QUANTIFIED PRENATAL PREP EXPOSURE AND PERINATAL OUTCOMES AMONG KENYAN WOMEN

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PrIMA
PrEP IMPLEMENTATION FOR MOTHERS IN ANTENATAL CARE

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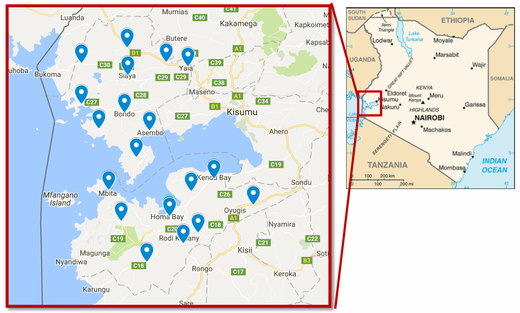
Background

- Safety studies of prenatal PrEP use to date rely on maternal self-report of PrEP adherence which may not accurately measure infant PrEP exposure.
- We evaluated perinatal outcomes following maternal PrEP use confirmed with tenofovir-diphosphate (TFV-DP) concentrations in dried blood spots (DBS).

Figure 1. Distribution of sites in Siaya and Homa Bay



Methods

- Data analyzed from a subset of women enrolled in a cluster RCT (NCT03070600) evaluating PrEP delivery strategies at 20 clinics in Western Kenya.
- Participants followed through 9 months postpartum
- TFV-DP levels were measured in DBS using liquid chromatography/tandem mass spectrometry among a random sample who self-reported PrEP use in the prior 30 days at ANC visits.
- PrEP-exposure during pregnancy was defined as having detectable TFV-DP in DBS
- Birth outcomes among women with and without prenatal PrEP exposure were compared, adjusting for partner HIV status, maternal age, gestational age, and syphilis using generalized estimating equations with a Poisson link.

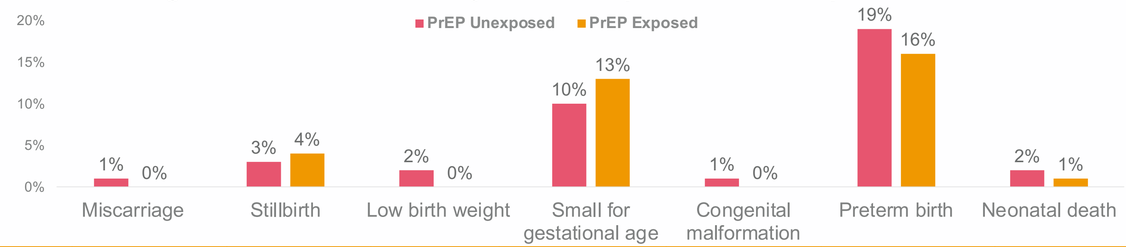
Results

Table 1. Baseline characteristics of participants

- 3608 mother-infant pairs
- 103 PrEP initiators randomly selected and had detectable TFV-DP in pregnancy (18% of all PrEP initiators)
- Key differences between PrEP exposed/unexposed in Table 1

	N (%) or Median (IQR)		
	PrEP Unexposed (n=3505)	PrEP Exposed (n=103)	p-value
Age (years)	24 (21, 28)	27 (23, 32)	<0.001
Partner living with HIV	2%	30%	<0.001
Partner HIV status unknown	30%	38%	0.01
Gestational age at enroll (wks)	24 (20, 30)	24 (20, 28)	0.14
Primigravida	28%	11%	<0.001
Positive Syphilis Results	1%	3%	0.03
STI diagnosis	2%	8%	<0.001

Figure 2: Birth outcomes by confirmed prenatal PrEP exposure status

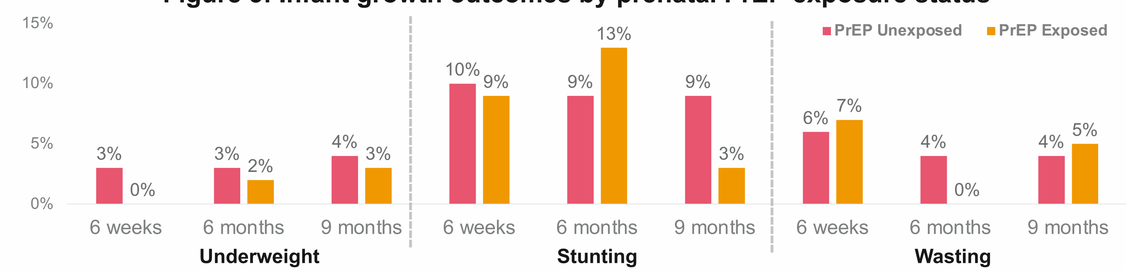


Adjusted PR (95% CI)	-	1.1 (0.1, 9.4)	-	1.4 (0.8, 2.5)	-	0.9 (0.6, 1.5)	0.7 (0.1, 5.0)
P-value	-	0.95	-	0.28	-	0.75	0.69

Adjusted for maternal age, partner HIV status (negative or positive/unknown), syphilis status, gestational age at enrollment
*PR and P-value not shown for miscarriage, low birth weight, and congenital malformation due to 0% prevalence among PrEP-exposed

No differences in adverse birth outcomes by quantified prenatal PrEP exposure detected

Figure 3: Infant growth outcomes by prenatal PrEP exposure status



Adjusted PR (95% CI)	-	0.5 (0.1, 3.1)	0.8 (0.2, 2.6)	1.1 (0.5, 2.8)	1.6 (0.8, 3.2)	0.4 (0.6, 3.0)	1.1 (0.4, 2.9)	-	1.2 (0.4, 3.5)
P-value	-	0.44	0.68	0.77	0.18	0.38	0.79	-	0.80

Adjusted for maternal age, partner HIV status (negative or positive/unknown), syphilis status, gestational age at birth
*PR and P-value not shown for underweight at 6 weeks and wasting at 6 months due to 0% prevalence among PrEP-exposed

No differences in adverse growth outcomes by quantified prenatal PrEP exposure detected

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Conclusions

- Similar to prior safety data that relied on self-reported PrEP use, we found no differences in adverse perinatal outcomes among Kenyan women with prenatal PrEP exposure confirmed with a biologic measure.
- Our results suggest that PrEP use during pregnancy does not influence birth outcomes
- Additional data from an extension cohort will assess longer term growth and development.

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