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Title: Do patients adherent on PREP exposed to HIV have sero-conversion symptoms and falsely reactive HIV tests?

Background: Truvada is licensed for use as pre-exposure prophylaxis (PrEP) for the reduction of HIV in the US. In the UK, PrEP is only widely available via enrolment to the PROUD study for men who have sex with men (MSM). Participants are randomised to immediate daily Truvada for two years or deferred Truvada for the last year only.

Case: Patient M presented to his local GUM clinic reporting a significant increase in unprotected passive anal intercourse in the previous 6 months. He was enrolled in the PROUD study and was randomised to the immediate Truvada. At baseline he had a HIV negative POCT and serum test. At his 3 month PROUD visit he was unwell complaining of flu like symptoms and malaise for 5 weeks; rectal pain, bleeding and constipation for 2 weeks and 8kg weight loss. He reported passive anal intercourse 8 weeks previously with several known HIV positive partners. An HIV POCT test was performed which was p24 Antigen and Antibody reactive (Determine HIV-1/2 Ag/Ab Combo). He also had rectal gonorrhoea. At this stage Patient M was advised to discontinue taking his Truvada immediately.

The following day, a serum HIV test collected on the same day as POCT (Abbott Architect framework and confirmed by Biomerieux Vider) was negative. An HIV RNA (Abbott PCR) was <40 copies/ml. Samples taken on the same day as the reactive HIV POCT were analysed for Tenofovir and emtricitabine levels and these were consistent with the patient's report of 100% adherence.

Conclusions: There are two possibilities: firstly that he was sufficiently exposed to HIV to have a positive Determine but PrEP prevented an established infection, or alternatively the Determine result was falsely reactive. The manufacturers report a false positive rate of 2/1623 for antibodies, but there is very little data on false positive for both p24 Antigen and Antibody together. Sensitivity of POCTs in seroconverting MSM is 96% compared to 98% for a 4th generation test. Confirmatory HIV testing in MSM on PrEP is needed to inform decisions about continued treatment.