



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

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## 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.

These standards have been developed by Dr. Liam Townsend, a Specialist Registrar in Infectious Diseases 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 have been reviewed by the Sexual Health Strategy Implementation and Clinical Advisory Groups and have been used to inform a review of the readiness of public STI clinics to implement PrEP in line with these standards. Following the review, the standards were finalised.

In 2019, PrEP will become available through the HSE and it is intended that these standards will be used by all services and health care professionals providing PrEP.

These standards represent current best practice and outline the responsibilities of services, service managers, service providers and healthcare professionals, as well as establishing the expectations of service users. The standards are in line with the goals of the National Sexual Health Strategy, regarding sexual health services, specifically “Equitable, accessible and high quality sexual health services, which are targeted and tailored to need”.<sup>1</sup>

These standards address all eight themes identified within the National Standards for Better Healthcare<sup>2</sup> specifically: person-centred care and support; effective care and support; safe care and support; better health and wellbeing; leadership, governance and management; workforce; use of resources and use of information.

In line with the objectives of National Standards for Better Healthcare, these PrEP standards were developed to:

- Help ensure that service providers are accountable to the public, service users and those who fund them.

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<sup>1</sup> National Sexual Health Strategy 2015-2020. <https://health.gov.ie/healthy-ireland/national-sexual-health-strategy-2015-2020/>

<sup>2</sup> A Guide to the National Standards for Safer Better Healthcare. HIQA 2012. <https://www.hiqa.ie/sites/default/files/2017-01/Safer-Better-Healthcare-Guide.pdf>

- Help the people in charge of services identify what they are doing well, and where they need to improve.
- Help ensure that the quality and safety of services is the same no matter where people live in Ireland or what health service they use – no matter where the service is, it should be safe.
- Describe what should be in place for day-to-day services to be safe and effective, including both core and desirable standards.

In developing these standards a **core** set of standards has been identified as a requirement for services providing PrEP to those who meet eligibility criteria for PrEP as part of a combination HIV prevention approach. Achieving these core standards should be considered as key performance indicators and adherence to these standards can be audited by services.

In addition this document also sets out **desirable** standards that PrEP centres should strive to achieve and can be used as part of a quality improvement initiative.

Six standards have been developed as outlined below. Within the document the **core** or **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. Information Governance
6. Patient and Public Engagement

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

These standards are listed for review one year post implementation of PrEP in the HSE. In the interim, urgent changes will be made where required.

The Sexual Health and Crisis Pregnancy Programme 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 1**.

## Standard 1: Access

### Quality Statement

People should be able to self-refer for PrEP assessment.

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 **desirable** that those referred for assessment for PrEP be seen (or be issued with an appointment to be seen) within ten working days.

### Quality Measures

Clinic policy that indicates self-referral as an option for access to service

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

Services will be required to demonstrate their access policy in relation to self-referral:

- Percentage of those referred for assessment for PrEP that are seen within 10 working days, including
  - those self-referring for PrEP assessment
  - those referred from other services for PrEP assessment
- Percentage of those issued an appointment for PrEP assessment that attend that appointment

This will be measured through:

- Audit of PrEP referrals within services
- Audit of PrEP appointment DNA rates
- Audit of waiting times to accessing PrEP services.

### 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 seen or issued an appointment to be seen within a reasonable timeframe. This information should be available to be viewed by the general public, in line with local policy.

## 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 the full suite of combination HIV (and STI) prevention<sup>3</sup> and STI management to attendees in line with national clinical management protocol for PrEP<sup>4</sup>, specifically:

- Access to condoms<sup>5</sup>
- Vaccination against HAV, HBV, HPV in line with national immunisation guidelines<sup>6</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 (PEP), in line with the national PEP guidelines<sup>7 8</sup>
- STI treatment within the service<sup>9</sup>
- Partner notification
- Discussion in relation to safer sex, alcohol and drug use.

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<sup>3</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>

<sup>4</sup> Clinical Management Protocol for PrEP in Ireland

<sup>5</sup> SHCPP approved PrEP Services can access condoms through SHCPP.

<sup>6</sup> HSE Immunisation Guidelines, <http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/>

<sup>7</sup> Guidelines for the Emergency Management of Injuries and Post-exposure Prophylaxis (PEP) <http://www.hpsc.ie/a-z/EMIToolkit/>

<sup>8</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, arrangements must be made and available in writing to ensure that a PEP access pathway (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>9</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 arrangements must be made and available in writing to ensure that a timely syphilis treatment access pathway is 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.

## Quality Standards

It is a **core** requirement that services providing PrEP have availability of the full suite of STI and HIV prevention services.

## Quality Measures

Availability of all HIV/STI prevention tools as outlined above.

Availability of agreed access pathway arrangements for PEP and syphilis treatment where these services are not available within the PrEP service.

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

Services will be required to demonstrate availability of the core STI/HIV prevention tools outlined above.

Prior to approval as a PrEP service, there will be a requirement to demonstrate evidence of the agreed access pathway for PEP and syphilis treatment where these services are not available within the PrEP service.

## Service User Information

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

## 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 are referred to appropriate services within a reasonable timeframe. These include, but are not limited to, access to PEP, treatment of syphilis, substance abuse services, psychological services, HIV services and urological 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 be able to demonstrate their referral mechanisms and pathways.

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

Services will be required to 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>10</sup> and HPSC notification guidelines<sup>11</sup>, PrEP services should meet all statutory obligations for disease surveillance and ensure that all STI notification is carried out within a reasonable timeframe.

PrEP monitoring and evaluation: 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 within a reasonable timeframe.

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 disease surveillance and PrEP monitoring and evaluation.

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

Services will be required to demonstrate the arrangements that are in place for HIV and STI surveillance and PrEP monitoring and evaluation<sup>12</sup>.

### Service User Information

Service users should be aware of the statutory obligations around disease notification and of the national PrEP monitoring and evaluation framework.

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<sup>10</sup> Infectious Diseases (Amendment) Regulations.

<http://www.irishstatutebook.ie/eli/2015/si/566/made/en/pdf>

<sup>11</sup> Available from <https://www.hpsc.ie/notifiablediseases>

<sup>12</sup> See HIV PrEP Monitoring and Evaluation Framework

## Standard 3: Clinical Assessment and Management

### Quality Statement

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 patients receiving PrEP have their eligibility criteria assessed and documented at baseline and at quarterly follow-up.

It is a **core** requirement that all patients receiving PrEP have information regarding their sexual history documented at baseline and at quarterly follow-up.

It is a **core** requirement that all patients receiving PrEP have their HIV negative status confirmed prior to or at time of issue (and where indicated reissued) with PrEP.

It is a **core** requirement that all patients receiving PrEP have appropriate renal monitoring prior to being issued (and where indicated reissued) with PrEP.

It is a **core** requirement that all patients receiving PrEP are contacted regarding the need for treatment of incident STIs within 10 working days of the final result being available.

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

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

It is a **core** requirement that all patients receiving PrEP be offered condoms as part of their care.

It is a **core** requirement that all patients receiving PrEP be offered syphilis, chlamydia and gonorrhoea testing at baseline and quarterly follow up.

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

## Quality Measures

All patients being assessed for PrEP should have a PrEP assessment completed at baseline and quarterly follow up.

All patients issued with PrEP should have all appropriate STI/HIV prevention and STI treatment offered and documented.

All patients issued with PrEP should have their HIV negative status confirmed prior to or at time of issue of PrEP.

All patients issued with PrEP should have appropriate renal monitoring prior to issue of PrEP.

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

Services will be required to demonstrate how they propose to ensure that all the quality measures outlined above will be met.

Services are encouraged to assess the outcomes in those receiving PrEP in line with the quality measures outline above

## Service User Information

People taking PrEP can expect to be seen at least quarterly for assessment.

At baseline and quarterly 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 provided 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 10 working days of the final lab result being available and to be offered appropriate vaccination.

They can expect that PrEP will be provided 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 all results (including 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 all results to patients and that this is done within a reasonable timeframe.

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

Services will be required to demonstrate the arrangements that are in place for managing results.

At set up: Services will be required to demonstrate how they will communicate abnormal or inconclusive results to those on PrEP within 10 working days of the final result being available.

On audit: Services will be asked to participate in an audit of time to communication of abnormal or inconclusive results and the proportion that receive results within 10 working days of the final result being available.

### **Service User Information**

People in receipt of PrEP can expect to receive any abnormal or inconclusive results within 10 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: 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 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>13</sup> and Infectious diseases legislation<sup>14</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?*

Services will be required to 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 clinics can expect to have all their data treated in a confidential manner in line with appropriate legislation.

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<sup>13</sup> Data Protection Act 2018, available at <http://www.irishstatutebook.ie/eli/2018/act/7/enacted/en/html>

<sup>14</sup> Infectious Diseases (Amendment) Regulations <http://www.irishstatutebook.ie/eli/2015/si/566/made/en/pdf>

## Standard 6: 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?*

Services will be required to demonstrate the arrangements that are in place for receiving patient and public feedback and making the information available to service users.

Services will be required to 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, if necessary, regarding any comments or complaints made.

# Appendix 1: 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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