



Performance and Acceptability of a Urine Point-of-Care Test for Drug-Level Feedback Counselling on PrEP use among Young Women in South Africa

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Conflict of interest disclosure

- I have no conflicts of interest to declare



Background

- Adherence to daily oral PrEP is challenging, particularly for adolescents
- VOICE trial participants reported a desire for PrEP adherence feedback during counselling
- No effect of drug-level feedback counselling (DLFB) using dried blood spots (DBS) in HPTN 082
 - Difficulties with counselling about behaviour in the past
 - Operational challenges e.g. missed visits, delays in receiving results
 - Incorrect messaging with transcription errors of results
 - High cost - \$100 per test
- A urine Point of Care (POC) tenofovir (TFV) assay may overcome these challenges

Sample week	Results week	Threshold		Counseling message
Week 4	Week 8	≥500 fmol/punch		Key message: You are doing really well! Keep up the good work and remember that taking one PrEP pill every day is needed for strong protection against HIV.
Week 8	Week 13	≥700 fmol/punch		
Week 4	Week 8	16.6-499 fmol/punch		Key message: It looks like you are trying to take the PrEP pills, but may have missed some doses. Remember that taking one pill every day is needed for strong protection against HIV. How can we help you do even better?
Week 8	Week 13	16.6-699 fmol/punch		
Week 4	Week 8	BLQ (<16.6 fmol/punch)		Key message: It looks like you haven't been able to take the PrEP pills. Is PrEP something that you are still interested in? If yes, how can we help you?
Week 8	Week 13	BLQ (<16.6 fmol/punch)		



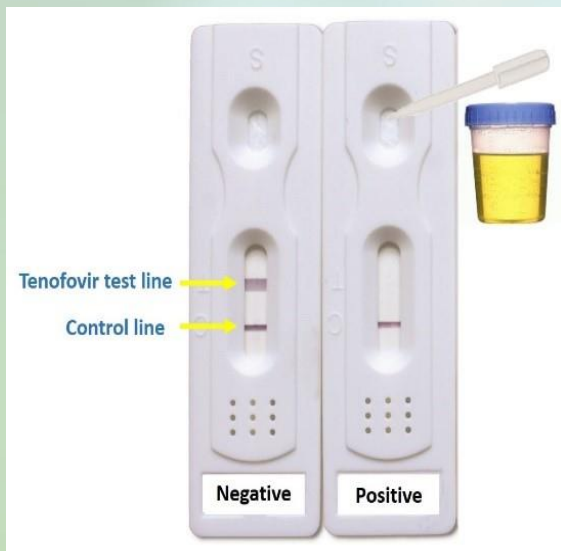
Methods

- Nested within a sequential multiple assignment randomized trial to evaluate oral PrEP adherence strategies, including DLFB
- Sub-set of AGYW, aged 18-25 years, taking oral PrEP at exit visit
- Urine POC TFV assay with DLFB counselling by clinician
 - Positive test (TFV detected) = PrEP use in last 4-7 days
- DBS samples (N=115) for comparison
 - Intracellular tenofovir diphosphate (TFV-DP) ≥ 700 fmol/punch = high adherence in last 4-8 weeks
- Acceptability assessed via computer assisted self-interview (CASI)



Methods

Urine Tenofovir Assay



Counselling Messages (Adapted from HPTN 082)



Control line only (one line appears on test)

Key message: It looks like you took a PrEP pill recently, you are doing great! Remember that taking one PrEP pill every day is needed for strong protection against HIV. Are you still interested in taking PrEP after your participation in this study is complete today?



Control and tenofovir test line (two lines appear on test)

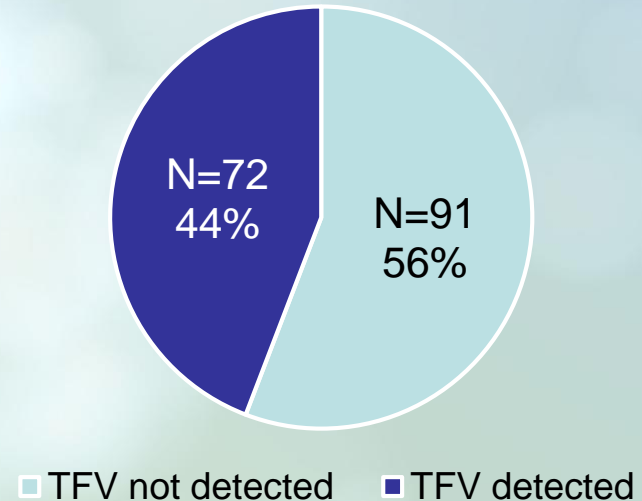
Key message: It looks like you haven't been able to take the PrEP medication in the past few days. Is PrEP something that you are still interested in? If yes, how can we help you continue to access PrEP after your participation in this study is complete today?



Results: Participants characteristics and Urine TFV results

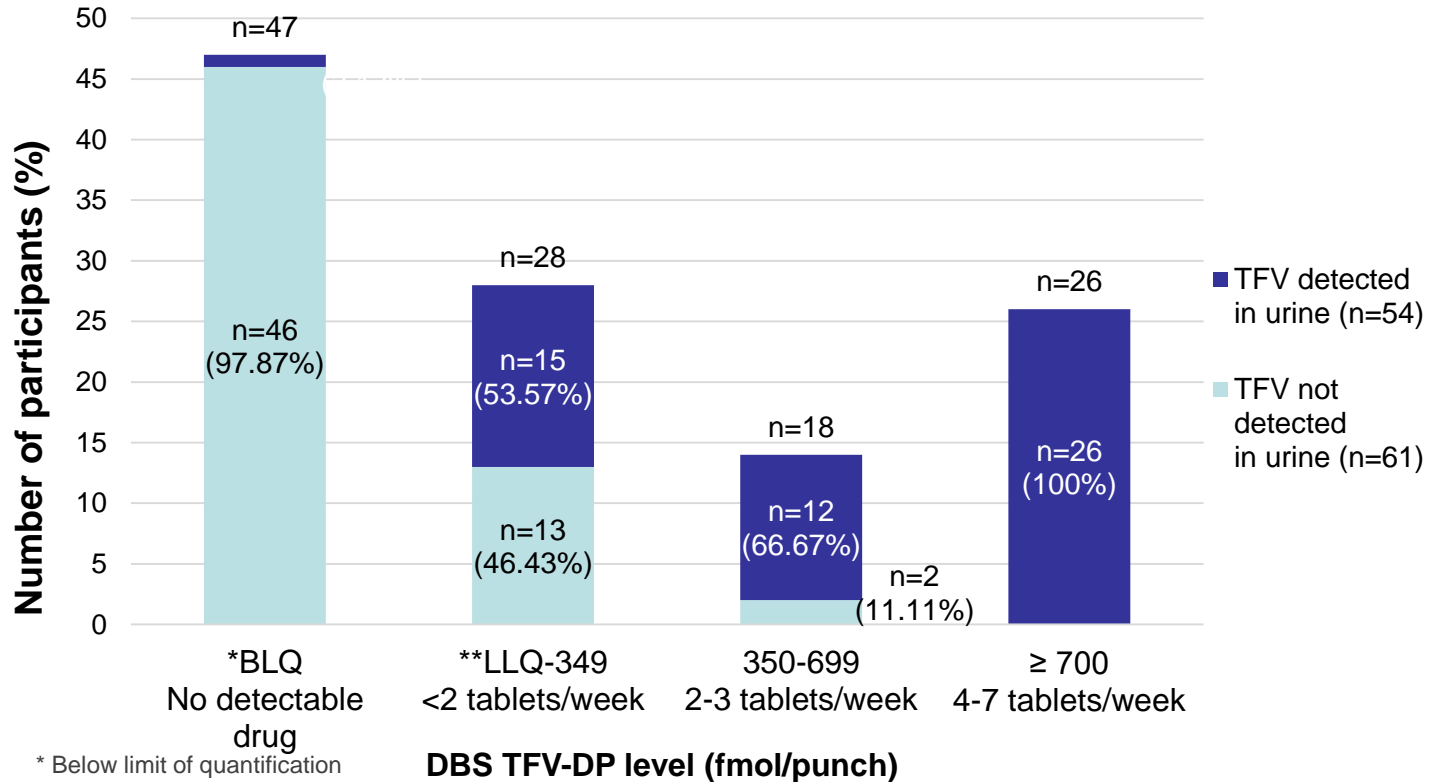
Baseline characteristics (N=163)	N (%) or Median (IQR)
Age (years)	21.0 (20.0 - 23.0)
Student	72 (44.2%)
Unemployed	68 (41.7%)
VOICE risk score	7.0 (6.0 - 8.0)
STI diagnosed at enrolment	44 (27.0%)
Previous PrEP use	3 (1.8%)

Urine POC TFV assay results at exit (M9)





Results: Comparison of DBS and Urine TFV results (N=115)



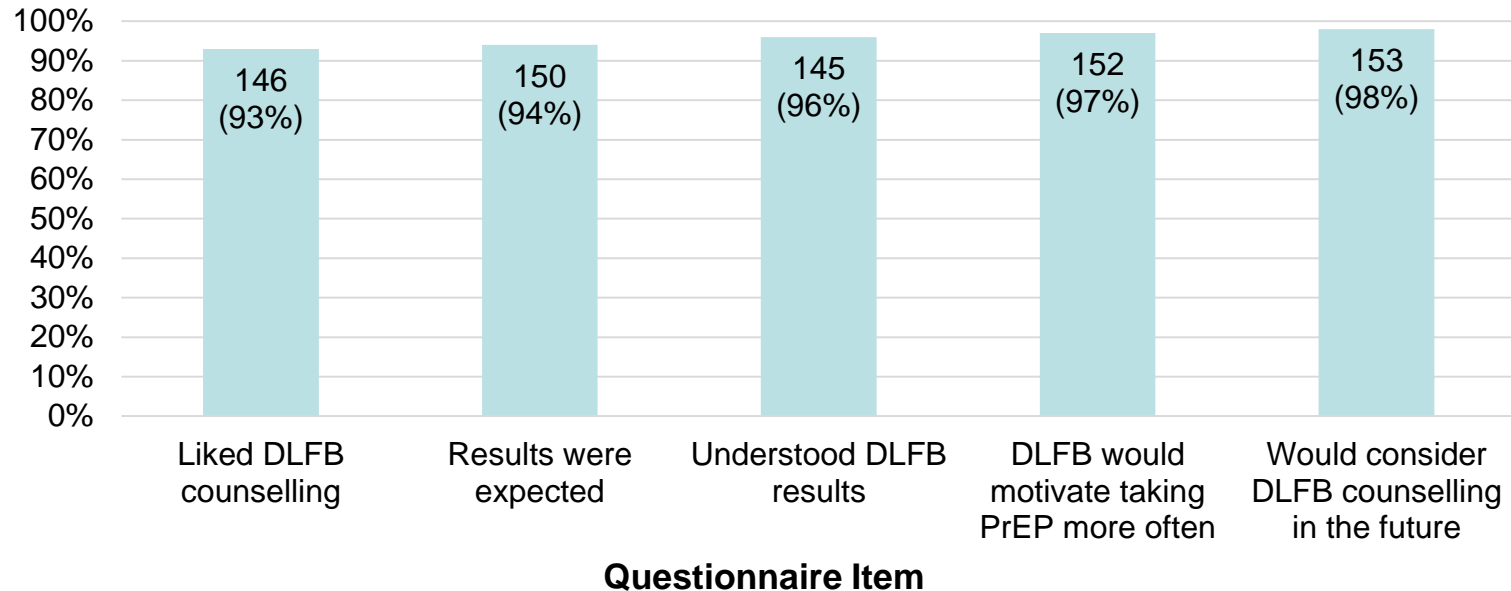
* Below limit of quantification

** Lower limit of quantification

DBS TFV-DP level (fmol/punch)



Results: Acceptability of DLFB counselling using a urine POC assay (N=156)





Conclusions

- First study that shows how a urine POC assay performs compared to TFV-DP in DBS
- A negative urine POC test was successful in identifying women with poor adherence who could benefit from adherence support.
- Positive POC tests were less able to discriminate between consistent and inconsistent or poor PrEP adherence compared to the DBS.
- DLFB counselling using a urine POC assay was acceptable, and easier to implement than DBS-based counseling.
- A urine POC assay may be a novel, efficient and relatively easy strategy to implement to guide discussions about recent PrEP adherence with AGYW.
- Further research is needed to evaluate the effectiveness of urine POC-based DLFB counselling for adherence support.



#ADHERENCE2022



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