



TRANSFORMING
THE UK'S
RESPONSE
TO HIV



WHY IS PrEP NEEDED?

- **PrEP is highly effective at preventing HIV in both gay men and heterosexuals.**

The evidence for the effectiveness of PrEP in gay men is derived largely from the PROUD and Ipergay studies.^{1,2} They both found that PrEP was 86% effective – i.e. it stopped 17 out of every 20 HIV infections that would have happened without PrEP. In the UK study, PROUD, one HIV infection was stopped for every 13 gay men who took PrEP.

They tested different ways of taking PrEP. In PROUD, daily PrEP; in Ipergay, intermittent PrEP. Both ways of taking PrEP are effective.

Studies with heterosexual men and women show that PrEP works well in people who are able to take it consistently. For example, an African study showed that it was 75% effective – i.e. it stopped 15 out of every 20 HIV infections that would have happened without PrEP.³

In the US over 30,000 people, mostly gay men, are now taking PrEP. In at least two programmes offering PrEP to gay men at high risk of HIV, there have been no infections at all when many would have been expected if PrEP wasn't provided.

- **PrEP is needed if HIV infections are to start going down in the UK, especially in gay men.**

It is estimated that 2800 gay men in the UK acquired HIV in 2014 – about 8 gay men getting HIV every day.⁴ PrEP is necessary in England because while condoms, testing, and treating HIV-positive people are just about containing the HIV epidemic at its current level, infections in gay men are not decreasing, and more and more gay men are living with HIV every year. A recent study showed that

¹ McCormack S et al. *Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial*. The Lancet 387: 53-60, 2016.

² Molina JM et al. *On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection*. New England Journal of Medicine 373:2237-2246, 2015.

³ Baeten JM et al. *Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women*. New England Journal of Medicine 367: 399-410, 2012.

⁴ Public Health England *HIV in the UK – Situation Report 2015 – Incidence, prevalence and prevention*.

PrEP could make all the difference and, when compared to other HIV prevention measures, had the most powerful single effect.⁵

Whilst infections amongst heterosexual men and women are occurring at a lower rate, there are also heterosexuals who are at high risk of HIV acquisition and who could benefit from PrEP.

- **PrEP will save money, by preventing future HIV infections.**

For each individual who acquires HIV, the personal impact is considerable. In addition, the cost to the NHS is very high – one person's treatment over their lifetime costs around £360,000.⁶ Analyses have shown that there are several scenarios in which PrEP would be cost-effective or even cost-saving (in other words, start recouping its cost straight away).^{7,8} PrEP programmes are likely to save the NHS money so long as PrEP is provided to people at high risk of infection, or there is a reduction in the price of PrEP drugs (for example, when PrEP drugs come off patent in 2018, allowing less expensive generic drugs to come onto the market), or intermittent PrEP (rather than daily PrEP) is used. There's more information on costs and cost-effectiveness towards the end of this document.

What about concerns about PrEP?

Condoms

Some people are concerned that PrEP could lead to gay men abandoning condoms. The argument against this is that despite 30 years of HIV prevention work championing condoms, only a minority of gay men use them every time. PrEP will mostly be used by people who already find it difficult to consistently use condoms. Studies so far have either found no changes in sexual behaviour or small changes which are by far outweighed by the prevention benefits of PrEP.

The bottom line: There's little evidence that providing PrEP will result in big changes in condom use. It protects people who already have problems using them.

Other sexually transmitted infections (STIs)

Another related concern is that PrEP could lead to people catching more STIs like chlamydia and gonorrhoea. This is a possibility, though so far few of the scientific trials have seen rises in infections in people using PrEP. Even if STIs do rise, none of them has the same impact as HIV – an incurable lifelong infection that is lethal if left untreated and is highly stigmatised.

The bottom line: There's little sign of PrEP causing rises in other STIs. Even if they do rise, none are as serious as HIV.

⁵ Punyacharoensin N et al. *Effect of pre-exposure prophylaxis and combination HIV prevention for men who have sex with men in the UK: a mathematical modelling study*. The Lancet HIV 3: e94-e104, 2016.

⁶ Nakagawa F et al. *Projected Lifetime Healthcare Costs Associated with HIV Infection*. PLOS One 10(4): e0125018, 2015.

⁷ Cambiano V et al. *Is pre-exposure prophylaxis for HIV prevention cost-effective in men who have sex with men who engage in condomless sex in the UK?* BASHH Spring conference, Glasgow, 2015.

⁸ Ong K-J et al. *Will HIV PrEP given to high-risk MSM in England be cost-effective? Preliminary results of a static decision analytical model*. Public Health England Conference, Coventry, 2015.

Side-effects

Side-effects are another concern. Some people do experience mild initial side-effects when they start PrEP, but these soon go. While tenofovir, one of the drugs, can occasionally cause kidney problems and bone mineral loss, no PrEP study has seen these in more than 1% of participants and the effects reverse when PrEP is stopped.

The bottom line: PrEP rarely causes serious side-effects.

Resistance

Despite concerns, studies show that PrEP is extremely unlikely to result in more cases of drug-resistant HIV. When PrEP prevents HIV infection, the person does not have HIV so cannot have drug-resistant HIV. Resistance may occur in people who begin PrEP when they are already in the early stages of HIV infection (before tests can detect HIV), but will only happen rarely. While some strains of HIV are resistant to the drugs used as PrEP, they are rarely transmitted and so far there has only been one case of PrEP failure due to drug-resistant HIV.

The bottom line: There is no evidence that PrEP will lead to many more cases of HIV drug resistance.

Financial cost

Providing PrEP will involve an initial outlay, but the costs to the health system will later be recouped as fewer people need HIV treatment. Most of the cost of PrEP consists of the price of the drugs used. As these drugs come off patent from 2018, it is likely that much cheaper generic versions of the drugs will be available relatively soon. The cost of drugs will be borne by NHS England while the running costs of the sexual health clinics which will provide PrEP are covered by local authorities. PrEP is unlikely to make much difference to clinic costs as most people who need PrEP are already attending frequently for HIV and STI testing.

The bottom line: PrEP will represent some initial cost to the NHS, but this will be considerably smaller than the current bill for HIV treatment.

More details on cost-effectiveness

Two cost-effectiveness models for PrEP in the UK have been developed.

The first model⁹ showed that daily PrEP use in gay men would be cost saving – i.e. actually start recouping its cost straight away, because of fewer HIV infections – if it was taken by gay men who had sex without a condom with five or more partners in a three-month period. It would be cost-effective – i.e. although it would not save money immediately it would be a good investment – if taken by gay men who had sex without a condom with three or more partners or who had had a sexually transmitted infection in the last three months. If drug prices were to fall by 50%, or everyone took intermittent PrEP as in Ipergay, then PrEP would be cost-saving for all these groups.

⁹ Cambiano V et al. *Is pre-exposure prophylaxis for HIV prevention cost-effective in men who have sex with men who engage in condomless sex in the UK?* BASHH Spring conference, Glasgow, 2015.

The second model¹⁰ showed that PrEP would be cost saving when given to gay men with an HIV incidence of 5% a year. In other words, it would save money if given to a group of gay men where, without taking PrEP, one in every 20 would have acquired HIV within a year. This is roughly similar to HIV incidence in gay men attending STI clinics who have had condomless sex as receptive partners in the last year. Importantly, the model only assumed that PrEP was 64% effective – this figure was used as a conservative estimate of PrEP’s effectiveness although it was actually 86% in the PROUD study. If PrEP is assumed to be 86% effective, it is more likely to be cost-saving.

Some people believe that PrEP will not be cost-effective unless drug prices are reduced. This is not the case – price reductions are only essential if the NHS extends access to PrEP to people who are at a lower risk of getting HIV.

The bottom line: Given to gay men at high risk of HIV, PrEP will be cost-effective or could even start saving money now, especially if it is as effective as it was in PROUD and if at least a proportion of users take it intermittently.

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Document prepared by NAM and NAT on behalf of a group of community organisations and activists.

¹⁰ Ong K-J et al. *Will HIV PrEP given to high-risk MSM in England be cost-effective? Preliminary results of a static decision analytical model.* Public Health England Conference, Coventry. 2015.