PrEP public consultation: guidance and summary

Q. What is the NHS England 45-day public consultation?

A. The consultation is the same public consultation that was put on ice at the start of this year by NHS England. It asks for opinion on the policy specification on PrEP that was written by NHS England's Clinical Reference Group on HIV (and a sub-group specifically looking at PrEP).

The deadline to submit a response is 23 September 2016.

The full consultation, and the online survey to fill in, can be found here: https://www.engage.england.nhs.uk/consultation/specialised-services

If you are responding as an individual, please don't be put off by the first page which asks for your Job Title and Organisation. You can still submit your responses and leave these (or any of the question boxes) blank.

Q. Why is it important that you respond to the consultation?

A. A high number of positive responses, especially where they encourage improvements in the proposed policy, will add pressure on NHS England by demonstrating strong public support.

We have developed a template response to help individuals respond to the consultation (see page 6). We strongly encourage you to put in your views in support of PrEP.
It is of course entirely up to you what you write. If in what you write you are able to draw on your own experiences as an individual that will certainly add to the impact of what you say (Question 5 might be a good place to add in something from your own experience or the experience of those you know). You may well want to put things in your own words. We have in this template response put in some suggested text in response to the questions,

- which can guide you in what you write yourself,
- or which you can selectively use and build on in what you write,
- or which you can simply copy as something which reflects what you want to say.

It's up to you. **We also encourage as many organisations as possible to respond. We have developed a detailed draft response** which organisations (and any individuals who wish to) can read and draw on, copy or use as you see fit in putting together your own response.

Q. What do we think of the consultation document?

A. Our view overall of the consultation documents is as follows:

- We welcome the overall proposal for the commissioning of PrEP.
- The eligibility criteria for PrEP need to be clarified and strengthened for heterosexuals.
- The underlying assumptions in the cost effectiveness section of the impact assessment both underestimate the HIV transmission rate among those who would access PrEP and underestimate the effectiveness of PrEP. This means that the case for the cost-effectiveness of PrEP is unnecessarily weakened.
- Generic drugs will be available from 2018 and this will make PrEP much cheaper.
- The proposal will have far reaching and beneficial impacts on equality, though if not commissioned, the opposite would be true.
- There are concerns that the NHS England prioritisation process is not set up to prioritise prevention technologies, and that some of the particular benefits of PrEP may therefore not be recognised. This needs to be addressed.
- Some of the wider benefits of PrEP should also be brought to the attention of the NHS England panel (which the prioritisation matrix allows for). These include benefits to mental health, innovation, equalities and the wider health and social care system.

Q. Is there a summary of the documents referred to in the public consultation?

A. Yes: there are three key documents referred to in the public consultation. In addition, there are two further background documents to the consultation for information, the Clinical Panel Report and the Engagement Report where, we suggest, no comments are needed. We have summarised the three documents referred to in the public consultation briefly below:

1. **Evidence Review:** This document looks at the methodology used in compiling the evidence, the results of that evidence (both national and international studies were looked at) for different groups, and a summary of that evidence, including cost-effectiveness. It concludes that PrEP with necessary price reductions is cost-effective for an affordable public health programme of sufficient size. The cost-effectiveness

and budgetary impact of PrEP provision have been calculated for inclusion in the integrated impact assessment (below).

2. **Impact Assessment:** This document looks at the current and future patient population and demography / growth, the existing and new patient pathways, the service organisation including geography, implementation and collaborative commissioning, the cost and its impacts to both NHS England and to the NHS as a whole, the funding, financial risks, value for money and cost profile. The most pertinent of which is in the value for money section which sites the two UK cost-effectiveness analyses and concludes that PrEP may be cost-effective and cost-saving, though initially PrEP does represent a cost pressure for the NHS.

3. **Policy Proposition:** This document includes an equality statement, explains the proposed intervention bringing together the evidence base and cost-effectiveness, but it also explains about how PrEP would be commissioned, governed and audited in practice.

    - The equality statement explains that NHS England will work in line with the Equality Act 2010 and the Human Rights Act 1998.

    - The proposed intervention is around the use of antiretroviral drugs (PrEP) before exposure to HIV, given to people who don't have HIV to prevent an established infection. The groups proposed to be eligible for PrEP are:

        1. men who have sex with men, trans men and trans women: PrEP is recommended for HIV negative individuals in these groups who fulfil the criteria of:

            - having had a documented negative HIV test in the preceding year;
            - have had condomless anal intercourse in the previous 3 months;
            - are anticipated to have condomless anal intercourse in the next 3 months.

        2. serodiscordant / serodifferent couples (couples with different HIV status): PrEP is recommended for the HIV negative partner (confirmed by a documented negative HIV test in he preceding year) of a diagnosed person with HIV who is not known to be virally supressed and where condomless sex is anticipated.

        3. heterosexual men and women: PrEP is recommended for HIV negative heterosexual people clinically assessed and known to have had condomless sex with a person with HIV (who is not known to be virally

supressed) within the past 3 months and for whom it is anticipated that this will happen again, either with the same person or another person with similar status, and so is clinically assessed and considered to be at high risk of HIV acquisition.

- The evidence base for PrEP includes three randomised studies demonstrating effectiveness, two of which were in Europe (the UK PROUD trial and France's IPERGRAY).

- Cost-effectiveness for daily oral PrEP given to MSM in the UK have had two analyses. The first model concluded that daily PrEP use among MSM was cost-effective when targeted at MSM reporting five or more condomless sex partners in the last year, when presenting with a bacterial STI, or in men having condomless sex if the cost of antiretrovirals (for treatment and for use in PrEP) was reduced by 50% of the current British National Formulary list price. The second model looked at PrEP being offered to selected GUM clinic attendees for a one-year period compared to their life-time risk. The model suggested that PrEP is cost saving when delivered to MSM with high incidence of 5 per 100 person years, if PrEP effectiveness is at least 64%. In both analyses the period over which PrEP is cost effective and cost saving is most sensitive to the estimated HIV incidence in those eligible and to the price of antiretrovirals (ARVs).

- PrEP would be commissioned following a documented and full sexual and clinical risk assessment by a suitably qualified healthcare professional in a level 3 GU service. The eligibility criteria outlined above should be applied to establish if there is a high risk of HIV acquisition and eligibility for PrEP. The treating clinician monitors PrEP as part of an active risk reduction including health education and safer sex promotion. And the patient remains actively involved in the risk reduction intervention and is able to affirm their appropriate adherence to PrEP. This is recorded and monitored. PrEP will be stopped if the eligibility criteria is no longer met or if the person taking PrEP has confirmed HIV infection.

- The governance arrangements for PrEP would sit with Local Authorities who commission sexual health services. To ensure the quality, safety and appropriate use of PrEP:

  - access will be via named providers only;

  - all selected providers will need an agreed pathway for referral into HIV care and treatment for all patients who are tested as HIV positive, before, during or after they are prescribed PrEP;

- all selected providers will need to separately record and invoice for use of drug for PrEP.

- The funding arrangements would be that NHS England will reimburse the cost of the antiretroviral drugs used for PrEP and Local Authorities will fund the service costs associated with PrEP.

- The audit requirements for PrEP would be that all selected providers must submit individual requests for prior approval, monitor data via Public Health England surveillance systems and STI data via GUMCAD for the monitoring of impact of PrEP on STI rates.

Example response below

For individuals: example response

Please see below example responses to the key questions in the PrEP consultation. The final response must be filled in by online form. As the first few questions are related to information about you we have begun at question 5.

Don't be put off by the questions on organisation and job role – these are for organisational responses but it is fine to respond as an individual.

Question 5: Has all the relevant evidence been taken into account?

Yes

Comments:

The evidence for the effectiveness of PrEP (pre-exposure prophylaxis) is well summarised. I strongly support the provision of this exciting new prevention option by the NHS to those at high risk of getting HIV. I believe it should be made available as soon as possible. It will be cost-effective and in the long run save the NHS money. It will prevent many people getting an extremely serious condition and, for some of them, it will stop them unknowingly passing it on to others. It will reduce the unequal burden of HIV on certain groups such as men who have sex with men, and black African communities, especially black African women.

Question 6: Does the impact assessment fairly reflect the likely activity, budget and service impact?

No

If you have selected 'No', what is inaccurate?

I welcome most of the content of the impact assessment including the overall conclusion that PrEP will be both cost-effective and cost-saving over time. This conclusion needs to be more clearly stated.

This is all the more striking given how conservative many of the assumptions were in coming to that conclusion. It must be kept in mind that calculations of cost do not yet take account of Gilead's 'best and final' price for the drug Truvada. The estimates of HIV transmission rate in the group who would access PrEP are also low and not borne out by the PROUD and IPERGAY studies and experience of implementation in the US. I believe the effectiveness of PrEP has been shown to be much higher than that in some of the models referred to (for example one model uses a very low estimate of 64%). I also think the impact assessment plays down unnecessarily the availability of generic drugs from 2018 and the very significant fall in price which will result from that. PrEP will in my view save the NHS even more money and more quickly than the impact assessment estimates.

Question 7: Does the proposed policy accurately describe the groups for whom PrEP should be routinely commissioned?

No

Comments:

It's good to see the focus on PrEP being available to MSM, trans* men and trans* women at risk as well as those in relationships with HIV positive partners whose viral load is not yet suppressed. But there are also some heterosexuals at high risk of HIV and the policy needs to be flexible enough to allow clinicians to provide PrEP when this becomes apparent. Requiring, for heterosexuals, that it be known that a recent partner had HIV (and that also a future partner will too) ignores the fact that most HIV transmissions are from people who don't yet know they have HIV. It will not allow PrEP to be given to some heterosexuals at imminent and significant risk of getting HIV. The criterion should be expanded to include heterosexuals where a recent partner is suspected of having HIV or is known to be at high risk of getting HIV, and future partner(s) likewise.

Question 8: Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?

Comments:

Gay men and BAME heterosexual men and women are disproportionately affected by HIV in the UK. PrEP will reduce HIV transmissions and so reduce this health inequality. It will be important for PrEP to be available on the NHS to ensure this prevention intervention can be accessed by anyone who needs it regardless of their income or social advantages. Without PrEP available free of charge from sexual health clinics we will see PrEP only accessed by relatively privileged people, which will lead to further inequalities in relation to HIV.

Question 9: Are there any changes or additions you think need to made to this document, and why?

Comments:
Changes need to be made as summarised in my responses above.

In addition, NHS England needs to be able to assess the benefits of PrEP over a lifetime, not just a five-year period, as current guidance suggests.

NHS England should also bear in mind that PrEP will:

- Improve mental health by reducing anxiety around HIV and reducing the numbers who get HIV and the associated mental health harms
- Improve the health and social care system more broadly as there are fewer people with HIV needing treatment and care, and there is better engagement with clinical services of those with significant sexual health needs
- Stimulate innovation in HIV prevention and sexual health promotion.

THANK YOU

For taking the time to show your support for PrEP.