



# Practical Guidance for Healthcare Workers in Ireland on HIV Pre Exposure Prophylaxis (PrEP)

December 2017

---

## Table of Contents

1. Background and context.....	2
2. PrEP in Ireland .....	3
2.1 HIV PrEP working group.....	3
2.2 Current PrEP availability in Ireland .....	4
2.2.1 PrEP in community pharmacies.....	4
2.2.2 Sourcing generic PrEP online .....	4
2.2.3 Important considerations .....	5
3. Determining suitability for PrEP .....	5
3.1 Who may be a suitable candidate for PrEP? .....	5
3.2 Who may not need PrEP? .....	6
3.3 When is PrEP contraindicated?.....	6
4. Monitoring Individuals on PrEP .....	7
4.1 History & discussion to document.....	7
4.2 Recommended assessment .....	7
4.2.1 First visit.....	7
4.2.2 Subsequent visits:.....	9
4.3 Adverse Events and Statutory Notification of STIs and HIV .....	10
Appendix 1. Timelines for starting/stopping PrEP .....	11
Appendix 2. Patient Information Leaflet .....	12

## 1. Background and context

There is a large body of evidence, including from European studies<sup>1 2</sup> favouring the use of Pre-exposure prophylaxis (PrEP), specifically tenofovir/emtricitabine orally, in HIV prevention. The European Medicines Authority granted approval for the use of **once daily** Truvada® for reducing the risk of sexually acquired HIV-1 on 22<sup>nd</sup> of August 2016<sup>3</sup>, in combination with safer sex practices. US, Kenya and South Africa have implemented programmatic roll-out, and use has increased substantially in several US cities including San Francisco where no new HIV infections have been recorded in over 1200 individuals enrolled in a PrEP programme in 2014<sup>4</sup>.

In Europe, PrEP is currently available in France and Scotland. England and Wales have recently commenced public health trials on PrEP. The European AIDS Clinical Society recommends PrEP for those at substantial risk of acquiring HIV, in line with the World Health Organisation recommendations, and several European countries are preparing their own national clinical guidelines or Position Statements.

Truvada® for PrEP is not currently available through the HSE in Ireland. Gilead made a submission to the HSE National Centre for Pharmacoeconomics in June 2017 and following a rapid review a full pharmacoeconomic evaluation was recommended and is awaited. Truvada® came off patent in the summer of 2017, however the ability to use generic preparations is under question given that Truvada® has a supplementary protection certificate in place which does not expire until 2020. This supplementary protection certificate is currently the subject of a case taken by a number of generic companies against Gilead in the UK and subsequently referred to the European Court of Justice.

A number of generic PrEP preparations are registered with the HPRA. On December 1<sup>st</sup> 2017, Teva Pharmaceuticals Ireland announced that its generic PrEP preparation will be available on private prescription through community pharmacies in Ireland from Monday 4<sup>th</sup> December 2017.

In addition, health care professionals and community advocates are aware that people are sourcing generic PrEP preparations over the internet and not presenting for monitoring and evaluation whilst taking PrEP.

---

<sup>1</sup> Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. McCormack S et al. Lancet. 2016 Jan 2;387(10013): 53-60. doi: 10.1016/S0140-6736(15)00056-2. Epub 2015 Sep 9

<sup>2</sup> On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection. Molina JM et al. N Engl J Med. 2015 Dec 3;373(23):2237-46. doi: 10.1056/NEJMoa1506273. Epub 2015 Dec 1

<sup>3</sup> <http://www.gilead.com/news/press-releases/2016/8/european-commission-grants-marketing-authorization-for-gileads-oncedaily-truvada-for-reducing-the-risk-of-sexually-acquired-hiv1>

<sup>4</sup> [http://www.natap.org/2016/IAC/IAC\\_64.htm](http://www.natap.org/2016/IAC/IAC_64.htm)

This guidance has been drafted by experienced clinicians in Ireland who sit on the HIV PrEP working group. Earlier versions were drafted in September 2016 and October 2017<sup>5</sup>. The position statement issued by BASHH/BHIVA<sup>6</sup>, which includes “Practical Guidance for healthcare workers”, has been used, with permission, as a framework in the development process. Guidance, opinion and information were also sought from the Irish Medical Council, the Health Products Regulation Authority and Legal Opinion was sought via the HSE Legal department.

This guidance is for healthcare professionals who are seeing patients who may already be buying PrEP from the internet, for patients who are making enquiries about PrEP or for patients deemed suitable candidates for PrEP and who may wish to avail of PrEP on a private prescription.

The requirement for this information and guidance document may ultimately be replaced by national clinical guidelines for HIV PrEP in Ireland once a mechanism for availability of PrEP within the HSE is identified. In the meantime updates to this practical guidance will be circulated in response to changes in availability of PrEP as they occur and in response to emerging pertinent information.

## 2. PrEP in Ireland

PrEP is an important addition to the suite of HIV prevention tools which includes access to: HIV testing; condoms; support around behavioural and risk modification; HIV post exposure prophylaxis; STI testing, treatment and management; and access to antiretroviral therapy for people living with HIV.

### 2.1 HIV PrEP working group

To develop recommendations around PrEP in Ireland, the HSE Sexual Health and Crisis Pregnancy Programme has convened a multisectoral working group. It is the view of the working group that individuals on PrEP should have access to the full suite of combination HIV (and STI) prevention<sup>7</sup> and STI management, specifically:

- Condoms

---

<sup>5</sup> Practical Guidance for Healthcare Workers in Ireland on HIV Pre Exposure Prophylaxis (PrEP) September 2016, October 2017 circulated via SSSTDI and IDSI

<sup>6</sup> <http://www.bhiva.org/documents/Publications/BHIVA-BASHH-Position-Statement-on-PrEP-in-UK-May-2016.pdf>

<sup>7</sup> HIV and STI prevention among men who have sex with men, ECDC Guidance, 2015, <https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/hiv-sti-prevention-among-men-who-have-sex-with-men-guidance.pdf>

- Vaccination against HAV, HBV, HPV in line with national immunisation guidelines<sup>8</sup>, as well as the ability to deliver further vaccinations in the setting of disease outbreaks
- HIV testing using accredited diagnostics and laboratories
- STI testing using accredited diagnostics and laboratories
- Post exposure prophylaxis, in line with the national PEP guidelines<sup>9</sup>
- STI treatment
- Partner notification
- Discussion, support and onward referral where appropriate in relation to safer sex, alcohol and drug use.

Furthermore clinicians providing PrEP should be competent in the assessment and management of STIs and HIV risk. These requirements have been incorporated into national standards. It is intended that these standards will be applied in the event that PrEP becomes available through the HSE.

## 2.2 Current PrEP availability in Ireland

### 2.2.1 PrEP in community pharmacies

The branded PrEP product, Truvada<sup>®</sup>, is available on private prescription following licensing for the PrEP indication in August 2016.

As of 4<sup>th</sup> December 2017 the generic PrEP product from Teva Pharmaceuticals Ireland is available on a private prescription through community pharmacies in Ireland.

### 2.2.2 Sourcing generic PrEP online

Results from Ireland of an internet based survey in several European countries in 2016 found that of the 365 responses from Ireland to the question on “informal PrEP use”, 12 (3.4%) were accessing PrEP themselves<sup>10</sup>. Despite the recent availability of generic PrEP through community pharmacies some individuals may still elect to source PrEP online.

In Ireland, it is illegal to source prescription medication (including over the internet) without a prescription<sup>11</sup>. We should inform patients about this as most will not be aware of this fact.

A doctor is not under any legal obligation when providing a prescription to either state where the medicine is to be sourced, or to satisfy himself/herself that a patient is not sourcing the medicine online. However there is an ethical onus on the prescriber to educate the patient about ways to

---

<sup>8</sup> HSE Immunisation Guidelines, <http://www.hse.ie/eng/health/Immunisation/hcpinfo/guidelines/>

<sup>9</sup> <http://www.hpsc.ie/a-z/EMIToolkit/>

<sup>10</sup> FlashPrEP Europe, Ireland early results, personal communication, HIV Ireland

<sup>11</sup> <http://www.irishstatutebook.ie/eli/2003/si/540/made/en/print>

ensure they are getting best product. Therefore it is possible for doctors to write prescriptions for patients who may subsequently source medication over the internet. Doctors are not under any obligation to write prescriptions for PrEP.

In Ireland, it is illegal to supply prescription medication by mail order, which includes supplying prescription medication over the internet<sup>8</sup>. The Health Products Regulatory Authority (HPRA) provides information to the public in relation to the sourcing of medicines over the internet<sup>12</sup>. Given that it is illegal to supply prescription medicines over the internet, customs and excise will seize parcels suspected of containing prescription medicines and hand them over to the HPRA. The HPRA will thereafter make contact with the recipient of the parcel. The HPRA have indicated that when they contact an individual following seizure of medicines, their primary objective is to gain further information on the supplier of medicines and not to take cases against individuals.

### 2.2.3 Important considerations

Individuals being issued with a prescription for PrEP, should have an assessment of risk and suitability for PrEP and discussion around taking PrEP, adherence and the need for regular assessment whilst on PrEP. Individuals on PrEP should attend a health care provider for assessment, monitoring and evaluation at least every three months.

The following sections provide guidance on determining suitability for PrEP; monitoring individuals on PrEP and reporting adverse events to the HPRA and mandatory reporting of STIs and HIV.

## 3. Determining suitability for PrEP

### 3.1 Who may be a suitable candidate for PrEP?

Of note, there is no one set of internationally accepted clinical eligibility criteria for PrEP. The WHO recommends that PrEP be offered to individuals where the risk of incident HIV infection is 3 per 100 person years or higher<sup>13</sup>.

PrEP may be suitable in the following circumstances:

#### **For MSM or transgender female having sex with men, who are:**

- HIV negative
- sexually active with likelihood of remaining sexually active in the next 3 months

---

<sup>12</sup> [http://www.hpra.ie/docs/default-source/publications-forms/information-leaflets/dangers-bpmo\\_web.pdf?sfvrsn=8](http://www.hpra.ie/docs/default-source/publications-forms/information-leaflets/dangers-bpmo_web.pdf?sfvrsn=8)

<sup>13</sup> Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection <http://www.who.int/hiv/pub/arv/arv-2016/en/>

**AND one of the following:**

- had condomless anal sex (CAI) with at least two different partners over the last 6 months
- had an episode of STI (early infectious syphilis, rectal chlamydia (including LGV), rectal gonorrhoea, acute HBV, sexually acquired HCV) over the last 12 months
- have taken a course or courses of PEP over the last 12 months
- have used drugs associated with chemsex over the last 6 months

**For a HIV negative sexual partner of a HIV positive person who is not known to be on suppressive ART:**

- the HIV positive person should be encouraged to go on ART
- PrEP may be used while awaiting sustained (6 months) virological suppression.

### **3.2 Who may not need PrEP?**

People may not require PrEP if they are:

- in a monogamous relationship with a HIV positive partner who is confirmed to be on suppressive ART for at least 6 months
- in a monogamous relationship with a partner who is known to be HIV negative.

### **3.3 When is PrEP contraindicated?**

PrEP is contraindicated in the following people:

- HIV positive
- unknown HIV status
- poorly adherent to PrEP (i.e. < 4 days per week of a daily dosing schedule) with continued high risk exposure
  - In these circumstances consideration should be given to stopping PrEP as there is a significant risk for HIV infection and development of resistance
- allergic to tenofovir disoproxil and/or emtricitabine

## 4. Monitoring Individuals on PrEP

Individuals on PrEP (regardless of how it is sourced) should have regular follow up, at least every 3 months.

In addition to an individual risk associated with unmonitored PrEP use, there is a significant potential public health risk.

It is strongly recommended that clinicians give consideration to the full suite of HIV (and STI) prevention tools and appropriate monitoring of individuals before prescribing PrEP.

### 4.1 History & discussion to document

- Sexual history
- HIV and STI screens in the last year, and date of the last HIV test
- Vaccination needs in line with national immunisation guidelines
  - Hepatitis A, B (all) and HPV (<26 years)
- History of bone or renal disease
- List of current medication
- Importance of 3-monthly HIV/STI screen, more frequently may be required
- Review patient's current/proposed PrEP dosing schedule (EBD or daily)
- Discuss timelines around starting/stopping PrEP, see **Appendix 1** for further information
  - Discuss need for follow up HIV and STI testing if stopping PrEP
  - Ensure awareness around PEP, including how to access, if stopping PrEP
- Potential risks of online purchase of medication and provision of HPRA information (available to download [http://www.hpra.ie/docs/default-source/publications-forms/information-leaflets/dangers-bpmpo\\_web.pdf?sfvrsn=2](http://www.hpra.ie/docs/default-source/publications-forms/information-leaflets/dangers-bpmpo_web.pdf?sfvrsn=2))
- Risk reduction including information and support with Chemsex as appropriate
- Recognition of HIV seroconversion symptoms, symptoms of STIs and clear advice around the need to attend with symptoms
- Provide with patient information leaflet (see **Appendix 2**)

### 4.2 Recommended assessment

#### 4.2.1 First visit

Where it is known that the patient is accessing PrEP or about to start PrEP, the following assessment is recommended:

- 4<sup>th</sup> generation venous blood HIV test

- Where there has been a recent risk for HIV acquisition the HIV test should be repeated in 4 weeks
- HBV testing, directed by history
- Start HBV vaccination if immunity unknown
  - on-demand PrEP is not recommended in chronic hepatitis B infection, if continuous PrEP is started, appropriate medical review (Hepatology or Infectious Diseases) is required before cessation
- HAV testing and subsequent vaccination if indicated
- Chlamydia and Gonorrhoea NAAT testing
  - Multisite testing for MSM in line with BASHH 2014 MSM guidance<sup>14</sup>
  - First void urine for heterosexual men
  - Vulvovaginal swab (provider or self-taken) for women
- Syphilis serology
- In line with national guidelines<sup>15</sup>, HIV negative MSM should be offered testing annually for HCV as part of an overall STI screen. More frequent testing may be required if clinically indicated, e.g. an unexplained rise in ALT, a diagnosis of a new STI, or if a risk exposure has occurred such as contact with a known case of HCV, or other risk behaviours including chemsex
- In line with national guidelines<sup>18</sup>, HCV testing should be considered part of routine sexual health screening for:
  - people who are HIV positive
  - sex workers
  - people who inject drugs
  - or if indicated by the clinical history e.g. unexplained jaundice
- Serum creatinine and eGFR
  - Consider renal referral in those with eGFR <60 mls/min/1.73m<sup>2</sup> at baseline before starting PrEP
- Urinalysis
- Confirm mechanisms for contacting patient with results/updates etc.

---

<sup>14</sup><http://www.bashh.org/documents/BASHH%20Recommendations%20for%20testing%20for%20STIs%20in%20MSM%20-%20FINAL.pdf>

<sup>15</sup> [http://health.gov.ie/wp-content/uploads/2017/08/HepC-NCG-15\\_Summary\\_v8.pdf](http://health.gov.ie/wp-content/uploads/2017/08/HepC-NCG-15_Summary_v8.pdf)



#### 4.2.2 Subsequent visits:

For patients who are on PrEP, follow up is recommended at least every 3 months:

- 4<sup>th</sup> generation venous blood HIV test
- Chlamydia and Gonorrhoea NAAT testing
  - Multisite testing for MSM in line with BASHH 2014 MSM guidance<sup>16</sup>
  - First void urine for heterosexual men
  - Vulvovaginal swab (provider or self-taken) for women
- Syphilis serology
- In line with national guidelines<sup>18</sup>, HIV negative MSM should be offered testing annually for HCV as part of an overall STI screen. More frequent testing may be required if clinically indicated, e.g. an unexplained rise in ALT, a diagnosis of a new STI, or if a risk exposure has occurred such as contact with a known case of HCV, or other risk behaviours including chemsex
- In line with national guidelines<sup>18</sup>, HCV testing should be considered part of routine sexual health screening for:
  - people who are HIV positive
  - sex workers
  - people who inject drugs
  - or if indicated by the clinical history e.g. unexplained jaundice
- Urinalysis every visit (further investigation if protein 1+ or more)
- Creatinine/eGFR
  - Check serum creatinine annually if eGFR >90 ml/min/1.73m<sup>2</sup>, no nephrotoxic drugs, no relevant medical conditions and <40 years.
  - Check serum creatinine every six months if eGFR >90 and >40 years
  - Check serum creatinine every three months if eGFR 60-90 ml/min/1.73m<sup>2</sup> or on other nephrotoxic drugs or has other relevant medical conditions
  - Stop PrEP and consider renal referral if eGFR falls to <60 ml/min/1.73m<sup>2</sup> on PrEP
- Discuss HIV risk, including whether or not they still need to be on PrEP, and provide risk reduction including information and support with Chemsex as appropriate

---

<sup>16</sup><http://www.bashh.org/documents/BASHH%20Recommendations%20for%20testing%20for%20STIs%20in%20MSM%20-%20FINAL.pdf>

- Where a patient is found to be HIV positive at follow up, they should be seen urgently by a senior doctor and/or referred to HIV services. Information in relation to time and date of last dose of PrEP and dosing schedule should be obtained and documented.
- Confirm mechanisms for contacting patient with results/updates etc.

### **4.3 Adverse Events and Statutory Notification of STIs and HIV**

Any adverse events should be reported through the HPRA, <https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form>.

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

## Appendix 1. Timelines for starting/stopping PrEP

The BHIVA/BASHH guidelines on the use of HIV PrEP (2017)<sup>17</sup> review the evidence around starting and stopping PrEP and make the following recommendations. Of note, these guidelines have not been finalised but this is expected in the near future as the consultation process has now closed.

It has been shown that the pharmacokinetics of TDF and FTC vary by tissue.<sup>18</sup> Available data suggest that time to clinical protection for TDF and FTC (and active metabolites) is shortest in the lower gastrointestinal tract, followed by peripheral blood mononuclear cells and then in the female genital tract.

- The time to clinical protection for anal sex has been evaluated in a single RCT (IPERGAY), starting with double-dose of TDF-FTC 2–24hrs before sex. This is supported by pharmacokinetic data in animal studies.
- The time to clinical protection for vaginal sex has been extrapolated from pharmacokinetic studies of TDF-FTC and there is consensus for a lead-in time for protection of 7 days.
- Data from IPERGAY demonstrates that, when PrEP is taken to prevent HIV acquisition from anal sex, dosing can be stopped when an oral dose has been taken 24 hours and 48 hours after the last episode of potential exposure. This is supported by animal and pharmacokinetic studies when the person is receptive, but there are fewer data for foreskin and urethra.
- There is consensus that, when taken to prevent HIV acquisition from vaginal sex, TDF-FTC can be stopped when a daily oral dose has been taken for 7 days after the last episode of potential exposure.

---

<sup>17</sup> <http://www.bhiva.org/PrEP-guidelines-consultation.aspx>

<sup>18</sup> Patterson KB, Prince HA, Kraft E, et al. Penetration of tenofovir and emtricitabine in mucosal tissues: implications for prevention of HIV-1 transmission. *Science Translational Medicine*. 2011;3(112):112-114

## Appendix 2. Patient Information Leaflet

**Please note, the English version of this leaflet was updated in July 2018 – see individual PrEP leaflets.**

# HIV PrEP in Ireland

---

### **Information booklet for people who are on PrEP or are considering accessing PrEP**

The HSE Sexual Health and Crisis Pregnancy Programme (SHCPP) and the HIV PrEP working group strongly encourages people who are on PrEP, to attend a health care provider for regular monitoring while taking PrEP.

The HSE SHCPP and the HIV PrEP working group strongly encourage people who are accessing medicines online to be aware of the potential risks associated with this.

PrEP refers to a combination pill containing tenofovir DF and emtricitabine. When taken correctly in combination with other HIV prevention measures, PrEP dramatically reduces the risk of HIV sexual transmission.

---

This booklet was produced with kind permission from i-Base to adopt their resource for use in Ireland. The original i-Base resource is available at <http://i-base.info/uk-guide-to-prep/>.

The legal situation in Ireland regarding prescription medications is different to other countries and information provided in this document is based on legal advice obtained by the HSE SHCPP on behalf of the HIV PrEP working group.

---

December 2017

## Contents

HIV PrEP: Some background .....	14
What is HIV PrEP? .....	14
Who might benefit from taking PrEP?.....	14
Is there anyone who should not take PrEP?.....	14
How well does PrEP work? .....	15
PrEP and side effects .....	15
PrEP and drug resistance .....	16
PrEP and other sexually transmitted infections (STIs) .....	16
Does PrEP interact with any other medications? .....	16
Sourcing PrEP .....	17
Getting PrEP on prescription .....	17
Buying PrEP online .....	17
Before you start PrEP .....	18
1. Speak with your healthcare provider about your intention to start PrEP.....	18
2. Get a 4 <sup>th</sup> generation HIV test .....	18
3. Test for hepatitis B.....	18
4. Get vaccinated against hepatitis A and B .....	19
5. Check your kidneys .....	19
6. Check for other sexually transmitted infections (STIs).....	19
How to take HIV PrEP .....	19
1. Daily PrEP: for anal and vaginal sex.....	19
2. Event Based Dosing (EBD): only for anal sex .....	19
3. What to do if you miss a pill? .....	20
Routine care if you are taking HIV PrEP.....	21
Stopping HIV PrEP .....	21
Other considerations .....	22

## HIV PrEP: Some background

### What is HIV PrEP?

PrEP stands for Pre-Exposure Prophylaxis. HIV PrEP is taken before sex to prevent HIV infection. PrEP is used by HIV negative people to prevent them from becoming HIV positive.

Currently licensed PrEP is in tablet form. It is a combination tablet containing two drugs: tenofovir DF and emtricitabine. Both tenofovir DF and emtricitabine are medicines used to treat HIV. The brand name for this is “Truvada”. The combined tablet was approved for HIV treatment in 2004 and for use as PrEP in the United States in 2012. In August 2016, Truvada® was licensed for use as PrEP in Europe, including Ireland. Small surveys carried out in Ireland have shown that some people are accessing generic PrEP online. As of 4<sup>th</sup> December 2017, generic PrEP is available on a private prescription through community pharmacies.

PrEP is not currently available in Ireland through the HSE.

### Who might benefit from taking PrEP?

If you are HIV negative and don't always use condoms, then PrEP could reduce your risk of HIV.

You may have a higher risk of HIV if you:

- Are having sex with HIV positive partners who are not on treatment or whose treatment may not be working properly
- had a recent sexually transmitted infection (STI), especially a rectal infection or syphilis
- have previously used PEP (post-exposure prophylaxis)
- are using recreational drugs for sex (crystal meth, mephedrone or GHB), also known as ChemSex.

Discuss this with your doctor or nurse if you are not sure.

### Is there anyone who should not take PrEP?

PrEP should not be used:

- If you are HIV positive.

PrEP is usually not necessary:

- If you are only having sex with HIV positive partners who are on treatment and have an undetectable viral load.
- If you are using condoms consistently and happy to continue doing so.

## How well does PrEP work?

PrEP has been shown in many studies to be highly effective at reducing the risk of HIV infection and works extremely well if taken correctly.

The PROUD study carried out in several sexual health clinics in England, enrolled more than 500 gay and other men who have sex with men (MSM) and included some trans women. One group took daily PrEP as soon as they enrolled in the study (immediate group). The other group started PrEP after a year (delayed group).

In October 2014, PROUD reported that PrEP dramatically reduced the risk of HIV infection (by 86%). Nearly all new HIV infections happened in people in the delayed PrEP group. The few infections that happened in the immediate PrEP group were in people who had not taken PrEP properly.

The IPERGAY study, from France and Canada, also reported an 86% reduction in a similar high risk group of gay men and trans women. IPERGAY used event based dosing (EBD) rather than daily PrEP. There is more information on event based dosing later in the leaflet.

There are also good results from heterosexual studies. The Partners PrEP study in Africa reported a 96% reduction in new HIV infections in people taking PrEP correctly.

In PrEP studies where HIV infections have happened, not taking the medication properly was the biggest factor for those who became HIV positive.

## PrEP and side effects

The majority of people taking PrEP do not report side effects.

However, like all other medicines, PrEP has the potential to cause side effects. Mild nausea, diarrhoea, bloating and headache were reported in the first month by less than 1 in 10 people. These side effects then usually stop.

PrEP can also affect your kidneys, which is why monitoring is important. In the small proportion of people taking PrEP who developed reduced kidney function, these changes reversed on stopping PrEP. This risk is higher if you are aged 40 and over or if you already have reduced kidney function when you start PrEP.

PrEP can also reduce bone density by between 1% and 2%, causing slight thinning of the bones. This loss reverses after PrEP is stopped. This side effect might be more important if you already have low bone density related to other factors. It might also be important if you are younger than 30 as your bones are still developing.

## PrEP and drug resistance

If PrEP is taken correctly, there is very little chance of developing resistance.

If you become HIV positive while taking PrEP, there is a small risk of developing drug resistance to one or both drugs. This means that these drugs may not work as well in future treatment for HIV.

In PrEP studies, very few people became HIV positive whilst taking PrEP. In those who did, less than 1 in 20 developed drug resistance.

The possibility of drug resistance increases if:

- you start PrEP and you are already HIV positive
- you take a break from PrEP and don't check your HIV status before re-starting
- you don't take enough doses for protection and become HIV positive.

In February 2016, a case was reported of someone who became HIV positive even though he was taking his PrEP correctly. This was because he caught HIV from a partner who was already resistant to the drugs in PrEP. This is a rare event as drug resistance in people living with HIV, to tenofovir DF and emtricitabine is not very common.

## PrEP and other sexually transmitted infections (STIs)

PrEP will not protect against other STIs. Using condoms at the same time as PrEP will reduce the risk of getting other STIs and condom use is recommended for people taking PrEP.

Regular STI testing, at least every three months, is recommended for people taking PrEP.

## Does PrEP interact with any other medications?

Tenofovir DF and emtricitabine don't interact with many other medicines. (Interaction means that two or more drugs combined together can cause problems or side effects).

You should always tell your doctor (including your GP) if you are prescribed other medicines. You can also ask a pharmacist. Say you are taking PrEP so that they can check for any interactions, including with over-the-counter meds.

One important interaction is between tenofovir DF and non-steroidal anti-inflammatory drugs (NSAIDs), especially diclofenac. Together these can cause kidney problems. Other medicines from within this class include ibuprofen and naproxen. Avoid using these medicines if you are taking PrEP, or let your doctor know if you need to take them.

For trans people taking PrEP, there is no reason to expect PrEP will change the effectiveness of hormone therapy.



## Sourcing PrEP

### Getting PrEP on prescription

The branded PrEP product, Truvada®, is available on private prescription following licensing for the PrEP indication in August 2016.

As of 4<sup>th</sup> December 2017 the generic PrEP is available on a private prescription through community pharmacies in Ireland.

Before getting a prescription for PrEP from your doctor, you should discuss the routine care and monitoring that will be necessary while you are taking PrEP, and where you will go for this.

### Buying PrEP online

**The following is not a recommendation but information to help you with any decision you make:**

It is possible to buy generic PrEP products over the internet.

**In Ireland, it is illegal for a person to source prescription medication without a prescription.** This means that if you want any prescription medication you must have a prescription.

Doctors can (but are not obliged to) provide a prescription to patients who may want to source medication over the internet.

**In Ireland, it is illegal to supply medication by mail order, including over the internet.** The Health Products Regulation Authority (HPRA) provides information for the public in relation to sourcing medication over the internet. This is available at <http://www.hpra.ie/docs/default-source/publications-forms/information-leaflets>.

**These laws are in place to protect the public from bogus suppliers and there is always a possible risk if you choose to buy PrEP (or any other medication) online that you are not receiving genuine product.**

## Before you start PrEP

### 1. Speak with your healthcare provider about your intention to start PrEP

It is recommended that you talk to a health care professional if you are planning to take, or are already taking PrEP.

### 2. Get a 4<sup>th</sup> generation HIV test

It is really important to have an HIV test before or as you start PrEP, and to have regular tests when you are taking PrEP.

PrEP can only be used if you are HIV negative. If you are already HIV positive and don't realise it, you could develop resistance to drugs that you may need for treatment.

Most laboratory based HIV testing is '4th generation' HIV blood testing. This is also called a 'combined antigen/antibody' test. This test has a window period of approximately four weeks. It is the usual type of blood sample, taken from your arm, which is done at your GP or sexual health clinic.

The majority of current finger-prick HIV tests, are '3rd generation' HIV blood testing. This checks for HIV antibodies only. This test has a window period of approximately three months. Please do not rely on a finger-prick test result alone before you start PrEP.

Don't start PrEP if you have flu-like symptoms and if you had a recent HIV risk. Flu-like symptoms may be related to recent HIV infection (HIV seroconversion). If you experience these it is really important to have a HIV test before starting or if you are already taking PrEP.

If you do start PrEP and had a risk in the last four weeks, you should have another 4th generation HIV blood test four weeks after starting; just to be sure an early infection was not missed.

If you are starting PrEP after PEP, it is best to start immediately if you have ongoing risks. Ideally you should have an HIV blood test around the time you finish PEP/start PrEP plus another HIV blood test four weeks into PrEP.

### 3. Test for hepatitis B

It is essential to test for hepatitis B because PrEP medicines are active against both HIV and hepatitis B.

You can still use PrEP if you have hepatitis B, but it needs to be used more carefully.

People with hepatitis B need to take PrEP every day with medical advice and monitoring, especially if you want to stop.

Event based dosing (EBD) is not suitable for people who have hepatitis B (or who don't know their hepatitis B status).

#### 4. Get vaccinated against hepatitis A and B

Hepatitis A and B vaccination is recommended for men who have sex with men (MSM) and people who inject drugs (PWID).

This is a good time to be vaccinated, or to boost a previous vaccine.

#### 5. Check your kidneys

Kidney monitoring just involves a blood test for creatinine, and a urine test for protein. These should ideally be done just before or on the day you start PrEP with your health care provider.

#### 6. Check for other sexually transmitted infections (STIs)

This is always a good idea! This includes testing for syphilis, chlamydia, gonorrhoea and Hepatitis C.

## How to take HIV PrEP

For PrEP to be most effective, the medicine needs to be at protective levels at the time that HIV exposure may happen. As the body takes a while to absorb medicines, this means PrEP needs to be taken both **before** sex and for several days **afterwards**.

### 1. Daily PrEP: for anal and vaginal sex

- Taking one pill per day, every day.

The European Medicines Authority has licensed **daily** use of PrEP to prevent sexual acquisition of HIV.

#### Anal sex

For anal sex, daily PrEP has the most evidence. You need to take at least two tablets of PrEP between 2 and 24 hours before anal sex to make sure that the drug levels are high enough to be protected.

You need to take PrEP every day, and continue daily.

#### Vaginal sex

For vaginal sex, you need to take daily PrEP. You also need to take PrEP daily for 7 days before sex to reach drug levels that give the highest protection. This is because PrEP does not get into the vaginal tissues as well as it gets into rectal tissues.

### 2. Event Based Dosing (EBD): only for anal sex

- Taking two pills before sex as a double dose and a single pill 24 and 48 hours after.

Although there is less data on using event based dosing (EBD), it was shown to be effective in the iPERGAY study.

### **Anal sex**

You need to take at least two tablets of PrEP (double dose) between 2 and 24 hours before anal sex. The before-sex dose is very important to make sure that there is enough medicine in the body when you have sex.

You need to continue taking one pill every 24 hours for the days you are having condomless anal sex.

After your last condomless anal sex, you need to take a single pill 24 and 48 hours later.

Further information and examples on EBD can be found at <http://i-base.info/uk-guide-to-prep/>. It is best to have a conversation with your doctor before considering EBD for PrEP.

**EBD is NOT suitable for any form of vaginal sex.**

**EBD is NOT suitable if you have hepatitis B and it is really important to know your hepatitis B status before taking PrEP.**

### **3. What to do if you miss a pill?**

If you miss one, or even two pills occasionally, don't stop PrEP, just carry on once you remember.

There is still likely to be enough drug in your body to protect against HIV.

If you are missing several doses each week, you are not going to be protected against HIV if you are having condomless sex. Remember that you may need to consider PEP in a situation where you have missed several doses of PrEP and haven't used a condom or had a condom accident.

Pick a regular time to take your PrEP and try to stick to this each day. Link it to a routine task like brushing your teeth. It doesn't have to be the exact same time but it will help get you into a routine.

If you have a break from PrEP and have risks during this time, it is important to consider PEP and have another HIV test.

If you are not sure of anything, please discuss further with your doctor or nurse.

## Routine care if you are taking HIV PrEP

Once you have started PrEP, monitoring is important. If you are currently using PrEP and have not been monitored, talk to your health care professional about doing this now.

Every 3 months:

- have a '4th generation' (antigen/antibody) HIV blood test
- have a full screen for other STIs
- have a urine dipstick test for protein when you have your STI check-up; if there is more than a trace, an additional blood or urine test can be done to check your kidney function.

Every 12 months:

- have a blood test to check your kidney function
  - sometimes this needs to be done more frequently
- have a hepatitis C test
  - Sometimes this needs to be done more frequently.

## Stopping HIV PrEP

There may come a time when you might decide that you want to stop PrEP altogether. Discuss your decision to stop with your healthcare provider.

If possible, discuss any plans to stop PrEP with any regular sex partner(s) and get tested for HIV and other STIs at the same time. Make sure you both have a 4th generation HIV test four weeks after the last risk.

### **Anal sex**

If you've been taking PrEP to prevent HIV through anal sex don't stop taking it until 48 hours after the last risk for HIV. During this time, take PrEP at your regular time.

### **Vaginal sex**

If you've been taking PrEP to prevent HIV through vaginal sex don't stop taking it until 7 days after the last risk for HIV. During this time, take the PrEP at your regular time.

### **Injecting/slamming drugs**

If you're at risk of HIV through injecting drugs or slamming Chems, you should continue taking it until 7 days after the last risk for HIV. During this time, take the PrEP at your regular time.

If your circumstances change in the future, you can restart PrEP.

Remember if you have stopped PrEP and have a sexual exposure risk, you should consider PEP (post exposure prophylaxis). Ideally this should be as soon as possible but no later than 72 hours after the risk.

## Other considerations

Although PrEP is very effective at stopping HIV, it can also change how you feel about your sex life, including risks for HIV. Your clinic can provide a chance to talk about this in confidence.

Talk to your nurse, doctor or health advisor about how you feel about PrEP, and how PrEP affects the risks you sometimes take.

Other things affect taking risks, including how you feel about yourself, pressure from other people, and using alcohol and recreational drugs. Extra support is also available that can help with many of these issues.

Tell the nurse or doctor if your health has changed, or if you start new medications.

Other STIs are important. This is a reason to still carry and use condoms.

December 2017

# Shláinte Gnéis agus Clár Thoirchis Ghéarchéime Sexual Health & Crisis Pregnancy Programme