Clinical management guidance for individuals taking HIV PrEP within the context of a combination HIV (and STI) prevention approach in Ireland

May 2022
Amendment September 2022
Language amendment March 2023

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Guideline Revisions

September 2022
An amendment was made to the guidelines in September 2022 around the PrEP dosing schedule for trans men and trans women.

March 2023
HIV language was updated to 'people living with HIV' where appropriate in line with the People First Charter. This does not include the text quoted from other publications in the appendices.

1. Background and Development Process

Worldwide HIV remains a significant cause of morbidity and mortality with an estimated 37.6 million people living with HIV at the end of 2020 and an estimated 1.5 million new HIV infections in that year[1]. Provisional data from the Health Protection Surveillance Centre, examining trends between 2019 and 2020, in Ireland, report 532 HIV notifications in 2019 giving a rate of 11.2 per 100,000 population which represents a 2% increase compared to 2018 (n=522)[2]. In 2020, there were 444 notifications giving a rate of 9.3 per 100,000 population which represents a 17% decrease compared to 2019[3]. In recent years, gay, bisexual and men who have sex with men (gbMSM) have borne a significant proportion of the burden of new HIV diagnoses in Ireland, with sex between men reported as the likely route of transmission in 262 (53%) of the 492 new HIV diagnoses in 2017[4]. A further 33% of cases were reported as being heterosexually acquired indicating that the vast majority of new cases of HIV (86%) in Ireland were sexually acquired.

There are a number of effective strategies to prevent sexual acquisition of HIV and other sexually transmitted infections (STIs). These include HIV testing; STI testing and treatment; condoms; vaccination; health promotion and risk reduction education; support and education around sexual behaviour, alcohol and substance misuse; pre-exposure prophylaxis (PrEP); post exposure prophylaxis following sexual exposure (PEPSE) and, treatment as prevention (TasP) for people living with HIV.

HIV PrEP is the most recently developed effective HIV prevention intervention. Currently licensed PrEP is the pre-emptive use of oral antiretroviral therapy (combination tenofovir disoproxil fumarate/ emtricitabine) by HIV-negative people to reduce the risk of HIV infection. The Health Information Quality Authority (HIQA) concluded a health technology assessment on the introduction of a PrEP programme in Ireland in 2019. From reviewing the evidence, HIQA found that PrEP is safe and highly effective at preventing HIV in people at substantial risk. Additionally, implementing a PrEP programme would be considered cost saving compared with standard care[5]. Ireland began implementation of a national PrEP programme in November 2019 with ring-fenced funding of €5.4 million in budget 2020.

One of the priority clinical actions in the National Sexual Health Strategy[6] is to develop and implement guidance on the use of antiretroviral therapy, including PrEP, for HIV prevention. Responsibility for implementation of the sexual health strategy lies with the HSE Sexual Health and Crisis Pregnancy

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[1] https://www.hiv.gov/hiv-basics/overview/data-and-trends/global-statistics

[2] HSE Health Protection Surveillance Centre. HIV in Ireland: Latest trends including 2019 and 2020 provisional data, November 2021. https://www.hpsc.ie/a-z/hivandaids/hivdataandreports/HIV_trends_provisional_20192020_v3.pdf

[3] Due to the impact of the COVID-19 pandemic, there was a reduction in the number of HIV notifications during 2020. This is likely to be due to a number of factors including long periods of national lockdown, social and physical distancing measures; reduced sexual health and GP services and reduced testing opportunities. The COVID-19 pandemic also affected the collection and reporting of enhanced data variables, such as probable route of transmission, region of origin, history of previous positive test, for HIV notifications during 2019 and particularly during 2020. Initiatives to improve data quality are currently underway but all enhanced data for this time period should be interpreted with caution.

[4] HSE Health Protection Surveillance Centre. HIV in Ireland, 2017. Dublin: HSE HPSC; 2018. http://www.hpsc.ie/a-z/hivstis/hivandaids/hivdataandreports/2017reports/

[5] HTA of a PrEP programme, https://www.hiqa.ie/reports-and-publications/health-technology-assessment/hta-prep-programme

[6] http://health.gov.ie/healthy-ireland/national-sexual-health-strategy-2015-2020/

Programme (SHCPP). To address PrEP, the programme previously convened a multisectoral HIV PrEP working group to develop recommendations and guidelines in relation to PrEP in Ireland.

The working group developed National standards[7] which were agreed by both the Sexual Health Strategy Clinical Advisory and Implementation Groups. There are a number of core standards which must be met by services providing free PrEP. There are additional desirable standards for delivery of HIV PrEP as part of combination HIV prevention, which services are encouraged to meet.

The first set of national guidelines on PrEP[8] was published in November 2019 and listed for review in October 2021. The guidelines set out the clinical eligibility criteria for access to free PrEP for individuals in addition to guidelines for assessment and follow up of individuals in receipt of PrEP.

In preparing this updated document, the Medical Director/Clinical Lead of SCHPP reviewed international guidelines, undertook a literature review and convened a guideline review group comprising the identified PrEP clinical leads at public services in Ireland, tasked with developing a draft document. The draft document was made available for review and consultation by relevant stakeholders in January 2022 with amendments made where required. Prior to publication the guidelines were presented to the HSE Chief Clinical Officer (CCO) Clinical Forum. In parallel the patient information leaflet was updated to reflect guideline changes and key stakeholder feedback on previous versions.

This current document sets out the updated clinical eligibility criteria for free PrEP and updated guidelines on the assessment and monitoring of those on PrEP. The guidelines on assessment and monitoring of those on PrEP are relevant to all those in receipt of PrEP, not just those who meet criteria for free PrEP.

Key changes are in the following areas:

- Eligibility criteria
    - addition of likely to engage in condomless anal sex in the next three months
- Follow up and monitoring
    - Incorporation of the 45 day window period for HIV testing
    - Renal monitoring
    - Frequency of follow up determined by potential exposure
    - Online STI/HIV testing option for stable patients
- New section on when PEPSE is needed in people taking PrEP

This document is listed for review in May 2024. In the interim, urgent changes will be made where required. The programme has responsibility for arranging, coordinating and disseminating any changes to this document to all relevant stakeholders.

[7] www.sexualwellbeing.ie/prepproviders

[8] Clinical management guidance for individuals taking HIV PrEP within the context of a combination HIV (and STI) prevention approach in Ireland. HSE. Version 1.1 October 2019. Available from Sexual Health & Crisis Pregnancy Programme (SHCPP) upon request.

2. Scope and Purpose of this document

This document is intended for use by appropriately trained health care providers involved in the provision of care to individuals at substantial risk for sexual acquisition of HIV who may be eligible for free PrEP and to individuals who are taking PrEP but do not meet criteria to receive it free of charge. This document is intended for use alongside the national standards for PrEP.

This document sets out the agreed, evidence-based, clinical eligibility criteria for free PrEP through the HSE in Ireland.

Additionally, this document sets out guidance on assessment and follow up of those taking PrEP.

It is anticipated that the clinical guidance aspect of this document may be adapted within services as local clinic protocols are developed. It is recognised that in some circumstances the optimum management of a patient may be outside these guidelines. Deviation from these guidelines is not recommended unless under the supervision of a consultant in Genitourinary Medicine or Infectious Diseases.

This document does not address the use of PrEP in non-sexual contexts. People who inject drugs may be at risk of sexual acquisition of HIV and therefore may otherwise be suitable for PrEP.

3. How is PrEP available in Ireland?

PrEP is available free of charge through the HSE to those who meet clinical eligibility criteria and are deemed to be at substantial risk of acquiring HIV through sexual exposure.

In developing clinical eligibility criteria for free PrEP, the guideline review group has considered eligibility criteria in other jurisdictions and the available evidence around risk of sexual acquisition of HIV across a range of situations in a variety of populations. A summary of the evidence is presented in **Appendix 1**.

Other individuals who do not meet eligibility criteria for PrEP may elect to pay for PrEP medication themselves. There are certain situations in which PrEP is not recommended as set out in section 3.2. Regardless of how individuals avail of PrEP, the assessment and monitoring principles as set out in later sections are recommended.

3.1 Who is clinically eligible for free PrEP?

HIV negative individuals who are aged 17 years or older[9] and fall into one of the categories set out below:

1. **Men who have sex with men[10] or transgender women who have sex with men who are:**
    - sexually active with likelihood of remaining sexually active in the next 3 months

[9] In Ireland the age of consent for sexual intercourse is 17 years. The age of consent for medical treatment is 16 years. A combination of tenofovir disoproxil and emtricitabine is licensed for use as HIV PrEP in adolescents. Individuals under 17 years of age who are otherwise eligible for PrEP should be offered PrEP with due regard to child protection and safeguarding in line with current legislation and local clinic policy.

[10] This term includes transgender men, recognising that whilst there is an absence of data in this group, the risk is likely to be substantial as they are in the same sexual networks as other men who have sex with men.

AND one of the following:

- reported condomless anal sex with at least two partners[11] over the last 6 months
- likely to engage in condomless anal sex in the next 3 months
- episode of documented or reported acute STI[12] over the last 12 months
- documented or reported use of HIV post-exposure prophylaxis following sexual exposure (PEPSE) over the last 12 months
- reported engagement in chemsex[13] over the last 6 months

2. **Individuals having condomless sex with a person living with HIV who is not stably suppressed on antiretroviral therapy, specifically:**
    - where the person living with HIV is not on antiretroviral therapy
    - where the person living with HIV has initiated antiretroviral therapy but has not yet achieved virological suppression to <200copies/ml over a 6 month period of treatment
    - where the person living with HIV has loss of virological control on antiretroviral therapy and the risk of HIV transmission has been deemed by a consultant in Genitourinary Medicine/ Infectious Diseases, with experience in management of HIV, to be substantial and warrant PrEP for the HIV-negative partner.

    Additional Guidance for these situations:
    - In these circumstances, the HIV-negative person and the person living with HIV may be attending the same clinical service and present for assessment together. Both parties should be advised to use condoms and made aware of post exposure prophylaxis (PEPSE).
    - Where they are not attending the same clinical service, liaison between services is recommended before making decisions regarding PrEP. Consent for sharing of information from both parties should be sought before information is shared.
    - In exceptional circumstances, where an individual is known to be at risk and consent for sharing of information, from either party, with other clinicians is not forthcoming, information may need to be shared without consent between clinicians in line with Irish Medical Council guidance.[14]

3. **Other individuals considered by a consultant in Genitourinary Medicine/Infectious Diseases, with experience in management of HIV, to be at substantial risk for sexual acquisition of HIV.**

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[11] Where the HIV status of the partner(s) is unknown to the potential PrEP candidate.

[12] Acute STIs include (but are not necessarily limited to) gonorrhoea, chlamydia, LGV, primary HSV, acute sexually acquired hepatitis B, acute sexually acquired hepatitis C and early infectious syphilis. Available evidence indicates that rectal bacterial infections are associated with a greater risk of HIV infection than overall bacterial STIs, see **Appendix 1**. Acute STIs do not include anogenital warts or non-primary HSV.

[13] Chemsex is intentional sex under the influence of psychoactive drugs, mostly among MSM and particularly associated with crystal methamphetamine, GHB/GBL, mephedrone and sometimes ketamine.

[14] https://issuu.com/mcirl/docs/guide_to_professional_conduct_and_e?e=12642421/35694606

3.2 Who is not eligible for free PrEP?

A person who is:

- in a monogamous relationship with a partner who is living with HIV confirmed to be stably virally suppressed on ART[15]
- in a monogamous relationship with a partner who is known to be HIV negative
- unwilling to attend for follow up.

3.3 Situations where PrEP may be harmful

- Individuals who report sub-optimal adherence (for daily dosing schedules - less than 4 days a week for anal sex protection and less than 6 days a week for vaginal sex protection) with continued significant risk for sexual acquisition of HIV.
    - Consider the need for PEPSE.
    - There is a substantial risk for acquisition of HIV and subsequent development of antiretroviral resistance.
    - Support may be required around adherence, modification of HIV risk through support on other risk reduction strategies, alcohol and substance misuse (including chemsex).
    - Where there is continued suboptimal PrEP adherence with continued risk of HIV acquisition, PrEP should not be continued.
- Significant renal impairment (eGFR <60mls/min1.73m^2) at baseline or that develops while taking PrEP
    - Significant renal impairment (eGFR <60mls/min1.73m2) at baseline or that develops while taking PrEP. Such situations should be managed by a consultant in Genitourinary Medicine or Infectious Diseases with experience in PrEP delivery and access to Renal Medicine assessment. Moving from daily dosing to an event-based schedule may be an option in this circumstance. Switching to a tenofovir alafenamide (TAF) based regimen may be clinically appropriate but TAF based PrEP is not currently funded. See **Appendix 2** for additional detail on renal monitoring and thresholds.

3.4 Contraindications to PrEP (at baseline and in follow up)

If a person:

- is HIV positive
- has an undocumented HIV status
- is allergic to tenofovir disoproxil and/or emtricitabine.

[15] Suppressed to <200copies/ml for at least 6 months

3.5 PrEP and pregnancy

HIV seroconversion in pregnancy represents a significant risk for vertical transmission of HIV[16] [17].

The antiretroviral pregnancy registry collects information on pregnancy outcomes in women living with HIV taking antiretroviral therapy in pregnancy. The most recent report from January 1989 through to 31st of January 2021 did not identify increased birth defect rates compared to two general population registers in the United States (Metropolitan Atlanta Congenital Defects Programme, 2.72%, 95% CI 2.68-2.76 and Texas Birth Defects Register 4.17%, 95% CI 4.15-4.19) following first trimester exposure to tenofovir disoproxil fumarate (108/4483, 2.41%, 95% CI 1.98 – 2.90) or emtricitabine (104/3952, 2.63%, 95%CI 2.15-3.18)[18].

Limited information on the use of PrEP in pregnancy in women at risk for HIV did not identify any PrEP-related pregnancy complications with a median duration of PrEP exposure of 30 weeks in 16 women[19].

Pregnant people at substantial risk of sexual acquisition of HIV should be informed of the protective effect of PrEP in averting HIV infection and informed of the available information in relation to the safety of use of tenofovir disoproxil and emtricitabine in pregnancy. People at substantial risk of HIV who meet eligibility criteria should be offered PrEP as part of combination HIV prevention regardless of pregnancy status or risk of conception. Pregnancy status should be established in people who can become pregnant who are being considered for PrEP and taking PrEP.

3.6 Other situations

Some individuals may not meet the eligibility criteria for free PrEP but elect to pay for PrEP themselves. In such circumstances, individuals are encouraged to have HIV and STI testing in line with exposure risk, renal monitoring and be linked with an appropriate service for ongoing assessment whilst taking PrEP.

4. Clinical assessment

This section outlines the potential steps in a patient journey from being identified as being at substantial risk of HIV, through to being assessed for PrEP, taking PrEP and being followed up whilst on PrEP. It is anticipated that services will adapt this to develop clinic specific protocols, including the development of telephone and other virtual clinical assessments.

It is recognised that many services rapidly adapted their service delivery to ensure ongoing care, in line with national standards, during the COVID19 pandemic. Many of these rapid adaptations have been successful

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[16] Paediatric HIV: the experience in Ireland 2004-2011. Al-Assaf N1, Maoldomhnaigh CO, Gavin P, Butler K. Ir Med J. 2013 Jul-Aug;106(7):198-200.

[17] Targeting points for further intervention: a review of HIV-infected infants born in Ireland in the 7 years following introduction of antenatal screening. Ferguson W, Cafferkey M, Walsh A, Butler K. J Int Assoc Physicians AIDS Care (Chic). 2008 Jul-Aug;7(4):182-6. doi: 10.1177/1545109708320685. Epub 2008 Jul 14

[18] http://www.apregistry.com/forms/interim_report.pdf, accessed 5th October 2021

[19] Use of HIV pre-exposure prophylaxis during the preconception, antepartum and postpartum periods at two United States medical centers. Seidman DL et al. Am J Obstet Gynecol. 2016 Nov;215(5):632.e1-632.e7. doi: 10.1016/j.ajog.2016.06.020. Epub 2016 Jul 19

in building efficiencies into services, including telephone and other virtual health consultations. The table of recommended assessments is outlined in **Appendix 2: PrEP clinical assessment checklist**

4.1 Identifying people at risk of HIV

Some people may recognise their risk of HIV and self-refer for PrEP assessment and some may have been referred for PrEP assessment. Others may not recognise that they are at substantial risk of HIV or may not be aware of PrEP. In such circumstances HIV risk and eligibility for PrEP will become apparent on sexual history taking.

In assessing people at risk for HIV, consideration needs to be given to timing of last potential exposure, type of exposure and need for PEPSE.

- Consultations should be able to identify people at substantial risk of HIV (and eligible for PrEP) from their sexual history, anticipated future sexual behaviour, history of STIs, history of PEPSE use, history of chemsex by determining:
    - Last sex
        - Type of sex (anal, vaginal, oral and insertive, receptive or both[20])
        - Use of condoms
    - Number of sexual partners in the last 3 months
        - Type of sex (anal, vaginal, oral and active, passive or both)
        - Use of condoms
    - For MSM or trans women having sex with men
        - Number of condomless anal sex partners in the last 6 months
    - HIV status of sexual partners
        - If partner is living with HIV, document treatment status and virological suppression status
    - STIs in the last 12 months
    - PEPSE in the last 12 months
    - Use of chems during sex in the last 6 months
        - Individuals who engage in chemsex should be asked about "slamming" (injecting drug use) and informed of safe injection and needle sharing practice.
        - More information on chemsex and support services is available through the HSE Drugs and Alcohol helpline (Tel 1800 459 459) and on the drugs.ie, http://drugs.ie/ghb and Man2Man.ie websites, http://man2man.ie/alcohol-drugs-cigarettes/chemsex/.
        - For information or referral in regard to GHB/Crystal Meth Detoxification, contact the National Drug Treatment Centre on 01 6488600 and ask for the Club Drug Clinic, the referral form is available on https://www.sexualwellbeing.ie/for-professionals/supports/club-drugs-clinic-ireland/.

[20] Insertive sex is also referred to as active or "top". Receptive sex is also referred to as passive or "bottom". Some individuals engage in insertive and receptive sex and are sometimes described as "versatile".

4.2 Addressing HIV risk and baseline assessment of those eligible for free PrEP or otherwise wishing to take PrEP

For individuals eligible for free PrEP or considering paying for PrEP, consultations should include:

- Provision of information on HIV/STI risk reduction
    - safer sex practices, provision of condoms, where indicated brief intervention regarding alcohol, drugs (including information around safer injecting and needle exchange for individuals "slamming" chems) and further support/referral if required
- Documentation of medical conditions
    - If PrEP is being considered, renal conditions and other medical conditions that may impair renal function, for example, diabetes mellitus and hypertension
    - If PrEP is being considered, bone conditions or risk factors for low bone mineral density (see **Appendix 2**)
- Documentation of current medication(s)
    - If PrEP is being considered, medications (including over the counter drugs and supplements, particularly protein supplements) that may be nephrotoxic should be documented.
    - Long term use of PrEP in combination with medicines that may impact on bone metabolism, for example phenytoin and carbamazepine, may warrant assessment of bone density.
    - Currently available PrEP (tenofovir disoproxil/emtricitabine) is not anticipated to have significant interactions with the majority of other medications, including gender affirming hormones. The University of Liverpool HIV drug interaction checker is a valuable HIV drug-drug interaction resource freely available here, https://www.hiv-druginteractions.org/checker. However, given that some studies have shown a reduction in tenofovir exposure in transwomen taking feminising hormones daily dosing is recommended in this group unless under the supervision of a consultant in Genitourinary Medicine or Infectious Diseases (see appendix 2)
- Documentation of drug allergy status
- Clinical examination as required
- Baseline investigations include
    - HIV testing
        - 4th generation laboratory venous blood HIV test
        - Rapid HIV testing can be performed (4th generation) to enable same day PrEP initiation but should not replace 4th generation laboratory venous blood testing
    - HIV viral load testing should be performed in individuals reporting symptoms and signs suggestive of HIV seroconversion[21]. PrEP should NOT be started until HIV infection has been excluded in those with symptoms and signs of HIV seroconversion. Individuals in these

[21] Common symptoms of HIV seroconversion are rash and fever. Other symptoms include arthralgia, sore throat, malaise and headache. Not all individuals' experience or report symptoms of HIV seroconversion.

circumstances should have their care managed by a consultant in Genitourinary Medicine/Infectious Disease with experience in HIV diagnosis and diagnostics.

- HIV viral load testing should be considered in individuals reporting a particularly high risk exposure in the preceding 4-6 weeks. Deferral of PrEP initiation should be considered until HIV infection has been excluded. Individuals in these circumstances should have their care managed by a consultant in Genitourinary Medicine/Infectious Disease with experience in HIV diagnosis and diagnostics.
- Hepatitis B sAg testing and additional Hepatitis B markers as directed by history unless documented as hepatitis B immune. Individuals identified as having Hepatitis B infection should have their care managed by a consultant in Genitourinary Medicine/Infectious Disease with experience in managing Hepatitis B infection in collaboration with Hepatology services.
- Hepatitis A IgG testing if previous vaccination not reported or not documented as hepatitis A immune
- Syphilis serology
- Hepatitis C testing in line with national guidelines
  - All MSM should have baseline and at least annual hepatitis C testing
  - see **Appendix 2** for further details on hepatitis C testing
- Chlamydia and gonorrhoea NAAT testing from all relevant anatomical sites (can be self-taken or provider taken)
  - where indicated gonorrhoea culture from urethra, pharynx and rectum
- Check serum creatinine, eGFR and urinalysis[22]

- Provide treatment as required, including PEPSE where indicated
- Offer vaccination as indicated, in line with national guidelines, see **Appendix 2**
  - Hepatitis A and B, HPV
- Discuss PrEP and provide written information (see Patient Information Leaflet[23])
- For patients requiring PEPSE, arrangements should be made to start PrEP at the end of the PEPSE course
- If eligible for free PrEP, document PrEP eligibility
- Confirm contact details and preferred mechanism for contacting where need arises.

4.3 Starting PrEP

- Confirm negative HIV status
  - Confirmed negative 4th generation venous blood HIV test within last 4 weeks
  - To avoid unnecessary delays in PrEP initiation, it is appropriate to give the PrEP prescription at the time of initial PrEP assessment with an agreed mechanism to inform the person of

[22] If considering same day initiation of PrEP it is not necessary to wait for these results before PrEP initiation but may be prudent to do so in those at risk of chronic kidney disease (for example hypertension, diabetes, >40 years)

[23] PrEP patient information is available on www.sexualwellbeing.ie/prep and leaflets can be ordered through www.healthpromotion.ie

the HIV result before starting PrEP. A same day rapid HIV test[24] with a 4th generation venous blood test in process can be considered.

- Determine if in HIV window period[25] at time of baseline HIV test and arrange for repeat HIV testing at 6 weeks. PrEP can be initiated in these circumstances once symptoms/signs of HIV seroconversion have been excluded and the potential exposure is not deemed to be very high risk and the patient is aware to make contact in the event of developing symptoms of HIV seroconversion.
- Determine if symptoms or signs of HIV seroconversion (see 4.2 re HIV viral load testing and deferring PrEP initiation in this situation). Individuals in these circumstances should have their care managed by a consultant in Genitourinary Medicine/Infectious Disease with experience in HIV diagnosis and diagnostics.
- Check results from previous visit, if applicable
    - Treat STIs, offer vaccination where required
- Check serum creatinine, eGFR results, where available
    - Review medical history and determine when next creatinine check indicated
    - See clinical assessment checklist, **Appendix 2**, for frequency of renal monitoring and recommendations in the setting of impaired renal function
    - Discuss the importance of renal monitoring and potential for renal function decline and loss of bone density in the setting of PrEP
- Discuss PrEP and document patients decision regarding starting
    - Discuss lead in times, adherence and dosing schedule, see **Appendix 2** and section 4.5 on missed doses, need for PEPSE
- Address any queries in relation to PrEP and follow up
- Prescribe tenofovir disoproxil/emtricitabine one tablet once daily or for event based dosing if appropriate
- Confirm contact details and preferred mechanism for contacting where need arises.

4.4 Follow up visits

- In general all patients taking PrEP should have three monthly HIV/STI testing.
- All patients taking PrEP should have a renal profile performed three months after initiation. Subsequent renal monitoring will be determined by results, age, co-medication and co-morbidities as outlined in **Appendix 2**.
- For patients taking event based PrEP the frequency of follow up will be determined by potential exposure risk. For example if a person has not had any sexual contacts since they last had a negative screen and there are no concerns that they were within a HIV or syphilis window period at that time, HIV/STI testing can be deferred. Therefore, for some patients three monthly visits will not be necessary. Services should develop mechanisms for communicating follow up needs with patients on event based PrEP.

[24] Oral rapid HIV tests are not recommended in this circumstance
[25] The window period for a 4th generation laboratory HIV test is 45 days, https://www.bhiva.org/file/5f68c0dd7aefb/HIV-testing-guidelines-2020.pdf

- For some individuals it is appropriate to have some follow up visits via telephone or other virtual assessment methods. This is at the discretion of the clinical lead at each PrEP service.
- Determine if still taking PrEP
    - If no longer taking, determine and document reason(s) for stopping and assess understanding of when to seek PEPSE/PrEP in future
    - Assess adherence and understanding of starting/stopping rules, missed doses and when to seek PEPSE
- Reassess eligibility criteria
    - Document if still eligible or no longer eligible
    - If eligible, document whether or not wishes to continue PrEP
- Reiterate HIV/STI risk reduction
    - Safer sex practices, provision of condoms, brief intervention regarding alcohol, drugs and further support/referral if required
- Take sexual history
    - Document sexual exposure history since last seen
    - Determine if symptoms of STI
    - Determine if symptoms or signs of HIV seroconversion (see 4.2 re HIV viral load testing and deferring PrEP in this situation)
- Examination as required
- Investigations
    - 4th generation venous blood HIV test, syphilis serology
    - Hepatitis C testing (annually unless otherwise indicated)
    - Chlamydia and gonorrhoea NAAT testing from all relevant anatomical sites (can be self-taken or provider taken)
        - where indicated, gonorrhoea culture from urethra, pharynx and rectum
    - Serum creatinine, eGFR
        - See clinical assessment checklist for frequency of renal monitoring and recommendations in the setting of impaired renal function
- Vaccination follow-up as required
- In asymptomatic, well informed patients online STI and HIV testing can be considered for biannual follow up, with in person attendance at other times. Agreed criteria[26] for biannual online STI and HIV testing are:
    - 17 to 40 years of age;
    - up to date with recommended vaccines;
    - no clinical concerns around PrEP adherence;

[26] It is recognised that there may be other individuals deemed suitable to avail of online STI/HIV testing outside of these agreed criteria, this is at the discretion of a consultant in Genitourinary Medicine/Infectious Diseases with experience in PrEP delivery.

- no active concerns for mental health, alcohol or substance misuse or other issues that would warrant face to face attendance;
- no concerns around ability to navigate the online STI/HIV testing platform;
- agreed mechanism for confirming negative HIV status before prescribing PrEP;
- no history of previous syphilis[27].

- Prescribe tenofovir disoproxil/emtricitabine one tablet once daily or for event based dosing if appropriate.
- Confirm contact details and preferred mechanism for contacting where need arises.
- Confirm and document follow up plans.

4.5 Missed doses and need for PEPSE in PrEP users

The need for PEP in people with missed doses of PrEP depends on the length of time since the last dose of PrEP and the site of exposure. This has been adapted from the 2021 BASHH/BHIVA PEP guidelines[28]

Oral sex only

- If the only exposure has been through oral sex, regardless of the number of missed doses of PrEP, **PEP is not indicated.**

Anal sex

- Daily PrEP, where fewer than 4 pills have been taken in the last 7 days - **PEP is indicated within 72 hours of condomless anal sex.**
- Event-based PrEP, where any dose of an event-based schedule has been missed - **PEP is indicated within 72 hours of condomless anal sex.**

Vaginal sex/Frontal or neovaginal sex

- If more than 48 hours have elapsed since last dosing or if fewer than six tablets have been taken within the previous 7 days – **PEP should be considered within 72 hours of condomless vaginal sex.**

5. Surveillance, reporting and data collection

5.1 Statutory notification HIV and STIs

Statutory notification of incident HIV and STIs should be undertaken in a timely manner, see http://www.hpsc.ie/notifiablediseases/notifyinginfectiousdiseases/.

5.2 Adverse drug events

Any adverse events occurring in individuals on PrEP should be reported through the HPRA, via https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form.

[27] For patients with a history of previous syphilis, quantitative RPR testing may be required to assess for reinfection. This is not achievable with current online syphilis testing.

[28] UK Guideline for the use of HIV Post-Exposure Prophylaxis 2021 https://www.bhiva.org/file/6074031a87755/PEPSE-guidelines.pdf

5.3 National monitoring of PrEP

The data required for national PrEP monitoring will be achieved through a combination of HSE PCRS data collection, service provider based data collection, established HIV and STI surveillance data collection and periodic, nationally coordinated audit.

The impact of the global COVID19 pandemic and the HSE cyber-attack on services ability to provide follow up information is recognised and acknowledged. SHCPP will continue to work with services to gather PrEP data as part of the ongoing monitoring and evaluation of PrEP rollout in Ireland.

Appendix 1. Evidence supporting the agreed eligibility criteria for free PrEP

1) Behaviour, conditions and associated HIV incidence in gay, bisexual and men who have sex with men

In Ireland gay, bisexual and men who have sex with men (gbMSM) represent the greatest proportion of newly-diagnosed HIV infections. There is no data available in Ireland on behaviour or conditions and incident HIV. Available epidemiological information on newly diagnosed cases of HIV does not include information on sexual behaviour or drug use during sex (chemsex). In 2018, of the 147 new diagnoses (excluding those previously diagnosed with HIV abroad) in gbMSM, 23.1% of cases had an acute STI at the time of the HIV diagnosis (10.9% syphilis, 7.5% chlamydia and 8.2% gonorrhoea) [29]. Information on STI diagnoses in these individuals in the year or six months prior to their HIV diagnosis is not currently available.

There is no information on HIV risk in transgender women in Ireland. However, worldwide they are estimated to be at a 49 times greater risk of HIV than the general population[30].

The table below presents information from a range of sources on behaviour, conditions and associated HIV incidence in MSM.

HIV-negative men (and transgender women) having sex with men		
	Associated HIV incidence	
Risk Factor	**Per 100 person years**	**95% CI**
1. data source: Health in Men Study, New South Wales, Australia (2001-2007)		
Overall, regardless of practice	0.78	0.59 – 1.02
Rectal GC in the last 6 months	7.01	2.26 – 21.74
Rectal CT in the last 6 months	3.57	1.34 – 9.52
Methamphetamine use in the last 6 months	1.89	1.25 – 2.84
2. data source: GUMCAD, Public Health England MSM attendees (2014)		
Overall	1.8	1.7 – 2.0
Recent bacterial STI	3.3	2.9 – 3.9
Recent rectal bacterial STI	4.3	3.9 – 6.2

[29] Personal correspondence, HSE-HPSC, 2022.

[30] Baral SD et al. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis. 2013 Mar;13(3):214-22. doi: 10.1016/S1473-3099(12)70315-8

	Associated HIV incidence	
Risk Factor	**Per 100 person years**	**95% CI**
3. data source: PROUD study, HIV incidence in the deferred PrEP arm and baseline characteristics		
Overall	9.1	
Rectal STI in the last 12 months	17.4	10.8 – 28.0
2 -4 condomless anal sex partners in the preceding 90 days	12.8	7.17 – 22.9
PEPSE in the preceding 12 months	10.9	6.07 – 19.4
Participating in chemsex in preceding 90 days	10.4	6.19 – 17.5

2) Impact of suppressive antiretroviral therapy on risk of HIV acquisition

The HPTN 052 clinical trial and the HIV Partner cohort studies have demonstrated the efficacy of suppressive antiretroviral therapy in preventing onward transmission of HIV in HIV serodifferent sexual couples, over a range of different sexual exposure types.

1. HPTN 052 randomised controlled trial of early versus deferred ART initiation[31]			
	Number of infections	**HIV incidence per 100 person years**	**95% CI**
Overall, linked partners	46		
Early, linked partners	3	0.07	0.01 – 0.2
Deferred, linked partners	43	1.03	0.74 – 1.38
Relative risk reduction early versus delayed, 93%			
2. HIV PARTNER 1 observational study[32]			
	Number of infections	**HIV incidence per 100 couple years**	**Upper limit 95% CI**
Overall	0	0	0.3
Heterosexual women			
Any condomless sex	0	0	0.97

[31] Cohen MS et al. Prevention of HIV-1 infection with early antiretroviral therapy N Engl J Med. 2011 Aug 11;365(6):493-505. doi: 10.1056/NEJMoa1105243. Epub 2011 Jul 18.

[32] Rodger AJ et al. Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy. JAMA. 2016 Jul 12;316(2):171-81. doi: 10.1001/jama.2016.5148. Erratum in: JAMA. 2016 Aug 9;316(6):667. Erratum in: JAMA. 2016 Nov 15;316(19):2048.

Condomless vaginal sex ejaculation	0	0	1.50
Condomless vaginal sex no ejaculation	0	0	1.55
Condomless anal sex ejaculation	0	0	12.71
Condomless anal sex no ejaculation	0	0	8.14
Heterosexual men			
Any condomless sex	0	0	0.88
Condomless insertive anal sex	0	0	7.85
MSM			
Any sex	0	0	0.84
Condomless insertive anal sex	0	0	1.00
Condomless receptive anal sex ejaculation	0	0	2.70
Condomless receptive anal sex no ejaculation	0	0	1.68
3. HIV PARTNER 2 observational study[33]			
	Number of infections	**HIV incidence per 100 couple years**	**Upper limit 95% CI**
Condomless anal sex	0	0	0.23
Condomless insertive anal sex	0	0	0.27
Condomless receptive anal sex with ejaculation	0	0	0.57
Condomless receptive anal sex no ejaculation	0	0	0.43
Any condomless anal sex with STI	0	0	3.17

3) Time Limited PrEP in HIV serodifferent couples

Temporary PrEP for HIV negative partners of people living with HIV who are initiating antiretroviral therapy has been shown to be acceptable and effective in averting sexual acquisition of HIV in resource limited setting [34]

[33] Rodger AJ et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. Lancet. 2019 May 2. pii: S0140-6736(19)30418-0. doi: 10.1016/S0140-6736(19)30418-0.

[34] Integrated Delivery of Antiretroviral Treatment and Pre-exposure Prophylaxis to HIV-1-Serodiscordant Couples: A Prospective Implementation Study in Kenya and Uganda. Baeten JM et al. PLoS Med. 2016 Aug 23;13(8):e1002099. doi: 10.1371/journal.pmed.1002099. eCollection 2016 Aug.

4) PrEP eligibility criteria from a range of international settings

England

BHIVA, 2018 https://www.bhiva.org/file/5b729cd592060/2018-PrEP-Guidelines.pdf

1. MSM:

Recommendations

- We recommend that PrEP with on-demand or daily oral TD-FTC should be offered to HIV-negative MSM who are identified as being at elevated risk of HIV acquisition through condomless anal sex in the previous 6 months and ongoing condomless anal sex. (1A)
- We recommend that PrEP with on-demand or daily oral TD-FTC should be offered to HIV-negative MSM having condomless anal sex with partners who are HIV positive, unless the partner has been on ART for at least 6 months and their plasma viral load is <200 copies/mL. (1A)

Good practice point

- Consider PrEP on a case by case basis in MSM with current factors other than condomless anal sex in previous 6 months that may put them at increased risk of HIV acquisition. See Section 5.

2. Heterosexual populations:

Recommendations

- We recommend that daily oral TD-FTC should be offered to HIV-negative heterosexual men and women having condomless sex with partners who are HIV positive, unless the partner has been on ART for at least 6 months and their plasma viral load is <200 copies/mL. (1A)
- We suggest that PrEP with daily oral TD-FTC should be offered on a case-by-case basis to heterosexual men and women with current factors that may put them at increased risk of HIV acquisition. See Section 5.1. (2B)

Good practice point

- For women using DMPA, PrEP is likely to counteract an increase in HIV acquisition. However, women at risk of HIV acquisition should be offered an alternative form of contraception to DMPA if available, whether or not they opt to take PrEP.

3. PWID:

Recommendations

- We suggest that PrEP is not recommended for people who inject drugs where needle exchange and opiate substitution programmes are available and accessed by the individual. (2C)
- We recommend that existing harm-reduction strategies such as needle exchange and opiate substitution programmes should be encouraged for people who inject drugs. (1D)

Good practice points

- Consider PrEP on a case by case basis in people who inject drugs in an outbreak situation or with other factors that put them at increased risk of HIV acquisition. See Section 5.
- Interventions for chemsex should be encouraged for people who are identified as being at elevated risk of HIV acquisition through report of injecting drug use during chemsex (slamming).

4. Trans people:

Recommendations

- We recommend that PrEP with daily oral TD-FTC should be offered to HIV-negative trans women who are identified as being at elevated risk of HIV acquisition through condomless anal sex in the previous 6 months and ongoing condomless sex. (1A)
- We recommend that daily oral TD-FTC should be offered to HIV-negative trans women and trans men having condomless sex with partners who are HIV positive, unless the partner has been on ART for at least 6 months and their plasma viral load is <200 copies/mL. (1A)

Good practice points

- PrEP could be considered on a case-by-case basis in trans women and trans men with current factors other than condomless anal sex that may put them at increased risk of HIV acquisition. See Section 5.
- In trans people who are having only anal sex, on-demand PrEP could be used as it is likely to have the same biological efficacy as seen in MSM.
- For both trans women and trans men a discussion should be had regarding unknown PrEP efficacy for frontal (vaginal) sex.
- A discussion should be had, both at PrEP initiation and maintenance visits, that there are no known interactions between TD-FTC and feminising or masculinising hormones.

5. Young people (15–25 years):

Recommendations

- We recommend that PrEP with daily or on-demand oral TD-FTC should be offered to young MSM (15–25 years) who are identified as being at elevated risk of HIV acquisition through condomless anal sex in the previous 6 months and ongoing condomless anal sex. (1A)
- We recommend that PrEP with TD-FTC should be offered to young people having condomless anal sex with partners who are HIV positive, unless the partner has been on ART for at least 6 months and their plasma viral load is <200 copies/mL. (1A)
- We recommend that PrEP with daily oral TD-FTC should be offered to young HIV-negative trans women who are identified as being at elevated risk of HIV acquisition through condomless anal sex in the previous 6 months and ongoing condomless sex. (1A)
- Routine BMD scanning in young people initiating PrEP is not recommended. (1D)

Good practice points

- Consider PrEP with daily oral TD-FTC on a case-by-case basis in young people with current factors other than condomless anal sex that may put them at increased risk of HIV acquisition. See Section 5.
- In young trans people who are having only anal sex, on-demand PrEP could be used as it is likely to have the same biological efficacy as seen in MSM.
- The risks and benefits of providing PrEP for adolescents should be weighed carefully in the context of UK laws and judgements about autonomy in healthcare decision-making (e.g. Fraser competency), and balanced against protecting young people from harm.
- A discussion about side effects including impact upon bone density in young people should be held at PrEP initiation and maintenance visits.

Scotland

NHS https://prep.scot/

Individuals who are:

- Aged 16 or over.
- Have a confirmed HIV negative test in a sexual health clinic.
- Able to attend for regular 3 month reviews.
- Willing to stop taking PrEP when no longer eligible.
- Resident in Scotland.

Plus, one or more of the following criteria:

- Current sexual partners, irrespective of gender, of people who are HIV positive **who have a detectable viral load.**
- Cis and transgender gay and bisexual men, men who have sex with men, and transgender women **with a documented bacterial rectal sexually transmitted infection in the last 12 months.**
- Cis and transgender gay, bisexual men and men who have sex with men, 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.**
- Individuals, irrespective of gender, at an equivalent highest risk of HIV acquisition, as agreed with another specialist clinician.

European AIDS Clinical Society

EACS October 2021 https://www.eacsociety.org/media/final2021eacsguidelinesv11.0_oct2021.pdf

1. PrEP should be used in adults at high-risk of acquiring HIV infection when condoms are not used consistently. Before PrEP is initiated, HBV serology status should be documented.
2. Recommended in HIV-negative men who have sex with men (MSM) and transgender individuals when condoms are not used consistently with casual partners or with HIV-positive partners who are not virally suppressed on treatment. A recent STI, use of post-exposure prophylaxis or chem-sex may be markers of increased risk for HIV.
3. May be considered in HIV-negative heterosexual women and men who are inconsistent in their use of condoms and have multiple sexual partners where some may have untreated or inadequately suppressed HIV infection.

Wales, 2018 http://www.wales.nhs.uk/sitesplus/documents/888/Prep%20Wales%20Service%20Guide%20June%202018.pdf

1. MSM, transgender people having sex with men

Necessary Aspects

- A documented confirmed 4th generation HIV negative test at initiation of PrEP
- Reporting condomless anal intercourse in the previous three months with multiple partners/on multiple occasions
- Considered likely to engage in repeated condomless intercourse in the next three months with multiple partners/on multiple occasions
- Proof of Welsh residency provided

Further Guidance

- Where available, use point of care testing (fourth generation test).

2. HIV negative partner of a HIV positive person

Necessary Aspects

- HIV positive partner is not virally suppressed or level of suppression is unknown
- Condomless intercourse is anticipated or has occurred within the past three months
- Proof of Welsh residency provided

Further guidance

- PrEP should be recommended where the treating clinician recommends and monitors treatment as part of wider risk reduction (e.g. health education, safer sex promotion)
- Treatment as prevention for the HIV positive partner should be considered.

3. HIV negative heterosexuals

Necessary Aspects

- Known to have had condomless sex with a person with HIV with unknown viral suppression within the past three months
- Anticipated to have condomless sex with person, or person of similar status, again
- Proof of Welsh residency provided

Further guidance

- PrEP should be recommended where the treating clinician recommends and monitors treatment as part of wider risk reduction (e.g. health education, safer sex promotion)

New Zealand

2019 https://www.nzaf.org.nz/media/2884/ashm_prep_tool_nzaf_update_04.pdf
https://www.nzaf.org.nz/media/2885/ashm_prep_nz_guidelines_09.pdf

1. Men who have sex with men (MSM), trans & gender diverse people

High risk of HIV and eligible for funded PrEP

- Likely to have multiple events of CLAI in the next 3 months;

And having any one of the following:

- At least one episode of receptive CLAI with one or more casual male partners in the last 3 months;
- Rectal gonorrhoea, rectal chlamydia or infectious syphilis diagnosis during the last 3 months;
- Methamphetamine use in the last 3 months OR 2.CLI with a regular HIV+ partner who is not on treatment and/or has a detectable viral load.

Not eligible for funded PrEP; could consider self-funded PrEP

- Insertive CLAI with any casual male partner (in last 3 months or expected in next 3 months)
- Travelling to a high-HIV prevalence country and anticipates risk

2. Heterosexual people

High risk of HIV and eligible for funded PrEP

- CLI with a regular HIV+ partner who is not on treatment and/or has a detectable viral load.

Not eligible for funded PrEP; could consider self-funded PrEP

- Receptive CLI with any casual MSM partner (in last 3 months or expected in next 3 months) Travelling to a high-HIV prevalence country and anticipates risk

3. People who inject drugs

Not eligible for funded PrEP; could consider self-funded PrEP

- Shared injecting equipment with an HIV+ individual or with MSM of unknown HIV status (in last 3 months or expected in next 3 months)

Australia

ASHM PrEP Guidelines, 2019 https://www.nzaf.org.nz/media/1985/ashm-prep-guidelines-sep-2019.pdf

The **2017 ASHM PrEP guidelines** classified a person's risk of HIV acquisition as high or low based on criteria from the HIM study[35] and recommended that an individual had to report HIV risk in the 3 months before commencing PrEP and that the individual anticipated that they would have HIV risk in the 3 months after commencing PrEP. Individual's risk of HIV acquisition were classified as high or low based on evidence from the HIM study. Additionally, in the 2017 guidelines, clinicians were invited to consider offering PrEP on a case-by-case definition to people who did not meet high- or medium-risk criteria.

Importantly, the **2019 ASHM PrEP guidelines** no longer classify a person's risk of HIV acquisition as high or low and no longer require that an individual demonstrate HIV risk in the previous 3 months. Instead the 2019 guidelines provide behavioural examples of what would make a person suitable for PrEP, including whether a person's quality of life would be likely to improve if they were offered PrEP, e.g. people with high levels of anxiety about HIV acquisition.

1. PrEP suitability criteria for men who have sex with men

HIV risk in the previous 3 months and the future 3 months

The clinician should prescribe PrEP if the patient describes a history of any of the following HIV acquisition risks in the previous 3 months and if the patient foresees that there are likely to be similar acquisition risks in the next 3 months:

- At least one episode of condomless anal intercourse (insertive or receptive) with a regular HIV-positive partner who is either not on treatment, or who is on treatment but has a detectable HIV viral load
- At least one episode of receptive condomless anal intercourse with any casual male partner
- One or more episodes of engaging in sexualised drug use, sometimes referred to as 'chemsex'. In the Australian context this typically involves the use of crystal methamphetamine (Ice), but can also include the use of gamma hydroxybutyrate (GHB)
- One or more episodes of rectal gonorrhoea, rectal chlamydia or infectious syphilis, including any STIs diagnosed at screening for PrEP
- More than one episode of anal intercourse where a condom slipped off or broke where the HIV serostatus of the partner was not known, or where the

[35] Poynten IM, et al Defining high HIV incidence subgroups of Australian homosexual men: implications for conducting HIV prevention trials in low HIV prevalence settings. HIV Med 2010;11:635-41.

partner was HIV positive and not on treatment or had a detectable viral load on treatment.

HIV risk in the future 3 months

The clinician should prescribe PrEP if the patient foresees that they will have HIV acquisition risk in the upcoming 3 months, despite not having had HIV acquisition risk in the previous 3 months.

Note: The following list is not exhaustive and there are likely to be many other scenarios where PrEP could be suitably offered for people whose HIV risk acquisition is exclusively in the future:

- When a person plans to travel during which time they anticipate that they will be having condomless sex with casual partners
- When a person plans to return home to an overseas country which has a high HIV prevalence during which time they anticipate that they will be having condomless sex with casual partners
- When a person reports that they have recently left a monogamous relationship and will be having condomless sex with casual partners in the future
- When a person reports that they will be entering or leaving institutional or correctional facilities in the near future where they may have condomless sex with casual partners in the future
- When a person presents with concerns of deteriorating mental health and a history of having previously increased their HIV acquisition risk behaviour in this setting
- When a person presents with a history of intermittent binge drinking of alcohol or recreational drug use and a history of having had increased their HIV acquisition risk behaviour in this setting.

The clinician should consider prescribing PrEP also in the following circumstances:

- When an HIV serodiscordant couple experience undue suffering and anxiety about inter-couple HIV transmission despite the positive partner being virologically suppressed on treatment
- When a person reports being so anxious about HIV infection that it may prevent them from having regular HIV testing, or engaging in any form of anal sex
- When a person presents with a history of recurrent genital ulceration or dermatoses (e.g. psoriasis), as this may increase the risk of HIV transmission.

2. PrEP suitability criteria for trans and gender diverse people

HIV risk in the previous 3 months and the future 3 months

The clinician should prescribe PrEP if the patient describes a history of any of the following HIV acquisition risks in the previous 3 months and if the patient foresees that there are likely to be similar acquisition risks in the next 3 months:

- At least one episode of condomless anal intercourse (insertive or receptive) with a regular HIV-positive partner who is either not on treatment, or who is on treatment but has a detectable HIV viral load
- At least one episode of receptive condomless anal intercourse with any with any casual bisexual male partner of unknown status
- More than one episode of anal or vaginal intercourse where a condom slipped off or broke where the HIV serostatus of the partner was not known, or where the partner was HIV positive and not on treatment or had a detectable viral load on treatment
- One or more episodes of engaging in sexualised drug use, sometimes referred to as ‘chemsex’. In the Australian context this typically involves the use of crystal methamphetamine (Ice) but can also include the use of gamma hydroxybutyrate (GHB)
- One or more episodes of rectal gonorrhoea, rectal chlamydia or infectious syphilis including any STIs diagnosed at screening for PrEP.

HIV risk in the future 3 months

The clinician should prescribe PrEP if the patient foresees that they will have HIV acquisition risk in the upcoming 3 months, despite not having had HIV acquisition risk in the previous 3 months:

- When a person plans to travel during which time they anticipate that they will be having condomless sex with casual partners
- When a person plans to return home to an overseas country which has a high HIV prevalence during which time they anticipate that they will be having condomless sex with casual partners
- When a person reports that they have recently left a monogamous relationship and will be having condomless sex with casual partners in the future
- When a person reports that they will be entering or leaving institutional or correctional facilities in the near future where they may have condomless sex with casual partners in the future
- When a person presents with concerns of deteriorating mental health and a history of having previously increased their HIV acquisition risk behaviour in this setting
- When a person presents with a history of intermittent binge drinking of alcohol or recreational drug use and a history of having had increased their HIV acquisition risk behaviour in this setting.

The clinician should consider prescribing PrEP also in the following circumstances:

- When an HIV serodiscordant couple experience undue suffering and anxiety about inter-couple HIV transmission despite the positive partner being virologically suppressed on treatment
- When a person reports being so anxious about HIV infection that it may prevent them from having regular HIV testing or engaging in any form of anal or vaginal sex
- When a person presents with a history of recurrent genital ulceration or dermatoses (e.g.psoriasis), as this increases the potential risk of HIV transmission.

3. PrEP suitability criteria for heterosexuals

HIV risk in the previous 3 months and the future 3 months

The clinician should prescribe PrEP if the patient describes a history of any of the following HIV acquisition risks in the previous 3 months and if the patient foresees that there are likely to be similar acquisition risks in the next 3 months

- At least one episode of condomless anal or vaginal intercourse (insertive or receptive) with a regular HIV-positive partner who is either not on treatment, or who is on treatment but has a detectable HIV viral load
- At least one episode of receptive anal or vaginal condomless intercourse with any casual HIV-positive partner or a male homosexual or bisexual partner of unknown status
- Episodes of planned condomless insertive or receptive vaginal sex in an effort to conceive with an HIV-positive partner, regardless of the HIV-positive partner's viral load

HIV risk in the future 3 months

The clinician should prescribe PrEP if the patient foresees that they will have HIV acquisition risk in the upcoming 3 months, despite not having had HIV acquisition risk in the previous 3 months:

- Future episodes of planned condomless insertive or receptive vaginal sex in an effort to conceive with an HIV-positive partner, regardless of the HIV-

positive partner's viral load

- When a person plans to travel to countries with high HIV prevalence during which time they anticipate having condomless sex with casual partners who are HIV positive or of unknown HIV serostatus
- When a person plans to return home to an overseas country which has a high HIV prevalence during which time they anticipate that they will be having condomless sex with casual partners
- When a person reports that they have recently left a monogamous relationship and will be having condomless sex with a casual HIV-positive partner, or a male or female partner of unknown HIV serostatus from a country with high HIV prevalence, or a male partner who is thought to have sex with men
- When a person presents with concerns of deteriorating mental health and a history of having had increased their HIV acquisition risk behaviour in this setting
- When a person presents with a history of intermittent binge drinking of alcohol or recreational drug use and a history of having had increased their HIV acquisition risk behaviour in this setting.

The clinician should consider prescribing PrEP also in the following circumstances:

- When an HIV serodiscordant couple experience undue suffering and anxiety about inter-couple HIV transmission despite the positive partner being virologically suppressed on treatment.

4. PrEP suitability criteria for people who inject drugs

HIV risk in the previous 3 months and the future 3 months

The clinician should prescribe PrEP if the patient describes a history of any of the following HIV acquisition risks in the previous 3 months and if the patient foresees that there are likely to be similar acquisition risks in the next 3 months:

- Shared injecting equipment with an HIV-positive person or with a gay or bisexual man of unknown HIV status
- At least one episode of condomless anal or vaginal intercourse (insertive or receptive) with a regular HIV-positive partner who is either not on treatment, or who is on treatment but has a detectable HIV viral load
- At least one episode of receptive anal or vaginal condomless intercourse with any casual HIV-positive partner or a male homosexual or bisexual partner of unknown status.

HIV risk in the future 3 months

The clinician should prescribe PrEP if the patient foresees that they will have HIV acquisition risk in the upcoming 3 months, despite not having had HIV acquisition risk in the previous 3 months.

- A person has recently (re)commenced injecting drugs and is injecting with a person who is HIV positive, or with a gay or bisexual man whose HIV status is unknown
- When a person plans to travel to countries with high HIV prevalence during which time they anticipate injecting drugs with other people who are HIV positive or of unknown HIV serostatus
- When a person reports that they will be entering, or leaving institutional or correctional facilities in the near future during which time they may inject drugs with people who are HIV positive or of unknown HIV serostatus.

United States

NIH, https://hivinfo.nih.gov/understanding-hiv/fact-sheets/pre-exposure-prophylaxis-prep

CDC, https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Figure 2 Assessing Indications for PrEP in Sexually Active Persons

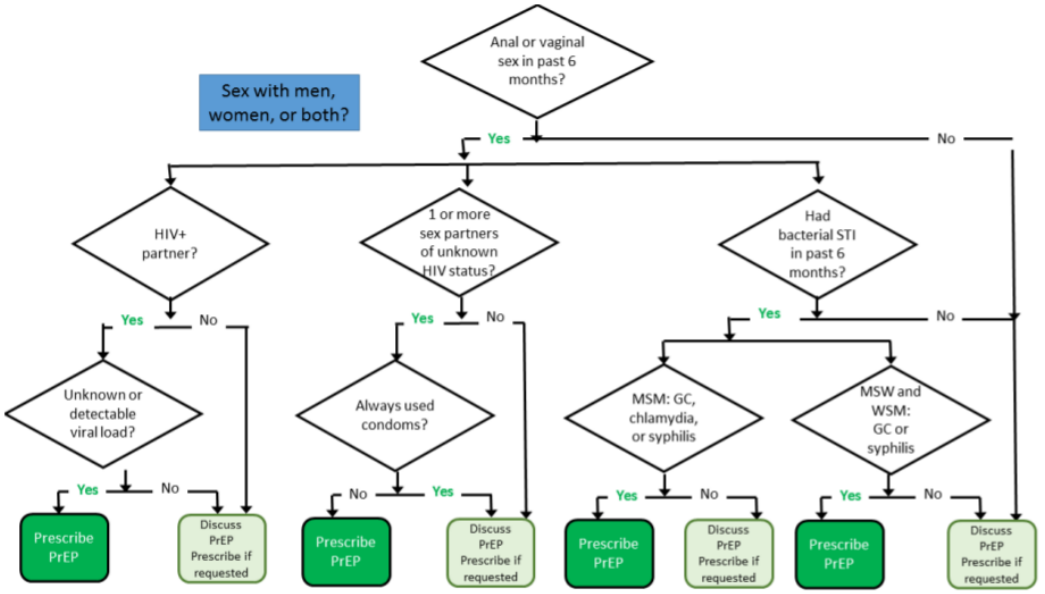

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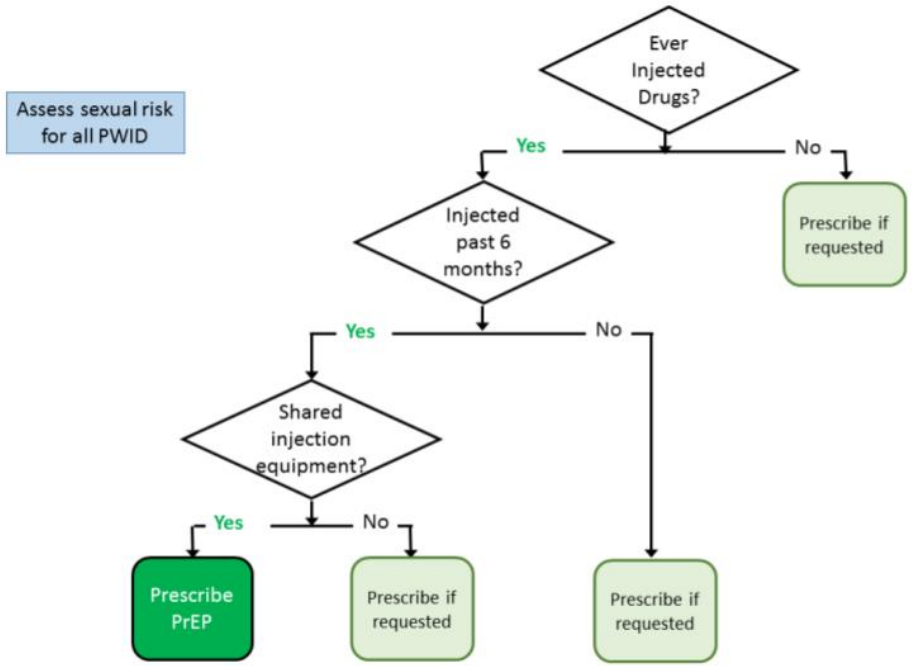
Figure 3 Assessing Indications for PrEP in Persons Who Inject Drugs



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Appendix 2. PrEP Clinical Assessment Checklist

	Baseline assessment before starting PrEP	Follow up			Comments
		1 month after starting PrEP (will be required for some)	Every 3 months on PrEP (some patients will require less frequent follow up, see section 4.4)	Annually on PrEP	
Discuss HIV risk and assess eligibility for PrEP	X	X	X		
Discuss HIV and STI risk reduction strategies	X	X	X		
Offer and provide condoms	X	X	X		
Discuss chemsex and alcohol use and offer support and referral	X	X	X		
Discuss and agree dosing schedule	X	X	X		➢ PrEP is licensed for daily use and can be offered to all people who are eligible for PrEP ➢ Event based dosing[36] (EBD) has been shown to be effective for men having anal sex with other men. EBD can be considered in men having sex with other men where sex is infrequent (for example less than 2 times per week) and where the individual is able to allow adequate time for taking the first dose before having sex[37].

[36] Sometimes referred to as on demand dosing or 2+1+1 dosing

[37] EVENT-DRIVEN ORAL PRE-EXPOSURE PROPHYLAXIS TO PREVENT HIV FOR MEN WHO HAVE SEX WITH MEN: UPDATE TO WHO'S RECOMMENDATION ON ORAL PREP, https://apps.who.int/iris/bitstream/handle/10665/325955/WHO-CDS-HIV-19.8-eng.pdf?ua=1

					➢ EBD is not recommended where protection is needed for vaginal/frontal sex ➢ EBD is not recommended in people who are hepatitis B surface antigen positive. ➢ EBD can be considered in transgender people who only require protection for anal sex when under the care of a consultant in Genitourinary Medicine or Infectious Diseases
Discuss lead in time and stopping PrEP	X	X	X		1. Daily dosing schedule *Anal sex* ➢ Starting: 2 tablets between 2 and 24 hours before sex ➢ While on PrEP take one tablet every 24 hours ➢ Stopping: continue one tablet every 24 hours until two tablets have been taken after last sexual episode *Vaginal sex* ➢ Starting: 1 tablet daily for 7 days before vaginal sex ➢ While on PrEP one tablet every 24 hours ➢ Stopping: continue one tablet every 24 hours for 7 days after last vaginal sex 2. Event based/On demand dosing schedule **only where appropriate as outlined above** One sexual episode ➢ take 2 pills 2 – 24 hours before sex ➢ take 1 pill 24 hours later ➢ take 1 more pill 24 hours after that Multiple sexual episodes over a number of days ➢ take 2 pills 2 – 24 hours before sex ➢ take 1 pill 24 hours later ➢ continue one tablet every 24 hours until two tablets have been taken after the last sexual encounter
Discuss and assess adherence.	X	X	X		If on daily PrEP and taking fewer than recommended doses (<4 doses per week for men having anal sex; <6 doses per week for

Provide support where adherence suboptimal					people having vaginal/frontal sex) and at substantial risk for acquisition of HIV, serious consideration should be given to stopping PrEP
4th generation HIV testing **HIV viral load testing where concerns for recent HIV seroconversion**	X	+/-	X		➢ A negative 4th generation venous blood HIV test must be documented within four weeks prior to first starting PrEP. ➢ To avoid delays in PrEP initiation, the prescription can be provided with clear instructions to the patient not to start PrEP until the HIV test result is available. ➢ Point of care HIV test can be considered in these situations with a 4th generation venous blood HIV test in progress. ➢ Where an individual is within the window period at first starting PrEP repeat HIV test at 6 weeks, see section 4.2 and 4.3. ➢ Discuss symptoms of HIV seroconversion with patient and advise to attend if such symptoms develop ➢ Where there are concerns for HIV seroconversion the individual should have their care managed by a consultant in Genitourinary Medicine/Infectious Disease with experience in HIV diagnosis and diagnostics. ➢ PrEP should not be continued if there the risk of seroconversion is considered real. ➢ In follow up, online 4th generation HIV testing is appropriate for stable patients, see section 4.4. Local arrangements for confirming HIV status must be in place before prescribing further PrEP.
Hepatitis A testing	X				All patients who are hepatitis A non-immune should be offered and encouraged to avail of hepatitis A vaccination

Hepatitis B testing **All patients to have HBsAg at baseline and follow up if not documented as hepatitis B immune** **Additional hepatitis B markers as indicated from history**	X		+/-		Any patient identified with active hepatitis B infection should have their hepatitis B and PrEP assessment and care their care managed by a consultant in Genitourinary Medicine/Infectious Diseases with experience in managing Hepatitis B infection in collaboration with Hepatology services. All patients who are hepatitis B non-immune should be offered and encouraged to avail of hepatitis B vaccination. Any patient who is hepatitis B non-immune and potentially exposed to hepatitis B should be managed in line with the hepatitis B PEP guidelines.[38]
Hepatitis C testing	X		+/-	X	Annual hepatitis C testing is recommended for MSM. Please read footnote for further information on hepatitis C testing[39]
Syphilis serology	X	+/-	X		Where an individual is within the window period at first starting PrEP a repeat test at 6 weeks, see section 4.2 and 4.3.
Serum creatinine/ eGFR[40]	X		for some	X	**All individuals starting PrEP should have creatinine measured and eGFR at baseline and three months post PrEP initiation.** **eGFR >90 mls/min/1.73m^2 [41]**

[38] Emergency Management of Injuries Guidelines, www.emitoolkit.ie

[39] Hepatitis C testing should be considered part of routine sexual health screening in the following circumstances: People who are HIV positive; Commercial sex workers; PWID; If indicated by the clinical history e.g. unexplained jaundice; When other risk factors for hepatitis C are present, for example MSM. The full set of recommendations around hepatitis C testing are available in the national hepatitis C screening guidelines, http://health.gov.ie/wp-content/uploads/2017/08/HepC-NCG-15_Summary_v8.pdf

[40] It is important to note that in general laboratory reported eGFR's do not take account of an individual's weight or muscle mass. At the extremes of body mass and muscle mass non-weight based eGFR calculations are less reliable and may not accurately reflect renal function. In these circumstances it is recommended that the weight is checked and the eGFR calculated using the Cockcroft Gault equation http://www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation/. In addition there is racial variation in GFR such that in Black-African populations a correction factor should be applied. It is recommended that in assessing and monitoring Black-African patients for or on PrEP that the appropriate correction factor is checked with the local laboratory.

[41] The working group notes that in the product datasheets for PrEP medication, the recommendations around renal monitoring have different eGFR thresholds. The variance with the thresholds reflects the way eGFR is reported in some laboratories whereby in some institutions the eGFR is not quantified above 60 mls/min/1.73m^2 and is simply reported as >60 mls/min/1.73m^2. The working group sought specialist renal physician input in drafting this section on renal monitoring.

					At baseline and in follow up ➢ </=40 years and no identified risks for renal impairment, measure creatinine and eGFR **annually** whilst on PrEP ➢ >40 years, and/or identified risks for renal impairment, measure creatinine and eGFR **6 monthly** whilst on PrEP **eGFR 60-90 mls/min/1.73m^2** ➢ At baseline and/or in follow up measure creatinine and eGFR **at least 6 monthly** whilst on PrEP **eGFR <60 mls/min/1.73m^2** **Baseline eGFR <60mls/min/1.73m^2** ➢ Assess for relevant medical conditions, nephrotoxic drugs creatine supplements and consider renal referral. PrEP should only be commenced under the supervision of an appropriately trained and experienced consultant with due regard to potential risks and benefits on a case by case basis. **Follow up** eGFR falls to <60mls/min/1.73m^2 ➢ Assess for relevant medical conditions, nephrotoxic drugs, creatine supplements and consider renal referral. PrEP should only be continued under the supervision of an appropriately trained and experienced consultant with due regard to potential risks and benefits on a case by case basis. Routine urinalysis for proteinuria is not recommended in follow up for those with normal renal function (eGFR >90mls/min/1.73 m^2) and no risks for renal impairment
CTNG multisite testing	X	+/-	X		Where an individual is within the window period at first starting PrEP repeat HIV test at 6 weeks, see section 4.2 and 4.3. Multisite gonorrhoea culture where indicated

Vaccination review	X	X	X		Vaccination in line with NIAC recommendations[42] 1. Hepatitis B vaccination is recommended for all people attending STI clinics 2. Hepatitis A vaccination is recommended for MSM 3. HPV vaccination is recommended for MSM up to and including 45 years of age
Assess LMP, contraception and do urine pregnancy test where indicated	X	X	X		Pregnancy or trying to conceive is not considered a contraindication to PrEP in those at substantial risk of HIV
Bone health for patients taking PrEP	Bone loss is associated with use of tenofovir disoproxil and is usually reversible on cessation of tenofovir disoproxil. Individuals taking tenofovir disoproxil based PrEP should be informed of this risk. Individuals with pre-existing low bone mineral density or risk factors for low bone mineral density (>50 years, smoking, alcohol excess, low body weight, some medication and in particular steroids) should be advised to reduce their risk for low bone mineral density by stopping smoking, reducing alcohol intake, increasing weight bearing exercise and ensuring an adequate intake of calcium and vitamin D. Tenofovir disoproxil based PrEP in individuals with documented osteoporosis should only be prescribed following careful consideration of the risks and where the individual is engaged with appropriate care for their osteoporosis.				

[42] HSE Immunisation Guidelines, http://www.hse.ie/eng/health/Immunisation/hcpinfo/guidelines/

Sláinte Ghnéis &
Clár um Thoirchis Ghéarchéime

Sexual Health &
Crisis Pregnancy Programme