ecdc
EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

EACS
European AIDS Clinical Society

European standards of HIV prevention and care: Module on pre-exposure prophylaxis

ECDC OPERATIONAL SUPPORT

European standards of HIV prevention and care: Module on pre-exposure prophylaxis

This report by the European Centre for Disease Prevention and Control (ECDC) was coordinated by Teymur Noori.

The draft version was produced under a specific contract with the European Centre for Disease Prevention and Control (ECDC). The European AIDS Clinical Society (EACS) was awarded this specific contract under 'European standards of HIV care' (service contract number: ECDC/2022/0210)

This report on standards of care for Pre-Exposure Prophylaxis is one in a series of standards for HIV care. Other reports in the series can be found on ECDC's website at https://www.ecdc.europa.eu/en/infectious-disease-topics/hiv-infection-and-aids/ecdceacs-standards-hiv-care

ECDC would like to acknowledge the support, guidance, and quality assurance throughout the duration of the project provided by members of the Standards of Care Advisory group: Alma Cicic (Montenegro), Caroline Hurley (Ireland), Cianán Russell (ILGA-Europe), Cristina Mussini (Italy), Cristiana Oprea (Romania), Deniz Gökengin (Türkiye), Dominique Van Beckhoven (Belgium), Ferenc Bagyinszky (Germany), Georg Behrens (Germany), Jose Bernardino (Spain), Omar Syarif (GNP+),Teymur Noori (ECDC).

ECDC would also like to thank the technical writing group for their time, energy, and technical expertise in the drafting of the Standards of Care: Writing group Lead Miłosz Parczewski (Poland), Alma Cicic (Montenegro), Anna Koval (Ukraine), Ann Sullivan (UK), Bartosz Szetela (Poland), Bogusz Aksak-Wąs (Poland), Caroline Hurley (Ireland), Cianán Russell (ILGA-Europe), Deniz Gökengin (Türkiye), Eva Orviz (Spain), Ferenc Bagyinszky (Germany), Fiona Burns (UK), Georg Behrens, (Germany), Jean-Michel Molina (France), Jessika Deblonde (Belgium), Omar Syarif (GNP+), Pep Coll (Spain), Sime Zekan (Croatia).

ECDC would also like to thank the SoC project Core Group members for their dedicated support to preparing the application for this project, providing day-to-day support to the working process; Ann Sullivan (Expert EACS), Daniel Simões (Expert Community), Dorthe Raben (CHIP), Esteban Martinez (Expert EACS), Fiona Burns (Expert EACS), Jürgen Rockstroh (Expert EACS), Joelle Verluyten (EACS), Miłosz Parczewski (Expert EACS), Sanjay Bhagani (Expert EACS).

ECDC would also like to thank the European Standard of Care Coordination team in EACS and CHIP for jointly coordinating the work and ensuring support to all phases of the project. The project team consists of Joelle Verluyten (EACS) and Dorthe Raben (CHIP) including project coordinators, Anne Raahauge, Susanne Olejas (CHIP) and Olga Fursa (CHIP).

Suggested citation: European Centre for Disease Prevention and Control. European standards of HIV prevention and care: Module on pre-exposure prophylaxis. Stockholm: ECDC; 2025.

Stockholm, June 2025

ISBN 978-92-9498-806-5
doi: 10.2900/4677371
Catalogue number TQ-01-25-036-EN-N

Contents

Tables

Abbreviations

AG	Advisory Group
ART	Antiretroviral therapy
CHIP	Centre of Excellence for Health, Immunity, and Infections
CSO	Civil Society Organisation
DOI	Declaration of interest
EATG	European AIDS Treatment Group
ECDC	European Centre for Disease Prevention and Control
EACS	European AIDS Clinical Society
EU/EEA	European Union/European Economic Area
FTF	Face-To-Face
FTC	Emtricitabine
GBMSM	Gay, bisexual, and other men who have sex with men
GNP+	Global Network of People living with HIV
HCP	Healthcare provider
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HPV	Human Papilloma Virus
HMIS	Health Management Information Systems
I	Indicators
ID	Infectious Diseases
iPREX	Preexposure Prophylaxis Initiative
LAI PrEP	Long-acting injectable PrEP
Mpox	Mpox virus (formerly Monkeypox)
NFP	National Focal Point
NGO	Non-governmental organisation
PLHIV	People living with HIV
PrEP	Pre-exposure prophylaxis
QS	Quality Statement
SDG	Sustainable Development Goals
SoC	Standards of care
SRH	Sexual and Reproductive Health
STIs	Sexually transmitted infections
TDF	Tenofovir Disoproxil Fumarate
TDx	Tenofovir Disoproxil
TAF	Tenofovir Alafenamide
WHO	World Health Organization
3TC	Lamivudine

Background and introduction

An estimated 2 334 662 people are living with HIV in Europe and Central Asia, 1 944 695 of whom (83%; range 65–100%) have been diagnosed [1]. In 2023, 110 486 people were diagnosed with HIV in the WHO European the region [2]. Of these new diagnoses, 54% were made at a late stage of infection (CD4 cell count < 350 cells/mm3 at the time of diagnosis), including 34% with advanced HIV infection (CD4 cell count < 200 cells/mm3) [2]. Early identification of recent HIV infection helps detect people during a period of increased transmissibility and reduces the risk of spread of onwards transmission [3].

Pre-exposure prophylaxis (PrEP) with antiretroviral medications is a highly effective tool in preventing new HIV infections [4-7]. Roll-out of oral tenofovir disoproxil/emtricitabine (TDx/FTC) based PrEP effectively reduced incidence among key populations at substantial risk of HIV acquisition through sexual exposure[8-10], but wider scale implementation of PrEP is necessary to accelerate progress towards the UN sustainable development goal 3.3 of ending the AIDS epidemic by 2030.

The implementation of HIV PrEP has improved substantially since 2016, but there is still a great deal of variation in the implementation across countries. In 2023, thirty-two countries reported that 203 362 people received PrEP at least once in the last 12 months. Also, in this period 30 countries in Europe and Central Asia had developed and implemented national PrEP guidelines, and system-funded PrEP was available through the healthcare system of 15 countries [11]. Even within these countries, PrEP is not always fully available, and some countries also have restrictions around eligibility. For certain key populations (prisoners, people who inject drugs and undocumented migrants), PrEP often remains inaccessible or only available through private clinics or at-cost. This creates a financial barrier to care for these populations [12].

By the end of 2023, 13 countries in Europe and Central Asia had not yet formally implemented PrEP through their healthcare systems. In 15 countries, PrEP was available for free at public facilities and in 4 countries PrEP was free if the individual had insurance. In 14 countries PrEP was available at cost [11]. PrEP is typically provided in clinical settings, such as infectious disease clinics and sexual health clinics, and in most countries in the WHO European region requires a prescription from a medical doctor. In 2022, doctors were able to prescribe PrEP in 36 countries, but four of these countries specified that the prescribing doctor had to be an infectious disease specialist. Members of the nursing profession were only able to prescribe PrEP in two countries, and pharmacists were not able to prescribe PrEP in any European country. This may create barriers to access for key groups [13].

What are standards of care for HIV?

The standards of care (SoC) for HIV define the expected, or desired, quality of prevention, treatment, and care for people at risk of HIV acquisition or living with HIV.

The standards are based on a scientific rationale, as well as the responsibilities of each stakeholder and ensure that people receive appropriate, high-quality prevention and care that aligns with the most up-to-date medical knowledge and ethical standards.

The European Centre for Disease Prevention and Control (ECDC) in partnership with the European AIDS Clinical Society (EACS) have developed standards of care in the areas of HIV testing, pre-exposure prophylaxis (PrEP), antenatal screening, commencement of ART, and HIV and co-morbidities (add links to SoC modules).

Each standard is based on the following structure:

1. brief description of the rationale for the standard.
2. quality statements describing best practice based on current guidelines, evidence, and expert opinion.
3. related measurable and auditable outcome indicators used to assess the quality and effectiveness of the services.
4. numeric values for defined targets.

The standards are person-centred in their approach with a specific focus on being equitable, non-discriminatory, relevant, appropriate, and accessible for people at risk of or living with HIV.

Who is the intended audience of the standards of care?

These standards of care are designed for three distinct audiences:

- people at risk of acquiring HIV or people who are living with HIV;
- people responsible for the provision and delivery of HIV-related services (service providers);
- people who have responsibility for policy, guidance development and commissioning or funding of HIV services (Commissioners and public health institutes).

Methodology

An advisory group and topic-specific writing groups consisting of representatives from clinical care providers, public health practitioners, community organisations and people living with HIV from across Europe were established (see Annex 1). The advisory group provided overarching advice throughout the duration of the project, supported the prioritisation of module selection, prioritisation of quality statements and indicators and reviewed the SoC module. The topic-specific writing groups have developed the quality statements, indicators, and targets (under the guidance of an EACS expert lead writer), and also reviewed the final SoC testing module.

In developing the standard, a combination of consensus-building techniques, such as the RAND/UCLA Appropriateness method and the Delphi method, were used. The RAND method is a formal consensus technique that combines scientific evidence with expert opinions to create guidelines, recommendations, and quality indicators, particularly in healthcare settings – this method was used to identify topics for the SoCs and for developing quality statements and indicators. The Delphi method is a structured communication process that gathers expert opinions and facilitates consensus through multiple rounds of questions and feedback – this method was used as part of the writing group meetings.

The methodology has been described in more detail in the method paper on ECDC's website at: https://www.ecdc.europa.eu/en/infectious-disease-topics/hiv-infection-and-aids/ecdceacs-standards-hiv-care

Quality statements, indicators, and targets

The SoC for PrEP is divided into topics under which quality statements and indicators have been developed. The topics are listed below followed by the rationales and quality statements describing best practises and the minimum service and care that a person at risk of HIV should expect to be able to access relative to HIV risk or status and across the life-course.

Topics

1. Access to PrEP
2. PrEP initiation, including safety aspects
3. Continuum of PrEP care (including adherence and post-exposure prophylaxis)
4. PrEP delivery, integrated services, and combination prevention
5. Staff training
6. Monitoring and evaluation

For each of the quality statements listed below, indicators and targets have been developed to support monitoring of the various quality statements.

A detailed overview of quality statements, indicators, numerator, denominator, targets, and data source can be found in Annex 2.

1. Access to pre-exposure prophylaxis (PrEP)

Rationale

Pre-exposure prophylaxis (PrEP) access, delivery methods and implementation practices are notably different and not fully equitable across countries ranging from fully system-funded, to partially reimbursed to fully payable or with limited availability [20, 21]. Large scale, real-life analyses indicate that long-term protection provided by PrEP is needed to reach the SDG of ending AIDS by 2030. However, there remains a large unmet need for PrEP implementation within the system-funded programmes across countries in Europe [15, 16, 22]. Only expanding equitable access to reach all individuals in need of PrEP would allow to meet the UNAIDS 2025 PrEP target, which is critical to reaching the SDG goal of 'ending AIDS' by 2030 [23, 24].

Table 1. Quality statements, indicators, and targets for topic 1 'Access to PrEP'

Quality statement **1.1 All people at risk of acquiring HIV should be offered and have equitable access to PrEP.**	
Indicator* **1.1 Percentage of countries offering PrEP**	**Target** 100%
1.2 Percentage of countries across Europe providing system-funded PrEP.	**Target** 100%
1.3 Number of current PrEP users in a country	**Target** Targets to be established and defined following implementation of audits
1.4 Number of new PrEP users in a country	**Target** Targets to be established and defined following implementation of audits
1.5 Percentage of countries with availability of long-acting injectable PrEP	**Target** Targets to be established and defined following implementation of audits
1.6 PrEP-to-need ratio (PnR) for a country across key populations	**Target** Targets to be established and defined following implementation of audits

** Indicators highlighted in bold have been selected for prioritisation in order to maximise acceptability and feasibility of adoption and reporting against the standards.*

2. PrEP initiation, including safety aspects

Rationale

Safety and avoiding harm in people using PrEP remains a high priority [8-10, 15] and is a marker of excellence in healthcare care. Prior to initiating PrEP, it is critical to consider the exposure history and risk of recently acquired HIV infection. Therefore, it is essential to exclude undiagnosed infections both at PrEP initiation and during follow-up care. For this purpose, appropriate HIV testing should be undertaken for those with suspected or probable acute infection using antigen/antibody combination assays or nucleic acid amplification testing [8, 25-27]. Timely detection of acute/recently acquired HIV infection and initiation of antiretroviral therapy (ART), as well as identification of drug-resistant variants, is essential from both a population and individual perspective. Such an approach aims to reduce the risk of onward transmission and preserve effective PrEP options [28].

Furthermore, delayed detection of HIV infection while on PrEP has been associated with increased risk of drug resistance, limiting ART options [29]. PrEP users may also be vulnerable to contracting hepatitis B virus (HBV), even though tenofovir based agent-use is associated with decreased risk of HBV infection [30]. Vaccination against HBV remains a well-established and successful method for HBV prevention and should be accessible to all PrEP users [31]. On the other hand, among people living with chronic HBV, PrEP use appears safe when at risk of non-adherence or discontinuation [32]. Also, due to risk (albeit low) of toxicities, especially related to kidney and bone aspects in cases of TDx use, relevant biochemical testing strategies should be available at predefined intervals in addition to alternative PrEP options (e.g. TAF in individuals with impaired kidney function) [8, 33]. Lastly, TDx/FTC has a proven safety profile in pregnancy and during the breastfeeding period [34, 35].

Table 2. Quality statements, indicators, and targets for topic 2 'PrEP initiation, including safety aspects'

Quality statement 2.1 PrEP should be initiated with full consideration of clinical safety including reliable exclusion of HIV infection.	
Indicator **2.1 Percentage of countries following international (e.g. EACS) or national PrEP safety guidelines, that include option for alternative PrEP regimens for safety reasons**	**Target** 100%
2.2 Percentage of PrEP users older than 50 years and with baseline eGFR <90 with kidney function assessed at least annually	**Target** 90%
2.3 Percentage of PrEP users with reliable* exclusion of HIV infection prior to initiating PrEP *Baseline negative HIV test for people without recent risk exposure, repeated testing for people with recent risk exposure at baseline	**Target** 95%

Quality statement 3.1 All PrEP users should be tested for hepatitis B and if non-immune, effectively immunised.	
Indicator **3.1 Percentage of countries with system-funded HBV vaccination available to PrEP users**	**Target** 100%
3.2 Percentage of PrEP users with HBV status verified using: a) HBsAg (active replication), or b) anti-HBc (past/active infection)	**Target** 90% 80%
3.3 Percentage of PrEP users tested HBsAb negative immunised with HBV vaccination	**Target** 80%

Quality statement 4.1 Clear pathways for rapid and reliable diagnosis of HIV as well as antiretroviral treatment initiation should be ensured for PrEP users.	
Indicator 4.1 Percentage of PrEP services with established pathways for rapid identification of HIV infection among PrEP users	**Target** 80%
4.2 Percentage of PrEP users with recently acquired HIV infection	**Target** --
4.3 Percentage of PrEP users with recently acquired HIV infection initiated on ART	**Target** 95%

Quality statement 5.1 Priority resistance testing for PrEP users recently infected with HIV should be available.	
Indicator **5.1 Percentage of countries with resistance testing available for PrEP users with recently acquired HIV infection**	**Target** 100%
5.2 Percentage of PrEP users with recently acquired HIV infection who undergo resistance testing prior to ART initiation	**Target** 80%

[*] *Indicators highlighted in bold have been selected for prioritisation in order to maximise acceptability and feasibility of adoption and reporting against the standards.*

3. Continuum of pre-exposure prophylaxis care (including adherence and post-exposure prophylaxis)

Rationale

Supporting the patient journey along the continuum of PrEP care and reducing barriers to PrEP access contributes to adherence and persistence in PrEP use. Retention strategies should be optimised, as PrEP discontinuation rates are usually high [36, 37]. Major barriers to PrEP persistence include substance use (including chemsex), mental health and housing issues, cost, insurance, and access to healthcare [38]. Low PrEP adherence and condomless sexual exposures may lead to HIV acquisition, and most cases of HIV acquisition in people taking PrEP occur due to incorrect drug dosing and/or tolerance issues. To promote optimal dosing, adherence should be monitored and factors influencing adherence, such as tolerance issues, should be discussed and addressed [39].

Non-adherent populations may benefit from post-exposure prophylaxis (PEP) as an additional preventive measure [8]. Suboptimal TDx/FTC PrEP adherence is clearly defined across guidelines, allowing for the identification of non-adherent PrEP users who should be offered PEP as soon as possible, but not later than 72 hours after exposure. PEP initiation in PrEP-naïve individuals should be seen as an opportunity to follow PEP immediately with a PrEP offer. To facilitate PrEP use, both on-demand and daily TDx/FTC dosing strategies may be used interchangeably among cisgender men based on individual risk, tolerance, medical history, and financial capabilities. Both dosing strategies have been proven to be highly effective in reducing the rates of HIV acquisition [40]. However, for transgender populations, optimal dosing strategies (on-demand or continuous) should be decided individually based on the actual personal risk and concomitant use of gender-affirming therapies.

Table 3. Quality statements, indicators, and targets for topic 3 'Continuum of PrEP care'

Quality statement	
6.1 PrEP adherence should be assessed and addressed routinely whenever PrEP is dispensed.	
Indicator	**Target**
6.1 Percentage of people on PrEP with documentation of adherence assessment	80%

Quality statement	
7.1 For men, continuous daily and on-demand PrEP dosing should be available interchangeably and individualised in line with relevant guidelines.	
Indicator	**Target**
7.1 Percentage of countries with availability of both continuous and on-demand PrEP	100%

Quality statement	
8.1 In the event of high-risk sexual exposure without appropriate PrEP use, system funded HIV post-exposure prophylaxis (PEP) should be immediately available.	
Indicator	**Target**
8.1 Percentage of countries with availability of system funded PEP for high-risk sexual exposures	100%

[*] *Indicators highlighted in bold have been selected for prioritisation in order to maximise acceptability and feasibility of adoption and reporting against the standards.*

4. Pre-exposure prophylaxis care delivery, integrated services, and combination prevention

Rationale

Combination prevention approaches have resulted in an increase of PrEP use [15]. To expand effective PrEP use, it is vital to implement combination prevention integrating a variety of sexual health-related services, including testing, vaccination, counselling, simplifying and individualising access with consideration of the local population needs. A wide array of models for PrEP delivery have been successfully established worldwide. These include, but are not limited to, delivery in specialist clinics (infectious disease and HIV units, STI/genitourinary clinics), primary care centres, sexual health centres, community-based organisations (checkpoints). In most settings, however, PrEP is highly medicalised. There is a significant benefit from a wide offer of delivery approaches that commonly have convenient opening hours [41, 42]. Integration with sexual and reproductive health (SRH) services has also been shown to improve effective use of PrEP [16, 21]. Such integration brings expanded skills development and a reduction in workload [15] and therefore improved efficiency.

Novel PrEP delivery methods, such as the use of telemedicine and online communication technologies to create virtual platforms for delivering PrEP services, have the potential to remove barriers for PrEP uptake and persistence and support its effective use [43]. Only virtual tools that are secure, ensure confidentiality and have been fully evaluated in relation to access and use should be implemented. The principles of good clinical practice need to be maintained regardless of which pathway of delivery is chosen. In order to optimise clinical and public health outcomes for HIV and other STIs during the follow-up period, relevant STI testing should be integrated in PrEP care strategies and offered to users according to current guidelines [8-10]. Services should integrate relevant STI prophylaxis, screening, treatment and follow-up as an integral part of PrEP programmes with a focus on HAV and HBV vaccination, optional HPV, MPOX and other relevant immunisations as well as treatment of both asymptomatic and symptomatic STIs [44-47].

Table 4. Quality statements, indicators, and targets for topic 4 'PrEP delivery, integrated services and combination prevention'

Quality statement 9.1 PrEP users should have access to a wide choice of delivery locations and integrated services, including in primary healthcare and community-based settings to improve ease and equity of access.	
Indicator 9.1 Percentage of countries with PrEP available in at least one non-medical (community) setting	**Target** --
9.2 Percentage of PrEP prescribed by setting: specialist infectious diseases/sexual health clinic, primary healthcare, and non-medical (community-based) facilities	**Target** --

Quality statement 10.1 PrEP services may be managed remotely if clinical safety and proper clinical management is ensured.	
Indicator 10.1 Percentage of people with remote/on-line consultation who adhere to the testing guidelines and recommended timeline for follow-up visits	**Target** 80%

Quality statement 11.1 PrEP should be used as an opportunity to integrate appropriate STI screening, treatment, and follow-up care, including partner notification.	
Indicator 11.1 Percentage of countries with system-funded NAAT based *Chlamydia trachomatis* and *Neisseria gonorrhoea* screening for PrEP users	**Target** 90%
11.2 Percentage of countries with system funded syphilis VDRL/RPR screening for PrEP users	**Target** 90%

Quality statement 12.1 In PrEP users, HIV and STI testing should be performed at regular intervals as predefined by national and international guidelines.	
Indicator **12.1 Percentage of PrEP users being tested for HIV at least every 6 months**	**Target** 80%
12.2 Percentage of PrEP users tested for syphilis and STI (gonorrhoea, chlamydia) at least annually	**Target** 80%

Quality statement 13.1 PrEP should be a part of comprehensive combination prevention, which includes personalised immunisation strategy (HAV, HPV, MPOX), as well as screening, prevention, and treatment of sexually transmitted infections.	
Indicator 13.1 Percentage of countries with MPOX vaccination option available for PrEP users	**Target** 90%
13.2 Percentage of countries with system funded HAV and HPV vaccination available for PrEP users	**Target** 90%
13.3 Percentage of PrEP users offered and immunised against HAV, MPOX, HPV	**Target** 80%

[*] *Indicators highlighted in bold have been selected for prioritisation in order to maximise acceptability and feasibility of adoption and reporting against the standards.*

5. Staff training

Rationale

Relevant and continuous training allows for the maintenance of high-quality PrEP service delivery, especially from the perspective of integrated services. Training of healthcare staff helps engrain the necessary behaviours, attitudes, skills, and knowledge to deliver high-quality, safe, person-centred care and can reduce fear and stigma, as well as help health professionals protect themselves and others [48].

Initiation, continuation, and effective use of PrEP is affected by health providers' knowledge about PrEP, combination prevention approaches and ability to discuss sexual risk [48]. Training needs to equip health providers with a solid understanding of how PrEP works, and the confidence to initiate clients onto PrEP and motivate them to continue with this method while their risk remains high.

Table 5. Quality statements, indicators, and targets for topic 5 'Staff training'

Quality statement 14.1 Well defined staff competency frameworks should be in place, including relevant training and competence assessment allowing for safe and efficient PrEP delivery both in medical and community settings.	
Indicator 14.1 Percentage of countries with inclusion of PrEP-related training in curriculum of key medical specialties: a) infectious diseases, b) genitourinary medicine, c) dermatology/venerology, d) obstetrics/gynaecology, e) urology, f) primary healthcare.	**Target** 100% for a,b,c 90% for d,e,f
14.2 Percentage of services with PrEP training programmes or competency assessment relevant for PrEP delivery available for healthcare providers	**Target** 100%
14.3 Percentage of providers who completed a recognised training programme or competence assessment relevant for PrEP delivery	**Target** 80%

** Indicators highlighted in bold have been selected for prioritisation in order to maximise acceptability and feasibility of adoption and reporting against the standards.*

6. Monitoring and evaluation

Rationale

Rolling out PrEP has exposed gaps in the ability to monitor and assess the use of PrEP and assess whether PrEP programmes effectively reduce HIV risk for individuals and communities.

Accurate data on demographics and uptake across key populations are essential to monitor equity of access and outcomes. This information is essential to ensure that PrEP programmes meet users' needs and to assess their impact and effectiveness at the community and national levels. Routine monitoring and robust evaluations are therefore critical [49]. Strengthening the link between data collected through national healthcare databases, community-led monitoring and population-level or surveillance surveys would provide a more accurate picture of trends in PrEP use, programmatic gaps, and prevailing attitudes or perceptions of users, providers, and communities [49].

Furthermore, monitoring of indicators for coverage and impact can help countries, implementers and funders understand and assess the benefits of PrEP programmes. Collection of data on costs and utilisation of PrEP-related programming such as demand generation, community outreach, and implementation of combination prevention programmes will therefore help to ensure and optimise the access, availability, uptake, adherence during periods of HIV risk and effectiveness of PrEP. To address and monitor PrEP implementation, ECDC has produced guidance for monitoring of PrEP programmes in the EU/EEA encompassing three thematic domains related to PrEP (pre-uptake, uptake, and coverage, continued effective use) with corresponding indicators [50] to be used across countries.

Table 6. Quality statements, indicators, and targets for topic 3 'Monitoring and evaluation'

Quality statement 15.1 Every country should initiate standardised national protocols for monitoring of PrEP implementation.	
Indicator 15.1 Percentage of countries collecting, analysing, and reporting data on key European level PrEP indicators in line with national protocols for monitoring of PrEP implementation	**Target** 90%

** Indicators highlighted in bold have been selected for prioritisation in order to maximise acceptability and feasibility of adoption and reporting against the standards.*

Applying the standards

One essential tool to support the application and measurement of these standards is the process of auditing. Audits at clinic and structural/policy level provide a reference point against which to benchmark the quality of HIV prevention or care services.

The indicators listed in the standards are either structural, process or outcome indicators (defined in Annex 2). Many of the structural indicators are collected annually through the 2004 Dublin Declaration monitoring. On the other hand, to evaluate performance against the process indicators, in particular at the clinical service level, cyclical audits can generate results to form recommendations to improve quality and provision of care. Clinical level audits can thus supplement data collected through the Dublin Declaration monitoring. Specifically, findings from clinical audits could be used to identify areas of underperformance to produce specific clinic recommendations and drive quality improvement.

On a broader scale, auditing can assess the quality-of-care patients receive in Europe, guide service commissioning, and support the development of public health, clinical, and community guidelines.

References

1. European Centre for Disease Prevention and Control (ECDC). Continuum of HIV care. Monitoring implementation of the Dublin Declaration on partnership to fight HIV/AIDS in Europe and Central Asia: 2023 progress report. Stockholm: ECDC; 2023. Available at: https://www.ecdc.europa.eu/en/publications-data/hiv-continuum-care-monitoring-implementation-dublin-declaration-2023
2. European Centre for Disease Prevention and Control (ECDC), WHO Regional Office for Europe (WHO Europe). HIV/AIDS surveillance in Europe 2023 – 2022 data. Stockholm: ECDC; 2023. Available at: https://www.ecdc.europa.eu/en/publications-data/hivaids-surveillance-europe-2023-2022-data
3. Nikolopoulos GK, Tsantes AG. Recent HIV Infection: Diagnosis and Public Health Implications. Diagnostics (Basel). 2022;12(11). Available at: https://pubmed.ncbi.nlm.nih.gov/36359500
4. Grant RM, Lama JR, Anderson PL, McMahan V, Liu AY, Vargas L, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med. 2010;363(27):2587-99. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa1011205
5. Baeten JM, Donnell D, Ndase P, Mugo NR, Campbell JD, Wangisi J, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. N Engl J Med. 2012;367(5):399-410. https://pubmed.ncbi.nlm.nih.gov/22784037
6. Molina JM, Capitant C, Spire B, Pialoux G, Cotte L, Charreau I, et al. On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection. N Engl J Med. 2015;373(23):2237-46. Available at: https://pubmed.ncbi.nlm.nih.gov/26624850
7. McCormack S, Dunn DT, Desai M, Dolling DI, Gafos M, Gilson R, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. Lancet. 2016;387(10013):53-60. Available at: https://pubmed.ncbi.nlm.nih.gov/26364263
8. European AIDS Clinical Society (EACS). EACS Guidelines, version 12.0. 2023. Available at: https://www.eacsociety.org/media/guidelines-12.0.pdf
9. British HIV Association. Standards of care for people living with HIV. 2018. Available at: https://www.bhiva.org/standards-of-care-2018
10. US Public Health Service. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update – A Clinical Practice Guideline. 2021. Available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
11. European Centre for Disease Prevention and Control (ECDC). Pre-exposure prophylaxis for HIV prevention in Europe and Central Asia Monitoring implementation of the Dublin Declaration – 2023 progress report. Stockholm: ECDC; 2023. Available at: https://www.ecdc.europa.eu/en/publications-data/hiv-pre-exposure-prophylaxis-prevention-dublin-declaration-2023
12. Legido-Quigley H, Pocock N, Tan ST, Pajin L, Suphanchaimat R, Wickramage K, et al. Healthcare is not universal if undocumented migrants are excluded. Bmj. 2019;366:l4160. Available at: https://www.bmj.com/content/366/bmj.l4160
13. Kornilova M, Roshchupkin G. Assessment of the availability of PrEP, the main barriers to implementing PrEP, and scaling up PrEP in the EECA Region. Tallinn: Eurasian Coalition on Male Health; 2019. Available at: https://ecom.ngo/resource/files/2021/05/assessment-of-the-availability-of-prep-the-main-barriers-to-implementing-prep-and-scaling-up-prep-in-the-eeca-region.pdf
14. European Centre for Disease Prevention and Control (ECDC). Public health guidance on HIV, hepatitis B and C testing in the EU/EEA: An integrated approach. Stockholm: ECDC; 2018. Available at: https://www.ecdc.europa.eu/en/publications-data/public-health-guidance-hiv-hepatitis-b-and-c-testing-eueea
15. World Health Organization (WHO). Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance. Geneva: WHO; 2022. Available at: https://www.who.int/publications/i/item/9789240053694
16. World Health Organization (WHO). Prevention and control of sexually transmitted infections (STIs) in the era of oral pre-exposure prophylaxis (PrEP) for HIV. Geneva: WHO; 2019. Available at: https://www.who.int/publications/i/item/prevention-and-control-of-stis-in-the-era-of-prep-for-hiv
17. British HIV Association (BHIVA) BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP). 2018. Available at: https://www.bhiva.org/PrEP-guidelines
18. European AIDS Clinical Society (EACS). GDPR: EACS General Privacy Policy. Available at: https://www.eacsociety.org/privacy-policy
19. People First Charter, 22 March 2024. Available at: https://peoplefirstcharter.org
20. Grulich AE, Jin F, Bavinton BR, Yeung B, Hammoud MA, Amin J, et al. Long-term protection from HIV infection with oral HIV pre-exposure prophylaxis in gay and bisexual men: findings from the expanded and extended EPIC-NSW prospective implementation study. Lancet HIV. 2021;8(8):e486-e94. Available at: https://pubmed.ncbi.nlm.nih.gov/34217426

21. Sullivan AK, Saunders J, Desai M, Cartier A, Mitchell HD, Jaffer S, et al. HIV pre-exposure prophylaxis and its implementation in the PrEP Impact Trial in England: a pragmatic health technology assessment. Lancet HIV. 2023;10(12):e790-e806. Available at: https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(23)00256-4/fulltext
22. Hayes R, Schmidt AJ, Pharris A, Azad Y, Brown AE, Weatherburn P, et al. Estimating the 'PrEP Gap': how implementation and access to PrEP differ between countries in Europe and Central Asia in 2019. Euro Surveill. 2019;24(41). Available at: https://pubmed.ncbi.nlm.nih.gov/31615599
23. European Centre for Disease Prevention and Control (ECDC). Evidence brief: Pre-exposure prophylaxis for HIV prevention in Europe and Central Asia - Monitoring implementation of the Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia – 2020/2021 progress report. 2022. Available at: https://www.ecdc.europa.eu/en/publications-data/hiv-infection-prevention-pre-exposure-prophylaxis-monitoring-dublin
24. AIDSVu. PrEP Use Across the U.S. at the County-Level, 2020. 4 April 2020. Atlanta: AIDSVu; 2020. Available at: https://aidsvu.org/news-updates/prep-use-across-the-u-s-at-the-county-level
25. Wang W, Zhao S, Wu Y, Duan W, Li S, Li Z, et al. Safety and Efficacy of Long-Acting Injectable Agents for HIV-1: Systematic Review and Meta-Analysis. JMIR Public Health Surveill. 2023;9:e46767. Available at: https://pubmed.ncbi.nlm.nih.gov/37498645
26. Fonner VA, Ridgeway K, van der Straten A, Lorenzetti L, Dinh N, Rodolph M, et al. Safety and efficacy of long-acting injectable cabotegravir as preexposure prophylaxis to prevent HIV acquisition. Aids. 2023;37(6):957-66. Available at: https://pubmed.ncbi.nlm.nih.gov/36723489
27. Landovitz RJ, Donnell D, Clement ME, Hanscom B, Cottle L, Coelho L, et al. Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women. N Engl J Med. 2021;385(7):595-608. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa2101016
28. Elliott T, Sanders EJ, Doherty M, Ndung'u T, Cohen M, Patel P, et al. Challenges of HIV diagnosis and management in the context of pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), test and start and acute HIV infection: a scoping review. J Int AIDS Soc. 2019;22(12):e25419. Available at: https://pubmed.ncbi.nlm.nih.gov/31850686
29. Misra K, Huang JS, Udeagu CN, Forgione L, Xia Q, Torian LV. Pre-exposure prophylaxis (PrEP) use history in people with antiretroviral resistance at HIV diagnosis: Findings from New York City HIV surveillance and partner services, 2015-2022. Clin Infect Dis. 2023. Available at: https://pubmed.ncbi.nlm.nih.gov/37976185
30. Mizushima D, Takano M, Aoki T, Ando N, Uemura H, Yanagawa Y, et al. Effect of tenofovir-based HIV pre-exposure prophylaxis against HBV infection in men who have sex with men. Hepatology. 2023;77(6):2084-92. Available at: https://pubmed.ncbi.nlm.nih.gov/36960800
31. Gökengin D, Noori T, Alemany A, Bienkowski C, Liegon G, İnkaya A, et al. Prevention strategies for sexually transmitted infections, HIV, and viral hepatitis in Europe. Lancet Reg Health Eur. 2023;34:100738. Available at: https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(23)00157-6/fulltext
32. Mohareb AM, Larmarange J, Kim AY, Coffie PA, Kouamé MG, Boyd A, et al. Risks and benefits of oral HIV pre-exposure prophylaxis for people with chronic hepatitis B. Lancet HIV. 2022;9(8):e585-e94. Available at: https://pubmed.ncbi.nlm.nih.gov/35817068
33. O Murchu E, Marshall L, Teljeur C, Harrington P, Hayes C, Moran P, et al. Oral pre-exposure prophylaxis (PrEP) to prevent HIV: a systematic review and meta-analysis of clinical effectiveness, safety, adherence and risk compensation in all populations. BMJ Open. 2022;12(5):e048478. Available at: https://bmjopen.bmj.com/content/12/5/e048478
34. Mugo NR, Hong T, Celum C, Donnell D, Bukusi EA, John-Stewart G, et al. Pregnancy incidence and outcomes among women receiving preexposure prophylaxis for HIV prevention: a randomized clinical trial. JAMA. 2014;312(4):362-71. Available at: https://pubmed.ncbi.nlm.nih.gov/25038355
35. Joseph Davey DL, Pintye J, Baeten JM, Aldrovandi G, Baggaley R, Bekker LG, et al. Emerging evidence from a systematic review of safety of pre-exposure prophylaxis for pregnant and postpartum women: where are we now and where are we heading? J Int AIDS Soc. 2020;23(1):e25426. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6948023
36. Coukan F, Murray KK, Papageorgiou V, Lound A, Saunders J, Atchison C, et al. Barriers and facilitators to HIV Pre-Exposure Prophylaxis (PrEP) in Specialist Sexual Health Services in the United Kingdom: A systematic review using the PrEP Care Continuum. HIV Med. 2023;24(8):893-913. Available at: https://pubmed.ncbi.nlm.nih.gov/37078101
37. Edeza A, Karina Santamaria E, Valente PK, Gomez A, Ogunbajo A, Biello K. Experienced barriers to adherence to pre-exposure prophylaxis for HIV prevention among MSM: a systematic review and meta-ethnography of qualitative studies. AIDS Care. 2021;33(6):697-705. Available at: https://pubmed.ncbi.nlm.nih.gov/32530302
38. Spinelli MA, Laborde N, Kinley P, Whitacre R, Scott HM, Walker N, et al. Missed opportunities to prevent HIV infections among pre-exposure prophylaxis users: a population-based mixed methods study, San Francisco, United States. J Int AIDS Soc. 2020;23(4):e25472. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7159249

39. Sepodes B, Rocha J, Batista J, Figueira ME, Dráfi F, Torre C. Implementation and Access to Pre-exposure Prophylaxis for Human Immunodeficiency Virus by Men Who Have Sex With Men in Europe. Front Med (Lausanne). 2021;8:722247. Available at: https://pubmed.ncbi.nlm.nih.gov/34513883
40. Molina JM, Charreau I, Spire B, Cotte L, Chas J, Capitant C, et al. Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study. Lancet HIV. 2017;4(9):e402-e10. Available at: https://pubmed.ncbi.nlm.nih.gov/28747274
41. Mujugira A, Karungi B, Mugisha J, Nakyanzi A, Bagaya M, Kamusiime B, et al. "I felt special!": a qualitative study of peer-delivered HIV self-tests, STI self-sampling kits and PrEP for transgender women in Uganda. J Int AIDS Soc. 2023;26(12):e26201. Available at: https://onlinelibrary.wiley.com/doi/full/10.1002/jia2.26201
42. Cambiano V, Miners A, Lampe FC, McCormack S, Gill ON, Hart G, et al. The effect of combination prevention strategies on HIV incidence among gay and bisexual men who have sex with men in the UK: a model-based analysis. Lancet HIV. 2023;10(11):e713-e22. Available at: https://pubmed.ncbi.nlm.nih.gov/37923485
43. Matacotta JJ, Rosales-Perez FJ, Carrillo CM. HIV Preexposure Prophylaxis and Treatment as Prevention - Beliefs and Access Barriers in Men Who Have Sex With Men (MSM) and Transgender Women: A Systematic Review. J Patient Cent Res Rev. 2020;7(3):265-74. Available at: https://pubmed.ncbi.nlm.nih.gov/32760758
44. Nguyen VK, Greenwald ZR, Trottier H, Cadieux M, Goyette A, Beauchemin M, et al. Incidence of sexually transmitted infections before and after preexposure prophylaxis for HIV. Aids. 2018;32(4):523-30. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5865505
45. Raccagni AR, Ceccarelli D, Trentacapilli B, Galli L, Lolatto R, Canetti D, et al. Viral Hepatitis and Human Papillomavirus Vaccination During HIV Pre-Exposure Prophylaxis: Factors Associated With Missed Vaccination. J Acquir Immune Defic Syndr. 2023;93(5):351-5. Available at: https://pubmed.ncbi.nlm.nih.gov/37220020/
46. Deputy NP, Deckert J, Chard AN, Sandberg N, Moulia DL, Barkley E, et al. Vaccine Effectiveness of JYNNEOS against Mpox Disease in the United States. N Engl J Med. 2023;388(26):2434-43. Available at: https://pubmed.ncbi.nlm.nih.gov/37199451
47. Traeger MW, Cornelisse VJ, Asselin J, Price B, Roth NJ, Willcox J, et al. Association of HIV Preexposure Prophylaxis With Incidence of Sexually Transmitted Infections Among Individuals at High Risk of HIV Infection. JAMA. 2019;321(14):1380-90. Available at: https://pubmed.ncbi.nlm.nih.gov/30964528
48. Care Training Courses and Learning Methods For Your Care Service. Available at: https://www.theaccessgroup.com/en-gb/blog/hsc-care-training-courses-and-learning-methods-what-s-best-for-your-care-service
49. Next-Generation M&E for Next-Generation PrEP. AIDS Vaccine Advocacy Coalition; 2021. Available at: https://www.prepwatch.org/wp-content/uploads/2021/07/MeasuringImpact.pdf
50. European Centre for Disease Prevention and Control (ECDC). Monitoring HIV pre-exposure prophylaxis programmes in the EU/EEA. Stockholm; ECDC: 2022. Available at: https://www.ecdc.europa.eu/en/publications-data/monitoring-hiv-pre-exposure-prophylaxis-programmes-eueea

Annex 1. Contributors to the development of the standards

SoC Advisory Group members

Alma Cicic	Public Health, Montenegro
Caroline Hurley	Public Health, Ireland
Cristiana Oprea	Clinician, Romania
Cristina Mussini	Clinician, Italy
Cianán Russell	Community, Europe
Deniz Gökengin	Clinician, Türkiye
Dominique Van Beckhoven	Public Health, Belgium
Ferenc Bagyinszky	Community, Global
Georg Behrens	Clinician, Germany
Jose Bernardino	Clinician, Spain
Omar Syarif	Community, Global

PrEP Writing Group members

Miłosz Parczewski	Clinician, EACS Expert, Poland – Writing Lead
Alma Cicic	Public Health, Montenegro
Anna Koval	External Expert, Ukraine
Ann Sullivan	Clinician, EACS Expert, UK
BartoszSzetela	External Expert, Poland
Bogusz Aksak-Wąs	Clinician, external consultant, Poland
Caroline Hurley	Public Health, SoC Advisory Board, Ireland
Cianán Russell	Community, SoC Advisory Board, Europe
Deniz Gökengin	Clinician, SoC Advisory Board, Türkiye
Eva Orviz	External Expert, Clinician, Spain
Ferenc Bagyinszky	Community, SoC Advisory Board, Germany
Fiona Burns	Clinician, SoC Advisory Board, UK
Georg Behrens	Clinician, SoC Advisory Board, Germany
Jean-Michel Molina	External expert, EACS Guidelines, France
Jessika Deblonde	External expert, Public Health Belgium
Pep Coll	External Expert, Spain
Sime Zekan	External Expert Croatia
Syarif Omar	Community, Advisory Board, GNP+ Global

Annex 2. Overview of quality statements, indicators, and targets

The indicators[i] that have initially been selected for prioritisation in order to maximise acceptability and feasibility of adoption and reporting against the standards are highlighted in green and bold writing in the table.

Access to PrEP

Quality statements	Indicator	Type of indicator	Key audience	Numerator	Denominator	Targets	Data source
1.1 All people at risk of acquiring HIV should be offered and have equitable access to PrEP	**1.1 Percentage of countries offering PrEP**	**Structural**	**Policy/public health**	**Number of countries with PrEP available within the medical system**	**Number of countries**	**100%**	**National level data sources** **Or Dublin Declaration monitoring**
	1.2 Percentage of countries across Europe providing system funded PrEP	**Structural**	**Policy/public health**	**Number of countries with available system funded (reimbursed) PrEP**	**Number of countries**	**100%**	**National level data sources** **Or Dublin Declaration monitoring**
	1.3 Number of current PrEP users in a country	**Process**	**Healthcare providers**	**The number of people who received PrEP for HIV prevention at least once during the last 12 months***	**Not applicable or per 100 000 population (optional)**	**- ****	**Dublin Declaration monitoring** **or** **National level data sources**
	1.4 Number of new PrEP users in a country	**Process**	**Healthcare providers**	**Number of people who received PrEP for HIV prevention for the first time during the last 12 months***	**Not applicable or per 100 000 population (optional)**	**- ****	**Dublin Declaration monitoring** **or** **National level data sources**
	1.5 Percentage of countries with availability of long-acting injectable PrEP	**Structural**	**Policy/public health**	**Number of countries with long-acting injectables for PrEP available**	**Number of countries**	**- ****	**Dublin Declaration monitoring**

[i] Indicators highlighted in bold have been selected for prioritisation in order to maximise acceptability and feasibility of adoption and reporting against the standards.

Quality statements	Indicator	Type of indicator	Key audience	Numerator	Denominator	Targets	Data source
	1.6 PrEP-to-need ratio (PnR) for a country across key populations	**Process**	**Policy/public health**	**Number of people who used PrEP at least once in the last 12 months, disaggregated by key population if available**	**Estimated number of people in need of PrEP, disaggregated by key population if available**	**- ****	**Dublin Declaration monitoring** **or** **National level data sources**

** Or shorter reporting period (as applicable) in case PrEP implementation was initiated less than 12 months ago.*
*** Targets to be established and defined following implementation of audits.*

PrEP initiation, including safety aspects

Quality statements	Indicator	Type of indicator	Key audience	Numerator	Denominator	Targets	Data source
2.1 PrEP should be initiated with full consideration of clinical safety including reliable exclusion of HIV infection	**2.1 Percentage of countries following international (e.g. EACS) or national PrEP safety guidelines, that include option for alternative PrEP regimens for safety reasons**	**Structural**	**Policy/public health**	**a) Number of countries with national PrEP safety guidelines available for medical practitioners/or following international PrEP guidelines that include system funded (reimbursed) alternative PrEP options for safety reasons**	**Number of countries**	**100%**	**Review of national guidelines** **or** **Questionnaire to national HIV focal points**
	2.2 Percentage of PrEP users older than 50 years and with baseline eGFR <90 with kidney function assessed at least annually	Process	Healthcare providers	Number of people above 50 years of age who received PrEP at least once in the last 12 months and had glomerular filtration rate measured at least annually	Number of people above 50 years of age who received PrEP for HIV prevention at least once in the last 12 months	90%	Audit
	2.3 Percentage of PrEP users with reliable* exclusion of HIV infection prior to initiating PrEP *Baseline negative HIV test for people without recent risk exposure,	**Process**	**Healthcare providers**	**Number of people who received PrEP at least once in the last 12 months who had an HIV test performed prior to initiating PrEP**	**Number of people who received PrEP at least once in the last 12 months**	**95%**	**Audit**

Quality statements	Indicator	Type of indicator	Key audience	Numerator	Denominator	Targets	Data source
	repeated testing for people with recent risk exposure at baseline						
3.1 All PrEP users should be tested for hepatitis B and, if non-immune, effectively immunised	**3.1 Percentage of countries with system funded HBV vaccination available to PrEP users**	**Structural**	**Policy/public health**	**Number of countries with available system funded (reimbursed) HBV vaccination available for PrEP users**	**Number of countries**	**100%**	**Review of national guidelines or Questionnaire to national HIV focal points**
	3.2 Percentage of PrEP users with HBV status verified using: a) HBsAg (active replication), or b) anti-HBc (past/active infection)	Process	Healthcare providers	a) Number of people who received PrEP at least once in the last 12 months with Hepatitis B surface antigen testing performed prior to PrEP initiation b) Number of people who received PrEP at least once in the last 12 months with Hepatitis B core antibody testing performed prior to PrEP initiation	Number of people who received PrEP for HIV prevention at least once in the last 12 months	a) 90% b) 80%	Audit
	3.3 Percentage of PrEP users tested HBsAb negative immunised with HBV vaccination	Outcome	Healthcare providers	Number of people who received PrEP at least once in the last 12 months who tested negative to Hepatitis B surface antigen and were immunised with HBV vaccination	Number of people who received PrEP at least once in the last 12 months who tested negative to Hepatitis B surface antigen	80%	Audit
4.1 Clear pathways for rapid and reliable diagnosis of HIV as well as antiretroviral treatment initiation should be ensured for PrEP users	4.1 Percentage of PrEP services with established pathways for rapid identification of HIV infection among PrEP users	Structural	Healthcare providers	Number of services prescribing PrEP with established pathways for rapid identification of HIV infection among people who received PrEP at least once in the last 12 months, especially for symptomatic cases	Number of services prescribing PrEP	80%	Audit

Quality statements	Indicator	Type of indicator	Key audience	Numerator	Denominator	Targets	Data source
	4.2 Percentage of PrEP users with recently acquired HIV infection*	**Process**	**Healthcare providers**	**Number of people who received PrEP at least once in the 12 months who were diagnosed with HIV, classified as recent HIV infection***	**The number of people newly diagnosed with HIV in the last 12 months**	**-****	**National level data sources** **or** **Audit**
	4.3 Percentage of PrEP users with recently acquired HIV infection initiated on ART	**Process**	**Healthcare providers**	**Number of people who received PrEP at least once in the 12 months testing positive for HIV infection who were initiated on ART**	**Number of people who received PrEP at least once in the last 12 months testing positive for HIV infection**	**95%**	**Audit**
5.1 Priority resistance testing for PrEP users recently infected with HIV should be available	**5.1 Percentage of countries with resistance testing available for PrEP users with recently acquired HIV infection**	**Structural**	**Policy/public health**	**Number of countries with resistance testing available for people recently diagnosed with HIV who received PrEP at least once in the last 12 months**	**Number of countries**	**100%**	**Review of national guidelines** **or** **Questionnaire to national HIV focal points** **Or** **National level data sources**
	5.2 Percentage of PrEP users with recently acquired HIV infection who undergo resistance testing prior to ART initiation	Process	Healthcare providers	Number of people who received PrEP at least once in the last 12 months and tested positive for HIV infection who had a resistance test performed prior to initiating ART	Number of people who received PrEP at least once in the last 12 months who tested positive for HIV infection	80%	Audit

* *Classification of recent infection based on either laboratory evidence of recent infection, last negative HIV test within 12 months of HIV diagnosis, or clinical evidence of acute infection (ref Croxford et al 2022).*
** *Informative for monitoring of PrEP uptake in the context of new infections but no specific target value is expected.*

Continuum of PrEP care

Quality statements	Indicator	Type of indicator	Key audience	Numerator	Denominator	Targets	Data source
6.1 PrEP adherence should be assessed and addressed routinely whenever PrEP is dispensed	6.1 Percentage of people on PrEP with documentation of adherence assessment	Process	Healthcare providers	Number of who received PrEP at least once in the last 12 months with adherence assessment performed at least once	Number of people who received PrEP at least once in the last 12 months	80%	Audit
7.1 For men, continuous daily and on-demand PrEP dosing should be available interchangeably and individualised in line with relevant guidelines	7.1 Percentage of countries with availability of both continuous and on-demand PrEP	Structural	Policy/public health	Number of countries with available for on-demand and continuous PrEP for high-risk sexual exposures	Number of countries	100%	Review of national guidelines or Questionnaire to national HIV focal points
8.1 In the event of high-risk sexual exposure without appropriate PrEP use, system funded HIV post-exposure prophylaxis (PEP) should be immediately available	**8.1 Percentage of countries with availability of system funded PEP for high-risk sexual exposures**	**Structural**	**Policy/public health**	**Number of countries with available system funded (reimbursed) PrEP for high-risk sexual exposures**	**Number of countries**	**100%**	**Review of national guidelines or Questionnaire to national HIV focal points**

PrEP delivery, integrated services and combination prevention

Quality statements	Indicator	Type of indicator	Key audience	Numerator	Denominator	Targets	Data source
9.1 PrEP users should have access to a wide choice of delivery locations and integrated services, including in primary healthcare and community-based settings to improve ease and equity of access	9.1 Percentage of countries with PrEP available in at least one non-medical (community) setting	Structural	Policy/public health; community-level service providers	Number of countries with PrEP available in non-medical settings	Number of countries	-*	Dublin Declaration monitoring
	9.2 Percentage of PrEP prescribed by setting: specialist infectious diseases/sexual health clinic, primary healthcare, and non-medical	Process	Healthcare providers; community-level service providers	Number of PrEP users with PrEP prescribed via specialist infectious diseases/sexual health clinic, primary healthcare, community-	Number of services prescribing PrEP, disaggregated by setting: specialist infectious diseases/ sexual health clinic, primary	-*	National level data sources or Audit

Quality statements	Indicator	Type of indicator	Key audience	Numerator	Denominator	Targets	Data source
	(community-based) facilities			based and other settings, (disaggregated by provider)	healthcare, community-based and other settings)		
10.1 PrEP services may be managed remotely if clinical safety and proper clinical management is ensured	10.1 Percentage of people with remote/on-line consultation who adhere to the testing guidelines and recommended timeline for follow-up visits	Process	Healthcare providers	Number of people who received PrEP at least once in the last 12 months users who were followed-up remotely who and adhered to testing guidelines and recommended timeline for follow-up visits	Number of people who received PrEP at least once in the last 12 months who were managed remotely	80%	Audit
11.1 PrEP should be used as an opportunity to integrate appropriate STI screening, treatment, and follow-up care, including partner notification	11.1 Percentage of countries with system funded NAAT based Chlamydia trachomatis and Neisseria gonorrhoea screening for PrEP users	Structural	Policy/public health/Healthcare providers	Number of countries with available system funded (reimbursed) NAAT based CT/NG screening for PrEP users	Number of countries	90%	Review of national guidelines Consider adding to Dublin Declaration monitoring (i.e. spit per STI)
	11.2 Percentage of countries with system funded syphilis VDRL/RPR screening for PrEP users	Structural	Policy/public health	Number of countries with available system funded (reimbursed) VDRL/RPR screening for PrEP users	Number of countries	90%	Review of national guidelines Consider adding to Dublin Declaration monitoring (i.e split per STI)
12.1 In PrEP users, HIV and STI testing should be performed at regular intervals as predefined by national and international guidelines	**12.1 Percentage of PrEP users being tested for HIV at least every 6 months**	**Process**	**Healthcare providers; Community-level service providers**	**Number of people who received PrEP at least once in the last 12 months who were tested for HIV at least every 6 months**	**Number of people who received PrEP for HIV prevention in the last 12 months**	**80%**	**Audit**
	12.2 Percentage of PrEP users tested for syphilis and STI (gonorrhoea,	Process	Healthcare providers; community-level service providers	Number of people who received PrEP at least once in the last 12 months who were tested for	Number of people who received PrEP at least once in the last 12 months	80%	Audit

Quality statements	Indicator	Type of indicator	Key audience	Numerator	Denominator	Targets	Data source
	chlamydia) at least annually			STI at least annually			
13.1 PrEP should be a part of comprehensive combination prevention, which includes personalised immunisation strategy (HAV, HPV, MPOX), as well as screening, prevention, and treatment of sexually transmitted infections	13.1 Percentage of countries with MPOX vaccination option available for PrEP users	Structural	Policy/public Health	Number of countries with system funded (reimbursed) Mpox vaccination available for PrEP users	Number of countries	90%	Review of national guidelines or Questionnaire to national HIV focal point
	13.2 Percentage of countries with system funded HAV and HPV vaccination available for PrEP users	Structural	Policy/public health	Number of countries with system funded (reimbursed) HAV vaccination available for PrEP users	Number of countries	90%	Review of national guidelines or Questionnaire to national HIV focal point
	13.3 Percentage of PrEP users offered and immunised against HAV, HPV, MPOX	Process	Policy/public health	Number of people who ever received PreP who were offered and vaccinated against HAV, MPOX, HPV	Number of people who ever received PrEP for HIV prevention	80%	Audit

* Informative for monitoring of PrEP uptake across a variety of settings but no specific target value is expected.

Staff training

Quality statements	Indicator	Type of indicator	Key audience	Numerator	Denominator	Targets	Data source
14 Well defined staff competency frameworks should be in place, including relevant training and competence assessment allowing for safe and efficient PrEP delivery both in medical and community settings	14.1 Percentage of countries with inclusion of PrEP-related training in curriculum of key medical specialties: a) infectious diseases, b) genitourinary medicine, c) dermatology /venerology, d) obstetrics/gynaecology, e) urology,	Structural	Policy/public health	Number of countries with PrEP training included in curriculum of key medical specialties offering care-related to infectious diseases and STI, disaggregated by medical speciality (a) infectious diseases, b) genitourinary medicine, c) dermatology	Number of countries	100% for a,b,c 90% for d,e,f	Questionnaire to national HIV (or other) focal point

Quality statements	Indicator	Type of indicator	Key audience	Numerator	Denominator	Targets	Data source
	f) primary healthcare			/venerology, d) obstetrics/gynaecology, e) urology, f) primary healthcare			
	14.2 Percentage of services with PrEP training programmes or competency assessment relevant for PrEP delivery available for healthcare providers	Structural	Policy/public health	Number of services with PrEP training programmes or competency assessment relevant for PrEP delivery available for healthcare providers	Number of services	100%	Questionnaire to national HIV (or other) focal point
	14.3 Percentage of providers who completed a recognised training programme or competence assessment relevant for PrEP delivery	Process	Healthcare providers	Number of PrEP providers with documentation of recognised PrEP training or competency assessment	Number of PrEP providers	80%	Questionnaire to national HIV (or other) focal point

Monitoring and evaluation

Quality statements	Indicator	Type of indicator	Key audience	Numerator	Denominator	Targets	Data source
15.1 Every country should initiate standardised national protocols for monitoring of PrEP implementation.	15.1 Percentage of countries collecting, analysing and reporting data on key European level PrEP indicators in line with national protocols for monitoring of PrEP implementation	Structural	Policy/public health	Number of countries collecting, analysing and reporting data on key European level PrEP indicators in line with national protocols for monitoring of PrEP implementation	Number of countries	90%	Dublin Declaration monitoring National level data sources Questionnaire to national HIV focal point

European Centre forDisease Prevention and Control (ECDC)

Gustav III:s Boulevard 40
16973 Solna, Sweden

Tel. +46 858 60 10 00
ECDC.info@ecdc.europa.eu

www.ecdc.europa.eu

Publications Office
of the European Union