HIV pre-exposure prophylaxis (PrEP) Monitoring & Evaluation Framework

February 2024

1. Introduction and background

Ireland commenced a national HIV pre-exposure prophylaxis (PrEP) programme in November 2019. Prior to the commencement of the PrEP programme, National Standards for the delivery and management of HIV PrEP in Ireland [1] were developed. Free PrEP medication is available to individuals who meet clinical eligibility criteria[2] attending HSE approved PrEP services. These include public PrEP services, some general practice (GP) services and private providers. PrEP medication is dispensed on foot of a valid prescription to those who meet eligibility criteria through community pharmacies who are then reimbursed by the HSE. Registration of an individual's clinical eligibility and reimbursement of community pharmacies for PrEP medication dispensed is done through the HSE Primary Care Reimbursement Service (PCRS).

A monitoring and evaluation framework is required in order to understand how the PrEP programme is performing. Within the national standards for PrEP, a **core** quality standard is '*that all PrEP services participate in national monitoring and evaluation requirements for PrEP within a reasonable timeframe'*.[1]

It is acknowledged that a range of approaches and methodologies are needed to monitor and evaluate the national PrEP programme. This monitoring and evaluation framework was developed by the SHCPP in collaboration with the multisectoral PrEP working group. This is a working document and is subject to change over time as appropriate.

2. Key Performance Indicators (KPIs)

This section outlines the KPIs that will be monitored at the national level by the Sexual Health and Crisis Pregnancy Programme (SHCPP).

The KPIs have been informed by national reporting requirements to European Centre for Disease Prevention and Control (ECDC)/UNAIDS and the ECDC tool for monitoring HIV PrEP programmes in the EU/EAA.[3]

The ECDC Monitoring Tool was developed using a rigorous consensus building approach, is grounded in scientific evidence and informed by inputs from a broad panel of clinical, research and community experts from different EU/EEA countries and organisations. The ECDC Monitoring Tool outlines indicators under three domains: pre-uptake; uptake and coverage; continued and effective use, according to key steps of the PrEP care continuum. The tool assigns levels of priority to each indicator: core; supplementary and

[1] National Standards for the Delivery and Management of Pre-Exposure Prophylaxis (PrEP) for HIV www.sexualwellbeing.ie/prepproviders

[2] Clinical management guidance for individuals taking HIV PrEP within the context of a combination HIV (and STI) prevention approach in Ireland www.sexualwellbeing.ie/prepproviders

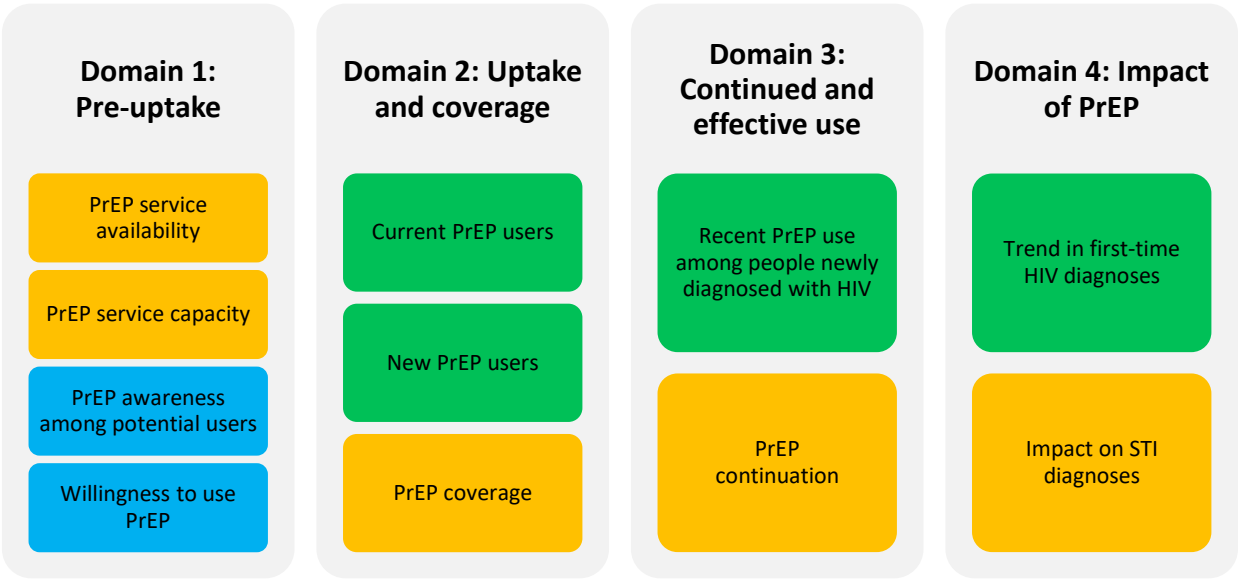
[3] European Centre for Disease Prevention and Control. Monitoring HIV pre-exposure prophylaxis programmes in the EU/EEA – July 2022. Stockholm: ECDC; 2022. https://www.ecdc.europa.eu/en/publications-data/monitoring-hiv-pre-exposure-prophylaxis-programmes-eueea

optional. The core indicators are considered essential to facilitate consistency of data collection across the EU, and together with the selected supplementary and optional indicators, will ensure that the necessary information is being collected to inform service planning and delivery.

In addition, the SHCPP with the PrEP working group, have developed a set of indicators that measure the impact of the PrEP programme. These indicators are outlined under Domain 4: Impact of PrEP.

Assessment of the quality of the PrEP programme is achieved through The National Standards for the delivery and management of HIV PrEP in Ireland.

Figure 1: Visual matrix of the included indicators along with their respective thematic domains and assigned levels of priority (**green** = core indicator; **orange** = supplementary indicator; **blue** = optional indicator)



Domain 1: Pre-uptake of PrEP will be monitored through SHCPP PrEP programme data, the collection of data from PrEP service providers, and national behavioural surveillance surveys (e.g. EMIS).

Domain 2: Uptake and coverage will be monitored through the collection of data from PCRS, HPSC and national behavioural surveillance surveys (e.g. EMIS).

Domain 3: Continued and effective use will be monitored through the collection of data from already established HIV surveillance systems and through periodic audit with PrEP services.

Domain 4: Impact of PrEP will be monitored through the collection of data from already established HIV/STI surveillance systems and through periodic audit with PrEP services.

2.1 Domain 1: Pre-uptake

This domain outlines four indicators, each set to measure a different aspect of a PrEP programme's progress in creating awareness, engaging people who do not (yet) use PrEP, PrEP service availability and capacity. From a provider perspective, the indicators 'PrEP service availability' and 'PrEP service capacity' aim to track access to PrEP services across Ireland and service capacity to see new PrEP users.

In addition, the suggested indicators, 'PrEP awareness among potential users' and 'willingness to use PrEP' increase insight into the pre-uptake stages of PrEP from a user perspective, the latter being a closer proxy of the anticipated use of PrEP. It shows how well the concept of PrEP for HIV prevention permeates certain communities or population groups.

In combination, these indicators could reveal discrepancies between those who intend to use PrEP, and access to PrEP across Ireland. Their measurement over time may be useful to monitor the PrEP programmes progress in meeting the need for PrEP in Ireland.

2.1.1 KPI: PrEP service availability (supplementary)

Description: This indicator aims to describe the availability of PrEP services in different geographical areas within a country.

Numerator: The number of facilities that offer PrEP per 100,000 population in each HSE Health Region.

Data collection methodology:

For the purpose of this framework, a 'PrEP service' is defined as any clinic or GP practice, which houses at least one healthcare provider approved by the HSE to prescribe free PrEP, including delivering the first prescription.

Routine data collection from SHCPP:

- Number of approved PrEP services nationally
    - National database of PrEP providers in place, data available at any time

Disaggregation (see 2.5):

- Public PrEP services
- Private/GP PrEP services
- Geographical area (by HSE Health Region, including a map for visual representation)[4]

[4] Health Atlas can be used to clarify which Health Region an address lies within https://finder.healthatlasireland.ie/

2.1.2 KPI: PrEP service capacity (supplementary)

Description: This indicator aims to collect complementary data on PrEP service capacity.

Data collection methodology:

Periodic data collection from PrEP services:

- Service delivery capacity at the facility level
    - Maximum number of clients (total new and return) that can be seen per week or weekly average (factoring in AL)
    - Ability to see new PrEP users within agreed standards timeframes[5]
    - Waiting time for first PrEP appointment[6]
    - Data collected by SHCPP periodically

Disaggregation (see 2.5):

- Public PrEP services
- Private/GP PrEP services
- Geographical area (by HSE Health Region)

2.1.3 KPI: PrEP awareness among potential users (optional)

Description: This indicator aims to track the awareness of PrEP as an HIV-prevention option among a specific population group.

Numerator: The number of people who report being aware of the existence of PrEP as an HIV-prevention option (regardless of whether PrEP is available to them), among the denominator.

Denominator: The number of people from a sample population who are questioned about PrEP awareness.

Data collection methodology:

Periodic health surveys that investigate attitudes and perceptions regarding PrEP, to monitor progress over time.

Existing survey tools:

- Key population: Gay, bisexual and men who have sex with men (gbMSM)
    - European Men who have sex with Men Internet Survey (EMIS)
        - Numerator: Those who respond 'yes' to EMIS Q: Have you heard of PrEP?
        - Denominator: All EMIS survey respondents from Ireland

[5] National Standards for HIV PrEP in Ireland, available on www.sexualwellbeing.ie/prepproviders
[6] Data collection methodology may change if we have a national waiting list at some stage.

- Consider EMIS questions in regards to 'PrEP eligibility', to additionally report on 'PrEP awareness among the eligible population'. EMIS asks a number of questions that are in line with Irish eligibility guidance (e.g. if they are sexually active; had an STI in the last 12 months; had condomless sex; and engaged in chemsex).
- Data is collected every few years (Ireland supports and contributes financially to the delivery of EMIS. If EMIS is not being conducted, Ireland should consider doing own survey.)

Other survey options:

- Cross-sectional, non-longitudinal surveys may provide useful baseline insights and provide an estimation of the level of awareness of PrEP among other key populations/populations of interest.

Disaggregation (see 2.5):

- Sex and gender identity
- Age
- Key populations

2.1.4 KPI: Willingness to use PrEP (optional)

Description: This indicator aims to measure whether individuals among a specific population group are willing to use PrEP if it was available/offered to them.

Numerator: The number of individuals who report their willingness to use PrEP if it were offered/available to them, among the denominator.

Denominator: The number of people from a sample population who are questioned about their willingness to use PrEP.

Data collection methodology:

Periodic health surveys that investigate attitudes and perceptions regarding PrEP, to monitor progress over time.

Existing survey tools:

- Key population: Gay, bisexual and men who have sex with men (gbMSM)
  - European Men who have sex with Men Internet Survey (EMIS)
    - Numerator: Those who respond 'quite likely' and 'very likely' to EMIS Q: If PrEP was available and affordable to you, how likely would you be to use it?
    - Denominator: All EMIS survey respondents from Ireland

- Consider EMIS questions in regards to 'PrEP eligibility', to additionally report on 'willingness to use PrEP among the eligible population'. EMIS asks a number of questions that are in line with Irish eligibility guidance (e.g. if they are sexually active; had an STI in the last 12 months; had condomless sex; and engaged in chemsex).
- Data is collected every few years (Ireland supports and contributes financially to the delivery of EMIS. If EMIS is not being conducted, Ireland should consider doing own survey.)

Other survey options:

- Cross-sectional, non-longitudinal surveys may provide useful baseline insights and provide an estimation of the level of willingness to use PrEP among other key populations/ populations of interest.

Disaggregation (see 2.5):

- Sex and gender identity
- Age
- Key populations

2.2 Domain 2: Uptake and coverage

Understanding who is accessing PrEP and whether PrEP is reaching those who could benefit most from it, is essential to the monitoring of any PrEP programme. Given their importance, the indicators 'current PrEP users' and 'new PrEP users', are labelled as 'core' indicators.

In addition, trying to understand PrEP use among the population who may need PrEP (i.e. 'PrEP coverage') was also deemed relevant and is included as a 'supplementary' indicator.

2.2.1 KPI: Current PrEP users (core)

Description: This indicator aims to keep track of how many people used PrEP during the reporting period.

NB: National reporting requirement to ECDC/UNAIDS.

Numerator: The number of unique individuals who received PrEP for HIV prevention at least once during the reporting period.

Data collection methodology:

For the purpose of this framework, a 'current PrEP user' is defined as an individual who had a prescription 'filled' at least once during the reporting period. A community pharmacy submitting a reimbursement

against an individual's prescription through PCRS, means that the individual had a prescription 'filled'. It may underestimate the number of current PrEP users as individuals who use an "on demand" schedule may use PrEP within the reporting timeframe but may not need to have a prescription filled.

Routine data collection from PCRS:

- Number of individuals for whom PrEP was reimbursed (had a prescription filled) at least once during the reporting period
    - PCRS provide quarterly and annual aggregate data
    - Data is reported annually to ECDC/UNAIDS.

Disaggregation (see 2.5):

- Sex
- Age
- Geographical area (HSE Health Region)

Additional routine data collection from PCRS:

- Number of individual PrEP users (new and return) approved for free PrEP medication on the PCRS system during the reporting period.
    - This data is used as a proxy for PrEP clinic activity. This data is also used by SHCPP when responding to ad hoc queries (Parliamentary, media, etc.) on the PrEP programme.
    - Although this data provides an indication of PrEP clinic activity, it does not take account of visits PrEP users may have to clinics for treatment of incident STIs or other matters not requiring their PrEP provider to approve them for free PrEP in PCRS. Furthermore, a PrEP user's approval is valid for 12 months. As such, this proxy marker of clinic activity underrepresents true clinic activity.
        - PCRS provide quarterly and annual aggregate data
        - This data was provided by PCRS for the first time for 2022 (annual)

2.2.2 KPI: New PrEP users (core)

Description: This indicator aims to monitor how many people used PrEP for the first time in their lives during the reporting period.

NB: National reporting requirement to ECDC/UNAIDS.

Numerator: The number of unique individuals who received PrEP for HIV prevention for the first time during the reporting period.

Data collection methodology:

For the purpose of this framework, a 'new PrEP user' is defined as an individual who "filled" a PrEP prescription through the national programme for the first time. A community pharmacy submitting a reimbursement against an individual's prescription through PCRS, means that the individual had a prescription 'filled'. This is a subset of KPI 2.2.1.

Routine data collection from PCRS:

- Number of individuals for whom PrEP was reimbursed (had a prescription filled) for the first time during the reporting period
    - PCRS provide quarterly and annual aggregate data
    - Data is reported annually to ECDC/UNAIDS.

Disaggregation (see 2.5):

- Sex
- Age
- Geographical area (HSE Health Region)

2.2.3 KPI: PrEP coverage (supplementary)

Description: This indicator aims to describe how many people currently use PrEP relative to the population in need of PrEP.

Numerator: The number of people who used PrEP at least once during the reporting period.

Denominator: The estimated number of people that are eligible for PrEP, according to local PrEP-eligibility criteria.

Data collection methodology:

Numerator: see KPI 2.2.1

Denominator:

- Periodic health surveys, such as EMIS, that include questions regarding PrEP eligibility and willingness to use PrEP (KPI 2.1.4). We will test this indicator after next EMIS.
- Methodology may change if we have a national waiting list at some stage.

Alternative indicator for PrEP coverage: PrEP-to-need ratio (PnR) (supplementary)

Description: This indicator aims to compare the number of PrEP users relative to the number of new HIV diagnoses in a given area, or among a certain population group.

Numerator: The number of people who used PrEP at least once during the reporting period in Ireland.

Denominator: The number of people newly diagnosed with HIV in Ireland during the reporting period.

Data collection methodology:

For the purpose of this framework, a 'newly diagnosed' person is defined as a person who has been diagnosed with HIV for the first time ever. As per HPSC 2022 report[7], **first-time HIV diagnoses** are defined as HIV diagnoses in Ireland **excluding** those with a previous HIV diagnosis and those whose previous history of HIV diagnosis is unknown.

Numerator: see KPI 2.2.1

Denominator:

Routine HIV surveillance data from HPSC:

- The number of first-time HIV diagnoses in Ireland during the reporting period,[8] and consider:
    - Other subgroups, such as probable country of infection
- This data is dependent on prompt and complete return of the HIV ESFs by service providers to the relevant Department of Public Health, including:
    - Previously diagnosed with HIV in Ireland or abroad
    - Probable country of infection.

Disaggregation (see 2.5):

- Sex
- Age
- Geographical area (HSE Health Region)

Limitations:

- Reporting time delay and data completeness.
- There is also currently no established threshold that indicates whether a specific PNR could be considered acceptable or favourable, but tracking the trend over time will be useful to monitor progress.

[7] HIV in Ireland, 2022. https://www.hpsc.ie/a-z/hivandaids/hivdataandreports/
[8] This information will be circa 9 months in arrears.

2.3 Domain 3: Continued and effective use

The impact of PrEP on the HIV epidemic is highly dependent on the continuous and effective use of PrEP as long as people are at risk of HIV. On an individual level, people adapt the use of PrEP according to actual or perceived HIV risk, therefore stopping PrEP for a time, and re-starting at a later point, can be an appropriate part of PrEP use.

At a population level, gathering data on different aspects related to PrEP use over time, and on HIV seroconversions among (former) PrEP users, might reveal certain trends and flag potential areas that warrant further investigation.

Given its importance, monitoring previous PrEP use among people who experienced an HIV seroconversion is labelled as a 'core indicator' and proxy of effective use of PrEP. The indicator 'PrEP continuation' is included as a 'supplementary indicator' to increase insight into how users engage with PrEP over time.

2.3.1 KPI: Recent PrEP use among people newly diagnosed with HIV (core)

Description: This indicator aims to measure how many people who experienced an HIV seroconversion, recently accessed PrEP.

Numerator: The number of people who received PrEP at least once in the 12 months prior to being diagnosed with HIV, among the denominator.

Denominator: The number of people newly diagnosed with HIV during the reporting period.

For the purpose of this framework, a 'newly diagnosed' person is defined as a person who has been diagnosed with HIV for the first time ever. As per HPSC 2022 report[9], **first-time HIV diagnoses** are defined as HIV diagnoses in Ireland **excluding** those with a previous HIV diagnosis and those whose previous history of HIV diagnosis is unknown.

Data collection methodology:

Routine HIV surveillance data from HPSC will be used for both numerator and denominator.

Numerator:

- The number of individuals among the denominator, who received PrEP at least once in the 12 months prior to being diagnosed with HIV.
    - This data is dependent on prompt and complete return of the HIV ESFs by service providers to the relevant Department of Public Health, including:
        - if the individual received PrEP in the 12 months prior to their diagnosis in Ireland

[9] HIV in Ireland, 2022. https://www.hpsc.ie/a-z/hivandaids/hivdataandreports/

        - if the individual was on PrEP at the time of their HIV diagnosis in Ireland
            - if yes, was PrEP being taken correctly at the time of HIV diagnosis

Denominator:

- The number of first-time HIV diagnoses in Ireland during the reporting period,[10] and consider:
    - Other subgroups, such as probable country of infection
- This data is dependent on prompt and complete return of the HIV ESFs by service providers to the relevant Department of Public Health, including:
    - Previously diagnosed with HIV in Ireland or abroad
    - Probable country of infection.

Disaggregation (see 2.5):

- Assigned sex at birth and gender identity
- Age
- Key populations for PrEP

Additional comments:

- At the service level, it is expected that a new HIV diagnosis in a patient on PrEP will be an exceptional event and should be investigated to determine if PrEP was being taken correctly or if there may have been a 'true' PrEP failure.[11]
- If there is a concern that there may have been a 'true' PrEP failure, the service should notify the National Sexual Health Medical Director/Clinical Lead in SHCPP.
- HPSC review this data on a monthly basis, and should it be documented that an individual was on PrEP at the time of diagnosis, HPSC will follow up with the local Department of Public Health or the clinical service as relevant, to determine if this was documented on the EIS and CIDR correctly, or if there may have been a 'true' PrEP failure.

Limitations:

- Reporting time delay and data completeness.

[10] This information will be circa 9 months in arrears.

[11] A 'true' PrEP failure or breakthrough infection, is where an individual with reported optimal adherence, acquires HIV whilst on PrEP.

2.3.2 KPI: PrEP continuation (supplementary)

Description: This indicator aims to describe how many people who started PrEP continue to use it in the 12 months after PrEP initiation.

Numerator: The number of people who had at least one follow-up visit in the 12 months after PrEP initiation, among the denominator.

Denominator: The number of people who were prescribed PrEP for the first time during the previous reporting period.

Data collection methodology:

For the purpose of this framework, a 'PrEP follow-up visit' is defined as any routine contact between the PrEP user and the provider for the purpose of clinical PrEP guidance. It may consist of an in-person visit, online appointment or phone call.

For the purpose of this framework, someone who was 'prescribed PrEP for the first time' is defined as an individual who received a prescription for free PrEP through the national programme for the first time.

Both numerator and denominator data will need to come from the same source. PCRS cannot provide continuation data. Data could be collected from PrEP services through periodic audit.

Numerator:

- Number of individuals who had at least one follow-up PrEP visit in the current reporting period (i.e. current reporting year)

Denominator:

- The number of individuals who received a prescription for free PrEP through the national programme for the first time in the previous reporting period (i.e. previous calendar year)

Disaggregation (see 2.5):

- Assigned sex at birth and gender identity
- Age
- Key populations for PrEP

2.4 Domain 4: Impact of PrEP

Understanding the ultimate impact of PrEP on new HIV diagnoses is important to the monitoring of any PrEP programme. Given its importance, the 'trend in first-time diagnoses' is included as a 'core' indicator.

In addition, understanding other impacts of a PrEP programme is important, and monitoring the impact of PrEP on STI diagnoses was also deemed relevant and is included as a 'supplementary' indicator.

2.4.1 KPI: Trend in first-time HIV diagnoses (core)

Description: This indicator aims to measure the possible impact of the national PrEP programme over time on the number and rate of first-time HIV diagnoses.

Numerator: The number and rate of first-time HIV diagnoses during the reporting period, monitored over time.

Data collection methodology:

As per HPSC 2022 report[12], **first-time HIV diagnoses** are defined as HIV diagnoses in Ireland **excluding** those with a previous HIV diagnosis and those whose previous history of HIV diagnosis is unknown.

Routine HIV surveillance data from HPSC:

- The number and rate of first-time HIV diagnoses in Ireland during the reporting period,[13] and consider:
    - Other subgroups, such as probable country of infection
    - Stage of infection based on CD4 count and other parameters[14]
- This data is dependent on prompt and complete return of the HIV ESFs by service providers to the relevant Department of Public Health, including:
    - Previously diagnosed with HIV in Ireland or abroad
    - Probable country of infection
    - Acute infection[15] status and CD4 count at time of HIV diagnosis.

Disaggregation (see 2.5):

- Assigned sex at birth and gender identity
- Age

[12] HIV in Ireland, 2022. https://www.hpsc.ie/a-z/hivandaids/hivdataandreports/
[13] This information will be circa 9 months in arrears.
[14] Stage of infection includes acute infection, recent infection (CD4 cell count of 500 or over 500 cells per mm3 at diagnosis) and late diagnosis (CD4 cell count < 350 per mm3). ECDC HIV/AIDS surveillance in Europe 2023 (2022 data) https://www.ecdc.europa.eu/en/publications-data/hivaids-surveillance-europe-2023-2022-data
[15] ECDC criteria for acute infection include: HIV negative test in the last six months, evidence of seroconversion illness, p24 antigen or an indication based on any other clinical or laboratory criteria.

- Key populations for PrEP

Limitations:

- Reporting time delay and data completeness.
- PrEP is delivered as part of a combination HIV prevention approach, that includes HIV treatment (TasP) and the promotion of other HIV prevention strategies such as condom use and harm reduction. It is not possible to attribute an improvement in the trend of first-time diagnoses to one single strategy.

2.4.2 KPI: Impact on STI diagnoses (supplementary)

Description: This indicator aims to measure incident STI's among PrEP users.

Numerator: The number and rate of new STI diagnoses in people on PrEP during the reporting period, among the denominator.

Denominator: The number and rate of new STIs diagnosed, during the reporting period.

Data collection methodology:

Both numerator and denominator data will need to come from the same source.

Data could be collected through the HSE home STI testing service, HPSC enhanced surveillance data (EIS only) or periodic audit with PrEP services.

- Number and rate of new STI diagnoses, within a specific sample, during the reporting period
    - In the general sample
    - In individuals documented/self-reported to be on PrEP
    - By type of STI

Disaggregation (see 2.5):

- Assigned sex at birth and gender identity
- Age
- Key populations for PrEP

2.5 Disaggregation

Disaggregation of monitoring data along some basic socio-demographic characteristics is key to gain a better understanding of the profile of PrEP users, to recognise specific PrEP needs within certain sub-populations or geographical areas, and to identify and mitigate possible disparities related to PrEP.

The ECDC PrEP Monitoring Tool advises on a limited set of 'core characteristics' related to the profiles of PrEP users that are particularly important to consider. PCRS are not able to provide disaggregation for all 'core characteristics' as part of the routine reporting on PrEP use to SHCPP. Given their relevance, PrEP services should strive as much as possible to include the core characteristics in their own monitoring.

Additional supplementary characteristics are listed below as part of the disaggregation of the 'key populations' indicator. PCRS are not able to provide any disaggregation by key population and Pubic Health do not collect data on all these characteristics either. PrEP services should include this disaggregation where feasible.

2.5.1 Assigned sex at birth and gender identity (core)

- Assigned sex at birth (collect where possible)
- Reported sex (collect if only option available, e.g. collected from PCRS)
    - male
    - female

- Gender identity
    - man
    - trans man
    - woman
    - trans woman
    - non-binary

2.5.2 Age (core)

- Age group
    - 15–19 years
    - 20–29 years (20-24 and 25-29)
    - 30–39 years (30-34 and 35-39)
    - 40–49 years (40-44 and 45-49)
    - 50+ years

2.5.3 Geographical area of residence (core)

- Area of residence of the PrEP user (collect where possible)
    - Reported by County or HSE Health Region
- Area where PrEP was dispensed (as a proxy for residence, collected from PCRS)
    - Address of dispensing pharmacy, by Local Health Office (LHO)
    - Reported by HSE Health Region

2.5.4 Key populations

- Gay, bisexual and men who have sex with men (gbMSM) (core)
    - Transgender women who have sex with men
- Migrant status (core)
    - Country of birth
- Sex workers (supplementary)
- People who inject drugs (PWID) (supplementary)
- Sexualised drug use ('chemsex') (supplementary)
- Prisoners (supplementary)

Appendix 1. HSE Health Regions