



Evidence from PROUD to answer NHS England's questions on Pre-Exposure Prophylaxis

On 21st March NHS England announced that they would not be considering PrEP in competition with specialised commissioning treatments as part of the annual Clinical Priorities Advisory Group (CPAG) prioritisation process in June as the NHS England HIV Clinical Reference Group had expected. This decision was challenged by the National AIDS Trust (NAT) on 12th April. In light of the challenge, NHS England agreed that their position on commissioning PrEP be reconsidered by the Specialised Services Committee (SSC). As such we will find out by the end of May whether the PrEP policy will be reviewed by CPAG.

In the March announcement NHS England stated that there were “remaining questions around how PrEP could be commissioned in the most cost effective and integrated way to reduce HIV and sexually transmitted infections in those at highest risk”. They announced that instead of making PrEP widely available to people at risk of HIV, they will be funding test sites offering PrEP to 500 MSM at high risk of HIV infection in order to “inform future arrangements for the commissioning and provision of this innovative intervention”.

In this policy update we lay out how the PROUD study has already provided scientifically robust and conclusive evidence on the questions they raise.

Integrating the delivery of PrEP into sexual health services to reduce HIV and other sexually transmitted infections in those at highest risk:

Effectiveness of PrEP at reducing HIV in those at highest risk

Previous placebo-controlled trials had already shown that PrEP, when taken regularly, could prevent HIV. PROUD added to this evidence, showing that PrEP is highly effective in a ‘real world’ setting, delivered through sexual health clinics in England when participants

knew they were taking an active drug. The net effect of PrEP was a reduction of HIV infections by 86%. To achieve this level of protection, participants in PROUD must have been good at taking their tablets regularly when they were at risk. PROUD also demonstrated that the offer of PrEP is taken up by those at highest risk of HIV.

Other sexually transmitted infections

PROUD found no significant differences in sexually transmitted infections between men who were in the PrEP and no-PrEP groups.

Can it be implemented and integrated into sexual health services?

The PROUD study was carried out in the 13 sexual health clinics which, overall, see nearly half the MSM that attend a clinic each year in England. These included the busiest clinics that see a large number of MSM as well as clinics with a smaller number of attendees, showing that PrEP can be implemented in both settings. The trial was pragmatic, with no screening visits and no additional adherence support. This demonstrates that UK sexual health clinics are able to roll out PrEP effectively, integrated into their routine HIV and STI risk reduction services. We fail to see what NHS England's early implementer test sites will add to this.

Need for longer-term data

The NHS England statement says that longer-term data are required to be certain that PrEP can make a significant contribution to sexual health and well-being. PROUD is continuing to follow-up participants until the end of September 2016, which will give us an average of around 3 years of follow-up. Delaying a decision on whether to implement PrEP until we have even longer-term data will put thousands of men at risk of HIV in the meantime, while we already know that PrEP is effective at preventing HIV. Longer-term monitoring of the impact

of a PrEP programme on other STIs was already included in the plan to commission PrEP put forward by the PrEP policy sub-group of the HIV Clinical Reference Group.

'Real life' cost-effectiveness and affordability

Based on data from the PROUD study, two cost-effectiveness models of PrEP for MSM in the UK were developed to see under what conditions PrEP would be cost effective, and what effect it could have on the UK HIV epidemic. The preliminary results of the modelling, along with previous studies looking at the cost-effectiveness of PrEP, indicate that the main drivers of whether or not it is cost effective are HIV incidence and drug prices. If PrEP was targeted at those at highest risk of HIV (similar to those who took part in the PROUD trial), or the price of Truvada falls below 50% of the current full list price, PrEP is likely to be cost-effective (or even cost-saving) in England. These results were presented to the PrEP policy sub-group of the HIV Clinical Reference Group, who were tasked with developing a commissioning policy proposal for NHS England, and fed into their recommendations. We are unclear what NHS England's early implementer test sites scheme, providing PrEP to an additional 500 men, will add to this evidence.

Unanswered questions

NHS England are correct in saying that there are unanswered questions about PrEP. However, the questions they identified are not the unanswered ones. We know PrEP prevents HIV. We know there are 6000 new HIV infections in this country each year. We know sexual health clinics in England can deliver PrEP. NHS England's plan to provide PrEP for an additional 500 men at high risk of HIV infection will not add to our existing knowledge. Future research on PrEP should focus on issues such as:

- delivery of PrEP to transgender and non-binary people, and heterosexual women and men at risk of HIV infection
- the roll out of event-based dosing

Our unanswered questions

If the PrEP policy is not subject to CPAG review, we are keen to hear from NHS England what the process will be for considering commissioning PrEP at the end of the two year 'early implementer test sites' programme. We are also awaiting confirmation of how they will offer "a period of further support... to the participants enrolled in the PROUD study".

Further information

- NHS England. [Update on commissioning and provision of Pre Exposure Prophylaxis \(PrEP\) for HIV prevention](#). March 2016
- McCormack S, Dunn D, Desai M, Dolling D, Gafos M, Gilson R, et al. [Pragmatic open-label randomised trial of pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection: the PROUD study](#). The Lancet. 2015
- NAM briefing on PrEP <http://www.aidsmap.com/PrEP/page/2983346/>
- Cambiano V, Miners A, Dunn D, McCormack S, Gill N, Nardone A, et al. Is pre-exposure prophylaxis for HIV prevention cost-effective in men who have sex with men who engage in condomless sex in the UK? Abstract O1. BASHH Spring Conference 2015; 1-3 June 2015; Glasgow, Scotland.
- Ong K, Desai S, Desai M, van Hoek AJ, Nardone A, Gill N. The cost-effectiveness of Pre-Exposure Prophylaxis (PrEP) to prevent HIV acquisition by high-risk MSM in England – results of a static decision analytical model. Public Health England Annual Conference; 15-16 September 2015, Coventry.

Contacts

For more information on the PROUD study, please email mrcctu.trial-proud@ucl.ac.uk or visit http://www.ctu.mrc.ac.uk/our_research/research_areas/hiv/studies/proud/

Credits

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