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

December 2024

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Guideline Revisions

October 2019
The first National PrEP guidelines were published.

May 2022
A full review and update was conducted.

September 2022
An amendment was made to the guidelines 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.

December 2024
A full review and update was conducted.

1. Background and Development Process

Worldwide HIV remains a significant cause of morbidity and mortality with an estimated 39.9 million people living with HIV at the end of 2023 and an estimated 1.3 million new HIV infections in that year[1].

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.

Ireland commenced a HIV PrEP programme in November 2019, following a Health Information Quality Authority (HIQA) led health technology assessment (HTA) which found that the introduction of a PrEP programme in would be safe and highly effective at preventing HIV in people at increased risk. Additionally, implementing a PrEP programme would be considered cost saving compared with standard care[2]. Data from the Health Protection Surveillance Centre reported 911 total HIV diagnoses in Ireland in 2023. The majority of these (61%) were in people already known to be living with HIV, with 19% in people diagnosed with HIV for the first time and 20% with unknown history. There were 173 first time diagnoses in Ireland during 2023, giving a rate of 3.4 per 100,000 population. This is very similar to the rate in 2022 and lower compared to pre-pandemic (4.0 per 100,000 population in 2019) and earlier years. The key population group affected by HIV remains gbMSM, and there has been a 56% decline in rate of HIV among gbMSM since the peak in 2015 suggesting that PrEP is having an impact at preventing new infections[3].

Within the HSE, responsibility for the PrEP programme lies with the Sexual Health Programme (SHP, formerly Sexual Health and Crisis Pregnancy Programme) who lobby for resources; develop guidelines and standards; monitor PrEP KPIs and activity. Much of the work of the SHP on PrEP is done in collaboration with the SHP convened multisectoral HIV PrEP Working Group.

The first set of national guidelines on PrEP[4] was published in October 2019 with subsequent updates in 2022, 2023 and 2024. The guidelines set out the clinical eligibility criteria for access to free PrEP for individuals in addition to guidelines for assessment, initiation and follow up of individuals using PrEP.

In preparing this updated document, the Clinical Lead of SHP reviewed international guidelines, particularly the 2024 draft BASHH/BHIVA PrEP guidelines[5] and shared the document with the HIV PrEP working group for review and input. Following this, the document was shared with the SHP Clinical Advisory Group prior to sign off and publication. In parallel the patient information leaflet was updated to reflect guideline changes and key stakeholder feedback on previous versions.

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[1] https://www.unaids.org/en/resources/fact-sheet, accessed 11/12/2024.

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

[3] HSE-Health Protection Surveillance Centre. HIV Slideset2023. Dublin: HPSC; November 2024. https://www.hpsc.ie/a-z/hivandaids/hivdataandreports/

[4] 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 Programme (SHP) upon request.

[5] Draft BASHH/BHIVA guidelines on the use of HIV pre-exposure prophylaxis (PrEP)(2024), V3.0 24/09/2024 available on the BASHH website for consultation until end of November 2024

This current document sets out the updated clinical eligibility criteria for free PrEP and updated guidelines on the assessment, initiation and monitoring of those using PrEP. As with previous iterations of the guidelines, provision of PrEP care should not be in isolation but as part of an overall combination care package to reduce HIV risk and negative sexual health outcomes.

In the 2024 guidelines, key changes are in the following areas:

- Eligibility criteria
  - A further move towards determining individual suitability versus strict eligibility criteria.
  - Specific mention of PrEP for people who inject drugs (PWID)
- Updates to starting and stopping rules for PrEP
- Follow up and monitoring
  - Renal monitoring
- Updates to requirements for PEP in people using PrEP
- The language amendments applied to the guidelines in March 2023 have been retained in this version in line with the People First Charter. This does not include the text quoted from other publications that are included in the appendices.

This document is listed for review in December 2026. 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.

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 increased-risk of HIV who are considering and/or using PrEP. This document is intended for use alongside the national standards for PrEP.

This document sets out the agreed, factors that determine an individual's suitability for free PrEP through the HSE in Ireland. Additionally, this document sets out guidance on assessment, initiation of and follow up of those using 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.

3. How is PrEP available in Ireland?

PrEP medication is available free of charge through HSE approved PrEP providers to those who are deemed likely to benefit from the intervention and for whom it is not contraindicated. At this time the pathway to free PrEP care is via the network of public PrEP clinics. Individuals attending other approved PrEP providers (such as GP or private providers) will incur costs associated with the consultation, investigations, treatment of STIs and vaccines. The vision of the SH programme and the PrEP WG is that all aspects of HIV and STI prevention and care are provided free at point of entry to all individuals who would benefit, regardless of where they attend.

In considering factors that determine an individual's suitability for free PrEP, the guideline review group has considered eligibility criteria in other jurisdictions and the available evidence around risk of acquisition of HIV across a range of situations in a variety of populations. A summary of the evidence is presented in **Appendix 1**. As acknowledged in the 2022 guidelines, there has been an international move towards an individual's anticipated future HIV risk and suitability for PrEP, rather than relying solely on their preceding documented risk, in determining their suitability for PrEP.

3.1 Who should be offered PrEP?

PrEP should be offered to HIV negative individuals, regardless of their gender, gender identity or sexual orientation, who have rates of HIV higher than the general population and would benefit from a reduction in HIV risk including:

1. **Men who have sex with men[6] or transgender women who have sex with men who are:**
    - sexually active and/or likely to be sexually active in the next 3 months

    AND one of the following:
    - reported condomless anal sex with at least two partners[7] over the last 6 months
    - likely to engage in condomless anal sex in the next 3 months
    - episode of documented or reported acute STI[8] 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[9] 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 warrant PrEP for the HIV-negative partner.

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

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

[8] 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.

[9] 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.

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.[10]

3. **Other individuals considered to be at increased-risk for acquisition of HIV, including.**
    a. **People who inject drugs who may share injecting equipment**
        - Some individuals who inject drugs may benefit from PrEP to prevent acquisition of HIV. It is recommended that when providing PrEP to people who inject drugs that it is under the supervision of a consultant in Genitourinary Medicine or Infectious Diseases, in collaboration with drug treatment support services. Due regard should be given to the role of needle exchange and opioid substitution therapy in preventing blood borne virus acquisition in these individuals.
    b. **Cisgender, transgender and non-binary persons having or likely to have condomless sex with an increased risk of HIV**

3.2 Who is not eligible for free PrEP?

A person who is:

- in a mutually monogamous relationship with a partner who is living with HIV confirmed to be stably virally suppressed on ART[11]
- in a mutually 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 and injecting drug use protection) with continued significant risk for acquisition of HIV.
    - Consider the need for PEPSE.
    - There is an ~~i~~increased 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.

[10] https://issuu.com/mcirl/docs/guide_to_professional_conduct_and_e?e=12642421/35694606
[11] Suppressed to <200copies/ml for at least 6 months

- 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 or to Cabotegravir IM may be clinically appropriate but neither TAF nor Cabotegravir based PrEP are currently funded in Ireland. 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 any of the medications available for PrEP in Ireland.

3.5 PrEP and pregnancy

HIV seroconversion in pregnancy represents a significant risk for vertical transmission of HIV[12] [13].

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 2024 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 (129/5014, 2.57%, 95% CI 2.15 – 3.05) or emtricitabine (151/5030, 3.00%, 95%CI 2.55-3.51)[14].

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[15].

Pregnant people at-increased-risk 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 increased risk of HIV 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.

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[12] 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.

[13] 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

[14] https://www.apregistry.com/forms/interim_report.pdf, accessed 7th November 2024

[15] 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

3.6 PrEP and young people

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.

4. Clinical assessment

This section outlines the potential steps in a patient journey from being identified as being at increased 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.

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 increased risk of HIV or may not be aware of PrEP. In such circumstances HIV risk and eligibility for PrEP will become apparent on taking a complete 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 the time sensitive need for PEP in line with national PEP guidelines[16].

- Consultations should be able to identify people at increased risk of HIV from their sexual history, anticipated future sexual behaviour, history of STIs, history of PEP use, history of drug use including chemsex, by determining:
    - Last sex
        - Type of sex (anal, vaginal, oral and insertive, receptive or both[17])
        - 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

[16] Guidelines for the Emergency Management of Injuries (EMI) and Post-Exposure Prophylaxis (PEP) https://www.hpsc.ie/a-z/emi/

[17] 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”.

- Use of chems during sex in the last 6 months
    - Individuals who engage in chemsex should be asked about injecting drug use ("slamming") and informed of safe injection and non-needle sharing practice.
    - More information on chemsex and support services is available through the HSE Drugs and Alcohol helpline (Tel 1800 459 459), Man2Man.ie websites, https://man2man.ie/chemsex/ and on the drugs.ie, https://drugs.ie/ghb.
    - For information or referral in regard to GHB 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/.

4.2 Addressing HIV risk and baseline assessment

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) and further support/referral as 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) particularly those 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 HIV Antigen/Antibody laboratory blood test

        - Rapid HIV testing can also be performed (4th generation) to enable same day PrEP initiation but should not replace 4th generation laboratory blood testing
    - HIV viral load testing should be performed in individuals reporting symptoms and signs suggestive of HIV seroconversion[18]. PrEP should NOT be started until HIV infection has been excluded in those with symptoms and signs of HIV seroconversion. Individuals in these 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 where there is a significant concern for recent HIV acquisition 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 surface Antigen (sAg) testing and additional Hepatitis B markers as directed by vaccine history. 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[19]
- 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 and Mpox
- Discuss PrEP and provide written information (see Patient Information Leaflet[20])
- 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.

[18] 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.

[19] 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)

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

4.3 Starting PrEP

- Confirm negative HIV status
    - Confirmed negative 4th generation laboratory blood HIV test within last 4 weeks, in general a laboratory HIV test is sent on the day of starting PrEP.
    - 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 the HIV result before starting PrEP. A same day rapid HIV test[21] with a 4th generation blood test in process can be considered.
- Determine if in HIV window period[22] 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 safe starting, safe stopping
    - If the risk of HIV acquisition is through **receptive anal sex**, oral PrEP can be started with a double dose (two pills, TDF-FTC) 2-24 hours before sex, continued with one tablet daily as long as protection is needed, and safely stopped with a single dose daily for two days after last sex.
    - If the risk of HIV acquisition is through **insertive anal/vaginal/neovaginal sex**, oral PrEP can be started with a double dose (two pills, TDF-FTC) 2-24 hours before sex, continued with one tablet daily as long as protection is needed and safely stopped with a single dose daily for two days after last sex.
    - If the risk of HIV acquisition is through **receptive vaginal/neovaginal sex,** oral PrEP can be started with a double dose (2 pills, TDF-FTC) 2-24 hours before sex , continued with one tablet daily as long as protection is needed and safely stopped with a single dose daily for seven days after last sex.

[21] Oral rapid HIV tests are not recommended in this circumstance

[22] The window period for a 4th generation laboratory HIV test is 45 days, https://www.bhiva.org/file/5f68c0dd7aefb/HIV-testing-guidelines-2020.pdf

    - If the risk of HIV acquisition is through **injecting drug use**, oral PrEP can be started with a double dose (two pills, TDF-FTC) 2-24 hours before, continued with one tablet daily as long as protection is needed and safely stopped with single dose daily for **seven days** after last injecting drug use.
- Discuss adherence and dosing schedule, including suitability for event based dosing, see **Appendix 2** and section 4.5 on missed doses, need for PEP
- 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, see **Appendix 2** for further details on suitability for event based dosing
- Document decision regarding starting, confirm contact details and preferred mechanism for contacting where need arises.

4.4 Follow up visits

- In general patients using PrEP should have three monthly HIV/STI testing. The exact timing of follow up visits can be determined by individual need
- For patients using 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.
- 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)
- Physical examination as required
- Investigations
    - 4th generation 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, **Appendix 2**, for frequency of renal monitoring and recommendations in the setting of impaired renal function

- Vaccination follow-up as required
- In asymptomatic, patients online STI and HIV testing can be considered for biannual follow up, with in person attendance at other times. Agreed criteria[23] for biannual online STI and HIV testing are:
  - 17 to 40 years of age, individuals over 40 years may also be suitable for this follow up pathway. It is not recommended for those aged 17 years and under;
  - up to date with recommended vaccines;
  - no clinical concerns around PrEP adherence;
  - 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 or if previously treated syphilis a negative RPR in follow up[24].
- 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 PEP 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.

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.**

Condomless Anal sex (insertive/receptive) or Insertive vaginal/neovaginal sex

If >7 days since last oral PrEP dose:

[23] 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.

[24] For patients with a history of previous syphilis, quantitative RPR testing is required to assess for reinfection. Current syphilis testing within the home STI testing service allows for a semi quantitative RPR. Any reactive RPR should be confirmed with formal blood draw.

- PrEP should be restarted with a double dose (2 tablets TDF-FTC) as soon as possible, preferably within 24 hours and no later than 72 hours after exposure, continue daily while seeking urgent PEP assessment.
- If no PrEP medication, seek urgent PEP assessment as soon as possible within 72 hours.

If </=7 days since last oral PrEP dose:

- Resume PrEP as prescribed as soon as possible.
- If no PrEP medication, seek urgent PEP assessment as soon as possible within 72 hours.

Condomless Receptive vaginal/frontal, neovaginal sex

If >3 days since last oral PrEP dose:

- PrEP should be restarted with a double dose (2 tablets TDF-FTC) as soon as possible, preferably within 24 hours and no later than 72 hours after exposure, continue daily while seeking urgent PEP assessment.
- If no PrEP medication, seek urgent PEP assessment.

If </=3 days since last oral PrEP dose:

- PrEP should be resumed with a double dose (2 tablets TDF-FTC) as soon as possible, continue daily single tablet dosing and make contact with PrEP service.
- If no PrEP medication, seek urgent PEP assessment.

Risk through injecting drug use:

If >4 days since last oral PrEP dose:

- PrEP should be restarted with a double dose (2 tablets TDF-FTC) as soon as possible in the 24 hours and no later than 72 hours since exposure and continue daily while seeking urgent PEP assessment.
- If no PrEP medication, seek urgent PEP assessment.

If </=4 days since last oral PrEP dose:

- PrEP should be resumed with a double dose (2 tablets TDF-FTC) as soon as possible, continue daily single tablet dosing and make contact with PrEP service.
- If no PrEP medication, seek urgent PEP assessment.

Missed post coital dose for event-based PrEP

- We recommend that, for event-based oral PrEP users who are late with, or missed, the first post-coital dose, the first post-coital dose can still be taken up to 48 hours after sex, provided at least one tablet was taken before sex; the second post-coital dose should be taken 24 hours after the first to complete the course.
- We recommend that if more than 48 hours have elapsed after last sexual risk, the first dose should be taken and advice should be sought within 24 hours regarding PEP.
- If the individual does not have any PrEP medication, they should seek urgent PEPSE assessment.

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.

For individuals who experience gastrointestinal side effects following the double dose (two pills), the loading dose can be taken as two separate tablets 6-12 hours apart once the double dose is taken within 2 to 24 hours before exposure.

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.

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 2023, 13% of all first-time diagnoses were co-infected with at least one acute bacterial STI: chlamydia, gonorrhoea and/or early infectious syphilis. The proportion co-infected with a bacterial STI was higher (26%) among gbMSM[25]. 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[26].

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
	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

[25] HSE-Health Protection Surveillance Centre. HIV Slideset2023. Dublin: HPSC; November 2024

[26] 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

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[27]			
	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[28]			
	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
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

[27] 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.

[28] 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.

3. HIV PARTNER 2 observational study[29]			
	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 [30]

4) Recently updated International PrEP Guidelines

United Kingdom, 2024
Draft BASHH/BHIVA guidelines on the use of HIV pre-exposure prophylaxis (PrEP)(2024), V3.0 24/09/2024 available on the BASHH website for consultation until end of November 2024. The final version is expected to be published on the BASHH website in early 2025.

Europe, 2024
European AIDS Clinical Society, October 2024 https://www.eacsociety.org/guidelines/eacs-guidelines/

Australia and New Zealand, 2023
https://prepguidelines.com.au/wp-content/uploads/2023/12/PrEP-Guidelines_Final_ver2.pdf

[29] 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.

[30] 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.

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		➢ Oral PrEP is licensed for daily use and can be offered to all people who are eligible for PrEP ➢ Event based dosing[31] (EBD) has been shown to be effective for men having anal sex (insertive and receptive) with other men. ➢ EBD can be used for protection over one 24 hour period of sex or over several days, for example at weekends or on holidays. ➢ EBD can be considered where protection is needed for receptive anal sex in men, insertive anal and insertive vaginal sex where sex is infrequent (for example less than 2 times per week, not on consecutive days) and where the individual is

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

					able to allow adequate time for taking the first dose before having sex[32]. ➢ EBD is not recommended where protection is needed for receptive vaginal/frontal sex or injecting drug use ➢ EBD is not recommended in people who are hepatitis B surface antigen positive. ➢ EBD may be suitable in individuals who have baseline renal impairment or develop renal impairment on daily TDF/FTC once there are no contraindications to EBD ➢ EBD can be considered in transgender people who only require protection for anal sex (receptive/insertive) or insertive vaginal sex when under the care of a consultant in Genitourinary Medicine or Infectious Diseases
Discuss safe starting and safe stopping PrEP	X	X	X		1. Daily dosing schedule *Protection needed for Anal (insertive and receptive for cismen) and insertive vaginal/frontal/neovaginal 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 sex *Protection needed for receptive Vaginal sex/frontal/neovaginal sex* ➢ Starting: 2 tablets between 2 and 24 hours before sex ➢ While on PrEP one tablet every 24 hours ➢ Stopping: continue one tablet every 24 hours for 7 days after last sex

[32] 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

					2. Event based/On demand dosing schedule **only where appropriate as outlined above** One 24 hour period of protection ➢ take 2 pills 2 – 24 hours before sex ➢ take 1 pill 24 hours later ➢ take 1 more pill 48 hours after the double dose Multiple sexual episodes over more than one 24 hours period ➢ 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 sex
Discuss and assess adherence. **Provide support where adherence suboptimal**	X	X	X		Provide adherence support and education using patient information resources. Of note, suboptimal PrEP adherence may lead to PrEP failure and breakthrough HIV infection. For daily PrEP users this is of significance where <4 doses per week are taken for insertive vaginal, anal and receptive anal sex (in men) protection or <6 doses per week are taken for people having receptive vaginal/frontal sex protection
Missed doses					See section 4.5
4th generation HIV testing **HIV viral load testing where concerns for recent HIV seroconversion**	X	+/-	X		➢ A negative 4th generation laboratory blood HIV test must be documented within four weeks prior to first starting PrEP. In general, this will be done on the day of 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 laboratory blood HIV test in progress. ➢ Where an individual is within the window period at first starting PrEP repeat HIV test at 6 weeks following most recent potential exposure, 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 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 (i.e. Hepatitis B surface antigen positive) should have their hepatitis B and PrEP assessment and 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.[33]

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

Hepatitis C testing	X		+/-	X	Annual hepatitis C testing is recommended for MSM. Please read footnote for further information on hepatitis C testing[34]
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. Individuals who have had previously treated syphilis will remain T. pallidum EIA positive. Diagnosis of re-infection is made on basis of RPR in follow up. Individuals who have a positive RPR following successful treatment may be best managed at a consultant led PrEP clinic. Individuals who have a negative RPR following successful treatment should be referred to a consultant led STI clinic for management of a new positive RPR in follow up. The home STI testing service is not suitable for syphilis monitoring in individuals who have a positive RPR following successful syphilis treatment
Serum creatinine/ eGFR	X		for some	X	**All individuals starting PrEP should have creatinine measured and eGFR at baseline .** ➢ PrEP can be started while waiting for creatinine and eGFR results ➢ Assessment for proteinuria is not recommended at baseline where eGFR is normal ➢ Assessment for proteinuria in follow up is not recommended where eGFR remains normal ➢ All patients should be informed of the impact of creatine and protein supplements on creatinine measurements and advised to discontinue for 2 to 4 weeks before scheduled renal blood tests

[34] 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

					eGFR >90 mls/min/1.73m^2 [35] At baseline and in follow up ➢ </=40 years and no identified risks for renal impairment, including medical conditions and potentially nephrotoxic medications, measure creatinine and eGFR **annually** whilst on PrEP ➢ >40 years, and/or identified risks for renal impairment, including medical conditions and potentially nephrotoxic medications, measure creatinine and eGFR **6 monthly** whilst on PrEP **eGFR 60-90 mls/min/1.73m^2** ➢ At baseline and/or in follow up ➢ Assess for relevant medical conditions, nephrotoxic drugs creatine supplements ➢ If the lab used MDRD to calculate eGFR, recalculate with CKD-EPI 2009 but do not include ethnicity[36] ➢ If taking creatine supplements advise discontinuation and repeat 2 to 4 weeks post discontinuation ➢ Consider moving to event based dosing where appropriate ➢ If CKD-EPI 60 to 69 repeat in 3 months, UA and/or UPCR ➢ If CKD-EPI 70 to 89 repeat in 6 months, UA and/or UPCR ➢ TAF/FTC and Cabotegravir may be a suitable alternative in this circumstance but are not currently funded in Ireland

[35] 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.

[36] Currently, in Ireland, the most commonly used equations for estimating GFR are based on The Modification of Diet in Renal Disease Study (MDRD) and Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) both of which include a factor for adjustment based on ethnicity. In line with international recommendations, the National Clinical Pathology Programme does not recommend application of corrections to eGFR based on race or ethnicity. The recommended eGFR calculation tool is the CKD-EPI 2009 without inclusion of race correction. Please see here for the full advice from the National Clinical Pathology Programme with further information and recommendations on the role of eGFR in monitoring renal function.

					eGFR <60 mls/min/1.73m^2 at baseline or in follow up **Baseline eGFR <60mls/min/1.73m^2** ➢ Assess for relevant medical conditions, nephrotoxic drugs creatine supplements and consider renal referral. TDF/FTC PrEP should only be commenced or continued under the supervision of an appropriately trained and experienced consultant in Genitourinary Medicine/Infectious Diseases with due regard to potential risks and benefits on a case by case basis. ➢ TAF/FTC and Cabotegravir may be a suitable alternative in this circumstance but is not currently available
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[37] 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 4. Mpox vaccination in line with NIAC recommendations
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 increased risk of HIV

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

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. People under 24 years of age may not have completed bone formation. 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.