01112



A Point-of-Care Urine Test Improves Accuracy of Self-Reported PrEP Adherence among women in Uganda

Kidist Zewdie[1], Timothy Muwonge[2], Timothy Ssebuliba[2], Felix Bambia[2], Josephine Badaru[2], Olivia Nampewo[2], Gabrielle Stein[1], Kenneth Mugwanya[1,3], Katherine Thomas[3], Christina Wyatt[4], Michael T. Yin[5], Guohong Wang[6], Monica Gandhi[7], Andrew Mujugira[2,3,] Renee Heffron[8]

[1]Department of Epidemiology, University of Washington, Seattle, WA, USA, [2]Infectious Diseases Institute, Makerere University, Kampala, Uganda, [3]Department of Global Health, University of Washington, Seattle, WA, USA, [4]Department of Medicine, Division of Nephrology, Duke University School of Medicine, Durham, NC, USA, [5]Department of Medicine, Division of Infectious Diseases, Columbia University, New York, US, [6]Department of Toxicology, Abbott, Santa Rosa, CA, USA, [7]Department of Medicine, University of California San Francisco, San Francisco, CA, USA, [8]Department of Medicine, University of Alabama at Birmingham, Birmingham, USA

BACKGROUND

- High HIV incidence rates and low PrEP persistence and adherence among young women in East and Southern Africa
- Drug-level monitoring could help improve PrEP adherence in young women
- Point-of-care tenofovir (POC TFV) urine test: detects tenofovir (TFV) concentrations in urine with 96% sensitivity and 100% specificity; takes <5 minutes to run and is anticipated to cost <$2 per test (once commercially available)

Study objective: Determine whether the POC TFV assay improves self-reporting of PrEP use and sexual behavior

METHODS

- Participants: sexually active women without HIV, ages 16-25 years in Kampala, Uganda
- Follow-up: quarterly for 24 months with HIV prevention counseling, PrEP dispensation, and adherence counseling
- POC TFV test introduced as part of routine study procedures half-way through the study
- PrEP adherence measured via:
  - a) self-report (using most or all the time),
  - b) pill counts (≥80% pill use)
  - c) quantification of tenofovir diphosphate (TFV-DP) in dried blood spots (DBS)
- Accurate self-reported PrEP use = self-reported high PrEP adherence + detectable levels of TFV-DP in DBS (≥25 fmol/punch)
- Statistical methods: generalized estimated equation (GEE) logistic regression model with an independent correlation structure

ACKNOWLEDGEMENTS

We have tremendous gratitude for the women who participated in this study and persevered through research appointments during the Covid-19 pandemic; and for the talented staff at the Infectious Diseases Institute clinical research site in Kasangati, Uganda, for the innovation and precision that they applied to operationalize this study.

Participants

- 146 Ugandan women used the urine POC test
- Median age was 19 and 50% were between 18-21 years
- 88% were unmarried with a steady partner; 12.0% were unmarried without a steady partner
- 49% earned their own income; 97% received some financial or material support from a partner

Baseline sexual behavior

Partners HIV status	
Negative	46 (32%)
Unknown	99 (68%)
Any condomless sex, last 3 months	
No	35 (24%)
Yes	111 (76%)
Any condomless sex, last week	
No	82 (56%)
Yes	64 (44%)
Multiple partners in past 3 months	
No	47 (32%)
Yes	99 (68%)

We observed greater reporting of **condomless sex, low PrEP adherence**, and more **accurate** reports of PrEP adherence with the urine POC TFV test

POC urine test results and PrEP adherence by pill count and self-reported sexual behavior

Characteristic	All Tested, N = 146 (column %)	Not detectable, N = 98 (row %)	Detectable, N = 48 (row %)	Kappa (95% CI)
Adherence by pill count, past month				0.16 (0.04, 0.29)
Low	45 (31%)	37 (82%)	8 (18%)	
High	101 (69%)	61 (60%)	40 (40%)	
Adherence by DBS				0.51 (0.34, 0.68)
Undetectable	97 (83%)	79 (81%)	18 (19%)	
Detectable	20 (17%)	3 (15%)	17 (85%)	
Self-reported PrEP use, past month				0.23 (0.08, 0.39)
Low	77 (53%)	60 (78%)	17 (22%)	
High	69 (47%)	38 (55%)	31 (45%)	

Self-reported adherence and sexual behavior change before and during the POC test

	Visit with point of care urine test: Yes	No	OR (95% CI)	p-value
Self-reported adherence				
High	69 (47%)	106 (73%)	Ref.	
Low	77 (53%)	40 (27%)	2.96 (1.89, 4.67)	0.001
Any condomless sex, last 3 months				
Yes	110 (75%)	98 (68%)	1.47 (1.04, 2.06)	0.029
No	36 (25%)	47 (32%)	Ref.	
Any condomless sex, last week				
Yes	36 (25%)	44 (30%)	0.75 (0.47,1.19)	0.2
No	110 (75%)	101 (70%)	Ref.	

- During visits where the POC test was administered, there was a 61% concordance between self-reported PrEP adherence and detectable level TFV-DP measured by DBS (OR 4.86, 95% CI: 2.85, 8.30, p<0.001)

CONCLUSIONS

- Introduction of a POC urine test for TFV substantially improved the accuracy of self-reported PrEP adherence in this sample of young women from Uganda
- Moderate concordance between the POC urine TFV and TFV-DP in DBS
- Greater reports of condomless sex and low PrEP adherence when the POC urine test was used
- Future research should estimate the effectiveness of the test when integrated into a PrEP program for adherence monitoring

Author contact: Kidist Zewdie (email: kzewdie1@uw.edu)

Funding: The Kampala Women's Bone Study was funded by the Eunice K. Shriver National Institute of Child Health and Human Development (R01HD089843). KZ was supported by an STD/AIDS Research Training Grant (T32 AI07140) funded by the National Institute of Allergy and Infectious Diseases. Gilead Sciences, Inc . donated FTC/TDF medication.