Urine Tenofovir Testing to Measure PrEP Adherence Among Youth in a Real-World Setting

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ID #1732

Background

- The effectiveness of TDF/FTC taken as HIV pre-exposure prophylaxis (PrEP) is limited by poor adherence
- Young men who have sex with men (yMSM) and transgender women of color (TWc) have the highest risk of new HIV infections
- Urine tenofovir (TFV) levels have been shown to be highly correlated with plasma TFV levels
- Urine TFV levels can accurately predict when last dose of TDF/FTC was taken

<table>
<thead>
<tr>
<th>Urine TFV Level</th>
<th>Adherence Level</th>
<th>Date Last Dose</th>
<th>Date Sampled</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100ng/mL</td>
<td>High</td>
<td>3 days ago</td>
<td>7 days ago</td>
</tr>
<tr>
<td>&gt;100ng/mL</td>
<td>Moderate</td>
<td>7 days ago</td>
<td>14 days ago</td>
</tr>
<tr>
<td>&gt;1000ng/mL</td>
<td>Low</td>
<td>14 days ago</td>
<td>21 days ago</td>
</tr>
</tbody>
</table>

- Philadelphia FIGHT is an urban FQHC & active participant in research serving at-risk youth through the Y-HEP Health Center

Study Design

- Single arm observational cohort study
- 48 week study
- Designed to evaluate the drop-in model of Y-HEP

Objectives

1) Achieve 70% program retention at 48 wks
2) Evaluate adherence to PrEP through 48 wks using medication pick-ups and urine TFV levels
3) Assess behavioral change through the reported number of risk behaviors at wk 24 and 48 as well as the change in incidence of STIs over the study period

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Methods

- PrEP administered to 50 yMSM and TWc at a youth drop-in center over 48 wks
- Needs-based medication dispensation schedule
- Weekly, bi-weekly, or monthly pick-up schedules determined by clinician assessment of needs & patient preference
- Retention measured by proportion of patients initiating TDF/FTC who pick up ≥ 50% of their medications through 48 wks AND who have a study visit in the 48-wk window
- Adherence was measured by:
  - Proportion of study subjects with detectable (>1000ng/mL) urine TFV concentrations collected every 2 or 4 weeks
  - Proportion of medication pick-ups visited attended, defined as: a) occurring during the assigned study week or b) occurring outside the designated week but prior to next scheduled visit – these are labeled “out-of-window”

Results

<table>
<thead>
<tr>
<th>Table 1. Baseline Characteristics (n=50)</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (range)</td>
<td>22.4 (18-29)</td>
</tr>
<tr>
<td>African-American Race</td>
<td>32 (64)</td>
</tr>
<tr>
<td>Ethnicity Hispanic/Latino</td>
<td>9 (18)</td>
</tr>
<tr>
<td>Transgender (Male to Female)</td>
<td>5 (10)</td>
</tr>
</tbody>
</table>

- Self-Identified Sexual Orientation
  - Gay/Homosexual 35 (70)
  - Bisexual 13 (26)

- Risk Factors for HIV
  - HIV partner 4 (8)
  - Inconsistent Condom Use 40 (80)
  - History of STI 29 (58)
  - Exchange of Sex for Commodities 9 (18)
  - Drug/Alcohol Use 37 (74)
  - History of Incarceration 11 (22)
  - Partner(s) of Unknown HIV Status 27 (54)
  - 4 or More Partners in last 6 months 15 (30)

- Urine collected Q2 or 4 weeks depending on pick-up schedule.
- Clean catch and 1st daily void not required

Retention in Care is High through 48 wks

<table>
<thead>
<tr>
<th>Week</th>
<th>%</th>
<th>% Adjusted for “Out-of-Window” PrEP pick-ups</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>84</td>
<td>70</td>
</tr>
<tr>
<td>24</td>
<td>62</td>
<td>70</td>
</tr>
<tr>
<td>36</td>
<td>62</td>
<td>70</td>
</tr>
<tr>
<td>48</td>
<td>50</td>
<td>70</td>
</tr>
</tbody>
</table>

Urine TFV Concentrations remain high in the majority of subjects over 48 wks

<table>
<thead>
<tr>
<th>Week</th>
<th>% Fully Protected</th>
<th>% Somewhat Protected</th>
<th>% Slight Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>100</td>
<td>60</td>
<td>30</td>
</tr>
<tr>
<td>24</td>
<td>90</td>
<td>70</td>
<td>30</td>
</tr>
<tr>
<td>36</td>
<td>80</td>
<td>60</td>
<td>40</td>
</tr>
<tr>
<td>48</td>
<td>70</td>
<td>50</td>
<td>20</td>
</tr>
</tbody>
</table>

Risk & Attitude Change between wks 24 and 48 on PrEP, by adapted Risk Assessment Battery

- Significant Decrease
- No Change
- Significant Increase

Week 24-48 Wks

- 12 diagnoses of Syphilis wks 24-48
- 6 cases of chlamydia in participants wks 24-48
- No statistically significant difference detected in positivity rates

Conclusions

- PrEP can successfully be delivered to a young, high-risk population with high program retention
- Urine TFV measurement provides useful information about recent adherence to PrEP
- PrEP did not change behavior among yMSM over 48 wks
- Incident STIs remain high (but do not increase while on PrEP), stressing the need to maintain high PrEP adherence in this population

Future Steps

- Can a point of care urine TFV assay provide to monitor and enhance adherence to PrEP in a real-world setting?

References

1. C. Koang et al., CID, February 2015
2. C. Koang et al., HPC, May 2016