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Prenatal PrEP exposure and language development among children at 5 years

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BACKGROUND

- There is some evidence that in utero antiretroviral (ARV) exposure may be associated with language delay, however evidence is limited and mostly derived from studies of children with exposure to both maternal HIV and ARVs
- 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 assessed the relationship between prenatal PrEP exposure and language development at 60 months among mother-child pairs without HIV.

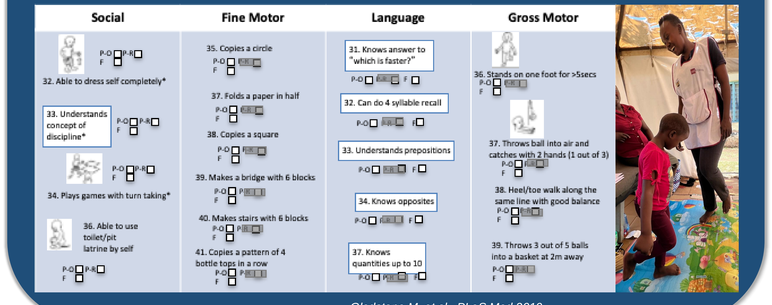
METHODS

- In the parent study, HIV-negative women in Western Kenya were enrolled and offered oral tenofovir disoproxil fumarate (TDF)-based oral 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 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 lower language scores at 5 years

RESULTS

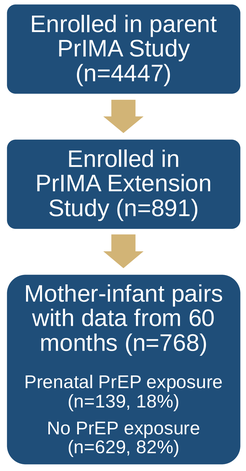


Figure 1. Inclusion flow chart

Table 1. Characteristics of mother-child pairs

Characteristic	PrEP exposure during pregnancy: Any (n=139)	None (n=629)
	% or Median (IQR)	
Maternal age, years	27 (22-32)	25 (22-30)
Currently married	91%	92%
Only primary school education	69%	55%
No. of living children	2 (1-3)	2 (1-3)
Partner living with HIV or of unknown status*	68%	38%
Preterm birth	10%	9%
Child age, months	60 (48, 62)	60 (48, 61)
Gestational age at PrEP initiation, weeks	27 (22-31)	-
Duration of PrEP use in pregnancy, months	2.4 (1.4-3.5)	-

Table 2: Language development score at 60 mos. by prenatal PrEP exposure

	N	Mean (SD)	Coefficient[1] (95% CI)	P-value
Any PrEP exposure during pregnancy				
No prep exposure	629	37.1 (1.6)	Ref·	
Prep exposure	139	36.8 (1.6)	-0.13 (-0.45, 0.19)	0.42
Trimester of first PrEP exposure				
No PrEP exposure	629	37.1 (1.6)	Ref·	
1st trimester	7	36.9 (1.2)	-0·13 (-1·73, 1·25)	0·77
2nd trimester	61	37.0 (1.6)	0·12 (-0·51, 0·26)	0·59
3rd trimester	71	36.7 (1.7)	-0·53 (-1·01, 0·05)	0·30
Duration of PrEP exposure during pregnancy				
No PrEP exposure	629	37.1 (1.6)	Ref·	
<4wks	11	36.5 (2.0)	-0.61 (-1.65, 0.43)	0.25
4-12wks	72	36.8 (1.6)	-0.30 (-0.74, 0.13)	0.17
>12wks	56	37.0 (1.6)	0.15 (-0.30, 0.61)	0.51

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

CONCLUSIONS

- Child language development at 5 years did not differ by prenatal PrEP exposure
- Our findings suggest that PrEP use during pregnancy does not impact language development through early childhood
- These data support prior studies showing safety of prenatal PrEP use
- Contributes to the few data on language development following ARV exposure without the confounder of HIV exposure
- Results suggest that exposure to ARVs without HIV exposure is not associated with adverse language development outcomes.



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