Preparing for PrEP: Estimating the size of the population eligible for HIV pre-exposure prophylaxis among men who have sex with men in England

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ABSTRACT (word count 260)

Objectives

The size of the population of men who have sex with men (MSM) who may be eligible for HIV pre-exposure prophylaxis (HIV-PrEP) in England remains unknown. To plan for a national PrEP implementation trial, we estimated the number of MSM attending sexual health clinics (SHCs) that may be eligible for HIV-PrEP in England.

Methods

STI surveillance data from 2010-2015 from the GUMCAD surveillance system were used to estimate the annual number of HIV-negative MSM who may be eligible for HIV-PrEP in England. Based on national eligibility criteria, we identified HIV-negative MSM attending SHCs with a HIV-negative test in the past year, and used diagnosed bacterial STI (past year) in this group as a proxy for condomless sex and eligibility for HIV-PrEP. We estimated HIV incidence per 100 person-years (py) in these groups in 2014.

Results

During 2010-2015, the number of HIV-negative MSM attending SHCs with a HIV-negative test in the past year doubled from 14,643 to 29,023, and HIV incidence in this group was 1.9 (95% CI 1.6-2.2) per 100py in 2014. In the same period, the subgroup with a bacterial STI diagnosis (past year), and therefore considered potentially eligible for HIV-PrEP in this analysis, increased from 4,365 (30%) to 10,276 (35%). HIV incidence in this subgroup was 3.3 (95% CI 2.7-4.0) per 100py in 2014.

Conclusions

In 2015, approximately 10,000 HIV-negative MSM were considered potentially eligible for HIV-PrEP based on clinic history in GUMCAD. These data were used to inform the initial

recruitment target for the PrEP Impact Trial and will inform future evaluations at a population level.

KEY MESSAGES

- Estimating the size of the population that may be eligible for HIV-PrEP is essential to support service planning and delivery of a large-scale national programme.
- For 2015, we estimated that 10,000 HIV-negative MSM were potentially eligible for HIV-PrEP, in whom HIV incidence was 3.3 per 100 person-years.
- These data informed the initial recruitment target for the PrEP Impact Trial. Early recruitment data suggest that we have underestimated HIV-PrEP need among MSM.

INTRODUCTION

Pre-exposure prophylaxis (PrEP) for HIV is the use of antiretroviral drugs before HIV exposure to prevent infection. Evidence from randomised controlled trials suggests that HIV-PrEP reduces the risk of HIV infection by 86% among gay, bisexual and other men who have sex with men (MSM) at high risk of HIV and is thought to have the potential as a national intervention, in combination with wider prevention methods, to reduce HIV incidence at a population level. [1-3]

MSM are the population group most at risk of acquiring HIV infection in the UK. In 2017, 53% (2,330) of new HIV diagnoses were reported among MSM who are a key target group for HIV prevention initiatives.[4] The absolute number of individuals accessing HIV-PrEP in England is likely to be determined primarily by the number of MSM at high risk of HIV acquisition. Thus, while other populations are eligible for HIV-PrEP, this paper focuses on MSM.

In 2016, NHS England (NHSE) committed to funding a large three-year trial of HIV-PrEP to be delivered through sexual health clinics (SHCs).[5] The PrEP Impact Trial, which started recruiting in October 2017, aims to address key outstanding public health and implementation questions before a national HIV-PrEP programme can be rolled-out in England.[6]

The NHSE proposed pathway for the delivery of HIV-PrEP is through SHCs. Practical estimates of the potential numbers eligible for HIV-PrEP are therefore needed to project the likely costs associated with HIV-PrEP provision and for services to plan for appropriate capacity and delivery. We used national sexually transmitted infection (STI) surveillance data to estimate the size of the MSM population likely to be eligible for HIV-PrEP in England.

METHODS

Data source

We used data from GUMCAD, the national STI surveillance system in England; this records all attendances at genitourinary medicine (GUM) clinics and integrated GUM/sexual and reproductive health services (referred to as SHCs).[7] Each attendance is reported with clinical and demographic information. Patient records can be linked within, but not across clinics using clinic numbers that are unique to each individual.

Study population and time period

Individuals were included if they attended a SHC at least once during 2010-2015, and clinical and demographic data associated with their first attendance in each year were retained. All MSM who were HIV-negative or not known to be HIV-positive at their first attendance in a given year (defined as no clinical record indicating a HIV diagnosis at the same clinic and hereafter referred to as HIV-negative MSM) who were ≥15 years were included. Men were defined as MSM if they self-identified as either gay or bisexual at least once during their clinic attendance history.

Estimating the need for HIV-PrEP in MSM

Our analysis was based on the NHSE proposed eligibility criteria for HIV-PrEP,[8] which consider MSM to be at high risk of HIV acquisition and eligible for HIV-PrEP if they meet the following criteria:

- Currently HIV-negative with a documented negative test during a previous episode of care in the last year (42-365 days)
- Reporting condomless sex in the past 3 months
- Confirms likelihood to engage in condomless sex in the next 3 months.

We estimated the number of HIV-negative MSM who had a HIV-negative test in the 42-365 days prior to their first attendance of the year (hereafter referred to as recent HIV-negative test); at the time of conducting this analysis, a recent HIV-negative test was used as a marker

of increased risk of HIV acquisition. The 42-day interval reflects the duration of a standard episode of care used to analyse all GUMCAD data.[7] Sexual behaviours are not currently collected in GUMCAD, so we used diagnosis of a bacterial STI at first attendance and/or in the past year as a proxy for condomless sex to define the group of MSM at higher risk of HIV and therefore likely to be eligible for HIV-PrEP.

Estimating HIV incidence

Kaplan-Meier analysis was used to estimate HIV incidence among HIV-negative MSM attending SHCs in 2014. The analysis included individuals with an initial HIV-negative test during 2014 and who had at least one subsequent HIV test undertaken between 42-365 days after their initial test. Any HIV test within 42 days of the initial test was considered to belong to the same testing episode and was discounted. Individuals were followed from the date of their initial HIV test until their HIV diagnosis or last attendance within 1 year of the initial test.[9] (Supplementary figure) HIV incidence was similarly estimated for the group of HIV-negative MSM with a recent HIV-negative test and for the sub-group with a bacterial STI diagnosis in the past year.

RESULTS

The number of HIV-negative MSM attending SHCs increased by 68% from 69,392 in 2010 to 116,546 in 2015, and the number of those MSM who had also had a recent HIV-negative test nearly doubled from 14,643 to 29,023 in the same period (Table 1). The number of HIV-negative MSM with a recent HIV-negative test and a bacterial STI diagnosis in the past year (i.e. those considered eligible for HIV-PrEP) increased from 4,365 (30%) in 2010 to 10,276 (35%) in 2015.

To estimate HIV incidence in 2014, we identified 37,228 HIV-negative MSM with a subsequent HIV test within one year who contributed 24,709 person-years of follow-up time. There were 429 new HIV diagnoses, giving an overall HIV incidence of 1.8 (95% CI 1.6-2.0) per 100py. HIV incidence was 1.9 (95% CI 1.6-2.2) per 100py among the group of HIV-negative MSM with a recent HIV-negative test, and 3.3 (95% CI 2.7-4.0) per 100py among the subgroup of MSM with a bacterial STI diagnosis in the past year.

Table 1. Number of HIV-negative MSM clinic attendees at sexual health clinics in England by clinical risk group, 2010-2015

Clinical risk group	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**
MSM clinic attendees HIV-negative or not known to be HIV-positive*	69,392	79,092	88,840	95,831	109,919	116,546
MSM clinic attendees HIV-negative or not known to be HIV-positive* AND with a recent HIV-negative test 42-365 days prior to initial attendance in calendar year (and the proportion of all HIV-negative MSM clinic attendees)	14,634 21% *of all HIV negative attendees*	15,439 *20% of all HIV negative attendees*	18,957 *21% of all HIV negative attendees*	*21,670* *23% of all HIV negative attendees*	*25,092* *23% of all HIV negative attendees*	29,023 *25% of all HIV negative attendees*
- Number (and proportion) of whom had a bacterial‡ diagnosis in previous year and/or at first attendance of year	4,365 30%	4,840 31%	6,131 32%	6,979 32%	*8,202* *33%*	*10,276* *35%*

*The number of MSM who in GUMCAD by the end of their first attendance of the calendar year have no clinical records to indicate a HIV diagnosis at the same clinic.

‡ Bacterial STI diagnosis was defined as a diagnosis of chlamydia, gonorrhoea, syphilis (primary, secondary or early latent), lymphogranuloma venereum (LGV), non-specific genital infection (NSGI), donovanosis or chancroid at any anatomical site.

DISCUSSION

Based on prior clinical history in GUMCAD, we observed an annual increase in HIV-negative MSM attending SHCs, and estimated that around 10,000 MSM were potentially eligible for HIV-PrEP in England in 2015. HIV incidence among the group of MSM who may be eligible for HIV-PrEP was nearly double that of all HIV-negative MSM.

This is the first analysis to estimate the size of the population of HIV-negative MSM eligible for HIV-PrEP in England and is based on a pragmatic approach using the most comprehensive source of data available. However, our analysis used proxy measures of risk based on available clinical history in GUMCAD. We were not able to follow individuals across clinics, and therefore might have underestimated the number of MSM who had a recent HIV-negative test or bacterial STI diagnosis at a different clinic. In addition, GUMCAD does not collect data on sexual behaviour, and we used recent diagnosis of a bacterial STI as a proxy for condomless sex. Although recent bacterial STI was also used in devising the NHSE HIV-PrEP eligibility criteria,[8] we recognise that it is an imperfect measure of recent risk because it excludes individuals who may be at high risk of HIV but were not diagnosed with a bacterial STI. We do not mean to imply that an STI diagnosis is required to be eligible for HIV-PrEP; the analysis represents our best estimate of HIV-PrEP need among MSM in England using available national surveillance data.

Our analysis included STI diagnoses from any anatomical infection site (genital, rectal and pharyngeal), which might have overestimated the number of MSM who were eligible for HIV-PrEP because some MSM with pharyngeal infections might use condoms for anal sex. However, in 2015, pharyngeal-only infections represented 7.6% (784/10,276) of all bacterial STI diagnoses among HIV-negative MSM with a recent HIV-negative test, and so the effect is likely to be small. We also recognise that other individuals are likely to be eligible for HIV-PrEP, including those who have not yet attended a SHC, or partners of people living with HIV

who are not yet on treatment nor have detectable viral loads. Nevertheless, our approach provides a replicable method that can be used to compare a defined high risk group over time.

Alternative estimates of the proportion of MSM attending SHCs and eligible for PrEP were recently generated using data from the AURAH study; a cross-sectional study at 20 SHCs that recruited HIV-negative (or undiagnosed) individuals attending for routine tests (2013-2014).[10] The study found that 45.1% (670/1484) of MSM in the study population had a confirmed HIV-negative test result and reported condomless sex in the past 3 months, and thus may represent the proportion of SHC attendees eligible for PrEP.[11] While the data source and methodology used to generate these estimates differs from our own, they suggest that PrEP eligibility in MSM is higher than we have estimated.

Our estimates were used to inform the recruitment target for the PrEP Impact Trial (10,000).[12] As of October 2018, 9,000 individuals are currently enrolled in the trial with the need being greatest among MSM.[4] These data suggest that our proxy measures of high risk may have underestimated HIV-PrEP eligibility among MSM. Although our estimates provided insight into the size of the MSM population likely to be eligible for HIV-PrEP in England in 2015, the actual need for and uptake of HIV-PrEP depends on interactions between clinical, social, and behavioural factors during low and high risk periods for individuals.[13] Furthermore, the delivery of PrEP through SHCs may have increased the number of first-time attendees who may be at higher risk of HIV and other STIs; in the first year of the Scottish NHS programme, nearly 20% of individuals prescribed PrEP had never attended a SHC, or had not attended in the past 10 years.[14] An additional 3,000 places have now been made available on the PrEP Impact Trial.[15] Looking ahead, sexual behaviours and HIV-PrEP consultations will be monitored longitudinally through a future enhancement to GUMCAD.[16]

We have used national surveillance data, which records all attendances at SHCs, to estimate the number of MSM who may be eligible for HIV-PrEP. This approach takes advantage of high

quality surveillance data that will inform national and local level service planning and will be a valuable component of future evaluations of any HIV-PrEP programme.

WORD COUNT

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AUTHOR CONTRIBUTIONS

HMi, SD & ONG designed the analysis and developed the methodology. HMo, KJO, MF & NF provided support with data analysis and interpretation of the data. HMi wrote the first draft of the manuscript with advice from NF and HMo. All authors read the manuscript and provided comments.

BMJ STATEMENT

COMPETING INTERESTS

JS, MD and ONG are sub-investigators for the PrEP Impact Trial in England and members of the trial management group. No other potential conflicts of interest to disclose.

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ETHICS STATEMENT

As GUMCAD is a routine public health surveillance activity, no specific consent was required from the patients whose data were used in this analysis. PHE has permission to handle data obtained by GUMCAD under section 251 of the UK National Health Service Act of 2006 (previously section 60 of the Health and Social Care Act of 2001), which was renewed annually by the ethics and confidentiality committee of the National Information Governance Board until 2013. Since then the power of approval of public health surveillance activity has been granted directly to PHE.

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