



European standards of HIV prevention and care: Module on HIV testing ECDC OPERATIONAL SUPPORT

**European standards of HIV prevention and care: Module on HIV testing** 





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

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# **Abbreviations**

ART	Antiretroviral therapy
CHIP	Centre of Excellence for Health, Immunity, and Infections
EACS	European AIDS Clinical Society
ECDC	European Centre for Disease Prevention and Control
EU/EEA	European Union/European Economic Area
FWC	Framework contract
GAM	Global AIDS Monitoring Framework (UNAIDS)
GCP	Good clinical practice
GDPR	General Data Protection Regulation
HBV	Hepatitis B virus
HIV	Human immunodeficiency virus
IC	Indicator Condition
MSM	Men who have sex with men
PLHIV	People living with HIV
PN	Partner Notification
PWID	People who inject drugs
QS	Quality statements
SDG	Sustainable Development Goals
SoC	Standards of Care
STI	Sexually transmitted infections
WHO	World Health Organization

# **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]. This is approximately one in six (17%) people living with HIV in Europe and Central Asia being unaware of their status. In the 26 EU/EEA countries with reported data, 91% (706 541; range 77–98%) of the estimated 778 237 people living with HIV had been diagnosed. This is equivalent to nearly one in 10 people living with HIV (9%) in the EU/EEA having an undiagnosed HIV infection.

In 2023, there were 110 486 people newly diagnosed with HIV across Europe and Central Asia [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]. Late HIV diagnosis remains a challenge in all countries in the region. The percentage of people newly diagnosed who were diagnosed late varied across transmission categories and age groups but was highest for people who acquired HIV through heterosexual sex (55.0% all; 60.9% for men and 53.9% for women) and people who inject drugs (47.0%), and lowest for men who have sex with men (41.0%). Late diagnosis increased with age, ranging from 35.8% among people aged 20–24 years at diagnosis, to 66.5% among those aged 50 years or above [2].

### 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); and
- people who have responsibility for policy, guidance development and commissioning or funding of HIV services (Commissioners and public health institutes).

# Methodology

### How were the standards of HIV care developed?

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 drafting of the HIV testing standard has included a review of existing HIV epidemiological data and evidence, and international and national guidelines [4-8].

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

### Quality statements, indicators, and targets

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

#### **Topics**

- 1. General (overall quality statement)
- 2. Testing policies
- 3. Testing strategies
- 4. Consent
- 5. Diagnosis and transfer to care
- 6. Staff training
- 7. 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. General**

### Rationale

HIV testing is key to achieving the global target of 95% of PLHIV knowing their status. Furthermore, it is the essential step by which an individual gains access to the remainder of the care continuum, treatment, and virological control or the prevention pathways, as appropriate. While progress has been made on diagnosing PLHIV, HIV case finding remains challenging across the European region, with few countries having reached the first target [1,2].

Testing coverage remains low in key populations in many European countries with large variation between subregions, countries, and key population groups [1,2]. Furthermore, late diagnosis continues to jeopardise the health of PLHIV and is associated with poorer health outcomes, increased risk of HIV transmission and higher healthcare costs [11].

#### Table 1. Quality statements, indicators, and targets for topic 1 'General (overall quality statement)'

<b>Quality statement</b> 1 Everybody living with HIV should be aware of their status in order to access timely treatment and care.	
Indicator	Target
1.1 Percentage of PLHIV who are aware of their status	95%
1.2 Percentage of people diagnosed late (CD4 cell count <350 cells/uL) or very late (CD4 cell count <200 cells/uL or AIDS diagnosis)	TargetDecrease in total number of people diagnosed late by 2% per annum

# 2. Testing policies

# Rationale

European guidelines describe who, where, and when to test for HIV – with clear recommendations for policy development at national level and implementation in both healthcare and community settings [3-5], with many European national testing guidelines following these European recommendations. However, effective implementation of the guidelines appears to be mostly insufficient as demonstrated by countries reporting little change in the level of late diagnosis over time, with a few exceptions (UK, France) [6,7].

#### Table 2. Quality statements, indicators, and targets for topic 2 'Testing policies'

Quality statement 2.1 Policy makers and local authorities and other commissioners of HIV testing services should design HIV testing programmes that ensure equitable access to HIV testing at all levels of healthcare and to key populations in the community based on local epidemiology.	
IndicatorTarget2.1 Percentage of countries that analyse HIV prevalence data by demographics100%and key populations100%	

#### **Quality statement**

2.2 Community-based testing, including community-led testing, for key populations should be an integral part of national testing programmes and should involve the active participation (including planning, governance and delivery with peer testers and navigators) of the relevant communities.

Indicator	Target
2.2 Percentage of national HIV testing strategies that include community- based testing for at least one key population	100%

Quality statement 2.3 HIV self-testing and self-sampling should be offered as an additional approach to HIV te	estina services.
Indicator 2.3 Percentage of national testing strategies that include self-testing and self- sampling	Target 100%

#### **Quality statement**

2.4 Universal opt-out testing should be implemented in settings where the aim is for all people attending to accept HIV testing.

Indicator	Target
2.4 Percentage of high HIV prevalence healthcare services* with an opt-out	85%
HIV testing policy	

\* Healthcare services covering a population where the HIV prevalence is high (e.g. >1%) and/or services where those attending have a high prevalence e.g. TB clinic).

Quality statement	
2.5 HIV testing algorithms should achieve at least 99% positive predictive value and use a combination of tests with $\geq$ 99% sensitivity and $\geq$ 98% specificity and should follow WHO recommendations.	
Indicator	Target
2.5 Percentage of national testing strategies with HIV testing algorithms that follow WHO recommendations	100%

# 3. Testing strategies

### Rationale

Effective HIV testing strategies should be developed according to national epidemiological data and tailored to local populations, maximising the opportunity for testing in both clinical and non-clinical settings. This necessitates comprehensive, accurate data being reported by key demographics and population groups [3].

Testing outside of healthcare services is a particularly important approach to reach certain groups at higher risk of HIV infection, such as people who inject drugs (PWID), men who have sex with men (MSM), sex workers (SWs) transgender men and women, migrants and displaced persons including incarcerated and homeless people.

Expanding HIV testing outside of healthcare settings improves testing coverage and the identification of undiagnosed infection in populations at risk of HIV. In recent years, self-sampling and self-testing have emerged across the European region as both acceptable and a convenient method for accessing an HIV test and are recommended in European guidelines [3-5].

Engaging the community in all stages of testing programmes from design to delivery is key. Delivery of HIV testing services by lay providers may also help close the testing gap, while increasing uptake and acceptability of HIV testing among key populations and other priority groups and is recommended in European guidelines [3,5].

#### Table 3. Quality statements, indicators, and targets for topic 3 'Testing strategies'

#### **Quality statement**

3.2 All people belonging to key population groups\* should be routinely offered and recommended HIV testing; those at ongoing risk should retest annually, or more frequently depending on risk.

(\* Key populations: MSM, transgender men and women, PWID, migrants and displaced persons, sex workers, incarcerated and homeless people)

Indicator 3.2a Percentage of people belonging to a key population tested for HIV at least once in the past 12 months	Target 80%
Indicator	
3.2b Percentage of people belonging to a key population tested for HIV at least once in the past 12 months, who are attending a specific healthcare setting	
Indicator	-
3.2c Percentage of people from key populations who are aware of their HIV status in the past 12 months (survey based)	

#### **Quality statement**

<b>3.3</b> HIV testing should be offered to all people attending high HIV prevalence (>1%) healthcare settings**. <i>(**</i> Healthcare services covering a population where the HIV prevalence is high (eg. >1%) and/or services where those attending have a high prevalence eg. TB clinic).	
<ul> <li>Indicator</li> <li>3.3 Percentage of people attending a high HIV prevalence healthcare setting who are tested for HIV</li> </ul>	Target 85% or annual performance increase of 5% from baseline/previous year

<b>Quality statement</b> 3.4 HIV testing should be routinely offered and recommended for all people presenting with indicator conditions (IC) or with symptoms where an IC is included in the differential diagnoses.		
<ul> <li>Indicator</li> <li>3.4 Percentage of people presenting with indicator conditions (IC), or with symptoms where an IC is included in the differential diagnoses, who are tested for HIV</li> </ul>	Target 85% or annual performance increase of 5% from baseline/previous year	
<b>Quality statement</b> 3.5 All HIV testing should be delivered as part of an integrated testing programme including h appropriate; TB and STI testing should also be included when indicated.	epatitis B and C testing where	
- P	Townsh	

Indicator	Target
No indicator	

3.6	Quality statement 3.6 All children potentially at risk of having undiagnosed HIV infection should have their status determined in a timely fashion.		
Indi 3.6	cator Percentage of HIV exposed infants who have a documented virological HIV	Target 95%	
	test result within 6 weeks of birth		

<b>Quality statement</b> 3.7 HIV testing promotion should be part of a combination HIV prevention approach.	
licator Ta	Target
indicator	

Quality statement		
3.8 HIV testing promotion messages and communications strategies should be adapted for the different target populations and designed to reach people with HIV who do not know their status and those at ongoing risk.		
Indicator	Target	

<b>Quality statement</b> 3.9 Participation of community members and key populations should be encouraged in all steps of the testing process from demand creation and designing of services to encouragement of service utilisation and engagement.	
Indicator 3.9a Percentage of HIV testing services with a record of community/key population involvement in service development and access pathways	<b>Target</b> 80%
Indicator	Target
If an audit has not been conducted:	80%
3.9b Percentage of countries where key populations participate in developing national policies, guidelines and strategies	

# 4. Consent

### Rationale

Opt-out testing and indicator condition (IC) based testing has proven highly effective within healthcare settings to expand HIV testing and provide more timely diagnosis. These approaches aim at reaching people who are in contact with the healthcare system for other reasons, to offer HIV testing. It has been demonstrated that these approaches increase testing coverage and have the potential to normalise testing and reduce stigmatisation in healthcare settings, in addition to being cost-effective interventions [8].

Importantly, HIV testing should be voluntary in all situations. As a way to increase testing, guidelines recommend that individualised pre-test counselling and written consent for HIV testing should no longer be required, as both are barriers to increasing testing coverage [3,9].

#### Table 4. Quality statements, indicators, and targets for topic 4 'Consent'

Quality statement	
4.1 HIV testing should be voluntary in all situations.	
Indicator	Target
4.1 Proportion of national HIV testing strategies, guidelines or policies that state that HIV testing should be voluntary	100%

Quality statement	
4.2 Individualised pre-test counselling and written consent for HIV testing should no longer be required when undertaking HIV testing.	
Indicator	Target

# **5.** Diagnosis and transfer to care

## Rationale

As testing programmes are expanded, an important consideration is to ensure pathways are in place from all testing sites to care facilities for timely initiation of care and treatment [3,4].

#### Table 5. Quality statements, indicators, and targets for topic 5 'Diagnosis and transfer to care'

Qual	Quality statement		
t	<sup>5.1</sup> All HIV testing services, including those in the community and self-sampling and testing, should establish robust, effective referral pathways with other service providers, including treatment facilities and prevention services <sup>*</sup> , to ensure timely access to treatment and care or prevention as appropriate. This should include the offer of peer support/navigators and relevant health information <sup>**</sup> (* i.e. combination prevention: including condoms, PrEP, PEP, harm reduction services, drug treatment programmes, repeat testing)		
	(** can be via written material provided by the testing service or via referral/directions to where a person can seek additional information [e.g. website, specialised healthcare setting, community-based prevention support service])		
Indic	cator	Target	
5.1	Description of UTV/ to stime and increase with documents documents to		
5.1	Proportion of HIV testing services with documented care pathways to HIV treatment and support services	Specialised HIV testing services (including community) 95%	

#### **Quality statement**

 5.2
 A confirmatory test should be offered within 5 working days of a reactive HIV test, in order to facilitate timely access to treatment, care and support.

 Indicator
 Target

 5.2
 Proportion of people having a confirmatory test within 5 working days of a reactive HIV test

 90%

#### **Quality statement**

5.3 A person newly diagnosed with HIV (i.e. with a positive confirmatory test) should be clinically assessed in line with National Guidelines by an HIV specialist clinician and offered access to peer or psychological support within a maximum timeframe of 2 weeks after the result of the confirmatory test is available.

Indicator	Target	
5.3 Proportion of newly diagnosed patients attending an HIV specialist appointment within 2 weeks of their initial HIV diagnosis (Exclusion: people offered an appointment within 2 weeks who decline)	90%	

#### Quality statement

5.4 There should be robust processes in place to enable follow-up of any non-attendees.	
Indicator	Target
5.4 Proportion of services that have a documented procedure for those people who do not attend their initial appointment in order for them to access treatment and care	95%

#### Quality statement

5.5 Antiretroviral therapy (ART) initiation should occur as soon as possible following a confirmed HIV diagnosis, taking into account patient preference and clinical condition

#### Indicator

5.5 Median time for newly diagnosed individuals to commence ART --

Target

Quality statement	
5.6 National frameworks should enable timely and equitable partner notification (PN) to ensure that all partners are offered testing.	
Indicator	Target
5.6 Proportion of countries with legislation allowing partner notification	100%

Quality statement							
5.7 Partner notification should be voluntary and offer anonymity and provider assisted referral and being mindful of a patient's personal safety. Partner notification should be initiated in a timely manner by the service confirming the HIV diagnosis.							
Indicator	Target						
5.7 Proportion of newly diagnosed patients with a documented discussion of, or referral for partner notification in the clinic record for the appointment providing the confirmatory testing result (including those in whom it was initiated at the reactive result appointment)	95%						

# 6. Staff training

# Rationale

notification

Ensuring that staff delivering testing in both community and healthcare settings are properly trained is important in order to ensure high quality care and patient experience, increased levels of testing and effective implementation of planned testing interventions.

#### Table 6. Quality statements, indicators, and targets for topic 6 'Staff training'

and awareness of local policy/legal framework around testing and partner

<b>Quality statement</b> 6.1 Any trained testing provider (i.e. healthcare professionals and lay/peer testers) should be HIV test results as appropriate for their setting. This includes testing for hepatitis B and C, ST testing is being delivered.			
Indicator	Target		
6.1 Proportion of individuals delivering HIV testing who have documentation that they have received the relevant training	95%		
<b>Quality statement</b> 6.2 All providers should be trained in offering testing services in a non-judgmental and non-st confidentiality of the clients and have awareness of legal and local policy issues around testin			
Indicator	Target		
6.2 Proportion of testing services with documentation of training records/SOPs that include the requirement for non-judgmental, non-stigmatising attitude	100%		

# 7. Monitoring and evaluation

## Rationale

Detailed, ongoing monitoring and evaluation of testing programmes is key to understand what interventions are effective and the circumstance of people's diagnosis. Testing data, including relevant demographic data, should be collected at all services offering testing and reported to national monitoring and surveillance systems [3,5].

#### Table 7. Quality statements, indicators, and targets for topic 7 'Monitoring and evaluation'

Quality statement					
7.1 All data collected should be treated as confidential and the staff collecting and storing data should be properly trained to maintain an individual's confidentiality.					
Indicator	Target				
7.1 Proportion of testing services that have written policies in place to protect the confidentiality of their patients in line with GDPR	100%				

Quality statement	
7.2 All HIV testing services should report testing data through standard national monitoring an	d surveillance systems.
Indicator	Target
7.2 Proportion of HIV testing services reporting testing data through national monitoring and surveillance systems	Clinical/laboratory HIV testing services 95%
	Community HIV testing services 80%

#### **Quality statement**

7.3 HIV testing indicators/metrics should be standardised with core European level testing indicators to allow for cross-country comparison of testing strategies and their impact and should be reported by key demographics and populations.

Indie	cator	Target
7.3	Proportion of countries reporting core European level testing indicators by	100%
	key demographics and populations	

<b>Quality statement</b> 7.4 HIV testing should be monitored across all settings and include time to linkages to care.	
Indicator	Target
No indicator	

#### **Quality statement**

7.5 Data for measuring progress toward the first of the UNAIDS 30-60-80 targets<sup>\*</sup> should be collected, analysed and reported.

(\* 30% of testing and treatment services to be delivered by community-led organisations; 60% of the programmes to support the achievement of societal enablers to be delivered by community-led organisations; 80% of service delivery for HIV prevention programmes for key populations and women to be delivered by community, key population and women-led organisations)

#### Indicator

7.5 Percentage of countries collecting, analysing and reporting data on progress 100% towards the first of the UNAIDS 30-60-80 targets\*

\* 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 levels 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 <u>2004 Dublin Declaration monitoring</u>. On the

Target

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.

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# Annex 1. Contributors to the development of the standards

### **SoC Advisory Group members**

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# **Annex 2. Overview of quality statements and indicators**

The indicators<sup>1</sup> that have initially been selected for prioritisation to maximise acceptability and feasibility of adoption and reporting against the standards are highlighted in green and bold.

### General

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Data source
	1.1 Percentage of PLHIV who are aware of their status	Outcome indicator	Policy/public health	Number of PLHIV who know their status	Estimated number of PLHIV	95%	National level data sources or Dublin Declaration monitoring
1.1 Everybody living with HIV should be aware of their status in order to access timely treatment and care	1.2 Percentage of people diagnosed late (CD4 cell count<350 cells/uL) or very late (CD4 cell count<200 cells/uL or AIDS diagnosis)	Outcome indicator	Policy/public health	Number of people newly diagnosed with HIV in calendar year with CD4<350 or <200 or AIDS. Exclude seroconverters (11) (people with laboratory evidence of recent infection; last negative HIV test within 12 months of HIV diagnosis; or clinical evidence of acute infection) and previous positives (available data permitting)	Number of people newly diagnosed with HIV in calendar year	Decrease in total number of people diagnosed late by 2% per annum	National level data sources or Annual ECDC/WHO HIV Surveillance in Europe reports

# **Testing policies**

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
2.1 Policy makers and local authorities and other commissioners of HIV testing services should design HIV testing programmes that ensure equitable access to HIV testing at all levels of healthcare and to key populations in the community based on local epidemiology	2.1 Percentage of countries that analyse HIV prevalence data by demographics and key populations	Structural indicator	Policy/public health	Number of countries that analyse data by demographics and key populations	Number of countries	100%	Questionnaire to national HIV focal points or Consider adding to Dublin Declaration monitoring
2.2 Community-based testing, including community-led testing, for key populations should be an integral part of national testing programmes and should involve the active participation (including planning, governance and delivery with peer testers and navigators) of the relevant communities	2.2 Percentage of national HIV testing strategies that include community-based testing for at least one key population	Structural indicator	Policy/public health	Number of countries that include recommendations for community- based testing in their national testing strategies, guidelines or policies	Number of countries	100%	Dublin Declaration monitoring or Review of national strategies, guidelines or policies
2.3 HIV self-testing and self-sampling should be offered as additional approach to HIV testing services	2.3 Percentage of national testing strategies that include self-testing and self-sampling	Structural indicator	Policy/public health	<ul> <li>a) Number of countries that include self-testing in their national testing strategies, guidelines or policies</li> <li>b) Number of countries that include self- sampling in their national testing strategies, guidelines or policies</li> </ul>	Number of countries	100%	Dublin Declaration monitoring or Review of national strategies, guidelines or policies

2.4 Universal opt-out testing should be implemented in settings where the aim is for all people attending to accept HIV testing	2.4 Percentage of high HIV prevalence healthcare services <sup>2</sup> with an opt- out HIV testing policy	Structural indicator	Healthcare providers	Number of services in high prevalence areas with an opt- out HIV testing policy	Number of services in high prevalence areas	85%	Audit
2.5 HIV testing algorithms should achieve at least 99% positive predictive value and use a combination of tests with ≥99% sensitivity and ≥98% specificity and should follow WHO recommendations.	2.5 Percentage of national testing strategies with HIV testing algorithms that follow WHO recommendations	Structural indicator	Policy/public health	Number of countries adhering to WHO recommendations on testing algorithms	Number of countries	100%	Review of national strategies, guidelines or policies or Questionnaire to national HIV focal points Or Consider adding to Dublin Declaration monitoring

### **Testing strategies**

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
3.1 HIV testing should be delivered in an enabling environment that removes barriers such as stigma, discrimination, and criminalisation	3.1 No indicator (part of the overarching principle of the standards – see section above in document)		healthcare providers; community-level testing providers	-	-	-	-

<sup>2</sup> Healthcare services covering a population where the HIV prevalence is high (eg. >1%) and/or services where those attending have a high prevalence eg. TB clinic).

3.2 All people belonging to key population groups* should be routinely offered and recommended HIV testing; those at ongoing risk should retest annually, or more frequently depending on risk (* Key populations: MSM, transgender men and women, PWID, migrants and displaced persons, sex workers, incarcerated and homeless people)	<ul> <li>3.2a Percentage of people belonging to a key population tested for HIV at least once in the past 12 months.</li> <li>Where the key population denominator data is not available nationally:</li> <li>3.2b Percentage of people belonging to a key population tested for HIV at least once in the past 12 months, who are attending a specific healthcare setting</li> </ul>	Process indicator	healthcare providers; community-level testing providers	Number of people in key populations tested for HIV in last 12 months Number of people in key populations tested for HIV in specific healthcare setting in last 12 months (STI service, prison reception, substance misuse treatment centre, healthcare service for sex workers or migrant centre, other)	Number of people in key populations (national estimate)	80% Alternative target: 10% increase per annum OR, 75th centile of performance of a number of comparable services (service type, geographical location) where at least some services are achieving the 80% target. Target can be modified by multi- stakeholder agreement [(12), Appendix 2]	National level data sources
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Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
	Where data are available from a special survey: 3.2c Percentage of people from key populations who are aware of their HIV status in the past 12 months (survey based)			Number of survey respondents belonging to a key population who report having been tested in the last 12 months	Number of survey respondents belonging to a key population		Dublin Declaration monitoring
<ul> <li>3.3</li> <li>HIV testing should be offered to all people attending high HIV prevalence (&gt;1%) healthcare settings**</li> <li>(** Healthcare services covering a population where the HIV prevalence is high (eg. &gt;1%) and/or services where those attending have a high prevalence eg. TB clinic).</li> </ul>	3.3 Percentage of people attending a high HIV prevalence healthcare setting who are tested for HIV	Process indicator	healthcare providers	Number of attendees in high prevalence settings who are tested for HIV	Number of attendees in high prevalence settings within given timeframe	85% or annual performance increase of 5% from baseline/prev ious year	Audit
3.4 HIV testing should be routinely offered and recommended for all people presenting with indicator conditions (IC) or with symptoms where an IC is included in the differential diagnoses	3.4 Percentage of people presenting with indicator conditions (IC), or with symptoms where an IC is included in the differential diagnoses, who are tested for HIV	Process indicator	healthcare providers	Number of people presenting with an indicator condition who are tested for HIV within a given timeframe	Number of people presenting with an indicator condition within given timeframe	85% or annual improvement 5% from baseline/prev ious year	Audit
3.5 All HIV testing should be delivered as part of an integrated testing programme including hepatitis B and C testing where appropriate; TB and STI testing should also be included when indicated	3.5 No indicator	-	Policy/public health healthcare providers	-	-	-	

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
3.6 All children potentially at risk of having undiagnosed HIV infection should have their status determined in a timely fashion	3.6 Percentage of HIV exposed infants who have a documented virological HIV test result within 6 weeks of birth	Process indicator	healthcare providers	Number of live births to women living with HIV who have record of virological HIV test within 6 weeks of birth	Number of live births to women living with HIV	95%	Audit
3.7 HIV testing promotion should be part of a combination HIV prevention approach	3.7 No indicator	-	Policy/public health	-	-	-	-
3.8 HIV testing promotion messages and communications strategies should be adapted for the different target populations and designed to reach people with HIV who do not know their status and those at ongoing risk	3.8 Percentage of national HIV testing promotion strategies that are targeted to key populations	Structural indicator	Policy/public health	Number of promotion strategies targeted at key populations	Number of HIV testing promotion strategies	95%	Audit
3.9 Participation of community members and key populations should be encouraged in all steps of the testing process from demand creation and designing of services to encouragement of service utilisation and engagement	<ul> <li>3.9a</li> <li>Percentage of HIV testing services with a record of community/key population involvement in service development and access pathways</li> <li>If an audit has not been conducted:</li> <li>3.9b</li> <li>Percentage of countries where key populations participate in developing national policies, guidelines and strategies</li> </ul>	Process indicator	Policy/public health healthcare providers	Number of HIV testing services with record of relevant community involvement Number of countries where key populations participate in developing national policies, guidelines and strategies	Number of HIV testing services Number of countries	80%	Audit Dublin Declaration monitoring

### Consent

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
4.1 HIV testing should be voluntary in all situations	4.1 Proportion of national HIV testing strategies, guidelines or policies that state that HIV testing should be voluntary	Structural indicator	Policy/public health	Number of countries documenting that HIV testing should be voluntary in their national HIV testing strategies, guidelines or policies	Number of countries	100%	Review of national strategies, guidelines or policies or Questionnaire to national HIV focal points or Consider adding to Dublin Declaration monitoring
4.2 Individualised pre-test counselling and written consent for HIV testing should no longer be required when undertaking HIV testing	4.2 Proportion of national HIV testing strategies, guidelines or policies that do not recommend pre-test counselling or written consent	Structural indicator	Policy/public health	Number of countries that do not recommend i) pre-test counselling or ii) written consent in their national HIV testing guidelines or strategies	Number of countries	i) 100% ii)100%	Review of national strategies, guidelines or policies or Questionnaire to national HIV focal points or Consider adding to Dublin Declaration monitoring

# Diagnosis and transfer to care

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
<ul> <li>5.1</li> <li>All HIV testing services, including those in the community and self-sampling and testing, should establish robust, effective referral pathways with other service providers, including treatment facilities and prevention services*, to ensure timely access to treatment and care or prevention as appropriate. This should include the offer of peer support/navigators and relevant health information**</li> <li>(* i.e. combination prevention: including condoms, PrEP, PEP, harm reduction services, drug treatment programmes, repeat testing)</li> <li>(** can be via written material provided by the testing service or via referral/directions to where a person can seek additional information (e.g. website, specialised healthcare setting, community-based prevention support service))</li> </ul>	5.1 Proportion of HIV testing services with documented care pathways to HIV treatment and support services	Structural indicator	Healthcare providers	Number of HIV testing services with documented care pathway to treatment and support services	Number of services offering HIV testing – specialist and general	Specialised HIV testing services (including community) 95% general healthcare services undertaking HIV testing (including primary care) 80%	Audit
5.2 A confirmatory test should be offered within 5 working days of a reactive HIV test, in order to facilitate timely access to treatment, care and support	5.2 Proportion of people having a confirmatory test within 5 working days of a reactive HIV test	Process indicator	healthcare providers	Number of people with initial reactive test having a confirmatory HIV test within 5 working days	Number of people with initial reactive test	90%	Audit
5.3 A person newly diagnosed with HIV (i.e. with a positive confirmatory test) should be clinically assessed in line with National Guidelines by an HIV specialist clinician and offered access to peer or psychological support within a	5.3 Proportion of newly diagnosed patients attending an HIV specialist appointment within 2 weeks of their initial HIV diagnosis (Exclusion: people offered an	Process indicator	healthcare providers	Number of people newly diagnosed who attend HIV specialist appointment within 2 weeks, or have a CD4	Number of people newly diagnosed with HIV	90%	Audit

maximum timeframe of 2 weeks after the result of the confirmatory test is available	appointment within 2 weeks who decline)			count or VL within 2 weeks, of their date of diagnosis			
5.4 There should be robust processes in place to enable follow-up of any non-attendees	5.4 Proportion of services that have a documented procedure for those people who do not attend their initial appointment in order for them to access treatment and care	Structural indicator	healthcare providers	Number of treatment and care services with documented procedure for those people who do not attend their initial appointment	Number of treatment and care services	95%	Audit
5.5 Antiretroviral therapy (ART) initiation should occur as soon as possible following a confirmed HIV diagnosis, taking into account patient preference and clinical condition	5.5 Median time for newly diagnosed individuals to commence ART	Process indicator	healthcare providers	Time from date of diagnosis to ART initiation (for those without exclusions)	Number of people initiating treatment		Audit
5.6 National frameworks should enable timely and equitable partner notification (PN) to ensure that all partners are offered testing	5.6 Proportion of countries with legislation allowing partner notification	Structural indicator	Policy/public health	Number of countries that allow partner notification OR: where partner notification is included in national testing strategies, guidelines or policies	Number of countries	100%	Review of national strategies, guidelines or policies Dublin Declaration monitoring
5.7 Partner notification should be voluntary and offer anonymity and provider assisted referral and being mindful of a patient's personal safety. Partner notification should be initiated in a timely manner by the service confirming the HIV diagnosis	5.7 Proportion of newly diagnosed patients with a documented discussion of, or referral for partner notification in the clinic record for the appointment providing the confirmatory testing result (including those in whom it was initiated at the reactive result appointment)	Process Indicator	healthcare providers	Number of people newly diagnosed with documented discussion of or referral to partner notification	Number of people newly diagnosed	95%	Audit

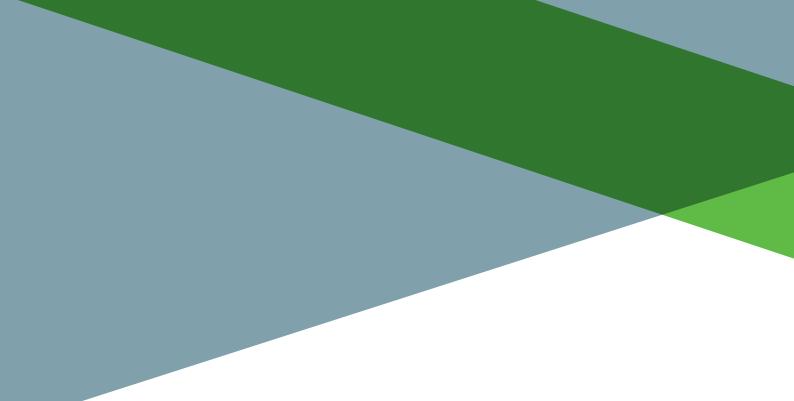
# Staff training

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
6.1 Any trained testing provider (i.e. healthcare professionals and lay/peer testers) should be able to offer, carry out, and give HIV test results as appropriate for their setting. This includes testing for hepatitis B and C, STIs and TB where integrated testing is being delivered	6.1 Proportion of individuals delivering HIV testing who have documentation that they have received the relevant training	Process indicator	health providers	Number of individuals delivering HIV testing who have documented relevant training	Number of individuals delivering HIV testing	95%	Audit
6.2 All providers should be trained in offering testing services in a non- judgmental and non-stigmatising manner, ensuring the confidentiality of the clients and have awareness of legal and local policy issues around testing and partner notification	6.2 Proportion of testing services with documentation of training records/SOPs that include the requirement for non- judgmental, non- stigmatising attitude and awareness of local policy/legal framework around testing and partner notification	Structural indicator	healthcare providers	Number of HIV testing services with documentation of training records/SOPs	Number of HIV testing services	100%	Audit

# Monitoring and evaluation

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
7.1 All data collected should be treated as confidential and the staff collecting and storing data should be properly trained to maintain an individual's confidentiality	7.1 Proportion of testing services that have written policies in place to protect the confidentiality of their patients in line with GDPR	Structural indicator	healthcare providers Community-level testing providers	Number of testing services with a written confidentiality policy	Number of testing services	100%	Audit
7.2 All HIV testing services should report testing data through standard national monitoring and surveillance systems	7.2 Proportion of HIV testing services reporting testing data through national monitoring and surveillance systems	Process indicator	Healthcare providers; policy/public health	Number of HIV testing services reporting testing data through national monitoring and surveillance systems	Number of HIV testing services	Clinical/laboratory HIV testing services 95% Community HIV testing services 80%	Questionnaire to national HIV focal points or Audit
7.3 HIV testing indicators/metrics should be standardised with core European level testing indicators to allow for cross- country comparison of testing strategies and their impact and should be reported by key demographics and populations	7.3 Proportion of countries reporting core European level testing indicators by key demographics and populations	Process indicator	Policy/public health	Number of countries reporting data on core testing indicators by key population and demographics at European level	Number of countries	100%	National level data sources or Dublin Declaration
7.4 HIV testing should be monitored across all settings and include time to linkages to care	7.4 No indicator	-	Policy/public health healthcare providers	-	-	-	-

7.5 Data for measuring progress toward the first of the UNAIDS 30-60-80 targets* should be collected, analysed and reported (*30% of testing and treatment services to be delivered by community-led organisations; 60% of the programmes to support the achievement of societal enablers to be delivered by community-led organisations; 80% of service delivery for HIV prevention programmes for key populations and women to be delivered by community, key population and women-led organisations)	7.5 Percentage of countries collecting, analysing and reporting data on progress towards the first of the UNAIDS 30-60-80 <sup>3</sup> targets*	Process indicator	Policy/public health	Number of countries appropriately collecting, analysing and reporting data on the proportion of community-led testing services, in line with the first of the UNAIDS 30- 60-80 targets*	Number of countries	100%	National level data sources or Dublin Declaration monitoring or Questionnaire to national HIV focal points
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