EVALUATING URINE WITH DRIED BLOOD SPOTS TO ASSESS TENOFOVIR LEVELS FOR PREP ADHERENCE

Abstract Number:

400

Abstract Type:

General Abstract

Authors:

Rupa R Patel[1], Linden Lalley-Chareczko[2], Laura C Harrison[1], Peter Anderson[3], K. Rivet Amico[4], Rachel Presti[1], Kenneth H Mayer[5], Ganesh S Moorthy[6], Athena Zuppa[7], Helen C Koenig[6]

Institutions:

[1]Washington University in St. Louis, St. Louis, MO, [2]Philadelphia FIGHT, Philadephia, PA, [3]University of Colorado Denver, Aurora, CO, [4]University of Michigan, Ann Arbor, MI, [5]Fenway Health, Boston, MA, [6]University of Pennsylvania, Philadephia, PA, [7]Children's Hospital of Philadelphia, Philadelphia, PA

Presenting Author:

Dr Rupa Patel, MD

Background:

Antiretroviral pre-exposure prophylaxis (PrEP) is effective in preventing HIV when taken daily. However there are limited ways to objectively monitor adherence in the clinic. Urine has been shown to be highly correlated with plasma tenofovir (TFV) levels, with urine TFV levels >1000 ng/mL demonstrating recent (last 1-2 days) adherence to TFV, levels 10-1000 demonstrating adherence within the previous week but not in the last 1-2 days, and levels <10 indicative of no TFV in the previous week. In this study, we determined the sensitivity of urine TFV levels with dried blood spot (DBS) values.

Methods:

Fifty-three paired urine-DBS specimens were obtained from 53 patients enrolled in a PrEP adherence study at Washington University in St. Louis between May and August 2016. Sensitivity, specificity, and positive and negative predictive values (PPV, NPV) were calculated for urine TFV >1000 ng/mL, using DBS as a gold standard with DBS TFV-disphosphate (DP) ≥700 (4 or more doses/week) and ≥1250 (7 or more doses/week) fmol/punch and DBS emtricitabine-triphosphate (FTC-TP) levels (indicating dosing in the last 48 hours).

Results:

Patient median age was 29 years, 92% were male, 53% white, 91% MSM, and median time on PrEP was 11 months. 92% of patients had urine TFV >1000 ng/mL, 2% had 10-1000 ng/mL, and 6% had <10 ng/mL. Majority (94%) had ≥700 fmol/punch DBS TFV-DP. Urine TFV levels >1000 ng/mL demonstrated sensitivity of 94% (95% CI: 83-99) and PPV was 96% (95% CI: 86-100) for ≥700 fmol/punch and 100% (95% CI: 90-100) and 71% (95% CI: 57-83) for ≥1250 fmol/punch. Urine TFV's specificity and NPV were not reported for DBS given high levels of adherence among the patient sample. Urine TFV >1000 ng/mL had a sensitivity

of 98% (95% CI: 89-100) and PPV was 96% (95% CI: 86-100) for detectable DBS FTC-TP. Urine TFV specificity and NPV were 60% (95% CI: 15-95) and 75% (95% CI: 19-99) for DBS FTC-TP.

Conclusion:

Clinic settings would benefit from rapid and objective PrEP adherence monitoring. Urine TFV levels had high sensitivity and PPV compared to DBS TDF-DP and FTC-TP in a sample of very adherent PrEP patients. Further assessments of nonadherent PrEP patients are needed to fully understand the comparability of the 2 assays. Urine testing has the potential to improve PrEP follow up care and to objectively identify patients in need of intensified adherence counseling and support.

Epidemiology/Public Health:

(T) Prevention Interventions

Keywords:

Clinical monitoring
Clinical pharmacology
HIV prevention
Medication Adherence
Preexposure prophylaxis (PrEP)

Additional Information about the Submission

Prior Presentation or Publication: In general, CROI does not accept work that has been previously published or publically presented (especially if at conference of more than 400 attendees). Consideration may be given to a submission if meaningful newer data or different analyses are included. Have your study data or abstract information been published, submitted for publication where publication is anticipated on or before December 31, 2016, or presented at any other major national or international scientific or medical conferences (ie, generally 400 or more attendees)?

No

CROI Scholarship Application

Which of the following scholarships are you applying for?

None