Preparing for the commissioning of Pre-Exposure Prophylaxis (PrEP) in England

Considerations for developing, commissioning, implementing and monitoring PrEP scale-up in England.

Prepared by the PrEP Commissioning Planning Group and PrEP Oversight Board.

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Table of Contents

EXECUTIVE SUMMARY

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 (tenofovir-disoproxil and emtricitabine, or TD/FTC) that are also used –sometimes in combination with other medicines – to treat diagnosed HIV. 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; PrEP is much less effective if not taken correctly.

The evidence regarding the effectiveness of PrEP is robust. Recent findings from several international 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, 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 sexually transmitted infections (STI), all of which were provided to trial participants.

In England, investigation of population-level provision of PrEP has commenced through the PrEP Impact trial, which 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 – depending on agreement from all involved parties – will be recruited to the trial over three years. HIV negative people attending NHS level 3 sexual health clinics (SHC) and up to 10 independent providers (IP) in England will have their risk of acquiring HIV assessed by the 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.

In preparing for a future PrEP programme across England, a PrEP Commissioning Planning Group (PCPG) was established to develop recommendations for a high-quality national PrEP programme. This report of the PCPG highlights a number of key considerations for organisations and professional bodies responsible for funding, commissioning, or policy development including the Department of Health and Social Care, NHS England, Public Health England, Local Authorities, Specialty Societies, including BASHH and BHIVA, and the community sector, all of whom are represented in PCPG membership. Among the most important considerations include:

1. PrEP affords the opportunity to significantly contribute to the elimination of new HIV infections. A national HIV PrEP programme must go beyond the provision of drugs and adopt a **whole system approach** which: identifies and initiates those at risk of HIV and not accessing PrEP currently; helps those at risk to identify appropriate prevention options; and supports their journey along it.

2. There are **additional costs of introducing PrEP at scale that will require funding**. 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 SHC 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 (e.g. renal impairment) or other complexities which may increase risk or affect adherence; and the need for enhanced community mobilisation and engagement, especially for women, trans people, black African communities, younger and BME 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. The cost pressures will fall on different commissioners and service providers and will therefore require continued close collaboration for resolution.

3. There are **additional opportunities with a national PrEP programme.** A national HIV PrEP programme affords the opportunity to champion equality throughout the delivery of PrEP and **strengthen relationships not only with MSM but especially other groups at high risk of HIV acquisition** who may not otherwise engage with sexual health services. PrEP is a critical tool to unlock the needs of these communities and a PrEP programme is not exclusively a sexual health intervention. There are significant collateral benefits to health and wellbeing and we will need to continue to support commissioners to be able to fund all the elements of an effective HIV transmission reduction strategy.

4. In considering commissioning a national HIV PrEP programme, our vision is 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 now to achieve this.

This document provides a practical guide for organisations responsible for the commissioning of various aspects of a PrEP programme for the prevention of HIV infection in England. It incorporates and takes account of existing clinical guidelines (e.g. from BHIVA/BASHH) on the provision of PrEP, and also the emerging findings of the PrEP Impact trial in England. A summary of recommendations from this report is found in Table 1.

Table 1: Summary of recommendations to prepare for commissioning the HIV PrEP programme

Vision

HIV PrEP should be a fully integrated, key component of a comprehensive national HIV prevention programme in England. All individuals at high risk of acquiring HIV should have access to high quality information, support, treatment, and monitoring for their most suitable HIV prevention option(s) (which may or may not include PrEP as part of a combination prevention approach), irrespective of their gender, ethnicity, sexuality, disability, geographic area of residence or socio-economic background.

Eligibility

It is recommended that the eligibility for PrEP in a national programme be harmonised with the most up to date PrEP guidelines and other clinical guidance (at the time of this report, the 2018 BASHH/BHIVA guidelines). All commissioners should ensure that they have proportionate arrangements in place to ensure that individuals being provided with PrEP meet the criteria described in the BASHH/BHIVA guidelines.

The programme

A HIV PrEP programme for England must be comprised of the following key components:

Provision of and access to PrEP

Plan for the commissioning of a predominantly level 3 SHC-based programme, governed by the following principles which must be considered upon implementation [PrEP Programme Oversight Board (to be continued/established)]:

- Recognition of the significant variation nationally in geography, epidemiology, and clinic size. Therefore, national standards around the PrEP programme should be flexible enough to allow implementation appropriate to the local communities, their needs and local service configuration, including service providers themselves. Inequalities are not acceptable.
- The need for additional access points / pathways to ensure equity of access – to consider non-level 3 SHC pathways, e.g. level 1 and 2 SHC, primary care (including non-traditional delivery e.g. app-based provision of GP services), maternity, termination of pregnancy services. This will require working with communities on the acceptability of potential pathways to be commissioned as well looking at delivery.
- The provision of a national minimum dataset and assessment toolkit, required to project and meet the currently unknown need of non-MSM who may need PrEP.

- Acknowledgment that, while a large number of patients with complex needs will participate in the programme, the majority of PrEP consultations will be non-complex and delivery should be as cost-efficient as possible.
- Consideration of how best to meet the standards of care and the needs of ageing populations – both simple and complex – and an acknowledgement of the potential significant impact on infrastructure.

Comprehensive health promotion

- Additional funding to be identified to provide nationally-coordinated health promotion and education interventions to facilitate equity of access. [DHSC]
- PHE to utilise national health promotion programmes to underpin national coordination of a PrEP health promotion programme, including identifying areas lacking health promotion and/or NGO presence. [PHE]
- PHE to target the HIV innovation fund to support projects aimed at raising awareness and community activation on HIV PrEP. [PHE]
- Local authorities to assess the degree to which local communities are aware of PrEP availability and utilising local services, and target local promotion services appropriately. [Local Authorities (LAs)]

Monitoring uptake and use of programme

- PHE to work with professional organisations including BASHH and NGOs to ensure that robust data codes are available to monitor the implementation of a full national programme ahead of the 'go live' date. [PHE]

Monitoring outcomes of programme

- Continue to update estimates of PrEP need with results of modelling studies and Impact trial interim analysis. [PHE]
- Review implications of the revised estimates for commissioning locally. [LAs]

Programme review and evaluation

- Support routine contract monitoring by local HIV and sexual health commissioners of PrEP uptake and inequalities by providing minimum PrEP programme standards, and supporting local use of a national PrEP Equity Audit tool based on national GUMCAD information system. [PHE]
- Work with research funders, including NIHR, to support ongoing research and evaluation of PrEP implementation and scale up, including any necessary changes after the trial. [PHE]
- Develop a plan for publication of key PrEP programme indicators at a local authority and clinic level (using existing databases such as Fingertips and/or GUMCAD) to promote transparency and accountability, in collaboration with BASHH and SHC. [NHSE, PHE]

Additional core requirements

A commissioned PrEP programme cannot simply be extended within current arrangements. At the core of the commissioned PrEP programme are six additional requirements to support all commissioners, which will support equitable and effective delivery of a national programme:

1. Clear, evidence-based standards for the programme with clear PrEP eligibility criteria, with accompanying quality metrics, which can be introduced into local service models, including pathways from non-SHC settings;
2. Clear, readily available information on need for and estimates of uptake upon which to base local decisions and service and financial planning;
3. Clear arrangements on commissioning and funding responsibilities, including any implications for cross-charging between authorities for PrEP-related sexual health service attendances;
4. Additional funding to meet the increased projected need, including for increased need for STI-related treatment and care;
5. Resources, with innovation and guidance, to develop effective practice for targeted promotion of PrEP and, depending on commissioning responsibility, for adherence support; and
6. Additional funding to provide coordinated interventions to ensure equity of access, especially for women and BAME groups who are poorly reached by trials and studies in England and internationally.

Preparations for commissioning the programme

- Create a PrEP Programme Oversight Board (or similar) to oversee preparation for and delivery of the national programme, including the range of stakeholders described in this document. [TBC]

- Continue to update estimates of PrEP need with results of modelling studies and interim results of Impact trial. [PHE]
- Review implications of the revised estimates for programme and drug commissioning locally. [LAs, NHSE]
- Map data and funding flows to ensure contract compliant arrangements for commissioners of drug and of services. [NHSE, LAs]
- National minimum standards of service provision and reporting must be developed and adhered to by commissioners across the country. [PHE, ESHC]
- Annual health equity audits should be undertaken and reported. [PHE]
- Integrate key equity indicators in routine GUM surveillance for monitoring and reporting. [PHE]
- All localities should routinely review their PrEP uptake data to identify areas of underutilisation, inequalities or gaps in provision, and take appropriate action. [LAs, ADPH, NHSE]
- National surveillance data to guide and update estimates of PrEP need (defined as all those at risk) and demand with results of modelling studies and Impact trial. [PHE]
- Professional bodies, especially BASHH/BHIVA, to review / update clinical guidelines in line with emerging findings from Impact trial. [BASHH/BHIVA]
- Work with community sector and people using PrEP to understand communities' views on and preferences for PrEP. [PHE, THT/NAT, LAs, NHSE]
- The PrEP programme must be a central part of the comprehensive HIV reduction strategy. Provide clear guidance in national policies and commissioning guidance on the importance of integrated, comprehensive provision. [DHSC, NHSE, PHE, LAs]
- Work with English sexual health commissioners to determine the most appropriate method of ensuring that local sexual health service specifications include PrEP assessment and provision as part of an integrated HIV prevention strategy, based upon contemporary evidence of best-practice and effectiveness (appropriate funding to be provided). [LAs, LGA, PHE]

PURPOSE OF THIS DOCUMENT

This document is a guide for the commissioning of a national PrEP programme, borne out of a report from the PrEP Commissioning Planning Group (PCPG). This document summarises the current landscape of PrEP provision in England and suggests areas of consideration for the implementation of a high-quality national PrEP programme upon culmination[1] of the Impact trial. The PCPG is a time-limited task and finish group with representatives from NHS England, Public Health England, Local Authority, the Department of Health and Social Care, BASHH, BHIVA, the Impact trial, and HIV non-governmental organisations.

These considerations build upon the recently published BASHH/BHIVA PrEP guidelines,[2] which provide the specification for commissioned clinical practice, and are based on literature current at the time of writing. These considerations place PrEP within the wider context of combination prevention and reflect on the implications of a national PrEP programme on commissioners, clinics, and the wider sexual health system.

These considerations have been presented to the PrEP Oversight Board, to be discussed with policy makers and lead commissioners for a national commissioned programme (PHE, NHSE, LGA and DHSC). Whilst these considerations form the initial proposals for future PrEP commissioning, they may also, at a later date and with the culmination of the Impact trial, serve as the basis for agreed commissioning recommendations and inform the planning of models of commissioning, delivery, and drug supply.

BACKGROUND

HIV pre-exposure prophylaxis

HIV pre-exposure prophylaxis (PrEP) has been shown to be highly effective[2] in protecting against acquiring HIV-1 infection. PrEP currently involves individuals taking a tenofovir and emtricitabine combination daily or prior to and following potential sexual exposure to HIV. Engagement with a PrEP programme yields further opportunities to synergistically improve overall health. Uptake of PrEP can engage new patients in sexual health care, encourage STI testing, and facilitate regular consultations with clinicians.

The effectiveness and efficacy of PrEP has been established in multiple trials across the world, including the PROUD study conducted in England. Although PROUD addressed the questions it set out to answer (and stopped early due to proven effectiveness), the relatively small sample within the Sexual Health Clinic (SHC) setting left key questions unanswered about large-scale use of PrEP. The PrEP Impact trial aims to address those outstanding questions and provide the data required to inform national PrEP commissioning policy in England.

1 Whilst the Impact trial runs until September 2020, key data to inform commissioning will be available both before and after this date. In order to make commissioning decisions, commissioners require data to inform accurate budget planning. It is the recommendation of this group that commissioners ensure there is no gap in time between people accessing PrEP on the trial and via a commissioned programme.

2 BHIVA/BASHH (2018) Guidelines on the use of HIV pre-exposure prophylaxis (PrEP). Available at: https://www.bhiva.org/file/5b729cd592060/2018-PrEP-Guidelines.pdf

The PrEP Impact trial

The ongoing HIV PrEP Impact trial[3,4] started in October 2017 and is sponsored by Chelsea & Westminster Hospital NHS Foundation Trust, jointly co-ordinated by the Trust and PHE, funded by NHS England (PrEP drug and trial costs), and supported by local authorities (through funding the costs of additional attendances at SHCs, excluding PrEP drug costs). Impact is a non-interventional, non-randomised trial designed to provide a pragmatic health technology assessment of PrEP implementation. The trial aims to recruit 26,000 participants over three years from Level 3 sexual health services; it aims to address outstanding questions regarding PrEP eligibility, uptake and duration of use, and impact on the incidence of HIV and other STIs.

Cost-effectiveness of PrEP

Several studies have reported the cost-effectiveness of PrEP to be highly dependent on the incidence of HIV in the target population, and on drug costs[2,5] Among MSM at high-risk of HIV, PrEP is both cost-effective and cost-saving considering the avoided HIV treatment costs and the collateral benefits to 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 clinic 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 oro-phayngeal 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).

PrEP and STIs

There is evidence to suggest that PrEP implementation may be associated with an increase in STI diagnoses among MSM;[6,7] a direct or causal link with PrEP is still being investigated. A systematic review and meta-analysis identified a 24% increase in the odds ratio of any STI diagnosis among those using PrEP.[9] 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.[8,9] Rates of STI acquisition among Impact trial participants will be assessed in final trial analyses.

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

3 PrEP Impact trial Management Group (2018) Protocol Revision – February 2018.

4 https://www.prepimpactTrial.org.uk/

5 NICE (2016) ESNM78: Pre-exposure prophylaxis of HIV in adults at high risk: Truvada (emtricitabine/tenofovir disoproxil). Available from: https://www.nice.org.uk/advice/esnm78/chapter/Key-points-from-the-evidence

6 Traeger MW, Schroeder SE, Wright EJ, et al. (2018) Effects of Pre-exposure Prophylaxis for the Prevention of HumanImmunodeficiency 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.

7 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)

8 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.

9 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.

reduction in onward transmission. PrEP is also an important tool to increase engagement of those most at risk for poor sexual health, which may include diagnosing undiagnosed HIV infection.

PrEP within a national HIV transmission elimination strategy

The Department of Health and Social Care is supporting nation-wide efforts to eliminate HIV transmission in England by 2030. PrEP is an effective prevention tool and a potential turning point for accelerating HIV elimination. However, it is not the only way to prevent infection. PrEP must be considered within a combination prevention approach including other biomedical and behavioural approaches to mitigating personal risk. With progressive strengthening of combination prevention (including condom use, expanded HIV testing, prompt anti-retroviral therapy (ART), PEP and PrEP), HIV transmission, AIDS and HIV-related deaths could be eliminated[10] in the UK. Recent encouraging reductions in HIV incidence are dependent upon sustained prevention efforts. Inconsistencies in diagnosis rates (including late diagnoses) between groups and geographies demonstrate that combination prevention needs to be replicated for all those at risk of acquiring of HIV, whoever they are and wherever they live.

HIV prevention and sexual health commissioners will have an important role to play in ensuring that HIV PrEP is integrated into wider efforts to reduce HIV and other STIs. The more prevention options people choose, the greater their protection. Some HIV prevention strategies, such as using condoms, can also provide protection against other STIs, which PrEP does not. Promotion of these strategies is essential in a commissioned programme, particularly due to the decline in condom use and increase in STIs observed in other countries that have introduced population PrEP programmes. These additional interventions (and associated financial support) will need a novel, innovative approach (not just 'continue' or 'within the current'). These activities will need to occur within and outside of where PrEP will be delivered, and be undertaken by community organisations, and GU and other health professionals.

OVERVIEW OF PrEP COMMISSIONING IN ENGLAND

Vision

HIV PrEP should be a fully integrated, key component of a comprehensive national HIV prevention programme in England. All individuals at high risk of acquiring HIV should have access to high-quality information, support, drugs, and monitoring for their most suitable HIV prevention option(s) (which may or may not include PrEP as part of a combination prevention approach), irrespective of their gender, ethnicity, sexuality, geographic area of residence or socio-economic background.

Foundational principles for PrEP provision in England

1. **Coverage:** A national PrEP programme should achieve equitable coverage and should ensure appropriate risk assessments, models, and projections are made to identify those who may be missed. Programme delivery must also support those on PrEP to adhere to the programme to maximise its effectiveness.

10 Elimination means no new HIV transmissions and no HIV-related deaths.

2. **Equity**: The burden of HIV is not evenly distributed, nor is the use of PrEP as a method of HIV prevention. The principle of equity – across different risk and demographic groups, and geographically – must be evident throughout the commissioned PrEP programme, from knowledge and creating demand in at-risk individuals (e.g. via targeted health promotion programmes), to access, uptake, use, and importantly, in outcomes. In line with this principle, provision of various aspects of the programme must be proportionate to need.
3. **Quality data and intelligence**: The use of the programme (and its equity) will not be static. Data collection must be comprehensive and monitored and reported on an ongoing basis to ensure programme ambitions are achieved and maintained.
4. **Flexibility and adaptability**: It will be important to recognise the natural tensions between the universal ambitions of this programme and local variations in sexual health commissioning. Therefore, the commissioned PrEP programme will need to remain flexible to local implementation, whilst specifying national standards that support an equitable and inclusive delivery, and ensuring that local areas and services achieve these minimum standards. Not delivering minimum standards will lead to people travelling to SHCs that are perceived to be of higher quality, with impacts on those clinics being able to deliver other sexual health services (e.g. contraception, STI testing and treatment).
5. **Impact**: The principal aim of PrEP is to reduce HIV acquisition; however, PrEP is also a mechanism within a population health toolkit to reduce the incidence of HIV. The programme must monitor not only the impact of the commissioned programme on individual PrEP use, but also on HIV incidence, unintended consequences (e.g. STIs, psychosocial complications, and displacement of other SHC attendees with subsequent adverse outcomes), and positive impacts on general health and wellbeing and specifically on sexual health in a holistic sense (not just the absence of infection).

Eligibility for PrEP in England

Who should receive PrEP?

It is recommended that the eligibility for PrEP in a national programme be harmonised with the most up to date treatment guidelines and other clinical guidance, for example at the time of this document's publication, the 2018 BASHH/BHIVA guidelines[2]. This would need to be agreed by the lead commissioner of the PrEP programme. The BASHH/BHIVA recommended eligibility criteria are summarised in Table 2. The eligibility criteria should be considered a minimum and should not replace clinical judgement. Eligibility relates to individuals already engaged in care with sexual health services and assessment should be undertaken at each attendance, if appropriate. Pathways from other health and social care settings must be developed to ensure the programme is accessible to those most at risk.

Table 2. 2018 BASHH/BHIVA guidance on PrEP eligibility

<table>
<tr><th colspan="2">Recommend PrEP</th></tr>
<tr><td colspan="2">(i) HIV-negative MSM and trans women who report condomless anal sex in the previous 6 months and on-going condomless anal sex. (1A)
(ii) HIV-negative individuals having condomless sex with partners who are HIV positive, unless the partner has been on ART for at least 6 months and their plasma viral load is <200 copies/mL. (1A)</td></tr>
<tr><th colspan="2">Consider PrEP on a case-by-case basis</th></tr>
<tr><td colspan="2">PrEP may be offered on a case-by-case basis to HIV-negative individuals considered at increased risk of HIV acquisition through a combination of factors that may include the following:</td></tr>
<tr><td>Population-level indicators
Heterosexual black African men and women
Recent migrants to the UK
Transgender women
People who inject drugs
People who report sex work or transactional sex</td><td>Clinical indicators
Rectal bacterial STI in the previous year
Bacterial STI or HCV in the previous year
Post-exposure prophylaxis following sexual exposure (PEPSE) in the previous year; particularly where repeated courses have been used</td></tr>
<tr><td rowspan="2">Sexual behaviour/sexual-network indicators
High-risk sexual behaviour: reporting condomless sex with partners of unknown HIV status, and particularly where this is condomless anal sex or with multiple partners
Condomless sex with partners from a population group or country with high HIV prevalence (see UNAID definitions [1])
Condomless sex with sexual partners who may fit the criteria of ‘high risk of HIV’ detailed above
Engages in chemsex or group sex
Reports anticipated future high-risk sexual behaviour
Condomless vaginal sex should only considered high risk where other contextual factors or vulnerabilities are present</td><td>Drug use
Sharing injecting equipment
Injecting in an unsafe setting
No access to needle and syringe programmes or opioid substitution therapy</td></tr>
<tr><td>Sexual health autonomy
Other factors that may affect sexual health autonomy
Inability to negotiate and/or use condoms (or employ other HIV prevention methods) with sexual partners
Coercive and/or violent power dynamics in relationships (e.g. intimate partner/domestic violence)
Precarious housing or homelessness, and/or other factors that may affect material circumstances
Risk of sexual exploitation and trafficking</td></tr>
</table>

All commissioners should ensure that they have proportionate arrangements in place to ensure that individuals being provided with PrEP meet the criteria described in the BASHH/BHIVA guidelines.

Exclusion criteria

- Individuals in monogamous relationships with HIV positive partners on ART for ≥6 months with an undetectable viral load
- Individuals without a current negative HIV test
- Individuals diagnosed with HIV
- Individuals with contraindications to use

Similar to Welsh[11] and Australian[12] models of delivery, the commissioned PrEP programme will include a clinical assessment of individuals’ self-reported past and likelihood of future risk behaviour. However, the decision to prescribe may be taken on a case-by-case basis following clinical assessment and personal circumstances, in line with the BASHH/BHIVA guidelines.

Sexual health services in England are open-access and this is the expectation for the implemented PrEP programme.[13] The programme should also be available to those under 16 years if eligible and

11 HIV Expert Group (2018). Pre-exposure Prophylaxis (PrEP) for HIV – Service Guide

12 Wright E, Grulich A, Roy K, et al. (2018) Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine HIV pre-exposure prophylaxis: clinical guidelines.

13 English residency is initially recommended, as both Wales and Scotland currently limit their PrEP access to residents of each respective country. Mandatory cross-charging arrangements between English local authorities and with other UK countries will need to be established, prior to programme launch, to facilitate English SHCs providing PrEP to any UK resident.

assessed to be Fraser competent. All people should also receive a risk assessment for sexual exploitation and abuse, in line with BASHH/BHIVA guidelines.

Eligibility for PrEP does not mean that PrEP is the only possible prevention choice for an individual. Once eligibility has been ascertained, PrEP should be offered as one of the options within combination prevention.

COMMISSIONING PrEP: CONSIDERATIONS

The following considerations for commissioning PrEP in England are aligned with the five principles of a national programme. While recognising that there is ongoing learning from the Impact trial as well as PHE-led mathematical modelling, the below domains are comprehensive, robust and will provide a strong foundation for future refinement.

1. Estimating future demand for PrEP in England

Commissioners will require information on the estimated number of PrEP users and how this may evolve over time to be able to determine service configurations, plan for undue pressures, and ensure resources are available to meet the projected need.

Modelled need for programme (and population profile)

Using data from the GUMCAD information system 2012 through 2017, initial (high level, confidential) data from the PrEP Impact trial, log-linear models, and a categorical logistic regression model, PHE has estimated the future PrEP programme size for MSM in England given various assumptions and scenarios. This includes all those eligible for PrEP, including those who may continue to purchase privately (though it is expected that this will be a small minority) who will require ongoing monitoring, testing and support at SHCs.

The estimated number of PrEP-related additional attendances each quarter is expected to rise gradually to become substantial by 2023/24 – when an estimated 50,000 MSM will be using PrEP. Given the current challenges of extending PrEP use to women and others who may be at higher risk of HIV acquisition than the general population, PHE has recommended that a 5% addition is made to the planning projections to account for these groups.

Considerations

- Continue to update estimates of PrEP need with results of modelling studies and Impact trial analyses. [PHE]
- Review implications of the revised estimates for programme and drug commissioning locally [LAs, NHSE]

PrEP and health equity

For a commissioned PrEP programme to be effective, focused programmes must be provided alongside universal health promotion to prevent/mitigate inequality of access. However, the PCPG acknowledges the inequalities in the current landscape of health promotion and clinical provision across England. To develop and deliver an equitable PrEP programme, equity needs to be achieved not only in outcomes, but in locality, uptake, and provision.

Early data from the Impact trial indicate possible inequalities in PrEP uptake in a level 3 SHC setting that should be addressed in commissioning a national programme. Younger MSM, black African men and women, and heterosexual men and women eligible for PrEP have been less likely to engage with the trial (and possibly SHCs) and therefore less likely to access PrEP, despite elevated risk for HIV. These data may reflect barriers to accessing SHCs that need to be overcome to ensure equity in access to PrEP. Provision of PrEP through alternative settings may be required for some populations and additional interventions and support will be required, to ensure that any contact with a health or social care setting provides a gateway into the PrEP programme.

Considerations

- National minimum standards of service provision and reporting should be developed and adhered to by commissioners across the country. [PHE, LAs]
- Annual health equity audits should be undertaken and reported. [PHE]
- Integrate key equity indicators in routine GUM surveillance for monitoring and reporting. [PHE]
- All localities should routinely review their PrEP uptake data to identify areas of underutilisation, inequalities or gaps in provision, and take appropriate action. [LAs, ADPH, NHSE]

2. Factors influencing potential demand for PrEP

Commissioners will need to understand the systematic and individual factors that may influence the potential demand for PrEP. For local commissioners, some of these factors will depend on local demography, service configurations, clinical management strategies, and decisions made by patients with increasing confidence and familiarity with PrEP use.

Trends in sexual health clinic (SHC) attendance

The number of SHC attendances has increased year-on-year for the past decade. A key issue is whether past trends in SHC attendees beginning a new period of engagement with services will continue over the next 5 years or whether they will tail off.

PrEP stop rates

Stop rates describe the proportion of people who discontinue PrEP use in a given period. A key assumption in the projection of PrEP period prevalence is the duration of PrEP use after starting or alternatively the quarterly stop rate. The quarterly stop rate for the purposes of planning the commissioned PrEP programme is 9%.

Dosing (switching between daily and on-demand PrEP use)

The rate at which PrEP users convert from daily to on-demand use (i.e. ‘event-based’ dosing) will be defined by the Impact trial and other literature when further information on pattern of use has been obtained. The trial conversion rate may underestimate the rate of event-based dosing outside of a trial environment; however, it remains the best estimate available in an English context.

The switch to intermittent PrEP will not reduce the estimated number of PrEP users, nor will it necessarily reduce the number of clinic attendances. However, it will impact the volume of drugs being procured and prescribed as an underpinning of the overall programme. Although event-based dosing is likely, it remains desirable that access to regular HIV testing is ensured.

Frequency of attendance for clinical monitoring

Current BASHH/BHIVA guidelines recommend that, in addition to undertaking monitoring investigations, regular assessment permits review of adherence (e.g. through pill counts, review of

pill app reminder) and side effects, and facilitates discussions around changes in risk behaviour to determine the need for ongoing PrEP. In providing repeat courses of PrEP, providers should obtain a thorough sexual and drug use history and assist in the decision of when to use PrEP (especially in cases of on-demand use) and when to discontinue use. In most circumstances, an initial 3-month supply (90 tablets) of tenofovir-disproxil / emtricitaine (TD-FTC) should be provided in order to promote return for review of adherence, tolerability and to ensure 3-monthly HIV and STI testing to minimise prolonged use of PrEP in the presence of a new HIV infection.

Monitoring of individuals receiving PrEP should focus on excluding HIV, monitoring for side effects and toxicities, screening for and treating sexually transmitted infections, risk reduction and promoting adherence. At a population level, surveillance is required to understand how PrEP is used and to monitor clinic attendance and other characteristics of PrEP users and non-users and will enable follow-up to estimate HIV incidence in these groups.

Changing PrEP uptake rates

In addition to changing trends in MSM beginning new clinic engagement periods, there is a possibility of varying PrEP uptake rates. Individuals who are more likely to start PrEP may have done so at the beginning of scale-up and the remaining pool of individuals could have a lower PrEP uptake rate than observed so far. Additionally, there are believed to be several thousand people purchasing PrEP privately in the UK (who may or may not be receiving monitoring at SHCs), some of whom may choose to switch to the NHS programme once it is established. It is not possible to estimate to what extent those purchasing privately may or may not switch to the commissioned PrEP programme, therefore estimates in this report account for all those in need of PrEP.

Another assumption of current projections is that uptake rates remain constant within individuals; i.e. that ‘lower risk’ individuals (within the high risk cohort) will have the same probability of uptake at each subsequent attendance at clinic. It is possible that individuals not starting PrEP when first offered will be more likely to take up PrEP when offered again, due to increased familiarity with and/or trust in the programme. This would primarily affect individuals in the highest risk category based on their prior clinical risk who are most likely to be observed in multiple quarters.

Considerations

- National surveillance data to guide and update estimates of PrEP need (defined as all those at risk) and demand with results of modelling studies and Impact trial. [PHE]
- Professional bodies especially BASHH/BHIVA to review / update clinical guidelines in line with emerging findings from Impact trial. [BASHH/BHIVA]
- Work with community sector and people using PrEP to understand communities’ views on and preferences for PrEP. [PHE, THT/NAT, LAs, NHSE]

3. Requirements for equitable, effective PrEP provision and associated costs

Local authorities – as lead commissioners for level 3 SHCs – are working to manage the twin challenges of significant growth in need and demand for, and use of services concurrently with central government cuts to the Public Health Grant. There are substantial differences between local authorities and between services in terms of demography, new HIV and STI diagnoses, and in levels of activity and testing. For some, there are significant cross-boundary flows of residents using services; for others, there is relatively little movement between areas.

Context: local service transformation

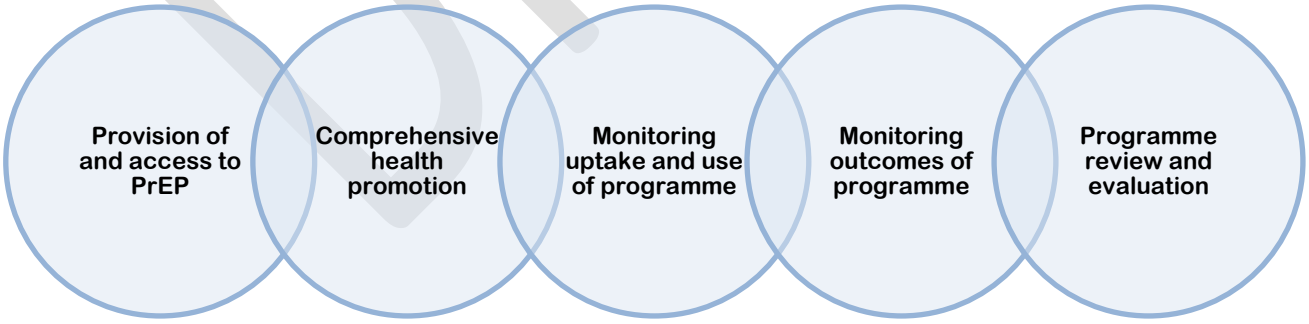
Many local authorities are transforming services, for example by introducing integrated sexual health services or through increasing use of digital technologies to offer online self-sampling for HIV and STIs. In most areas, transformation has been part of new procurements or new commissioning agreements. Most providers of these new services are NHS trusts, but there are also a small number of IP. Different funding mechanisms have been applied as part of these changes, such as new integrated tariffs, other tariff arrangements or block funding. Local authorities are also increasingly working together in geographic groupings to help plan or commission services collaboratively, and to develop common approaches to shared issues such as cross-charging between areas. There is also innovation and transformation in local sexual health promotion services, with PrEP promotion and provision of information already becoming incorporated into local HIV prevention campaigns and activities. Therefore, PrEP will be commissioned in a complex landscape which is transforming to meet increasing need and demand with less funding and fewer resources.

The implications of introducing PrEP will vary significantly between authorities and services depending on the size of their at-risk populations, how services are configured and organised, the amount of movement between areas, and in the planning and funding arrangements for services. The projected levels of need produced by PHE for this document indicate sharply increased levels of service use, even if the underlying growth rate in attendances over the past decade begins to slow. If that underlying growth rate does not slow, then pressures will be even greater for sexual health services and commissioners. This will increase pressure on resources and access (with the potential for unintended consequences on access to clinics for non-PrEP related attendances, e.g. emergency and ongoing contraception, STI testing and treatment; as well as impacting on access to PrEP) without commensurate funding increases. A lack of additional funding for the PrEP programme will also lead to inequalities in access to and provision of the PrEP programme, with some areas better able to withstand the increased pressure compared to others.

Key ingredients

The key elements of a commissioned PrEP programme for England – different to the Impact trial – are set out in Figure 1.

Figure 1: Key ingredients of an equitable, effective PrEP programme for England



Provision of and access to PrEP

Equity of access to PrEP is of primary importance. There are multiple points along the patient pathway to PrEP at which (non-sexual health) professionals can intervene and support uptake. Additional support is needed not only to signpost at-risk people into sexual health clinics to receive PrEP, but also to improve the offer and uptake among those at higher risk who are already

attending services. The nature of the clinical interaction at point of prescription and along the patient pathway to PrEP is important in facilitating and encouraging uptake, particularly among the most vulnerable; those most at risk may require additional support to overcome various structural barriers to support access and use of PrEP.

Considerations

- Plan for the commissioning of a predominantly level 3 SHC-based programme, governed by the following principles which must be considered upon implementation: [PrEP Programme Oversight Board (to be continued / established)]
  - Recognition of the **significant variation nationally** in geography, epidemiology, and clinic size. Therefore, national standards around the PrEP programme should be flexible enough to allow implementation appropriate to the local communities, their needs and local service configuration, including service providers themselves. Inequalities are not acceptable.
  - The **need for additional access points / pathways** to ensure equity of access – to consider non-level 3 SHC pathways, e.g. level 1 and 2 SHC, primary care (including non-traditional delivery e.g. app-based provision of GP services), maternity, termination of pregnancy services. This will require work with communities about the acceptability about potential pathways for commissioning as well as working through deliverability.
  - The provision of a **national minimum dataset and assessment toolkit**, required to project and meet the currently unknown need of women and others accessing PrEP.
  - Acknowledgment that, while a large number of individuals with complex needs will participate in the programme, the majority of PrEP consultations will be non-complex and delivery should be as **cost-efficient as possible**.
  - Consideration of how best to meet the **standards of care and the needs of ageing populations** – both simple and complex – and an acknowledgement of the potential significant impact on infrastructure.

Some indicative estimates of the potential resource implications have been calculated based on scenarios produced by PHE. These implications are based on data arising from the Impact trial and international literature and should be considered informative but not definitive. The resource implications include:

- Appointments will take longer
- Staffing is on average more senior than non-PrEP STI screening appointments
- An increase in the regularity of appointments and screening
- PrEP drug costs
- Approximately 30% of PrEP users may have co-morbidities or complexities that may require further resources[14]
- Expected increase in STIs (24%), requiring treatment and further attendances
- Annual, or more frequent where indicated, renal assessment tests for PrEP users

Further work on costings of pathways for PrEP will be carried out by a Clinical Working Group convened under the aegis of the PrEP Commissioning Planning Group. Moreover, should new service models be developed that are cheaper, such as using online services for STI follow-up self-sampling testing, then projected additional service costs will need to be revised appropriately.

[14] Based on Scottish PrEP programme.

Comprehensive health promotion

Promotion of HIV PrEP should be integrated throughout the commissioned programme and be embedded within existing promotion of combination prevention and sexual health. Current investment in health promotion is highly variable. An equitable PrEP programme cannot be achieved without the equitable provision of health promotion, which will require additional funding.

Developing awareness and understanding of PrEP in the population is necessary to drive demand and reduce inequalities in uptake. Targeted work should include engaging young MSM, black African and other minority ethnic groups at risk, trans people, women, and other at-risk groups, in particular through locally delivered health promotion.

Considerations

- Additional funding to be identified to provide nationally coordinated health promotion and education interventions to facilitate equity of access, based upon contemporary evidence of best-practice and effectiveness. [DHSC]
- PHE to utilise National Health Promotion programmes to underpin national coordination of a PrEP health promotion programme, including identifying areas lacking health promotion and/or NGOs. [PHE]
- PHE to target HIV innovation fund to support projects aimed at raising awareness and community activation on HIV PrEP, as part of combination prevention. [PHE]
- Local authorities to assess the degree to which local communities are aware of PrEP availability and utilising local services, and target local promotion services appropriately. [LAs]

Monitoring uptake and use of programme

Monitoring is essential for a programme of this nature and allows for the quantification of the rate of uptake, coverage and scale of the programme. Through effective monitoring, it may also be possible to identify those not accessing the service and where additional efforts to recruit may be necessary.

Considerations

- PHE to work with professional organisations including BASHH and NGOs to ensure that robust data codes are available to monitor the implementation of a full national programme by June 2019 for implementation by October 2019. [PHE]

Monitoring outcomes of programme

It is proposed that quarterly monitoring is continued in a commissioned PrEP programme. The increased adoption of sexual health e-services as part of a commissioned sexual health system means that over time, other monitoring options may be available in the commissioned PrEP programme.

It is recommended that there is appropriate flexibility in the commissioned PrEP programme to allow the most clinically- and cost-effective method of monitoring for a region or local area to be utilised.

Considerations

- Continue to update estimates of PrEP need with results of modelling studies and interim analysis of Impact trial. [PHE]
- Review implications of the revised estimates for commissioning locally. [LAs, NHSE]

Programme review and evaluation

The commissioned PrEP programme should be continually reviewed, with oversight provided by the appropriate local contract review process led by local commissioners. In addition, a national programme oversight board should be established to ensure smooth transition and scale up of a national PrEP programme is achieved.

As the number of individuals using PrEP rises following the introduction of the programme, evaluation will be an important tool to ensure continued impact, effectiveness, and cost-effectiveness of the programme. This evaluation should be supported at national and local levels to continue to address emerging implementation questions; review progress on addressing inequalities; and examining new methods for the provision and monitoring of PrEP. The cost of ongoing programme review and evaluation will need to be determined as part of next steps.

Considerations

- Support routine contract monitoring by local HIV and sexual health commissioners of PrEP uptake and inequalities by providing minimum PrEP programme standards, and supporting local use of national PrEP Equity Audit tool. [PHE]
- Create PrEP Programme Oversight Board (or similar) to oversee preparation for and delivery of national programme, including the range of stakeholders described in this document. [NHSE, PHE]
- Work with research funders including NIHR to support ongoing research and evaluation of PrEP implementation and scale up, including necessary changes. [PHE]
- Develop a plan for publication of key PrEP programme indicators at a local authority and clinic level (using existing databases such as Fingertips and/or GUMCAD) to promote transparency and accountability. [NHSE, PHE]

Additional core requirements for commissioning a HIV PrEP programme for England

At the core of the commissioned PrEP programme are six additional requirements to support all commissioners, which will ensure equitable and effective delivery of a national programme. These are set out in Table 4.

Table 4: Additional core requirements to support local provision

Clear, **evidence-based standards for the programme with clear eligibility criteria**, with accompanying quality metrics, which can be introduced into local service models, including pathways from non-SHC settings	Clear, readily available information on need for and **estimates of uptake** upon which to base local decisions and service and financial planning	Clear arrangements on **commissioning and funding responsibilities**, including any implications for cross-charging between authorities for PrEP-related sexual health service attendances	Additional **funding to meet the increased projected need**, including for increased needs for STI-related treatment and care, and exploring innovative models of care delivery	Resources, with innovation and guidance, to develop **effective practice for targeted promotion** of PrEP and, depending on commissioning responsibility, for adherence support	Additional funding to provide coordinated interventions to **ensure equity of access**, especially women and BAME groups that are poorly reached by Trials and studies in England and internationally

4. Roles and responsibilities

PrEP is not currently available on the NHS but is available to purchase privately (with GU-based monitoring available) and for eligible patients, through the Impact trial with drug costs funded by NHS England. NHS England works in partnership with a range of different stakeholders in a programmatic approach to HIV prevention, including Public Health England, local authorities, clinical leads and bodies, and community sector organisations. Safeguarding children and vulnerable adults is a core responsibility of every partner and will be a central to PrEP programme delivery.

Department of Health and Social Care

The Department of Health and Social Care (DHSC) supports the Government's Health Ministers in leading the nation's health and care to help people live healthier lives for longer ensuring that people have the support, care and treatment they need, with the compassion, respect and dignity they deserve. The DHSC supports the NHS to ensure efficient, productive, safe, timely and high quality hospital care; whilst transforming out of hospital care to keep people living better for longer in their community. The DHSC also works across government departments to support a health in all policies approach and ensure adequate resources are available to fund health programmes.

The DHSC supports and advises Ministers to shape policy, set direction and to lead key strategic debates, while remaining accountable for delivering our commitments, acting as guardians of the health and care framework and as trouble-shooters (to take action when necessary to solve complex issues). They work closely with key partners in the health and care system, our Arm's Length Bodies (ALBs) and agencies, local authorities, across government, and with both patients and the public, ensuring that we are all working with a single focus – patients and service users.

NHS England

NHS England (NHSE) is an executive non-departmental public body which leads and oversees the planning, funding and delivery of healthcare provision in England. They are mandated to improve the country's health and wellbeing by arranging high quality care in a way that meets current demand and is sustainable into the future. In 2017/18, NHSE had a funding allocation of £110 billion to commission healthcare services, both directly and via the 207 Clinical Commissioning Groups (CCGs). NHSE allocates most of the funding it receives to CCGs and supports them to commission services on behalf of their patients. NHSE also undertakes direct commissioning of specialised, primary care and other services. Together they account for £105 billion of total commissioning expenditure. NHSE also works alongside Justice teams to commission the full range of health interventions and prevention activities in prisons and other custodial settings.

NHS England shares with the Secretary of State for Health and Social Care the legal duty to promote a comprehensive health service in England, in accordance with the NHS Act 2006 (as amended by the Health and Social Care Act 2012). Each year, the Government sets out its expectations of the service and the funding we will receive in the form of a mandate which is laid before Parliament. This mandate sets the direction for the NHS, describes the government's healthcare priorities and helps to ensure the NHS is accountable to Parliament and the public.

Public Health England

Public Health England's (PHE) purpose is to protect and improve the nation's health and wellbeing and reduce health inequalities. PHE's nine teams across England do this through world-leading science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is a nationwide executive agency of the DHSC, and a distinct delivery organisation with operational autonomy. PHE provides government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support, and a range of specialist public health services.

Local authorities

Upper tier and unitary councils are mandated to provide or make arrangements for open access sexual health services for all those present in the area. These mandated services encompass: preventing the spread of STIs, testing, diagnosis and treatment of STIs and provision of a comprehensive range of contraception. Councils are responsible for funding open access services for their own residents. The Department of Health has issued guidance on cross-charging between authorities for use of these services. It should be noted that commissioning responsibility for HIV and STI testing and for contraception can vary according to setting and service. Councils may also choose to commission non-mandated additional sexual health services, such as in general practice or community pharmacy, young people's sexual health services, online services, as well as community HIV prevention, outreach, and sexual health promotion.

Responsibilities which support the provision of PrEP in mandated open access sexual health services as described in the 2018 BASHH/BHIVA guidelines[2] include: regular (quarterly) STI and HIV testing in high-risk groups, and the diagnosis and treatment of STIs, including partner notification. It should be noted that the scale-up of a national PrEP programme would undoubtedly represent additional costs for many local authorities to discharge these responsibilities.

Non-governmental organisations (NGOs) and advocacy groups ('community sector')

The community sector offers valuable commissioning support and expertise to commissioners, specifically around needs-assessment, business intelligence, service re-design, and public and patient engagement. Community organisations' in-depth knowledge of specific conditions or population groups, and close connections with service users can be of great value to those charged with achieving NHE's vision of high-quality commissioning: that expert commissioning support should come from a range of providers, including community sector organisations. The involvement of people living with HIV and people using PrEP, and the community organisations that serve and represent them, in programme development and implementation will improve the relevance, acceptability and effectiveness of programmes, in line with the GIPA principles.[15] Community organisations have a role in ensuring that PrEP users are involved in helping to design, participate in, and monitor the impact of a PrEP programme. The community sector though – like the public sector - is increasingly financially squeezed. The scale-up of a national PrEP programme would require continued investment to support NGOs to discharge these responsibilities, especially for engaging hard to reach and high-risk groups.

Specialist societies

Specialist societies play an important role in PrEP commissioning. Critical among these is the publication and dissemination of guidelines. They are also important to mobilise their practitioners to change clinical and commissioning practice. Finally, specialist societies are represented on the governance, oversight and leadership and development of the Impact trial and options for future commissioning of PrEP in England. They will continue to play a critical role in the implementation of a national PrEP programme. ADPH, BASHH, BHIVA, and the English HIV and Sexual Health Commissioners Group have all played key roles in shaping national and local practice and policy for health promotion, research, commissioning and evaluation of important HIV prevention programmes, including PrEP.

15 UNAIDS (2007) Policy Brief: the Greater Involvement of People Living with HIV. Available from: http://data.unaids.org/pub/briefingnote/2007/jc1299_policy_brief_gipa.pdf

General practice

Not all individuals feel comfortable accessing, or are able to access, sexual health clinics. Many people, especially outside of London and other major cities, choose to access their GP for sexual and reproductive health services. Ensuring GPs are part of a HIV PrEP system (initially in terms of identification and referral) will maximise opportunity to reach women, black African communities, and other at-risk groups.

GPs have a key role to play in raising awareness of personal risk of HIV, identifying risk, and referring to SHCs for provision. GP-specific tools and guidance will be required to support this. In principle, prescribing and delivering PrEP through primary care might be considered under future commissioning arrangements with appropriate data governance and guidance.

COMMISSIONING PLAN / NEXT STEPS

This document and the recommendations detailed within have been presented to the PrEP Programme Oversight Board and will be further discussed with lead commissioners for the programme, including PHE, NHS England, and Department of Health and Social Care.

This document will remain live and will be updated with the most recent analyses from the Impact trail and national and local authority-level estimates in order to support the commissioning process.

Preparing for the commissioning of Pre-Exposure Prophylaxis (PrEP) in England

Considerations of the PrEP Commissioning Planning Group

APPENDICES

November 2019

APPENDIX 1: KEY STAKEHOLDERS AND PROPOSED RESPONSIBILITIES

Stakeholder	Proposed key responsibilities in HIV PrEP programme
Department of Health and Social Care (DHSC)	The DHSC works with key arm's length bodies to support and hold to account in carrying out their responsibilities for commissioning HIV PrEP. These include: ▪ NHS England (NHSE) and NHS Improvement (NHSI) responsible for commissioning prescribed HIV treatment and care services, tendering and reimbursement of provision of medication used for PrEP and management of clinical co-morbidities; ▪ Health Education England (HEE) who work across England to deliver high quality education and training for a better health and care workforce; ▪ Public Health England (PHE) who work to protect and improve the nation's health and wellbeing, and reduce health inequalities; ▪ The Care Quality Commission (CQC) who monitor, inspect and regulate health and social care services; and ▪ The National Institute for Health Research (NIHR) who support health and care research, including the Impact trial.
NHS England	▪ Funding the Impact trial – in order to answer key questions about eligibility, uptake and duration of use, and impact on the incidence of HIV and other STIs. ▪ Tendering for and reimbursing the cost of tenofovir disproxil and emtricitabine used for PrEP in accordance with commissioning criteria and ensuring this is fully integrated into existing drug procurement pathways. ▪ Commissioning of specialised care and HIV treatment services. ▪ Management of complications and co-morbidities associated with HIV PrEP (e.g. significant renal impairment). ▪ Working with local CCGs and GPs to raise awareness about local HIV PrEP pathways and ensure integration into local HIV and sexual health service provision in primary care where appropriate.
Public Health England	▪ Modelling, surveillance, monitoring of PrEP need and uptake. ▪ Providing data and evidence to support effective commissioning of the PrEP programme. ▪ Working with DsPH, commissioners to ensure robust data are available to inform local policy and practice. ▪ Leveraging national HIV prevention programme resources to fund innovation projects, PrEP promotion and marketing, community outreach and activation, and NGO support. ▪ Working with academic partners to research the effectiveness and impact of PrEP in England, and with professional organisations and PrEP users themselves to develop evidence-based practice guidance.
Local authorities and level 3 sexual health clinics	Ensuring that local authority-commissioned level 3 sexual health clinics (SHCs) are able to: ▪ Prescribe licensed tenofovir disproxil and emtracitabine combination medication for people who are HIV negative who meet recommended criteria to reduce their risk of HIV acquisition, in accordance with the drug commissioning criteria set down by NHS England; ▪ Educate patients about the medications and the regimen to maximise their safe use; ▪ Provide support for medication adherence to help patients achieve and maintain protective levels of medication in their bodies; ▪ Provide HIV risk-reduction support and prevention services or service referrals to help patients minimise their exposure to HIV; ▪ Provide effective contraception to women who are taking PrEP and who do not wish to become pregnant;

	▪ Monitor patients to detect HIV infection, medication toxicities, and levels of risk behaviour in order to make indicated changes in strategies to support patients' long-term health; ▪ Avoid unintended consequences of PrEP provision on other patients accessing these services, e.g. for STI testing/treatment or contraception, including through developing innovative models of delivery; and ▪ Provide the monitoring, testing and support described above for people privately purchasing PrEP. Additionally, local authorities will be responsible for: ▪ Determining local HIV prevention and associated health promotion programmes that promote PrEP alongside a range of other prevention measures.
General practice and Clinical Commissioning Groups (CCGs)	▪ Raising awareness of and normalising PrEP as part of general sexual health promotion and HIV prevention efforts (at both individual and population level). ▪ Assessing HIV acquisition risk in patients and discussing PrEP as a prevention option. ▪ Referring eligible patients to SHCs for PrEP. ▪ Management of clinical co-morbidities
Non-governmental organisations (NGOs) and advocacy groups ('community sector')	▪ Maintaining/building relationships with both local CCGs and local authority commissioners. ▪ Clearly articulating how value is added to the commissioning process and working with local commissioners to develop an explicit menu of options and packages of support. ▪ Considering partnering with other community sector organisations to share resources for sourcing and responding to bids, and to offer commissioners a range of services. ▪ Considering the sustainability of the PrEP support services on offer within the community sector, ensuring there is a local funding strategy in place. ▪ Considering and advocating for the views and preferences of people using PrEP.
Specialist societies	▪ Providing expert consensus and clinical guidance. ▪ Supporting strategic forums to bring together those with provider and commissioning responsibilities for sexual health, reproductive health and HIV services. ▪ Facilitating improved population and patient level outcomes in sexual health and HIV in England. ▪ Maintaining strong links with NHSE, PHE, DHSC, the community sector and the LGA around PrEP policy and implementation. ▪ Ensuring the experience of sexual health, reproductive health and HIV providers and commissioners is influencing the commissioning landscape. ▪ Helping to support effective implementation of PrEP that results in improved population and patient level outcomes and reduces inequalities, which may include audits of clinical practice.

*Additional funding to deliver all aspects of the programme is required and will need to be identified by the Department of Health and Social Care and its arm's length bodies.

APPENDIX 2: THE IMPACT TRIAL - LESSONS TO DATE

Profile of those on the trial

A detailed profile of those on the trial will be available in 2020. Of the 9,226 people recruited at the end of October 2018, approximately 2% were women and others, with the majority being MSM. This aligns with other trials and programmes.

Uptake of trial places

The Impact trial was designed to test the hypothesis that the PrEP need estimates of the 2015-16 national multi-stakeholder and multi-disciplinary policy development group were broadly correct. These estimates were based upon expert assessment of timely SHC data on attendees. Already, however, there are strong indications that attitudes to PrEP and its use among MSM and clinical staff have shifted rapidly and are substantially different from even the very recent past. In 2016, it was generally thought that many MSM at high HIV risk as defined by the 3 categories would choose not to use PrEP (i.e. 50%) and that of those who do choose PrEP, many would prefer event-based dosing (i.e. 50%).[16] Similarly, it was assumed that engaging clinicians to recruit actively to a PrEP Trial across all the 200 specialised sexual health services in England would be a prolonged challenge. However, there has been a much higher uptake of PrEP trial places than even the initial 'surge' scenario estimates predicted, as described above.

Notable amongst the early recruits is the very high proportion accepting the recommendation that they begin PrEP. A number of factors are thought to explain the high uptake of PrEP. Firstly, the broad public debate and advocacy around PrEP in 2016 created a substantial PrEP demand among MSM (reflecting need) and resulted in a significant number of people purchasing PrEP on the internet that has continued to date. Although precise numbers are unknown, it is thought that a few thousand MSM in England were already on PrEP by the time the trial began[17] (which has increased further with time), and other sources have produced higher though unverified estimates. Secondly, contemporaneous to the public debate, there was broad clinician engagement in the development of guidelines for managing those self-purchasing or taking privately prescribed PrEP, together with a growing professional awareness that PrEP could accelerate the fall in new HIV diagnoses in MSM that was generating much interest. GUM clinicians were also encouraged by the General Medical Council as early as 2016 to support the use of PrEP.

However, demand and uptake of PrEP in the trial from women and other groups attending GU services has been much lower than the places allocated, although this does not necessarily reflect a lesser need in these groups. Although this remains broadly similar with other international PrEP studies, this indicates significant inequalities in awareness, knowledge, access, uptake, and use of PrEP in women and other persons eligible for PrEP, which must be addressed in commissioning a PrEP programme for England.

There are good grounds for considering that the higher than estimated number of early MSM recruits may undermine the capability to provide reliable estimates of key parameters that inform the trial objectives, and the interpretation of the trial results. The very high initial recruitment implies that many fewer trial places will be available in later months for clinicians to actively risk assess MSM (and others) who may be less aware of PrEP and its benefits and relevance to their lifestyles, and

16 NHS England (2016) Policy Consultation on Pre-Exposure Prophylaxis (PrEP) for HIV (F03X06). https://www.engage.england.nhs.uk/consultation/specialised-services/

17 Nardone A (2017) Personal Communication: Gay Men's Sexual Health Survey – preliminary analysis of data collected in late-2016.

many of these will be from those sections of the community (e.g. younger or BME MSM) who continue to suffer from health inequalities in access and outcomes.

Additionally, despite the public health benefits, transferring those previously self-sourcing and funding PrEP onto the trial may affect the results, as information on prior PrEP use and the duration of such use in these cases has not been systematically collected. Thus, the total duration of trial PrEP use in these individuals may under-estimate the total duration on PrEP in those considered to represent the high end of the spectrum of risk.

Current promotion of PrEP

Health promotion activities raise awareness and knowledge of PrEP. There were 106 PrEP health promotion activities across England as of August 2018.[18] The majority of these (n=71) were from community organisations. These were largely outreach programmes, compared to health promotion within the NHS which tended to be focused on staff training. Most interventions were far reaching, targeted at multiple population groups at higher risk for HIV: MSM, women, heterosexual men, and trans men and women.

Activities targeting a single group were rare. Where a health promotion activity was targeted at a single group, this was most likely to be MSM, cis women, trans men and women, or clinical staff. No health promotion activities were identified solely targeting heterosexual men.

Health promotion was geographically concentrated, with 40% of activities targeted to London. Conversely, West Midlands, North East, and East of England were supported by less than three health promotion activities each across community organisations and the NHS.

Data collected and knowledge gaps

There are outstanding questions that the trial was not designed to address. There is no accurate estimate of current PrEP users, including those accessing PrEP privately. The application of eligibility criteria will inevitably be, at times, subjective and clinician-dependant and yet we cannot measure how risk assessments are applied in practice. The nature of a clinical interaction may be an important determinant of a patient's comfort discussing PrEP and of whether PrEP is prescribed at a later point than might otherwise be appropriate. Further investigation into the patient and professionals pathway leading to a PrEP prescription may expose unconventional entry or distribution points in the system, or equally, may identify challenges to access.

The development of GUMCAD codes to appropriately capture PrEP-related activity is necessary for performance monitoring and programme evaluation, and for accurate payment for service delivery. This work is ongoing and will consider lessons from Scotland and Wales.

APPENDIX 3: LESSONS FROM PrEP IMPLEMENTATION

Approaches to commissioning and providing PrEP across the UK have differed and this document includes approaches and learning from the devolved administrations. However, understanding the magnitude of the difference in the disease burden across the nations is key. In 2017, there were 3,973 new HIV diagnoses in England, significantly greater than the number diagnosed in Scotland (186) and Wales (104). This highlights the differences in projected PrEP need within the UK. Furthermore, PrEP has been privately sourced by patients for approximately four years. There are

18 PHE (2018) PrEP and Health Promotion activity.

no reliable estimates of how many people are utilising privately-sourced PrEP, though community organisations have undertaken some work indicating it may be over 10,000 across the UK.[19]

Wales

On 28 April 2017, the Welsh government announced an all-Wales study to provide the drug Truvada® as PrEP to all those resident in Wales who might benefit. The study was intended to last three years, and commence no later than summer 2017. Public Health Wales and the Independent HIV Expert Group were asked to work together to deliver the study.

PrEP in Wales is accessed via integrated sexual health clinics. The population on PrEP in Wales (approximately 500) is significantly less than those in the Impact trial currently and significantly lower than the number projected to enrol in a national programme in England. Early implementation reflections include: a need to encourage uptake of PrEP, managing geographic variations in access and uptake, and managing higher than anticipated co-morbidities among individuals taking PrEP. The latter has required increased monitoring and often referral to specialist medical services,[20] and this will need consideration in a commissioned English programme.

Scotland

The national PrEP programme in Scotland was launched in 2017 without a national implementation plan; rather, sexual health clinics were encouraged under a block contract to begin supplying generic tenofovir and emtricitabine as PrEP.

Initial projections of need did not accurately predict those presenting to services for PrEP after commencement of the national programme. Approximately 1,000 people were expected to access PrEP within the first year, however, the number accessing PrEP was double that. This demand has placed some strain on clinical capacity leading local providers to consider the best approaches to accommodate the programme within existing resources and capacity. Fewer people in the Scottish PrEP programme could be managed routinely, according to standard protocol, and by nursing staff. The mean age of people presenting for PrEP (35 years) has been older than initially expected. As such, co-morbidities (in particular renal complications requiring ongoing management, as well as contraindications for PrEP) have placed an additional, largely unexpected burden on the system. The wider (non-sexual health) team required to support these individuals imposes further financial and workforce costs. Moreover, approximately 30% of people accessing PrEP were new to the sexual health system. This was a positive outcome and demonstrated the role of PrEP as a tool to unlock the health needs of key communities. However, new attendees attracted greater costs with respect to initial screenings and vaccinations. Community organisations were key partners in the Scottish PrEP programme. They were largely responsible for driving engagement with the programme and for the higher than expected number of attendances.

19 Paparini S, Nutland W, Rhodes T, et al (2018) DIY HIV prevention: Formative qualitative research with men who have sex with men who source PrEP outside of clinical trials. PLoS ONE 13(8): e0202830.

20 Knapper C, Birley H, Couzens Z, et al (2018) How to do it: setting up a PrEP service in an integrated sexual reproductive health service setting. Sex Transm Infect;94:327-330.