Local Government Association

Towards the routine commissioning of pre-exposure prophylaxis (PrEP)

FAQs for officers and elected members

Guidance

PrEP

FAQs for elected members

What is PrEP?

Pre-exposure prophylaxis, or PrEP, is a way for people who do not have HIV to prevent HIV infection by taking a pill every day (daily dosing), or before and after likely exposure (event-based dosing). This consists of two medicines that are also used – sometimes in combination with other medicines – to treat diagnosed HIV. PrEP is not a vaccine and only provides protection from HIV so long as it's taken as prescribed.

Why is PrEP important in the fight against the spread of HIV?

In 2018, 4,484 people were newly diagnosed with HIV in the UK, although new HIV diagnoses have been declining over recent years, an estimated total of 103,800 people were living with HIV in the UK in 2018, with seven per cent (7,500) unaware of their infection.

The UK is one of the first countries to meet the UNAIDS 90-90-90 targets. The report 'Progress towards ending the HIV epidemic in the United Kingdom 2018[1]' estimates that in 2017, 92 per cent of people living with HIV in the UK have been diagnosed, 98 per cent of those diagnosed were on treatment, and 97 per cent of those on treatment were virally suppressed.

The UK Government has set out a commitment to end transmission of HIV in England by 2030.

PrEP is also important for broader sexual health. It provides an opportunity for individuals at higher risk of HIV and sexually transmitted infection STIs – some of whom will not have been accessing prevention services previously – to regularly engage with sexual health and health promotion services.

How does PrEP work?

When someone is exposed to HIV, these medicines work to keep the virus from establishing a permanent infection. When taken in accordance with recommended use, PrEP has been shown to significantly reduce the risk of HIV infection in people who are at high risk.

Is PrEP effective?

Recent findings from several international and UK-based clinical trials have demonstrated safety and a substantial reduction in the rate of HIV acquisition for men who have sex with men (MSM); men and women in heterosexual HIV-discordant couples (those where one partner is HIV-positive and the other is not); heterosexual men and women recruited as individuals, and to a lesser effect, people who use drugs, all of whom were prescribed either daily or event-based oral antiretroviral PrEP.

The demonstrated efficacy of PrEP was in addition to the effects of regular condom provision, sexual risk-reduction counselling, and frequent testing, diagnosis and treatment of STIs all of which were provided to trial participants.

1 www.hivpreventionengland.org.uk/wp-content/uploads/2018/12/PHE-HIV_annual_report_2018.pdf

What is the PrEP Impact Trial?

In England, investigation of population-level provision of PrEP has commenced through the PrEP Impact Trial. This will enable NHS England and local authorities to understand how many people need PrEP, how many will want to take it, and for how long.

Up to 26,000 people will be recruited to the trial over three years. HIV negative people attending NHS level 3 sexual health clinics and up to 10 independent providers in England will have their risk of acquiring HIV assessed by clinic staff. If an individual meets the trial eligibility criteria, they will be offered PrEP. Recruitment to the trial started in October 2017, with final follow-up completed in October 2020.

Ring-fenced places on the trial have been set aside for 1,300 women and underserved black, Asian and minority ethnic (BAME) groups.

For more information on the total numbers recruited to the trial visit the NHSE website, alternatively you can visit the trial website for details which individual clinics are recruiting.

Is PrEP available in other UK countries?

PrEP is available in NHS sexual health clinics to eligible Welsh, Scottish and Northern Ireland residents. PrEP is also available in other countries such as France, Australia, the US, Canada, Kenya and Israel.

Will PrEP be rolled out nationally to anyone that wants it?

We want to ensure equitable and consistent provision to those identified as being at high-risk as soon as practically possible; based on the interim analysis from the impact trial. A seamless transition from trial to routine access is the goal, and commissioners and stakeholders have started planning how to achieve this.

To develop recommendations for a future, high-quality national PrEP programme in England, a PrEP Commissioning Planning Group (PCPG) was established.

At the point of writing, no definitive start date has been confirmed.

How will you avoid exacerbating disparities between access and uptake in high-risk populations?

Data from the USA and other developed countries suggest that PrEP uptake tends to be lower in women, BAME, transgender, younger and older MSM communities and there may be a social gradient too, systematically disadvantaging access for those who are socio-economically deprived.

The importance of health equity/variations will become a particular factor following the end of the trial. Local systems are well placed to monitor and address these issues as the programme is expanded and implemented.

Are there costs associated with PrEP?

There are additional costs of introducing PrEP at scale that will require funding. NHS England and NHS Improvement have agreed to fund the drug costs (generic emtricitabine/tenofovir) of a routinely commissioned PrEP service. While some of these financial burdens may be absorbed by current funding streams, we anticipate that additional financial resource will be needed to meet the costs of:

- increased drug provision (compared to the trial)
- increased and significantly longer sexual health clinic attendances for PrEP initiation and continuation
- more frequent HIV and STI testing within current guidelines and potentially increased treatment costs associated with increased STIs
- management of previously undiagnosed co-morbidities (eg renal impairment) or other complexities which may increase risk or affect adherence
- the need for enhanced community mobilisation and engagement, especially for women, trans people, black African communities, younger and BAME MSM groups, and other underserved groups.

Differences in trial compared to programme delivery of PrEP, particularly around adherence, consent, and dosage, are such that trial data are indicative but not definitive.

What is the likely PrEP delivery model going to look like in England?

While this is still to be confirmed and contingent upon new resources to manage a nationwide programme, the model that is currently being tested as part of the trial, should be the base assumption. Innovative developments such as digital management are being tested to help manage costs and pressure on services.

Ultimately there will not be a 'one size fits all' approach (since there are local variations in sexual health service commissioning) and that it will be up to local systems, working together, to determine how best to use resources to ensure equitable delivery of PrEP, ensuring that it meets local need, engages local partners and communities, and aligns with locally commissioned sexual health services.

How cost effective is PrEP?

Several studies have reported the cost-effectiveness of PrEP to be highly dependent on the incidence of HIV in the target population and drug costs.[2] Among MSM at high-risk of HIV, PrEP is both cost-effective and cost-saving considering the avoided HIV treatment and social care costs, and the collateral benefits to both participants and the wider sexual health system. Regular STI testing at follow-up may identify asymptomatic or recently contracted STIs, including hepatitis C.

Timely treatment should reduce onward transmission and may decrease the prevalence of these infections. Frequent attendance at sexual health clinics provides additional opportunities to provide vaccinations for hepatitis A and B, and HPV for those MSM aged 45 and under; the latter has been shown to reduce the incidence of anal warts and is expected to impact on anal and throat cancer rates.

PrEP provision may incur several costs depending on the individual. PrEP may engage people in the sexual health system who have not previously presented. New attendees receive a wide variety of standard tests and vaccinations, which require additional clinical support. For older people, longitudinal management may require support from a wider range of clinicians to address co-morbidities and polypharmacy (including any conditions detected at initial assessment).

2 www.nice.org.uk/advice/esnm78/chapter/Key-points-from-the-evidence

Does PrEP protect against STIs?

As PrEP only protects against HIV, condoms and other prevention interventions are important for the protection against other STIs.

There is evidence to suggest that PrEP implementation may be associated with an increase in STI diagnoses among MSM[3,4]; a direct or causal link with PrEP is still being investigated. A systematic review and meta-analysis identified a 24 per cent increase in the odds ratio of any STI diagnosis among those using PrEP. The mechanisms for this remain unclear, though a reduction in condom use and an increase in the number of sexual partners are thought to be contributing factors.[5,6] Rates of STI acquisition among impact trial participants will be assessed in final trial analyses.

There is currently no longitudinal data in UK, yet looking at STI incidence pre and post PrEP use – this will be vital to understand what is happening.

Frequent attendance at sexual health clinics for PrEP provision encourages more regular testing for STIs, which may lead to an increase in the diagnosis of asymptomatic infections and a subsequent reduction in onward transmission. PrEP is also an important tool to increase engagement of those most at risk of poor sexual health, which may include diagnosing HIV infection.

3 Traeger MW, Schroeder SE, Wright EJ, et al. (2018) Effects of Pre-exposure Prophylaxis for the Prevention of Human Immuno deficiency Virus Infection on Sexual Risk Behavior in Men Who Have Sex with Men: A Systematic Review and Meta-analysis. Clin Infect Dis 67(5):676-86.

4 Traeger MW, Asselin J, Price B, et al. Changes, patterns and predictors of sexually transmitted infections in gay and bisexual men using PrEP; interimanalysis from the PrEPX demonstration study. Journal of the International AIDS Society 2018;21(S6)

5 Holt M et al (2018) Community-level changes in condom use and uptake of HIV pre-exposure prophylaxis by gay and bisexual men in Melbourne and Sydney, Australia: results of repeated behavioural surveillance in 2013–17. Lancet HIV 5(8):PE448-456.

6 Molina JM et al (2017) Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study. Lancet 4(9):PE402-410.

Further information

PrEP Impact Trial
www.prepimpacttrial.org.uk

NHS England and NHS Improvement – PrEP Impact Trial Updates
www.england.nhs.uk/commissioning/spec-services/npc-crg/blood-and-infection-group-f/f03/prep-trial-updates/

Getting PrEP to those who need it
https://publichealthmatters.blog.gov.uk/2018/10/31/getting-prep-to-those-who-need-it/

National Aids Trust
www.nat.org.uk/tags/prep

Terrence Higgins Trust
www.tht.org.uk/hiv-and-sexual-health/prep-pre-exposure-prophylaxis?gclid=EAIaIQobChMIor-mgKmK5gIVBLDtCh1dSwRvEAAYASAAEgJRr_D_BwE

Local Government Association
18 Smith Square
London SW1P 3HZ

Telephone 020 7664 3000
Fax 020 7664 3030
Email info@local.gov.uk
www.local.gov.uk

For a copy in Braille, larger print or audio,
please contact us on 020 7664 3000.
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