

Government response: Update on PrEP Impact trial in England

Considerable progress has been made in preparing for the [HIV pre-exposure prophylaxis \(PrEP\) trial](#) that was announced by NHS England and PHE last December as a major extension to the [national HIV prevention programme](#). The trial, called the PrEP Impact Trial, will include at least 10,000 participants over the next 3 years and will answer key outstanding questions on the extent of need, uptake and duration of use of PrEP in the setting of sexually transmitted infection (STI) clinics in England. Our aim is to have the trial started by the summer of 2017.

The trial protocol is complete, trial participant eligibility criteria have been endorsed by experts in the field and by community representatives, and independent peer review has been conducted. The Medicines and Healthcare products Regulatory Agency (MHRA) has been consulted about trial categorisation and a relevant opinion received. Submission for ethics committee approval is imminent.

STI clinic attendees considered to be at high risk of acquiring HIV will be eligible to participate in the trial. Heterosexual and transgender individuals and gay men will be clinically risk-assessed as part of combination prevention and those at high risk offered PrEP. To ensure equity of access across the country, the trial sites will include as many as possible of the over 200 level-3 STI clinics.

A number of STI clinics have expressed an interest in joining the trial. Site participation standards are being finalised and all level-3 STI clinics will be written to in the next 2 weeks enquiring about capacity, willingness to meet the standards and to be a trial site. The likely trial site and per-participant costs are being assessed prior to detailed discussion with the trial management team which will include STI service provider representation.

PHE's Prevention Innovation Fund in 2017 to 2018 is seeking proposals that will address knowledge, awareness and understanding of PrEP and other PrEP related questions, especially in currently under-served populations in the community (e.g. higher-risk heterosexuals, black and minority ethnic group gay men and transgender communities). To register interest in the fund please send an email with your name, email address and organisation name to hiv.prevention@phe.gov.uk.

PrEP drug supply will be paid for and secured by NHS England. Competitive procurement has begun and all relevant supplier-manufacturers have been written to. A market engagement meeting is scheduled for later in April as part of this process.

Overarching governance arrangements, in the form of a PrEP Programme Oversight Board with joint leadership from PHE and NHS England, is in place to support the trial and to use the findings to prepare for a subsequent PrEP

programme. Membership includes the Local Government Association (LGA) and the Association of Directors of Public Health (ADPH).