DEPARTMENT OF GLOBAL HEALTH

UNIVERSITY of WASHINGTON

PRENATAL PREP EXPOSURE AND NEURODEVELOPMENT AMONG CHILDREN AT 48 MONTHS

939

Lauren Gomez[1], John Kinuthia[1,2], Felix Abuna[2], Sarah Benki-Nugent[1], Julia Dettinger[1], Anna Larsen[1], Mary Marwa[2], Nancy Ngumbau[2], Ben Odhiambo[2], Salphine Watoyi[2], Joshua Stern[1], Barbra A. Richardson[1], Grace John-Stewart[1], Jillian Pintye[1]

[1]University of Washington, Seattle, WA, US [2]Kenyatta National Hospital, Nairobi, Kenya

Background

- HIV pre-exposure prophylaxis (PrEP) is recommended during pregnancy and breastfeeding for those at high-risk for acquiring HIV
- PrEP use during pregnancy is safe when considering perinatal outcomes, however data on longer-term neurodevelopmental outcomes beyond the neonatal period are lacking
- We evaluated the association between prenatal PrEP exposure and child neurodevelopment

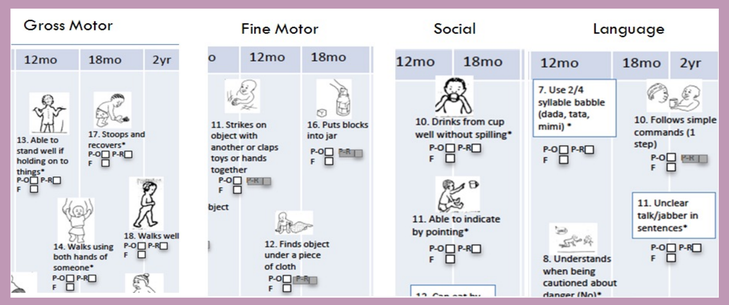
Methods

- In the parent study, HIV-negative women in Western Kenya were enrolled and offered oral tenofovir disoproxil fumarate (TDF)-based PrEP during pregnancy and followed through 9 months postpartum regardless of PrEP status (NCT03070600).
- A subset of mother-child pairs were enrolled into an extension cohort and followed through 60 months post-birth to evaluate long-term safety outcomes following prenatal PrEP exposure

Malawi Developmental Assessment Tool (MDAT)

- Culturally-relevant, low-cost, validated for ages 0-6yr
- 36-42 pass/fail items; continuous domain-specific scores
- Incorporates similar items found in Denver/Bayley's
- Requires intensive training, but is accessible





Gladstone M. et al. PLoS Med 2010.

Statistical methods

- Generalized estimated equations (GEE) regression models, clustered by facility, and adjusted for maternal education, infant age and sex, gestational age at birth, and partner HIV status
- PrEP exposure: PrEP prescription during ANC and self-reported PrEP pill swallowing
- Women who initiated PrEP postpartum, HIV-seroconverted, or had multiple births were excluded

In utero exposure to PrEP was not associated with neurodevelopmental outcomes through 48 months

Results

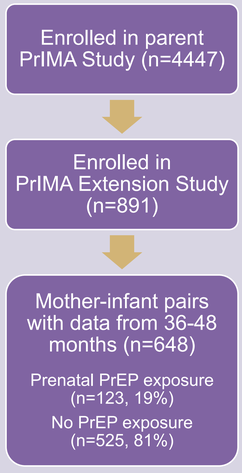


Figure 1. Inclusion flow chart

Table 1. Characteristics of mother-child pairs

Characteristic	PrEP exposure during pregnancy: Any (n=123)	None (n=525)
	% or Median (IQR)	
Maternal age, years	27 (25-35)	26 (25-33)
Currently married	92%	91%
Education, years	10 (8-12)	11 (8-13)
No. of living children	4 (3-5)	3 (2-4)
Partner living with HIV or of unknown status*	67%	37%
Preterm birth	10%	9%
Child age, months	28 (22, 33)	28 (21, 31)
Gestational age at PrEP initiation, weeks	27 (22-31)	-
Duration of PrEP use in pregnancy, weeks	12 (7-17)	-

Table 2: Domain specific neurodevelopmental scores at 36- and 48- mos. by prenatal PrEP exposure

	Median (IQR): Any PrEP exposure during pregnancy: Any (n=123)	None (n=525)	Adjusted Coeff (95% CI)	P-value*
36-months				
Social	30 (26, 31)	28 (26, 31)	0.07 (-1.61, 1.76)	0.86
Language	29 (27, 31)	29 (26, 31)	0.54 (-1.57, 2.66)	0.59
Fine Motor	30 (29, 34)	32 (28, 34)	-0.50 (-1.49, 0.49)	0.34
Gross Motor	31 (29, 33)	31 (29, 34)	-0.17 (-1.19, 0.85)	0.75
48-months				
Social	33 (31, 34)	33 (31, 34)	0.17 (-0.67, 1.01)	0.67
Language	34 (32, 35)	35 (33, 36)	-0.45 (-1.23, 0.33)	0.26
Fine Motor	38 (36, 39)	38 (37, 40)	-0.59 (-1.39, 0.21)	0.18
Gross Motor	36 (35, 37)	36 (35, 37)	-0.12 (-0.67, 0.43)	0.64

**Adjusted for child age and sex, gestational age at birth, maternal education, and partner HIV status and clustered by site*

Conclusion

- Child neurodevelopmental outcomes through 48 months did not differ by prenatal PrEP exposure
- Our findings suggest that PrEP use during pregnancy does not impact child neurodevelopment through early childhood
- These data support prior studies showing safety of prenatal PrEP use
- Contributes to the few data on neurodevelopment following ARV exposure without the confounder of HIV exposure



Consent for photography was given for non-commercial use. Depicted images are for illustrative purposes only; they do not imply any particular health status, attitudes, behaviors, or actions on the part of any person who appears in the photographs.

Acknowledgements

We gratefully thank the study staff and stakeholders, including the Siaya and Homa Bay County Ministry of Health, and community advisory board for their support on this project. **Most of all, we thank the women and children who have participated in these studies.**

Funding: R01AI25498, R01HD100201 NIH