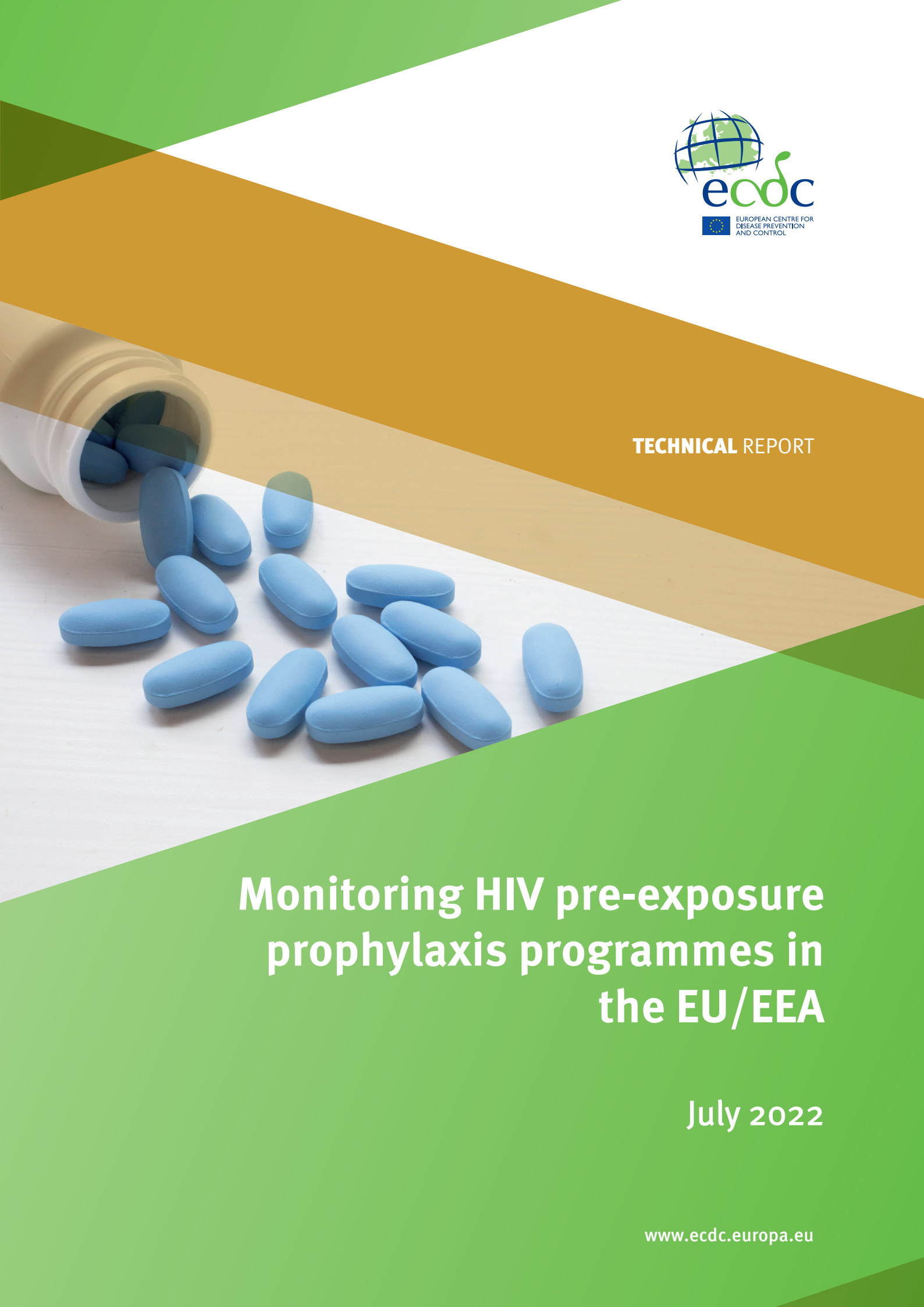

TECHNICAL REPORT

Monitoring HIV pre-exposure prophylaxis programmes in the EU/EEA

July 2022

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Abbreviations

CBO	Community-based organisation
EACS	European AIDS Clinical Society
EMIS	The European Men-Who-Have-Sex-With-Men Internet Survey
HIV	Human immunodeficiency virus
MS	Member States (of the European Union)
MSM	Men who have sex with men
PEPFAR	The United States President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV
PnR	PrEP-to-need ratio
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
STI	Sexually transmitted infection
TDF/FTC	Tenofovir disoproxil fumarate/emtricitabine
UK	United Kingdom
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

Executive summary

A steady decline in the annual number of new HIV diagnoses has been observed in the European Union (EU) and European Economic Area (EEA) over the last decade. However, there remain considerable disparities in the rate of decline and the burden of new HIV infections between countries and among different population groups. In order to achieve the 95-95-95 targets set out by the Joint United Nations Programme on HIV/AIDS (UNAIDS), a strong and sustained focus on HIV prevention is paramount. This will entail scaling up combination prevention programmes based on scientific evidence, including the implementation of pre-exposure prophylaxis (PrEP) across the EU/EEA region.

In 2015, the European Centre for Disease Prevention and Control (ECDC) recommended that EU/EEA countries consider integrating PrEP into their existing HIV-prevention packages for those most at risk of HIV infection. In 2021, ECDC published an operational guidance that outlined key principles and minimum standards for PrEP programmes and service delivery, to support EU/EEA countries in their PrEP implementation efforts. In order to make evidence-based evaluations of the performance of PrEP programmes, it is imperative to monitor their success in terms of reaching and supporting those who can benefit most from PrEP. This calls for relevant and actionable data that are feasible to collect as well. In addition, a streamlined approach to PrEP monitoring across EU/EEA countries is required to paint a more detailed picture of the regional progress of PrEP roll-out and its impact on the HIV epidemic.

Mindful of the substantial variations in health systems and epidemiological contexts between EU/EEA countries, this publication aims to contribute to a harmonised PrEP-monitoring approach. To this end, a rigorous consensus-building approach was applied, 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 result of this consensus-building exercise is a monitoring tool that provides countries with a reference set of commonly agreed indicators for data reporting to improve comparability, while giving practical advice on different options for data collection to allow for sufficient flexibility. It is intended to be used by PrEP programme implementers (e.g. public health authorities, non-governmental and community organisations or researchers) or other stakeholders in the design and implementation of national or sub-national PrEP programmes.

The tool is structured along three key steps of a care continuum adapted to PrEP: pre-uptake, uptake and coverage, and continued and effective use of PrEP.

In addition, based on the input of the expert panel, all indicators are assigned a specific level of priority for reporting:

- 'core indicators' (i.e. essential indicators that should be feasible to report on);
- 'supplementary indicators' (i.e. indicators that are meaningful to report on, but the feasibility of reporting is context-specific);
- 'optional indicators' (i.e. reporting on these indicators is only possible by using additional research efforts).

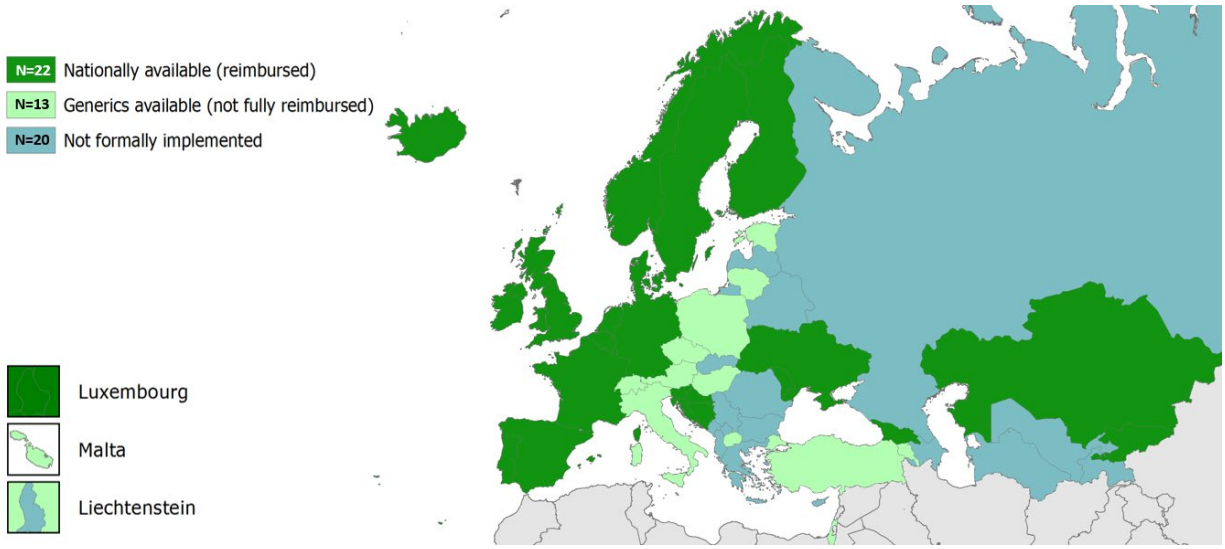
For all indicators, useful data sources are suggested, and recommendations are made for disaggregation along relevant characteristics to reveal PrEP-related disparities. Possible data sources include routine surveillance data (preferred), population size estimates and special surveys. Anticipated benefits and challenges for data collection and reporting are discussed briefly for each indicator. Users of the tool are encouraged to actively engage with the provided suggestions, and make adaptations where necessary. As such, this document does not set a normative standard, but intends to assist users in making informed decisions on the implementation of measurable indicators adapted to their local contexts.

Introduction

Background

The efficacy and safety of oral pre-exposure prophylaxis (PrEP) to prevent HIV acquisition has been demonstrated through several high-quality clinical trials [1-3]. Subsequently, in 2015, ECDC recommended that the EU/EEA countries should consider integrating PrEP into their existing HIV-prevention packages for those most at risk of HIV infection [4]. As of the end of 2021, 22 countries in the WHO European Region have made PrEP available and fully reimbursed (see Figure 1).

Figure 1. Status of the formal implementation of PrEP in the WHO European Region, 2021



Source: European Centre for Disease Prevention and Control. Monitoring implementation of the Dublin Declaration. Stockholm: ECDC; 2021 (unpublished data)

To translate the clinical efficacy of PrEP into comprehensive programmes that can effectively reach and support those who benefit from using it, ECDC has undertaken several actions to guide EU/EEA countries in their PrEP implementation efforts. These actions culminated in the development of an operational guidance, entitled 'HIV Pre-Exposure Prophylaxis in the EU/EEA and the UK: implementation, standards and monitoring' [5]. In this guidance, 10 core principles were outlined that define and represent effective PrEP programmes. In addition, quality statements and minimum standards were included to guide the operationalisation of these principles and track their progress and implementation in real-world settings. The final core principle for PrEP programmes described in this guidance pertained to the need of delivering services in a monitored system, wherein some basic data on the performance and effectiveness of the programme are gathered and reported on.

An effective PrEP programme is one in which people at substantial risk of HIV are adequately identified, are offered PrEP, and then receive continued support to use it as needed [6]. To achieve this, PrEP programmes need to be appropriately focused on the epidemiological profile of potential PrEP candidates within their specific organisational context (e.g. relying on available infrastructure and resources to deliver appropriate services). Scientific experts consulted for the ECDC operational guidance agreed that EU/EEA countries would benefit from a more harmonised approach towards PrEP programme monitoring, to track national and regional progress in this regard. The experts also identified the need for well-defined and relevant indicators, that could be useful for countries in different phases of PrEP implementation, while being feasible to collect and report on.

Therefore, a practical tool was developed as an additional guidance to:

- support EU/EEA countries in identifying meaningful indicators for PrEP programme monitoring, sensitive to their respective epidemiological and organisational contexts.
- offer insight into the anticipated benefits and challenges of using certain data sources to report on these indicators.
- recommend a minimum set of 'core indicators' to be collected and reported on in a standardised way across Member States of the EU/EEA, to allow for some comparison at a regional level.

Key considerations

Before an in-depth description of how this tool is organised and can be used, in this section we will highlight some key concepts, definitions and principles that guided the various steps of its development.

1. Programmatic monitoring approach: The tool is focused on outlining possible ways to measure the performance and implementation of PrEP programmes, with the overarching goal to maximise its impact on the HIV epidemic. Therefore, it focuses on collecting and reporting data that can inform and guide actions towards achieving this goal on a programmatic level. We define a PrEP programme as, 'a coherent set of activities as part of routine services that aim to identify, reach, and provide PrEP to the target population (however defined)'. This is different from a purely clinical-monitoring approach, where the main aim is to ensure the safe and effective use of PrEP among individual clients. Nevertheless, individual-level data could be used, and are even vital, to report on programmatic indicators for PrEP.

2. HIV prevention cascade: As a basic, monitorable framework to organise and synthesise different components that are key to the successful implementation of PrEP, we relied on the concept of the 'HIV prevention cascade' [7]. Complementary to the HIV treatment cascade, this approach focuses on outlining the different steps in the continuum of implementing preventive interventions (such as PrEP), and aims to display points where inefficiencies (or 'bottlenecks') occur. In the spirit of its initial conceptualisation, we distinguished between two perspectives to look at the case of PrEP:

- **The user perspective**: Here, the cascade explores the trajectory of people at risk of HIV infection, and how the acquisition of HIV could be successfully prevented through perceiving their risk well and undertaking action to adopt and adhere to PrEP.
- **The provider perspective**: This cascade focuses on programme staff identifying a 'target population' who could benefit from PrEP, making PrEP available and accessible to them, and tracking uptake and effective use of PrEP in the target population.

Both perspectives offer complementary insights relevant to the monitoring of PrEP programmes, and may even partially overlap. For the development of this tool, we included both provider-oriented and user-oriented indicators that may inform progress along different steps of the HIV prevention cascade for PrEP (see later).

3. Core principles for the tool:

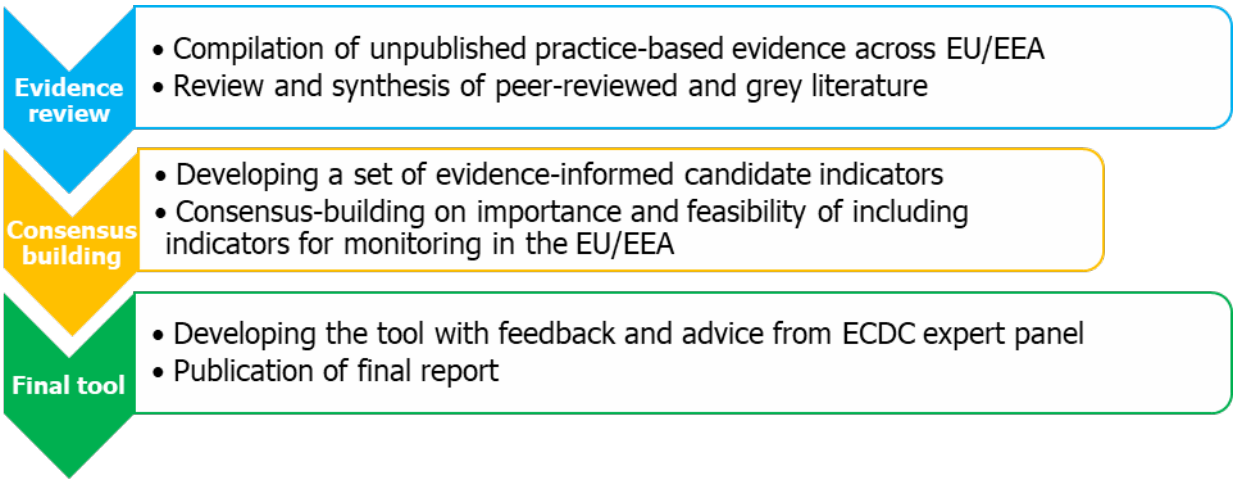
- **Pragmatism and applicability**: This tool, first and foremost, aims to serve as a practical guidance to support Member States of the EU/EEA in their efforts to implement a monitoring system for PrEP. The focus is on the sharing of knowledge and valuable experiences, both informed by available evidence and current practice, in a way that is useful for programme implementers working in different contexts (e.g. resources, infrastructure and data systems).
  Therefore, we opted not to standardise the indicator requirements towards data collection and reporting methods, as this would limit their generalisability across the region. We did ensure indicators contain uniform and clear definitions, and present numerators and denominators for their reporting if relevant and applicable, to allow for some comparison (especially for the 'core indicators'). In addition, to ensure feasibility of data collection, we refer to existing routine health information systems as the first option. For questions that routine monitoring systems cannot answer, we highlight synergies with research efforts (e.g. through special surveys). Lastly, using routine monitoring data, we present alternative proxy measures for indicators that could be particularly challenging to report on.
- **Relevance**: All indicators in this tool have undergone thorough review by an international expert panel, and were included based on their perceived level of importance and feasibility. The indicators reflect different aspects of PrEP implementation and will hopefully contribute, in conjunction with other data, to a better understanding of a PrEP programme's overall performance. However, we do acknowledge that certain types of information might be more relevant in certain settings compared to others, or at different time points of PrEP roll-out, as reflected in the tool.
- **Person-centredness**: During the process of developing this tool, we were sensitive to the principles of 'person-centred monitoring' as outlined in existing WHO guidelines [6]. This implies an approach that does not merely focus on measuring the service 'output' (e.g. the number of HIV tests or people on treatment), but places the person at the centre of measuring the access to and performance of health services [6]. A key priority applied throughout the tool is that of, 'first of all, do no harm'. During data collection, management and reporting, individuals' privacy must be ensured and protected at all times. All data collection activities must therefore adhere to the European Union General Data Protection Regulation 2016/679 (GDPR) [8]. Moreover, active reflection on unintended yet potential consequences of monitoring activities on the perpetuation of stigma and discrimination towards certain population groups must be undertaken. We have included relevant guidance in those sections of the tool that particularly warrant such active consideration.

Developing the tool

Under the guidance of ECDC, this tool was developed by a research team with specific thematic (i.e. HIV PrEP) and technical (i.e. monitoring and evaluation) expertise. Additionally, a multidisciplinary panel of clinical, public health and community experts, representing a diverse range of organisations and institutions from different Member States of the EU/EEA, guided the research process and provided feedback at all stages of the project.

The research team took a three-phased approach to develop this tool (see Figure 2).

Figure 2. A three-phased approach to the development of a PrEP monitoring tool for the EU/EEA



Phase 1 involved a comprehensive review by collecting and synthesising relevant evidence (both published and unpublished) on indicators useful for the monitoring of PrEP programmes. A rapid online survey was sent out to national experts of different Member States, aiming to collect useful practice-based experiences with monitoring PrEP, as well as exploring the needs and expectations for a new monitoring tool. Additionally, we conducted a systematic scoping review of internationally published, peer-reviewed literature as well as grey literature to identify programmatic indicators currently used or suggested to monitor PrEP.

In **phase 2**, we focused on reviewing the evidence collected in phase 1 to develop a list of evidence-informed candidate indicators relevant for PrEP monitoring. In total, 21 candidate indicators were identified and derived from the evidence review. In the next step, a modified Delphi technique was used to find consensus among ECDC expert panellists on the final set of indicators to be included in the tool [9]. First, panellists quantitatively rated the perceived importance of the candidate indicators in an online survey. They also provided additional qualitative comments on the feasibility of operationalising the indicators, and could choose to provide suggestions for indicator improvement. After this online survey, an online group meeting was organised with the panel to agree on indicators that were suitable to be included in a 'core set' for collection across the EU/EEA (i.e. with high levels of perceived importance and feasibility), and to finetune indicator definitions to improve clarity and increase the feasibility of data collection. Through a second online survey and a final meeting among a smaller steering group of expert panellists to resolve remaining issues, the final set of 'core' and 'supplementary' indicators was endorsed. As a result of the consensus-building process, some candidate indicators were slightly adapted and improved to better fit the specific EU/EEA context. Therefore, the final list of indicators differed from the initial list of candidate indicators derived from the literature review in phase 1.

In **phase 3**, the final list of agreed indicators was integrated in the format of a practical monitoring tool. The expert panel provided their final input and feedback before publication and dissemination of the current report.

Target audience

This tool aims to add value complementary to existing reporting frameworks of either local or global initiatives focused on monitoring data related to PrEP (e.g. ECDC Dublin Declaration monitoring framework, WHO and UNAIDS reporting). To this end, the tool addresses the following groups of audience:

- PrEP programme managers, monitoring and evaluation specialists, and public health authorities concerned with PrEP programme design and implementation at national and/or sub-national levels.
- Additionally, (health) professionals and practitioners tasked with the delivery of PrEP services and/or data collection both at the facility-level and community-level, will benefit from its use.
- Lastly, researchers focusing on certain aspects relevant to the monitoring of PrEP might also turn to this tool for inspiration and/or guidance.

Organisation of the tool

The main body of this tool consists of indicator sheets. These are developed to give a practical overview of the expected added value of each included indicator, and to outline how relevant data can be gathered to report on them.

In order to guide the reader through this tool, the indicator sheets are organised into three thematic domains that align with the key steps of an adapted PrEP care continuum: pre-uptake, uptake and coverage, and continued and effective use.

In addition, each indicator is assigned a level of priority for reporting by the Member States, based on the ratings from the ECDC expert panel. These priority levels include:

- 'core indicators' (i.e. essential indicators that should be feasible to report on);
- 'supplementary indicators' (i.e. indicators that are meaningful to report on, but the feasibility of reporting is context-dependent);
- 'optional indicators' (i.e. reporting on these indicators is only possible by using additional research efforts).

The priority levels are colour-coded, with dedicated colours consistently used across the indicator sheets, in order to clearly link the indicators to their assigned level of priority.

Figure 3. The thematic indicator domains according to three key steps of the PrEP care continuum

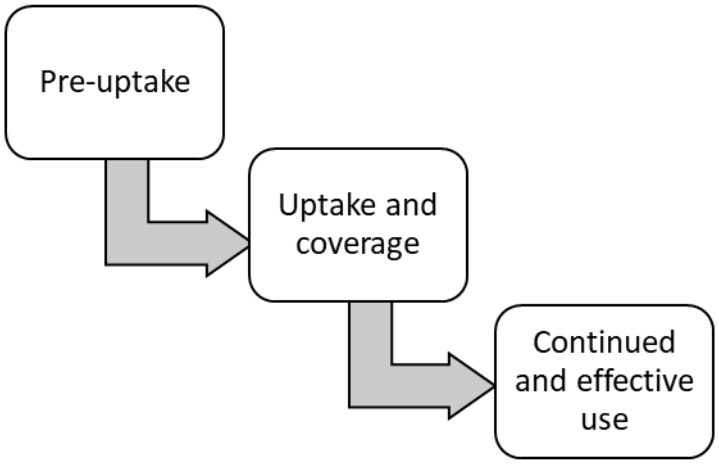


Table 1. Priority levels for the reporting of the different indicators

Priority level	Description
Core	These indicators were identified by the expert panel as providing very important information in key areas of the PrEP roll-out that are feasible to collect at the same time. Their unanimous high ratings for both importance and feasibility demonstrate their universal utility and applicability across different settings. Hence, these indicators are considered 'core', and are deemed essential to be reported across EU/EEA countries, improving comparability at a regional level.
Supplementary	These indicators were deemed important by the expert panel as they reported on meaningful aspects of successful PrEP implementation. However, the panel identified several potential feasibility issues towards their implementation. Therefore, these indicators should be considered 'supplementary', as the ultimate decision on their reporting depends on the context and feasibility of specific EU/EEA countries.
Optional	These indicators were seen as providing information that might be useful to guide particular aspects of the design and monitoring of PrEP programmes. Yet, as these are only feasible to report on using additional research efforts (e.g. survey methods), they are considered 'optional'. The ultimate cost-benefit of their reporting is determined by local implementers.

How to use the tool

This tool is intended to navigate decisions on *which* programmatic PrEP indicators could be useful to monitor in the context of the EU/EEA, while providing insight into *how* these indicators could be measured and reported on.

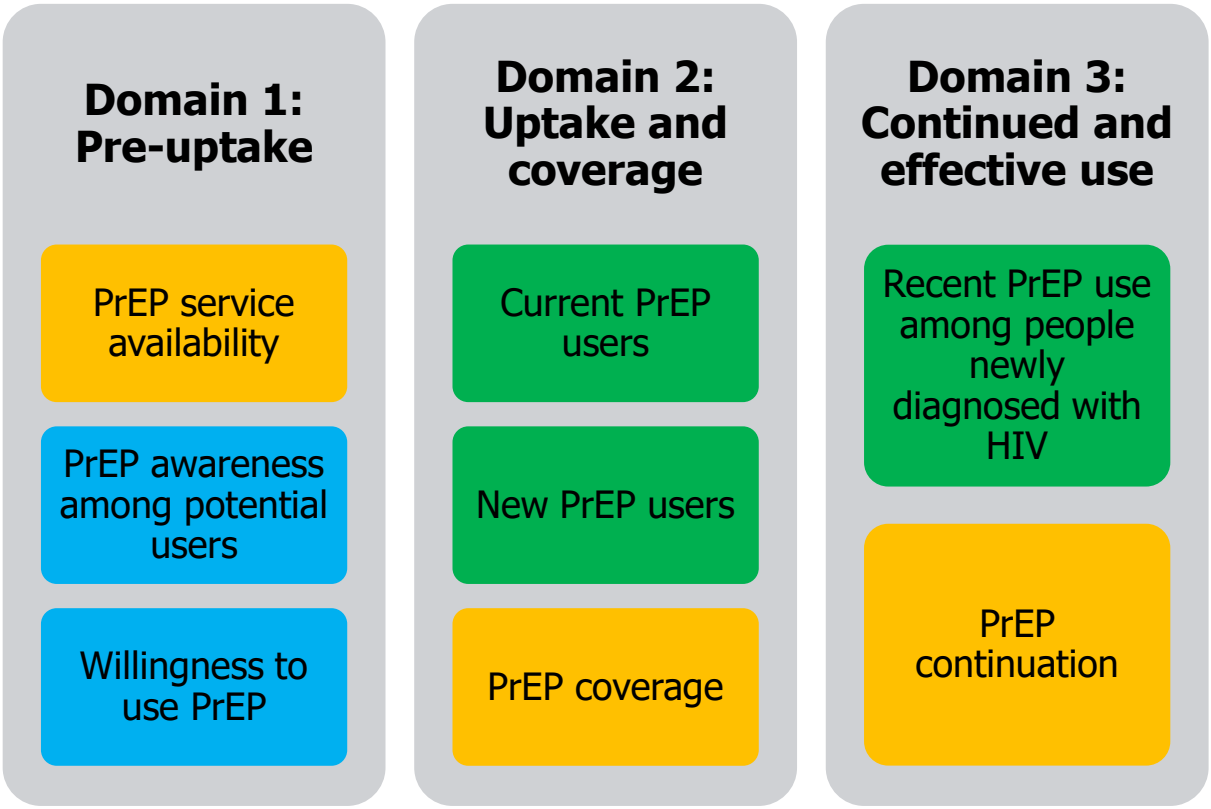
This tool, therefore, does not set a normative standard. Rather, it provides guidance on the different options that are available to monitor PrEP programmes, as well as the rationale behind implementing certain indicators. The tool offers a prioritisation based on colour codes (see the short overview displayed in Table 1). For every indicator, key benefits and anticipated challenges related to data collection and reporting are highlighted in the indicator sheets.

Thus, this tool can be used to make informed decisions on the implementation of measurable indicators for PrEP programme monitoring adapted to the local context.

Overview of the included indicators

In this section, we will take a comprehensive look at the various included PrEP indicators and what each of them entails. To begin with, we will look at a broad overview of the indicators vis-à-vis their respective domains and the levels of priority assigned to each of them.

Figure 4. 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

Indicator name	Description
PrEP service availability	This indicator aims to describe the availability of PrEP services in different geographical areas within a country.
PrEP awareness among potential users	This indicator aims to track the awareness of PrEP as an HIV-prevention option among a specific population group.
Willingness to use PrEP	This indicator aims to measure whether individuals among a specific population group are willing to use PrEP if it was available/offered to them.

Domain 2: Uptake and coverage

Indicator name	Description
Current PrEP users	This indicator aims to keep track of how many people used PrEP during the reporting period.
New PrEP users	This indicator aims to monitor how many people used PrEP for the first time in their lives during the reporting period.
PrEP coverage	This indicator aims to describe how many people currently use PrEP relative to the population in need of PrEP.

Domain 3: Continued and effective use

Indicator name	Description
Recent PrEP use among people newly diagnosed with HIV	This indicator aims to measure how many people who experienced an HIV seroconversion, recently accessed PrEP.
PrEP continuation	This indicator aims to describe how many people who started PrEP continue to use it in the 12 months after PrEP initiation.

Now, we will explore each indicator under the three domains in greater details, in terms of the different factors informing the implementation of a PrEP programme, its effective administration and the evaluation of its performance. We will also examine the potential limitations and challenges encountered at various phases of a PrEP programme, and make recommendations for data collection and reporting.

Domain 1: Pre-uptake

This domain outlines three indicators, each set to measure a different aspect of a PrEP programme's progress in gaining visibility, creating awareness and engaging people who do not (yet) use PrEP. From a provider perspective, the indicator 'PrEP service availability' aims to track access to PrEP services by showing to whom PrEP is available in a certain geographical area.

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. 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 have an awareness of PrEP and those who intend to use it, the latter being a closer proxy of the anticipated use of PrEP. Their measurement over time may be useful to track the impact of demand creation activities conducted within a PrEP programme.

1.1 PrEP service availability	
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 a given geographical area within a country.
Denominator	N/A
Suggested reporting period	12 months
Priority level	Orange (supplementary)
Rationale for reporting	Geographical access to PrEP services is a prerequisite for uptake. Proximity to facilities that offer PrEP is an aspect of access that may be especially relevant in contexts where PrEP follow-up is conducted through regular (e.g. tri-monthly) in-person visits. The number of PrEP-providing facilities per 100 000 population in a certain area may demonstrate an indication of access, and identify areas in which the community is relatively underserved by PrEP-delivering services. This indicator is therefore in line with the previously identified principle in the ECDC operational guidance for PrEP, namely the commitment to ensure broad access on a population-level.
Data collection methodology	A 'PrEP service' is defined as any clinic and/or facility which houses at least one healthcare provider licensed to prescribe PrEP, including delivering the first prescription. The presence of potential PrEP providers can be identified through clinic lists maintained by health departments and existing registries of licensed practitioners, as well as web searches and referrals from other providers. For monitoring PrEP providers in a specific area, areas are to be defined by individual Member States. It is recommended that this indicator is aligned with existing administrative units (such as cities, provinces or sub-states). Smaller units are more likely to reveal potential inequities in availability that may warrant further investigation. If a Member State perceives disaggregating data on PrEP service availability by certain areas as irrelevant or unfeasible, 'a given area' can be defined as the country.
Disaggregation	To provide a more granular insight into geographical access, countries are encouraged to provide visual representations of the location and spread of PrEP services in a given geographical unit, to identify those areas that are relatively deprived of (or overserved by) PrEP services.

1.1 PrEP service availability	
Limitations and anticipated challenges	Limitation: The number of facilities where PrEP is available is an imperfect proxy to measure PrEP access. It may not reflect the true number of clients served, as people could encounter structural barriers to access even if services are available near them. It also does not take into account the need for PrEP in a given area. Possible mitigation strategy: Consider complementing this indicator with an indicator of the need for local PrEP (e.g. 'PrEP-to-need ratio' per geographical area; see 'optional additional data collection'). In addition, countries are advised to include information on the capacity or volume of PrEP clients of each facility (see 'optional additional data collection').
	Limitation: As this indicator focuses on PrEP delivery through (healthcare) facilities, it does not take into account options of remote services for PrEP, such as tele-consultations and/or self-testing for HIV and/or STIs. Possible mitigation strategy: We recommend reporting separately on experiences with remote models of care and follow-up for PrEP, for instance, by describing elements of access related to these services (e.g. the populations that have been reached).
Optional alternative indicator	The number of facilities where PrEP is available per geographical area.
Optional additional data collection	• Countries are advised to complement this indicator with additional information regarding the available resources and staff (i.e. service delivery capacity) at a facility-level. This could include data on opening hours of the clinic, number and profiles of staff experienced in delivering PrEP care, and the maximum number of clients that can be followed up with (e.g. on a weekly basis). • Research could be dedicated to (periodically) assess the average waiting time at each delivery point for PrEP, for a (first) PrEP visit, as an additional and complementary proxy measure for access. • Information on the type of delivery setting where PrEP is available could be collected (e.g. sexual health clinic, HIV clinic, primary care setting, family planning clinic, community health centre, etc.). This provides additional insight into the differentiation of care according to the setting (i.e. reflecting the availability of different options for people with different needs). • In addition to this indicator, we refer to the narrative descriptions of experiences with PrEP service delivery models (e.g. type of providers, type of settings where PrEP is delivered, PrEP policies and financing etc.), as reported in the 'country case studies' accompanying the ECDC PrEP operational guidance and the Dublin Declaration monitoring framework [5]. • This indicator may be combined with the indicator 'PrEP-to-need ratio' (see sheet 2.3 bis.) to have an indication of how the availability of PrEP services is adapted to the local PrEP needs.

1.2 PrEP awareness among potential users	
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.
Suggested reporting period	The interval period of reporting this indicator is determined by the feasibility of collecting data on a regular basis. Repeated measurement and reporting among a similar population group provides increased insight into the progress of creating PrEP awareness over time.
Priority level	Blue (optional)
Rationale for reporting	Awareness of PrEP as a valid HIV-prevention option is a necessary first step for potential PrEP candidates towards developing informed opinions on its intended use, which may eventually result in the uptake of PrEP. A broad sense of awareness of PrEP among the general population may contribute to a stigma-free environment related to PrEP and HIV, facilitating PrEP uptake. On a more programmatic level, low levels of PrEP awareness among specific populations may lead to the identification of opportunities for additional demand-creation efforts.
Data collection methodology	This indicator can only be reported when relying on research efforts that investigate individuals' personal attitudes and perceptions regarding PrEP. Such data are ideally collected periodically through surveys of strategically chosen populations (e.g. key populations that could benefit from PrEP), to monitor progress over time. However, cross-sectional, non-longitudinal surveys may also provide useful baseline insights, particularly in settings preparing for the introduction of PrEP and in the early establishment phase of a PrEP programme (e.g. to have an estimation of the level of awareness of PrEP pre-implementation).

1.2 PrEP awareness among potential users	
Disaggregation	It is highly recommended to disaggregate the number of current PrEP users by the following user characteristics: Assigned sex at birth and gender identity, age, key populations for PrEP (see sheet 4.1).
Limitations and anticipated challenges	Challenge: Conducting large-scale surveys on PrEP requires extensive human and financial resources, and different population groups require tailored approaches for recruitment. Therefore, conducting surveys for monitoring may not be feasible on a regular basis. Possible mitigation strategies: • Integrate questions on 'PrEP awareness' into existing sub-national or national health surveys. • Rely on available data from existing (international) surveys to calculate national estimates (e.g. EMIS-2017; see also [10]).
Optional alternative indicator	N/A
Optional additional data collection	• Consider combining the data collection on 'PrEP awareness' with data on 'Willingness to use PrEP' (see sheet 1.3), given their dependence on similar methods (e.g. adding questions to the same survey). Together, these indicators might reveal a possible mismatch between 'awareness' and 'willingness to use' that may inform the need for further investigation. • Consider integrating questions on 'PrEP awareness' with questions aimed at eliciting whether individuals have accurate knowledge about PrEP and where to source it (see also [11]). • Consider integrating questions on 'PrEP awareness' with questions on 'PrEP eligibility' within the same survey, to additionally report on 'PrEP awareness among the eligible population'. Such questions will depend on locally applied eligibility criteria for PrEP, and allow to measure what proportion of PrEP-eligible survey respondents are aware of PrEP. This may reveal, for instance, to what extent campaigns to create awareness for PrEP among certain populations could result in an impact on PrEP uptake.

1.3 Willingness to use PrEP	
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.
Suggested reporting period	The interval period of reporting this indicator is determined by the feasibility of collecting data on a regular basis. Repeated measurement and reporting among a similar population group provides increased insight into progress over time.
Priority level	Blue (optional)
Rationale for reporting	Similar to 'PrEP awareness among potential users' (see sheet 1.2), 'willingness to use PrEP' reflects a key step in the thought process of potential PrEP candidates on their trajectory of PrEP uptake. This step is closer to the actual use of PrEP than 'PrEP awareness'. On a programmatic level, this indicator may provide insights into the potential unmet demand for PrEP among certain (surveyed) populations.
Data collection methodology	This indicator can only be reported when relying on research efforts that investigate individuals' personal attitudes and perceptions regarding PrEP. Ideally, such data are periodically collected through surveys among strategically chosen populations (e.g. key populations that could benefit from PrEP), to monitor progress over time. However, cross-sectional, non-longitudinal surveys may also provide useful baseline insights, particularly in preparatory settings for the introduction of PrEP, and in the early establishment phase of a PrEP programme (e.g. to have an estimation of the relative demand for PrEP pre-implementation).
Disaggregation	It is highly recommended to disaggregate the number of current PrEP users by the following user characteristics: Assigned sex at birth and gender identity, age, key populations for PrEP (see sheet 4.1).
Limitations and anticipated challenges	Challenge: Conducting large-scale surveys on PrEP requires extensive human and financial resources, and therefore, may not be feasible on a regular basis.

1.3 Willingness to use PrEP	
	Possible mitigation strategies: • Integrate questions on 'willingness to use PrEP' into existing sub-national or national health surveys. • Rely on available data from existing (international) surveys to calculate national estimates (e.g. EMIS-2017; see also [10]).
Optional alternative indicator	N/A
Optional additional data collection	• Consider combining data collection on 'willingness to use PrEP' with data on 'PrEP awareness among potential users' (see sheet 1.2), given their dependence on similar methods (e.g. adding questions to the same survey). Together, these indicators might reveal gaps between 'awareness' and 'willingness to use' that may warrant further investigation. • Consider integrating questions on 'willingness to use PrEP' with questions on 'PrEP eligibility' within the same survey, to additionally report on 'willingness to use PrEP among the eligible population'. Such questions will depend on locally applied eligibility criteria for PrEP, and allow to measure what proportion of PrEP-eligible survey respondents want to use PrEP. This may provide useful information regarding the unmet need for PrEP, and possibly suggest that the benefits of PrEP may not be fully exploited among certain population groups.

Domain 2: Uptake and coverage

Understanding whether PrEP is reaching those who could benefit most from it, is essential to the monitoring of any PrEP programme. Given their high paired scores of importance and feasibility across the EU/EEA, the indicators, 'current PrEP users' and 'new PrEP users' were labelled 'core' by the expert panel. These indicators should therefore be reported by any PrEP programme in EU/EEA countries.

In addition, tracking PrEP use among the population in need (i.e. 'PrEP coverage') was deemed highly relevant by the expert panel. However, implementing this indicator will very likely be met with considerable challenges related to how the 'population in need' should be defined in a meaningful way. As such, this indicator was labelled 'supplementary', and we offer some key considerations and insights into a pragmatic alternative (i.e. the 'PrEP-to-need ratio') in the section, '2.3 bis. Alternative indicator for PrEP coverage'.

2.1 Current PrEP users	
Description	This indicator aims to keep track of how many people used PrEP during the reporting period.
Numerator	The number of unique individuals who received PrEP for HIV prevention at least once during the reporting period.
Denominator	N/A (optional for reporting at the EU-level: per 100 000 population)
Reporting period	12 months (calendar year)
Priority level	Green (core)
Rationale for reporting	The number of current PrEP users is key to assess the scope and reach of a PrEP programme at any stage of implementation. If measured repeatedly, it may give an indication of the expansion of the programme over time. Additionally, this indicator can signal possible gaps in PrEP access among certain population groups, or in a given geographical area, if disaggregated by relevant characteristics related to user profiles (see sheet 4.1). Lastly, monitoring this indicator can also be useful to predict future demands for PrEP, which, especially in the early stages of implementing PrEP, might be helpful to ensure the allocation of sufficient (human and infrastructural) resources and an uninterrupted supply of commodities. This indicator does not provide any insight into PrEP use over time (for 'PrEP continuation', see sheet 3.2).
Data collection methodology	This indicator aims to approximate actual PrEP use as much as possible, with some data sources providing closer proxies of PrEP use than others. We provide different options for data collection below, and briefly discuss their core strengths and weaknesses. An overview of potential data sources can be found in Annex 1. Ultimately, decisions on the use of a given data source for PrEP monitoring will depend on their local availability and the context-specific feasibility of collecting data through that source. • Prescription data: The data collection process should make a distinction between 'written' prescriptions (by healthcare providers) and 'filled' prescriptions (dispensed by pharmacies). The latter is a closer proxy to the actual use of PrEP. These have the benefit of using available data at a population level. The potential challenges for collecting data based on prescriptions are as follows: – The need for an algorithm to distinguish PrEP from other indications for tenofovir disoproxil fumarate/emtricitabine (TDF), for example, hepatitis treatment. – This process does not take into account PrEP obtained outside the official prescription system. – There is a limited opportunity to collect client-level data (e.g. on membership of key population).

2.1 Current PrEP users	
	• Claims data: This data collection process uses data from a health insurer (private or public) on 'filled' PrEP prescriptions. The benefits include: close proxy to the actual use of PrEP, and the use of available data at a population level. The potential challenges for collecting data based on claims are as follows: – The need for an algorithm to distinguish PrEP from other uses of TDF (e.g. hepatitis treatment). – This process does not take into account PrEP obtained outside the health insurance system. – There is a limited opportunity to collect client-level data (e.g. on membership of key population). • Facility registries: These have the benefit of collecting client-level data on a continuous basis that can be aggregated yearly. This allows collecting data related to facility visits, possibly including data on self-reported PrEP use, which represents a close proxy to actual use. In addition, other client-level data could be registered and reported (e.g. on membership of key population). • A major challenge relates to the additional administrative burden on local staff tasked with collecting this information, and the risk of double-counting when people visit multiple facilities for PrEP. Various data sources could be combined to provide plausible and more complete insights into different aspects of current PrEP use.
Disaggregation	It is highly recommended to disaggregate the number of current PrEP users by the following user characteristics: Assigned sex at birth and gender identity, age, key populations for PrEP (see sheet 4.1). It is advised to disaggregate the number of current PrEP users by the type of product that was used i.e. oral PrEP formulation, or injectable PrEP and/or implants in the future (see sheet 4.1).
Limitations and anticipated challenges	Limitation: Implementers should be aware of the specific limitations that come with each data source in terms of: proximity to actual PrEP use, completeness of the data source (i.e. missing data), the feasibility of collecting data on the profiles of PrEP users, and potential reporting delays.
	Limitation: Routine monitoring is unable to capture the number of people who use PrEP 'informally' (i.e. who access PrEP outside the official delivery points of the programme). Possible mitigation strategy: Query informal PrEP use in surveys among key populations and/or among people who sign up for HIV testing (e.g. through collaborations with CBOs).
	Challenge: Avoiding double-counting of individuals who move across services. Possible mitigation strategy: Assign unique identifier codes to PrEP clients.
	Challenge: Monitoring PrEP delivered through different types of settings (such as general practitioners and CBOs). Possible mitigation strategy: Opting for data sources that are independent of delivery settings (e.g. prescription data and/or claims data). Moreover, in case of collaboration models (e.g. where clients still visit specialised centres in combination with visits to their general practitioner), more elaborate data collection could still occur via facility registries upon visiting the centre.
Optional alternative indicator	N/A
Optional additional data collection	Collecting data on *where* PrEP was obtained, to have a view on the most commonly used (and potentially under-used) delivery settings for PrEP.

2.2 New PrEP users	
Description	This indicator aims to monitor how many people used PrEP for the first time in their lives during the reporting period.
Numerator	The number of unique individuals who received PrEP for HIV prevention for the first time during the reporting period.
Denominator	N/A (optional for reporting at the EU-level: per 100 000 population)
Reporting period	12 months (calendar year)
Priority level	Green (core)

2.2 New PrEP users	
Rationale for reporting	This indicator aims to identify and distinguish people who accessed PrEP for the first time ever (during the reporting period), from PrEP users who continued to use PrEP or re-started PrEP after a gap in use. The number of first-time PrEP users provides insight into the ability of a programme to newly engage people into using PrEP as an HIV-prevention method. In combination with additional information on the profile of new 'PrEP starters', it tracks progress in the accessibility of PrEP for certain population groups. Especially for early-stage PrEP programmes, this indicator may prove useful to track the expansion of the programme in terms of reaching new population groups with PrEP services (e.g. according to key populations or geographical area of residence, see sheet 4.1). Related indicators: • ECDC: Dublin Declaration monitoring framework • PEPFAR: Monitoring, Evaluation, and Reporting Indicator Reference Guide. MER 2.6 [17] • WHO: Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection, Module 5: PrEP 1 – PrEP uptake [6].
Data collection methodology	This indicator should comprise individuals for whom there is no record of prior PrEP use. A 'record of prior PrEP use' can be self-reported by PrEP clients or based on data maintained in specific databases. • Prescription data: The data collection process should make a distinction between 'written' prescriptions (by healthcare providers) and 'filled' prescriptions (dispensed by pharmacies). The latter is a closer proxy to the actual use of PrEP. These have the benefit of using available data at a population level. The potential challenges for collecting data based on prescriptions are as follows: – The need for an algorithm to distinguish PrEP from other uses of TDF (e.g. hepatitis treatment). – This process does not take into account PrEP obtained outside the official prescription system. – There is a limited opportunity to collect client-level data (e.g. on membership of key population); and a need for unique identifiers to track the prior use of PrEP. • Claims data: This data collection process uses data from a health insurer (private or public) on 'filled' PrEP prescriptions. The benefits include: close proxy to the actual use of PrEP, and the use of available data at a population level. The potential challenges for collecting data based on claims are as follows: – The need for an algorithm to distinguish PrEP from other uses of TDF (e.g. hepatitis treatment). – This process does not take into account PrEP obtained outside the health insurance system. – There is a limited opportunity to collect client-level data (e.g. on membership of key population); and a need for unique identifiers to track the prior use of PrEP. • Facility registries: These have the benefit of collecting client-level data on a continuous basis that can be aggregated yearly. This allows collecting data related to facility visits, possibly including data on self-reported PrEP use, which represents a very close proxy to actual use. In addition, other client-level data could be registered and reported (e.g. on membership of key population). A major challenge relates to the additional administrative burden on local staff tasked with the collection of this data. Different data sources could be combined to provide plausible and more complete insights into different aspects of new PrEP initiations.
Disaggregation	It is highly recommended to disaggregate the number of new PrEP users by the following user characteristics: Assigned sex at birth and gender identity, age, key populations for PrEP (see sheet 4.1). It is advised to disaggregate new PrEP initiations by the dosing regimen at start (e.g. daily or on-demand PrEP) and the type of product that was used i.e. oral PrEP formulation or injectable PrEP and/or implants in the future (see sheet 4.1).
Limitations and anticipated challenges	Limitation: Implementers should be aware of the specific limitations that come with each data source in terms of: proximity to actual PrEP use, completeness of the data source (i.e. missing data), the feasibility of collecting data on the profiles of PrEP users, potential reporting delays, and ability to track the prior use of PrEP.
	Challenge: When using facility registries, individuals may be misclassified as 'initiating' PrEP when they previously used PrEP at a different PrEP facility. Possible mitigation strategy: Unique client identifiers can be used to track individuals moving across services. PrEP providers may also document whether new PrEP clients have used PrEP prior to that moment.
	Challenge: The absence of data on the prior use of PrEP does not necessarily exclude that individuals have never used PrEP before. Possible mitigation strategy: Databases containing unique identifiers which can be searched up to the moment to ascertain if regulatory approval for PrEP was obtained in a country, or up until a specific (commonly agreed) point in time (e.g. three years back). In such a case, countries are encouraged to specify this time frame in their reporting.

2.2 New PrEP users	
Optional alternative indicator	N/A
Optional additional data collection	PrEP programmes might consider periodically assessing (e.g. through research and implementation science) how people were referred to PrEP services (e.g. self-referral, via family/friends, via community organisations or primary care practitioners etc.). This may provide additional insights into strategies that are particularly successful (or not) to engage people into using PrEP, to better focus on specific interventions in this regard.

2.3 PrEP coverage	
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.
Suggested reporting period	12 months. However, the exact reporting period is determined by the feasibility of collecting data on a regular basis. For the denominator, a baseline size estimation of the eligible population can be obtained at a specific point in time (e.g. through survey data), and then be used repeatedly to report progress on this indicator relative to this baseline over time.
Priority level	Orange (supplementary)
Rationale for reporting	Estimates of 'PrEP coverage' provide insights into the extent to which a PrEP programme has reached a target population for PrEP, and conversely, how many people who could benefit from PrEP are currently not accessing it ('unmet need'). Low PrEP coverage may signal potential issues that warrant further investigation, ranging from low PrEP awareness and/or willingness to use PrEP, to more structural barriers to access (e.g. financial or geographical barriers). Related indicators: United States Centres for Disease Control and Prevention: Core indicators for monitoring the Ending the HIV Epidemic initiative: Preexposure Prophylaxis (PrEP) Coverage [12].
Data collection methodology	For the numerator, data on PrEP use can be derived from prescription and claims databases, and/or collected continuously in PrEP facility registries to be aggregated periodically (see 'Current PrEP users: data collection methodology'). For the denominator, the size of the population in need of PrEP can only be estimated by combining routine surveillance data with research efforts (e.g. surveys based on local criteria for eligibility). For each relevant key population for PrEP, one can multiply the following components: (i) the estimated number of people who belong to a specific key population, and (ii) the estimated proportion of people from that key population who can be considered in need of PrEP. Component (i) can be estimated based on surveys held among the general populations (e.g. census data). Component (ii) can be estimated based on surveys held among specific key populations (e.g. as in sheets 1.2 and 1.3).
Disaggregation	It is highly recommended to disaggregate coverage data by the relevant key populations for PrEP (see sheet 4.1).
Limitations and anticipated challenges	Limitation: This indicator does not represent a true proportion of all those in need of PrEP who are currently using it, since the same (cross-sectional) size estimation of the eligible population is used repeatedly over time as denominator. In reality, the size of this population fluctuates continuously, as HIV risk (and hence, PrEP eligibility) is a fluid concept.
	Challenge: Estimating the size of the population in need of PrEP based on large-scale surveys requires extensive financial and human resources. Possible mitigation strategy: Countries could consider integrating questions to elicit PrEP eligibility (according to local guidelines) within existing surveys (see also sheets 1.2 and 1.3). In addition, national estimates of PrEP eligibility for certain key populations could be derived from existing (international) survey data (e.g. EMIS-2017 data for MSM; see also [10]).

2.3 PrEP coverage	
	Challenge: Previous experiences suggest that different approaches to conduct size-estimations can yield different outcomes to define the population in need of PrEP. Possible mitigation strategy: Triangulating different data sources (e.g. by conducting different surveys to estimate the proportion of PrEP-eligible people among a key population) may help mediate the biases of individual data sources.
Optional alternative indicator	If it is not feasible to arrive at size-estimations of the PrEP-eligible population, countries may consider calculating the 'PrEP-to-need ratio', which compares the number of PrEP users to the number of new HIV diagnoses, as a proxy for 'PrEP need' (see also additional sheet 2.3 bis.).
Optional additional data collection	N/A

2.3 bis. Alternative indicator for PrEP coverage: PrEP-to-need ratio (PnR)	
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 a given area (see 'numerator': sheet 2.1).
Denominator	The number of people newly diagnosed with HIV during the reporting period in a given area.
Suggested reporting period	12 months
Priority level	Orange (supplementary)
Data collection methodology	For the numerator, data on PrEP use can be derived from prescription and claims databases, and/or collected continuously in PrEP facility registries to be aggregated periodically (see 'Current PrEP users – data collection methodology'). For the denominator, data on new HIV diagnoses can be obtained from (national) HIV-surveillance databases. For examples, see also [13] and [14].
Limitations and anticipated challenges	Limitation: This indicator is not a true measure of coverage (i.e. it is not a proportion), but compares PrEP use to the 'epidemic need' for PrEP, based on the number of new HIV diagnoses. No thresholds have been currently established that indicate whether a specific PNR could be considered as acceptable or favourable. Nevertheless, this metric may prove particularly useful to reveal trends over time, and to allow for some comparison across populations and/or geographical areas.
	Limitation: The number of new HIV diagnoses does not equate HIV incidence, particularly in settings or populations with high rates of immigration and/or a large number of people with a late HIV diagnosis. The proposed denominator may therefore be an imperfect proxy measure for the actual need of PrEP. Possible mitigation strategy: Consider only including people newly diagnosed with HIV in the denominator, and not people who received a positive HIV test upon, or shortly after, migration to the current country of residence (e.g. a new HIV diagnosis among people with a low CD4 count or people who were already on antiretrovirals and virally suppressed at the time of their latest HIV test).

Domain 3: Continued and effective use

The ultimate 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. It has become increasingly clear that, on an individual level, people adapt the use of PrEP according to actual or perceived HIV risk [15]. Stopping PrEP for the time being, and re-starting at a later point, can therefore be a part of appropriate PrEP use.

As such, the development of suitable indicators to measure prevention-effective PrEP use is complicated by the challenge of collecting and aligning data on actual PrEP use with behavioural data reflecting HIV risk. Nevertheless, 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.

The expert panel identified two indicators to assist PrEP programme implementers in this regard: given its perceived high level of importance and feasibility, monitoring previous PrEP use among people who experienced an

HIV seroconversion was proposed as a 'core indicator' and proxy of effective use of PrEP. The indicator 'PrEP continuation' was additionally suggested as 'supplementary indicator' to increase insight into how users engage with PrEP over time.

3.1 Recent PrEP use among people newly diagnosed with HIV	
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, and who had at least one follow-up HIV test, among the denominator.
Denominator	The number of people newly diagnosed with HIV during the reporting period.
Reporting period	12 months (calendar year)
Priority level	Green (core)
Rationale for reporting	This indicator aims to direct attention to situations where an HIV seroconversion took place despite having had (recent) access to PrEP, and hence may flag possible missed opportunities for HIV-prevention programmes. While some of the structural barriers that drive new HIV diagnoses among recent PrEP users are clearly out of the control of service providers, it is important to gain insights into such missed opportunities to address them at a policy or health systems level. Hence, this indicator may help revealing where a PrEP programme did not succeed to engage people who were previously contacted by the programme about using PrEP appropriately. Outcomes may prompt further investigation into the potential reasons for seroconversion, in order to distinguish (exceptional) failures under optimal adherence from situations where PrEP was not used, or inappropriately interrupted (see 'optional additional data collection' later). Related indicators: WHO: Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection, Module 5: PrEP 4. HIV positivity among people who have been prescribed PrEP [6].
Data collection methodology	This indicator should comprise people who were found to have HIV during the reporting period and who received PrEP at least once during the 12 months prior to their first positive HIV test. People who tested positive for HIV upon determining PrEP-eligibility prior to PrEP initiation, should not be included in the indicator. Data on prior PrEP use can be collected from readily available prescription and claims databases, but only if unique identifying codes were used to link to relevant HIV databases containing data on HIV diagnoses, and if PrEP databases allow tracking of the date of the latest PrEP prescription and/or dispensation. Alternatively, databases containing information on HIV diagnoses could consider adding a variable on prior PrEP use. For instance, facility registries could collect data on prior PrEP use among clients newly diagnosed with HIV through (electronic) medical records or through self-reported prior PrEP use by clients (e.g. as part of existing provider-administered surveys for each client newly diagnosed with HIV). Similarly, new HIV seroconversions could also be documented in PrEP registries.
Disaggregation	It is highly recommended to disaggregate the number of current PrEP users by the following user characteristics: Assigned sex at birth and gender identity, age, key populations for PrEP (see sheet 4.1).
Limitations and anticipated challenges	Challenge: It could be a burden on clinicians having to systematically collect data on prior PrEP use among those experiencing an HIV seroconversion. Possible mitigation strategy: If feasible, data from readily available prescription and claims databases (for PrEP use) can be considered, if these could be linked to databases containing information on HIV diagnoses and allowed to track the date of latest PrEP prescription and/or dispensation.
	Challenge: Having to deal with 'missing data' on prior PrEP use among those acquiring HIV. Possible mitigation strategy: Consider reporting separately on the proportion of people diagnosed with HIV for whom data on prior PrEP use were missing, and for whom data on prior PrEP use were available. If the prevalence of missing data is high, caution should be exercised when interpreting the proportion of people who recently used PrEP among people newly diagnosed with HIV, and this should be transparently reported.
	Challenge: As the use of PrEP becomes more widespread, the proportion of people having (recently) used PrEP among those newly diagnosed with HIV is expected to increase. Caution should be exercised when interpreting such data. Possible mitigation strategy: When reporting on this indicator, it is advised to interpret these data taking into account the trend in the absolute number of people newly diagnosed with HIV and, if available, the suspected number of breakthrough infections among people with sufficient PrEP adherence, which is likely to be extremely low (see also [16]).

3.1 Recent PrEP use among people newly diagnosed with HIV	
Optional alternative indicator	The ratio of the number of new HIV diagnoses over the number of current PrEP users (as determined in sheet 2.1).
Optional additional data collection	Additional research and programmatic evaluation could try to identify the suspected timing of HIV acquisition and patterns of PrEP use among people who recently seroconverted, to gain insights into missed opportunities for prevention, such as: an undetected acute HIV infection upon PrEP initiation, structural barriers to PrEP services, PrEP discontinuation despite continued risk of HIV, sub-optimal PrEP adherence leading to unprotective drug levels during exposure to HIV, or – extremely rarely – breakthrough infections among adherent users. It is advised to perform additional testing for PrEP-related drug resistance on blood samples of clients who seroconverted and used PrEP recently, or who were found to be HIV-positive while on PrEP, prior to intensifying antiretroviral therapy (ART) treatment.

3.2 PrEP continuation	
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 PrEP refill or 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 in their lives during the previous reporting period.
Suggested reporting period	12 months
Priority level	Yellow (supplementary)
Rationale for reporting	Effective PrEP use is not necessarily defined by uninterrupted longitudinal use, given that individuals may use PrEP on-demand and/or 'cycle' in and out of periods of substantial risk of HIV. In the light of this challenge, the ECDC expert panel did not find consensus on a meaningful timepoint up until which to assess PrEP continuation rates in order to evaluate the performance of PrEP programmes. Yet, it was agreed that the time of PrEP initiation provides a useful starting point, since it gives a baseline indication of 'PrEP need', ideally based on a judgement of HIV risk as part of the PrEP eligibility screening process. Given that HIV risk is unlikely to change on the short-term for a large group of people, focusing on sustained PrEP use after initiation might reveal potential shortcomings of a PrEP programme to sufficiently support clients into using PrEP when they need it, or to access follow-up care. When this indicator is disaggregated by user characteristics (e.g. 'key populations' for PrEP), it may reflect whether certain population groups might disproportionately experience barriers to continuous engagement with PrEP (see sheet 4.1). It should be noted that experience with this indicator is currently too low to interpret low continuation rates as 'PrEP programme failures', as users may discontinue PrEP for many different, valid reasons. Countries are encouraged to pilot this indicator, if feasible, and report relevant experiences with its use. Furthermore, we stress the synergistic nature of using this indicator alongside additional evaluation and implementation science, to gain additional insights into the potential reasons of why PrEP users do not continue to use it after initiation, and to judge the ultimate relevance of this indicator on the long term. Related indicators: • WHO: Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection, Module 5: Monitoring and Evaluation – Early PrEP Continuation [6]. • PEPFAR: Monitoring, Evaluation, and Reporting Indicator Reference Guide. MER 2.6 [17].
Data collection methodology	The indicator is generated by counting the number of people who initiated PrEP in the previous reporting period, and who received a PrEP refill or returned for a PrEP follow-up visit in the subsequent 12 months. 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. The following databases could be used to report on this indicator: • Prescription data: The data collection process should make a distinction between 'written' prescriptions (by healthcare providers) and 'filled' prescriptions (dispensed by pharmacies). The latter is a closer proxy to the actual use of PrEP. These have the benefit of using available data at a population level.

3.2 PrEP continuation	
	The potential challenges for collecting data based on prescriptions are as follows: – The need for an algorithm to distinguish PrEP from other uses of TDF (e.g. hepatitis treatment). – This process does not take into account PrEP obtained outside the official prescription system. – There is a limited opportunity to collect client-level data (e.g. on membership of key population); and a need for unique identifiers to track the prior use of PrEP. Moreover, the prescription database should be able to provide information on the date the PrEP prescription was issued or filled in, in order to measure refills obtained within 12 months after initiation. • Claims data: This data collection process uses data from a health insurer (private or public) on 'filled' PrEP prescriptions. The benefits include: close proxy to the actual use of PrEP, and the use of available data at a population level. The potential challenges for collecting data based on claims are as follows: – The need for an algorithm to distinguish PrEP from other uses of TDF (e.g. hepatitis treatment). – This process does not take into account PrEP obtained outside the health insurance system. – There is a limited opportunity to collect client-level data (e.g. on membership of key population); and a need for unique identifiers to track the prior use of PrEP. Moreover, the prescription database should be able to give information on the date the PrEP prescription was issued or filled, in order to measure refills obtained within 12 months after initiation. • Facility registries: These have the benefit of collecting client-level data on a continuous basis. This allows collecting data related to facility visits, possibly including data on self-reported PrEP use, which represents a very close proxy to actual use. In addition, other client-level data could be registered and reported (e.g. on membership of key population). A major challenge relates to the additional administrative burden on local staff tasked with the collection of this data.
Disaggregation	It is highly recommended to disaggregate this indicator by the following user characteristics: Assigned sex at birth and gender identity, age, key populations for PrEP (see Sheet 4.1).
Limitations and anticipated challenges	Limitation: Population-level databases (e.g. prescription and claims data) have limited ability to distinguish infrequent and periodic PrEP use, from continuous and daily PrEP use. These databases provide information on the volume of PrEP distributed at a certain time point, and not on whether or when PrEP was actually used, nor on how it was intended to be used by the recipient.
	Challenge: PrEP use does not necessarily align with 'PrEP need'. Moreover, PrEP use can have a 'cyclical' nature (according to fluctuating HIV risk), so PrEP discontinuation does not necessarily imply sub-optimal use. Possible mitigation strategy: Perform further investigation into real-world 'patterns of PrEP use' and into the reasons for PrEP discontinuation (see 'optional additional data collection' below).
Optional alternative indicator	• All the people who started PrEP in the previous reporting period and who received PrEP at least once in the current reporting period (i.e. who had at least one facility visit or prescription refill in the current reporting period). • All the people who started PrEP in the previous reporting period and for whom there is no record of PrEP use (e.g. facility visit or PrEP refill) in the current reporting period (i.e. 'PrEP discontinuation'). • Measuring 'PrEP reversals' (i.e. issued PrEP prescriptions that were never filled) as measure of sub-optimal PrEP initiation (only possible using claims data; see also [18].
Optional additional data collection	• Programme evaluations and implementation science could focus on documenting how PrEP is used in real-world conditions, for instance through longitudinal follow-up of a cohort of PrEP users. Such research could provide more granular insights into individual patterns of stopping and re-starting PrEP, and what determines such 'cycles', to help identifying potential barriers to the sustained use of PrEP during periods of ongoing HIV risk. • Further research could be dedicated to periodically querying the reasons for PrEP discontinuation, guided by outcomes from routine monitoring (e.g. surveying those showing low PrEP continuation rates). The reasons could be categorised into broader groups, such as structural barriers (e.g. related to access), PrEP-related reasons (e.g. due to side-effects), client-related reasons (e.g. preference for alternative preventive options), or changing HIV risk. Preferably, such evaluations include a representative sample, comprising people who discontinued PrEP in consultation with a provider, and individuals who were lost to follow-up (for an example, see also [19]). • In addition to reporting on PrEP continuation by focusing on PrEP use itself, countries could consider carrying out periodic assessments (e.g. through research) of the adherence of PrEP users to regular HIV testing as a proxy measure of PrEP follow-up. Additionally, as most guidelines recommend quarterly HIV tests while on PrEP, the number of expected HIV tests could be estimated based on the number of PrEP prescriptions dispensed. This could then be compared to the number of HIV tests actually performed in a specific time period (for an example, see also [20]).

Disaggregating data

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 expert panel discussed the issue of disaggregated monitoring data and achieved consensus on a limited set of 'core characteristics' related to the profiles of PrEP users that are particularly important to consider. Given their relevance across the EU/EEA region, countries should strive as much as possible to embed this set of core characteristics in the reporting of related indicators on PrEP use (see indicator sheets in the previous section).

Consistent with the colour codes applied in the indicator sheets, these core characteristics are labelled in 'green'. In addition, the expert panel identified some supplementary characteristics that may be relevant to include in the disaggregation of some indicators, depending on local relevance and feasibility. These characteristics are labelled in 'orange'.

For all the socio-demographic characteristics listed below, we have included some considerations on data sources that could be used to report on them.

Figure 5. Visual matrix of the included characteristics and their assigned levels of priority (green = core disaggregation; orange = supplementary disaggregation).

4.1 Disaggregation		
General characteristics The items described below refer to some basic socio-demographic characteristics related to PrEP users that might be relatively easy to collect through most routinely used population-level databases.		
Characteristic	**Response categories and description**	**Data collection and reporting considerations**
Assigned sex at birth and gender identity	The variable, 'assigned sex at birth' constitutes a binary concept based on biological sex, with the following options: • male • female The variable, 'gender identity' values individuals' own subjective experiences and sense of their gender. Options for 'gender identity' should therefore strive to achieve maximum inclusiveness, and reflect a spectrum that goes beyond the binary 'male/female' categories. ECDC suggests the following response categories for gender identity: • man • trans man • woman • trans woman • non-binary However, these categories may be adapted based on existing local data collection and registration systems.	Ideally, both 'assigned sex at birth' and 'gender identity' are collected and reported together. However, not all databases might contain complete information on both variables (e.g. prescription and claims databases). In such cases, one of the two variables should be reported, with clear definitions accompanying the applied response categories (e.g. in terms of the populations included).
Age (group)	This variable refers to the age at the time that the person received PrEP during the reporting period. Suggested reporting categories include: • 15–19 years • 20–29 years • 30–39 years • 40–49 years • 50+ years However, these categories may be adapted based on existing local data collection and registration systems.	Particular attention should also be paid to gather PrEP-related information from adolescents and young people. Getting a clear idea of PrEP use among young people might be challenging due to legal issues (e.g. around consent) and/or restricted access to PrEP. However, understanding the needs of this population might reveal gaps that require specific attention (e.g. designing interventions tailored towards youth).

Geographical area of residence	This variable refers to the geographical areas in which PrEP users reside. We advise countries to report data according to response categories in line with existing administrative units or areas currently used for data registration and reporting (e.g. cities, provinces or states).	Information on the geographical location of PrEP users may reveal disparities in access, or bring attention towards areas that may be particularly underserved by PrEP services (see also sheet 1.1). Databases that may contain relevant data on geographical areas of residence include: • prescription and claims databases • facility registries and electronic medical records • survey data.

Key populations

The list of items below comprises key populations recognised by ECDC, but is not exhaustive. Countries may adapt this list, for instance, by adding key populations informed by local HIV epidemiology. When an individual belongs to multiple key populations for PrEP, all of them should be recorded.

As a general approach when collecting data on client-level characteristics, we wish to highlight the 'first of all, do no harm' principle. While from a health-equity point of view, gathering data on PrEP users' memberships to certain key populations is vital to track a programme's progress in meeting the needs of different sub-groups, preserving the privacy of individuals and protecting their confidentiality is a critical concern as well.

As key populations for PrEP may overlap with population groups that are subject to marginalisation and/or criminalisation in some settings, programme implementers should actively consider how the data will be collected and reported to prevent perpetuating discrimination and/or stigmatisation towards these groups.

Establishing data systems with in-built protection mechanisms, for instance, collecting individually identifiable information for electronic records and reporting forms, will be particularly important both to ensure data security and to foster and maintain trust among the broader population.

Characteristic	Response categories and description	Data collection and reporting considerations
Men who have sex with men (MSM)	The category of 'men who have sex with men' (MSM) is widely recognised as one of the main key populations for HIV in the EU/EEA region. Countries are highly recommended to track progress in reaching this group by disaggregating indicators related to PrEP use among those who self-identify as MSM.	Data on individuals' self-perceived membership of key populations for PrEP can be more challenging to reliably obtain compared to basic socio-demographics (such as age and gender). Programme implementers mainly rely on data sources with the ability to capture self-reported information on key population, such as facility registries (e.g. based on provider-administered surveys or clinical record data). Prescription and claims databases do not contain information on key populations for PrEP.
Migrant status	First-generation immigrants may experience particular (legal and socio-economic) vulnerabilities associated with increased HIV risk [21]. Disaggregation of PrEP-related indicators according to individuals' 'country of birth' may help reveal disparities related to migrant status.	Data on individuals' country of birth are often not routinely collected. Programme implementers mainly rely on data sources with the ability to capture self-reported information on this variable, such as obtained from facility registries (e.g. based on provider-administered surveys or clinical record data). Alternatively, data on 'nationality' can be used as an incomplete proxy of migration status.
Sex workers	Sex workers may, in some settings, be regarded as particularly vulnerable to acquiring HIV. Although data collection among this group may be particularly challenging because of (anticipated) stigma and/or fear of discrimination or criminalisation, reporting on this variable should be considered taking into account the local context.	Data on individuals' self-perceived membership of key populations for PrEP can be challenging to obtain reliably. Programme implementers mainly rely on data sources with the ability to collect self-reported information on self-identification as 'sex worker', such as facility registries (e.g. based on provider-administered surveys or clinical record data).

	We strongly advise to include data on 'assigned sex at birth' and 'gender identity' in the reporting on this variable, to distinguish between male, female and transgender sex workers.	Prescription and claims databases do not contain information on the status of PrEP users as sex workers.
People who inject drugs	People who inject drugs (PWID) may be confronted with punitive legal environments, stigma and discrimination, and barriers to accessing health services. Reporting on this variable should be considered where possible and feasible.	Data on individuals' self-perceived membership of key populations for PrEP can be challenging to obtain reliably. Programme implementers mainly rely on data sources with the ability to gather self-reported information on self-identification as PWID, such as facility registries (e.g. based on provider-administered surveys or clinical record data). Prescription and claims databases do not contain information on drug use among PrEP users.
Sexualised drug use ('chemsex')	In EMIS-2017, 'chemsex' was defined as the use of stimulant drugs to make sex more intense or last longer [22]. Sexualised drug use may increase HIV risk, particularly among men who have sex with men [23]. Countries may consider reporting on this practice to reveal the prevalence and extent of this practice in relation to PrEP, and to offer better support.	Programme implementers mainly rely on data sources with the ability to collect self-reported information on sexualised drug use, such as facility registries (e.g. based on provider-administered surveys or clinical record data). Prescription and claims databases do not contain information on drug use among PrEP users.
Prisoners	There is a need for essential HIV-prevention programmes to be available in closed settings, such as populations in prisons. Reporting on the number of PrEP users among prisoners may track progress in their accessibility to PrEP.	Data on this variable should be collected through the relevant facility registries delivering services to this group.

PrEP-related characteristics

The expert panel identified two variables related to PrEP use that may require specific attention. As next-generation PrEP products are expected to be introduced in the EU/EEA market in the foreseeable future, disaggregating the number of current PrEP users (see sheet 2.1) according to the type of product used may become particularly important to track the uptake of novel PrEP formulations (i.e. other than oral).

Related to new PrEP initiations (see sheet 2.2), describing the chosen PrEP-dosing regimen at start may reveal potential barriers in the implementation of on-demand PrEP regimens.

Characteristic	Response categories and description	Data collection and reporting considerations
PrEP products	This variable aims to describe which PrEP product is being used by current PrEP users (see sheet 2.1). Response categories should include all available and approved PrEP products in a given setting (e.g. oral TDF/FTC, and/or – in the future – injectable PrEP, implants or long-acting oral products).	When new PrEP formulations become available in the future, it may be especially valuable to learn about the potential differences in, and track the appeal of next-generation PrEP products (e.g. injectables and implants). This indicator should count each individual only once. If an individual uses multiple PrEP products during the reporting period, the PrEP product that was last used should be recorded. Data on the use of PrEP products could be derived from prescription and medical claims databases. Algorithms may be developed and validated that, like the algorithms that identify oral TDF/FTC for PrEP, can distinguish whether TDF/3TC, oral TDF, cabotegravir or islatravir are prescribed for PrEP (as opposed to other indications). In addition, data on the use of PrEP products can also be derived from facility registries.

PrEP-dosing regimen at the start	This variable aims to describe the chosen regimen at the start among people who initiated oral PrEP for the first time (see sheet 2.2). Response categories include 'daily' or 'on-demand' (also called 'event-driven' or 'non-daily') PrEP regimens.	Tracking this indicator in settings that offer non-daily PrEP regimens may provide some insight into the trends of the chosen PrEP regimen at the time of initiation. Especially in newly established PrEP programmes, or when on-demand PrEP has recently been approved, this indicator may flag potential implementation issues. Users may still switch to a different dosing regimen or may alternate between regimens after initiating PrEP. This indicator therefore, does not describe the actual dosage of PrEP used by individuals over time. Data on the chosen regimen at PrEP initiation can be documented in facility registries and aggregated periodically to provide facility-level, subnational-level or national-level estimates.

Integrating PrEP with existing monitoring systems

In the development of the indicator sheets in the previous sections, we have outlined, as much as possible, how data related to PrEP could be collected through existing population-level databases and facility-based registries.

In addition to the more specific programmatic indicators for PrEP, we highlight below some more generic opportunities to integrate PrEP with existing monitoring activities. We briefly discuss some particular initiatives and reporting tools, and stress their main strengths and limitations.

- **HIV surveillance**: Many countries have made considerable investments in setting up robust systems for collecting data to monitor the HIV epidemic, and to report on outcomes of HIV treatment programmes. Especially in the early phases of a PrEP programme, countries may opt to deliver PrEP at the same facilities which have the experience of delivering antiretrovirals to people living with HIV (PLHIV). Hence, data collection related to PrEP could, in such cases, rely on existing infrastructure and resources used for monitoring HIV programmes. However, as demand for PrEP increases and programmes are scaled up, the delivery models for PrEP may evolve to additionally include decentralised delivery options (e.g. through general practitioners and/or CBOs). Active consideration should be given to explore which alternative data sources could be used to monitor client-level data on PrEP use that are independent of specialised HIV clinics (e.g. prescription and claims databases).
- **Sexually transmitted infection (STI) surveillance**: PrEP is often provided in combination with STI-prevention options as part of a broader sexual health package. Most clinical guidelines on PrEP currently recommend regular asymptomatic screening for STIs among PrEP users, in addition to prompt treatment and partner notification upon STI diagnosis. Given the high burden of STIs among some groups of PrEP users, particularly MSM, countries may consider additionally reporting on the number of STI diagnoses among PrEP users. Appropriate indicators in this regard depend on local clinical guidelines for the monitoring of STIs among PrEP users, and on the possibility of linking data on STI diagnoses to individual PrEP use.
- **Drug safety monitoring**: As for any pharmaceutical product, monitoring and reporting of drug toxicity related to PrEP should be done as per the general requirements of the existing pharmacovigilance system. For monitoring aspects related to the clinical safety of individual PrEP clients, we refer to relevant clinical guidelines (e.g. EACS guidelines on PrEP [24]).
- **Dublin Declaration monitoring framework**: ECDC disseminates an annual online survey among nominated HIV focal points in the EU/EEA, usually national health authority representatives, to monitor progress in the implementation of the Dublin Declaration on Partnership to fight HIV/AIDS. Since 2016, this questionnaire also includes questions on PrEP availability, provision, and (barriers to) implementation. In addition to the quantitative indicators presented in this tool, the Dublin Declaration monitoring framework also tracks more narrative data related to the status of regulatory approval for PrEP, the availability of national guidelines on PrEP, and advances related to the PrEP delivery model (e.g. the cost of PrEP and the providers licensed to prescribe PrEP). These data provide very valuable complementary insights into the progress of implementing PrEP in EU/EEA countries.
- **ECDC operational guidance on PrEP implementation**: Lastly, in the previously published operational guidance by ECDC on 'HIV Pre-Exposure Prophylaxis in the EU/EEA and the UK: implementation, standards and monitoring' [5], 10 'core principles' for effective PrEP programme implementation were outlined. Each principle in this guidance was accompanied by more specific quality statements and minimum standards. The current tool focuses mainly on programmatic outcome data. Following up on the minimum standards for service delivery allows the tracking of complementary process data to evaluate the performance of PrEP programmes. Hence, in addition to measuring and reporting data on the indicators presented in this tool, countries are encouraged to periodically assess the progress made towards achieving the minimum standards for PrEP service delivery as outlined in the operational guidance.

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Annex 1. List of useful data sources

Table A1. Overview of the most commonly available data sources for data collection and reporting on PrEP, including main benefits and challenges.

Data Source	Available information	Benefits	Challenges	Additional comments
Pharmacy prescription databases	Population-based estimates of the number of people using PrEP in a certain period (which can subsequently be used to create the numerator in estimates of 'PrEP coverage' and/or 'PrEP-to-need ratio'). If unique identifier codes are available, longitudinal data can be used to estimate the number of PrEP initiations and/or develop indicators for PrEP continuation.	1) Algorithms can be applied to specific databases to distinguish tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) prescriptions for PrEP from other indications with high sensitivity and high specificity. For example, TDF/FTC for antiretroviral therapy (ART), hepatitis B virus (HBV) or post-exposure prophylaxis (PEP) infections. 2) Readily available data through routine monitoring (e.g. no additional data collection is needed). 3) Provides data at population-level.	1) Databases often do not cover the entire population (e.g. no data on informal PrEP use or PrEP use registered in another administrative unit). 2) Data may not be representative of the entire PrEP-using population (e.g. in the context of missing differential data among non-insured individuals). 3) Databases frequently contain data on age, sex and postal code, but not on race/ethnicity or membership of key populations (e.g. MSM or sex workers).	Provides estimates on 'written' prescriptions.
Pharmacy dispension databases				Provides estimates on 'filled' prescriptions (proxy closer to actual use than written prescriptions).
Medical claims databases	Population-based estimates of PrEP use, HIV-testing adherence (as proxy for retention), and HIV seroconversions, through AIDS-related virus (ARV) prescription or hospitalisation.			
Surveys (repeated)	1) Allows early investigation (pre-uptake) of cascade steps, such as 'awareness' or 'willingness-to-use'. 2) Allows investigation of relevant types of behaviour, such as – PrEP adherence, switches between dosing regimens, or HIV-risk behaviour (and hence PrEP eligibility). 3) Allows incorporation of relevant collections of sociodemographic data on PrEP users.	1) Flexibility: questions can be adapted to fit local contexts. 2) Allows gathering data on individual knowledge, attitudes and types of behaviour that are often not addressed by other data sources.	1) Large surveys are more likely to comprise convenience samples, and results may consequently not be generalisable to the whole population. 2) Self-reported outcomes are susceptible to information bias, including recall bias and social desirability bias. 3) Financial and human resources are required to develop, disseminate, administer and analyse surveys. 4) Possibility of low response rates.	1) Thus far, large-scale behavioural surveys to monitor PrEP have focused on MSM (e.g. EMIS-2017 survey). 2) Different sampling methods (e.g. venue, internet or telephone-based) may characteristically yield different population samples. Telephone surveys among the general population can be used to yield a representative study sample. 3) Generally, internet-based surveys are timely, have a lower cost than in-person surveys and have a broad geographical scope. Yet, attention should be paid to a possible digital divide.
Clinic/facility registries ('provider data')	Data collected at service-delivery sites for PrEP can be aggregated to provide national or sub-national estimates.	1) The data is routinely collected as part of (clinical) records. 2) Possibility to collect client-level data on membership of key populations, PrEP regimen of choice, adherence and continuation.	1) The burden of data collection is on the data providers. 2) There might be instances of missing data if the administrative load is high. 3) Requires streamlining of data collection across facilities to have meaningful data on a higher (e.g. national/regional) level. This needs digital reporting systems.	If digital information systems allow, clinically coded (client-level) data could be directly linked to a central database as part of routine surveillance.

Annex 2. List of ECDC expert panellists

Table A2. List of ECDC expert panellists who guided and supported the development of the tool

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