

Implementation of Daily Nevirapine (dNVP) Prophylaxis in HIV

Exposed Breastfeeding Infants in Western Kenya

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Background

- In July 2010, the World Health Organization (WHO) issued new guidelines for prevention of mother to child transmission of HIV
- For mothers who are not on HAART, either option A (maternal AZT during pregnancy with daily infant NVP until 1 week after cessation of breastfeeding) or option B (maternal triple ARVs during pregnancy and throughout breastfeeding) are reasonable
- The Kenya 2010 guidelines highlight option A

2010 World Health Organization PMTCT Guidelines

Maternal AZT + Infant ARV prophylaxis (Option A)	Maternal triple ARV prophylaxis (Option B)
Maternal Antepartum twice-daily AZT starting from as early as 14 weeks of gestation and continued during pregnancy. At onset of labour, sd-NVP and initiation of twice daily AZT + 3TC for 7 days postpartum. (Note: If maternal AZT was provided for more than 4 weeks antenatally, omission of the sd-NVP and AZT + 3TC can be considered; in this case, continue maternal AZT during labour and stop at delivery). Infant For breastfeeding infants: Daily NVP from birth for a minimum of 4 to 6 weeks, and until 1 week after all exposure to breast milk has ended. Infants receiving replacement feeding only: Daily NVP or sd-NVP + twice-daily AZT from birth until 4 to 6 weeks of age.	Maternal Triple ARV prophylaxis starting from as early as 14 weeks of gestation and continued until delivery, or, if breastfeeding, continued until 1 week after all infant exposure to breast milk has ended. Recommended regimens include: AZT + 3TC + LPV/r or AZT + 3TC + ABC or AZT + 3TC + EFV or TDF + 3TC (or FTC) + EFV. Infant Irrespective of mode of infant feeding: Daily NVP or twice daily AZT from birth until 4 to 6 weeks of age.

Table 1. ARV prophylaxis options recommended for HIV-infected pregnant women who do not need treatment for their own health

Objectives

- To monitor the implementation of daily nevirapine (dNVP) in breastfeeding infants of women not on HAART
- To investigate mother to child transmission (MTCT) rates at 6 weeks and 9-12 months
- To monitor reported daily NVP adherence; and assess NVP toxicity

Setting

- Family AIDS Care and Education Services (FACES)
- FACES is a PEPFAR-funded comprehensive HIV prevention, care and treatment program based primarily in Nyanza Province Kenya
- These results are from three FACES-supported clinics in Kisumu, Migori and Oyani

Methods

- Prospective 12 month evaluation
- Women not on HAART, who planned to breastfeed, were enrolled during pregnancy or after delivery
- At birth, infants were started on daily NVP syrup and followed prospectively (table 2)
- NVP dose was adjusted accordingly at visits and HIV test was performed at 6 weeks, 9-12 months
- NVP adherence and toxicity were assessed at each visit

Table 2. Daily nevirapine (dNVP) prophylaxis for HIV-exposed Infants

Age	Nevirapine dose
0 - 6 weeks	Birth weight < 2500g - 10 mg (1 ml) once daily Birth weight > 2500g - 15 mg (1.5 ml) once daily
6 weeks - 14 weeks	20 mg (2ml) once daily
14 weeks to 6 months	25 mg (2.5 ml) once daily
6 months - 9 months	30 mg (3ml) once daily
9 months - 12 months	40 mg (4 ml) once daily
> 12 months	50 mg (5 ml) once daily

Analysis

- Analysis was done using STATA 11
- Descriptive analysis was performed

Results

- Of the 282 eligible infants enrolled, daily NVP was initiated at birth for 229 (81%) infants
- For the remaining 53 infants, median age of NVP initiation was 7.5 weeks (IQR 6-15)
- Median maternal CD4 count at baseline during pregnancy was 633 cells/mm³ (IQR 468-788)
- Median age at first PCR was 6.2 weeks (IQR 5.5-7.1 weeks)
- Out of 280 available dried blood spot (DBS) results, 5 infants had a positive PCR test result (**6 week MTCT rate 1.8%**)
- Antibody tests were done for 108 (75.5%) out of 143 due for antibody testing, at a median age of 10.1 months (IQR 9.7-10.5 months)
- Two were confirmed positive giving an additional 1.8% MTCT
- 9-12 month MTCT rate was 3.6%**
- Caregivers of 253 infants (91.6%) reported complete adherence to NVP during the 7 days preceding their follow-up visits.
- No grade 3 or 4 adverse events associated with NVP were reported during the study.

Figure 1. Implementation of daily nevirapine from birth throughout breastfeeding in HIV-exposed infants

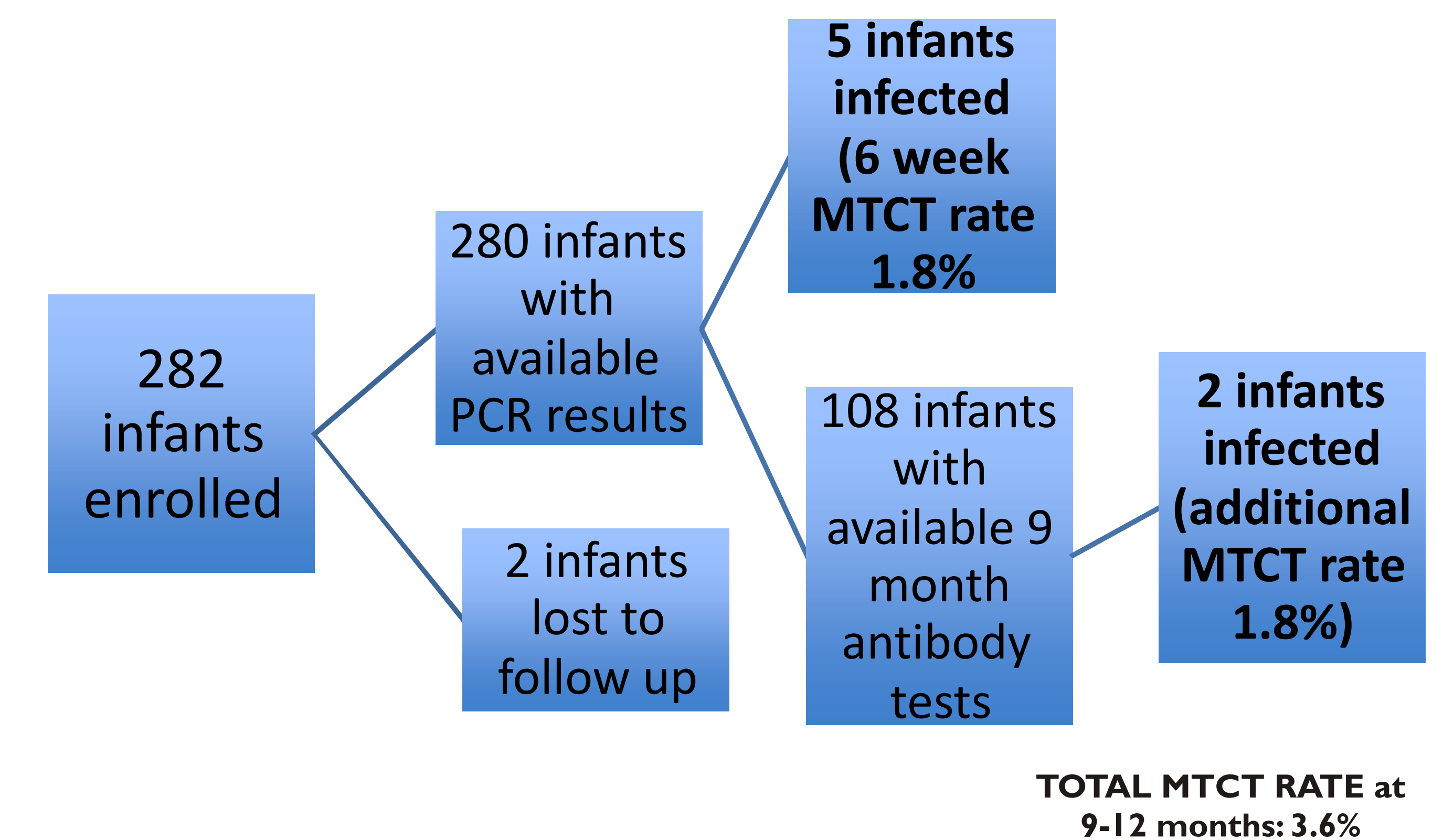


Table 3. Clinical characteristics of women and infants enrolled in implementation of daily infant nevirapine throughout breastfeeding

Variable	Median (IQR)
Median maternal CD4 count during pregnancy Cells/mm ³	633 (468-788)
Median age at NVP initiation Weeks	7.5 (6-15)
Median age at first PCR weeks	6.2 (5.5-7.1)
Median age at antibody test months	10.1 (9.7-10.5)

Conclusion

- One of the first programmatic studies on daily NVP since WHO guidelines were released in 2010
- There was a low rate of MTCT (3.6% at 9-12 months)
- There were no NVP-related toxicities
- Reported adherence to NVP was high
- Extended nevirapine (NVP) can be safely and effectively implemented in PMTCT programs

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