BACKGROUND
Existing biomarkers of PrEP adherence are limited by:
• High cost of assays
• Need to often ship samples offsite for analysis
• Need for specialized laboratory equipment and trained personnel

We developed a novel immunoassay that detects tenofovir (TFV) in urine within minutes, for eventual use at the point of care (POC)

OBJECTIVES
1. Compare urine TFV measurements by enzyme-linked immunoassay (ELISA) to TFV levels in plasma
2. Evaluate the ability of the immunoassay to predict HIV protection

METHODS
Participants: Sub-cohort of PrEP users in HIV serodiscordant couples (figure below) and HIV seroconverters from the Partners PrEP Study

TFV measurement: Stored urine was analyzed by ELISA; date-matched plasma was analyzed by liquid chromatography-tandem mass spectrometry (LC-MS/MS)

Analysis:
1. Calculated sensitivity and specificity of detectable urine TFV levels (≥ assay lower limit of quantification [LLOQ] of 1000 ng/mL) for detecting any plasma TFV (≥ LC-MS/MS LLOQ of 0.31 ng/mL)
2. Assessed whether urine TFV ≥1500 (a cutoff associated with PrEP dosing in the past day in a directly-observed therapy study) was predictive of HIV protection using a nested case-control design
   • Case samples: Collected at the visit of first HIV detection
   • Control samples: From participants who were HIV-negative at case HIV detection; matched 35:1 using risk set sampling
   • Rate ratios (RR) estimated using conditional logistic regression adjusting for age, sex, report of condomless sex at enrollment

RESULTS
292/300 individuals in the sub-cohort had an available urine sample
• 39% were female
• median age: 33 (IQR: 28-39)
22/52 cases had an available urine sample
• 55% were female
• median age: 33 (IQR: 27-39)

A novel urine tenofovir test showing recent PrEP adherence predicts a 71% HIV risk reduction among participants in a large PrEP trial.

CONCLUSIONS
• The novel urine TFV immunoassay was predictive of HIV protection in a large completed PrEP trial and had good sensitivity and specificity for TFV detection in plasma
• The assay could be a valuable tool for facilitating real-time feedback of PrEP use to both provider and patient, allowing for immediate adherence intervention

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Partners PrEP Study site PIs:

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For more information, contact Randy Stalter: rstalter@uw.edu