



# National Standards for the Delivery and Management of Pre-Exposure Prophylaxis (PrEP) for HIV

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February 2024

## Background and Context

The purpose of this document is to provide a set of national standards for the provision of HIV PrEP as part of combination HIV prevention in Ireland.

National Standards for HIV PrEP were first developed in 2019 prior to PrEP roll out. These were reviewed and updated in 2023 by the team at the SHCPP and the HIV PrEP working group. This multisectoral working group, with community representation, convened by the HSE Sexual Health and Crisis Pregnancy Programme (SHCPP), is tasked with developing clinical guidance documents and recommendations in relation to the use of HIV PrEP in Ireland.

These standards are evidence based and informed by engaging with those who use and provide our healthcare services. They outline the responsibilities of services, service managers, service providers and healthcare professionals, as well as establishing the expectations of service users in Ireland. They describe how services can achieve safe, quality, person-centred care and support. The standards are underpinned by the key principles set out in the Standards Development Framework<sup>1</sup>, specifically a human rights-based approach; safety and wellbeing; responsiveness, and accountability, all working together to achieve person-centred care and support.

The standards are in line with the goals of the National Sexual Health Strategy<sup>2</sup>, regarding sexual health services, specifically “Equitable, accessible and high quality sexual health services, which are targeted and tailored to need.”

Prior to publication, these standards will reviewed by the Sexual Health Clinical Advisory Group, and HSE Clinical Forum. It is intended that these standards be used by all services and healthcare professionals providing PrEP. It is acknowledged that in Ireland people may attend a public or a private PrEP Service. The service user’s decision around what type of service to attend may be informed by their choice and/or ability to access a public PrEP service. Within public PrEP services there is no cost to the individual for all care and treatment, including PrEP medication. Within private PrEP services, at this time there is a

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<sup>1</sup> Standards Development Framework: a principles-based approach. Status: Published on 29 Sep 2021, <https://www.higa.ie/reports-and-publications/guide/standards-development-framework-principles-based-approach>

<sup>2</sup> National Sexual Health Strategy 2015-2020. <https://health.gov.ie/healthy-ireland/national-sexual-health-strategy-2015-2020/>

cost for attendance, there may be a cost for investigation and treatment, but there is no cost for the PrEP medication.

The PrEP standards are presented under the following domains:

1. Access
2. Service Configuration
3. Clinical Assessment and Management
4. Management of Results
5. Clinical Governance and Staff Training
6. Information Governance
7. Patient and Public Engagement.

Under each of these domains there is a Quality Statement; Quality standard (core and desirable); Quality Measure (and how it can be measured) and Service user information.

To measure quality of care provided within services, additional information on proposed targets under domains 3 and 4, Clinical Assessment and Management and Management of Results are presented in Appendix 1. These can be used by services to audit their service and may be audited on a national basis from time to time.

In developing these standards, a **core** set of standards have been identified as the minimum standard that services providing PrEP should meet. The core standards should be considered as key performance indicators, against which services can measure their performance. In addition, this document also sets out a range of **desirable** and **highly desirable** standards that PrEP centres should strive to achieve and can be measured as part of quality improvement initiatives.

Seven standards have been developed as outlined below. Within the document the **core** or **desirable**, **highly desirable** status of the standard is clearly indicated:

1. Access
2. Service Configuration and Structure
  - 2.1. Availability of appropriate combination HIV prevention and STI management tools
  - 2.2. Links to other services
  - 2.3. Surveillance, monitoring and evaluation

3. Clinical Assessment and Management
4. Management of Results
5. Clinical Governance and Staff Training
6. Information Governance
7. Patient and Public Engagement

This document should be read in conjunction with the “Clinical management guidance for individuals taking HIV PrEP within the context of a combination HIV (and STI) prevention approach in Ireland”.

These standards will be reviewed and updated as needed two years following completion. In the interim, urgent changes will be made where required.

The Sexual Health and Crisis Pregnancy Programme (SHCPP) has responsibility for arranging, coordinating and disseminating any changes to these standards to all relevant stakeholders.

Terminology and acronyms used in this document are outlined in **Appendix 2**.

## Standard 1: Access

### Quality Statement

People should be able to self-refer to a [HSE approved PrEP service](#) for PrEP assessment.

All people referred for PrEP assessment should have access to PrEP services within a reasonable timeframe.

### Quality Standards

It is a **core** requirement that those seeking PrEP be able to do so without a referral letter.

It is a **core** requirement that those seeking PrEP assessment be contacted within 7 working days by the service they contacted and signposted to HIV/STI prevention resources and information.<sup>3</sup>

It is a **core** requirement that those seeking PrEP assessment be offered an appointment to be seen within 3 months of making contact with the service.

It is **desirable** that those seeking PrEP assessment be offered an appointment to be seen within 1 month of making contact with the service.

It is **highly desirable** that those seeking PrEP assessment be offered an appointment to be seen within 14 working days of making contact with the service.

### Quality Measures

All services providing PrEP should have a policy in place that indicates self-referral as an option for access to service.

All services providing PrEP should signpost those waiting for appointments to HIV/STI prevention resources.

Where possible services providing PrEP should monitor and report timeframes for offer of an appointment.

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<sup>3</sup> Information and resources on HIV/STI prevention are available on [www.sexualwellbeing.ie/sexual-health/](http://www.sexualwellbeing.ie/sexual-health/) and <https://man2man.ie/>.

### *How will this quality measure be assessed?*

Demonstrate access and appointment policy in relation to self-referral and signposting to resources.

Self-assessment or nationally coordinated assessment of timeframes for offer of an appointment.

### **Service User Information**

People looking to access PrEP services can expect to do so without the need for a referral letter, and expect to be offered an appointment to be seen within 3 months. Those looking to access PrEP can expect to receive information on HIV/STI prevention resources while they are waiting for their appointment.

## **Standard 2: Service Configuration and Structure**

### **2.1 Availability of appropriate combination HIV prevention and STI management tools**

#### **Quality Statement**

Services providing PrEP should be configured in such a way as to provide, or in certain specified circumstances as outlined below, provide access to combination HIV (and STI) prevention and STI management to attendees in line with national clinical guidelines<sup>4</sup>, specifically:

- Access to condoms and lubricant, available to all HSE approved PrEP services through the National Condom Distribution Service
- Vaccination against HAV, HBV, HPV, Mpox in line with national immunisation guidelines<sup>5</sup>, as well as the ability to deliver further vaccinations in the setting of disease outbreaks.

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<sup>4</sup> Clinical management guidance for individuals taking HIV PrEP within the context of a combination HIV (and STI) prevention approach in Ireland, <https://www.sexualwellbeing.ie/for-professionals/prep-information-for-service-providers/>

<sup>5</sup> Immunisation Guidelines for Ireland, <https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland>. It is recognised that at this time some private services do not have access to free vaccines for their service users. The SHCPP is currently working with the National Immunisation Office to

- HIV testing using accredited diagnostics and laboratories
- STI testing using accredited diagnostics and laboratories
- Post-exposure prophylaxis (PEP), in line with the national PEP guidelines<sup>6 7</sup>
- STI treatment within the service<sup>8</sup>
- Partner notification
- Discussion in relation to safer sex, alcohol and drug use.

## Quality Standards

It is a **core** requirement that services providing PrEP provide access to combination HIV (and STI) prevention and STI management to attendees in line with national clinical guidelines.

## Quality Measures

All services providing PrEP should provide access to all of the HIV/STI prevention tools as outlined above.

All services providing PrEP should have access pathway arrangements for PEP, syphilis treatment and vaccines in place, where these services are not available within the PrEP service.

### *How will this quality measure be assessed?*

Demonstrate access to the core STI/HIV prevention tools for their PrEP service attendees outlined above.

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increase availability of free vaccine within private PrEP services. In the meantime, an agreed referral pathway to free vaccines within public PrEP services is being explored.

<sup>6</sup> Guidelines for the Emergency Management of Injuries and Post-exposure Prophylaxis (PEP)

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

<sup>7</sup> It is recognised that PEP is not currently available through general practice and some other services. Where a service wishes to provide PrEP but does not currently have access to PEP, the service must have a PEP access pathway in place to ensure access (NOT limited to an emergency pack through an Emergency Department) within 72 hours following potential exposure to HIV is in place. This pathway should be indicated to individuals accessing PrEP.

<sup>8</sup> National guidelines on management of STIs are available here

<https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/conditions-and-treatments/genital/genital-conditions.html>. Syphilis should be managed at a specialised STI service and a timely syphilis treatment access pathway must be in place. This pathway should be indicated to individuals accessing PrEP. It is expected that the majority of chlamydia and gonorrhoea cases in PrEP patients will be managed completely within the PrEP service without a need to refer elsewhere.

## Service User Information

People attending PrEP services should expect access to a complete suite of HIV prevention and STI management services.

People attending PrEP services should be informed of the cost for attendance at an Emergency Department for out of hours PEP assessment.

## 2.2 Links to other services

### Quality Statement

Services providing PrEP should be configured in such a way as to ensure that attendees with needs beyond the scope of the service have a referral made to an appropriate service(s) within a reasonable timeframe. These include, but are not limited to, access to PEP, treatment of syphilis, substance abuse services, psychological services, HIV services, SATU, gynaecology and urology services.

### Quality Standards

It is a **core** requirement of PrEP services that all attendees with needs beyond the scope of the PrEP service are referred to appropriate services.

### Quality Measure

All services providing PrEP should have appropriate referral mechanisms and pathways to other services in place.

### *How will this quality measure be assessed?*

Demonstrate arrangements in place for onward referral where required.

## Service User Information

Attendees of PrEP services can expect to be referred onwards for appropriate care as required.



## 2.3 Surveillance, monitoring and evaluation

### Quality Statement

Disease Surveillance: In line with Infectious Disease legislation<sup>9</sup> and HPSC notification guidelines<sup>10</sup>, all PrEP services should meet all statutory obligations for disease surveillance and ensure that notification of all STIs (including enhanced surveillance where relevant) is carried out promptly.

PrEP monitoring and evaluation: All services providing PrEP should be configured in such a way as to ensure that all agreed national monitoring and evaluation requirements for PrEP are carried out within a reasonable timeframe.

### Quality Standards

Disease Surveillance: It is a **core** requirement that all PrEP services meet statutory disease notification and surveillance requirements promptly; immediately if an outbreak is suspected, within 7 working days of a laboratory diagnosis for routine notifications, and as close to time of diagnosis as possible for enhanced data.

PrEP monitoring and evaluation: It is a **core** requirement that all PrEP services participate in national monitoring and evaluation requirements for PrEP within a reasonable timeframe.

### Quality Measures

All services providing PrEP should have appropriate arrangements in place for timely disease surveillance and PrEP monitoring and evaluation.

#### *How will this quality measure be assessed?*

Demonstrate the arrangements that are in place for HIV and STI surveillance and PrEP monitoring and evaluation<sup>11</sup>.

### Service User Information

Service users should be aware of the statutory obligations around disease notification and the requirement for services to participate in a national PrEP monitoring and evaluation.

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<sup>9</sup> Infectious Diseases (Amendment) Regulations. <http://www.irishstatutebook.ie/eli/2015/si/566/made/en/pdf>

<sup>10</sup> Available from <https://www.hpsc.ie/notifiablediseases> and <https://www.hpsc.ie/notifiablediseases/notificationforms/>

<sup>11</sup> HIV PrEP Monitoring and Evaluation Framework (not yet published, will be available on [www.sexualwellbeing.ie/preproviders](http://www.sexualwellbeing.ie/preproviders))

## Standard 3: Clinical Assessment and Management

### Quality Statement

All people being assessed for PrEP or in receipt of PrEP should receive all the required care in the assessment and management of STIs and HIV prevention in a timely manner.

### Quality Standards

It is a **core** requirement that all people receiving PrEP have their eligibility criteria assessed and documented at baseline and follow-up.

It is a **core** requirement that all people receiving PrEP have an appropriate sexual history taken and documented at baseline and follow-up.

It is a **core** requirement that all people receiving PrEP have their HIV negative status confirmed prior to commencing and continuing PrEP.

It is a **core** requirement that all people considering event based (EBD) dosing PrEP have a confirmed negative hepatitis B surface antigen test before commencing EBD.

It is a **core** requirement that all people receiving PrEP have renal monitoring in line with national PrEP guidelines.

It is a **core** requirement that all people receiving PrEP are contacted regarding the need for treatment of incident STIs within 14 working days of the final result being available.

It is a **core** requirement that all people receiving PrEP with incident STIs have partner notification undertaken.

It is a **core** requirement that all people receiving PrEP are offered appropriate vaccination as part of their care.

It is a **core** requirement that all people receiving PrEP can avail of free condoms and lube as part of their care.

It is a **core** requirement that all people receiving PrEP are offered syphilis, hepatitis B (where not known to be immune), chlamydia and gonorrhoea testing at baseline and follow up.

It is a **core** requirement that all people receiving PrEP are offered hepatitis C testing in line with national HCV testing guidelines.

## Quality Measures

All people being assessed for PrEP should have appropriate assessments, in line with national guidelines, as part of their care

### *How will this quality measure be assessed?*

Demonstrate how they provide appropriate assessments, in line with national guidelines, to people receiving PrEP.

Additional information on targets for these quality measures are outlined in Appendix 1.

## Service User Information

People taking PrEP can expect to have assessments in line with national guidelines and their care needs.

At baseline and follow up, attendees can expect to have a full sexual and medical history taken, as well as any necessary examinations.

They can expect that PrEP can only be prescribed where there is a negative HIV test result and appropriate renal monitoring has been undertaken.

They can expect STI testing at baseline and follow up visits.

They can expect to be contacted regarding incident STIs within 14 working days of the final lab result being available and to be offered appropriate assessment and treatment.

They can expect that PrEP will be prescribed if indicated and appropriate.

People taking PrEP should ensure that the contact information they provide to PrEP services is accurate.

## Standard 4: Management of Results

### Quality Statement

All services providing PrEP should have access to final results of all investigations in a timely manner with robust mechanisms for:

- checking results
- responding appropriately to positive, abnormal or inconclusive results

- informing patients of results (including how many times to contact and by what means) in place for following up PrEP attendees with abnormal, inconclusive results.

## Quality Standards

It is a **core** requirement that all PrEP services have mechanisms for managing results in place for checking results and responding appropriately to abnormal or inconclusive results within a reasonable timeframe.

It is a **core** requirement that all people in receipt of PrEP who have abnormal or inconclusive results, have results communicated to them within ten working days of the final result being available.

It is **desirable** and **encouraged** that negative results are communicated to people in receipt of PrEP and within a reasonable timeframe.

## Quality Measures

All services providing PrEP should have appropriate arrangements in place for managing results, including arrangements for contacting those on PrEP.

All services providing PrEP should have appropriate arrangements in place to communicate abnormal or inconclusive results to those on PrEP within 10 working days of the final result being available.

It is desirable that services have a mechanism in place for communicating negative results to patients and that this is done within a reasonable timeframe.

### *How will this quality measure be assessed?*

Demonstrate the arrangements that are in place for managing results.

Additional information on targets for these quality measures are outlined in Appendix 1.

## Service User Information

People in receipt of PrEP can expect to be contacted about results requiring further action within 14 working days of the final lab result being available.

People in receipt of PrEP should be aware of how their results will be communicated to them and should ensure that they provide accurate contact details to PrEP services.

## Standard 5: Clinical Governance and Staff Training

### Quality Statement

All services providing PrEP must have appropriate clinical governance and staff training in place.

### Quality Standard

It is a **core** requirement that all public PrEP services have a nominated clinical lead who is a consultant in Genitourinary Medicine or Infectious Diseases.

It is a **core** requirement that within all public PrEP services, the nominated clinical lead oversees staff training within the PrEP service.

It is a **core** requirement within all general practice delivered PrEP services that each PrEP provider has completed agreed competencies prior to becoming an approved PrEP provider.

It is a **core** requirement that within all private, non-general practice PrEP services, that there is a nominated clinical lead who is a consultant in Genitourinary Medicine or Infectious Diseases.

It is a **core** requirement that all healthcare professionals involved in the provision of PrEP, have appropriate clinical governance and staff training in place.

### Quality Measure

All services providing PrEP should have appropriate clinical governance arrangements and staff training in place.

#### *How will the quality measure be assessed?*

For all public PrEP services, demonstration of a nominated Clinical Lead.

For general practice, demonstrate completion of agreed competencies.

For all PrEP providers, demonstrate clinical governance and staff training processes in place.

### Service User Information

Attendees of PrEP services can expect that their care is provided by appropriately trained staff.

## Standard 6: Information Governance

### Quality Statement

All services providing PrEP must treat patient information in a secure and confidential fashion. Patient information will only be shared with other healthcare professionals for public health or monitoring purposes, or if it is in the best interests of the patient or another party.

### Quality Standards

It is a **core** requirement that all PrEP services are compliant with General Data Protection Regulation (GDPR), the Data Protection Acts 1988 to 2018<sup>12</sup> and Infectious diseases legislation<sup>13</sup>.

### Quality Measure

All services providing PrEP must have appropriate infrastructure in place to ensure that patient information is recorded and stored in line with appropriate legislation.

#### *How will the quality measure be assessed?*

Demonstrate the arrangement and infrastructure in place to ensure that they are compliant with GDPR, the Data Protection Acts 1988 to 2018 and Infectious diseases regulations.

### Service User Information

Attendees of PrEP services can expect to have all their data treated in a confidential manner in line with appropriate legislation.

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<sup>12</sup> Data Protection Act 2018, available at <http://www.irishstatutebook.ie/eli/2018/act/7/enacted/en/html>

<sup>13</sup> Infectious Diseases (Amendment) Regulations <http://www.irishstatutebook.ie/eli/2015/si/566/made/en/pdf>

## Standard 7: Patient and Public Engagement (PPE)

### Quality Statement

People attending PrEP services will have the opportunity to provide feedback regarding the services received, as well as their opinions on alternative mechanisms of care delivery.

### Quality Standards

It is a **core** requirement that services providing PrEP have mechanisms for receiving patient and public feedback and suggestions in place.

It is a **core** requirement that services providing PrEP make information on the provision of patient and public feedback available to service users and the public.

It is a **core** requirement that services providing PrEP have mechanisms in place for responding to service user feedback.

It is **desirable** that services providing PrEP undertake service user satisfaction surveys.

### Quality Measures

All services providing PrEP should have mechanisms for providing feedback including information on how to provide feedback available within their service.

#### *How will this quality measure be assessed?*

Demonstrate the arrangements that are in place for receiving patient and public feedback and making the information available to service users.

Demonstrate the arrangements that are in place for responding to patient and public feedback.

### Service User Information

Attendees of PrEP services should expect the opportunity to provide feedback. People accessing PrEP services should have a clear pathway to make comments or complaints. They should receive feedback, as appropriate, regarding any comments or complaints made.

## Appendix 1: National Standards Targets

<b>Standard 2: Service Configuration and Structure; 2.3 statutory notification</b>
All notifiable infections identified in PrEP users should be notified within 7 days of final laboratory result Target 100% within 7 working days
All enhanced surveillance data should be completed and returned within a reasonable timeframe Target 80% of enhanced data completed within 1 month of final laboratory result
<b>Standard 3: Clinical Assessment and Management</b>
All PrEP patients will have their clinical eligibility criteria assessed and documented at visits Target 100%
All PrEP patients will have their sexual history documented at visits Target 100%
All PrEP patients will have their HIV negative status confirmed prior to each PrEP prescription Target 100%
All PrEP patients will have appropriate renal monitoring Target 90%
All PrEP patients with incident STIs will be contacted within 10 working days of final results being available Target 90%
All PrEP patients with incident STIs will have partner notification undertaken Target 90% of all patients with incident STIs will have partner notification discussed
All PrEP patients will be offered appropriate vaccination as part of their care Target 100%
All PrEP patients will be offered condoms as part of their care Target 100%
All PrEP patients will be offered syphilis, gonorrhoea and chlamydia testing at visits Target 100%
All PrEP patients will be offered HCV testing in line with national testing guidelines Target 100%
<b>Standard 4: Management of results</b>
Mechanism(s) in place for management of all abnormal or inconclusive results in PrEP patients in a reasonable timeframe (Y/N) Target 100%, measured when services are approved as PrEP providers
All PrEP patients with abnormal or inconclusive results will be informed within 10 working days of the final result being available Target 90%



## Appendix 2: Terminology and acronyms

### Terminology

The terms service manager, service provider, and service user are used throughout this document. These refer to:

- Services: this refers to any component of the care overseen by the managers, given by the providers, and received by the users.
- Service manager: any person or organisation that provides the infrastructure for the delivery of healthcare.
- Service provider: any person directly involved in the care of people accessing healthcare services.
- Service user: the people who use healthcare services, their nominated advocates, and potential users of healthcare services.

### Acronyms

- HAV            Hepatitis A virus
- HBV            Hepatitis B virus
- HCV            Hepatitis C virus
- HIV            Human immunodeficiency virus
- HPSC            Health Protection Surveillance Centre
- HPV            Human papilloma virus
- HSE            Health Service Executive
- PEP            Post-exposure prophylaxis
- PrEP            Pre-exposure prophylaxis
- STI            Sexually transmitted infection

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Clár um Thoirchis Ghéarchéime

**Sexual Health &  
Crisis Pregnancy Programme**