



The Commissioning of PrEP (Pre-Exposure Prophylaxis)

Following a recent Court of Appeal case relating to the commissioning of Pre-Exposure Prophylaxis (PrEP), this briefing outlines the background to the court ruling against the NHS and the impact this ruling will have on the boroughs.

Overview

Pre-Exposure Prophylaxis (PrEP) involves the use of an anti-retroviral (ARV) drug which may be prescribed to HIV negative people who are at high risk of contracting HIV. Using PrEP can prevent them from becoming infected. In March this year, after developing the draft PrEP policy by a working group that included local authority representatives, NHS England withdrew the policy from the annual prioritisation round, citing legal advice that NHS England was not the responsible commissioner.

This decision by NHS England was subsequently challenged through a Judicial Review. On 2 August the high court ruled that NHS England does have the power to commission PrEP. The judge ruled that NHS England had “mischaracterised the PrEP treatment as preventative when in law it is capable of amounting to treatment for a person with infection”.

NHS England decided to appeal this decision on the grounds that local authorities have the legal responsibility to provide services to prevent the spread of HIV. The appeal was heard on 15 September and in November a ruling handed down rejecting the NHS England appeal. PrEP will now be considered alongside other potential treatments and interventions when the NHS England prioritisation round is re-run, which is expected before the end of 2016.

Background

HIV is a key public health issue for London. Almost half of all new HIV diagnoses in England in 2014 were in London (49 per cent, 2,671) and HIV prevalence is higher in London than anywhere else in England, with 35,363 people in London living with diagnosed HIV (60 per cent higher than 2005). The key population groups at greatest risk of HIV infection are men who have sex with men (MSM) and black African communities.

London’s need for HIV prevention continues to rise, especially among key at-risk groups, and

PrEP can play a key role in preventing more Londoners from becoming infected with HIV. Results from a number of trials, including trials held in England, have shown how effective PrEP can be in preventing HIV negative people from becoming infected with HIV. With a 2015 PROUD study carried out in England reporting that use of PrEP reduced the risk of HIV infection by 86 per cent for gay and other men who have sex with men when delivered in sexual health clinics.

PrEP has also been shown to be cost-effective and even cost saving, to NHS England, when compared to treatment costs for someone with HIV. It costs almost £380,000 to treat one person with HIV across their lifetime, while the cost of providing PrEP drugs for one person is around £4,700 per year.

It must be noted that despite PrEP being effective in preventing HIV infection it is still the case that the best way to prevent contracting both HIV and sexually transmitted infections (STIs) is to use a condom, and the fact that PrEP may become available does not change the recommendation that condoms should always be used to prevent the spread of HIV and other STIs.

Initial decision by NHS England not to fund PrEP

An expert group, including representatives from medical research, patients, local authorities and sexual health providers, worked for 18 months with NHS England to advise whether PrEP drugs should be funded by NHS England, who have the responsibility to fund this class of drug. NHS England announced on 21 March 2016 that it will not fund PrEP drugs.

Instead NHS England proposed that, rather than introduce PrEP across the country, it would set up ‘test sites’ for two years in some local authorities, where PrEP would be available to those most at risk of contracting HIV. The test sites would have aimed to reach 500 people in total, and funding of £1million would have been made available for each of the two years to pay for the PrEP drugs.

LGA, ADPH (UK) and London Councils responded to this shift in direction in a joint letter to Simon Stevens, Director of NHS England on 12 April which was copied to Jeremy Hunt, Jane Ellison, Greg Clark and Duncan Selbie. The letter stated that:

“During implementation of the NHS and Care Act 2010, NHSE sought to retain commissioning of HIV therapeutics, to which PrEP and PEP belong. As PrEP is an ARV treatment as prevention, it is and should remain the responsibility of NHSE. Attempting to pass responsibility for funding PrEP drugs onto local authorities is a new burden and the new burdens doctrine and guidance has not been followed.”

Initial Judicial Review

The National Aids Trust took NHS England’s decision not to take PrEP forward to the consultation process, or to take it to the NHSE Clinical Priorities Advisory Group (CPAG), to judicial review. This was on the grounds that the decision was wrong in law, that the NHSE were unlawfully fettering their discretion and that no equality impact assessment had been carried out as to whether the decision would have a disproportionate impact on a particular disadvantaged group.

On 2 August 2016 in the High Court, Mr Justice Green ruled on the judicial review taken by National Aids Trust (NAT) against NHS England and decided that:

“There is nothing to prevent NHSE paying for PrEP drugs. NHSE had been arguing it had no power under the National Health Service Act 2006 to pay for public health functions, and that councils were responsible for providing PrEP drugs as they are responsible for preventative health

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“Even if NHSE does not have the power under the 2006 Act, NHSE could still pay for PrEP on the basis that it could be viewed as a treatment for a person with HIV infection, and that NHSE has a broad power to commission preventative treatments and could pay for that reason.”

NHS England immediately decided to appeal the decision.

Appeal outcome

The Court of Appeal issued its ruling on their appeal on 10 November 2016, in a judgment that confirms that NHS England can legally fund the HIV prevention drug PrEP.

Cllr Kevin Davis, London Councils’ Executive member for health, said in response to this ruling:

“We are pleased that the court has stood by the original judicial review decision that NHS England can be held responsible for funding the HIV prevention drug PrEP, which we have always said.

“Now the appeal has reached its conclusion, we urge NHS England to consider the results of its public consultation on PrEP and make a swift decision on how the drug will be made available.”

Having established clarity on the legal basis for commissioning, NHS England will now only fund PrEP if they consider it to be effective enough to meet NHS criteria. After having undertaken a consultation process, to which London Councils submitted a response, NHS England will begin the prioritisation process. A decision will be made at the Clinical Priorities Advisory Group where all potential new drugs and treatments which NHS England could commission will be ranked against each other, to see which are most effective and represent best value for money. NHS England will also negotiate with the PrEP drug manufacturers to try to reduce the price.

Commentary

The consideration of PrEP is a critically important issue for London as HIV prevalence is higher in London than anywhere else in England and the provision of PrEP will help to reduce the number of Londoners who become infected with HIV.

The ruling of the court also served to prevent the setting of a wider legal precedent with regards to the funding of preventative medicines. Had the courts ruled in favour of NHS England then local authorities may have found themselves being open to future legal challenges over the financial responsibility for similar preventative drugs or procedures. Had the provision of PrEP been decided to have been the responsibility of local authorities there would have been potentially high costs involved.

Public Health England (PHE) estimated that PrEP will add additional direct costs to boroughs of £176 per person in the first year, and £94 in subsequent years for those continuing on PrEP. Additional indirect costs to boroughs are estimated to be £208 per person in the first year.

The ruling of Mr Justice Green in the High Court provided a useful clarification to the difference between local authorities providing public health and NHS England having the power to commission preventative treatments.

Local Authorities clearly have a preventative role too, by pushing the safe sex message of using condoms and getting tested regularly, and by doing all it can to ensure an infrastructure exists through GUM provision for the delivery of an NHS-funded PrEP service. All these elements are needed in the fight against HIV.

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Despite the rhetoric being used by NHS England in the press coverage evidence shows that use of PrEP does not make people adopt riskier behaviours. The PROUD study did not find significant difference in risk behaviour between those not on PrEP and those prescribed PrEP at the commencement of the study. Neither did it find that people on PrEP had a higher incidence of STIs than the background rate for individuals of highest risk not on PrEP. Other studies of PrEP have consistently reported that being on PrEP did not result in people adopting riskier behaviours. Instead it gives people who already find it difficult to consistently use condoms a way to protect their health.

London Councils will keep the boroughs updated when NHS England make a decision on whether PrEP will be made available.

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