

PrEP in England: a trial for 10,000

PrEP in Europe, Amsterdam, February
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- **NHS England decision-making on PrEP**
- All anti-retroviral therapy commissioned by NHS England, including for prevention purposes (e.g PEP)
- Sept 2014 NHS England decision-making process begins – focus on evidence of efficacy, need, and cost-effectiveness
- Annual decision round for proposals set for June 2016
- March 2016 NHS England announce they do not have legal powers to commission PrEP because it is a prevention intervention – no clarity as to who else should commission the drug for PrEP



- **Community mobilisation on PrEP**
- United4PrEP coalition; Women and PrEP – clear community consensus and coordinated engagement
- Prepster website gives people latest info on PrEP and how to be active in fighting for its implementation
- Iwantprepnow website enables people to buy PrEP online from overseas (legal in UK for personal use)
- Sexual health clinicians agree official advice for clinics on how to support people interested in and/or using PrEP
- Campaigning organisations push for PrEP in media work and in Parliament



TRANSFORMING
THE UK'S
RESPONSE
TO HIV



UNITED
4
PrEP

'If PrEP was available on the NHS, I might not be HIV positive today.'

- Alex

#United4PrEP



UNITED
4
PrEP

'PrEP has the ability to get people talking about HIV. I have taken control and know I am protected.'

- Vincenzo

#United4PrEP



It's time to have your say on PrEP

Respond now

Consultation ends 23 September



- **The legal challenge**
- NAT took NHS England to judicial review in the High Court and then in the Court of Appeal – **NAT won both times** and NHS England accepted the Court of Appeal judgment that they could lawfully commission PrEP
- A key element in the favourable judgments was the Courts' view that PrEP was both prevention and treatment
- Decision-making process re-commenced – NB NHS England could still reject PrEP



- **Large-scale implementation trial announced 4 Dec 2016**
- £10 m funding over three years to provide PrEP to at least 10,000 people
- 10,000 roughly equivalent to modelled demand during NHS England decision-making process
- Trials/studies can use generic drugs in English law
- Commitment to implement trial findings ‘as part of a wider national roll out’



- **PrEP IMPACT trial questions:**
- What proportion of those attending sexual health clinics will be at high risk and eligible for PrEP?
- What proportion of those offered PrEP will accept it?
- What is the length of PrEP use in those who accept the offer?
- What is the impact on HIV incidence in the population?
- What is the impact on STI incidence in the population?



■ **Eligibility**

- a) MSM or trans women who currently test HIV negative, who also tested HIV negative earlier in the previous 12 months, and who report unprotected sex in the previous three months and consider they are likely to have unprotected sex (excluding oral sex) in the next three months.

- b) The HIV negative partner of someone with diagnosed HIV, who is not known to be virally suppressed and with whom unprotected sex is anticipated.

- c) HIV negative people who are clinically assessed and considered to be at similar high risk of HIV acquisition as those with a partner with HIV who is not known to be virally suppressed. In other words someone who doesn't fall into the criteria set out in a or b but whose situation is assessed to be at a similar level of risk.



- **IMPACT trial design and commencement**
- Large majority of English sexual health clinics have registered for the trial – each clinic is allocated its own number of trial places
- Separate allocations for ‘gay and bisexual men’ (7,600) and ‘women and other people’ (2,400)
- Each trial place can only be ‘used once’ whether that person is on PrEP for three years or three weeks
- Significant delay in first clinic opening for recruitment– not until October 2017
- Still many clinics not yet open for recruitment



- **Recruitment to date, as at 1 Feb**
- 84 clinics open for recruitment (out of 160)
- Two clinics completely filled allocations: further 13 filled MSM allocations
- 4,207 recruited (in less than four months! ..)



- **Ongoing issues**
- Promoting PrEP to those at risk other than white gay/bisexual men
- Have we got the allocation between gay/bisexual men and women/other people right? Have we got the allocation between clinics right?
- What do we do when clinic places fill up quickly? Increase number of places on the trial? Move soon to routine provision?
- How do we speed up clinics yet to open their doors?



Thank you

For more information on the PrEP IMPACT Trial
go to www.prepimpacttrial.org.uk

Please email further questions or comments to
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www.nat.org.uk



NAT (National AIDS Trust)

SHAPING ATTITUDES



CHALLENGING INJUSTICE



CHANGING LIVES

