



Maternal HIV Viral Load Threshold for Guiding Extended Infant Prophylaxis Initiation

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BACKGROUND

- ♦ WHO recommends infant postnatal prophylaxis (PNP) for breastfed HIV-exposed uninfected (HEU) children when the maternal viral load (VL) is ≥ 1000 cp/mL.
- PNP may then be stopped once maternal VL measures < 1000cp/mL.</p>
- In most countries, the very long VL turnaround times (several months) leave many children highly exposed without PNP (i.e. those mothers with VL≥1000 cp/mL).
- The 1000 cp/mL threshold is based on the risk of sexual transmission but may not be appropriate for PMTCT purposes.

HYPOTHESES

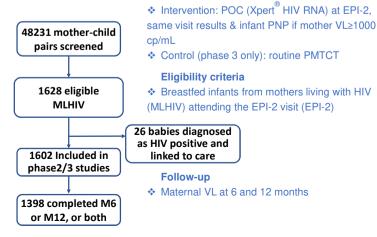
- A single VL at 2nd immunization visit (EPI-2, 6-8 weeks) can identify children at high risk of transmission (i.e. maternal VL≥1000) during breastfeeding.
- The usual threshold of VL positivity (i.e. ~40 cp/mL) could be a safer and pragmatic alternative for guiding PNP initiation in resource-constrained contexts.

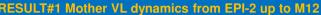
OBJECTIVES

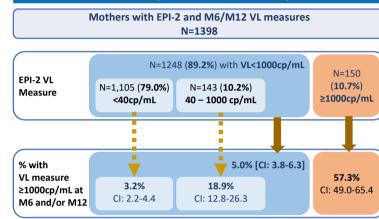
 To assess the risk of heightened HIV exposure during breastfeeding for children not eligible for PNP at EPI-2 (mother VL < 1000 cp/mL).
To challenge the VL threshold of 1000 cp/mL for PNP initiation.

METHODS

We pooled data from a phase 2 (NCT03869944) and a phase 3 (NCT03870438) intervention conducted in *Burkina Faso and Zambia* between 2019 and 2021.



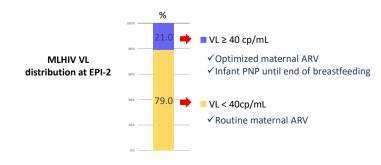




CONCLUSIONS AND KEY MESSAGES

- In resource-constrained settings, regardless of HIV prevalence and health system organization, a single HIV VL at early postnatal period can accurately identify infants requiring PNP for the breastfeeding period.
- ❖ For children born to mothers with VL ≥40 and <1000 cp/mL at EPI-2, and presently not eligible for PNP, the risk of high HIV exposure during breastfeeding remains high (6-fold that of children born to mothers with VL<40).</p>
- An alternative lower threshold (40 cp/mL) for PNP initiation at EPI-2 would greatly reduce this risk.

Proposed simplified PMTCT in resource-constrained contexts



RESULT#2: Risk of having a HIV VL ≥ 1000cp/mL at M6 or M12 according to EPI-2 VL								
Maternal VL at EPI-2 (cp/mL)	N	Crude RR [95%Cl]	N	aRR* [95%CI]	p-value			
	1398		1398					
<40		Ref.		Ref.				
[40 – 1000[6.0 [3.7–9.5]		6.0 [3.7–9.6]	<0.001			
≥1000		18.1 [12.7–25.8]		18.0 [12.6–25.7]	<0.001			

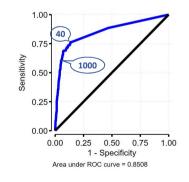
*aRR adjusted for ARV regimen at baseline (containing DTG or not); study arm (intervention or control); mother's age (15-19, 20-24, 25 and over). Other parameters not retained for the final model: country of origin, time of HIV diagnosis

Analysis by country

Burkina Faso (cp/mL)	N	aRR* [95%CI]	Zambia (cp/mL)	N	aRR [95%Cl]
	241			1157	
<40		Ref.	<40		Ref.
[40 - 1000[3.0 [1.3 - 6.6]	[40 - 1000[7.3 [4.1 – 13.1]
≥1000		6.5 [3.4 – 12.3]	≥1000		25.0 [16.2 - 38.5]

*aRR as above except for Burkina not adjusted for mother's age

RESULT#3: Performance of EPI-2 mother VL to predict future high HIV exposure (VL≥1000cp/mL)



VL threshold	Sensitivity	Specificity		
40 copies/mL	76%	86%		
1000 copies/mL	58%	95%		