Point-of-Care Urine Tenofovir Test Predicts Future PrEP Discontinuation among Young PrEP Users

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BACKGROUND

- Young men who have sex with men (MSM) and transgender women (TGW) have greater challenges with PrEP adherence and persistence, despite high HIV incidence
- POC urine tenofovir (TFV) testing permits real-time monitoring of TFV exposure at low cost
- We performed urine point-of-care (POC) testing among young PrEP users (age<30) at a high-volume PrEP clinic to examine:
  1. the relationship between low PrEP adherence and future PrEP discontinuation
  2. the accuracy of POC testing vs. liquid chromatography tandem mass spectrometry (LC-MS/MS)

METHODS

- Participants (age<30) were recruited at the time of a daily PrEP (F/TDF or F/TAF) visit and asked to provide a urine sample and complete a survey of HIV risk behavior, PrEP adherence, POC urine test acceptability (6/2021-5/2023)
- Assay has a cut-off of 1,500 ng/mL, indicative of no use in 3-4 days for F/TDF and no use in 1-2 days for F/TAF
- Examined accuracy vs. gold-standard of LC-MS/MS
- Adjusted logistic regression models analyzed the relationship between POC urine result at index visit and PrEP discontinuation, defined as no PrEP follow-up within ≥120 days of observation, given that only 90-day prescriptions were provided

RESULTS

- Sample: 100 participants with median age of 27 (**Table 1**)
- 12% identified as gender queer, 2% as TGW
- 23% identified as Hispanic, 20% Asian, 10% Black

- Low urine TFV at the index visit predicted future PrEP discontinuation (AOR 6.1; 95% CI: 1.4-11; p=0.005; 71% Sensitivity; 90% Specificity)
- Self-reported low adherence (<4 pills weekly) was not associated with PrEP discontinuation (p=0.18; 47% Sensitivity.; 83% Specificity)

Table 1: Study Participant Demographics

Age, median (IQR)	27 (21-29)
	Overall % (N=100)
Sexual orientation/Gender identity	
MSM	86
Gender queer	12
TGW	2
Race/Ethnicity	
White	43
Asian	20
Black	10
Latinx	23
Native American	2
Pacific Islander	2
Suboptimal PrEP adherence	
by POC urine TFV assay (<1,500ng/ml)	19
PrEP discontinuation	
(non-retention in care, >120 days without follow-up or refills)	21

Table 2: Past PrEP Discontinuation Reasons

Decreased sexual activity during COVID	32%
Perceived lower HIV risk	29%
Access issues (provider change, pharmacy)	15%
Side effect concerns	10%
Forgetfulness	5%
Cost barriers	2%

Figure: Performance of the POC Assay vs. Laboratory-based LC-MS/MS

POC urine LFA	LC-MS/MS: Positive	LC-MS/MS: Negative	
Positive	81	2	PPV = 97.6% (95% CI: 91.6-99.3%)
Negative	0	17	NPV = 100% (95% CI: 80.5-100%)
	Sensitivity = 100% (95% CI: 95.6-100%)	Specificity = 89.5% (95% CI: 66.9-98.7%)	

RESULTS CONTINUED

- Many (41%) reported temporarily stopping PrEP for more than a week in the past, mostly within the last half year
  - Most (61%) discontinued due to perceived lower HIV risk or lower sexual activity during COVID-19 (**Table 2**)
- At the index visit, 19% had low urine TFV
  - 21% went on to discontinue PrEP after the index visit
  - All of those with low TFV reported condomless anal sex with ≥2 partners of unknown status
- Assay showed 98-100% positive and negative predictive value vs. lab-based LC-MS/MS (**Figure)**
- Urine testing highly acceptable: 98% wanted to be able to use independently; 94% would if instead a clinician administered it
  - 90% thought test could be useful to ensure protection before sex such as for 2-1-1 PrEP

CONCLUSIONS

- In a diverse sample of young MSM and transgender women using PrEP, urine TFV POC testing predicted future PrEP discontinuation more accurately than self-report; with very high positive and negative predictive value compared to LC-MS/MS
- Urine POC testing can be a powerful tool for objectively measuring PrEP adherence and targeting PrEP adherence interventions towards those most likely to discontinue PrEP in the future despite ongoing HIV risk

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