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

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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 (yMSMc) 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

Urine [TFV] ng/ml	Adherence Level	Date Last Dose	Implication
>1000	Recent adherence	Within 48 hrs	HIV protection
>10 to >100	Low adherence	2-7 days ago	Suboptimal HIV protection, at risk of resistance
<10	Non-adherence	> 7 days ago	No HIV protection, low risk of resistance

- 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 yMSMc 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-up visits 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"

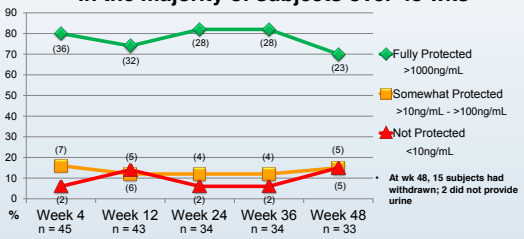
Results

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

Retention in Care is High through 48 wks

Retention (n=50)	%	% Adjusted for "Out-of-Window" PrEP pick-ups
Week 12	84	90
Week 24	62	74
Week 36	62	70
Week 48	50	70

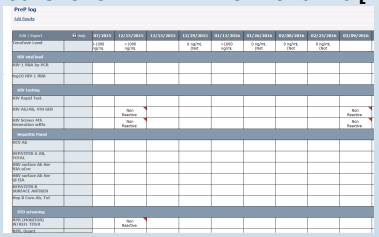
Urine TFV Concentrations remain high in the majority of subjects over 48 wks



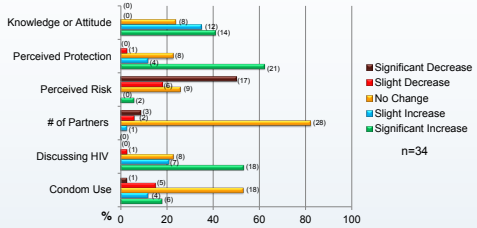
- At wk 48, 15 subjects had withdrawn; 2 did not provide urine

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

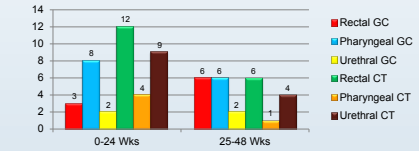
Screenshot of EMR with row for urine [TFV]



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



Diagnosed STIs over 48 wks (Incident Cases)



- 2 diagnoses of Syphilis wks 0-24; 2 diagnoses wks 25-48
- 0 cases of trichomonas or Hepatitis C diagnosed over 48 wks
- 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 yMSMc over 48 weeks
- 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 assist providers to monitor and enhance adherence to PrEP in a real world setting?

References

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