Drug Level Monitoring for PrEP Users: Feasible and Acceptable, but is it Necessary?

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ERM Pool[1,2], A Severn[1,2], J Paredes Sosa[1], O Stirrup[1,2], CM Mullender[1,2], M Fiorino[1,2], M Kohli[1,2], I Maan[1,2], R Owen[1], D Sally[1,2], E Suonpera[1,2], D Dunn[1], R Gilson[1,2], J Saunders[1,2]

1. Institute for Global Health, University College London, UK. 2. Mortimer Market Centre, Central and North West London NHS Foundation Trust, UK. 3. UK Health Security Agency (UKHSA)

BACKGROUND

- Adherence is vital for PrEP efficacy
- In the trials Proud and iPREX OLE 71-100% of participants had detectable tenofovir (TFV) levels[1,2]
- There is a lack of adherence data from UK/Europe outside of clinical trials
- Optimal support for PrEP adherence is not established and TFV drug level monitoring (DLM) could identify those not taking PrEP for adherence interventions
- Current laboratory DLM incurs a time lag for patient feedback
- We used a point of care (POC) urine PrEP DLM test to facilitate real time feedback
- It is not known whether DLM would be acceptable to PrEP users or feasible within a busy sexual health clinic.

AIMS

1. Is PrEP DLM testing acceptable and feasible?
2. Compare biochemically verified to self-reported adherence.
3. Describe PrEP adherence in a central London clinical cohort.

METHODS

- Eligibility: PrEP users aged ≥18 years attending a large sexual health clinic in London, UK
- Participants completed a electronic survey on PrEP use and were offered a POC urine PrEP DLM test (SureQuick Rapid Tenofovir Adherence Test, OraSure Technologies Inc.)
- PrEP DLM test detects TFV concentration >1000 ng/mL, consistent with PrEP use in the last 48 hours
- It is validated for both emtricitabine-tenofovir disoproxil fumarate (F/TDF) and emtricitabine-tenofovir alafenamide fumarate (F/TAF)

KEY MESSAGES

PrEP drug level monitoring is feasible and acceptable but unnecessary – self-reported PrEP adherence was highly accurate in our clinic sample.

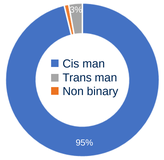
PrEP adherence was excellent – despite long-term PrEP use and recreational drug use.

Of daily PrEP users, 88% had adherence consistent with efficacy: ≥4 pills/week.

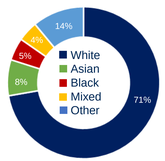
RESULTS

213 participants recruited from September 2021-October 2022.

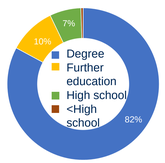
Gender



Ethnicity



Education



Age



Years
Median (IQR)

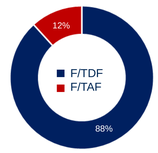
Recreational drugs*

38% Any drugs

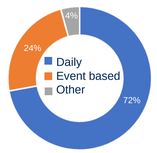
10% Crystal methamphetamine

*in the last 12 months

PrEP medication



PrEP regimen



Time on PrEP



Years
Median (IQR)

Acceptability

79.8% Participants reported in the survey that they were quite/very likely to accept a PrEP DLM test

94.3% Participants completed a PrEP DLM test when offered it in clinic

Feasibility



Minutes
Median (IQR)

Test completion time was feasible within appointments

2/199 Tests gave invalid results

RESULTS (continued)

Reported vs DLM adherence

- Overall, 182/197 (92.4%) of participants' self-reported PrEP use (within 48 hours) matched DLM results – in-keeping with the DLM test sensitivity (94.6%)[3]
- Eight participants reported no PrEP within 48 hours but DLM indicated TFV ≥1000 ng/mL.
- This may reporting bias, test error, or PrEP >48hr ago with maintained TFV levels

Adherence in Daily PrEP users

- Participants completed a retrospective diary of PrEP use in the past 7 days and were categorised according to whether they had taken ≥4 pills/week, or <4 pills/week

87.6% 134/153 participants reported taking ≥4 PrEP pills in the past 7 days

No demographic factors were significantly associated with likelihood of adherence, albeit in our homogenous clinic sample

Adherence in EBD PrEP users

83.4% Participants reported >50% condomless sex was covered by PrEP in the last month.

70.0% Participants reported >80% condomless sex was covered by PrEP in the last month

- EBD PrEP users may appropriately prioritise PrEP use, e.g. only for non-primary partners or partners with a detectable HIV viral load
- Therefore 100% use may not be necessary for EBD PrEP users

Reasons for missing PrEP

- Most participants reported rarely/never missing PrEP.
- Most frequent reported reasons were: forgetting, being busy, running out and not having sex.
- Side effects, privacy and stigma were not identified as reasons for missed PrEP in this cohort.

DISCUSSION

- Whilst **acceptable** and **feasible**, PrEP DLM testing is **unnecessary** as we found self-reported PrEP use was highly accurate
- **Adherence** was very good: 88% of daily users reporting adherence consistent with efficacy (≥4 pills/week) and 70.0% of EBD users reporting ≥80% of condomless sex covered by PrEP
- **In context:** We found better adherence than PrEP DLM studies based in US, South Africa and Zimbabwe: (48.4-83.0% at >4pill/week) [4-6]
  - Day2Day study found self-report over-estimated adherence by 10%, whereas we found no clinically significant difference between self report and test confirmed adherence[6]
- **Strengths:** real life undifferentiated sample of participants, good sample size, first UK-based quantitative study of PrEP adherence in clinic patients
- **Limitations:** single site, population was largely composed of white, university educated, cis gay men. Generalisability beyond this population is unknown
- **Further research** should assess acceptability, feasibility, and utility for adherence monitoring in populations underrepresented in this study

Email: e.pool@ucl.ac.uk
X: @erica_pool

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