulo. 66:e45.
18. Ramokolo V, Kuhn L, Lombard C, Jackson D and Goga AE: Impact of antenatal antiretroviral drug exposure on the growth of children who are HIV-exposed uninfected: the national South African Prevention of Mother to Child Evaluation cohort study. BMC Infect Dis 2022; 22(1): 908.
19. Ruel T, Penazzato M, Zech JM, Archary M, Cressey TR and Goga A: Novel Approaches to Postnatal Prophylaxis to Eliminate Vertical Transmission of HIV. Glob Health Sci Pract 2023; 11(2): 2200401.
20. Gupta A, Verma A, Kashyap M and Gautam P: ART in Prevention of Mother-to-Child Transmission of HIV. The Journal of Obstetrics and Gynecology of India 2020; 70: 18-22.

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