The UK PROUD PrEP Pilot Study: a baseline analysis

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Background

Previous pre-exposure prophylaxis (PrEP) studies have demonstrated the efficacy of PrEP. The public health benefit of PrEP will depend on effective targeting. In the UK, the effectiveness of free PrEP, delivered through the NHS sexual health clinic network, is being evaluated through the PROUD study, a randomised open label clinical trial.

Methods

In PROUD, eligible HIV negative gay and other men who have sex with men (MSM), aged 18 or above, who report condomless anal sex in the past 90 days, are randomized to receive Truvada as PrEP immediately or after 12 months in 13 sexual health clinics across England. Data on demographics, sexual behaviour and STIs are collected at enrollment in a privately completed questionnaire.

Results

Demographics:

By the 2nd June 2014, 545 participants had enrolled; baseline data were available on 511. The median age was 36 (IQR 30-43) (figure 1) . The majority (79%) were of white ethnicity (figure 2), 60% were educated at university degree level or above (figure 3). 72% were in full-time and 9% in part-time employment, 8% were unemployed, 11% other or no answer.

Figure 1: Age Distribution

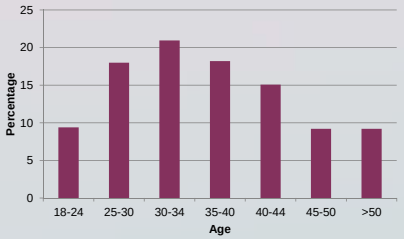


Figure 2: Ethnicity

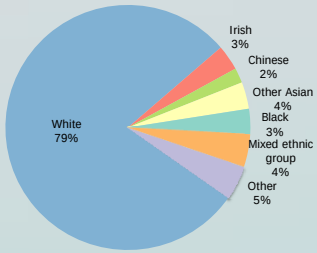
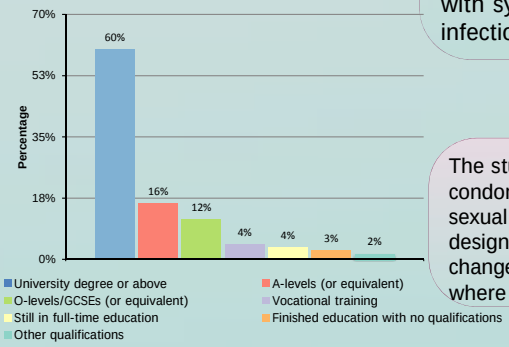


Figure 3: Education



Results

Risk factors:

- 46% of participants reported being in an ongoing relationship and 30% were living with a partner.
- In the 90 days before enrollment, the median number of total anal sex partners was 10 (IQR 4-20), and the median condomless receptive and insertive anal sex partners were 2 (IQR 1-5) and 3 (IQR 1-7) respectively.
- 36% used post exposure prophylaxis (PEP) in the past 12 months, 14% more than once.

STI frequency:

Participants had a median of 3 HIV tests in the previous year. Of those answering the STI questions (446 out of 511), rectal Gonorrhoea was reported by 27%, rectal Chlamydia by 22% and syphilis by 11% in the past year (figure 4). Of 279 participants tested at baseline, 12 (5%) were infected with rectal Gonorrhoea, 10 (4%) with Chlamydia, and 12 (5%) with syphilis (figure 5). 10/56 (18%) had concurrent infections.

Figure 4: Reported STI Last Year

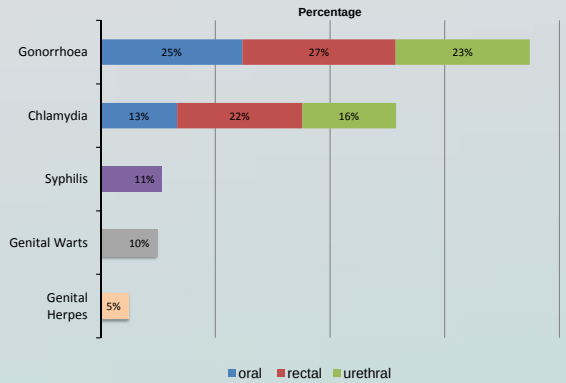
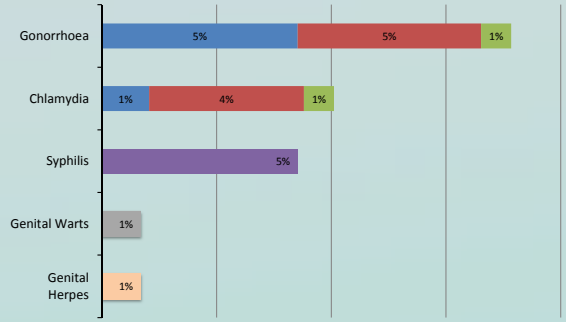


Figure 5: Diagnosed STI at baseline



Conclusions

The study is recruiting highly-educated gay and other MSM at high-risk of HIV infection according to the higher number of condomless sex partners, rates of STIs and PEPSE use reported compared to the general MSM population who attend sexual health clinics in England (http://www.hpa.org.uk/stiannualdatatables). This confirms that the wait-listed study design can recruit an appropriate high-risk study population. A randomised open label design is the best suited to collecting changes in sexual behaviour and STI rate during PrEP use and this data is the most relevant for NHS public health policy, where comparable data isn't currently available

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