The Impact of Daily Oral PrEP on Maternal Bone Mineral Density During Pregnancy and Postpartum: IMPAACT 2009

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No conflict of interest

Background

- Daily oral Pre-exposure prophylaxis (PrEP) as tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) –TDF/FTC is an important component of HIV prevention in pregnant and postpartum women. *
- No safety concerns have been noted for mother and pregnancy outcome
- Physiological changes during pregnancy as well as breastfeeding may exacerbate bone loss irrespective of being on TDF/FTC.
- We compared bone mineral density of women who initiated PrEP to women who declined PrEP during pregnancy and postpartum on this study.

**Stranix-Chibanda L 2021; Wang L 2013*

Methods: Study design

- IMPAACT 2009 was a parallel observational cohort study which assessed oral PrEP adherence and safety during pregnancy and postpartum.
- Eligible pregnant individuals ≤ 32 weeks gestation aged 16-24 years who were HIV negative were enrolled in four African countries.
- Participants opted to initiate or decline TDF/FTC at enrolment and could change throughout the study.
- Mother-infant pairs completed follow up visits through 26 weeks postpartum.

Methods: Analysis

- Maternal bone mineral density (BMD) of the lumbar spine and hip was assessed using dual-energy X-ray absorptiometry (DXA) scans at delivery and 26 weeks postpartum.
- PrEP exposure was defined as initiating PrEP at enrolment or before giving birth.
- Eligible for analysis were maternal participants who had DXA scan results within the analysis window.
- Differences in mean maternal BMD between antenatal PrEP-exposed and -unexposed participants at delivery and at 26 weeks postpartum were evaluated using t-tests assuming unequal variance. Differences in mean (PrEP-exposed and unexposed) and 95% confidence intervals (CIs) were calculated.

Results

- Between May-2022 and December 2022 , 350 women were enrolled ; 233 PrEP-exposed and 117 PrEP-unexposed , of whom 310 were retained through 26 weeks postpartum.
- Lost to follow-up being the main reason prior and post delivery for study discontinuation.

Results: Maternal Demographics

	PrEP exposed analysis set (N=201)	PrEP unexposed analysis set (N=99)	Total (N=300)
Country			
Malawi	19 (9.5%)	22 (22.2%)	41 (13.67%)
Uganda	44 (21.9%)	18 (18.2%)	62 (20.67%)
South Africa	23(11.4%)	10 (10.1%)	33(11.0%)
Zimbabwe	115 (57.2%)	49 (49.5%)	**164 (54.67%)**
Age			
Median	21.0	21.0	**21.0 (19.0, 22.0)**
Weeks on PrEP during Pregnancy			
Mean (SD)	11.76 (5.34)		**11.45 (5.39)**
Breastfeeding			
Yes	195 (97.0%)	93 (93.9%)	**288 (96.0%)**
No	6 (3.0%)	6 (6.1%)	**12 (4.0%)**

.SD=Standard deviation

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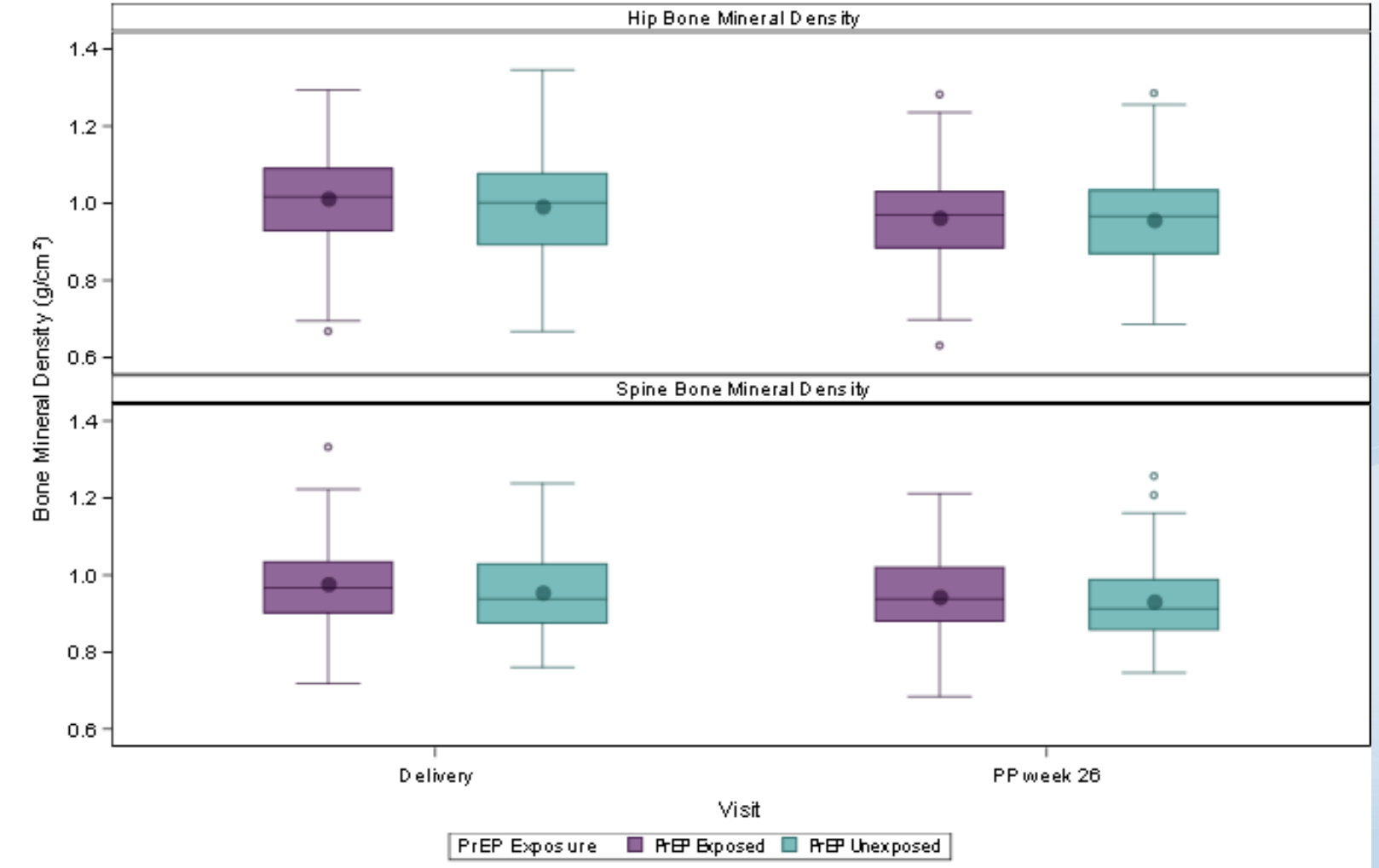
Results: Bone Mineral Density

- DXA scan availability either Hip or Spine scan at:
- Delivery:
  - PrEP exposed 171 (73%) had either Hip
  - PrEP unexposed 86 (74%)
- 26 weeks postpartum:
  - PrEP exposed 166 (71%)
  - PrEP unexposed 86 (74%).



Results: Bone Mineral Density

	PrEP exposed (N=201)	PrEP unexposed (N=99)	Mean difference for exposed-unexposed (95% CI)	P value
Hip BMD (g/cm^2)				
Delivery mean (SD) and T-test	1.01(0.11)	0.99 (0.13)	**0.02 (-0.01,0.05)**	**0.23**
PP week 26 mean (SD) and T-test	0.96 (0.11)	0.96(0.12)	**0.01(-0.03, 0.04)**	**0.72**
Spine BMD (g/cm^2)				
Delivery mean (SD) and T-test	0.98 (0.11)	0.95 (0.11)	**0.02 (-0.01,0.05)**	**0.13**
PP week 26 mean (SD) and T-test	0.94 (0.11)	0.93 (0.10)	**0.01(-0.02,0.04)**	**0.39**

PP week 26= Postpartum week 26; SD= Standard deviation
CI confidence intervals

Conclusion

- No difference in mean maternal BMD was observed at delivery and postpartum week 26 by PrEP exposure.
- Combining this with the other maternal safety and infant safety findings this study supports the use of TDF/FTC by pregnant and postpartum women to prevent HIV.
- Additional analysis are underway to adjust for concomitant drug exposure and breastfeeding.
- These findings are reassuring and support continued use of TDF/FTC for PrEP in pregnancy and postpartum.

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- Any Questions welcomed !