

HIV Pre-Exposure Prophylaxis (PrEP) in Ireland

PrEP estimates for populations at risk of sexual acquisition of HIV in Ireland

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1 Summary

Between October 2016 and March 2017, a group from the HSE Sexual Health and Crisis Pregnancy Programme (SHCPP) and Health Protection Surveillance Centre (HPSC) used available Irish data to develop a pre-exposure prophylaxis (PrEP) cascade to estimate the numbers of men who have sex with men (MSM) likely to avail of PrEP in the first year of its availability in Ireland. The estimates in this report are based on MSM aged 18-64 years; however, if PrEP becomes available in Ireland, it will be available to all age groups who meet the eligibility criteria.

With regard to the risk of sexually acquired HIV infection in other populations, and in the absence of Irish data, international estimated numbers were described. This process was undertaken in consultation with health care professionals and community stakeholders.

The key findings are:

- Using criteria for PrEP eligibility from France, an estimated 23% (95% CI, 22.7-23.3) of respondents from the MSM Internet Survey Ireland (MISI) would be eligible for PrEP.
- Applying a 50% correction factor for self-reporting bias, as convenience sampling tends to
 over-report sexual behaviours, and applying this proportion (11.5% (95% CI, 11.3-11.7)) to
 the estimated MSM population in Ireland aged 18-64 years, the number of MSM who may
 be eligible for PrEP is 9,947 (95% CI, 9,765-10,129).
- Applying ranges from 15%, 30% to 45% to reflect estimates for MSM engaged with existing STI and HIV testing services, the estimated number of MSM likely to present for PrEP in Ireland was 1,492-4,476 (95% CI, 1,423-4,574).
- Applying 58% for the assumed uptake of PrEP adjusted the estimated number of MSM in Ireland who may avail of PrEP within the first year of its availability to 865-2,596 (95% CI, 811-2,683). This estimate is approximately 1-3% of MSM aged 18-64 in Ireland.
- Applying the approach used in Scotland to estimate PrEP for those other than MSM, we
 considered the upper range of our PrEP estimate of 2,683, to be inclusive of other
 populations at substantial risk of sexually acquired HIV.

2 Introduction

Pre-exposure prophylaxis (PrEP) is the pre-emptive use of oral antiretroviral therapy (ART) in HIV negative people to reduce the risk of HIV infection. In 2014, the World Health Organization (WHO) recommended PrEP for men who have sex with men (MSM). However, in 2015, on the basis of further evidence of the effectiveness and acceptability of PrEP, WHO broadened its recommendation to include anyone at substantial risk of HIV infection be offered PrEP as an additional prevention choice, as part of combination prevention approaches [1].

In July 2016, the European Medicines Agency (EMA) licensed TRUVADA® for use as PrEP in combination with safer sex practices to reduce the risk of sexually acquired HIV infection in adults, making it the first medicine licensed for HIV prevention in Europe [2]. TRUVADA® is a coformulation of tenofovir disoproxil fumarate (TDF) plus emtricitabine (FTC).

As of March 2017, TRUVADA® is not available for PrEP in Ireland. However in Europe, it is available for use as PrEP in France [3] and Norway. When used in combination with safer sex practices and adherence to the dosing schedule, TRUVADA® has been found to reduce the relative risk of HIV infection by between 86 and 92% across a range of clinical settings [4-6].

In 2015, the rate of HIV diagnoses was 10.6 per 100,000 population in Ireland, the highest rate reported to date. Improvements to the national surveillance case definition in January 2015, an outbreak of HIV among people who inject drugs (PWID) and an increase in diagnoses among migrant MSM were thought to be contributors towards this increase [7]. Of note, 129 (27%) of the new diagnoses reported in 2015 had previously reported a positive HIV diagnosis abroad [8]. MSM are the group most affected by new HIV diagnoses in Ireland and since 2005, there has been a fourfold increase in new HIV diagnoses among MSM (from 60 in 2005 to 247 in 2015) [7].

In order to address one of the priority actions of the National Sexual Health Strategy [9], the HSE SHCPP established a multidisciplinary and multisectoral PrEP Working Group in May 2016. An understanding of the likely numbers of individuals eligible for PrEP was identified as an important requirement to inform decision-making about the introduction of PrEP in Ireland. Given the epidemiology of HIV in Ireland, it is anticipated that MSM will be largest group meeting criteria for use of PrEP to prevent sexually acquired HIV infection, and in this population, recent national sexual behaviour survey information is available [10].

The HSE SHCPP and HPSC convened a meeting of clinical and public health experts on 21 October 2016 (attendee list Appendix I). At this meeting, opinion and consensus was sought on:

- 1. MSM PrEP eligibility criteria for Ireland for use in estimates
- 2. The population size of MSM in Ireland
- 3. Estimated number of MSM eligible for PrEP in Ireland using data from MISI, a national online sexual behaviour study
- 4. Estimated number of MSM likely to avail of PrEP in Ireland having adjusted for self-reporting bias, likelihood of attending services and self-reported anticipated PrEP uptake from Ireland and the UK

A consultation meeting with the PrEP Working Group took place on 14 February 2017 (Attendee list in Appendix II). At this meeting, opinion and consensus was sought on:

- 1. The findings of the draft report
- 2. Inclusion of any outstanding issues that had not been considered in the report

Subsequent to the meeting of the PrEP Working Group, a revised draft report was submitted to the PrEP Working Group and Public Health HIV/STI Special Interest Group for consultation.

Thereafter, prior to publication, it was reviewed by the HSE Sexual Health Strategy

Implementation Group and the Royal College of Physicians of Ireland (RCPI) Sexual Health Clinical Advisory Group.

3 Methods

3.1 Determining eligibility criteria for PrEP

There are no standard international set of criteria for determining population eligibility for PrEP, as population groups at substantial risk of HIV differ between countries. We examined eligibility criteria from the United States [11, 12], France [13, 14], United Kingdom [15], and Australia [16]. These criteria are detailed in Appendix III.

3.2 Data source

From March to May 2015, the MSM Internet Survey Ireland (MISI), was carried out among adult MSM living in Ireland [10]. Men were asked questions about: HIV and STI testing and diagnosis; sexual behaviour; alcohol, drug and tobacco use; sexual health knowledge; awareness of health promotion and use of HIV and STI prevention strategies. We restricted our analysis to MISI respondents aged 18-64 years using the following self-reported key variables which were identified as the closest fit to the identified PrEP eligibility criteria.

- HIV status of respondents
- Condomless anal intercourse (CAI) with two or more non-steady partner(s) in the past
 12 months
- STI diagnosed in the past 12 months
- Ever treated with post exposure prophylaxis (PEP)
- Use of crystal methamphetamine, GHB or GBL, mephedrone, ketamine in the past 12 months

3.3 Determining population size of MSM in Ireland

We identified three studies [17-19] conducted between 2006 and 2015 which provided MSM population estimates in Ireland (Table 1). We applied the estimates to population numbers for 1,441,603 males in Ireland aged 18-64 years obtained from the Central Statistics Office (CSO), based on 2011 census data [20].

Table 1: MSM population in Ireland estimates sourced from Irish studies

Study name, year, reference	MSM population estimates (%)
Irish Study of Sexual Health and Relationships (ISSHR) (2006) [17]	3
My World Survey National Study of Youth Mental Health (2012) [18]	8*
Healthy Ireland Survey (2015) [19]	6

^{*} Gay or bisexual

3.4 Estimating the number of MSM eligible for PrEP at substantial risk of sexually acquired HIV

Using Stata 14 [21], we applied different international PrEP criteria to MISI data [10]. Where exact criteria to some MISI variables could not be applied, the most similar form was used. Any deviations were indicated. We applied adjustments to our estimates as detailed in sections 3.4.1-3.4.3 below and presented them with corresponding 95% confidence intervals (95% CIs). The cascade for calculating the PrEP estimates for Ireland is outlined in Figure 1.

3.4.1 Correction factor for self-reporting bias applied to MISI data

To account for self-reporting bias among MISI respondents, we applied a 50% correction factor to the estimated proportion of MISI respondents eligible for PrEP. This was based on research which found, on average, a two fold over-reporting of risk behaviour, STI outcomes and HIV testing in convenience surveys compared to probability based surveys [22]. We provide estimates without the correction factor in Appendix IV and V for sensitivity analyses.

3.4.2 MSM in existing STI and HIV testing services

Data regarding the proportion of MSM in existing STI and HIV testing services in Ireland is not available. However, in the last 12 months 15% and 17% of MSM from the Healthy Ireland Survey had an STI test or HIV test, respectively (Healthy Ireland Survey 2016 preliminary findings, personal communication), 20% of males reported having ever been tested for an STI in the Irish Contraception and Crisis Pregnancy Study 2010 [23] and 38% and 39% of MISI respondents reported having an STI and/or HIV test respectively, in the last 12 months [10]. We therefore applied ranges from 15%, 30% to 45% to provide a range of estimates for MSM in existing services.

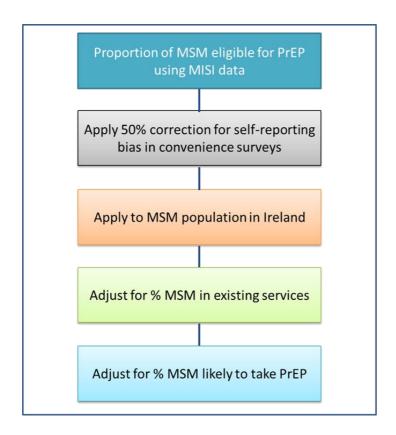


Figure 1: Cascade to estimate MSM eligible for PrEP in Ireland.

3.4.3 Assumed PrEP uptake rate

Finally, we applied a PrEP uptake rate of 58% based on results from an online survey of PrEP awareness and acceptability among MSM in Scotland, Wales, Northern Ireland and the Republic of Ireland [24].

3.5 Estimating the number of individuals eligible for PrEP at substantial risk of sexually acquired HIV

A dataset similar to MISI with sexual risk behaviour data for those other than MSM at substantial risk of HIV is not available.

When calculating PrEP estimates in Scotland, they accounted for PrEP provision by considering 5% or less of individuals other than MSM eligible to receive PrEP, which was within the calculated range of their estimate based on data for MSM [25]. We applied this approach to our PrEP estimates for Ireland based on data for MSM and considered the upper range of the estimate to be inclusive of those other than MSM at substantial risk of sexually acquired HIV.

4 Results

4.1 Proposed eligibility criteria for PrEP in Ireland

Following discussion at the consultation meeting with clinical and public health experts, there was agreement that PrEP eligibility criteria used in France [13, 14] was the most suitable for the purpose of PrEP estimates for Ireland.

In brief, PrEP is currently indicated in France for men and trans-people over 18 years of age who have sex with men and who have had CAI with at least two different sexual partners in the last 6 months; or episodes of STIs in the past 12 months; or had multiple PEP treatments in the last 12 months; or used drugs during sex [13, 14]. These criteria are outlined in full in Appendix III.

4.2 Size of the MSM population in Ireland

The 2015 Healthy Ireland Survey, which is nationally representative probability based survey, found that 6% of men had reported that their last sex was with a man [19]. This estimate was deemed to be reflective of the Irish MSM population at the consultation meeting. We applied this estimate to the CSO male population figure of 1,441,603 males aged 18-64 years, which gave an estimated 86,496 MSM in Ireland aged 18-64 years.

Community representatives on the PrEP Working Group requested that PrEP estimates for MSM in Ireland should also be calculated assuming the MSM population is 11%. A summary of PrEP estimates applied to this MSM population estimate can be found in Appendix V.

4.3 Estimates of proportion of MSM eligible for PrEP in Ireland using MISI data

Using the French PrEP eligibility criteria and applying them to MISI data, with some adaptations, we estimated that 23% (95% CI, 22.7-23.3) of MISI respondents would be eligible to receive PrEP (Table 2). These estimates are based on overlapping survey responses as shown in Figure 2.

Table 2: French PrEP eligibility criteria applied to MISI dataset

Survey questions	MISI data N (%)
Aged 18-64 years	3,045 (100)
Man/transman	3,045 (100)
Never received an HIV test result/last test was negative*	2,870 (94)
CAI with two or more non-steady partners in past 12 months**	370 (12)
Diagnosed with an STI in past 12 months	243 (8)
Ever treated with PEP***	119 (4)
Use of crystal methamphetamine, GHB or GBL, mephedrone, ketamine in the	181(6)
past 12 months****	
Eligible for PrEP	706 (23)‡

^{*}Number of men who reported to be HIV negative or did not know their HIV status

^{**}French implementation guidance is CAI with two or more partners in the **past six months**

^{***}Using MISI variable "ever used PEP" as a proxy for multiple PEP as in French PrEP eligibility criteria

^{****} French PrEP eligibility criteria broader in terms of drugs, and narrower in terms of their use during sex "use of drugs during sexual intercourse"

[‡]Number eligible for PrEP based on overlapping survey responses

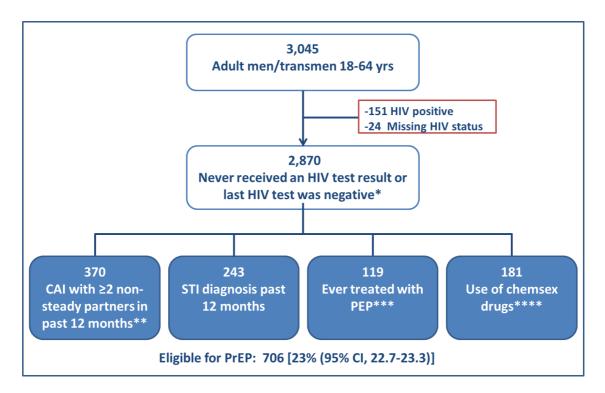


Figure 2: Estimated number of MSM eligible for PrEP applying French PrEP eligibility criteria to MISI data based on overlapping survey responses.

- *Number of men who reported to be HIV negative or did not know their HIV status
- **French implementation guidance is CAI with two or more partners in the past six months
- ***Using MISI variable "ever used PEP" as a proxy for multiple PEP as in French implementation guidance
- ****French implementation guidance broader in terms of drugs, and narrower in terms of their use during sex "use of drugs during sexual intercourse"

4.4 Estimates of MSM in Ireland eligible for PrEP based on French PrEP eligibility criteria

We used the 23% (95% CI, 22.7-23.3) of MISI respondents eligible for PrEP based on French PrEP eligibility criteria and applied it to the MSM population in Ireland, estimated to be 86,496, to obtain a crude estimate of 19,894 MSM (95% CI, 19635-20154) eligible for PrEP in Ireland. To account for self-reporting bias, we applied a 50% correction factor to proportion of MISI respondents eligible for PrEP, and applied this adjusted estimate (11.5% (95% CI, 11.3-11.7)) to the 6% MSM population, to obtain an estimated 9,947 MSM (95% CI, 9765-10129) eligible for PrEP in Ireland.

4.5 Adjustment of PrEP estimate with MSM engaged in existing services

Not all MSM at risk of HIV are engaged with existing services. In the absence of national data on the proportion of MSM engaged in services, we applied the following estimates from 15%,

30% to 45%. This adjusted the estimated number of MSM likely to present for PrEP in Ireland to between 1,492 and 4,476 MSM (95% CI, 1423-4574) (Table 3).

Table 3: Estimates with corresponding 95% confidence interval (95%CI) for the 11.5% MSM eligible for PrEP adjusted for self-reporting bias by proportion currently engaged in services

11.5% MSM eligible for PrEP adjusted for self-reporting bias n	15% engaged in services (95%CI)	30% engaged in services (95%CI)	45% engaged in services (95%CI)
	1,492	2,984	4,476
9,947	(1423-1562)	(2896-3075)	(4379-4574)

4.6 Assumed uptake of PrEP by eligible MSM in Ireland

We chose 58% for the assumed uptake of PrEP [24]. Applying this rate, approximately 865-2,596 MSM (95% CI, 811-2683) would likely avail of PrEP in Ireland, depending on the proportion of MSM engaged in services (Figure 3).

This suggested estimate of 865-2,596 MSM (95% CI, 811-2683) eligible for PrEP equates to 1-3% of the Irish MSM population aged 18-64 years who are likely to take PrEP, if available and PrEP will be available to all age groups who meet PrEP eligibility criteria.

4.7 PrEP estimates for other populations at substantial risk of sexually acquired HIV

Applying the approach used in Scotland to estimate PrEP for those other than MSM [25], we considered the upper range of our PrEP estimate of 2,683, to be inclusive of other populations at substantial risk of sexually acquired HIV (Figure 3).

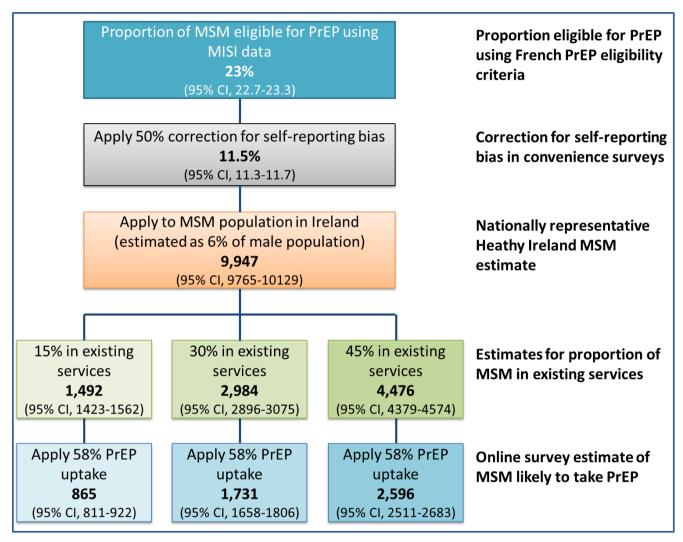


Figure 3: PrEP estimate cascade with corresponding 95% confidence intervals (95%CI), assuming 6% of the male population in Ireland are MSM and correcting for self-reporting bias.

5 Discussion

In order to have an estimate of the size of the MSM population in Ireland, we used the 6% estimate from the Healthy Ireland Survey [19], which is a nationally representative survey. With some adaptations, we applied the eligibility criteria used for PrEP in France [13, 14] to data from MISI [10].

To estimate the number of MSM in Ireland who would be eligible for PrEP, we corrected the proportion eligible for PrEP we obtained using MISI data for self-reporting bias to account for over-reporting of sexual risk behaviours in convenience sampling versus nationally representative sampling [22]. Although the study size was large, MISI respondents cannot be taken as representative of the MSM population in Ireland. Additionally, not all MSM in Ireland eligible for PrEP are engaged with existing services. Therefore, in the absence of nationally representative data, we applied a range of estimates for the proportion of MSM engaged with services. Finally, we adjusted the estimate to account for anticipated uptake of PrEP [24], and found that an estimated 865-2,596 MSM (95% CI, 811-2683) in Ireland were likely to avail of PrEP. This equates to 1-3% of the Irish MSM population aged 18-64 years and this is intended to reflect what may be experienced in existing services during the first year of PrEP availability.

There are some limitations to the methodology used for calculating these estimates. We were unable to apply some of the exact French PrEP eligibility criteria to the MISI data. However, where deviations occurred, these were indicated. In relation to the use of data from MISI to calculate the estimates, we applied a correction factor to account for a likely over estimation of various behaviours among MISI participants [22]. The estimate for PrEP uptake is based on information from an online survey of anticipated uptake in the event of PrEP availability [24]. Applying results from an online survey may not reflect actual uptake when an individual is presented with the option of going on PrEP.

As mentioned, MSM are likely to represent the largest group of those at risk for HIV meeting criteria for PrEP. This exercise has determined estimates for MSM, but has not taken account of those eligible in other risk groups i.e. sexually active heterosexuals at substantial risk of HIV acquisition, as datasets with sexual risk behaviours among these groups are not available. Scotland estimated the number eligible for PrEP among both MSM or non-MSM at risk of HIV by considering the upper range of their estimate, which was 1,100 individuals [25]. Applying this approach, we considered the upper bound of our estimate of 2,683, to be inclusive of other populations at substantial risk of sexually acquired HIV. The United States estimated that 18.5%

of PWID, and 0.4% of heterosexually active adults were eligible for PrEP [12].

Of note, in France, with a population ten times that of Ireland, 3,000-4,000 individuals availed of PrEP in its first year of PrEP roll out (Molina JM, personal communication).

It is important to acknowledge that the views of the MSM community [26] and relevant health care professionals [27] are that PrEP is available to all individuals at substantial risk of HIV acquisition, not just MSM. Further, that PrEP is available as part of an overall HIV prevention package, with an overall aim of reaching zero HIV transmission. Reported antiretroviral therapy coverage in Ireland is high and therefore likely numbers in serodiscordant relationships at risk is small [27].

6 Recommendations

We recommend that these PrEP estimates are reviewed following any roll out of PrEP in Ireland, in order to review sexual and/or substance use behaviour reporting and uptake of PrEP among MSM. Following from this, the estimates should be reviewed one year after PrEP implementation to calculate future projections. It is important to monitor PrEP uptake to assess its utilisation and to support the development of targeted implementation programs and policies to increase access for populations most at risk of HIV acquisition.

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8 Appendices

Appendix I: Consultation day attendee list with clinicians and public health experts

Attendee	Affiliation
Derval Igoe (Co-chair)	HSE Health Protection Surveillance Centre, Dublin
Fiona Lyons (Co-chair)	HSE Sexual Health & Crisis Pregnancy Programme, Dublin
Andrea Holmes	Bon Secours Hospital, Galway
Aoife Cotter	Mater Misericordiae University Hospital, Dublin
Caroline Hurley	HSE Sexual Health & Crisis Pregnancy Programme
Caroline Mason Mohan	Department of Public Health, HSE-West
Colm Bergin	St. James's Hospital, Dublin
Eve Robinson	HSE Health Protection Surveillance Centre, Dublin
Helen Hanley Hickey	University Hospital Limerick
Kate O'Donnell	HSE Health Protection Surveillance Centre, Dublin
Laura Nic Lochlainn	HSE Health Protection Surveillance Centre, Dublin
Liam Townsend	University Hospital Galway
Mary Dennehy	University Hospital Waterford
Paddy Mallon	Mater Misericordiae University Hospital, Dublin
Sam McConkey	Beaumont Hospital, Dublin
Sarah Doyle	Department of Public Health, HSE-South-East
Susan Clarke	St. James's Hospital, Dublin
Suzanne Cremin	South Infirmary Victoria University Hospital, Cork

Appendix II: Consultation day attendee list with PrEP Working Group

Attendee	Affiliation
Fiona Lyons (Chair)	HSE Sexual Health & Crisis Pregnancy Programme, Dublin
Derval Igoe	HSE Health Protection Surveillance Centre, Dublin
Caroline Hurley	HSE Sexual Health & Crisis Pregnancy Programme
Kate O'Donnell	HSE Health Protection Surveillance Centre, Dublin
Laura Nic Lochlainn	HSE Health Protection Surveillance Centre, Dublin
Mick Quinlan	Gay Health Network, Dublin
Noel Sutton	Gay Health Network, Dublin
Siobhan O'Dea	HSE Gay Men's Health Service
Shay Keating	National Drug Treatment Centre, , Dublin
Dominic Rowley	St James's Hospital, Dublin
Áine Duggan	GLEN LGBTI Equality Network
Arthur Jackson	Mercy University Hospital, Cork, Ireland.
Sile Dooley	St James's Hospital, Dublin
Miriam Moriarty	St James's Hospital, Dublin
Laura Mc Cullagh	National Centre for Pharmacoeconomics, Dublin
Caroline Mason Mohan	Department of Public Health, HSE-West
Linda Latham	HSE Women's Project, Dublin
Susan Clarke	HSE Gay Men's Health Service and St. James's Hospital, Dublin
Patricia Cremin	University Hospital Galway

Appendix III: International PrEP eligibility criteria

U.S. Public Health Service's clinical practice guidelines for PrEP [11]

- 1. Adult male
- 2. Without acute or established HIV infection
- 3. Any male partner in past six months
- 4. Not in a monogamous relationship with a recently tested HIV-negative man

AND at least one of the following:

- a) Any anal sex without condoms (receptive or insertive in past 6 months)
- b) Any STI diagnosed or reported in the past 6 months
- c) Is in an ongoing sexual relationship with an HIV positive male partner

US PrEP estimates based on available nationally representative data [12]

- 1. Men aged 18-59 years
- 2. Not known to be HIV positive
- 3. Sex with 2 or more men in past 12 months

AND at least one of the following:

- a) Any reported condomless sex in past 12 months
- b) STI diagnosis in past 12 months
- c) HIV status of partners could not be established

France PrEP eligibility criteria [13, 14]

PrEP is currently indicated in France for all persons over the age of 18 who do not routinely use condoms during sexual intercourse and who are at substantial risk of contracting HIV. In particular, gay men and trans people who have sex with men and at least one of the following criteria:

- Anal sex without a condom with at least two different sexual partners in the last 6 months
- b) Episodes of STIs in the past 12 months
- c) Multiple PEP treatments in the last 12 months
- d) Use of drugs during sex

UK PrEP proposed eligibility criteria for Group 1 [15]

MSM and trans women who are currently HIV negative and who are clinically assessed to be at substantial risk of HIV acquisition.

a) Have a documented confirmed HIV negative test during an earlier episode of care in the preceding year (i.e. 42-365 days ago)

AND

b) Report condomless intercourse in the previous 3 months

AND

c) Affirm likelihood of repeated condomless intercourse in the next 3 months

NSW Behavioural eligibility criteria for PrEP among "high risk" MSM (New South Wales Ministry of Health 2016) [16]

Being likely to have multiple events of condomless anal intercourse (CLAI), with or without sharing intravenous drug equipment, based on behaviour in the next 3 months (indicating sustained risk).

AND having any of the following:

- a) Regular sexual partner of an HIV-infected man (not on treatment and/or detectable viral load) with whom condoms were not consistently used in the last 3 months
- b) At least one episode of receptive CLAI with any casual HIV-infected male partner or a male partner of unknown HIV status in the last 3 months
- c) Rectal gonorrhoea, rectal chlamydia or infectious syphilis diagnosis during the last 3 months or at screening
- d) Methamphetamine use in the last 3 months

Appendix IV: PrEP estimate cascade assuming 6% of the male population in Ireland are MSM and without correcting for self-reporting bias

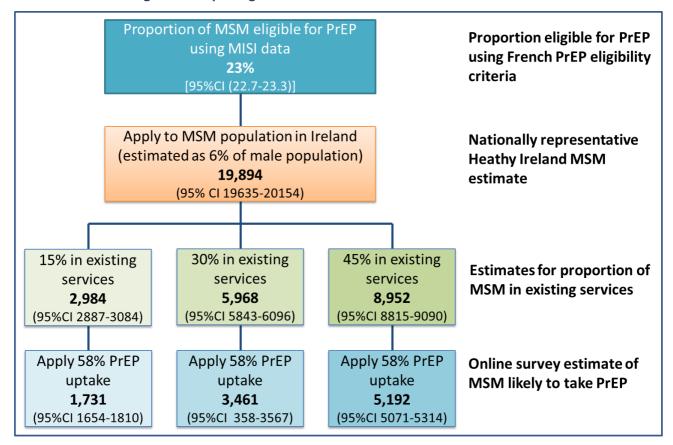


Figure IV: PrEP estimate cascade with corresponding 95% confidence intervals (95%CI), assuming 6% of the male population in Ireland are MSM and without correcting factor for self-reporting bias.

Appendix V: PrEP estimate cascade assuming 11% of the male population in Ireland are MSM with and without correction factor for self-reporting bias

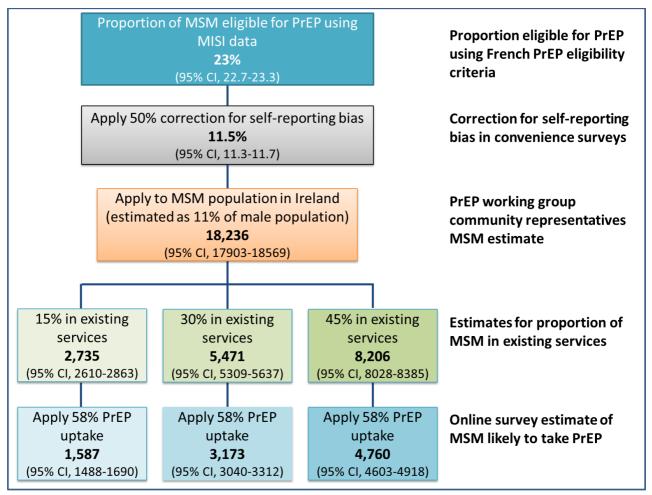


Figure V(a): PrEP estimate cascade with corresponding 95% confidence intervals (95%CI), assuming 11% of the male population in Ireland are MSM and correcting for self-reporting bias.

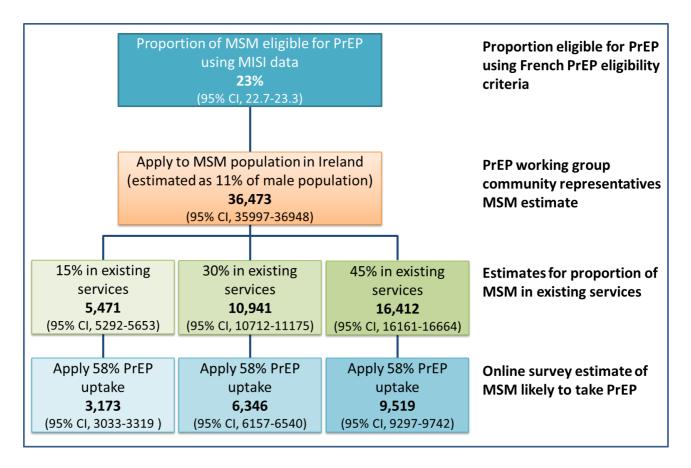


Figure V(b): PrEP estimate cascade with corresponding 95% confidence intervals (95%CI), assuming 11% of the male population in Ireland are MSM and without correcting factor for self-reporting bias.