High adherence to HIV pre-exposure prophylaxis (PrEP) in participants presenting for month 12 visit in *PRELUDE* open-label study in NSW, Australia

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Introduction and Aims

- Pre-exposure prophylaxis (PrEP) is a highly effective HIV prevention strategy, but efficacy is contingent upon adherence.
- There are issues with assessing adherence – biological measures are complicated and costly, and self-report often overestimates it.
- We evaluated participants' adherence to daily PrEP (7 pills/week) using four different adherence measures in *PRELUDE*, the PrEP demonstration project in New South Wales (NSW), Australia.

Methods

- Plasma tenofovir (TFV) and peripheral blood mononuclear cell (PBMC) TFV-diphosphate (TFV-DP) concentrations taken from a sub-sample of participants (n=108) 1, 6, and 12 months after PrEP initiation were analysed using liquid chromatography- tandem mass spectrometry.
- Facilitated recall – clinicians asked participants how many PrEP pills they had taken in the previous 7 days at each study visit (month 1, month 3, then quarterly thereafter).
- Self-report via online survey – participants reported the proportion of PrEP pills they had taken since their last survey (~90 days), in a confidential, unique survey following each study visit.
- Analyses were conducted using STATA. Descriptive statistics and chi-squared tests were used to compare participants. A non-parametric test for trend across ordered groups was used to identify changes over time. Sensitivity and specificity compared to PBMC [TFV-DP] were also calculated.

Results

- *PRELUDE* enrolled 321 gay and bisexual (GBM) men who were predominately at high risk of contracting HIV.
- Amongst participants who presented for their month 12 study visit (n=263; 81%), daily adherence across the study by plasma [TFV], PBMC [TFV-DP], self-report in the online survey, and facilitated recall to clinicians was 91%, 95%, 94%, and 90%, respectively.
- There were only 9 (3%) study visits where plasma or PBMC drug concentrations were below the protective range (4 pills/week).
- Statistically significant declines in daily adherence over time were observed for PBMC [TFV-DP] (p=0.001) and self-report via online survey (p<0.001) (Figure 1). There was also an increasing trend in non-responses to the online survey (p<0.001).
- At month 12, plasma [TFV], self-report, and facilitated recall were highly sensitive when compared to PBMC [TFV-DP], but given the low prevalence of non-adherence within the sample, specificity was low (Table 1).
- Facilitated recall to clinicians was equivalent to using plasma samples to identify non-adherers (i.e. same sensitivity) in this cohort.
- There was moderate loss to follow-up by month 12 (n=58; 19%). Participants who were lost to follow-up were less likely to ever report high HIV-risk practices, including condomless anal sex with casual partners (69% vs 90%, p<0.001), compared to those who completed their month 12 visit.

Figure 1: Comparison of adherence measures across follow-up in participants who presented for month 12 visit (n=263)

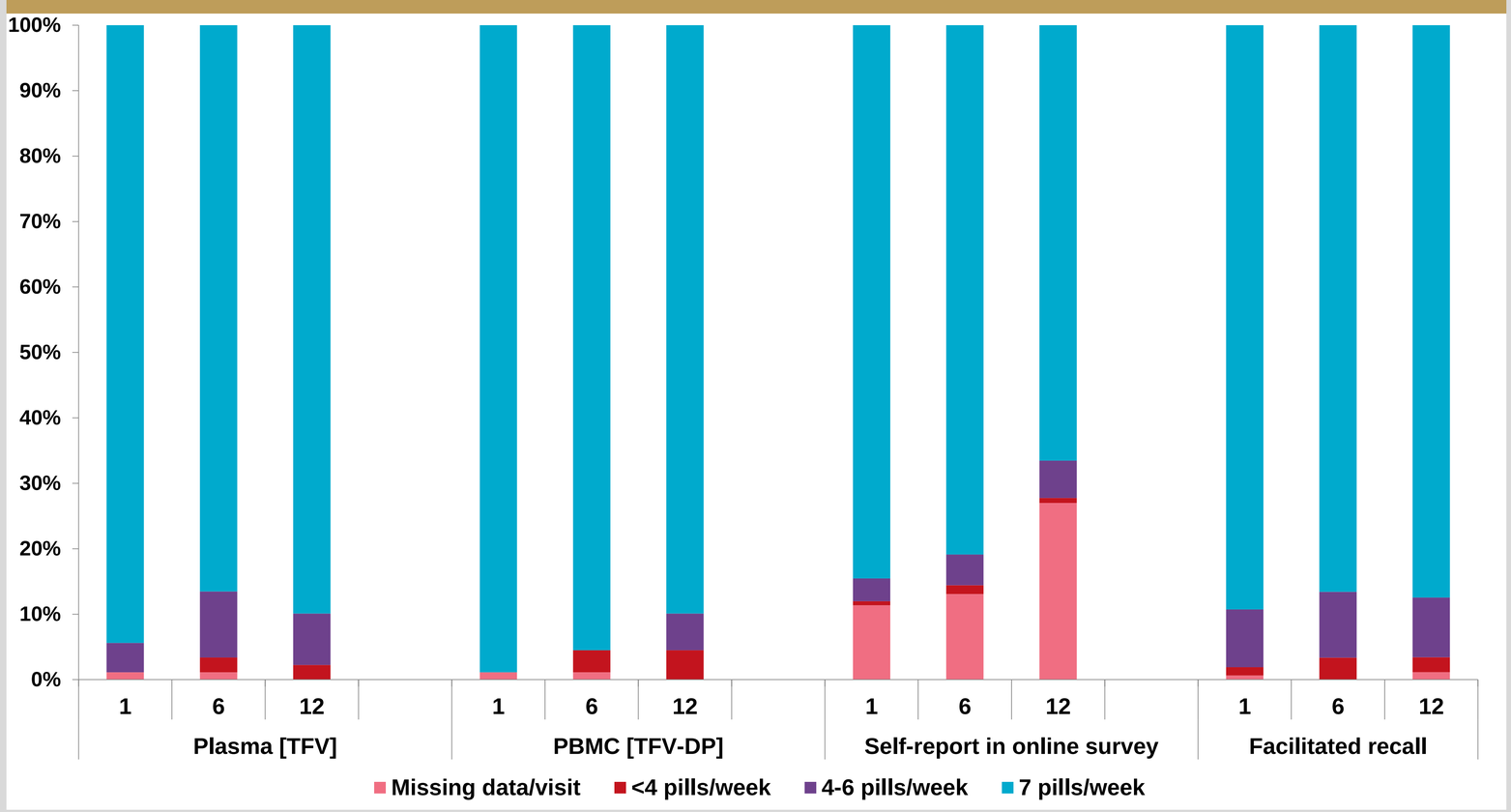

Table 1: Sensitivity/specificity of adherence tests compared to PBMC [TFV-DP] at month 12

	Sensitivity	Specificity
Plasma	92.5%	33.3%
Self-report in online survey	93.9%	25.0%
Facilitated recall to clinicians	88.8%	33.3%

Conclusions

- Adherence to daily PrEP was high and reported fairly consistently across each of the four measures for participants who attended their 12 month study visit.
- Almost 1 in 5 participants were lost to follow-up, but these men were at lower risk of HIV compared to those who remained on the study for 12 months.
- Clinicians asking participants how many pills they had taken in the previous week was equivalent to using plasma [TFV] to identify non-adherence in this population.

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