

HIV Pre-Exposure Prophylaxis (PrEP) in England We can't afford <u>not</u> to provide PrEP as part of routine sexual health services now when it prevents HIV transmission

What do we want to see

- The Department for Health, NHS England, Public Health England and Local Authorities to expedite discussions to make PrEP routinely available as soon as possible through a national programme.
- In the interim, the promised doubling of places on the Trial to be realised everywhere both inside and outside of London so that no one is turned away when trying to access the PrEP trial.
- Increased engagement to ensure all demographics who could benefit from PrEP, including trans, black African communities and women, are informed and encouraged to access PrEP.

The PrEP Impact Trial

Terrence Higgins Trust believes everyone who could benefit from Pre-Exposure Prophylaxis (PrEP), which is a drug taken to prevent HIV, should have access to it. October 2017 saw the start of a three-year Pre-Exposure Prophylaxis (PrEP) Trial in England.

The Trial was for up to 10,000 people (which increased to 13,000 people in September 2018) who are at risk of HIV. We cautiously welcomed the Trial, however we were clear that the Trial was not sufficient – even with the extra 3,000 places – and that NHS England must make good on its word to delivering a national PrEP programme as soon as possible. There have been reports of people becoming infected with HIV due to being unable to access the Trial, as reported in Buzzfeed <u>https://www.buzzfeed.com/patrickstrudwick/the-nhs-refused-to-give-this-man-the-hiv-prevention-drug</u> The Trial is still not large enough.

On 11th January 2019 NHS England endorsed the recommendation given by the Trial Management Group to double the number of places on the Trial from 13,000 to 26,000. Following political pressure, Secretary of State for Health & Social Care, Matt Hancock MP has committed to the doubling of places on the Trial but there still remains no timetable for this happening. Only 67% of Trial sites outside of London have agreed to double the number of places, with London Local Authorities only agreeing to a 60% increase in places.

This delay comes as over 100 Trial sites (over 50%) are now closed to gay and bisexual men and eight Trial sites have still yet to open meaning there is no PrEP access via the Trial in these areas. A full list of Trial sites can be found <u>here</u>.

England is now the only part of the UK where access to PrEP is capped. PrEP has been routinely available in Scotland and via an uncapped pilot in Wales since July 2017. Northern Ireland has also made PrEP available via Health and Social Care Services as part of a two year pilot project.

The World Health Organisation has recommended PrEP should be made available immediately for those at risk of HIV. Terrence Higgins Trust continues to campaign for PrEP to be routinely commissioned and has a long-term home as part of routine HIV prevention services. This is so that everyone who needs PrEP can access it locally, and as a spend to save initiative because accessing PrEP as part of the Trial is considerably more expensive that accessing it routinely through local sexual health services.

What is PrEP?

PrEP is a highly effective way to protect HIV negative people from becoming infected with HIV and involves people taking anti-HIV drugs when they are at risk of exposure to HIV. Currently, the generic version of the drug Truvada used as PrEP in the IMPACT Trial is Mylan, which combines two anti-HIV drugs that have been used routinely for many years.

Why is PrEP needed?

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 (2015) evaluated the effectiveness of PrEP in a high-risk group of men who have sex with men (MSM) which reflected 'real life' use of the anti-HIV drug. In total 545 men were randomly allocated to either take the PrEP drug Truvada straight away or to defer starting 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 study and these individuals either didn't take PrEP as prescribed, or were HIV positive at the start of the study but had not yet been diagnosed. When taken properly the effectiveness of PrEP is near 100%.

In Wales, following the introduction of PrEP, there has been no new HIV infections among those accessing PrEP via the national pilot.

Cost of PrEP

The commercial price of branded Truvada as PrEP is approximately £300 per month. The NHS England PrEP Trial is using generic PrEP – which can cost around £30 per month per person – the total cost to the NHS remains confidential due to commercial sensitivities. NHS England has committed £10m over three years to pay for the PrEP Trial. In September 2018, the High Court ruled that Truvada manufacturer, Gilead, should not be granted an extension of its patent on the drug. This paves the way for generic PrEP to be used routinely on the NHS. However we are waiting to find out whether Gilead is launching an appeal on this ruling.

Next steps

PrEP must be available for everyone who could benefit from it. We are still awaiting for all of the promised increase in Trial places to be available. They all need to be put in place as soon as possible– any further delay puts more people at risk of HIV. There are also still no timescales for when a national PrEP programme will be put in place.

In late 2019 we expect the interim analysis of the PrEP Trial to be published. This will provide all relevant parties with the adequate information they need to deliver a comprehensive national PrEP programme. We are pushing for this interim analysis to be available in the public domain.

PrEP is a game changer in the UK's HIV response, it is highly effective in reducing new HIV transmissions and must be made available to everyone who could benefit from it.

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