# Prenatal PrEP exposure and longitudinal birth outcomes in Kenya

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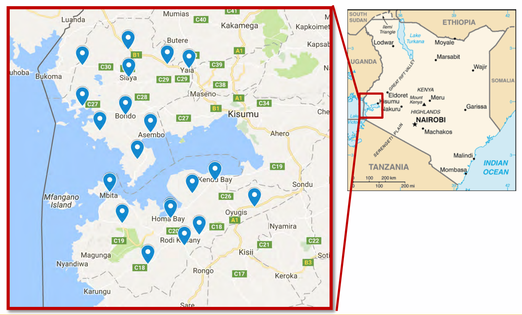
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PrIMA
PrEP IMPLEMENTATION FOR MOTHERS IN ANTENATAL CARE

## Background

- Pregnancy and postpartum are periods of high risk for HIV acquisition in high-burden settings.
- PrEP is an effective HIV prevention intervention.
- However, additional safety data are still needed on PrEP use in pregnancy and breastfeeding.
- The PrEP Implementation for Mothers in Antenatal Care (PrIMA) Study (NCT03070600) is a cluster randomized trial testing two strategies of PrEP counselling for Kenya mothers in antenatal care.
- We evaluated the relationship between prenatal PrEP exposure and birth outcomes among PrIMA participants as of March 2020.

Figure 1. Distribution of sites in Siaya and Homa Bay




## Methods

- Participants followed through 9 months postpartum
- PrEP exposure defined as any PrEP prescription during ANC
- Data on miscarriage, stillbirth, gestational age at birth, birth weight, birth length, and congenital malformations collected on all participants at six-weeks postpartum.
- Birth outcomes, including mortality, low birth weight (<2.5kg), small for gestational age (below 10th percentile), and preterm birth (gestational age <37 weeks) were compared by PrEP exposure status using generalized estimating equations (GEE) with a binomial link or a Gaussian link.

## Results

- 4,451 women enrolled during pregnancy.
- 4,261 delivered as of March 2020.
- 17% used PrEP at any time during pregnancy
- Compared to women who did not use PrEP, PrEP users were more likely to report HIV risk factors.

**Table 1: Characteristics of participants**

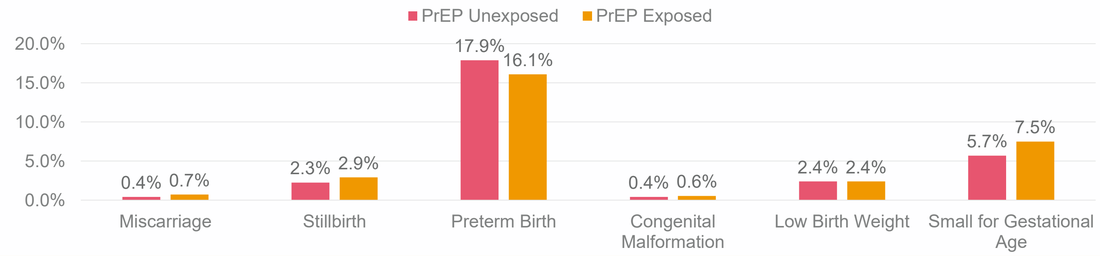
| | N (%) or Median (IQR) | | |
|---|---|---|---|
| | PrEP Unexposed (n=3,540) | PrEP Exposed (n=721) | p-value |
| **Age (years)** | 23.9 (20.9, 28.1) | 25.1 (21.0, 30.0) | <0.001 |
| **Partner HIV status** | | | |
| **HIV Negative** | 2411 (68.3%) | 280 (39.0%) | <0.001 |
| **HIV Positive** | 47 (1.3%) | 135 (18.8%) | |
| **No Current Partner** | 44 (1.2%) | 8 (1.1%) | |
| **Unknown** | 1026 (29.1%) | 295 (41.1%) | |
| **Gestational Age at Enrollment,** | 24.0 (20.0, 30.0) | 24.0 (20.0, 28.0) | 0.190 |
| **Lifetime number of sexual partners** | 2.0 (2.0, 3.0) | 3.0 (2.0, 4.0) | <0.001 |
| **Syphilis Test Results** | | | |
| **Negative** | 3453 (97.5%) | 685 (95.0%) | 0.001 |
| **Positive** | 27 (0.8%) | 15 (2.1%) | |
| **Not done** | 60 (1.7%) | 21 (2.9%) | |
| **Transactional sex** | 48 (1.4%) | 26 (3.6%) | <0.001 |
| **Diagnosed with or treated for an STI** | 67 (1.9%) | 37 (5.2%) | <0.001 |
| **Forced to have sex against your will** | 173 (4.9%) | 64 (9.0%) | <0.001 |
| **Intimate partner violence** | 224 (6.4%) | 111 (15.5%) | <0.001 |
| **Physically assaulted** | 183 (5.2%) | 70 (9.8%) | <0.001 |

**Table 2: Birth outcomes by PrEP exposure status**

| | Median (IQR) | | | | | |
|---|---|---|---|---|---|---|
| | PrEP Unexposed (n=3540) | PrEP Exposed (n=721) | Coeff (95% CI) | p-value | Adjusted Coeff (95% CI) | p-value |
| **Gestational age at birth (weeks)** | 38 (37, 40) | 38 (38, 40) | 0.22 (-0.63, 0.67) | 0.95 | 0.11 (-0.84, 1.06) | 0.81 |
| **Birthweight (kg)** | 3.5 (3.1, 3.8) | 3.4 (3.1, 3.8) | -0.01 (-0.10, 0.08) | 0.81 | 0.04 (-0.04, 0.13) | 0.32 |
| **Birth length (cm)** | 50 (50, 53) | 51 (50, 54) | 0.30 (-0.63, 1.23) | 0.11 | -0.40 (-2.03, 1.23) | 0.61 |

**~Adjusted for maternal age, partner HIV status (negative or positive/unknown), syphilis status**

Figure 2: Birth outcomes by PrEP exposure status




| | | | | | | |
|---|---|---|---|---|---|---|
| Odds Ratio (95% CI) | 1.77 (0.52, 6.03) | 1.29 (0.88, 1.91) | 0.88 (0.69, 1.11) | 1.31 (0.48, 3.59) | 1.02 (0.58, 1.78) | 1.32 (0.95, 1.85) |
| P-value | 0.36 | 0.20 | 0.28 | 0.60 | 0.95 | 0.10 |
| Adjusted odds ratio~ (95% CI) | 2.91 (0.76, 11.08) | 0.85 (0.43, 1.68) | 0.70 (0.53, 0.92) | Sample too small | 1.14 (0.65, 2.00) | 1.02 (0.57, 1.83) |
| P-value | 0.12 | 0.65 | 0.01 | Sample too small | 0.65 | 0.95 |

~Adjusted for maternal age, partner HIV status (negative or positive/unknown), syphilis status



*Consent provided for all photographs

## Conclusions

- **Our results suggest that PrEP use during pregnancy does not influence adverse birth outcomes.**
- Additional data from PrIMA and an extension cohort will assess longer term infant growth and development outcomes.

## Acknowledgements

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## A collaboration of:

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