

Implementation of HIV PrEP in Scotland:

**First Year
Report**

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The Scottish Health Protection Network (SHPN) is an obligate (jointly owned) network of existing professionals, organisations and groups in the health protection community across Scotland. The aims of the network are:

- To ensure Scotland has a Health Protection service of the highest quality and effectiveness that is able to respond to short term pressures and to long term challenges.
- To oversee the co-ordination of Scotland's health protection services under a network that promotes joint ownership and equitable access to a sustainable and consistent service.
- To minimise the risk and impact of communicable diseases and other (non-communicable) hazards on the population of Scotland and to derive long term public health benefits (outcomes) through the concerted efforts of health protection practitioners across Scotland.

In line with the above, SHPN supports the development, appraisal and adaptation of health protection guidance, seeking excellence in health protection practice.

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Preface

In July 2017, Scotland was the first country in the UK to implement HIV PrEP (HIV Pre Exposure Prophylaxis) – a national biomedical HIV prevention programme involving the provision of oral antiretroviral drugs to those at sexual risk of HIV – alongside comprehensive STI and HIV prevention services. In clinical trials PrEP has been shown to reduce the risk of sexually transmitted HIV by 75-86%.

Scotland is the first country worldwide to provide PrEP nationally as part of routine state-funded care to people who meet risk-based eligibility criteria.

This Report describes the implementation, monitoring, uptake, and limited outcomes associated with the first year of PrEP services. A scientific report with detailed epidemiological analysis is in preparation and an evaluation of service-level impact of providing PrEP services is in progress.

The Report was prepared by a writing committee stemming from Scotland's National HIV PrEP Coordinating Group: Nicky Coia, Claudia Estcourt, David Goldberg (Chair), Pauline McGough, Rak Nandwani, Nicola Steedman, Ruth Robertson, and Lesley Wallace. It has been written on behalf of the National Coordination Group and its subgroups (see [Appendix 1](#)).

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Special Thanks

We especially wish to thank Dr Mags Portman for the advice and help she provided to support PrEP being implemented in Scotland. Notably, Mags came to Edinburgh and advocated for PrEP when the Short Life Working Group made its recommendations to the Executive Leads in October 2016. Mags sadly passed away on 6 February 2019 at the age of 44.

Executive Summary

Introduction

- HIV PrEP (HIV Pre-Exposure Prophylaxis) is a novel prophylactic biomedical intervention comprising of two HIV antiretroviral drugs. Studies published in 2014 and 2015 demonstrated that when PrEP is prescribed to HIV negative people (especially men who have sex with men [MSM]) at risk of becoming infected sexually, their probability of HIV infection acquisition is reduced by approximately 86%.
- In 2016, the European Medicines Agency (EMA) approved Truvada® for use as HIV PrEP.
- In April 2017, the Scottish Medicines Consortium approved Truvada® for use within NHS Scotland and on 1st July, HIV PrEP became available officially in sexual health clinics throughout the country.
- Scotland was the first country in the UK to approve the provision of HIV PrEP by the NHS.

Implementing the HIV PrEP Service in Scotland

- PrEP is delivered in NHS Scotland using the existing network of specialist sexual health services (with alternative GP-led arrangements for the island NHS Boards).
- A considerable challenge was the absence of additional funding allocated for PrEP drugs or extra service support costs at a time when specialist sexual health services were already facing appreciable cost savings and increasing rates of sexually transmitted infections.
- Comprehensive training, coordinated and supported by NHS Education Scotland, was delivered to the specialist service multidisciplinary workforce responsible for PrEP assessment and care.
- Through partnership working the following public awareness raising resources were developed and deployed:
 - Prep.scot website
 - Know About PrEP– Prevent HIV
 - PrEP in Scotland
- A data collection system, incorporating the addition of newly devised specific codes to the Scotland-wide sexual health IT information system (NaSH), was developed and implemented.
- Standard appointment duration was insufficient to address PrEP assessment and other sexual health needs and health promotion. This required significant change in models of care in some health boards.
- NHS National Services Scotland National Procurement successfully commissioned, at significant cost saving, generic drugs for availability to sexual health services in November 2017.
- From January 2018, it was appreciated that the number of people commenced on PrEP was higher than had been projected; continuing high numbers of individuals starting PrEP for the first time, combined with the cumulative effect of those who had previously started PrEP, led to an exacerbation of pressure on services.

- Despite the service pressures and multiple challenges, one of the hallmarks of the first year of the NHS-delivered PrEP programme in Scotland has been the multi-disciplinary, multi-agency working across territorial and national NHS Boards, Scottish Government, the third sector and professionals with PrEP expertise elsewhere in the UK and abroad.
- Programme oversight has been greatly facilitated through the creation of a National PrEP Coordination Group and its three subgroups, and a governance arrangement which ensures accountability through NHS Board executives to the Minister for Public Health within Scottish Government.

Monitoring the Uptake of PrEP in Scotland

- NHS-supplied PrEP has been prescribed in 11 of 14 Scottish NHS Boards.
- 1,872 individuals were prescribed PrEP at least once in the first year of the Scottish NHS PrEP programme.
- 99% of those prescribed PrEP were MSM; the majority reported condomless anal sex with multiple partners as a reason for being eligible for NHS PrEP.
- 39% of those prescribed PrEP were in the age range 20-29 years and almost a third were aged 40 or above.
- The majority (74%) of those prescribed PrEP were prescribed a daily regimen rather than an event based one; around 1 in 10 patients were prescribed both types of regimen.
- Around one fifth of those prescribed PrEP were attending sexual health services for the very first time or for the first time in NaSH history; this suggests that PrEP is drawing patients in to services who are at high risk for HIV and other STIs.

Evaluating the Impact of HIV PrEP

- Less than five (1 to 4) MSM prescribed PrEP (at least once) HIV seroconverted; further investigations showed that PrEP drug levels were below protective levels at the time of suspected HIV acquisition.
- The majority of the 1,846 MSM prescribed PrEP were commenced on it during July-December 2017; accordingly, around 1000 person years of exposure post-initiation of PrEP was experienced during the first year. This means that the incidence of HIV among this group for the period July 2017-June 2018 was 0.1% - 0.4% (1-4 per 1000).
- Among those prescribed PrEP, rates of gonorrhoea (including rectal) testing and numbers diagnosed positive increased between the two 12 month periods either side of NHS PrEP introduction but rates of actual infection remained similar. Such rates were higher among those ever versus never prescribed PrEP; this observation indicates that the former are at higher risk of gonorrhea (and therefore HIV) infection and that the eligibility criteria for PrEP are likely to be appropriate.
- Similar observations were recorded for chlamydia with an increase in testing and diagnoses among MSM ever prescribed PrEP but no overall change in the proportion positive pre and during the first year of NHS PrEP.

- The increases in gonorrhoea and chlamydia diagnoses could be attributed to either improved detection, an actual increase in the incidence of infection or a combination of both; the explanation is likely to be the “combination” one but the ratio of the contributions is uncertain.

Research

- Scotland’s “first in the UK” implementation of PrEP as routine care in sexual health services has provided unique opportunities for research to inform PrEP care in Scotland, the wider UK and internationally.
- A strong research portfolio, drawing on strengths in mixed methods, multidisciplinary research has been developed.
- Current research themes include optimising PrEP clinical services, exploring opportunities for “ePrEP” (PrEP care online), PrEP community advocacy, PrEP and women of colour, and missed opportunities for PrEP in people who acquire HIV.
- Current combined PrEP-related research income is around £600,000.

Discussion

- During the first year of NHS PrEP implementation, 1,872 individuals were prescribed PrEP in sexual health settings throughout the country. This total exceeded predictions not least because a considerable number of high risk (for HIV) individuals who had never, or not for years, attended such services were possibly drawn to them by the concept of PrEP.
- Despite i) the short lead-in time following SMC approval to PrEP becoming available, ii) PrEP being a unique intervention, iii) the unavailability of additional funding for service implementation, iv) existing pressures on sexual health clinics and v) the extensive demand for PrEP as above, year one has been a resounding success in terms of establishing a new nationwide service – the first of its type in the UK and one of the first worldwide.
- This outcome speaks to the quality of the service providers, in particular the clinical staff, the existing model of integrated sexual health service delivery in Scotland, and existing and new coordination arrangements which ensure the sharing of best practice, consistency in approach and optimal governance and accountability.
- While nearly two thousand people were prescribed PrEP in the first year, very large numbers had been on it only a few months by the end of that year; accordingly, a further evaluation at the end of year two will be required to provide an informed understanding of impact and several years will be needed to undertake more sophisticated analyses to evaluate impact optimally.
- It is highly encouraging that only 1 to 4 of those prescribed PrEP – i.e. people at highest risk of HIV infection– acquired their HIV following initial prescription.
- With respect to PrEP impact on STIs other than HIV, likewise, it is too early to make well informed conclusions. What has been learned, however, is that among people prescribed PrEP, an increase in the number of those with gonorrhoea and chlamydia has been detected following the commencement of PrEP when compared to a similar time frame pre-PrEP ; this increase in diagnoses, however, has aligned with an increase in testing for these infections.

- In common with many settings, uptake has been largely limited to MSM because the awareness raising focus had been on this group for a number of years and the HIV risk among MSM having condomless penetrative anal sex with multiple partners is higher than that for any other group; it is crucial, however, that PrEP is seen as an intervention for all at high risk of HIV. More needs to be done to raise PrEP awareness among women, transgender/trans people and heterosexual men; in year two further work, including research, will be undertaken to decide how best to address their needs and, thereafter, tailor services appropriately and proportionately without generating unnecessary alarm and excessive demand.
- The development of new acceptable models of PrEP care, involving for example eHealth, could increase access to PrEP and reduce the burden on sexual health services.
- Further work on the cost-effectiveness of PrEP as a national prevention strategy needs to be undertaken.

Conclusion

- In conclusion, Scotland is one of the first countries worldwide to have successfully established a PrEP service which is truly national, free at the point of delivery and, to date, generally accessible to most deemed at high risk of acquiring HIV. In terms of HIV prevention, the early signs are favourable. While it is too early to draw conclusions on the impact of PrEP on high risk sexual behaviour and other STIs, there are some pointers suggesting an increase; but any possible increase is likely to be offset by PrEP's HIV impact and its ability to attract people at risk of HIV who would not normally access sexual health services and who, consequently, can reap the benefits of these.
- On a cautionary note, the success of the service implementation, and the cumulative nature of PrEP uptake, means that pressures on sexual health services which have already caused difficulties affecting both users and providers will continue to increase unless additional resources or efficiencies are identified. In year two, a formal evaluation of that impact is being undertaken.

1 Introduction

Despite major advances in testing and treatment, HIV still has a major impact on individual health and the economy. Although Scotland has met international targets for diagnosis, initiation and maintenance on therapy, new infections are still occurring.

An average of 356 reports of HIV have been recorded in men and women each year in the past five years; of these, almost two thirds were new diagnoses.¹ A notable (21%) decrease in the number of new diagnoses from 253 to 199 – the lowest number for 10 years – was observed between 2015 and 2016 but the number rose again to 228 in 2017. This pattern was most marked among MSM – a 34% decrease in new diagnoses (131 to 86) between 2015 and 2016; the number increased in 2017 but to a level lower than that observed in the years prior to 2016¹.

Oral HIV Pre-Exposure Prophylaxis (PrEP), an intervention whereby people who do not have HIV take anti-retroviral drugs to prevent HIV acquisition, is a key step towards the eradication of HIV. Clinical trials have established that PrEP can reduce risk of HIV acquisition by 86% in men who have sex with men (MSM)^{2,3} and by 75% in heterosexuals⁴.

In 2016, the European Medicines Agency (EMA) approved Truvada® for use as HIV PrEP. That year, an HIV PrEP Short Life Working Group (SLWG), commissioned by the Scottish Government through its Sexual Health and Blood-Borne Virus (SHBBV) Executive Leads Group, undertook preparatory work in relation to the prospect of HIV PrEP in Scotland. The Group strongly recommended that people in Scotland deemed eligible for PrEP should have access to it. The Group agreed eligibility criteria (see Table 1.1) and estimated that approximately 1000 of 1900 potentially eligible individuals (mostly MSM) would be prescribed HIV PrEP following the comprehensive implementation of a national service.

In April 2017 the [Scottish Medicines Consortium](#) approved Truvada® for use within NHS Scotland and on 1st July, HIV PrEP became available officially in sexual health clinics throughout the country.

Scotland was the first country in the UK to approve the provision of HIV PrEP by the NHS; this intervention is a welcome addition to a highly comprehensive prevention drive which also includes increasing the effort to promote condom use for casual sexual intercourse, frequent HIV/STI testing and the earliest possible treatment of HIV/STIs.

In May 2017, a National HIV PrEP Co-ordinating Group, accountable to the SHBBV Executive Leads Group, and three sub-groups – for (i) establishing the clinical service, (ii) education and awareness raising and (iii) monitoring, evaluation and research – were established (see [Appendix 1](#)).

This report, authored by the National Coordinating Group, describes in detail the work undertaken to establish and assess the impact of the service during the first year of implementation. A scientific report with detailed epidemiological analysis is in preparation and an evaluation of service-level impact of providing PrEP services is in progress.

Table 1.1: Eligibility criteria for the prescribing of NHS-funded PrEP in Scotland, 2017

HIV PrEP – UNIVERSAL CRITERIA

An individual who is:

- Aged 16 or over,
- HIV negative,
- Able to attend the clinic for regular 3 monthly review, including for monitoring, sexual health care and support and to collect prescriptions,
- Willing to stop NHS funded PrEP if the eligibility criteria no longer applies, and
- Resident in Scotland

RISK BEHAVIOUR ELIGIBILITY CRITERIA

An individual who is:

- A current sexual health partner, irrespective of gender, of people who are HIV positive and have a detectable viral load
- OR
- An MSM or transgender women with a documented bacterial rectal STI in the last 12 months
- OR
- An MSM or transgender women reporting condomless penetrative anal sex with two or more partners in the last 12 months, and likely to do so again in the next three months
- OR
- Irrespective of gender, an equivalent high risk of HIV acquisition, as agreed with another specialist clinician

HIV PrEP – NOT ELIGIBLE

An individual who is:

- Already HIV positive or suspected to be seroconverting to HIV,
- The HIV negative sexual partner of an HIV positive person who is on treatment and has undetectable viral load,
- Experiencing pre-existing medical conditions (such as renal impairment) that significantly increase the risk of TDF/FTC adverse events.
- Chronically infected with hepatitis B virus where TDF/FTC may be being used for therapy.

2 Implementing the HIV PrEP Service in Scotland

2.1 Overview

The SLWG proposed that PrEP should be delivered in NHS Scotland using the existing network of specialist sexual health services (with alternative GP-led arrangements for the island NHS Boards) as it considered this setting to be uniquely placed to i) provide regular HIV/STI testing and other prevention interventions, and ii) permit the collection of data for service monitoring and evaluation.

The SLWG considered multiple options for PrEP implementation to help formulate its recommendations. Accordingly, when SMC approval for PrEP was announced on 10th April 2017, a considerable exploration of the practicalities surrounding implementation had already been undertaken. The standard timescale for the availability of drugs after a positive SMC decision is 90 days but despite the unique characteristics of PrEP (i.e. it is not a treatment) there was a determination that this intervention should not be exceptionalised; therefore, the challenge was to operationalise PrEP delivery in Scottish sexual health services within a relatively short timescale by July 2017.

The co-operation of third sector organisations, community activists and NHS Boards across Scotland, combined with support from the Scottish Government, Health Protection Scotland (HPS) and Information Services Division (ISD) of National Services Scotland (NSS), provided the framework for co-ordinated implementation in NHS Scotland. There was mutual acknowledgment that progress would not have been made without this alliance.

The first year of PrEP in Scotland can be described in three distinct periods; preparation for delivery, an early implementation phase and an established service with increasing numbers.

2.2 Preparation for PrEP delivery: April to July 2017

Data and learning from other comparable settings were taken into account during the planning period; sources of information included WHO implementation guidance and the experience of PrEP delivery in France, Australia and San Francisco. As Scotland would be the first of the UK home nations to deliver an NHS-provided PrEP programme, there were concerns about the potential number of individuals presenting to services from elsewhere in the UK.

Funding the Programme

A considerable challenge was the absence of additional funding allocated for PrEP drugs or extra service support costs at a time when specialist sexual health services were already facing appreciable cost savings and increasing rates of sexually transmitted infections.

Agreement for a Consistent Approach

A meeting of NHS Board SHBBV Executive Leads and other key stakeholders was held on 16 May 2017 to reach consensus about PrEP eligibility criteria (including the “resident of Scotland” criterion) and to ensure equitable and consistent services without duplication of effort.

In the context of the SMC decision, all NHS Boards made a commitment to support PrEP delivery locally. This included the monitoring of individuals who had self-sourced PrEP and, at that time, the funding of PrEP drugs at full cost - i.e. the cost used in the SMC cost-effectiveness analysis. It was recognised that this would generate a significant cost-pressure—one which had been flagged over a year earlier by the SMC as part of the standard horizon scanning process for new therapies; accordingly, NHS Boards had been asked to factor this new element of HIV prevention into their budget planning.

Information Resources and Protocols

Rapid establishment of service infrastructure was required for the PrEP programme to start in early July 2017. It was appreciated that the new service needed to be innovative and agile and that initial arrangements would require adjustment as experience accumulated. Preparatory work involving the production of national information resources (eg the www.prep.scot website) brought together third sector representatives, peer educators, HIV literacy experts, and, throughout the UK, service providers. In parallel, NHS Boards developed local protocols and standard operating procedures – including those for testing and result management with linkage to HIV and STI care – to support safe and acceptable care pathways. Arrangements for co-operation between larger and smaller NHS Boards, taking into account cross-border flow and the reimbursement of PrEP drug costs if supplied outside area of residence, were agreed.

Workforce Education Development

Significant workforce education activity was undertaken to support the clinical and non-clinical workforce responsible for implementing HIV PrEP locally and nationally. Comprehensive training, utilising a range of resources including draft UK specialty society guidelines, was delivered to the specialist service multidisciplinary workforce responsible for PrEP assessment and care. The West of Scotland sexual health service Managed Clinical Network staged a training event on 30th May 2017 to support frontline staff; this included a speaker from one of the large London sexual health services where individuals were attending for monitoring following the self-purchasing of PrEP.

NHS Education Scotland (NES) with support from a wide range of stakeholders developed and published, on their website, educational resources for registered healthcare staff and the wider workforce involved in the delivery of the programme.

Data Collection

New data collection arrangements, including the addition of newly devised specific codes (see Section 4 of this report) to the Scotland-wide sexual health IT information system (NaSH), were implemented. These codes were designed to provide PrEP data collection consistency with elsewhere in the UK so that combined and comparative data analyses across the UK and, ideally, beyond would be possible.

2.3 Early Issues Arising from PrEP Service Implementation: July to December 2017

Addressing Complexities Surrounding the Patient Consultation

The implementation of the NHS-delivered PrEP programme coincided with prior arrangements to roll-out HPV immunisation in Scotland to men who have sex with men (MSM) aged 45 and under, from 1st July 2017. This added to the complexity and time required to see individuals who were potentially eligible for both PrEP and HPV vaccination. It was clear that a standard 20 minute sexual health appointment was insufficient for a new patient at high risk of HIV and other STI, to discuss PrEP in conjunction with other prevention initiatives as well as performing routine baseline investigations and delivering other required interventions. In some larger NHS Boards, this challenge was addressed by establishing a nurse-led pre-assessment consultation followed by a medical appointment to review results and, if appropriate, prescribe, PrEP, with adherence and dosing advice.

Staff concerns

In addition to concerns about adding to existing general service pressures, staff were worried that prioritising individuals (predominantly MSM) at highest risk of HIV acquisition, would limit service access to other populations. Staff anxiety about the potential side-effects and drug interactions of PrEP were evident despite their past experience of prescribing medications for HIV treatment and post-exposure prophylaxis.

Resolved Issues

Other staff concerns became less of an issue during the first phase of PrEP implementation. The availability of PrEP elsewhere in the UK and access to low-cost self-purchased PrEP resulted in few individuals going to the expense and trouble of travelling to Scotland purely to obtain PrEP. Accordingly, staff were not required to routinely confirm an individual's identity or residence for eligibility purposes as had been feared initially.

Peer support systems, including clinical network arrangements allowed clinicians to discuss complex eligibility issues and to promote consistency around eligibility decisions, including those for individuals who were ineligible under the agreed criteria but who still thought they merited PrEP.

It was considered advantageous that NHS-supported PrEP could be offered to individuals with lower rates of HIV literacy and who were unaware of PrEP prior to attendance.

PrEP Early Adopters

As anticipated, even in the absence of a public-facing awareness campaign for PrEP, there was a cohort of well-informed PrEP early adopters who had been waiting for access to NHS-PrEP following SMC approval; these included a small proportion who had been self-sourcing PrEP. These individuals, predominantly MSM, included appreciable numbers aged over 50 and/or at high risk of HIV infection who had either never, or not recently, attended sexual health services. This added to the complexity of navigating people through the PrEP care pathway, ensuring the

detection of previously undiagnosed HIV and/or STIs, clinical contraindications to therapy (e.g. those relating to renal function) and potential drug interactions.

Generic Medication

Despite variation in PrEP uptake numbers in different NHS Boards (with the majority accessing services in NHS Lothian and NHS Greater Glasgow & Clyde), those responsible for delivering PrEP services expressed concern about the financial impact of prescribing branded PrEP drugs at an NHS cost of £355 (ex VAT) for 30 days supply; uncertainty about the supplementary protection certificate (SPC) for branded Tenofovir Disoproxil Fumarate/Emtricitabine was identified. Although this was subject to legal challenge, NHS Services Scotland National Procurement successfully commissioned generic drugs at significant cost saving; an announcement was made in September 2017 and such PrEP was supplied to sexual health services in November 2017.

This process not only resulted in the availability of generic Tenofovir Disoproxil/Emtricitabine salts for HIV prevention purposes but also for HIV treatment ones. The Scottish HIV clinical leads had previously issued [national cost-sensitive prescribing guidance](#) for HIV therapy in June 2017; this led to cost savings to NHS Scotland several times larger than the full cost of the PrEP programme.

2.4 Established PrEP services with increasing numbers: January to June 2018

Scotland's Integrated Sexual Health Service Model

From January 2018, it was appreciated that the number of people commenced on PrEP was higher than had been projected; continuing high numbers of individuals starting PrEP for the first time, combined with cumulative attendances every three months by those who had previously started PrEP, led to an exacerbation of pressure on services.

Abnormal laboratory results require interpretation by clinical decision makers familiar with Internal Medicine competencies, as not all such results are clinically significant. Given Scotland's service model of integrated sexual health services – one which combines contraception & reproductive health with STI care – staff without physicianly competences found the demands posed by the introduction of this new intervention challenging. In this context, it was clear that PrEP implementation was stretching the wider service model and that redesign might be required.

Prescribing and Dispensing

During this third phase, temporary issues with PrEP medication supplies, necessitating the need to use alternative drugs from different generic manufacturers, arose. Adjustments to the NaSH IT system were needed to ensure that correct prescriptions were recorded. Given the volume of demand in some NHS Boards, a pragmatic dispensing approach was implemented; owing to lack of capacity for re-attendance, individuals were given supplies of PrEP medication on the day of baseline assessment, rather than collecting these once baseline results were confirmed as satisfactory. This led to occasional, though quickly rectified, errors including the over-supply of drug and PrEP being commenced despite ineligibility, (e.g. patients found to be HIV- positive at baseline).

PrEP Adherence

With PrEP numbers increasing and certain individuals starting daily PrEP but then shifting to event based dosing and vice versa, the need to dedicate sufficient time to promote adherence and thus avoid sexual health services developing a PrEP dispensing service mentality, was evident.

In many NHS Boards, however, service pressures meant there were insufficient resources to contact individuals who were late for, or had missed, follow-up appointments to monitor adherence.

Further Learning from the PrEP NHS Programme Experience

The delivery of PrEP as an NHS-supported programme, rather than from within the context of a clinical trial, generated new prescribing experiences; these included, for example, the continued use of PrEP during pregnancy and issues relating to the discontinuation of PrEP in an HIV negative individual once his HIV-positive partner had attained undetectable viral load for six months and had had no STIs.

Providing a Service for All Who Need it

It was acknowledged by all partner organisations that the NHS-supported PrEP programme – adopting clinically defined eligibility criteria based on cost effectiveness evaluations – had the potential to widen inequalities in health. The intervention, for example, might disproportionately benefit those MSM who were better educated and/or from more affluent backgrounds. In addition, other population groups whose HIV-risk was high might face barriers in accessing information about PrEP and/or the service itself.

These populations include:

- Women whose partners are living with HIV and have detectable viral loads,
- People who inject drugs or whose partners inject drugs,
- People whose partners are from countries with high HIV prevalence especially Sub Saharan Africa,
- Transgender women and men,
- People involved in exchanging sex for money or goods.

During the first year, the focus was on bedding in the service; nevertheless, engagement with individuals, as above, and/or their representatives was undertaken to assess needs in the context of PrEP. The challenge to ensure that all individuals who might benefit from PrEP have access to PrEP information and services is now well understood. In year two, further research and engagement will be conducted and services will be tailored accordingly to ensure that they are optimal for all.

Multi-Disciplinary, Multi-Agency Working

Despite the immense service pressures and multiple challenges, one of the hallmarks of the first year of the NHS-delivered PrEP programme in Scotland has been the multi-disciplinary, multi-agency working across territorial and national NHS Boards, the Scottish Government, the third sector and professionals with PrEP expertise elsewhere in the UK and abroad.

Coordination has been greatly facilitated through the creation of the National PrEP Coordinating Group and its three subgroups, and a governance arrangement which ensures accountability through NHS Board executives to the Minister for Public Health of the Scottish Government.

3 Education and Awareness Raising Initiatives

3.1 Background

HIV PrEP education and awareness raising initiatives for the public, specialists providing the service and the wider workforce were a key focus.

Initially, agencies worked together quickly to ensure basic general information was available to the public and the key workforces involved in delivering HIV PrEP.

3.2 Public Information Resources

Through partnership working involving the PrEP Education and Awareness Group, the following resources were deployed.

Public Information Resources

Prep.scot website	A single web based portal for online information about PrEP and links to where people could be signposted for PrEP was developed by HIV Scotland and launched in July 2018 to align with the programme launch. The content is based on material created through the Developing HIV Literacy project at University of Edinburgh in partnership with HIV Scotland.
Know About PrEP – Prevent HIV	Two resources (a 12 panel business-card sized leaflet and a 12 page booklet) with basic information on PrEP were already finalised and ready for use when PrEP became available in Scotland. These had been developed jointly by the University of Edinburgh and HIV Scotland and were part of the outputs of the Developing HIV Literacy project. These have been used by all services to raise awareness of PrEP. These were made available at no cost by the University of Edinburgh and were distributed to Health Boards by HIV Scotland.
PrEP in Scotland	A 16 page patient information booklet for those who have been prescribed PrEP was adapted for the Scottish context from an existing information resource produced by ibase in England. This was made available to health boards in August 2017. In the absence of national resources for the provision of information, NHS Greater Glasgow and Clyde undertook all work on the adaptations and funded the costs of the first print run. A second edition was adapted again by NHS Greater Glasgow and Clyde in 2018 following changes in procured drugs for PrEP. However with no national funding in place, individual health boards were asked to meet their own print costs.

These resources were used by a broad range of organisations to raise awareness of PrEP as part of ongoing work with the key populations most likely to benefit from it.

In addition, a considerable amount of work was undertaken to incorporate details about PrEP into pre-existing HIV information resources available across Scotland.

NHS Inform is Scotland's national health information service which provides people in Scotland with accurate and relevant information to help them make informed decisions about their own health and the health of the people for whom they care. During 2018, the NHS Inform [HIV](#) content was updated.

These initial resources were aimed at a more universal level rather than targeted at particular population subgroups. During the first year, organisations involved in the Education and Awareness subgroup engaged with certain diverse populations, likely to be eligible for PrEP and need more targeted resources, to assess need. It is planned that further needs assessment work with such groups will be undertaken in 2019 to inform the development of, and access to, such resources .

3.3 Workforce Education Development

The need for a competent and confident workforce was seen as key in helping to ensure the successful implementation of the HIV PrEP programme in Scotland.

To meet this need, NHS Education for Scotland worked extensively with clinical and non clinical stakeholders and convened expert groups to support the development of educational resources for both registered healthcare practitioners and the wider workforce involved in supporting this programme. Resources included training slides and webinars which were published (and will continue to be updated as required) and made available on the NES website. These resources are available at: [https://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/blood-borne-viruses-and-sexual-health/hiv-pre-exposure-prophylaxis-\(hiv-prep\)-in-scotland.asp](https://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/blood-borne-viruses-and-sexual-health/hiv-pre-exposure-prophylaxis-(hiv-prep)-in-scotland.asp).

Further educational interventions will continue to be identified and progressed through stakeholder feedback as the programme develops.

4 Monitoring the Uptake of PrEP in Scotland

4.1 Background

As described in Section 1, in May 2017 a National HIV PrEP Co-ordinating Group and three subgroups were established (See [Appendix 1](#)). One of these subgroups, the PrEP Monitoring and Research (PrEPMAR) Subgroup, was tasked with devising and implementing a system for monitoring and evaluating the Scottish national PrEP programme.

This involved:

- Establishing a mechanism to monitor and record uptake of PrEP and other characteristics of PrEP seekers/recipients in Scotland
- Establishing a mechanism to evaluate the impact of PrEP on the incidence of HIV and other STIs in those taking PrEP, and in the wider population

This section describes the development and integration of a system to record and monitor PrEP uptake in Scotland, and details first year results generated by this system. Section 5 further explains the PrEP impact evaluation plan and provides initial findings.

4.2 Methods and Data Sources for Monitoring PrEP Uptake

The Scottish National Sexual Health (NaSH) IT System

The primary data source for PrEP uptake in Scotland is the Scottish National Sexual Health (NaSH) IT System, a centralised web-based electronic clinical record system, which went live in March 2008. NaSH is a specific development of Excelicare (AxSys Technology, UK), and is a full electronic patient record, a booking and clinic management system, and can link to key repositories such as the Community Health Index (CHI) database and the Scottish Care Information (SCI) Store.

All eleven mainland NHS Boards in Scotland now use NaSH as their primary record system for specialist sexual health, providing an unparalleled opportunity to evaluate PrEP at the national level. NaSH now holds sexual health records of over 700,000 patients, with around 300,000 attendances recorded annually across the mainland NHS Boards in around 200 locations. Data forms include medical, family and sexual history, reproductive health and contraception, social history, test requests/results, patient actions/recalls, prescriptions, symptoms, physical examination details, partner notification, and referrals. NaSH also has the advantage of enabling all NaSH-using locations to access a single record if patients move across NHS Board boundaries.

Developing a Novel Clinical Coding System

To monitor PrEP implementation and use across Scotland, a novel clinical coding system was developed by the PrEPMAR group and introduced into NaSH to enable the identification of those assessed for PrEP and those initiated on it. This was done using the previously employed Sexually Transmitted Infections Surveillance System (STISS) coding function on NaSH which allowed the construction of a unique dataset for PrEP-related attendances, one which clinicians could access and complete on NaSH during/after a patient consultation involving PrEP.

When constructing Scottish PrEP-related codes, PrEPMAR reflected the eligibility criteria for PrEP developed by the original PrEP SLWG. PrEPMAR also liaised closely with colleagues in Public Health England to ensure as much comparability between codes in NaSH and those being used in the English [PrEP Impact Trial](#) to facilitate future data comparison across the nations. As it was anticipated that PrEP coding in Scotland would be done in real time by the clinical teams within sexual health clinics, the PrEPMAR group was keen to keep the codes as simple and as few in number as possible.

A coding guidance document was written to accompany the introduction of the new PrEP codes on NaSH and issued to clinical teams via the Scottish Sexual Health Lead Clinicians Group on 5th September 2017; although this was approximately eight weeks following the launch of the Scottish PrEP programme, mainland NHS Board clinicians were asked to retrospectively code any patients who had already been prescribed NHS PrEP in the intervening period. For reference, PrEP codes are shown in the table below; it should be noted that two of the codes (PrEPDEF and PrEPCON) were added later than the others, and communicated to clinics via updated PrEP coding guidance issued in November 2017.

Figure 4.1: PrEP service codes developed for use on the national sexual health IT system (NaSH) for individuals accessing NHS funded PrEP in the sexual health clinic setting

PrEP service code	Description
PREPe0	PrEP Does not meet NHS eligibility criteria
PREPe1	PrEP Partner(s) HIV-positive with a detectable viral load
PREPe2	PrEP Documented bacterial rectal STI in the last 12 months
PREPe3	PrEP Condomless penetrative anal sex with 2 or more partners in last 12m and risk likely in next 3m
PREPe4	PrEP Equivalent high risk of HIV acquisition, as agreed with another specialist clinician
PREPDAY	PrEP regimen: starting or continuing DAILY PrEP
PREPEBD	PrEP regimen: starting or continuing EVENT BASED PrEP
PREPDEF	PrEP prescription intended, but not prescribed today
PREPOWN	PrEP continued (through other source)
PREPDEC	PrEP offered and declined
PREPCON	PrEP medically contraindicated
PREPEND	PrEP stopped

orange = eligibility (as many as apply), green = regimen, pink = outcome

An electronic spreadsheet was developed for the three Scottish Island Boards who do not currently use NaSH; this was to be completed for each PrEP-related consultation and returned centrally for processing.

Episode 'reason for attendance' referring to PrEP, PrEP codes on eligibility and outcome, and PrEP prescription data were extracted from the national pseudoanonymised view of NaSH at Information Services Division, National Services Scotland, on 9th October 2018 and combined with the PrEP eligibility and outcome data from non-NaSH using services in Island Boards to complete the national picture.

The anonymised Patient ID was used to link a patient's PrEP prescription to their demographic information and episode history. Guidance advised that episodes could be within 28 days of a prescription; therefore only those episodes between 0 and 28 days of prescription were seen as valid. Sexual orientation was derived using the gender (s) of previous sexual partners (during the patient's lifetime) recorded by clinicians.

Data from 1st July 2017 to 30th June 2018 (inclusive) are presented.

4.3 Findings

Overall PrEP Uptake

Overall, a total of 161,041 individuals, of whom 11,472 (7%) were MSM attended NaSH-using sexual health services for any reason during the time period of analysis.

NHS-supplied PrEP has been prescribed in 11 of 14 Scottish NHS Boards, all of whom currently use NaSH for patient management.

In the first year of the Scottish PrEP programme, 1,872 individuals have had one or more prescriptions for PrEP; this amounted to a total of 4,432 prescriptions.

Gender and Sexual Behaviour of PrEP Recipients

Almost all individuals prescribed PrEP were male (1,855; 99%), with only 14 (0.7%) identifying as female (Appendix Table 4.1); the vast majority were MSM (1,846; 99% Appendix Table 4.1). At the time of analysis it was not possible to accurately calculate numbers of transgender/trans individuals via the NaSH pseudoanonymised national data view; such information, however, will be available in the future.

Those MSM prescribed PrEP constituted 16% of all MSM attending NaSH-using sexual health services; this indicates that a considerable proportion of MSM in Scotland are at significant risk of HIV acquisition.

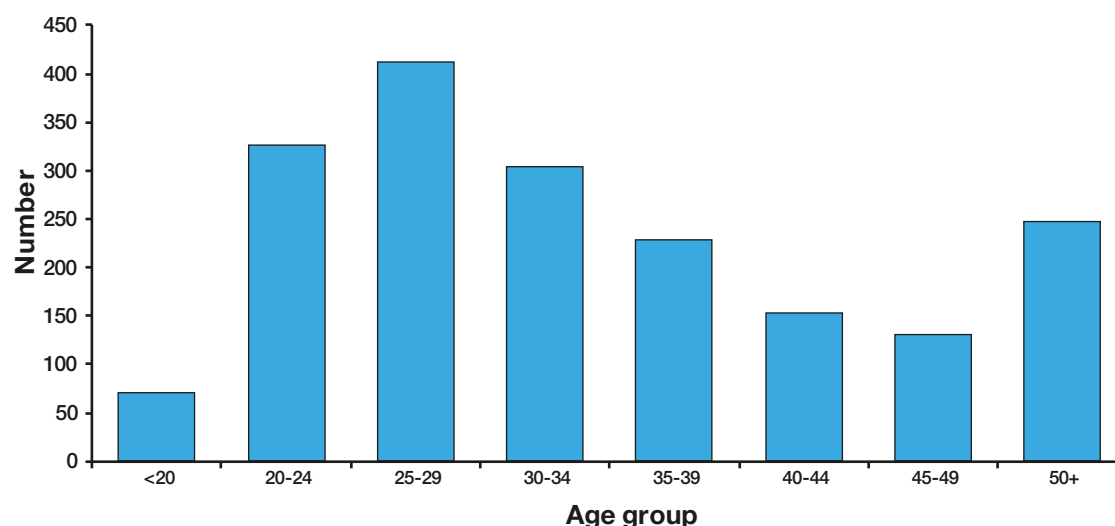
PrEP Prescriptions by NHS Board

Numbers of individuals prescribed PrEP and numbers of PrEP prescriptions by NHS Board can be found in Appendix Table 4.2.

Age of PrEP Recipients

Of the 1,872 individuals prescribed PrEP, the largest proportion (739; 39%) were aged 20-29 years (Appendix Table 4.3). A small proportion were under 20 years old (70; 4%) and almost a third were aged 40 or above (530; 28%).

Figure 4.2: Number of individuals prescribed PrEP by age group, Scotland, July 2017 to June 2018.



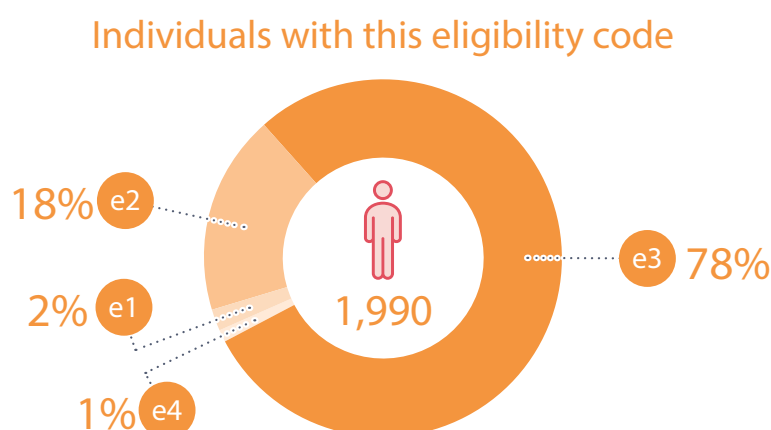
Eligibility Reasons for PrEP

PrEP eligibility reasons and associated codes can be found in Figure 4.1; in Scotland, individuals can be ascribed as many PrEP eligibility codes as apply to them.

For the time period analysed, data on eligibility coding (i.e. at least one of the codes PrEPe1-e4) were available for 1,681 (90%) of the 1,872 individuals prescribed PrEP (Appendix Table 4.4), with a total of 1,990 eligibility codes recorded.

The majority (1,567, 78% of 1990 codes) of the PrEP eligibility codes recorded applied to a reported history of condomless penetrative anal sex with two or more partners in the last 12 months and a risk of this again in the next three months. Around a fifth (18%) of codes applied to a documented bacterial rectal STI in the previous 12 months. Only small proportions of individuals belonged to other eligibility categories for PrEP:

- Partner HIV-positive with a detectable viral load 2%
- Equivalent risk of HIV acquisition, clinician judged 1%

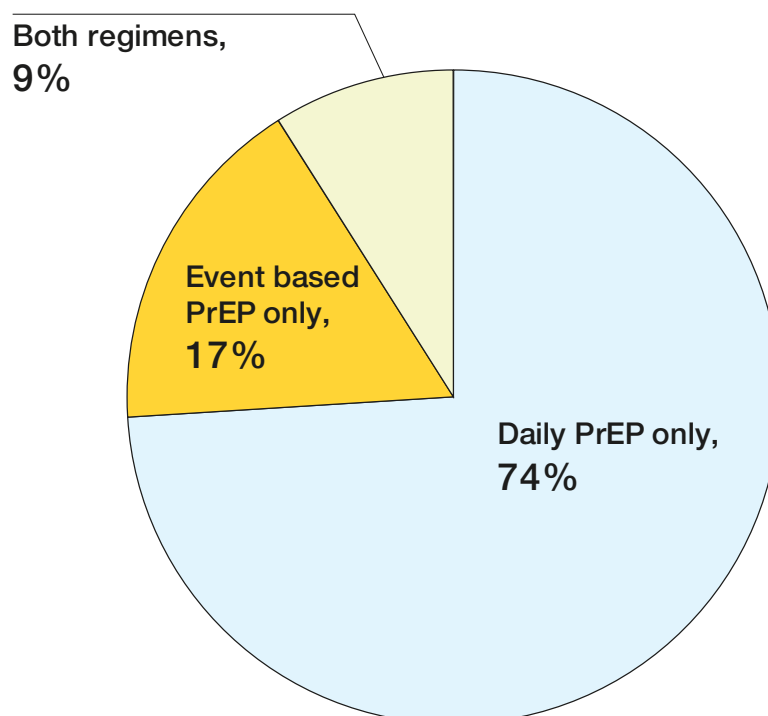


Choice of PrEP Regimen

Coded data on choice of PrEP regimen were available for 1,747 (93%) of the 1,872 individuals prescribed PrEP; for the remaining 7% it was possible to ascertain the type of PrEP regimen from the actual prescriptions.

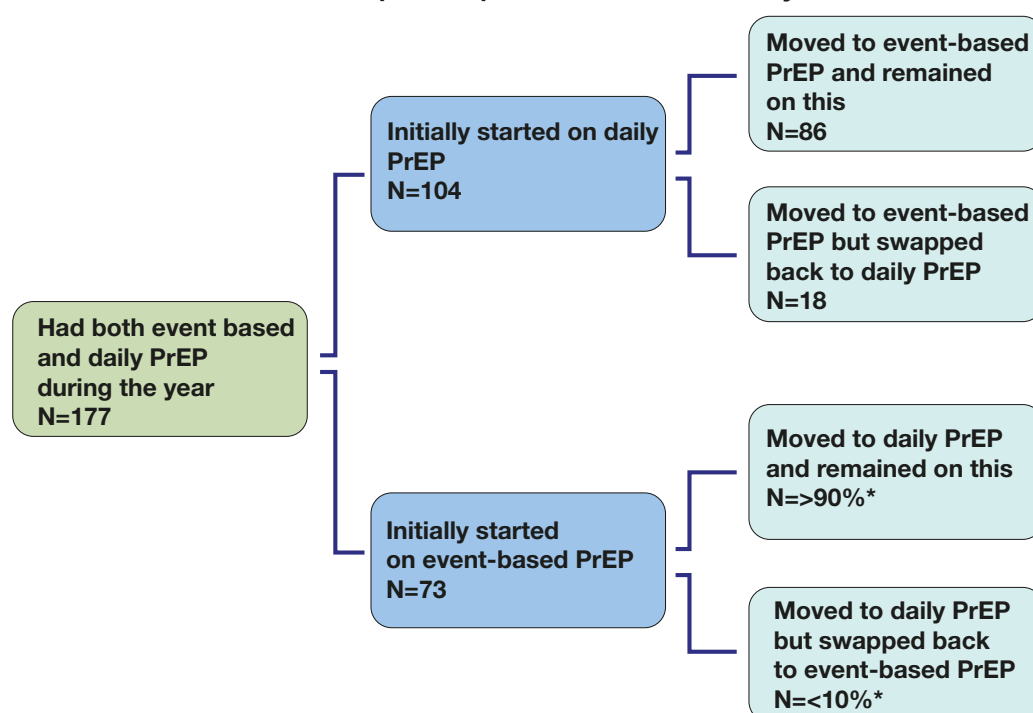
Almost three quarters (1,386; 74%) of individuals prescribed PrEP received only prescriptions for a daily PrEP regimen during the time period of analysis, and 17% (309 individuals) received only event-based PrEP during the year (Figure 4.3).

Figure 4.3: Proportion of individuals prescribed PrEP by choice of PrEP regimen



177 individuals (9%) had a combination of coded prescription regimens (both daily and event-based). Of these 177, 86 (49%) moved from an initial daily regimen to an event-based one by the end of the year and a slightly smaller proportion moved from an initial event regimen to a daily one. The remaining 21 (12%) moved from their initial regimen type to the other, and then back to their original regimen (Figure 4.4).

Figure 4.4: Pattern of switching PrEP regimen between daily and event-based dosing for 177 individuals with evidence of different prescriptions, Scotland, July 2017 to June 2018.

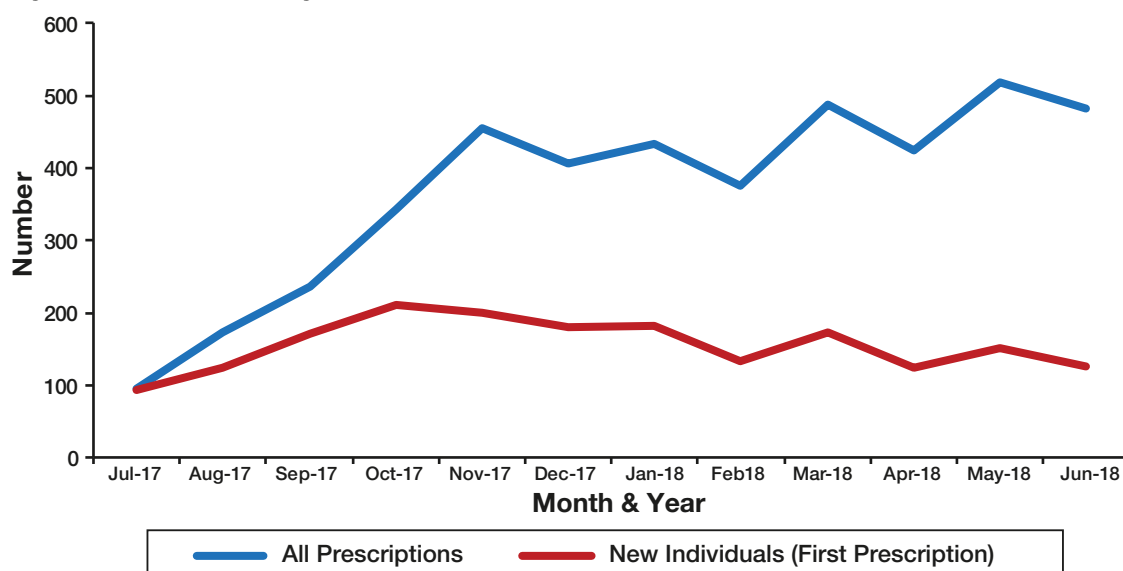


* Small numbers (<5) are suppressed due to the potential risk of disclosure.

Impact of the PrEP Programme on Sexual Health Services

Month by month analysis of national PrEP prescription numbers show a steep rise in both total and new prescription numbers over the first four months of the PrEP programme (Figure 4.5).

Figure 4.5: Number of PrEP prescriptions and number of new individuals prescribed PrEP by month and year, Scotland, July 2017 to June 2018.



Total numbers of PrEP prescriptions continued to rise over time, a reflection of the fact that those who start PrEP have to return to clinic on a regular (usually three-monthly) basis to be monitored appropriately, tested for HIV and other STIs, and to obtain repeat prescriptions. As of May-June 2018,

an average of approximately 500 prescriptions for PrEP per month across Scotland was observed, with a likely corresponding number of attendances at sexual health clinics.

New individuals starting PrEP (211) peaked in October 2017; thereafter, numbers gradually decreased over time but plateaued to a monthly average of 139 during May-June 2018.

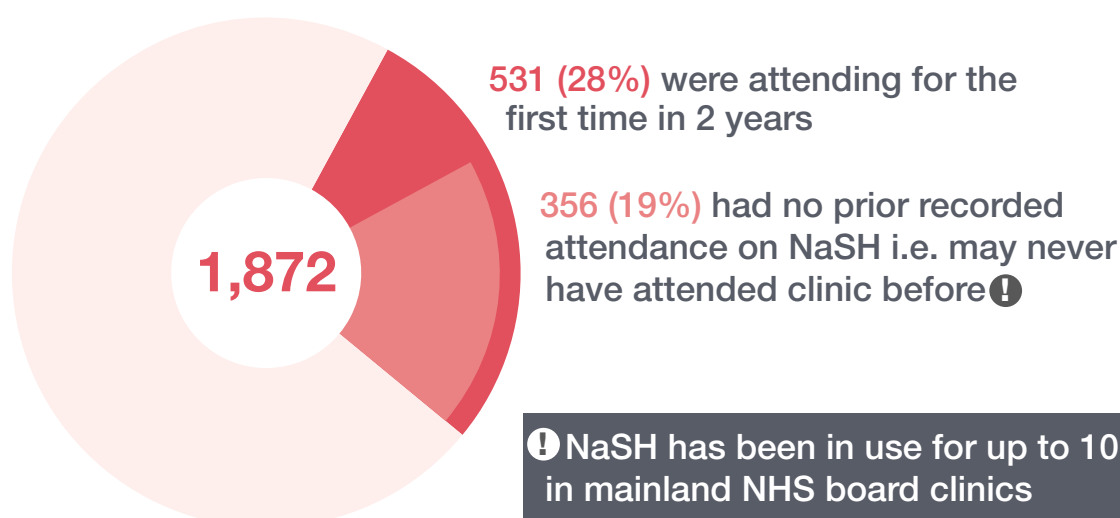
Those individuals prescribed PrEP are, by definition, eligible for PrEP because of a likely higher risk of HIV acquisition. These, therefore, are individuals who are also likely to be more at risk of other STI. It might be expected that such individuals were already attending sexual health services on a regular basis, prior to the launch of the PrEP programme, for holistic sexual health care including STI prevention advice and testing; however, this is not the case for a large proportion of those prescribed PrEP.

More than a quarter of those prescribed PrEP in the period analysed had not attended a NaSH-using Scottish sexual health clinic in the previous two years before PrEP was available (531; 28%). Furthermore, this includes almost one fifth (356 individuals; 19%) of those prescribed PrEP who had no previous record on NaSH. As NaSH was rolled out across most Scottish sexual health clinics more than 10 years ago, this means that these individuals had not attended these Scottish sexual health services in more than 10 years, and perhaps never before. This proportion of new attendees is strikingly similar to that reported from Wales, where 17% of their PrEP eligible individuals were thought to be completely new to sexual health services.⁵

These data are a clear indication that, in Scotland, individuals at high risk of HIV are attending sexual health clinics for PrEP either for the first time, or for the first time in a number of years of non-attendance. Although these are exactly the individuals who may benefit most from sexual health services to receive STI prevention packages and holistic sexual health care, the services themselves have therefore had to accommodate increased numbers of attendees, many of whom have complex sexual health needs.

Service Impact of PrEP

Individuals who were prescribed PrEP



Further analysis is ongoing to attempt to quantify the impact of the Scottish PrEP programme on the work of sexual health services.

Additional PrEP Outcomes

Analysis and reporting for these additional PrEP outcomes rely on data sources other than PrEP prescriptions. As detailed in the methods and data sources section (4.2), each episode of attendance(s) can be categorised according to a primary and secondary 'reason for attendance', one of which can be 'STI-PrEP'. This then means that we have a 'denominator' (albeit imperfect, see 'data quality' section) for those individuals who attend NaSH-using sexual health services in Scotland to discuss (potentially amongst other things) PrEP.

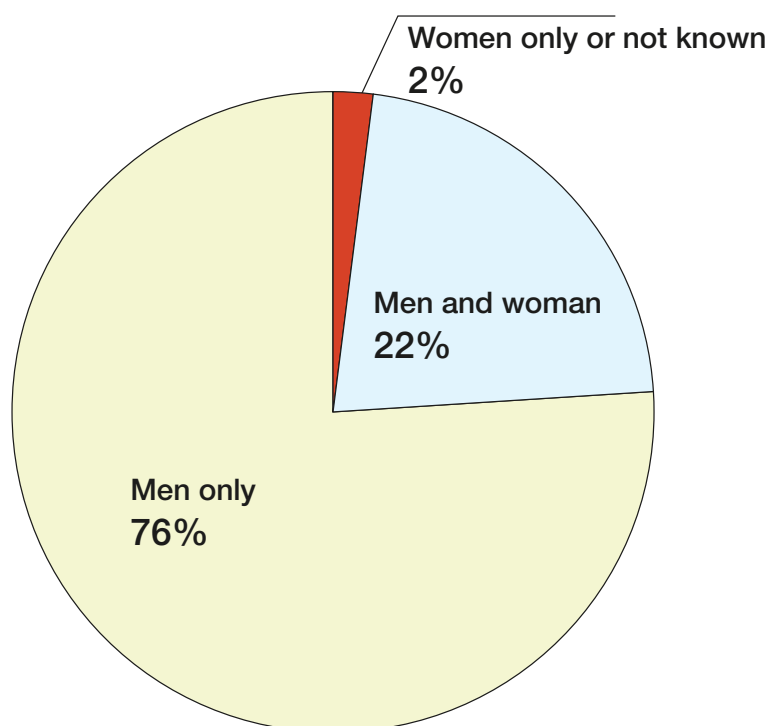
In the first year of the Scottish PrEP programme, there were a total of 2,467 individuals who attended services with either the primary or secondary reason for attendance recorded as 'PrEP'. This includes the 1,872 individuals who were actually prescribed PrEP during that year, but also some important groups of individuals who were not prescribed PrEP, either because they i) were ineligible, ii) declined PrEP when offered or iii) self-sourced PrEP from somewhere other than the NHS. There are also a number of individuals who are contraindicated to PrEP for medical reasons. All of these outcomes have NaSH PrEP codes which can be assigned by the assessing clinician; accordingly, an estimate of the numbers of patients in Scotland who fall in to these categories can be made.

People who Sought PrEP but did not Meet the Eligibility Criteria

2,056 (83%) of the 2,467 individuals with PrEP as a reason for attendance had a PrEP eligibility code (PrEPe0-PrEPe4) recorded.

274 individuals (11% of those with PrEP as a reason for attendance) were coded as ineligible for NHS PrEP; 99% (269) were MSM (Appendix Table 4.7).

Figure 4.6: Proportion of all men accessing NHS funded PrEP who were ineligible by gender of (lifetime) sexual partners, Scotland, July 2017 to June 2018.

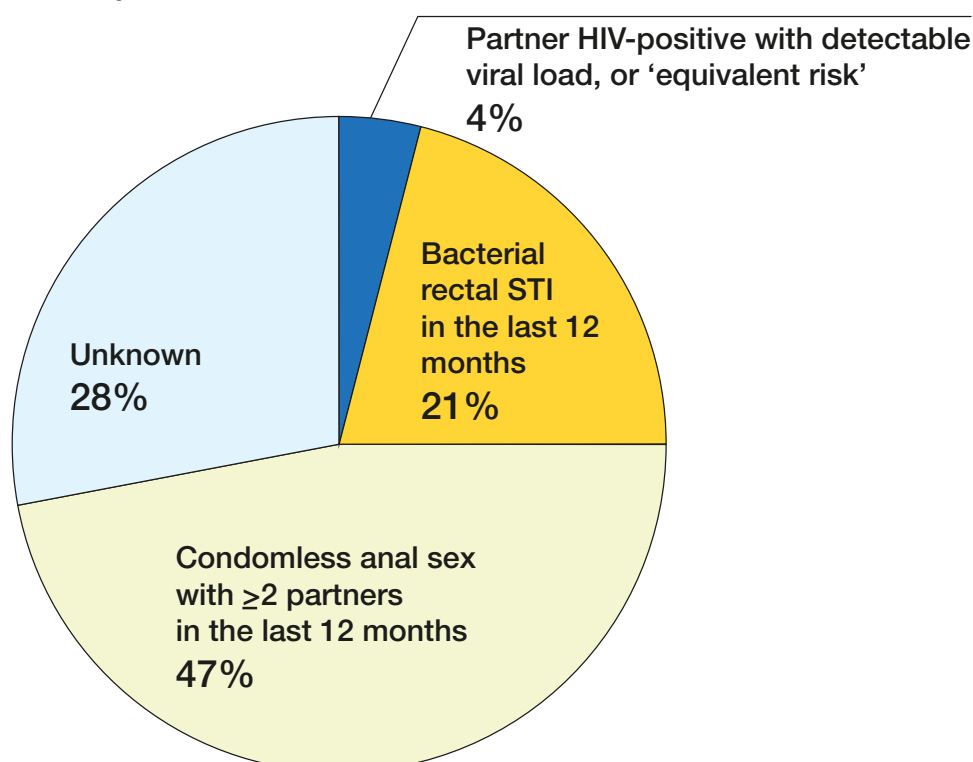


People Eligible for PrEP but who Chose to Decline it

133 individuals (5% of 2,467 with PrEP as reason for attendance) were coded as 'offered PrEP but declined' at least once during the first year of the PrEP programme. Of these, 128 (96%) were male, all of whom were MSM (Appendix Table 4.8).

Reason for PrEP eligibility was coded in 72% of individuals who had been coded as declining NHS PrEP (Figure 4.7); however, similar to those actually prescribed PrEP, the majority of 'PrEP decliners' appeared to be eligible for NHS PrEP because of a reported history of condomless penetrative anal sex with two or more partners in the last 12 months and a risk of this again in the next three months.

Figure 4.7: Proportion of individuals eligible and declined NHS funded PrEP by eligibility criteria, Scotland, July 2017 to June 2018.



However, of the 133 individuals who originally declined PrEP, 26 (20%) went on to be prescribed NHS PrEP later during the year and a small number (<5) were coded as self-sourcing non-NHS PrEP instead.

Non-NHS PrEP

For the time period of analysis, a total of 36 individuals (1.5% of 2,467 with attendance reason as PrEP) were coded as self-sourcing non-NHS PrEP (mostly through online pharmacies). This includes the small number (<5) who were eligible but declined NHS PrEP.

PrEP stopped and/or PrEP contraindicated

A total of 45 individuals were coded as having stopped PrEP during the first year. This represents 2% of the 1,872 patients who were prescribed PrEP during this time. This included the small number (<5) of patients who were also coded as contraindicated to PrEP; presumably the

contraindications were discovered after commencing PrEP. An additional 15 patients (0.6% of the 2,467 with attendance reason as PrEP) had a sole outcome code for being contraindicated to PrEP and never having commenced it. This finding is similar to Welsh data which reported 1% of eligible patients being contraindicated to PrEP.⁵ It should be noted, however, that the Scottish code for PrEP contraindication was developed and made available for recording later than the other PrEP codes (November 2017); therefore it is probable that some patients contraindicated for PrEP who presented between July and November 2017 have not been retrospectively coded with 'PrEPCON'.

Additional analysis, based on sequential prescription data in addition to PrEP coding, is planned to more accurately assess the numbers of individuals who may have stopped PrEP during the year.

Data Quality

NaSH was principally designed, and in Scotland is used, as a clinic and patient management system. In addition, PrEP coding is not mandatory for NHS Boards. PrEP eligibility, uptake and outcome data are therefore not complete for a variety of reasons; accordingly, there are likely to be underestimates in some domains.

For example, 'reason for attendance' in relation to a NaSH episode only allows the entry of a maximum of two principal (primary and secondary) reasons for attendance as judged by the clinician seeing the patient. It is possible, therefore, that PrEP as a reason for attendance might not be recorded if, for example, there are more than two reasons for a patient's attendance on any occasion. Furthermore, a patient may not cite PrEP as a reason for attendance themselves, but the subject may arise later as part of the consultation, and PrEP may not be recorded as a reason for attendance in these instances.

Prescription data for PrEP, when derived as actual numbers of NHS PrEP prescriptions and/or PrEP regimen prescribed, are considered accurate; however, the patient may not take PrEP according to the documented, prescribed regimen. Similarly, lifetime sexual history recording on NaSH (which is used to derive sexual orientation of patients for analytical purposes) is generally very complete for those prescribed PrEP on NaSH (1,870 of 1,872 i.e. 99.9% complete). However, care must be taken with interpretation as this item is based on self reporting and is derived from a lifetime record of gender of sexual partner - an approach which may not reflect current choices or risk profile.

We have worked in collaboration with Sexual and Reproductive Health Lead Clinicians across the Scottish NHS Boards to improve the completeness and accuracy of PrEP-related coding. Clinicians have been particularly helpful, for example, in completing retrospective coding of some individuals, either because they presented prior to coding being available on NaSH, or because coding was not completed at the time. Nonetheless, we still have considerable amounts of missing data in some areas of PrEP coding. For example, of the 2,467 patients who had PrEP as either a primary or secondary reason for attendance, 89% had any PrEP codes recorded and 83% had a PrEP eligibility code (PrEPe0-e4) recorded. For those 1,872 individuals prescribed PrEP, 94% of records were complete in terms of having a linked prescription and appointment and any PrEP coding, and 90% were complete in terms of having linked prescription/appointment and any PrEP eligibility (PrEPe1-e4) coding.

We were able to achieve 100% data completion on choice of prescribed PrEP regimen but only by combining PrEP regimen coding (93%) and prescription data (required for the other 7% of individuals).

4.4 Summary

In summary:

- At least 1,872 individuals have been prescribed PrEP at least once in the first year of the Scottish NHS PrEP programme.
- 99% of those prescribed PrEP so far are MSM, with the majority reporting condomless anal sex with multiple partners as a reason for being eligible for NHS PrEP.
- Although 39% of those prescribed PrEP are in the age range 20-29 years, almost one third are aged 40 or above.
- The majority (74%) of those prescribed PrEP have been prescribed a daily regimen rather than event based, but around 1 in 10 patients have been prescribed both types of regimen within the first year of the programme.
- Around one fifth of those prescribed PrEP may be attending sexual health services for the first time, or at least for the first time in NaSH history, suggesting that PrEP is drawing patients in to services who are at high risk for HIV and other STIs.

5 Evaluating the Impact of HIV PrEP

5.1 Background

PrEP is highly effective at reducing the incidence of HIV infection.^{2,3} The introduction of NHS funded pre-exposure prophylaxis (PrEP) in July 2017 provides an opportunity for reducing the incidence of HIV in Scotland and working towards HIV elimination to achieve the goals of UNAIDS [Fast-Track strategy](#). A recent study from New South Wales, Australia demonstrated a real world, population – level reduction in HIV incidence, likely as a result of rapid recruitment of high risk MSM to their PrEP programme.⁶ There are, however, concerns that reliance on a biomedical intervention to prevent infection may result in a decrease in condom use for some groups of the population, notably MSM; this in turn may increase the likelihood of individuals taking PrEP acquiring other STIs. This is known as risk compensation. Several modelling studies and real-life programmes to date have shown an increase in certain STIs in the first year of a PrEP programme^{3,6} and a recent systematic review on sexual risk behaviour in MSM showed that PrEP was associated with a statistically significant increase in rectal chlamydia when data were pooled from eight studies and an increase in any STI diagnosis, particularly in studies with recent data collection.⁷ The authors also demonstrated an increase in markers signalling an increase in condomless anal intercourse (CAI).⁷

Since the USA Food and Drug Administration (FDA) first licensed the use of PrEP in 2012, it has taken several years for programmes to be established, firstly in some parts of the USA and then in France in November 2015. In Europe, PrEP was approved by the EMA in July 2016 and since then, [several countries](#) have implemented trials or programmes with Scotland being the third country (after France and Norway) to announce health service-funded PrEP.⁸

Scotland's evaluation plan involves:

- Comparing the incidence of diagnosed HIV among MSM prescribed PrEP with the incidence of diagnosed HIV among MSM at similar HIV risk prior to its introduction in July 2017; and to similarly at risk MSM who were eligible for PrEP following its introduction but were not prescribed it.
- Comparing the incidence of diagnosed STIs among MSM prescribed PrEP with the incidence of diagnosed STIs during their pre-PrEP time period.

Notwithstanding an outbreak of HIV among people who inject drugs (PWID) in NHS Greater Glasgow & Clyde since 2015, MSM are the group most at risk of HIV infection in Scotland and account for 61% of all recent HIV infections in the last three years.

For the purposes of the year one report, the analyses are restricted to HIV, *Neisseria gonorrhoeae* (gonorrhoea) and *Chlamydia trachomatis* (chlamydia) testing and diagnoses. We report here on the trends in testing and diagnosis in the sexual health clinic setting among MSM and on MSM ever prescribed PrEP up to five years prior to the availability of NHS-prescribed PrEP (NHS PrEP) and in the first year of NHS PrEP (July 2017 to the end of June 2018). In future years, the group plan to include data on infectious syphilis and hepatitis C.

Statistical modelling of the effect of PrEP on HIV and STI incidence (as opposed to the incidence of diagnosed HIV and STI) is also planned in future years as the programme becomes established.

5.2 Methods and Data Sources

Data were extracted from NaSH on all men, including MSM, who have been tested for gonorrhoea and chlamydia along with data on MSM who have ever been prescribed PrEP using their prescription dates. The NaSH data on STI testing and diagnoses were examined for completeness alongside comparable laboratory data using the pseudonymised NaSH number in both systems for positive results and aggregate gonococcal and chlamydia testing data from one NHS Board area. A matching exercise was performed to examine the completeness of data in the NaSH system with laboratory data. A greater than 90% match with an identical trend in positive diagnoses over the five years of analyses for both chlamydia and gonorrhoea was observed. Supplementary work on the aggregate numbers on tests for 2016 and 2017 also match at over 90%.

Using the data on nucleic acid amplification tests (NAATs) performed for gonorrhoea and chlamydia, the data on testing and diagnoses were analysed for all men, for MSM and for the 1,834 of the 1,846 MSM for whom a PrEP prescription, between 1st July 2017 and 30th June 2018, and also a gonorrhoea and chlamydia test, were recorded. The data have been analysed by annual calendar quarter since January 2013 with a focus on the year before NHS PrEP availability- that is from 1st July 2016 to 30th June 2017 and the year following this using the calendar quarters from 1st July 2017 to 30th June 2018.

For this year one report, the analyses examine the incidence of gonorrhoea and chlamydia diagnoses among MSM ever prescribed PrEP during the time period pre-PrEP (since 2014) compared to on PrEP. Similarly, the number and proportion of new HIV diagnoses in MSM attending SRH clinics were analysed using the HIV testing data in NaSH along with the number of HIV diagnoses with laboratory characteristics of recent infection. The STI analyses have been sub-divided by anatomical site. MSM who are self sourcing PrEP are not included in the analysis (these account for a small number (21, 1.1%) of MSM attending for monitoring in the dataset). No distinction was made for men who use event based dosing rather than daily dosing of PrEP.

Data on selected STI diagnoses on all individuals undergoing testing in all clinical settings have been extracted from the laboratory positive diagnoses datasets stemming from the Electronic Communication of Surveillance Scotland (ECOSS) system hosted in HPS for gonorrhoea and chlamydia and from the National Enhanced Surveillance of Infectious Syphilis (NESISS) database for infectious syphilis.

An enhanced HIV diagnoses database containing data on all confirmed HIV diagnoses in Scotland is maintained at HPS. This contains information on new, first ever diagnoses and those who have arrived in Scotland already known to be HIV positive. The database also contains data on those who have evidence of a recently acquired infection based on laboratory testing for anti-HIV avidity antibodies in those newly diagnosed for the first time in Scotland.

All analyses have been performed at the Scotland level. The distribution of PrEP uptake by NHS Board is available in Appendix Table 4.2. The term NHS PrEP refers to PrEP prescribed by healthcare staff working for the NHS in Scotland.

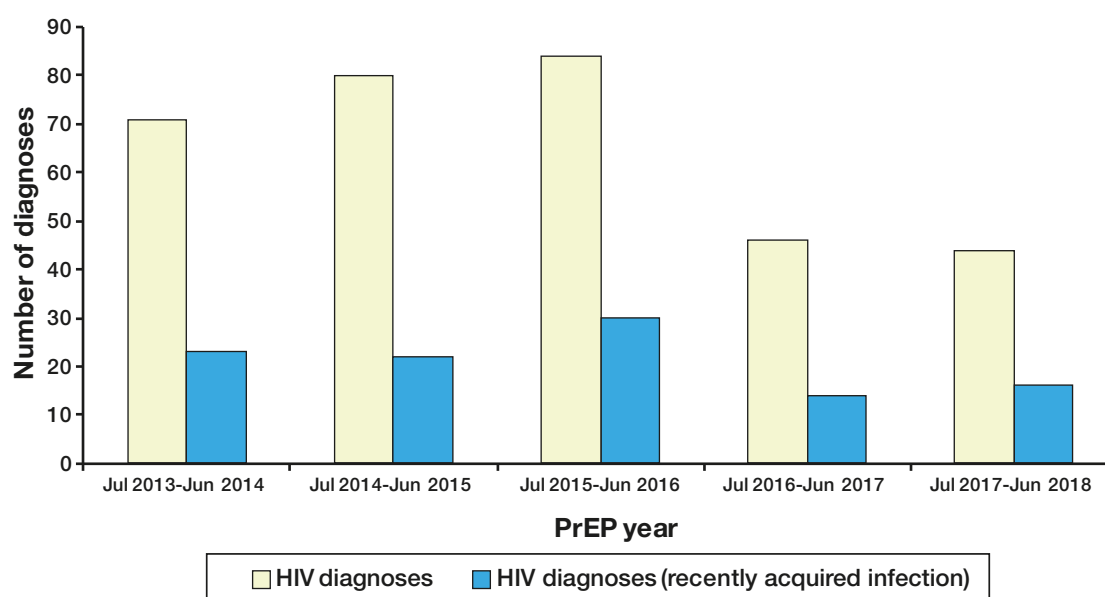
No uptake of PrEP in the island NHS Boards was reported. Further refinement includes work to determine length of time spent on PrEP and improvements in coding events on NaSH.

5.3 Results

HIV Epidemiology in Scotland: Background

Using time periods equivalent to July to June each year (a PrEP year) since 2013, reflecting the period pre-NHS PrEP (July 2013-June 2017) and time since its introduction (July 2017-June 2018), the number of new diagnoses in MSM is highest for the period July 2015-June 2016 and has decreased since. There was a similar peak in the number of diagnoses among men who had acquired their HIV recently (in the previous three months) at this time and a subsequent decrease in the year prior to NHS PrEP; this number has remained similar since NHS PrEP availability (Figure 5.1).

Figure 5.1: New diagnoses of HIV in MSM in the sexual health clinic setting by PrEP year, July 2013 to June 2018



Data source: HIV national database, Health Protection Scotland.

Data are presented on MSM diagnosed in the sexual health clinic setting only.

PrEP year: defined as 1st July to 30th June.

HIV Testing and Diagnoses in MSM in the Sexual Health Clinic Setting

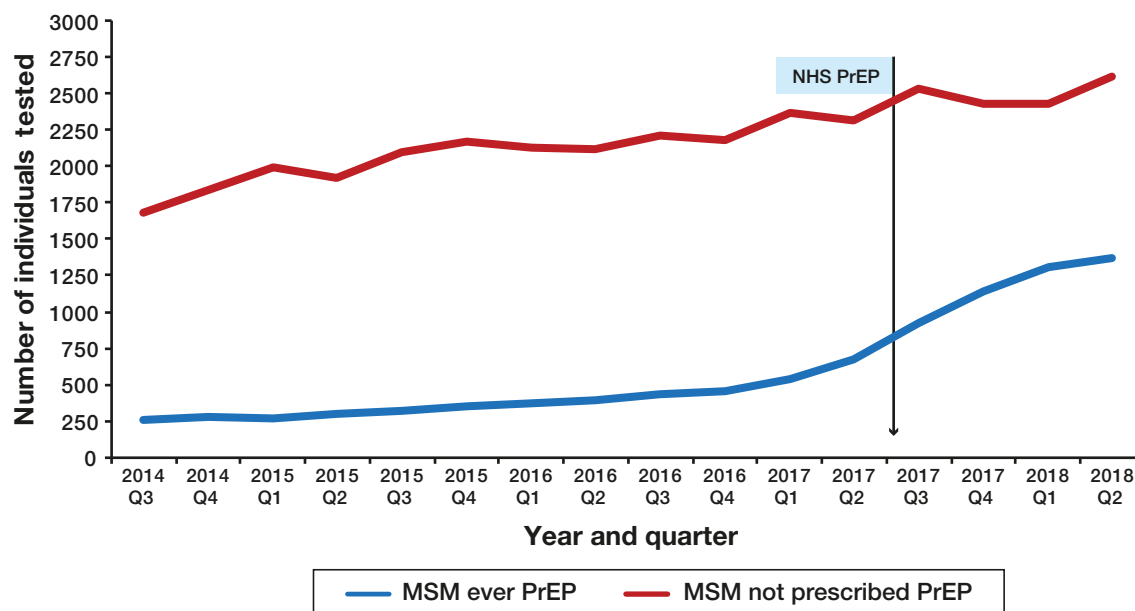
Among MSM, a 32% increase in HIV testing among MSM between the year prior to NHS PrEP (July 2016 to June 2017) and the year of NHS PrEP (July 2017 to June 2018) was observed; this increase was most notable among MSM who were ever prescribed PrEP (from 2,000 tests to over 4,700). By comparison only a 10% increase among those never prescribed PrEP was observed (Figure 5.2).

Of MSM tested for HIV, 4 per 1,000 were newly diagnosed positive in the year prior to NHS PrEP compared to 3 per 1,000 in the year following NHS PrEP introduction. Provisional corresponding rates for newly diagnosed recent infection(acquisition within three months of diagnosis) were 1 and 0.9 per 1,000, respectively.

Of the 1,846 MSM ever prescribed PrEP, less than five (1 to 4) are known to have become infected with HIV after having been prescribed PrEP. In these men, drug levels, as measured by segmental hair analysis, showed below protective levels at the time of suspected HIV acquisition.

The precise incidence of HIV among MSM following initiation of PrEP is still to be calculated bearing in mind the time of exposure for individuals ranges from less than one month (someone started in June 2018) to the full twelve months (someone started in early July 2017). Nevertheless, with the majority of the 1,846 having been commenced PrEP during July-December 2017, it is evident that around 1,000 person years of exposure, post-initiation of PrEP, has been experienced; accordingly, the incidence of HIV among this group for the period July 2017-June 2018 was 0.1% - 0.4% (1 to 4 per 1,000).

Figure 5.2: HIV testing in MSM ever prescribed PrEP and never prescribed PrEP by year and quarter in the sexual health clinic setting, July 2014 to June 2018.



Data source: National Sexual Health IT System (NaSH), Information Services Division.

Note: the data are presented based on NaSH extracts from sexual health clinics in the eleven mainland NHS Boards.

STI (excluding HIV) Epidemiology in Scotland: Background

Data on the diagnoses of selected STIs in all clinical settings for men and women, for only men and for MSM are shown in Table 5.1. The annual published reports indicate that there has been a year on year increase in both infectious syphilis and gonorrhoea diagnoses since 2015 particularly among all men and MSM; this continues into the first half of 2018.^{9,10} The trend is less clear with chlamydia diagnoses, the number of which increased in 2017 having been stable in the previous two years. The quarterly data for 2018 suggest that the number of diagnoses continues to increase; these observations also apply to only men and to MSM (as indicated by rectal infections). The rate of selected STIs has increased in MSM from 3.8% in the year prior to PrEP to 4.8% in the first year of NHS PrEP (Table 5.1).

Table 5.1: Number of diagnoses of selected sexually transmitted infections by quarter, July 2016 to June 2018.

	July 2016 - June 2017 Pre-PrEP	July 2017 - June 2018 PrEP period
STI (All)		
HIV	189	215
Chlamydia	15332	16046
Gonorrhoea	2374	2926
Infectious syphilis *	391	422
Total **	18097	19394
Rate per 100,000 population ~	510.4	546.6
STI (All men)		
HIV	147	153
Chlamydia	6161	6667
Gonorrhoea	1766	2145
Infectious syphilis *	373	401
Total **	8300	9213
Rate per 100,000 population ~	476.2	527.9
STI (MSM)		
HIV	91	76
Rectal chlamydia	684	950
Rectal gonorrhoea	663	809
Infectious syphilis (MSM) *	329	352
Total **	1676	2111
Estimated MSM population #	43574	43634
Estimated rate per 100,000 population	3846.4	4838.0

* Data source: laboratory positive diagnoses of chlamydia and gonorrhoea from all testing laboratories in Scotland via ECOSS and data from the National Enhanced Surveillance of Infectious Syphilis in Scotland (NESISS).

~ Using GROS mid year population estimates in those aged 15-64.

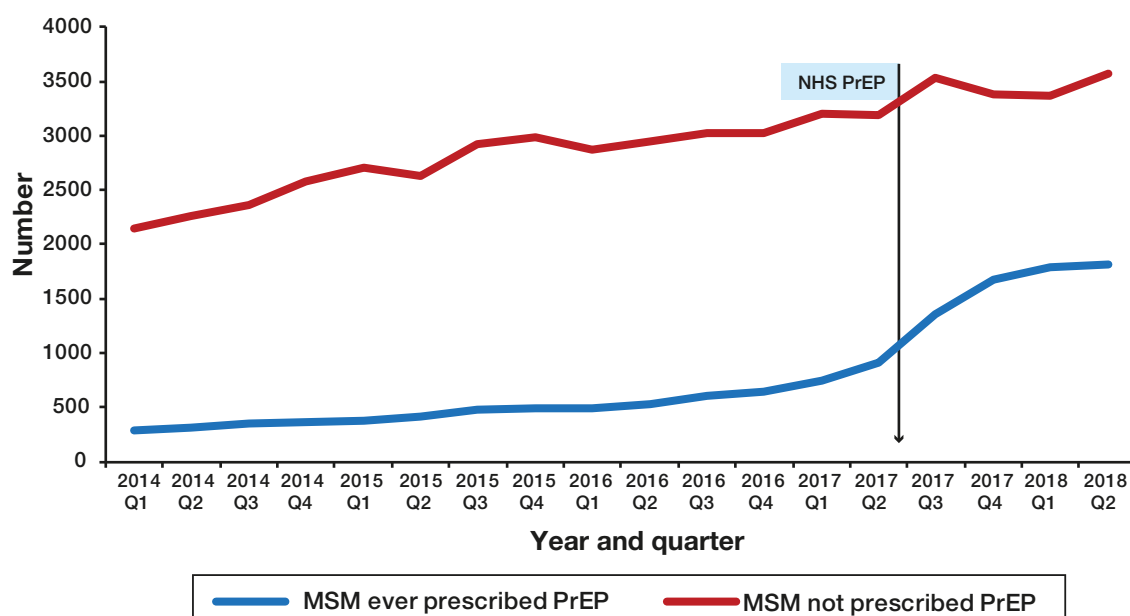
Using 2.5% MSM estimate of male population ([NATSAL3](#)).

** Does not include HIV totals.

Gonorrhoea Testing in MSM in the Sexual Health Clinic Setting

In sexual health clinics the number of men undergoing gonorrhoea testing has increased steadily since 2015; this trend is due primarily to an increase in testing among MSM (Figure 5.3). A 34% increase in testing among MSM between the year prior to the introduction of NHS PrEP and the year following its availability, was observed; this increase is due primarily to a more than doubling in the number of tests in MSM ever prescribed PrEP – a change which equate to almost 4,000 additional tests among this group in the year since NHS PrEP became available.

Figure 5.3: Gonorrhoea testing in MSM ever and never prescribed PrEP in the sexual health clinic setting, Scotland: January 2014 – June 2018.



Note: the data are presented based on NaSH extracts from sexual health clinics in the eleven mainland NHS Boards.

The number of MSM on PrEP does not include those who self source PrEP.

Gonorrhoea Diagnoses in MSM in the Sexual Health Clinic Setting

During the 12 months since the availability of NHS PrEP, the number of MSM testing gonorrhoea positive has increased by over 300 diagnoses; the proportion positive, however, remains unchanged at between 8 to 10%. (Figure 5.4, Table 5.2). During the latter half of 2015, an unexplained spike in the number and proportion of MSM diagnosed with gonorrhoea was evident. This observation is not evident in heterosexual men.

Gonorrhoea Diagnoses in MSM ever Prescribed PrEP in the Sexual Health Clinic Setting

A total of 1,846 MSM had ever taken PrEP by the end of June 2018. The length of time on PrEP varies, with around 400 individuals having first been prescribed PrEP during July-September 2017 (Figure 4.4); there are, however, gaps in the data as to the length of time they have been on PrEP.

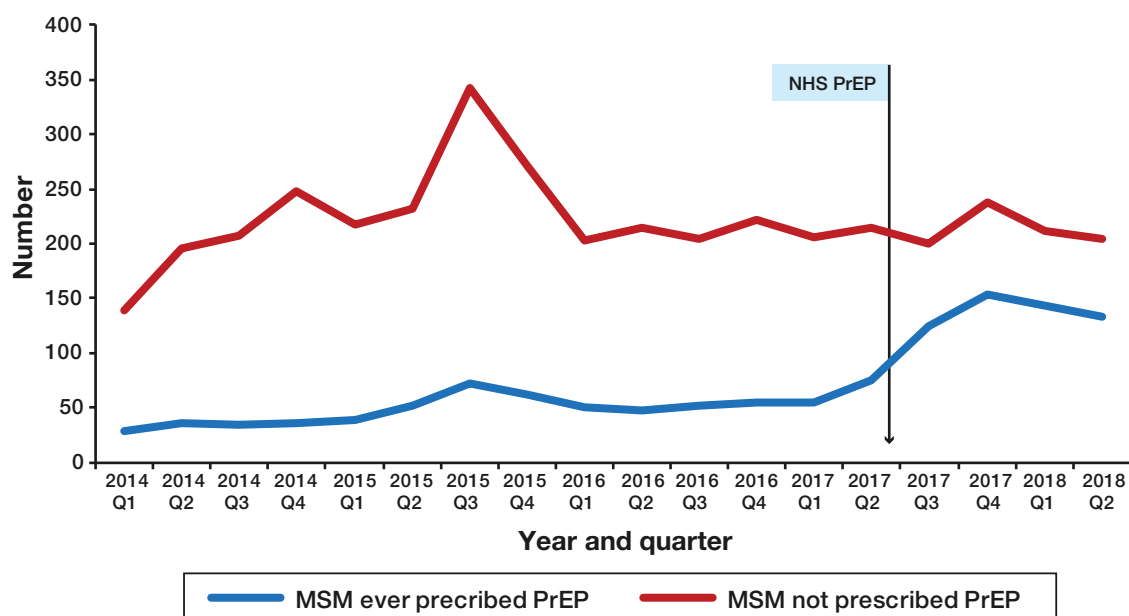
As indicated earlier, a proportion of MSM prescribed PrEP have either visited a sexual health clinic for the first time (19%), or had not attended within the previous two years (28%); similarly, 22% of MSM ever prescribed PrEP had a gonorrhoea test for the first time since 2014.

Among MSM ever prescribed PrEP, a greater than two-fold increase in both gonorrhoea testing and diagnoses between the 12 months before the introduction of NHS PrEP and the 12 months after, was observed; an additional 318 diagnoses in men ever prescribed PrEP compared to an additional eight in MSM not prescribed PrEP were made. These observations reflect multiple visits to the sexual health clinic for PrEP monitoring (including STI testing).

In the first six months of NHS PrEP, around 13% of MSM prescribed PrEP were diagnosed positive for gonorrhoea - a small increase on the proportions observed in the previous year;

in the first half of 2018, the proportion is similar to that for the year prior to NHS PrEP (Table 5.2). Accordingly, MSM ever prescribed PrEP appear to constitute a higher risk group for gonorrhoea, and thus HIV, acquisition, compared to MSM never prescribed it (Table 5.2).

Figure 5.4: Gonorrhoea diagnoses in MSM ever and never prescribed PrEP in the sexual health clinic setting, Scotland January 2014 – June 2018.



Note: the data are presented based on NaSH extracts from sexual health clinics in the eleven mainland NHS Boards.

The number of MSM on PrEP does not include those who self source PrEP.

Table 5.2: Proportion (%) of gonorrhoea positive episodes among all MSM, MSM ever prescribed PrEP and MSM never prescribed PrEP, undergoing gonorrhoea testing in sexual health clinics, July 2016 to June 2018.

					PrEP Period			
	2016 Q3	2016 Q4	2017 Q1	2017 Q2	2017 Q3	2017 Q4	2018 Q1	2018 Q2
All MSM	8.4 (7.4-9.4)	9.2 (8.2-10.2)	8.0 (7.1-8.9)	8.6 (7.7-9.6)	8.2 (7.4-9.1)	9.7 (8.8-10.7)	8.5 (7.7-9.4)	7.6 (6.8-8.4)
MSM not on PrEP	7.9 (6.9-9.0)	8.7 (7.6-9.8)	7.6 (6.6-8.6)	8.0 (7.0-9.0)	6.6 (5.8-7.5)	8.3 (7.3-9.3)	7.4 (6.4-8.3)	6.7 (5.8-7.6)
MSM ever prescribed PrEP*	11.2 (8.3-14.0)	11.6 (8.7-14.4)	9.7 (7.2-12.2)	11.1 (8.8-13.5)	13.3 (11.2-15.5)	13.4 (11.4-15.4)	11.1 (9.4-12.8)	9.7 (8.2-11.3)

* Ever prescribed PrEP between July 2017 and June 2018.

The number of MSM on PrEP does not include those who self source PrEP.

An episode is defined as one positive test per quarter.

The numbers in parentheses indicate 95% confidence intervals.

The data are presented based on NaSH extracts from sexual health clinics in the eleven mainland NHS Boards.

Rectal Gonorrhoea Testing and Diagnosis in MSM in the Sexual Health Clinic Setting

Testing for gonorrhoea at rectal sites in all MSM has been increasing since 2014. In the years preceding NHS PrEP, the proportion of positive rectal tests was higher among MSM ever prescribed PrEP compared to MSM never prescribed it. In the year prior to NHS PrEP, the proportion of MSM, ever prescribed PrEP and tested rectally for gonorrhoea, who were positive was 7%-8% (mean 7.3%) in each calendar quarter; no appreciable change in the year post NHS PrEP (7%-9% (mean 7.5%)), was observed (Table 5.3).

Table 5.3: Proportion (%) of rectal gonorrhoea positive episodes among all MSM, MSM ever prescribed PrEP and MSM never prescribed PrEP, undergoing rectal gonorrhoea testing in sexual health clinics, July 2016 to June 2018.

					PrEP Period			
	2016 Q3	2016 Q4	2017 Q1	2017 Q2	2017 Q3	2017 Q4	2018 Q1	2018 Q2
All MSM	5.8 (4.8-6.7)	5.8 (4.9-6.7)	4.9 (4.1-5.7)	5.6 (4.7-6.4)	4.8 (4.1-5.6)	6.5 (5.7-7.4)	5.2 (4.4-5.9)	4.7 (4.0-5.4)
MSM not on PrEP	5.4 (4.5-6.4)	5.6 (4.6-6.6)	4.3 (3.5-5.1)	4.9 (4.0-5.8)	3.9 (3.2-4.7)	5.3 (4.4-6.2)	4.3 (3.5-5.1)	3.8 (3.1-4.6)
MSM ever prescribed PrEP*	7.2 (4.8-9.7)	6.8 (4.4-9.2)	7.3 (5.1-9.6)	7.9 (5.7-10.0)	7.4 (5.6-9.2)	9.2 (7.5-11.0)	6.9 (5.5-8.4)	6.5 (5.1-7.8)

*Ever prescribed PrEP between July 2017 and June 2018.

The number of MSM on PrEP does not include those who self source PrEP.

An episode is defined as one positive test per quarter.

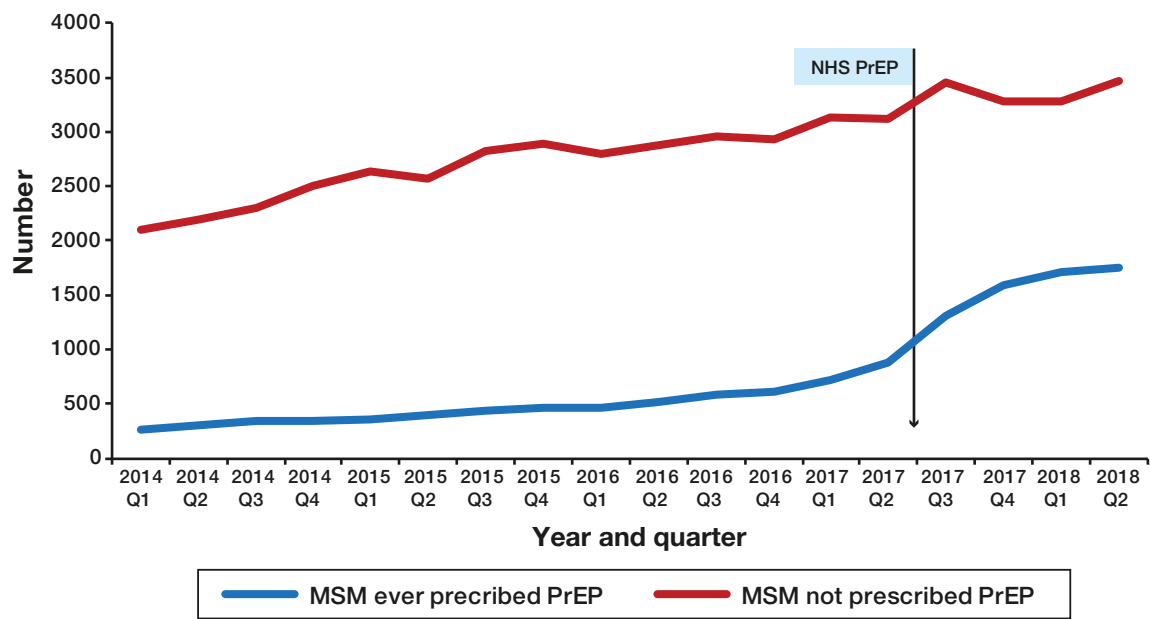
The numbers in parentheses indicate 95% confidence intervals.

The data are presented based on NaSH extracts from sexual health clinics in the eleven mainland NHS Boards.

Chlamydia Testing and Diagnoses in MSM in the Sexual Health Clinic Setting

Chlamydia testing in MSM has increased by 33% between the 12 month periods pre and post NHS PrEP introduction. As with gonorrhoea testing, this increase is primarily due to the more than doubling in the number of tests performed in MSM ever prescribed PrEP; an additional 3,500 tests were performed in this group compared with an additional 1,500 tests among those MSM never prescribed PrEP (Figure 5.5).

Figure 5.5: Chlamydia testing in MSM ever and never prescribed PrEP in the sexual health clinic setting, Scotland: January 2014 – June 2018.

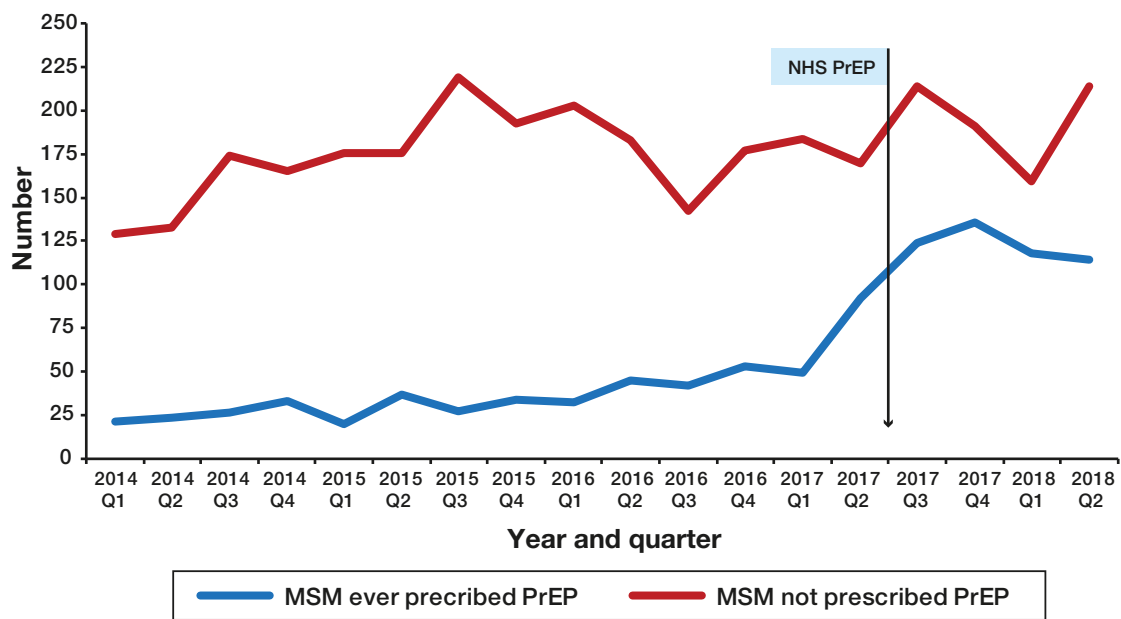


Note: the number of MSM on PrEP does not include those who self source PrEP.
The data are presented based on NaSH extracts from sexual health clinics in the eleven mainland NHS Boards.

Chlamydia Diagnoses in MSM ever Prescribed PrEP in the Sexual Health Clinic Setting

An additional 256 chlamydia diagnoses in MSM ever prescribed PrEP were made in the 12 months after NHS PrEP introduction (492) compared to the 12 months before (236); this compares with a 16% increase in diagnoses among those MSM never prescribed PrEP (Figure 5.6).

Figure 5.6: Chlamydia diagnoses in MSM ever and never prescribed PrEP in the sexual health clinic setting, Scotland January 2014 – June 2018.



Note: the number of MSM on PrEP does not include those who self source PrEP.
The data are presented based on NaSH extracts from sexual health clinics in the eleven mainland NHS Boards.

The proportion testing positive, however, has remained the same - an average of 10.7% (range 9%-14% per quarter) in the year prior to NHS PrEP and 10.7% (range 9%-13% per quarter) thereafter (Table 5.4). As observed for gonorrhoea, MSM prescribed PrEP are at higher chlamydia risk than those never prescribed it (Table 5.4).

Table 5.4: Proportion (%) of chlamydia positive tests among all MSM, MSM ever prescribed PrEP and MSM never prescribed PrEP, undergoing rectal gonorrhoea testing in sexual health clinics, July 2016 to June 2018.

					PrEP Period			
	2016 Q3	2016 Q4	2017 Q1	2017 Q2	2017 Q3	2017 Q4	2018 Q1	2018 Q2
All MSM	6.1 (5.2-6.9)	7.6 (6.7-8.6)	7.2 (6.3-8.1)	7.8 (6.9-8.7)	8.6 (7.7-9.5)	8.2 (7.3-9.0)	6.6 (5.9-7.4)	7.4 (6.6-8.2)
MSM not on PrEP	5.5 (4.6-6.4)	7.0 (6.0-8.0)	6.8 (5.9-7.8)	6.4 (5.4-7.3)	7.1 (6.2-8.0)	6.6 (5.7-7.6)	5.5 (4.7-6.4)	7.0 (6.1-7.9)
MSM ever prescribed PrEP*	9.0 (6.4-11.6)	11.2 (8.3-14.0)	8.8 (6.5-11.2)	13.7 (11.1-16.3)	13.4 (11.2-15.6)	11.9 (10.0-13.8)	9.1 (7.5-10.6)	8.4 (6.9-9.8)

*Ever prescribed PrEP between July 2017 and June 2018.

The number of MSM on PrEP does not include those who self source PrEP.

An episode is defined as one positive test per quarter.

The numbers in parentheses indicate 95% confidence intervals.

The data are presented based on NaSH extracts from sexual health clinics in the eleven mainland NHS Boards.

Rectal Chlamydia Testing and Diagnoses in MSM in the Sexual Health Clinic Setting

Rectal chlamydia testing in all MSM has been increasing steadily since 2014 and the proportion positive has remained stable at around 6.5% per year. In the years preceding NHS PrEP, the proportion of positive rectal chlamydia tests is higher among MSM ever prescribed PrEP compared to MSM never prescribed it. Among MSM prescribed PrEP, levels of rectal testing more than doubled in the year since NHS PrEP introduction compared to the previous year with a similar doubling in the number of positive rectal swabs; while fluctuations over calendar quarters are evident, the proportion positive over the two years is similar. (Table 5.5).

Table 5.5: Proportion (%) of rectal chlamydia positive tests among all MSM, MSM ever prescribed PrEP and MSM never prescribed PrEP, undergoing rectal chlamydia testing in sexual health clinics, July 2016 to June 2018.

					PrEP Period			
	2016 Q3	2016 Q4	2017 Q1	2017 Q2	2017 Q3	2017 Q4	2018 Q1	2018 Q2
All MSM	4.9 (4.0-5.7)	6.3 (5.3-7.2)	5.8 (5-6.7)	6.6 (5.7-7.5)	7.4 (6.5-8.3)	6.5 (5.7-7.4)	5.6 (4.8-6.4)	5.9 (5.2-6.7)
MSM not on PrEP	4.6 (3.7-5.5)	5.4 (4.4-6.4)	5.6 (4.6-6.5)	5.1 (4.2-6.1)	6.0 (5.1-6.9)	5.0 (4.1-6.0)	4.3 (3.4-5.1)	5.5 (4.6-6.5)
MSM ever prescribed PrEP*	6.5 (4.1-8.9)	10.4 (7.6-13.3)	7.0 (4.8-9.2)	11.7 (9.1-14.2)	11.4 (9.3-13.6)	9.9 (8.1-11.8)	8.2 (6.6-9.8)	6.7 (5.3-8.1)

*Ever prescribed PrEP between July 2017 and June 2018.

The number of MSM on PrEP does not include those who self source PrEP.

An episode is defined as one positive test per quarter.

The numbers in parentheses indicate 95% confidence intervals.

The data are presented based on NaSH extracts from sexual health clinics in the eleven mainland NHS Boards.

5.4 Summary

- In the context of an increase in HIV testing among MSM in the sexual health clinic setting, the proportion positive in the year before NHS PrEP introduction (4 per 1,000) was similar to that for the year after (3 per 1,000). Corresponding rates for diagnosed recent infection were 1 per 1,000 and 0.9 respectively.
- Less than five (1 to 4) MSM prescribed PrEP (at least once) HIV seroconverted; drug levels, as measured by segmental hair analysis, showed below protective levels at the time of suspected HIV acquisition.
- The majority of the 1,846 MSM prescribed PrEP were commenced on it during July-December 2017; accordingly, around 1000 person years of exposure, post-initiation of PrEP, was experienced during the first year. This means that the incidence of HIV among this group for the period July 2017-June 2018 was 0.1% - 0.4% (1 to 4 per 1,000).
- Among those prescribed PrEP, rates of gonorrhoea (including rectal) testing and numbers diagnosed positive increased between the two 12 month periods either side of NHS PrEP introduction but rates of infection remained similar. Such rates were higher among those ever versus never prescribed PrEP; this observation indicates that the former are at higher risk of gonorrhoea, and therefore HIV, infection and that the eligibility criteria for PrEP are appropriate.
- Similar observations were recorded for chlamydia with an increase in testing and diagnoses among MSM ever prescribed PrEP, and no overall change in the proportion positive pre and during the first year of NHS PrEP.
- The increases in gonorrhoea and chlamydia diagnoses could be attributed to either improved detection, an actual increase in the incidence of infection or a combination of both; the explanation is likely to be the “combination” one but the ratio of the contributions is uncertain. The excess of infection is unlikely to be due only to the identification of hitherto undetected infections because that hypothesis would assume that these were all asymptomatic ones or symptomatic infections which did not precipitate STI testing behaviour.

6 Research

6.1 Overview

Scotland's "first in the UK" implementation of PrEP as routine care in sexual health services has provided unique opportunities for research to inform PrEP care in Scotland, the wider UK and internationally. We have developed a strong research portfolio drawing on our strengths in mixed methods, multidisciplinary research. Current research themes include optimising PrEP clinical services, exploring opportunities for "ePrEP" (PrEP care online), PrEP community advocacy, PrEP and women of colour, and missed opportunities for PrEP in people who acquire HIV.

Our diverse projects bring together experts from academia, NHS, health services research, the third sector, public health, social science, and epidemiology, informed throughout by strong patient and public involvement. Our current combined PrEP-related research income is around £600,000, comprised of research grants and PhD studentships from prestigious funders which include the Chief Scientist Office, Wellcome Trust, Glasgow Caledonian University, British Association for Sexual Health and HIV (BASHH), and HPS.

Given the unique circumstances in Scotland, our work is in great demand and we have already presented early findings at national and international conferences: BASHH/BHIVA 2018, Five Nations Public Health Conference 2018, ECDC/WHO PrEP summit, Stockholm, 2018, in addition to providing briefings to the English PrEP Commissioning Planning Group to inform future PrEP roll out. Profs Estcourt and Goldberg bring expertise to England's PrEP Impact Trial as chair and member of the Impact Trial Steering Committee, respectively.

6.2 Summary of key projects:

- **Optimising services for people at highest risk of HIV: developing best practice in delivering HIV Pre-Exposure Prophylaxis (PrEP) through evaluation of early implementation across Scotland.**
Chief Scientist Office Research Grant, HIPS/17/47, 1.6.18-31.5.20, £295,687
Estcourt CS (PI), Flowers P, MacDonald J (researcher), Frankis J, Young I, McDaid L, HIV Scotland, Steedman N, Clutterbuck D, Nandwani R, Saunders J.
- **Optimising health care through theory-informed e-Health interventions: Developing an HIV ePrEP Clinic.**
Glasgow Caledonian University fully funded PhD studentship, 1.10.18-30.9.21, £64,50
Kincaid R (PhD student), Supervisory Team: Frankis J, Estcourt CS, Dalrymple J, Gibbs J.
- **Sex, drugs and activism: negotiating biological citizenship and pharmaceutical prevention. Qualitative research on the role of activism and collaborations between practitioners and community members and how this led to the implementation of PrEP across the UK.**
Wellcome Trust Seed Award, £92,800
Dr Ingrid Young (PI), University of Edinburgh, Dr Charlotte Jones.

- **Which individuals may benefit from targeted HIV prevention interventions? An evaluation of characteristics of people who have acquired HIV prior to and since the availability of NHS-funded PrEP in Scotland.**
BASHH PHE Fellowship, 1.10.18-30.9.19: (SpR salary, £8500)
Grimshaw C (PI), Nandwani R, Saunders J, Estcourt CS.
- **Exploring perspectives on pre-exposure prophylaxis for people who inject drugs amongst potential service providers and users.**
NHS Greater Glasgow & Clyde, £100,000, Sept 2017 to Aug 2019
Hutchinson S (PI), Smith M (researcher) GCU.
- **Exploring PrEP in women of colour in Scotland, London and Chicago**
University of Chicago, 1.6.18 \$8000, College Summer Research Fellows Fund and Third Year International Travel Grant. Ms Sarah Nakasone (PI), Estcourt CS, Young I, Shahmanesh M.

7 Discussion

During the first year of NHS PrEP implementation, 1,872 individuals (99% of whom were MSM) were prescribed PrEP in sexual health settings throughout the country. This total exceeded predictions not least because a considerable number of people at high risk of HIV who had never, or not for years, attended such services chose to attend because of the new PrEP intervention on offer.

Despite i) the short lead-in time following SMC approval, to PrEP becoming available, ii) PrEP being a unique intervention, iii) unavailability of additional funding for service implementation, iv) existing pressures on sexual health clinics, and v) the extensive demand for PrEP as above, year one has been a resounding success in terms of establishing a new nationwide service – the first of its type in the UK and one of the first worldwide. At very short notice, staff had to be trained, IT systems altered, a PrEP coordination structure and evaluation team established, new clinical protocols generated, and information resources developed and made accessible – all of which have been achieved.

The high uptake of PrEP speaks to the quality of the service providers, in particular the clinical staff, the existing model of integrated sexual health service delivery in Scotland, and existing and new coordination arrangements which ensure the sharing of best practice, consistency in approach and optimal governance and accountability.

While nearly two thousand people were prescribed PrEP in the first year, very large numbers had been on it only a few months by the end of that year; accordingly, a further of evaluation at the end of year two will be required to provide an informed understanding of impact and several years will be needed to undertake more sophisticated analyses to evaluate impact optimally. That said, it is highly encouraging that less than five (1 to 4) of those prescribed PrEP – i.e. people at highest risk of HIV infection – acquired their HIV following initial prescription; further analysis showed that PrEP drug levels, as measured by segmental hair analysis, were not protective at the time of suspected HIV acquisition.

The precise incidence of HIV among MSM following initiation of PrEP is still to be calculated bearing in mind the time of exposure for individuals ranges from less than one month (someone starting in June 2018) to the full twelve months (someone starting in early July 2017). Nevertheless, with the majority of the 1,846 MSM having been commenced PrEP during July-December 2017, it is evident that around 1,000 person years of exposure, post-initiation of PrEP, has been experienced; accordingly, the incidence of HIV among this group for the period July 2017-June 2018 was 0.1% - 0.4% (1 to 4 per 1,000) – a low rate in the context of this group's high risk for HIV and our understanding, from previous work, that the incidence of HIV among all MSM attending sexual health clinics and having an attributable HIV test was estimated to be approximately 1%.¹¹

In terms of PrEP impact on HIV among MSM generally, it is too early to comment. PrEP is only one of several HIV prevention interventions including behaviour modification, HIV testing, early HIV treatment and post exposure prophylaxis; accordingly, the quantification of the sole PrEP contribution to HIV prevention is highly complex.

With respect to PrEP impact on STIs other than HIV, likewise, it is too early to make well informed conclusions. Among those prescribed PrEP, an increase in the number of people

infected with gonorrhoea and chlamydia has been detected following the commencement of PrEP when compared to a similar time frame pre-PrEP. With rates of these infections pre and post-PrEP introduction not having changed, the increase so far could be attributed to either improved detection, an actual increase in the incidence of infection or a combination of both; the explanation is likely to be the “combination” one but the ratio of the contributions is uncertain. The excess of infection is unlikely to be due only to the identification of hitherto undetected infections because that hypothesis would assume that these were all asymptomatic ones or symptomatic infections which did not precipitate STI testing behaviour. These observations are consistent with those reported by other PrEP programmes.⁷

In common with many settings, uptake has been largely limited to MSM because the awareness raising focus had been on this group for a number of years and the HIV risk among MSM having condomless penetrative anal sex with multiple partners is higher than that for any other group; it is crucial, however, that PrEP is seen as an intervention for all at high risk of HIV. More needs to be done to raise PrEP awareness among women, transgender/trans people and heterosexual men; in year two, further work, including research will be undertaken to decide how best to address their needs and, thereafter, tailor services appropriately and proportionately without generating unnecessary alarm and excessive demand. The development of new acceptable models of PrEP care, involving for example eHealth, could increase access to PrEP and reduce the burden on sexual health services.

Although models and stages of PrEP implementation across the UK are varied, we have worked together very effectively to develop evidence and experience-based measures for evaluation purposes and the sharing of best practice. A key output is the development of unified definitions for data reporting and the development of a minimum dataset for regular national reporting; these will be adopted throughout the UK by the end of 2019, enabling useful comparisons to be made and permitting the generation of UK-wide datasets for further research.

Further work on the cost-effectiveness of PrEP as a national prevention strategy needs to be undertaken.

8 Conclusion

In conclusion, Scotland is one of the first countries worldwide to have successfully established a PrEP service which is truly national, free at the point of delivery and generally accessible to most deemed at high risk of acquiring HIV. In terms of HIV prevention, the early signs are favourable. While it is too early to draw conclusions on the impact of PrEP on high risk sexual behaviour and other STIs, there are some pointers suggesting an increase; but any possible increase is likely to be offset by PrEP's HIV impact and its ability to attract people at risk of HIV who would not normally access sexual health services and who, consequently, can reap the benefits of these.

On a cautionary note, the success of the service implementation, and the cumulative nature of PrEP uptake, means that pressures on sexual health services which have already caused difficulties affecting both users and providers, will continue to increase unless additional resources or efficiencies are identified. In year two, a formal evaluation of that impact is being undertaken.

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Appendix 1

SHPN HIV PrEP National Coordination Group Membership and Project Support

Name	Remit on Network	Job Title/Role	Organisation
David Goldberg	Chair	Consultant Epidemiologist and Professor of Public Health	Health Protection Scotland
Lesley Wallace	Scientific Support	Lead Epidemiologist	Health Protection Scotland
Lesley McGuire	Project Manager	Project Manager	Health Protection Scotland
Amanda Burridge	Service Delivery Manager	Service Delivery Manager	Health Protection Scotland
Ruth Robertson	Co-Chair SHPN-Workforce Education Development Group	Health Protection Education Programme Manager	NHS Education for Scotland
Rak Nandwani	Chair of HIV Clinical Leads	Consultant Physician in Sexual Health & HIV Medicine	NHS Greater Glasgow & Clyde
Pauline McGough	Chair of the HIV PrEP Clinical Services Workstream.	Consultant in Sexual & Reproductive Health	NHS Greater Glasgow & Clyde
	Chair of the SHPN-Scottish Lead Clinicians for Sexual Health & Reproductive Health		
Nicky Coia	Chair of the HIV PrEP Education and Awareness Raising Workstream.	Health Improvement Manager (Sexual Health) NHS Greater Glasgow and Clyde	NHS Greater Glasgow & Clyde
	Chair of the SHPN-Scottish Sexual Health Promotion Specialists Group		
Ann Eriksen	SHBBV Executive Leads of the NHS Boards	Executive Lead & Commissioner - Sexual Health & Blood Borne Virus	NHS Tayside
Claudia Estcourt	Co-Chair of the HIV PrEP Monitoring and Research Workstream	Professor of Sexual Health and HIV & Honorary Consultant	Glasgow Caledonian University
Nicola Steedman	Co-Chair of the HIV PrEP Monitoring and Research Workstream	Consultant in Public Health (Maternity and Reproductive. Health) Public Health and Intelligence, ISD / Senior Medical Officer, Scottish Government	Scottish Government/NHS NSS (ISD)

Name	Remit on Network	Job Title/Role	Organisation
Mary Stewart	Scottish Government Health Protection Team Representative	Branch Head Environmental Risks, Infections and Sexual Health Health Protection Division	Scottish Government
Laura Ferguson	National Procurement Representative	Commodity Manager	NHS National Procurement
John Saunders	Public Health England Representative	Consultant Epidemiologist	Public Health England
Zoe Couzens	Public Health Wales Representative	Principal in Public Health	Public Health Wales
Naresh Chada	Public Health Northern Ireland Representative	Senior Medical Officer (CMO Group, Department of Health, Northern Ireland)	Public Health Northern Ireland
Nicola Rowan	SHPN Manager	SHPN Manager	Health Protection Scotland
Katie Clayton	NSS Communications	Business Partner	National Services Scotland
George Valiotis (Nathan Sparling from Oct 2018)	HIV Scotland Representative	CEO	HIV Scotland
Suzanne McBride	Group Administration Manager	Group Administration Manager	Health Protection Scotland
Caroline Kelleher	Administrative Support Officer	Administrative Support Officer	Health Protection Scotland

Abbreviations:

SHPN Scottish Health Protection Network

SHPN-CC SHPN Coordination Group

SG Scottish Government

SHPN Sexual and Reproductive Health Lead Clinicians Group Membership and Project Support

Name	Remit on Network	Job Title/Role	Organisation
Pauline McGough	Chair	Consultant in Sexual & Reproductive Health	NHS Greater Glasgow & Clyde
Ruth Holman	SRH Clinical Lead	Consultant in Sexual & Reproductive Health	NHS Ayrshire & Arran
Maggie Gurnay	SRH Clinical Lead	Associate Specialist SRH	NHS Dumfries & Galloway
Karen Piesga	SRH Clinical Lead	Consultant in Reproductive Health	NHS Fife
Kirsty Abu-Rajab	SRH Clinical Lead	GUM	NHS Forth Valley
Ambreen Butt	SRH Clinical Lead	Service Lead Grampian Sexual Health	NHS Grampian
Lorraine Foster	Representative - Sexual Health Lead Nurses Group	Nurse Consultant	NHS Greater Glasgow & Clyde
Hame Lata	SRH Clinical Lead	Lead Clinician	NHS Highland
Anne McLellan	SRH Clinical Lead	Consultant SRH	NHS Lanarkshire
Sharon Cameron	SRH Clinical Lead	Consultant Gynaecologist and Sexual and Reproductive Health	NHS Lothian
Dan Clutterbuck	SRH Clinical Lead	Consultant in Genitourinary & HIV Medicine	NHS Lothian
Susan Laidlaw	SRH Clinical Lead	Consultant in Public Health Medicine	NHS Shetland
Sarah Allstaff	Vice-Chair	Genito Urinary Medicine Consultant	NHS Tayside
Anne Nicholson	SRH Clinical Lead	General Practitioner	NHS Orkney
Lesley Wallace	Epidemiologist	Principal Healthcare Scientist	Health Protection Scotland
Nicola Rowan	Service Manager	Scottish Health Protection Network Manager	Health Protection Scotland
Lesley McGuire	Project Manager	Project Manager	Health Protection Scotland

SHPN-HIV PrEP Education & Awareness Group Membership and Project Support

Name	Remit on Network	Job Title/Role	Organisation
Nicky Coia (Co-Chair)	Co-Chair	Health Improvement Manager (Sexual Health) NHS Greater Glasgow and Clyde	NHS Greater Glasgow & Clyde
George Valiotis	Co-Chair (till Oct 18)	CEO	HIV Scotland
Ruth Robertson	Co-Chair	Health Protection Education Programme Manager	NHS Education for Scotland
Amanda Burridge	Service Delivery Manager	Service Delivery Manager	Health Protection Scotland
Lesley McGuire	Project Manager	Project Manager	Health Protection Scotland
David Goldberg	HPS Representative	Consultant Epidemiologist and Professor of Public Health	Health Protection Scotland
Lesley Wallace	Scientific Support	Principal Healthcare Scientist	Health Protection Scotland
Nicola Rowan	Co-chair of the HIV PrEP Education and Awareness Group	Programme Manager	Health Protection Scotland
Pauline McGough	Chair of the HIV PrEP Clinical Services	Consultant in Sexual & Reproductive	NHS Greater Glasgow & Clyde
Julian Heng	Health Improvement Lead	HIL - Sexual Health	NHS Greater Glasgow & Clyde
David Bingham	Terrence Higgins Trust Rep	Health Improvement	Terrence Higgins Trust
Ingrid Young	Researcher	Chancellor's Fellow	University of Edinburgh
Alastair Rose	Represents Waverley Care & MSM	Health Improvement for SX/Waverley	Waverley Care
Zoe Kelly	Health Improvement Knowledge	Health Improvement Officer	NHS Ayrshire & Arran
Naresh Chada	PH Northern Ireland Representative	Senior Medical Officer	Public Health Northern Ireland
Katie Clayton	Specialist & Screening Services	Programme Manager	Health Protection Scotland
Suzanne McBride	Secretariat Support	Admin Manager	Health Protection Scotland
Zoe Couzens	Public Health Wales Representative	Sexual Health Lead	Public Health, Wales

PrEP Monitoring and Research Group (PrEPMAR) and Project Support

Name	Remit on Network	Job Title/Role	Organisation
Claudia Estcourt	Co-Chair	Professor of Sexual Health & HIV	NHS GGC and Glasgow Caledonian University
Nicola Steedman	Co-Chair	Clinical Lead for National Data (Maternity and Reproductive Health) Senior Medical Officer	NSS Information Services Division1 Scottish Government
Amanda Burridge	Service Delivery Manager	Service Delivery Manager	Health Protection Scotland
Lesley McGuire	Project Manager	Project Manager	Health Protection Scotland
Lesley Wallace	HIV/STI Epidemiology	Principal Healthcare Scientist	Health Protection Scotland
David Goldberg	Chair of PrEP National Co-ordination Group	Consultant Epidemiologist and Professor of Public Health	Health Protection Scotland
Grant Sugden	Third Sector Representative	Chief Executive	Waverley Care
Stuart Wrigglesworth	Data Analysis	Senior Analyst	NSS Information Services Division
Duncan McMaster	Data Analysis	Information Analyst	NSS Information Services Division
Celina Davis	Data Analysis	Principal Information Analyst	NSS Information Services Division
Ingrid Young	Researcher	Chancellor's Fellow	University of Edinburgh
Eric Chen	Researcher	National SHBBV Framework Research Co-ordinator	NHS Lothian
Maggie Watts	SHBBV Executive Leads group representative. Representative for 'non-NaSH-using' Boards	SH and BBV Executive Lead	NHS Western Isles
Dan Clutterbuck	Representative of HIV Clinical Leads/Sexual Health Clinical Leads	Consultant in Genitourinary & HIV medicine	NHS Borders and NHS Lothian
Andrew Winter	Chair of the NaSH User Management Group	Consultant in Genitourinary & HIV medicine	NaSH User Management Group and NHS GGC
John Saunders/ Monica Desai/ Hamish Mohammed	Representative of English Impact PrEP Trial	Various	Public Health England
Alan Yeung	Analyst	Principal Analyst	Health Protection Scotland

Appendix 2 Supplementary tables

Data on HIV PrEP uptake and use, July 2017 to June 2018

PrEP-number of individuals and prescriptions 1 July 2017 - 30 June 2018

Table 4.1: Overview

		Individuals	%		Prescriptions
Total	All GOSP	1,872	100	Total	4,432
Female	Total	14	0.7		
	Men and woman	6	0.3		
	Men only	8	0.4		
Male	Total	1,855	99.1		
	Not Known	2	0.1		
	Men and woman	406	21.7		
	Men only	1,440	76.9		
	Woman only	7	0.4		
Other	Total	*	*		
Unknown	Total	*	*		

Gender of sexual partners (GOSP) is taken from lifetime sexual history.

Other gender includes 'Ambiguous' + 'Other Specific'.

* Indicates values that have been suppressed due to the potential risk of disclosure.

PrEP-number of individuals and prescriptions by NHS Board 1 July 2017 - 30 June 2018

Table 4.2: Number of individuals and prescriptions by NHS Board of clinic

	Scotland	Ayrshire & Arran	Borders	Dumfries & Galloway	Fife	Forth Valley	Grampian	Greater Glasgow & Clyde	Highland	Lanarkshire	Lothian	Tayside
Individuals ¹	1,872	51	14	14	66	52	160	883	38	45	461	88
Prescriptions	4,432	121	29	37	116	144	288	2,166	82	127	1,077	245

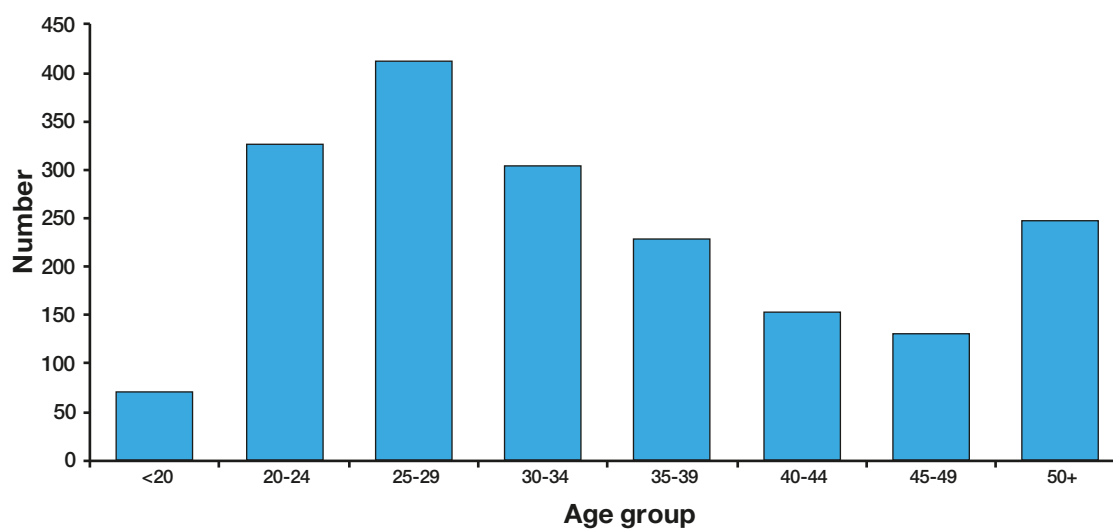
¹ NHS Board is based on the most recent board of prescription.

PrEP-individuals by age 1 July 2017 - 30 June 2018

Table 4.3: Individuals by age group

		Age group (at first prescribed)							
	Total	<20	20-24	25-29	30-34	35-39	40-44	45-49	50+
Total	1,872	70	327	412	304	229	153	130	247
Total (%)	100	3.7	17.5	22.0	16.2	12.2	8.2	6.9	13.2

Individuals by age at first prescription (N=1,872)



Eligibility codes for individuals¹ prescribed PrEP² 1 July 2017- 30 June 2018

Table 4.4: Eligibility codes recorded in any position

	Individuals ¹	%
Had at least one valid e1-e4 code	1,681	89.8
Had no valid e1-e4 code	191	10.2
Total	1,872	100

		Individuals ¹
PrEPe1	PrEP Partner(s) HIV-positive with a detectable viral load	42
PrEPe2	PrEP Documented bacterial rectal STI in the last 12 months	357
PrEPe3	PrEP Condomless penetrative anal sex with two or more partners in last 12m and risk likely in next 3m	1,567
PrEPe4	PrEP Equivalent high risk of HIV acquisition, as agreed with another specialist clinician	24
Total	Total number of eligibility codes recorded	1,990

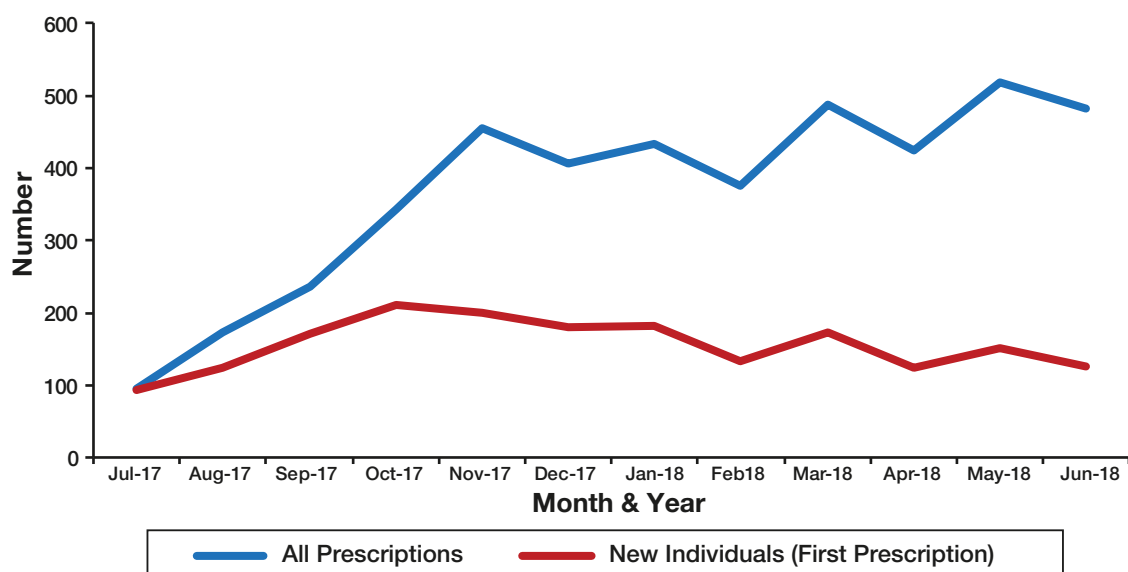
1 An individual or a single prescription can have more than one eligibility code recorded.

2 Prescriptions were linked to episodes (up to 28 days prior) in order to identify eligibility codes. When a prescription did not have an episode with a code, within 28 days of the prescription, it was marked as 'Invalid'.

PrEP prescriptions over time 1 July 2017- 30 June 2018

Table 4.5: By Month

	All Prescriptions	New Individuals (First Prescription)
Total	4,432	1,872
Jul-17	96	93
Aug-17	173	125
Sep-17	236	171
Oct-17	343	211
Nov-17	455	200
Dec-17	407	181
Jan-18	433	182
Feb-18	376	133
Mar-18	487	174
Apr-18	424	124
May-18	519	151
Jun-18	483	127



PrEP- individuals with no prior attendance 1 July 2017- 30 June 2018

Table 4.6: Previous Attendance

Of the 1,872 individuals receiving PrEP prescriptions:

531 individuals (28%) had no attendance recorded in the two years prior to the PrEP programme's roll out on 1st July 2017.

356 individuals (19%) had no attendance recorded in the two years prior, or at any other time prior to PrEP programme's roll out.

	No Prior Attendance	All Prescribed	First Attendance (%)
Total	356	1,872	19.0
Female	6	14	42.9
Male	350	1,855	18.9
Other	-	*	-
Unknown	-	*	-

Other gender includes 'Ambiguous' + 'Other Specific'

* Indicates values that have been suppressed due to the potential risk of disclosure.

PrEP- individuals coded as not meeting NHS eligibility criteria 1 July 2017 - 30 June 2018

Table 4.7: PrEPe0 - Did not meet NHS eligibility criteria

		Individuals	%
Total	All PrEPe0	274	100
Female	Total	-	-
Male	Total	273	99.6
	Not Known	*	*
	Men and woman	61	22.3
	Men only	208	75.9
	Woman only	*	*
Other	Total	*	*
Unknown	Total	*	*

Gender of sexual partners (GOSP) is taken from lifetime sexual history.

Other gender includes 'Ambiguous' + 'Other Specific'.

* Indicates values that have been suppressed due to the potential risk of disclosure.

PrEP-offered and declined 1 July 2017- 30 June 2018

Table 4.8: PrEPDEC - PrEP offered and declined by gender and GOSP, by codes recorded in any position

		Individuals	%
Total	All PrEPDEC	133	100
Female	Total	*	*
Male	Total	128	96.2
	Men and woman	33	24.8
	Men only	95	71.4
Other	Total	*	*
Unknown	Total	*	*
		Individuals	%
Total	All PrEPDEC	133	100
PrEPDEC with no e1-e4 code		37	27.8
PrEPDEC with PrEPe1 ¹		*	*
PrEPDEC with PrEPe2 ²		28	21.1
PrEPDEC with PrEPe3 ³		63	47.4
PrEPDEC with PrEPe4 ⁴		*	*

Gender of sexual partners (GOSP) is taken from lifetime sexual history.

Other gender includes 'Ambiguous' + 'Other Specific'.

1 Prepe1 PrEP Partner(s) HIV-positive with a detectable viral load.

2 Prepe2 PrEP Documented bacterial rectal STI in the last 12 months.

3 Prepe3 PrEP Condomless penetrative anal sex with two or more partners in last 12m and risk likely in next 3m.

4 Prepe4 PrEP Equivalent high risk of HIV acquisition, as agreed with another specialist clinician.

* Indicates values that have been suppressed due to the potential risk of disclosure.