At-Home Urine Tenofovir Testing is Feasible and Correlates with Adherence in Dried Blood Spots

1093

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BACKGROUND

- Objective, at-home measures of antiretroviral therapy (ART) adherence offers a convenient strategy to support remote HIV care.
- Urine point-of-care (POC) tenofovir (TFV) assays and TFV-diphosphate (TFV-DP) levels in dried blood spots (DBS) are objective measures of adherence, but their correlation has never been evaluated
- Further studies needed to assess acceptability of self-collecting samples for urine and DBS
- **Aims:**
  - ✓ Assess the ability of at-home urine TFV assays to predict adherence defined by TFV-DP in
  - ✓ Examine acceptability of self-collecting urine and DBS

METHODS

- Longitudinal analysis of the LetSync cohort enrolling couples with ≥1 partner living with HIV; index participants were Black men who have sex with men (BMSM)
- Recruited across the U.S.; follow-up at 5 timepoints (baseline; months 2, 4, 6, and 8)
- Participants self-collected paired urine POC TFV tests and DBS samples at home
  - ✓ Urine POC TFV results were submitted via photographs of completed tests
  - ✓ DBS cards were mailed for TFV-DP quantification by LC–MS/MS
- Adequate adherence was defined as ≥4 doses/week based on validated DBS TFV-DP thresholds, and above the POC assay threshold for urine (1,500 ng/ml)
- Generalized estimating equation (GEE) models assessed associations between urine TFV detection, DBS-defined adherence, and sample return
- Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the urine assay were calculated relative to DBS

RESULTS

- **Participants:** 86 people with HIV (PWH)
  - ✓ Median age 48 years (IQR, 35-58)
  - ✓ Race/ethnicity: 53% Black, 15% White, 24% multiracial/other, 5% Asian, 1% Native American; 30% Latino

Urine POC TFV testing provides a rapid, non-invasive method for **at-home ART adherence monitoring**, with high acceptability and strong correlation with another objective metric, tenofovir diphosphate (TFV-DP) in dried blood spots

RESULTS

- **Samples:** 341 paired same-day urine and DBS observations
- Participants with detectable urine TFV were nearly three times as likely to meet adequate DBS-defined adherence (≥4 doses/week) compared with those without detectable urine TFV
  - ✓ aRR = 2.86 (95% CI: 1.37–5.99), $p = 0.005$
- Urine samples had higher return rates than DBS across all timepoints
  - ✓ aRR = 1.04 (95% CI: 1.01–1.08), $p = 0.013$
  - ✓ 92% urine (396/430) vs 88% DBS (379/430)
- By month 8, participants with detectable viral loads had lower DBS return rates ($p = 0.013$), while the urine assay return remained high in this group

Table: Cross-tabulation of urine TFV POC test results and adherence classification based on DBS TFV-DP concentration.

Urine TFV POC Result	Adequate Adherence (≥4 doses/week)	Poor Adherence (<4 doses/week)	
TFV Detected	265	46	PPV = 85% (95% CI: 81–90)
TFV Not Detected	9	21	NPV = 70% (95% CI: 50–87)
	Sensitivity = 97% (95% CI: 95–99)	Specificity = 31% (95% CI: 18–44)	Accuracy = 84% (95% CI: 80–88)

CONCLUSIONS

- **Adherence Correlation**
  - ✓ First comparison of at-home urine TFV testing with DBS TFV-DP (in this case, with self-collected samples)
  - ✓ Urine TFV detection was strongly associated with DBS-defined adherence (≥4 doses/week), supporting the reliability of urine POC testing as an objective adherence measure

CONCLUSIONS

- **Pharmacologic Interpretation**
  - ✓ Lower specificity of urine TFV testing reflects differences in adherence ttme windows captured.
  - ✓ Intermittent ART use can result in detectable urine TFV even when DBS TFV-DP levels are below the threshold, explaining high sensitivity but lower specificity
- **Clinical Interpretation**
  - ✓ Urine TFV testing alone cannot exclude suboptimal long-term adherence.
  - ✓ Repeated non-detectable urine results may indicate emerging adherence challenges and support early intervention prior to virologic failure.
  - ✓ Higher return rates for urine samples across all time points suggest greater practicality and acceptability of urine sampling for at-home adherence monitoring than DBS
- **Implementation Implications**
  - ✓ Urine POC test can be self-administered at home, is non-invasive, and provides results within minutes. These attributes make it especially well-suited for decentralized and telehealth-based HIV care as a scalable, affordable tool for interim adherence monitoring.

ADDITIONAL KEY INFORMATION

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PLAIN LANGUAGE SUMMARY:
An at-home urine test provided quick information about recent HIV medication use and showed strong agreement with blood-based laboratory testing for adherence. Because it is easy to use and return, the urine test may support remote. telehealth HIV care.