How many MSM in Europe could benefit from PrEP – a 9 billion Euro question?

Ongoing high HIV incidence among men who have sex with men (MSM) around the world suggests that additional prevention tactics are required. While consistent condom use has been shown to be 80% effective at preventing HIV acquisition (in heterosexual couples), using emtricitabine/tenofovir as oral chemoprophylaxis, also known as pre-exposure-prophylaxis (PrEP), has the potential to be up to 95% efficacious. The deferred arms of two European PrEP studies have recently been stopped due to the effectiveness of PrEP in reducing HIV acquisition. The WHO and the US Centers for Disease Control and Prevention (CDC) have issued guidelines on who should qualify for PrEP, but there has been no indication of what proportion of MSM might meet these criteria. In this paper, we assess what proportion of MSM who participated in the European MSM Internet Survey (EMIS) would qualify for PrEP based on the CDC guidelines, which were chosen as they are the most comprehensive available guidelines. We close by suggesting a two-pronged approach to ensure optimal PrEP availability for MSM.

The detailed methods of EMIS have been reported elsewhere. In brief, EMIS was an anonymous, self-administered online survey conducted simultaneously in 25 languages across 38 countries, with a final sample size of 174,209 respondents. Participants were recruited through more than 230 social media/dating websites for MSM. Typical completion time was 20 min. No financial incentives were given. No IP addresses were collected. The survey was accessible online from 6 June to 31 August, 2010. More background information, including the English version of the questionnaire, is available at www.emis-project.eu.

After exclusion of 6013 respondents (3.5%) who were under 18 years old or reported never having had sex with men, and 1724 (1.0%) with missing data on HIV-testing history or sexual behaviour, the analytic sample includes 166,472 MSM (95.6%). The number of MSM in the 38 EMIS countries and the European Union who are eligible for PrEP according to the CDC are calculated by applying the eligibility criteria to the estimated MSM populations in each country. As national response rates across the 38 included countries differ substantially, country medians are reported.

CDC guidelines recommend PrEP for MSM who are adult, HIV negative, have had a male sex partner in the past six months, are not in a mutually monogamous relationship with a recently tested HIV-negative man and at least one of the following:

- Any anal intercourse without condoms (receptive or insertive) in the past six months.
- Any STI diagnosed or reported in past six months.
- Is in an ongoing sexual relationship with an HIV-positive male partner.

Given the overlap of the three indications, we prioritised them in the order above. As shown in Figure 1, 4.3% of EMIS respondents (median of 38 countries) reported having been diagnosed with HIV; 11.8% reported a steady partner of HIV-negative status and no other sexual partners in the last 12 months – these were classified as monogamous. According to CDC recommendations, 39.0% would qualify for PrEP because of unprotected anal intercourse in the past six months outside a monogamous relationship. An additional 1.0% would qualify solely because of reporting an STI in the past six months and an additional 0.7% solely based on reporting having a steady partner with diagnosed HIV. A total of 40.7% thus met the CDC guidelines for PrEP.

There are a number of important limitations to our estimates. EMIS was not a representative sample of MSM. Various lines of evidence suggest that EMIS sampled a somewhat higher-risk group of MSM. This would result in our estimates being too high. Another determinant of exaggerated estimates is the fact that the CDC guideline does not consider partners’ viral load – 57.5% of HIV-diagnosed EMIS respondents reported an undetectable viral load, and could be regarded as non-infectious. Other factors may result in our estimates being too low. One such factor is that a proportion of men who reported a steady partner of
HIV-negative status and no other sexual partners in the last 12 months reported a diagnosis of an STI in the previous six months. A reasonable case could be made that they be regarded as eligible for PrEP. Further studies are required to best define the risk profile that would obtain the optimal benefit from PrEP.

The 38 countries in EMIS have an estimated population of 5 million MSM aged 18 to 64. If our measures were representative, then approximately 2 million in the 38 EMIS countries or 1.4 million in the European Union (EU) would qualify for PrEP. The retail price of a year’s supply of standard PrEP (Truvada®) in the EU is 6500 € or 8100 US$. At this price, daily doses would cost 9.1 billion € per year for the 1.4 million men in the EU, excluding the other costs associated with PrEP implementation, which would require substantial health service infrastructure and staffing, and community education for MSM.

Studies are required to establish the cost effectiveness of various PrEP targeting strategies in the EU. A systematic review of five cost effectiveness studies in MSM in the USA and Peru found that PrEP’s cost effectiveness varied widely according to a number of factors including the degree of targeting and the cost of the emtricitabine/tenofovir. In studies with little targeting PrEP cost US$ 403–1779 per disability life year averted. This lower cost was largely due to the lower cost of emtricitabine/tenofovir in Peru. Cost effectiveness studies should not, however, limit themselves to the US$ 8100 annual cost for emtricitabine/tenofovir. Generic lamivudine/tenofovir is available at US$ 57 per year and the current European patent for Truvada® will expire in 2018. Various strategies could be used to reduce the price of the drugs used for PrEP.

More debate is required as to the optimal pricing of PrEP and who should pay for it. The provision of PrEP is not the only way to prevent HIV. This is quite different from the way that ART is the predominant way to prevent death from AIDS. PrEP also has no effect on reducing the transmission of other STIs. Although the provision of PrEP has not been found to lead to an increase in risk behaviours, there are three important caveats to this. Firstly, this was in the setting of trials that could provide considerable resources for counseling. Secondly, this was evaluated at an individual level only. At a population level it is likely that the provision of ART as therapy contributed to risk compensation in MSM as seen in certain countries. PrEP could have a similar effect. Thirdly, the PrEP used in all the trials thus far was free to participants. The results of the IPERGAY study suggest that intermittent PrEP (before and after sex) is as effective (and cheaper)
than uninterrupted PrEP. If people use PrEP in this way, it is possible that the number of sex acts with casual partners could vary inversely with PrEP prices. This raises the possibility that there may be an optimal price for PrEP for a particular population. Determining if this is the case would require not only empirical studies but also dealing with difficult ethical questions and, crucially, negotiations with affected communities.

We could consider considerable synergy and re-energise HIV prevention efforts if PrEP was made more accessible, but done so in a way that promotes safer sexual practices.

References


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