Purpose of the update and appendix

Who might need PrEP?

The risk of acquiring HIV is increased in:

1. MSM/trans women/trans men reporting condomless anal intercourse in the last 3/12 months and likely to do so again in following 3/12 months
2. The sexual partners of people who are HIV positive with a detectable viral load
3. HIV negative heterosexuals who have had condomless sex with a HIV positive individual, and likely to have condomless sex again with the same person, or another person with a similar status

Individuals fulfilling one of the criteria above who have requested PEP or had a bacterial STI in the last year or at the current visit should be considered at particularly high risk of HIV acquisition. Partners of HIV-positive individuals should preferably be seen both with and without their partner if possible. Individuals may present already on PrEP or with the intention to seek PrEP privately/online.

History and discussion to document

- Timing of last condomless sex acts
- HIV and STI screens in the last year, and date of the last HIV test
- History of bone or renal disease
- Importance of 3-monthly HIV/STI screen
- Importance of taking Truvada as directed
- Risks and benefits of online purchase of generic drug
- Risk reduction including information and support with chemsex as appropriate

Recommended tests

- Before or at time of starting PrEP:
  - 4th generation venous blood HIV test
  - Consider POCT and start PrEP same day if negative
  - HBV surface antigen (and start vaccination if immunity unknown; on-demand Truvada is not recommended in chronic hepatitis B infection and if continuous PrEP is started, hepatology review is required before cessation)
  - Serum creatinine and eGFR
  - Urinalysis
- On PrEP:
  - 3-monthly 4th generation venous blood HIV test +/- POCT
  - 3-monthly STI screen for MSM [as per BASHH 2014 MSM guidance]; STI screen as appropriate for heterosexuals
  - Urinalysis every visit (further investigation if protein 1+ or more)
  - Annual creatinine/eGFR (more frequent if abnormal at baseline or proteinuria or >50 or on concomitant medications that are relevant to renal function)

Note: POCT useful on the day of starting, and at any visit if risks were taken during a period when PrEP was not as per national guidelines on HIV testing.
Dosing

Event-based dosing for a single sex act comprises two tablets 2–24 hours before sex, one tablet 24 hours (22–26 hours) after the first dose, and another tablet 48 hours (46–50 hours) after the first dose.

- Heterosexuals/trans men/trans women: event-based dosing has not been investigated in heterosexuals; based on this and pharmacokinetic concerns, we recommend daily PrEP and do not recommend event-based PrEP. In the absence of other data, trans women and trans men should also be offered daily PrEP
- MSM: as daily and event-based PrEP showed similar efficacy, event-based PrEP should be discussed and offered.

Assessing adherence and adverse events

- Assessment 1-month after commencing PrEP (face-to-face, telephone, email or text) provides the opportunity to review adherence, adverse events and HIV/STI window periods
- Reasons for non-adherence including adverse events should be elicited and documented at each follow-up visit. Additional support, practical or psychological may be required. Adverse events should be reported through the yellow card scheme at https://yellowcard.mhra.gov.uk/

Coding and data collection

- Until processes for formal coding and outcomes monitoring are established, we strongly encourage clinics to collect data locally for visits when PrEP is started, continued or interrupted (including when interrupted because no longer at risk)

Online purchase of generic tenofovir/emtricitabine

- It is legal for a patient to obtain 3 months of generic drug via the internet for personal use
- A prescription is not required but some sellers may request this.
- The website www.iwantprepnow.co.uk has been set up by community advocates to provide information about PrEP and links to sellers. Sellers are added to the site only when generic drug has been purchased with no problems and therapeutic drug monitoring (TDM) has been carried out in at least one person showing presence of the drug.
- Supportive clinicians are working with ‘I Want PrEP Now’ to ensure generic drug efficacy, as far as possible, by sharing TDM results with an agreement to disseminate information if an unsatisfactory TDM result is obtained

Supplementary information that might be useful for clinics

- Flow chart
- PrEP user information leaflet. This leaflet draws on the information provided by the Dean Street PrEP clinic, and the PROUD clinics, which are supporting PrEP users in their GU clinics, particularly Mortimer Market (Mags Portman) and King’s (Killian Quinn). The draft was reviewed and amended by Simon Collins and Greg Owen as well as Dan Clutterbuck.
- Infographics. With thanks to Jean-Michel Molina and the IPERGAY team for providing the infographics for event-based dosing and to Laura Waters for providing a choice of symbols. These were sent to 128 PROUD participants for review. Of 17 who responded, 10 preferred the stick men.
Flow chart of procedures

Wanting to start PrEP

**First visit documentation**
- Reason for seeking PrEP
- Medical history relevant to Truvada
- Details of HIV/STI screens last 12m
- Timing of condomless sex acts last 3m
- If MSM: discussion of both regimens
- Reasons adherence is important before and after risk of exposure
- Risks and benefits of online purchase
- Results HIV/STI screen
- Decision to start and time to start
- Recommended follow-up
- Code locally or using GUMCADv3

**Offer**
- HIV/STI screen if indicated
- Include urinalysis and serum creatinine if appropriate
- PEPSE if appropriate
- Private prescription if available
- Community websites with information about online purchase
- See 1 or 3 months after starting PrEP for HIV/STI screen and urinalysis

Already started PrEP

**Quarterly visit documentation**
- Reason for continuing PrEP
- Regimen followed and reasons for non-adherence including adverse events
- Result of urinalysis and additional investigations ordered if indicated
- Results of HIV/STI screen
- Code locally or using GUMCADv3

**Offer**
- HIV/STI screen
- Urinalysis and serum creatinine if no baseline
- If sourced online check information about source on iwantprepnow, and offer TDM if appropriate and available
- See in 3 months for the next HIV/STI screen and urinalysis