

**Manchester City Council  
Report for Information**

**Report to:** Health Scrutiny Committee – 5 March 2019

**Subject:** Pre-Exposure Prophylaxis (PrEP) National Trial Expansion

**Report of:** Director of Population Health and Wellbeing

---

**Summary**

In January of this year NHS England announced plans to expand the Pre-Exposure Prophylaxis (PrEP) Impact Trial to 26,000 participants by 2020. This represents a doubling of the current number of people on the trial nationally. This report summarises the implications of the national trial expansion for Manchester.

**Recommendations**

The Committee is asked to note the report.

---

**Wards Affected:** All

---

**Alignment to the Our Manchester Strategy Outcomes (if applicable):**

<b>Manchester Strategy outcomes</b>	<b>Summary of how this report aligns to the OMS</b>
A thriving and sustainable city: supporting a diverse and distinctive economy that creates jobs and opportunities	A healthy workforce will contribute to the economic growth of the city and preventing people from being infected with HIV will have significant long term benefits
A highly skilled city: world class and home grown talent sustaining the city's economic success	
A progressive and equitable city: making a positive contribution by unlocking the potential of our communities	Increasing the access to the trial by Manchester residents will improve health outcomes for individuals and also result in savings for the NHS, through reduced treatment costs associated with HIV
A liveable and low carbon city: a destination of choice to live, visit, work	
A connected city: world class infrastructure and connectivity to drive growth	

**Contact Officers:**

Name: David Regan  
Position: Director of Population Health and Wellbeing  
Telephone: 0161 234 5595  
E-mail: d.regan@manchester.gov.uk

Name: Dr Chris Ward  
Position: Consultant Physician Genitourinary Medicine, The Northern  
Integrated Contraception, Sexual Health & HIV Service  
E-mail: chris.ward@mft.nhs.uk

**Background documents (available for public inspection):**

The following documents disclose important facts on which the report is based and have been relied upon in preparing the report. Copies of the background documents are available up to 4 years after the date of the meeting. If you would like a copy please contact one of the contact officers above.

Report to Manchester Health Scrutiny Committee on Sexual and Reproductive Health Services in Manchester – 19 June 2018

## 1.0 Introduction

- 1.1 Pre-exposure prophylaxis, or PrEP, is a way for people who do not have HIV, but who are at substantial risk of HIV infection to reduce their risk of acquiring HIV. This involves taking the PrEP drug as instructed, prior to any exposures that might put the individual at high risk of getting HIV. The single tablet PrEP drug contains two medicines (tenofovir and emtricitabine).
- 1.2 The PrEP Impact Trial aims to answer key questions about the use of PrEP by groups at a higher need in England. The first phase of the trial was announced by NHS England and Public Health England in December 2016 with plans to enrol 13,000 participants at high risk of acquiring HIV over a three year period starting in October 2017.
- 1.3 The eligibility criteria for the trial were based on the criteria published by NHS England as part of the consultation and developed in discussion with clinicians who participated in the Public Health England (PHE) PrEP Task and Finish Group and community representatives who participated in the Community Advisory Board convened by PHE. The criteria are:
  - a) Men who have sex with men (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 diagnosed with 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 does not fall into the criteria set out in a or b but whose situation is assessed to be at a similar level of risk.
- 1.4 The trial to date has been conducted in sexual health clinics in England. All specialised genitourinary medicine (GUM) clinics in England (i.e. level 3 sexual health clinics) were invited to participate in the trial and Manchester based clinics were part of the first wave of participants. Each trial site was allocated a ring-fenced number of participants.
- 1.5 The treatment pathway for trial participants is as follows:
  - i) Clinic attendees who are part of groups at high HIV risk are expected to be individually risk assessed when they attend clinics. Those who are eligible for, and accept the offer of PrEP are prescribed PrEP for three months, either on a daily dosing or event based regimen, depending on their risk profile. Daily dosing is when PrEP is taken on a daily basis. Event based dosing is when PrEP is taken before having sex.

- ii) All clinical care provided to participants is in line with clinical guidance for PrEP or established clinical practice for the off-label use of the medicines. Participants are offered PrEP as part of an active risk reduction intervention, including health education and safer sex promotion, to reduce and modify high risk behaviour. This may include the provision of free condoms, behaviour change interventions, other biomedical interventions such as post-exposure prophylaxis where relevant, the diagnosis and treatment of sexually transmitted infections (STIs), and regular HIV testing.

## 2.0 Phase One of the PrEP Impact Trial in Manchester

### Recruitment and waiting lists

- 2.1 The following table summarises current trial details across Greater Manchester clinics:

GM Clinics		MSM		Other groups		Current waiting list
		Places available	Recruited to date	Places available	Recruited to date	
1.	Northern Clinics					
	Hathersage (Mcr)	266	266	14	6	392
	Withington (Mcr)	78	67	3	1	57
	Tameside	25	25	2	0	15
	Trafford	30	30	1	0	20
	Stockport	22	21	2	0	22
2.	North Manchester (*)	19	19	10	0	TBC
3.	Oldham, Bury and Rochdale	Recruitment has just commenced				TBC
4.	Bolton/Salford	33	33	14	6	TBC

*\*The GUM Clinic at North Manchester General Hospital is part of the Northern Sexual and Reproductive Health Service, but for the purposes of the trial is designated as a separate site.*

- 2.2 There is evidence of people registering at different sites across Greater Manchester when waiting lists are full with patients putting their names on multiple waiting lists. This is understandable and is one of the reasons why there has been pressure to expand the number of trial places nationally.
- 2.3 Clinicians who support the trial must undertake specific research training in order to be able to recruit trial participants. In some clinics not all clinical staff have had the research training, therefore trial recruitment is dependent on just a few staff and this can create bottlenecks. Furthermore, smaller clinical sites rely on one member of staff (usually a consultant) to do all the recruitment, management of waiting lists, follow up and troubleshooting. This can have knock on effects on other areas of clinical workload and not surprisingly makes trial recruitment even more problematic.
- 2.4 The trial also aims to quantify MSM and other people at risk who have become positive whilst waiting for PrEP. Each clinical site has a different method of

capturing their waiting lists. The trial sites under Northern are currently trying to amalgamate all waiting lists centrally to arrive at a robust figure, however, due to confidentiality issues this cannot be done for all clinics in Greater Manchester because they are under different providers.

### **Monitoring and compliance**

- 2.5 Almost all trial participants need 4 visits a year (i.e. every 3 months) unless taking event based PrEP (see 1.5), in which case they can be seen slightly less. As all trial participants are defined as high risk of acquiring HIV, according to national guidelines, they should be attending clinics every 3 months anyway. However, due to access issues, the Northern are reporting that on average participants are attending 1-2 times a year. There has been good compliance with the trial by the majority of participants but access issues are impacting on compliance and there have been some issues with drug supply. This is partly due to process and clinical sign off issues relating to the roles of the research nurses and clinicians. The Northern plan to address this.
- 2.6 As the follow up of trial participants is incorporated into standard care processes, many on the trial have felt frustrated that they are unable to “reserve” future appointments. Patients are seen by all members of the sexual health team, both doctors and nurses, and PrEP Patient Group Directives (PGDs) are in place in the Northern service to help with this. PGDs allow for greater clinical flexibility in decision making and prescribing by nursing staff.

### **Impact on other services provided by the Northern**

- 2.7 There have been knock on effects on other HIV and sexual health services provided by the Northern and as reported above the trial processes have impacted upon clinical and administrative time. The clinic at Hathersage benefits from on site laboratory and sample testing facilities but on smaller sites like Trafford there can be processing issues and delays.

### **3.0 Proposals to expand the trial**

- 3.1 The trial is overseen by the PrEP Programme Oversight Board that is jointly chaired by Public Health England (PHE) and NHS England. The Programme Oversight Board has met since January 2017 and has representation from the Association of Directors of Public Health, Local Government Association and the English HIV and Sexual Health Commissioners Group (EHSCHG). The Deputy Chief Executive of the LGBT Foundation, Rob Cookson, is a lay member of the Board.
- 3.2 At the PrEP Oversight Board meeting on 15 January 2019, the main item for discussion was a recommendation from the research team to double the number of trial places so that it can address emerging questions from the trial and more robustly inform the design and rollout of a full national programme.
- 3.3 The Board supported this recommendation in principle, noting NHS England’s commitment to fully fund the drug costs associated with any increased uptake

and to make a research payment for each participant, in line with current arrangements.

- 3.4 However, before final approval is given, the Board asked that a rapid engagement exercise with local authority commissioners and research sites be undertaken to assess their capacity to accept additional places. This work is now underway and will run in parallel with obtaining research ethics approval for the change, which is a prerequisite before any additional places can be confirmed and released.

### **Manchester response**

- 3.5 Following the national announcement the Director of Population Health and Wellbeing, on behalf of Manchester Health and Care Commissioning as the designated commissioner, has been working closely with clinical colleagues at the Northern.
- 3.6 The discussions have highlighted the additional pressures that the expansion of the trial will place on local clinics and whilst drug costs and research costs will be funded by NHS England, the indirect costs (e.g. more patients attending requiring other sexual health services) are not.
- 3.7 The Local Government Association (LGA) and Association of Director of Public Health (ADPH) are currently assessing the potential impacts of the trial expansion and Manchester has responded to the ADPH survey. This will enable a case to be made to NHS England for a fully funded approach that does not place additional “unfunded burdens” on clinics or local authority commissioners.
- 3.8 However to ensure that a contingency fund is in place for any local trial expansion, the Director of Population Health has agreed with the Executive Member for Adult Health and Wellbeing, that resources previously set aside for innovation in sexual health will be redirected towards additional recruitment capacity. It is estimated that approximately 40-50 additional clinics will be needed in 2019/20 for an effective and safe recruitment process and an initial sum of £25,000 has been identified. This clearly demonstrates Manchester’s commitment to the trial expansion, whilst we continue to lobby through the ADPH and LGA for a fair allocation of resources from NHS England.
- 3.9 This commitment has enabled the Northern to apply for an increase in trial places before the initial 31 January 2019 deadline. There has been no formal response yet from NHS England or the sponsoring body (Chelsea and Westminster NHS Foundation Trust) on whether this request for extra places has been accepted. NHS England have expressed a desire to double the number of places nationally from 13,000 to 26,000 so this could simply mean a “doubling of slots” available for each site. They may however, just want to prioritise places for clinics with the greatest demand.

#### **4.0 Council Motion and next steps**

4.1 On 30 January 2019 the Council agreed the following motion.

*This Council:*

- 1) Demands that this Government reverses it's cuts to Public Health Services, including sexual health services, and allocates funds fairly according to need*
- 2) Calls on the Secretary of State for Health and NHS England to take action to prevent new HIV infections by ending the trial, guaranteeing future treatment for those on the trial and fully funding and rolling out PrEP on the NHS in England;*
- 3) Calls on Manchester MPs, the GM Mayor and the GM Health and Social Care Partnership to push for a fully funded rollout of PrEP on the NHS.*

If the NHS in England does eventually follow the approach of the NHS in Scotland by making PrEP readily available, MHCC, the City Council and local providers will need to manage the transition from trial participation to mainstream provision effectively.

4.2 Whilst lobbying continues it is important to plan now for the next steps of the trial expansion and address some of the community concerns about access issues for participants. The Director of Population Health and Wellbeing has therefore convened a meeting with Northern clinicians and the LGBTF on the 22<sup>nd</sup> March and a range of options for improving access and pre booking appointment slots will be considered.

4.3 It is hoped that by the time the meeting takes place, the National PrEP Programme Oversight Board will have made their final announcement about the trial expansion and that clinics will have received formal notification of the number of additional places they will be allocated. This will then allow the recruitment planning process to commence for implementation in 2019/20.