Point-of-Care Urine Self-Testing Feasibility to Measure TFV Adherence and Predict Viral Suppression

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Renata Buccheri[1,2], Megan J. Heise[1], Kevin Sassaman[1], Tyler Martinson[1], Hannah R. Schmidt[1], Alexa B. D'angelo[3], Dustin T. Duncan[4], Keith J. Horvath[5], Sabina Hirshfield[6], Renessa Williams[7], Mallory O. Johnson[1], Christian Grov[3], Adam Carrico[8], Monica Gandhi[1], Matthew A. Spinelli[1]

[1]University of California San Francisco, San Francisco, CA, US, [2]Vitalant Research Institute, San Francisco, CA, US, [3]City University of New York Graduate School of Public Health and Health Policy, New York, NY, US, [4]Columbia University Mailman School of Public Health, New York, NY, US, [5]San Diego State University, San Diego, CA, US, [6]State University of New York - Downstate Health Sciences University, Brooklyn, NY, US. [7]University of Miami School of Nursing and Health Studies, Coral Gables, FL, US, [8]Florida International University, Miami, FL, US.

BACKGROUND

- Only 68% of U.S. men who have sex with men (MSM) with HIV have achieved virologic suppression (VS), sufficiently low to compromise Ending the HIV Epidemic goals
- Objective monitoring of antiretroviral therapy (ART) adherence via drug-level testing can inform interventions
- Our group developed a rapid, low-cost urine point-of-care (POC) tenofovir (TFV) assay as an objective adherence metric
- Self-administration of the urine TFV assay among people with HIV (PWH) has not been previously studied

METHODS

- We assessed the association between a self-administered POC urine TFV rapid assay and VS in MSM with HIV on TFV-based ART, all of whom reported adherence challenges or virologic non-suppression
- Participants were recruited through a geosocial networking app, received mailed urine tests, and provided plasma at a certified laboratory for viral load testing
- Logistic regression examined the effect of TFV detection in urine on the likelihood of VS
- Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the urine assay compared to VS were calculated

RESULTS

- **87% of 762 MSM with HIV on a TFV regimen completed and uploaded a photo of the urine test to the study management system**

Self-administered at-home urine tenofovir testing is feasible and highly predictive of viral suppression

RESULTS

- Analytic sample characteristics (n=663):
  - Average age: 42.6 years (SD ± 11)
  - Race/ethnicity: 46% White, 31% Black, 17% multiracial/other, 2% Asian, 1% Native American; 21% Latino
  - 99% on ART with tenofovir alafenamide (TAF)
  - 58% reported stimulant use in past 3 months

Table: Comparison of Viral Suppression and Adherence on the POC Urine Tenofovir Test

	Viral Load		
POC Urine Result	**Suppressed (<200 copies/mL)**	**Unsuppressed (³200 copies/mL)**	
TFV Detected	**509**	**46**	**PPV = 92%** (95% CI: 89.1 – 93.9)
TFV Not Detected	**60**	**48**	**NPV = 44%** (95% CI: 34.9 - 54.3)
	Sensitivity = 89% (95% CI: 86.7 – 91.9)	**Specificity = 51%** (95% CI: 40.5 - 61.5)	**Accuracy = 84%** (95% CI: 81 – 86.7)

RESULTS

- 86% were virally suppressed
  - Of those, 11% had low adherence as measured via urine TFV detection
- **TFV detection was significantly associated with VS (OR=8.85, 95% CI 5.46-14.44, p<.001)**
- Among those with no detectable TFV:
  - 12% without VS reported >80% adherence
  - 61% with VS reported >80% adherence

CONCLUSIONS

- These results are the first to show the feasibility of self-monitoring of adherence using a POC urine test
- TFV presence in urine strongly predicted VS with a PPV of 92%, opening the potential for self-testing as an adherence check in-between viral load testing in the clinic
- Non-suppression despite TFV detection may indicate suboptimal adherence or ART resistance, while low TFV with VS may herald future treatment failure; both situations should prompt further intervention
- POC TFV testing offers a real-time strategy to identify adherence challenges and timely interventions for TFV-based ART

ADDITIONAL INFORMATION

Author Contact Information

Renata Buccheri – Renata.Buccheri@ucsf.edu

Matthew Spinelli – Matthew.Spinelli@ucsf.edu

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