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PrEP in Scotland

Nandwani R and Valiotis G, on behalf of the Scottish HIV Pre-Exposure Prophylaxis Short Life Working Group.

Scottish Health Protection Network (SHPN) October 2016.

Purpose:

Report to provide recommendations on HIV pre-exposure prophylaxis (PrEP) in Scotland to the Sexual Health & Blood Borne Virus Executive Leads from the HIV PrEP Short Life Working Group (SLWG).

Summary recommendations:

- 1. The HIV PrEP Short Life Working Group strongly recommends that people at the highest risk of HIV in Scotland are provided with the option of PrEP as part of a wider targeted national prevention programme delivered by the NHS in sexual health services, subject to delivery of the programme at a cost effective price and reflecting SMC advice where applicable.***
- 2. Pending a decision on the availability of NHS-funded PrEP medication, the HIV PrEP Short Life Working Group recommends that the Executive Leads endorse specialist sexual health services targeting support to provide advice and clinical monitoring to individuals who have either self-purchased PrEP medication or are considering doing so.***
- 3. Whilst a substantial proportion of PrEP support can be provided by appropriate internal prioritisation and input from wider existing structures, the HIV PrEP Short Life Working Group recommends that some additional funding is required for specific support and monitoring of PrEP in specialist sexual health services in Scotland, independently of the decision on NHS-funded PrEP medication.***
- 4. The HIV PrEP Short Life Working Group recommends the implementation of formal mechanisms to monitor and evaluate PrEP use in Scotland (independently of the decision on NHS funding) and to review the potential effects on new HIV infections, behavioural changes and impact on other STI rates.***
- 5. The HIV PrEP Short Life Working Group recommends that the provision of PrEP information is organised centrally, in co-ordination with other key clinical and community stakeholders.***
- 6. The HIV PrEP Short Life Working Group asks that NHS Scotland HIV prevention public messaging should be reviewed to emphasise that PrEP is not a replacement for condoms and that it remains important to have regular testing for HIV and other STIs.***

Methodology

At the 2 November 2015 Sexual Health & Blood Borne Virus Executive Leads' meeting, following a presentation by HIV Scotland, there was agreement to form a sub-group to provide recommendations to the Executive Leads on initiatives and strategies relating to HIV pre-exposure prophylaxis (PrEP) in Scotland.

The HIV PrEP Short Life Working Group (SLWG) consisted of advisers from the community, third sector, drug procurement, epidemiology, pharmacy, sexual health clinicians, sexual health promotion leads, HIV clinicians, and academics (See Appendix) to provide recommendations on initiatives and strategies relating to HIV and PrEP in Scotland. The group also included observers from the Scottish Government and from the Scottish Medicines Consortium, and was chaired by Dr Rak Nandwani (Sexual Health and HIV Consultant, NHS Greater Glasgow & Clyde).

PrEP is an effective HIV prevention intervention, using antiretroviral drugs to protect individuals at risk of acquiring HIV. The SLWG considered the use of PrEP, recognising that it could form one component of wider targeted HIV prevention for those at the highest risk of HIV acquisition in Scotland.

The group worked towards four deliverables:

1. A needs assessment;
2. Resource analysis with supporting information on potential budget impact;
3. Creating guidance for accessing and monitoring, and;
4. Information provision.

Background

HIV diagnoses in Scotland continue with an annual average of 359 during the past five years. The majority of infections are sexually transmitted. Men who have sex with men (MSM) account for 47% of all new HIV diagnoses since 2011 compared to 38% of diagnoses attributable to heterosexually acquired infection¹. Since 2014, using avidity testing, it has been possible to identify recently acquired HIV infection, which has been acquired within the previous three to four months. Data indicates that recent acquisition of HIV is highest among MSM with 35% of those being tested for recency proving positive compared to 19% in other groups. Therefore, MSM remain the group at highest risk of HIV in Scotland.

The medication currently recommended for PrEP interventions is a single fixed dose oral combination tablet that is commonly used to treat people with HIV. It comprises of two antiretroviral drugs taken once daily; Tenofovir disoproxil fumarate (TDF) plus Emtricitabine (FTC). The branded form of TDF/FTC is called Truvada[®]. It is already licensed for use as treatment in the UK for people with HIV and has been used in Scotland for a number of years. In 2016, the European Medicines Agency (EMA) licenced Truvada[®] for use as PrEP, paving the way for the manufacturer to make a submission to the Scottish Medicines Consortium (SMC) using a New Product Assessment Form. The usual assessment timeline for this process is 18 weeks, from receipt of submission to the publication of advice.

The SLWG considered the Evidence Review published by NHS England in October 2015² to inform decision-making about integrating PrEP into existing HIV prevention packages for those most at risk of HIV infection. The review also considered whether oral PrEP is clinically efficacious and what factors affect cost-effectiveness for key populations. The SLWG found

the evidence in this review to be relevant to Scotland and so have used this in addition to Scottish specific research on acceptability and epidemiology as detailed in this document.

A number of international randomised controlled trials have found oral PrEP to be effective reducing sexual HIV transmission in MSM and heterosexual men and women. In MSM, the risk of sexually acquired HIV-1 infection was reduced by 86% in uninfected adults in two clinical trials: PROUD³ and IPERGAY⁴.

The SLWG concluded that PROUD was the most applicable trial to the healthcare setting of NHS Scotland as it was performed in 13 sexual health clinics in England. The study was an open-label design in which half the 544 participants were randomly assigned to daily TDF/FTC in the first year and half were not. HIV incidence was significantly lower in individuals assigned to immediate PrEP (1.2 cases per 100 person years) compared with the deferred group (9.0 cases per 100 person years). This corresponds to a proportionate reduction of 86% (90% CI 64-96). In October 2014, based on early evidence of effectiveness, the trial steering committee recommended that all deferred participants should be offered PrEP immediately.

PROUD also confirmed that PrEP was highly effective in a real-world setting in a group of men engaging in sex with very high STI transmission risk. PROUD found no difference in the incidence of sexually transmitted infections in the two groups, including rectal gonorrhoea and chlamydia, despite a suggestion of risk compensation (more episodes of condomless anal sex) among PrEP recipients who had a high number of sexual partners. No serious adverse drug reactions were recorded; 28 adverse events, most commonly nausea, headache, and aching joints, resulted in interruption of PrEP. In a population matching those recruited to the PROUD study, 13 men (90% CI 9–23) would need to access PrEP for 1 year to avert one HIV infection.

Although unpublished and in a different health care environment from the UK, a further example indicating PrEP utility in a real-world setting was a community-based sexual health clinic based programme in San Francisco offering nurse-led PrEP⁵. There were no reported new HIV infections among 1252 men screened for the programme with 95% uptake in an 18-month period. Comparatively, the clinic diagnosed 82 new HIV infections among men not enrolled in the programme during the 18-month follow-up period.

Whilst the majority of HIV transmissions occurring in Scotland are in MSM and, therefore, potentially amenable to local prevention interventions, the SLWG noted evidence for the effectiveness of PrEP for heterosexual women and men in serodiscordant relationships from the PARTNERS study set in Kenya and Uganda⁶ and from the TDF2 study in Botswana⁷.

The Bangkok Tenofovir Study⁸ demonstrated 74% protection using once daily Tenofovir disoproxil fumarate (TDF) without Emtricitabine (FTC) among people who inject drugs. However, this study was performed in a setting where other prevention interventions to prevent blood borne virus transmission differed greatly from those in Scotland.

Deliverable 1: To estimate the number of individuals who might be eligible for PrEP in Scotland

Calculations estimate that the number of MSM eligible to receive PrEP in Scotland is 1700 (range 1500 to 1900). The SLWG consider that the total number of individuals eligible to receive PrEP in Scotland is likely to be closer to the higher estimate of 1900.

Assuming 58% uptake of PrEP by those eligible, the SWLG estimates approximately 1000 people (range 880 to 1100) will come forward to commence PrEP in Scotland in the first 12 months.

The SLWG selected two data sources as most informative to assess the number of individuals who might require PrEP in Scotland. These included data from the clinical IT system (NaSH) which comprises electronic patient records for all individuals seen in every specialist sexual health service in Scotland, and from the latest wave of data collection by the Medical Research Council (MRC) Gay Men's Sexual Health Surveys (which have been performed triennially in Scotland since 1996).

Reviewing HIV epidemiology data, the SLWG considered those at highest risk of HIV acquisition in Scotland were MSM. Those defined at highest risk had a rectal sexually transmitted infection (STI) diagnosed in the previous year and/or had participated in condomless anal intercourse (CAI) with two or more partners in the previous 12 months. These categories were consistent with a Public Health England analysis of baseline predictors in the no-PrEP group in the PROUD study⁹. CAIⁱ with two or more previous partners in the last 12 months with a partner of unknown or discordant status was also a marker of HIV transmission risk used in much of the behavioural fieldwork work with MSM in Scotland, including the Gay Men's Sexual Health survey 2014, and in the Social Media, MSM and Sexual Health (SMASHH) survey¹⁰.

The SLWG was also clear that PrEP should be considered for all individuals whose circumstances placed them at the highest risk of HIV acquisition in Scotland including men, women and transgender/non-binary individuals, however available Scottish data was limited other than for MSM. The SLWG incorporated this view when defining the eligibility criteria for PrEP (Deliverable 3). The SLWG considered that the proportion of individuals other than MSM eligible to receive PrEP in Scotland would be 5% or less and therefore would not significantly alter the calculated range estimates on the numbers eligible based on data for MSM given their existing margin of error.

Having defined individuals at highest risk of HIV acquisition in Scotland, the SLWG sought to quantify the number of MSM in Scotland who would fit the eligibility criteria of being diagnosed with a rectal STI and/or having CAI with two or more partners in the previous 12 months and who were not HIV-infected. This proved challenging as there was no single data source that provided this information.

Firstly, using the NaSH clinical data the estimated number of HIV negative MSM attending specialist sexual health clinics in Scotland in 2015 was 7600. Of this population, almost 900, with a negative HIV test in that year were diagnosed with a rectal STI. Thus, the proportion of MSM attending sexual health clinics with a rectal STI is 11.8% (900 of 7600) (Table 1).

ⁱ This report uses CAI as the main marker of risk, but the wording in the 2014 MRC survey used the term unprotected anal intercourse.

However, it was not possible to extract NaSH data for episodes of CAI with two or more partners among those with a rectal STI diagnosis. Therefore, data were extracted from the latest MRC Gay Men’s Sexual Health Survey which specifically included questions on reported CAI with two or more partners in the previous 12 months.

The 2014 wave of the survey comprised MSM recruited from gay venues (bars and saunas) in Glasgow, Edinburgh and Dundee. Data from the survey indicated that proportion of self-reported gay and bisexual men who believed themselves to be HIV negative or HIV status unknown and who reported CAI with two or more partners in the previous 12 months was 18.6% (CI 16.5% to 20.9%)ⁱⁱ (Table 1).

Data was also extracted from the survey on self-reported sexually transmitted infections (STI). The proportion of self-reported gay and bisexual men who believed themselves to be HIV negative or HIV status unknown and who reported an STI (at any unspecified site, including rectal) in the previous 12 months was 9.9% (CI 8.3% to 11.7%) (Table 1).

The missing information from Table 1 is the proportion of HIV negative MSM who have had CAI with two or more partners and who attend sexual health clinics. This was estimated by comparing the higher proportion of MSM attending a clinic with a confirmed rectal STI, 11.8%, with the lower proportion in the community self-reporting any STI, 9.9%. This difference may be partly explained by individuals with rectal STI being more likely to be symptomatic and therefore attend services. However, by applying an adjustment factor using the ratio of 11.8:9.9 = 1.2, to the proportion of survey MSM self-reporting CAI with two or more partners (18.6%), then 22.3% (range 19.8% to 25.1%) of clinic attendees would be in this category. When this adjustment factor is applied to the number of HIV negative men attending sexual health services, the estimated number of MSM eligible to receive PrEP in Scotland is 1700 (range 1500 to 1900) (Table 1). Additionally, an adjustment is required to accommodate PrEP provision to individuals who are not MSM, as highlighted previously. Therefore, the SLWG considered the number of individuals eligible for PrEP in Scotland to be nearer the higher estimate of 1900.

Table 1: Data sources and estimates of numbers at risk of HIV infection in Scotland

	DATA SOURCE	
	Gay Men’s Sexual Health Survey	NaSH clinic data
Denominator	1217*	7600**
Survey question: STI in previous 12 months	119/1205 (9.9%)*** (CI 8.3-11.7%) (unspecified site)	900/7600 (11.8%) (rectal STI only)
Survey question: CAI ≥2 partners	221/1188 (18.6%) (CI 16.5-20.9%)	1700 (22.3%)# <i>Range: 1500 to 1900</i>

*Number of gay and bisexual men who believed themselves to be HIV negative or did not know their HIV status. Note the change in the denominator which reflects the number who responded to these questions in the survey.

**Number of HIV negative MSM attending a GUM/SRH service in 2015

*** This number /proportion includes non rectal STIs in the previous 12 months. Denominator adjusted to reflect participants who answered this specific question.

This number is estimated by using the GMSHS numbers and applying an adjustment factor of 1.2 to generate estimated proportion of 22.3% (19.8% - 25.1%). These proportions were applied to the numbers attending the clinical service.

There is limited data on PrEP awareness and acceptability, with consequent uncertainty about what proportion of individuals at highest risk of HIV acquisition would consider taking

ⁱⁱ The data is provisional because they have not yet been published. The analysis was done by Health Protection Scotland.

PrEP if it was made available. The SLWG noted that PrEP availability may encourage some men to start using clinical services for the first time.

The SLWG considered data from an online self-completed survey of high risk (defined as reporting two or more CAI partners in the previous year) HIV negative/status unknown MSM recruited via gay sociosexual media from Scotland, Wales, Northern Ireland and the Republic of Ireland¹¹. 58.5% (226 of 386) of participants reported that they would be willing to take a daily pill to prevent HIV infection. If this was translated into a 'real world' situation in Scotland, this suggests that approximately 1000 people (range 880 to 1100) would present and be eligible in the first year. This would need to be reviewed 12 months after implementation for future years.

Deliverable 2: Resource analysis with supporting information on potential budget impact

PrEP medication

The Scottish Medicines Consortium (SMC) is the body responsible for providing advice on drugs that can be provided on prescription by NHS Scotland. Consideration of cost-effectiveness is part of the required process and as such SMC will issue advice to NHS Scotland on the cost-effectiveness of PrEP. The SLWG has therefore considered factors which may assist this analysis, including defining eligibility criteria and to provide an estimate of the amount of TDF/FTC which might be prescribed.

Cost of PrEP support, excluding drug costs

Although services are under considerable resource pressure already, the SLWG believes that a substantial proportion of PrEP support can be provided by appropriate internal prioritisation and input from wider existing structures, for example, the delivery of specialist staff training.

Pending a decision on the availability of NHS-funded PrEP medication, the SLWG recommends that the Executive Leads endorse specialist sexual health services targeting support to provide advice and clinical monitoring to individuals who have either self-purchased PrEP medication or are considering doing so. Self-purchasing of PrEP exacerbates inequalities (Deliverable 4), but given that individuals are already presenting to services, the SLWG believes that the benefits of wider engagement and prevention outweigh the risks whilst wider consideration is given to PrEP roll-out in Scotland.

Based on an estimate of 1000 individuals seeking PrEP medication in Scotland (Deliverable 1), the additional annual cost of advice and clinical monitoring can be calculated. This calculation is not dependent on NHS funding for TDF/FTC and therefore drug costs are excluded.

Tenofovir disoproxil fumarate can cause renal toxicity. Additional service costs over and above HIV and STI testing include blood and urine testing plus additional staff time for PrEP assessment, check of contra-indications, drug management, and counselling. This will include management of side-effects, dosing queries, and results review. The SLWG does not anticipate therapeutic drug monitoring of antiretroviral drugs will be required.

In the absence of service tariffs for NHS Scotland or existing costings for sexual health service attendances, the additional service costs can be estimated based on Public Health England costings which use a GUM pathway (from the PROUD study protocol); together with updated laboratory pathology prices (two PHE laboratories, and a University College London Provider to provide price list), and; prices of consumables obtained from the NHS England Supply Chain [Personal communication Cambiano V].

Cost of PROUD PrEP pathway in first year	£649
Cost of PROUD PrEP pathway in subsequent years	£567.70
Cost of clinic visits for MSM at high risk per year	£473.40

Additional cost of providing PrEP in first year = £649 – £473.40 = £175.60

Additional cost of providing PrEP in subsequent years = £567.70 – £473.40 = £94.30

At 4 visits per year (3 monthly follow up) = £94.30 divided by 4 = £23.58 per visit

Therefore, the estimated basic additional cost of PrEP advice and support for 1000 people (excluding drug costs) in first year = £175,600 across NHS Scotland.

Whilst a substantial proportion of PrEP support can be provided by appropriate internal prioritisation and input from wider existing structures, the SLWG recommends that some additional funding is required for specific support and monitoring of PrEP in specialist sexual health services in Scotland, independently of the decision on NHS-funded PrEP medication.

Drug costs

The PrEP Short Life Working Group note that the cost of branded Truvada® may change in the near future. This view is reinforced by the patent expiring in 2017 and the current availability of significantly cheaper generic formulations by manufacturers overseas.

NHS cost of branded Truvada® September 2016 as listed in British National Formulary (BNF) = £355.73 for a 30 day pack¹². Annual cost for 12 packs = £4268.76

This price excludes VAT. VAT is added if medication is dispensed in hospital settings. Community prescribing may be considered. The NHS Scotland Contract Price may also differ and is commercially sensitive.

The SLWG explored whether there were alternatives to prescribing branded medicine (such as reimbursement of individuals who purchased medication on-line for personal use) and the use of alternate antiretroviral agents (trial data less robust, variable health settings, specific considerations about levels in rectal tissue), but these options were ruled out. The use of generic TDF and FTC medication was also investigated. It is likely that both Tenofovir and Emtricitabine constituent agents will become available in generic form in the next 12-18 months, which have the potential to generate significant savings in NHS medicine expenditure. However, there is uncertainty in relation to future formulations and combination of the two constituent agents into a single fixed dose tablet. In addition, there needs to be clarification on whether the additional licence for prevention will extend the patent expiry for the branded product and if so any potential legal consequences of prescribing generics need to be considered.

Therefore, the SLWG was advised that any cost projections or estimates must be based on branded Truvada®, at the cost to NHS Scotland at that time. As the “best and final” cost of generic or branded TDF/FTC medication is yet to be determined, the SLWG reviewed other aspects that would inform such an analysis.

PrEP dosing regimens

PrEP dosing can be continuous or event-based, depending on individual circumstances. The IPERGAY study⁴ showed that intermittent dosing can be an effective intervention for MSM. This has not yet been demonstrated for other risk exposures. In the original publication, participants took a median of 15 pills a month⁴. The most recent available data from IPERGAY presented at the 21st International AIDS Conference in July 2016 reported that around two thirds of PrEP users used intermittent dosing and one third took PrEP continuously. Overall, participants used a mean of 18 pills a month¹³.

This data can be used to calculate a multiplier of $18/30 = 0.6$ that can be applied to provide an estimated cost of branded Truvada® per eligible person per year (ex VAT) of £2,561.

Assuming 95% of the 1000 individuals who commence PrEP in Scotland are MSM who may consider intermittent dosing, the total annual cost (ex VAT) of TDF/FTC prior to contract negotiation or generic substitution will be:

$$(950 \times 2561) + (50 \times \text{£}4269) = \text{£}2,432,950 + \text{£}213,450 = \text{£}2,646,400.$$

HIV care costs

Despite major improvements in mortality with antiretroviral therapy, HIV remains a life changing condition with significant physical and psycho-social impact. Based on a median life expectancy of 71.5 years, the average lifetime cost of HIV care in the UK is $\text{£}360,800^{14}$.

Cost-effectiveness data from outside Scotland

The most relevant resource analyses which are likely to be transferable to NHS Scotland come from Public Health England, incorporating data from the PROUD study conducted in a UK NHS specialist setting. Data has so far been published as conference abstracts¹⁵¹⁶. These analyses are likely to have been updated and published in peer-reviewed journals by the time the SMC considers cost-effectiveness of PrEP in Scotland.

Deliverable 3: Guidance for accessing and monitoring PrEP in Scotland

Regular engagement of individuals with specialist services is already a priority for existing clinics and is an important component of clinical studies of PrEP use. This engagement provides opportunities for dialogue, information, monitoring, regular STI testing, immunisation and additional prevention interventions.

With the backing of the Sexual Health Lead Clinicians group, the SLWG therefore recommends that PrEP initiatives be initially delivered by NHS Scotland through sexual health specialist services (with alternative *equivalent* arrangements for the island NHS boards). This provides the opportunity to integrate new interventions with existing services. These services are best placed to dispense medication, provide testing and offer clinical advice. In future, the SLWG anticipates the potential for community based support services being considered, as has been seen with testing and support for HIV post-exposure prophylaxis.

The SLWG supports a single national programme to be delivered consistently by all NHS boards, without the need to develop local business cases, in order to ensure equity of provision and prevent duplication of effort. A Scotland-wide programme also provides access to specialist advice from clinicians experienced in the use of TDF/FTC for HIV treatment.

The SLWG has ensured that NaSH prescription options have already been updated to clearly differentiate antiretroviral agents prescribed for HIV therapy, HIV pre-exposure prophylaxis, and HIV post-exposure prophylaxis, should a decision be taken to support NHS prescription of PrEP medication. This will provide a means for real-time reporting of prescriptions and monitoring costs.

The SLWG recommends the implementation of formal mechanisms to monitor and evaluate PrEP use in Scotland (independently of the decision on NHS funding) and to review the potential effects on new HIV infections, behavioural changes and impact on other STI rates. Health Protection Scotland in partnership with the Sexual Health Protection Network and other colleagues would be well placed to collaborate with academic institutions. The outcomes of this work would have significant international impact as well as informing service development in Scotland.

Proposed eligibility criteria for accessing PrEP in Scotland

Prescription of TDF/FTC is just one component of a wider targeted HIV prevention programme for those at highest risk subject to delivery of the programme at a cost effective price. The guidance will reflect SMC advice where applicable.

The criteria are informed by HIV epidemiology in NHS Scotland identifying those at highest risk of acquiring HIV and with an opportunity for local prevention.

Individuals at greatest risk of acquiring HIV are eligible for NHS Scotland funded HIV prevention interventions including TDF/FTC if ALL the following apply:

Universal criteria:

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

Plus one or more of the following:

1. Current sexual partners, irrespective of gender, of people who are HIV positive and with a detectable viral load.
2. MSM* and transgender women with a documented bacterial rectal STI in the last 12 months.
3. MSM* and 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.
4. Individuals, irrespective of gender, at an equivalent highest risk of HIV acquisition, as agreed with another specialist clinician.

(*The term MSM used here includes transgender men who have male sexual partners)

Not eligible.

1. Already HIV-positive or suspected HIV seroconversion.
2. Monogamous serodiscordant couples where the HIV+ partner is on treatment and has undetectable viral load.
3. Pre-existing medical conditions (such as renal impairment) that significantly increase the risk of TDF/FTC adverse events.
4. Individuals chronically infected with hepatitis B virus where TDF/FTC may be being used for therapy.

Notes

- Medication supply can be event-driven (for MSM* only) or continuous depending on individual circumstances. Prescription duration will reflect the anticipated usage to minimise wastage.

Deliverable 4: Information for health professionals, patients and the public about PrEP and available support, including a central online resource

The SLWG recognises that various levels of training and support for staff (through existing training mechanisms such as Managed Clinical Networks) will need to be developed. In-house training will need to start soon for core staff to raise awareness of PrEP online and provide patients and workers with consistent information. It is anticipated that NHS Boards with specialist services will be able to provide support for individuals who have obtained PrEP themselves, and that all NHS Boards will be able to support staff to provide advice on PrEP.

Given that PrEP medication is not currently available through the NHS in any of the UK home nations at the time of drafting this report, some individuals are accessing PrEP through private clinics or purchasing generic versions online using international websites. Both these methods of access present their own challenges. Obtaining branded medication for PrEP on private prescription can be expensive and is only available to those with sufficient funds. Individuals currently purchasing generic drugs online to use as PrEP may have little or no guidance on drug regimens or potential side effects and encounter conflicting or inaccurate information. There is also a risk of being sold counterfeit medicines, and these sources are only available to individuals with a sufficiently high level of HIV literacy (knowledge of and skills around HIV prevention strategies).

The SLWG believes that access to PrEP only by individuals with the ability to purchase drugs online or privately exacerbates inequalities and strengthens the link between socio-economic deprivation and HIV.

The SLWG recommends that the provision of PrEP information is organised centrally, in co-ordination with other key clinical and community stakeholders.

The SLWG also asks that NHS Scotland HIV prevention public messaging should be reviewed to emphasise that PrEP is not a replacement for condoms and that it remains important to have regular testing for HIV and other STIs.

Existing sources of information

- Practical guidance on testing and monitoring by specialist services is available in the BHIVA–BASHH Position Statement on PrEP in UK and does not require re-drafting for Scotland. <http://www.bhiva.org/documents/Publications/BHIVA-BASHH-Position-Statement-on-PrEP-in-UK-May-2016.pdf> [accessed 7 October 2016]
- The HIV Scotland ‘PrEP in Scotland’ 2016 report provides more general information for non-specialists and other interested persons. <http://www.hivscotland.com/our-policy-work/prep> [accessed 7 October 2016]
- A brochure called ‘Buying PrEP online: Safe use and NHS monitoring’ has been developed in collaboration by i-base, 56 Dean Street, BASHH, CliniQ, NHS Central and North West London, Prepster, and iwantprepnw.
- <http://i-base.info/guides/wp-content/uploads/2016/06/PrEP-leaflet-FINAL1.pdf> [accessed 7 October 2016]

Sources of information in development

- NHS Lothian have drafted both guidance for staff and a patient information brochure and it is anticipated that these could be shared with other NHS Boards.
- PrEP is anticipated to be included in the Sexual Health Prevention Network MSM HIV Prevention Guidance currently being updated.
- BHIVA and BASHH are also currently developing PrEP guidelines, available most likely in early 2017.
- Dr Ingrid Young, University of Edinburgh/University of Glasgow is leading a programme of work in collaboration with HIV Scotland on supporting HIV literacy skills in relation to PrEP that will inform future HIV and PrEP prevention messaging for potential PrEP users and health providers.

Appendix – Membership SLWG

Name	Occupation	Organisation
Dr Rak Nandwani (Chair)	Sexual Health and HIV physician (NHS GGC)	HIV Lead Clinicians Group
George Valiotis (Administrator)	CEO of the national HIV policy charity.	HIV Scotland
David Bingham	Third Sector service provision (Terrence Higgins Trust)	HIV Voluntary Sector Network
Dr Dan Clutterbuck	GUM physician (NHS Lothian & Borders)	BASHH MSM Special Interest Group
Nicky Coia	Health promotion specialist (NHS GGC)	Scottish Sexual Health Promotion Specialists Group
Laura Ferguson	Drug procurement (National)	NSS Drug Procurement
Gordon Garioch	Community member	Not affiliated
Kirsteen Hill	Pharmacist (NHS Tayside)	HIV specialist pharmacist
Dr Ruth Holman	Sexual Health Consultant (NHS Ayrshire & Arran)	Sexual Health Lead Clinicians Group
Dr Anne McClellan	Sexual Health Consultant (NHS Lanarkshire)	Sexual Health Lead Clinicians Group
Dr Lesley Wallace	Epidemiology (National)	Health Protection Scotland
Maggie Watts	Director of Public Health (NHS Western Isles)	SHBBV Executive Leads Group
Dr Ingrid Young	Social researcher (National)	University of Edinburgh
<u>Observers</u>		
Sharon Hems	Principal Pharmaceutical Analyst	Scottish Medicines Consortium
Dr Nicola Steedman	Senior Medical Officer & GUM consultant	Scottish Government

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