



Infant Extended Antiretroviral (ARV) Prophylaxis is Effective in Preventing Postnatal Mother-to-Child HIV Transmission at All Maternal CD4 Counts

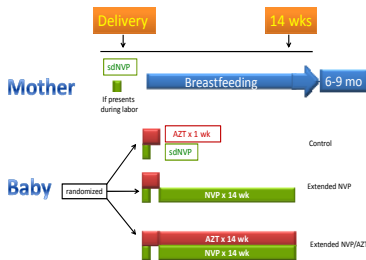
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Background

PEPI-Malawi Study Design



Results

Table 1. Postnatal HIV Infection Rates at Age 14 Weeks (end of extended prophylaxis) in Infants Uninfected at Birth by Maternal CD4 Category

Study Arm	Maternal CD4 Count Category (cells/uL)					
	CD4 ≤200		CD4 201-350		CD4 >350	
	% Postnatal Infection (95% CI)	Relative Risk (95% CI)	% Postnatal Infection (95% CI)	Relative Risk (95% CI)	% Postnatal Infection (95% CI)	Relative Risk (95% CI)
Control	17.6% (12.2-25.2)	1.0	9.0% (5.9-13.8)	1.0	5.5% (3.8-7.9)	1.0
Extended NVP	5.8% (3.0-10.8)	0.33 (0.16-0.68)	3.4% (1.7-6.7)	0.37 (0.17-0.84)	1.4% (0.7-3.0)	0.25 (0.12-0.59)
Extended NVP/AZT	6.1% (3.3-12.4)	0.36 (0.17-0.78)	3.2% (1.3-6.3)	0.32 (0.13-0.78)	2.3% (1.3-4.1)	0.42 (0.22-0.83)

PEPI-Malawi Original Study Results

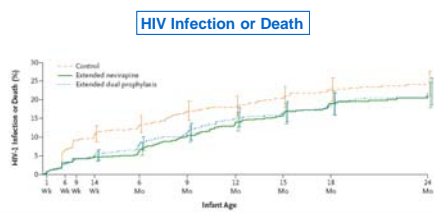
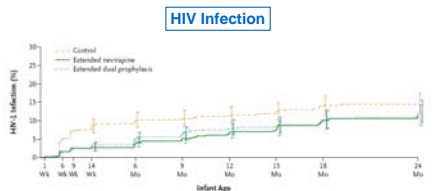
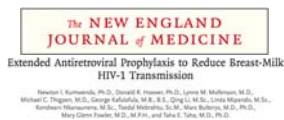


Figure 1. Kaplan-Meier: Postnatal HIV Infection Rates (% and 95% CI) in Infants Uninfected at Birth by Infant Age and Maternal CD4 Category

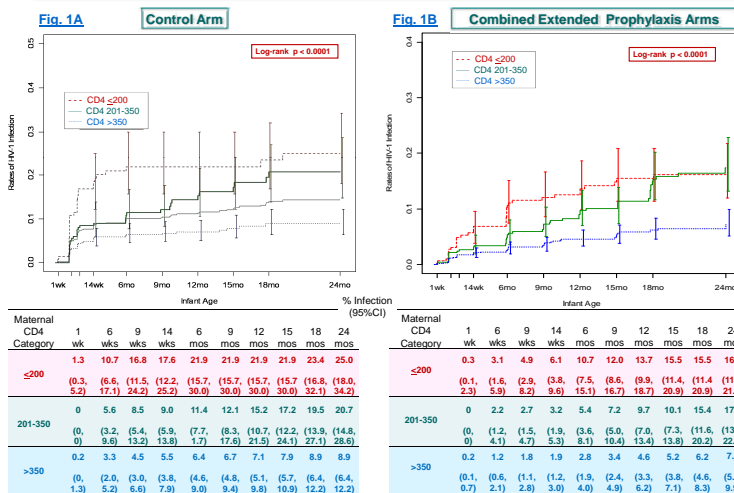
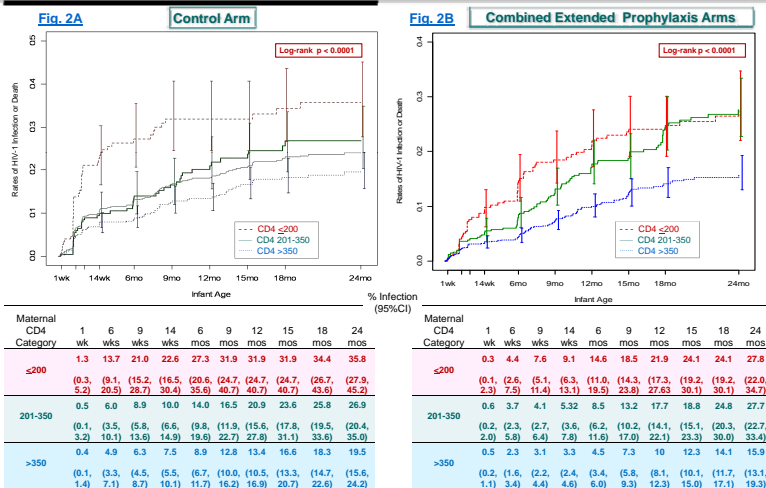


Figure 2. Kaplan-Meier: Postnatal HIV Infection or Death Rates (% and 95% CI) in Infants Uninfected at Birth by Infant Age and Maternal CD4 Category



Objectives and Methods

- This analysis examined whether baseline maternal CD4 cell count affected the efficacy of extended infant antiretroviral prophylaxis.
- Maternal baseline CD4 count was obtained between delivery and 3 days postpartum; CD4 count was categorized as ≤200, 201-350 and >350 cells/uL.
- Kaplan-Meier curves of cumulative HIV infection and HIV infection or death for infants not infected at birth were separately fit stratified by maternal CD4 category for the controls and for each extended prophylaxis arm.

Conclusions

- Extended infant antiretroviral prophylaxis was much more effective than the control regimen in reducing postnatal HIV infection in infants uninfected at birth at all maternal CD4 counts.
- However, even with infant prophylaxis, postnatal HIV infection rates for infants born to mothers with CD4 <350 cells/uL (the current eligibility threshold for treatment in US) were substantial; HAART initiation for treatment of women with CD4 <350 cells/uL would both benefit maternal health and reduce infant HIV infection.
- In contrast, postnatal transmission rates at age 14 weeks (when extended infant antiretroviral prophylaxis was stopped) for infants born to women with CD4 counts >350 were low (1.4% with extended NVP and 2.3% with extended NVP/AZT) and similar to what has been reported with maternal HAART prophylaxis (e.g., Thomas T, et al. KIBS study 15th CROI 2008 Abs 45aLB – postnatal transmission at age 12 weeks in infants born to women with CD4 >250 cell/uL who received HAART during breastfeeding was 1.7%).
- Use of infant prophylaxis should be considered to reduce breast milk HIV transmission risk in infants born to women with CD4 >350 cells/uL, while women with CD4 <350 cells/uL should receive HAART for their own health (which will also substantially reduce postnatal infection – Taha TE et al. 16th CROI 2009 Abs 92), which would be continued after breastfeeding cessation for maternal health.
- Continued postnatal transmission following completion of 14 weeks of extended infant prophylaxis suggests the need for more prolonged infant prophylaxis to significantly affect breast milk transmission in women who continue breastfeeding.

Acknowledgments

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