Make PrEP available on the NHS
Stop HIV. PrEP Now. #WhereisPrEP

Terrence Higgins Trust, the UK's largest voluntary sector provider of HIV and sexual health services, is calling on the government to make HIV pre-exposure prophylaxis (PrEP) available for those individuals at highest risk of HIV infection. The World Health Organisation (WHO) has made the same recommendation; PrEP should be made available immediately for those men who have sex with men (MSM) at greatest risk.

We are calling on:
– NHS England to fully fund PrEP for those at highest risk of HIV, as they cover the provision of all HIV drugs and this has always been the sole responsibility of NHS England;
– NHS England to review its communications around PrEP, which have included homophobic comments, have not always been factual, and have pitted health condition against health condition; as well as asking NHS England to not appeal the court's decision;
– Gilead to reduce the price of the drug used in PrEP so that it is affordable to the NHS.

What is PrEP?

PrEP is the most effective way to protect HIV-negative people from acquiring HIV and involves people taking anti-HIV drugs when they are at risk of exposure to HIV. Parallels have been drawn between PrEP and anti-malaria medication or the contraceptive pill used by women.

Currently, the drug used as PrEP is Truvada, which combines two anti-HIV drugs that have been used routinely for many years. Long-term side effects from Truvada are rare. Whilst around 10% of people taking Truvada as PrEP experience short-term side effects (e.g. headaches, fatigue, stomach problems) in the first few days of taking it, these problems usually disappear within two weeks.

Like HIV treatment, HIV prevention has evolved over time. Condoms are effective at preventing HIV but consistent condom use is not always a reality. Those most at risk of HIV transmission need a range of options and choices to best meet their individual needs and circumstances. PrEP – alongside other prevention interventions such as condom use, behaviour change, and regular HIV testing – must be a part of this.

PrEP is effective

The results of the UK based PROUD study of PrEP were published in the *Lancet* medical journal in September 2015. PROUD evaluated the effectiveness of PrEP in a high-risk group of MSM which reflected "real life" use of the anti-HIV drug as closely as possible: 545 men were randomly allocated to either take the PrEP drug Truvada straight away or to defer start of PrEP for a year. Both groups then had regular three-monthly clinic check-ups.

The results clearly showed that PrEP was highly effective at preventing HIV infection. Daily PrEP reduced the number of HIV infections by 86% in this group – only three men became HIV positive during the trial and these individuals either didn't take PrEP as prescribed, or were HIV positive at the start of the trial but had not yet been diagnosed. When taken properly the effectiveness of PrEP is near 100%.

In addition, the PROUD study showed virtually no difference in reports of condom use between the two groups and no difference in rates of other STIs– contradicting the claim that access to PrEP would somehow encourage an increase in risky sexual behaviour.

In France, the Ipergay study looked at an intermittent on-demand model of PrEP which also had an efficacy of 86%. France used both PROUD and Ipergay as evidence to approve the provision of PrEP on its health insurance system, since December 2015. PrEP has been available in the USA, following the approval of the Food and Drug Administration (FDA) since 2012, and is also available in Kenya, Israel and Canada.

Cost of PrEP to the NHS

The case has been made for the effectiveness of PrEP in preventing HIV transmission, and PROUD demonstrated that health clinics that participated in the trial can integrate PrEP into routine practice. The question of its cost-effectiveness has been considered over the last 18 months by a subgroup of the HIV Clinical Reference Group which advises NHS England. The two main costs associated with providing PrEP are: (1) the cost of the drug, and (2) the cost of providing it in a sexual health service setting.

1. Cost of drug

It has been estimated that the average lifetime cost to the NHS for a person living with HIV is £360,000. Around two thirds (68%) of these costs were for anti-HIV drugs. The cost of a year's HIV treatment is about £11,000 and of PrEP £5,000. The NHS obtains Truvada at a cost of £3,000–£4000 per person per year. People need to take HIV treatment for the rest of their lives but PrEP will generally be needed for a much shorter period. It is believed that the patent for one of the key drugs in Truvada, Tenofovir, expires in 2017, slashing the cost of the drug from this time. There has been a collective call on Gilead, from those involved in PrEP activism, to lower the price of Truvada for use in PrEP, as there are concerns that PrEP may not be deemed to be affordable.

2. Cost to sexual health services

As with other HIV and STI prevention options, PrEP should be provided in sexual health (GUM) clinics and the drug costs should be provided by NHS England. However NHS England are now disputing this and saying that local authorities should be meeting the cost of the drug as well as staffing and 'wrap-around' support – such as testing for other STIs and behavioural interventions. According to guidelines from NICE, MSM should be attending GUM clinics every three months. The vast majority of support services should therefore not incur further costs. **However, we are very concerned that if the appeal is won and the responsibility for PrEP is given to local authorities, then they will not have the money available to pay for PrEP, as they continue to suffer from central government budget cuts.**

PrEP is starting to be made available through private prescriptions at £400 for a 30-day supply of Truvada – vastly out of the price range for most individuals who need it. Truvada is also available to buy online at £35-£45 for a 30 day supply. Although a few sexual health clinics provide drug tests to verify the quality of purchased drugs, this option isn't always taken up or widely available, leading to the possibility of using unknown and unreliable quality generic Truvada. However, community groups, in the absence of availability through the NHS, are taking it upon themselves to identify and signpost to sources of online generic PrEP, and deal with ongoing supply issues. Several clinics across the country are providing 'wrap around' support for PrEP bought elsewhere, such as liver tests and monitoring.

All the steps so far around commissioning PrEP

- After 18 months of work, January 2016 saw the stakeholder consultation on PrEP which Terrence Higgins Trust and other stakeholders took part in.
- March 2016 – NHS England said that after seeking legal advice, PrEP was being taken out of the NHS England specialised commissioning process. Then they quickly put that decision on hold.

- May 2016 – NHS England confirmed its original statement that they are not responsible for commissioning PrEP, although they are the sole procurer of all HIV drugs. No alternative suggestions had been given as to where responsibility was supposed to lie to fund PrEP.
- July 2016 – the National AIDS Trust (NAT) took NHS England to court with a judicial review, over their decision not to fund PrEP.
- August 2016 - the judgement of NAT's court case was announced and it found that NHS England is responsible for funding PrEP through its specialised commissioning budget.
- Currently - NHS England are appealing the judgement. However, a public consultation on PrEP is happening alongside the appeal, for if the appeal is upheld and NHS England are responsible for funding PrEP.

Next steps

We believe that the court's judgement that NHS England is responsible for funding PrEP through specialised commissioning should be upheld. Whilst NHS England is appealing that decision, time is of the essence. A decision on whether PrEP would be made available should have been made in June 2016. Whilst we continue to wait for PrEP, rates of HIV in the MSM population continue to rise.

In June the government announced another new hurdle for PrEP to be available on the NHS. A NICE (National Institute for Health and Care Excellence) evidence review will be completed in the autumn and will look at "evidence for effectiveness, safety, patient factors and resource implications". It is unclear why this evidence review is needed as the PROUD study looked at the use of PrEP in a "real-life" setting. There will be £2 million made available for the PrEP pilot which will get underway at the end of this year and it will run for two years (until end 2018). Very little information on the pilot has been released.

The current situation with PrEP reinforces the impact of fragmentation of responsibility for HIV prevention and treatment post Health and Social Care Act 2012. It is increasingly unclear who is responsible for funding and commissioning vital HIV services.

The CRG was considering PrEP for MSM, trans-people and sero-discordant heterosexual couples only. Whilst this is a much needed first step, there is a clear need for PrEP in other groups at high risk of HIV in the UK including sex workers and members of the African community. UK-based research is needed to explore models of delivery that would ensure that those individuals who most need PrEP are identified and PrEP delivered to them. Currently, there is no research being undertaken into this, and no funding earmarked for this research. This must change. PrEP has been shown to be highly effective in preventing HIV and it must be available to all individuals at highest risk.

We can't afford <u>not</u> to provide PrEP on the NHS now when it will prevent HIV infection.

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