Pregnancy and Birth Outcomes Following Oral PrEP Use by Objective Levels of TDF/FTC in South Africa

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BACKGROUND

- Studies of TDF/FTC for PrEP measure exposure using self-reported recent adherence, which may over or under-report actual use.
- Ours is one of the first studies to compare pregnancy and birth outcomes using objective levels of tenofovir diphosphate (TDF-DP) in dried blood spots (DBS) in pregnant women.

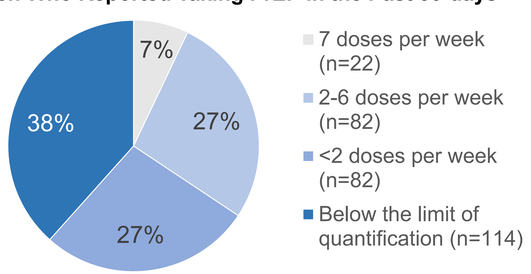
METHODS

- Enrolled pregnant women >15 years old without HIV at first antenatal care visit.
- Quantified TDF-DP levels in DBS in pregnant women who reported taking oral PrEP in the past 30 days (in 2nd or 3rd trimester).
- Logistic regression models with generalized estimating equations to evaluate **pregnancy and birth outcomes by TFV-DP (any vs. none),** adjusting for age, gestational age at baseline & gravidity.

RESULTS

- In 300 pregnant women who reported taking TDF/FTC as PrEP during pregnancy
  - **Median age = 26 years** (IQR=23-32 years)
  - **Gestation age at baseline=16 weeks** (IQR=12-21 weeks)

Figure 1. Quantified TDF-DP levels in DBS in Pregnant Women Who Reported Taking PrEP in the Past 30-days



- Over 1/3 had no TFV-DP in DBS (38%)
- 54% of women had levels comparable with 2-6 doses/week or <2 doses/week
- 7% had levels comparable with 7 doses/week in those reporting taking PrEP in last 30 days

Pregnancy & birth outcomes did not differ by PrEP exposure per TFV-DP levels, incl. pregnancy loss, pre-term birth or infants born small for gestational age

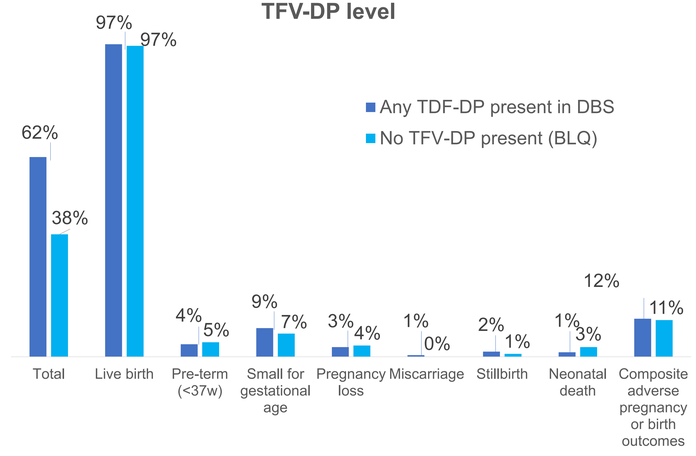
- **Older age, higher education and condomless sex in past month were correlated with** having TFV-DP concentrations corresponding with **>2 doses/week**
- Comparing women with **any TFV-DP in DBS (62%)** with those with **no TFV-DP (38%; Fig 1):**
  - 97% vs. 96.5% had live births (aOR = 1.35; 95% CI=0.45, 4.02)
  - **No difference in pregnancy or birth outcomes by TFV-DP level (Table 1)**
  - **Composite adverse pregnancy & birth outcome**: pregnancy loss (miscarriage, stillbirth), neonatal death, pre-term (<37 weeks gestation) and small for gestational age.
    - **12% of women with TFV-DP had an adverse pregnancy or birth outcome, vs. 11% in women without any TFV-DP** (aOR=0.98, 95% CI=0.47, 2.07) (**Fig 2)**

Table 1. Pregnancy and birth outcomes in pregnant women who reported taking oral PrEP by TFV-DP level (n=300 pregnant women on oral PrEP)

	Any TFV-DP present in DBS	No TFV-DP present (BLQ)	OR	aOR*
Total	186 (62%)	114 (38%)		
Live birth	180 (97%)	110 (96.5%)	1.55 (0.52, 4.58)	1.35 (0.45, 4.02)
Pre-term (<37w)	7 (3.9%)	5 (4.5%)	0.71 (0.23, 2.18)	0.51 (0.09, 2.74)
Small for gestational age	16 (8.9%)	8 (7.2%)	1.24 (0.51, 3.01)	1.24 (0.50, 3.08)
Pregnancy loss	6 (3%)	4 (3.5%)	0.81 (0.19, 3.71)	0.54 (0.12, 2.54)
Miscarriage	1 (0.5%)	0 (0%)		
Stillbirth	3 (1.6%)	1 (0.9%)	1.97 (0.20, 19.33)	2.67 (0.32, 22.11)
Neonatal death	2 (1.4%)	3 (3%)		
Composite adverse pregnancy or birth outcome	**22 (11.8%)**	**13 (11.4%)**	1.04 (0.45, 2.16)	0.98 (0.47, 2.07)

TFV-DP: tenofovir diphosphate; aOR: adjusted odds ratio; BLQ: below limit of quantification
* adjusted for maternal age and gestational age at baseline, gravidity

Figure 2. Pregnancy & birth outcomes in pregnant women (n=300) who reported taking oral PrEP by TFV-DP level



CONCLUSIONS

- Our study presents one of the first data comparing objective oral PrEP use with birth outcomes.
- **Pregnancy & birth outcomes did not differ by PrEP exposure per TFV-DP levels, including pregnancy loss, pre-term birth or small for gestational age.**
- **Limitations: s**mall sample size and differing time for TFV-DP analysis in pregnancy.
- **Our study provides further evidence that TDF-DP is safe for use in pregnancy and highlights the importance of counseling women on the effective use and safety of oral TDF/FTC as PrEP during pregnancy.**

ADDITIONAL KEY INFORMATION

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