Implementation of Daily Nevirapine (dNVP) Prophylaxis in HIV Exposed Breastfeeding Infants in Western Kenya

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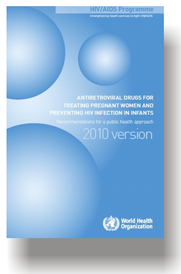
Background

- 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)
Mother	**Mother**
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 tail can be considered; in this case, continue maternal AZT during labour and stop at delivery).	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	**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.	*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)

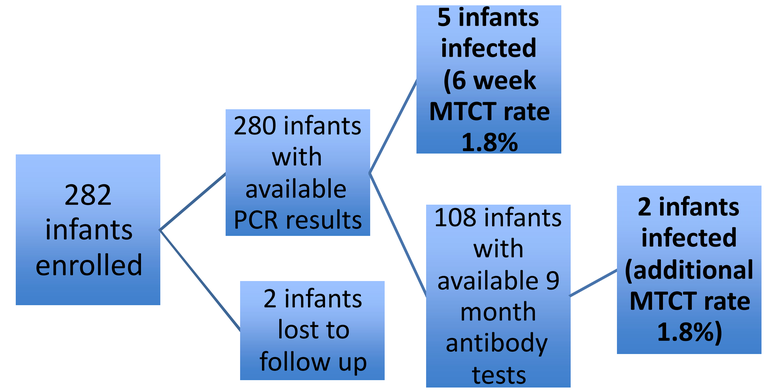
Analysis

- 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



TOTAL MTCT RATE at 9-12 months: 3.6%

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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