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European standards of HIV prevention and care: Module on Commencement of antiretroviral therapy (ART)

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Abbreviations

ART	Antiretroviral therapy
CHIP	Centre of Excellence for Health, Immunity, and Infections
EACS	European AIDS Clinical Society
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
HIV	Human immunodeficiency virus
HTS	HIV testing services
IC	Indicator Condition
MSM	Men who have sex with men
PLWH	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

Early initiation of antiretroviral therapy (ART) is a cornerstone of HIV care, conferring individual health benefits and reducing onward transmission. The World Health Organization (WHO) and European guidelines have, since 2015, recommended treating all adults living with HIV immediately upon diagnosis, regardless of CD4 count (a 'test-and-treat' approach) [1]. WHO further strongly endorses same-day ART initiation for those ready to start treatment [2]. This reflects the global shift toward rapid linkage from diagnosis to care, aiming to improve outcomes and move countries toward the 95-95-95 targets for 2030 [3].

An estimated 2 334 662 people are living with HIV in Europe and Central Asia, of whom 1 944 695 (83%; range: 65–100%) have been diagnosed [4]. Late diagnosis is a persistent challenge – over half of new HIV cases in the Region are diagnosed at an advanced stage. Nevertheless, treatment coverage among those aware of their infection has steadily improved. In 2018, 64% of people with a diagnosed HIV infection were receiving ART [5]. By 2023, this proportion was roughly 84% region-wide [4], indicating progress but still short of the 95% target. There is significant sub-regional variation: in western Europe nearly 95% of diagnosed individuals are on ART, whereas in Eastern European countries this figure is closer to 78% [4]. Such disparities highlight ongoing gaps in timely treatment access across the Region.

Additionally, health system and structural factors in parts of the Region impede rapid ART uptake. These include gaps in linkage-to-care infrastructure, stigma and discrimination in healthcare settings, and punitive legal environments that deter key populations from accessing services [6]. Geopolitical factors (conflict and migration) and recent public health crises (e.g. the COVID-19 pandemic) have also disrupted HIV service continuity in some countries, further delaying ART initiation. Addressing these challenges – by expanding prompt linkage protocols, training providers, and removing structural barriers – is essential for the Region to reach its ART coverage and HIV elimination targets.

By ensuring timely commencement of ART, countries can improve survival, prevent AIDS-related complications, and reduce HIV infectiousness – ultimately bending the curve of the epidemic in the WHO European Region [4].

What are standards of care for HIV?

The standards of care (SoC) for Commencement of ART 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, HIV and co-morbidities, and commencement of ART (https://www.ecdc.europa.eu/en/infectious-disease-topics/hiv-infection-and-aids/prevention-and-treatment/ecdceacs-standards-hiv).

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).

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 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.

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 [7-11].

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 Commencement of ART 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. Policy and access to ART;
2. Pre-ART assessment and testing;
3. Initiating ART;
4. Integrated care for key populations;
5. Community and support services;
6. Continuum of care;
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 sources can be found in Annex 2.

1. Policy and access to ART

Rationale

Given the benefits of early initiation of ART for those diagnosed with HIV, international guidelines (WHO, EACS) recommend that ART is offered to all people living with HIV regardless of CD4 count [8, 12]. In addition, there is robust clinical trial and cohort data demonstrating the effectiveness of ART in preventing onward HIV transmission [13, 14].

Table 1. Quality statements, indicators, and targets for topic 1 'Policy and access to ART'

Quality statement 1.1 All people diagnosed with HIV should be offered ART regardless of CD4 count, country of residence or other variables	
Indicator **1.1 Percentage of national policy/guidelines that stipulate that all people diagnosed with HIV are offered ART regardless of CD4 count, country of residence, or legal status**	**Target** **100%**

Quality statement 1.2 All people living with HIV should initiate ART as soon as possible after diagnosis, and ideally within 7 days of an HIV diagnosis unless specifically contraindicated (as per WHO guideline [15])	
Indicator **1.2.1 Percentage of countries recommending initiating ART within seven days of an HIV diagnosis**	**Target** **100%**
Indicator **1.2.2 Percentage of people living with HIV who initiate ART within seven days of an HIV diagnosis**	**Target** **95%**
Indicator **1.2.3 Percentage of people living with HIV who fail to initiate ART within seven days of presentation with documentation of specific contraindication**	**Target** **95%**

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

2. Pre-ART Assessment and testing

Rationale

Several tests and procedures must be performed in all cases before or at the start of ART to ensure that the efficacy and safety of ART can be properly monitored. In addition, some tests are used to evaluate the indication for concomitant measures, such as prophylaxis of opportunistic infections. Pre-ART counselling and education for ART readiness are essential to avoid ART interruptions and loss of follow-up of people initiating ART.

Table 2. Quality statements, indicators, and targets for topic 2 'Pre-ART assessment and testing'

Quality statement 2.1 All people living with HIV should have a documented baseline assessment including clinical history, clinical examination, and laboratory tests to enable safe and timely ART initiation.	
Indicator	**Target**
2.1 Percentage of people living with HIV who receive a documented baseline assessment in line with EACS guidelines [12] before or at the initiation of ART **This will involve**	
2.1.1 baseline CD4 count	**2.1.1** 97%
2.1.2 baseline HIV viral load	**2.1.2** 97%
2.1.3 full psychosocial history including lifestyle habits (smoking, alcohol, recreational drug use) and psychological morbidities	**2.1.3** 97%

Quality statement 2.2 All people living with HIV should be offered genotypic resistance testing prior to initiation of ART. However, genotype test result should not delay ART initiation.	
Indicator	**Target**
2.2 Percentage of people living with HIV who have baseline resistance testing	90%

Quality statement 2.3 People living with HIV about to initiate ART should be provided with sufficient information and support to successfully initiate ART and readiness to initiate ART should be documented.	
Indicator	**Target**
2.3.1 Percentage of people living with HIV initiating ART who have documented readiness to start therapy	2.3.1 95%
2.3.2 Percentage of people living with HIV who were provided with sufficient information and support to successfully initiate ART	2.3.2 95%

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

3. Initiating ART

Rationale

Once proven that a person with HIV is ready to start and committed to continue ART, therapy should be started as soon as possible in all cases, unless an indication for delayed ART initiation exists. If available, the first line regimen should be based on a second generation integrase strand transfer inhibitor or Doravirine [15]. Specific population groups such as pregnant women, people with active hepatitis B infection, and the paediatric population, among others, may require specific adaptations of the ART regimen.

Table 3. Quality statements, indicators, and targets for topic 3 'Initiating ART'

Quality statement 3.1 People living with HIV should be offered, where no contra-indication, first line regimen.	
Indicator **3.1 Percentage of people living with HIV initiating ART who are offered the EACS guideline first line regimen, where no contraindications exist**	**Target** **95%**

Quality statement 3.2 Where there is a contraindication or there is patient-preference for a different regimen, people living with HIV should be offered the best suitable regimen for them.	
Indicator 3.2 Percentage of people living with HIV initiating non-EACS guideline first-line regimen whose regimen choice is justified by valid clinical indication and/or patient choice.	**Target** 95%

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

4. Integrated care for key populations

Rationale

Key populations – such as men who have sex with men, people who inject drugs, sex workers, and transgender people – bear a significantly higher burden of HIV and often face substantial social, structural, and legal barriers to healthcare access [16]. Comprehensive, integrated care that encompasses HIV treatment, harm reduction, mental health services, and prophylaxis is crucial for improving retention in care, adherence to therapy, and viral suppression [16]. Tailored interventions addressing the unique challenges faced by key populations are associated with improved health outcomes and reduced HIV transmission rates [16].

Table 4. Quality statements, indicators, and targets for topic 4 'Integrated care for key populations'

Quality statement 4.1 All services providing HIV care should have processes in place to support key populations' (men who have sex with men, people who inject drugs, migrants, sex workers, people in prison) access to services	
Indicator	**Target**
4.1.1 Percentage of HIV care services that have processes, including policies or designated personnel in place to address issues in key populations' access to services	**100%**
Indicator	**Target**
4.1.2 Percentage of people from key populations initiating ART within seven days of an HIV diagnosis (unless of specific contraindication)	95%

Quality statement 4.2 Difficulties in taking ART should be identified, monitored, and should be addressed allowing patients to receive effective ART	
Indicator	**Target**
4.2.1 Percentage of institutionalised people living with HIV (e.g. in prisons, nursing homes) receiving ART who have access to care equivalent to that provided to people living with HIV outside of such settings	95%
Indicator	**Target**
4.2.2 Percentage of people living with HIV unable to take oral ART who are offered alternative treatment options (e.g. injectable ART)	95%

Quality statement 4.3 Women of reproductive age contemplating pregnancy should have a specific discussion about ART regimen and pregnancy plans/fertility	
Indicator	**Target**
4.3.1 Percentage of women of reproductive age diagnosed with HIV who have documented discussions about ART regimen and pregnancy plans/fertility	**90%**

Quality statement 4.4 Pregnant women about to initiate ART should have the same access to ART and outcome as the non-pregnant general population	
Indicator	**Target**
4.4.1 Percentage of pregnant women about to initiate ART who have the same access to ART as non-pregnant women	95%
Indicator	**Target**
4.4.2 Percentage of pregnant women about to initiate ART who achieve comparable outcomes as non-pregnant women	95%

Quality statement 4.5 For pregnant women on ART, discussion around risks and benefits of breastfeeding taking into account cultural, social and personal circumstances should be documented	
Indicator	**Target**
4.5 Percentage of pregnant women diagnosed with HIV who have a documented discussion about breastfeeding to make an informed decision	95%

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

5. Community and support services

Rationale

Community-based and support services, including peer-led interventions, psychosocial counselling, and strong linkages with local organisations, are critical for addressing the holistic needs of people living with HIV [16]. These services help mitigate stigma, support mental health, and improve treatment adherence. Evidence indicates that integrating community engagement and support into the continuum of HIV care enhances patient retention and promotes equitable health outcomes [16].

Table 5. Quality statements, indicators, and targets for topic 5 'Community and support services'

Quality statement 5.1 Individuals initiating (or on) ART should have access to community-based support services (such as peer support services, substance-use organisations, social and psychological support organisations)	
Indicator	**Target**
5.1 Percentage of HIV care services that have documented involvement of community members in services	**95%**

Quality statement 5.2 For people living with HIV specific needs in terms of mental health, substance abuse treatment, requirement of social services should be assessed, and help should be offered to those who need it	
Indicator	**Target**
5.2.1 Percentage of people living with HIV who have a documented assessment of mental health	**90%**
Indicator	**Target**
5.2.2 Percentage of people living with HIV who have a documented assessment of substance abuse treatment needs	90%
Indicator	**Target**
5.2.3 Percentage of people living with HIV who have a documented assessment of social service requirements	90%

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

6. Continuum of care

Rationale

The aim of HIV treatment is to achieve viral suppression, which allows people living with HIV to stay healthy and live longer. Individuals who are diagnosed promptly can expect a near-normal life expectancy if started promptly on treatment and retained in care [16]. Immediate ART, regardless of CD4+ count, has been shown to be beneficial for an individual's health [16]. Prompt ART initiation is also important as treatment as prevention: having an undetectable viral load while on ART means that there is no risk of ongoing transmission [16]. While the clinical goal of viral suppression is an HIV RNA <50 c/mL [12], HIV RNA <200 c/mL is not associated with a risk of sexual transmission [12, 14, 15, 17-20] (corresponding to the undetectable=untransmissible statement).

The HIV care continuum consists of several steps required to achieve viral suppression: being diagnosed with HIV, being linked into care (e.g. having visited an HIV healthcare provider within two weeks after learning they were HIV-positive), being retained in care (e.g. receiving medical care for HIV infection), achieving viral suppression. In 2013 UNAIDS launched goals to tackle the HIV epidemic: to have 90% of people living with HIV diagnosed, of which 90% on ART, and of which 90% with virological control. These goals have not been equally reached in all countries, and ongoing efforts need to be made towards achieving them. In 2020, the aspirations of testing, linkage to care/treatment and treatment success were raised to 95-95-95.

Some ARTs have in general a high potential for drug-drug interactions. ART is lifelong and drug-drug interactions are often unavoidable in people with co-morbid conditions: the potential for drug-drug interactions should therefore be considered systematically when selecting an ART regimen or when any new medicine is co-administered to existing ART, with particular attention to adjusting dosage and performing clinical monitoring when needed.

Table 6. Quality statements, indicators, and targets for topic 6 'Continuum of care'

Quality statement 6.1 All people living with HIV should receive clinical follow-up in line with EACS guidelines until established on treatment with an undetectable viral load	
Indicator 6.1.1 Percentage of people living with HIV receiving follow-up clinical assessments in line with the EACS guidelines	**Target** 95%
Indicator **6.1.2 Percentage of people living with HIV with an undetectable HIV RNA on ART six months after initiating ART**	**Target** **95%**

Quality statement 6.2 All people living with HIV should have HIV viral load testing to ensure undetectability six months after initiating ART	
Indicator **6.2 Percentage of people living with HIV having a viral load test at a minimum of six months after initiating ART**	**Target** **95%**

Quality statement 6.3 People living with HIV who fail to achieve viral suppression at six months should have a genotypic resistance test, an adherence check and potential drug-interactions assessed	
Indicator 6.3.1 Percentage of people living with HIV who fail to achieve viral suppression six months after initiating ART with a documented genotypic resistance test result	**Target** 95%
Indicator 6.3.2 Percentage of people living with HIV who fail to achieve viral suppression six months after initiating ART who have documented discussion of adherence to therapy	**Target** 95%

Quality statement 6.4 All people initiating on ART should have potential drug interactions recorded and communicated to other caregivers	
Indicator **6.4.1 Percentage of people living with HIV initiating ART who have documentation of potential drug interactions and all co-medications (including over-the-counter medications) recorded in their medical records**	**Target** **95%**
Indicator **6.4.2 Percentage of people living with HIV initiating ART whose potential drug interactions have been communicated to their primary care team or other relevant healthcare providers**	**Target** **100%**

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

7. Monitoring and evaluation

Rationale

Surveillance and reporting of ART initiation should be evaluable, so that tracking trends, guiding healthcare planning and prevention efforts may be aligned towards meeting sustainable development goals [21].

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

Quality statement 7.1 Every country should have standardised national protocols for monitoring ART provision	
Indicator 7.1 Proportion of countries collecting, analysing, and reporting data on key European level ART initiation indicators[1] in line with national protocols for monitoring HIV treatment provision	**Target** 95%

Quality statement 7.2 ART initiation indicators/metrics should be standardised within core European level HIV treatment indicators[1] (and should be reported by key demographics and populations)	
Indicator 7.2 Proportion of countries reporting core European level HIV treatment indicators (by key demographics and populations)	**Target** 100%

Quality statement 7.3 HIV care services should report ART initiation data through standard national monitoring and surveillance systems	
Indicator 7.3 Proportion of HIV care services that report ART initiation data through standard national monitoring and surveillance systems	**Target** 95%

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

[1] Core European level ART initiation indicators include time from diagnosis to linkage to care, time to ART initiation, use of guidelines recommended therapy.

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Annex 2. Overview of quality statements and indicators

The indicators 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.

1. Policy and access to ART

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Data source
1.1 All people diagnosed with HIV should be offered ART regardless of CD4 count, country of residence or other variables	**1.1 Percentage of national policy/guidelines that stipulate that all people diagnosed with HIV are offered ART regardless of CD4 count, country of residence, or legal status**	**Structural indicator**	**Policy/public health**	**Number of countries with national policies/guidelines that offer ART to all people diagnosed with HIV regardless of CD4 count, country of residence, or legal/entrance status**	**Number of countries**	**100%**	**Dublin Declaration monitoring**
1.2 All people living with HIV should initiate ART as soon as possible after diagnosis, and ideally within seven days of an HIV diagnosis unless specifically contraindicated (as per WHO guideline [15])	**1.2.1 Percentage of countries recommending initiating ART within seven days of HIV diagnosis**	**Structural indicator**	**Policy/public health**	**Number of countries recommending initiating ART within seven days of HIV diagnosis**	**Number of countries**	**100%**	**Dublin Declaration monitoring**
	1.2.2 Percentage of people living with HIV who initiate ART within seven days of an HIV diagnosis	**Process indicator**	**Clinicians/Healthcare providers**	**Number of people living with HIV who initiate ART within seven days of an HIV diagnosis**	**Total number of people living with HIV who present to HIV care services in whom immediate ART is not contraindicated**	**95%**	**Audit**
	1.2.3 Percentage of people living with HIV who fail to initiate ART within seven days of presentation with documentation of specific contraindication	**Process indicator**	**Clinicians/Healthcare providers**	**Number of people living with HIV who do not start ART within seven days of presentation with documentation of specific contraindications**	**Number of people living with HIV who do not start ART within seven days of an HIV diagnosis**	**95%**	**Audit**

2. Pre-ART assessment and testing

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
2.1 All people living with HIV should have a documented baseline assessment including clinical history, clinical examination, and laboratory tests to enable safe and timely ART initiation	**2.1** **Percentage of people living with HIV who receive a documented baseline assessment in line with EACS guidelines before or at the initiation of ART** **This will involve:** **2.1.1** **baseline CD4 count** **2.1.2** **baseline HIV viral load** **2.1.3** **Full psychosocial history including lifestyle habits (smoking, alcohol, recreational drug use) and psychological morbidities**	**Process indicator**	**Healthcare providers**	**Number of people living with HIV initiating ART who have a documented baseline assessment (as per EACS guidelines)** **2.1.1** **CD4 count** **2.1.2** **HIV viral load** **2.1.3** **Psychosocial history**	**Number of people living with HIV who initiated ART during the measurement period**	**2.1.1** **97%** **2.1.2** **97%** **2.1.3** **97%**	**Audit**
2.2 All people living with HIV should be offered genotypic resistance testing prior to initiation of ART. However, genotype test result should not delay ART initiation	2.2 Percentage of people living with HIV who have baseline resistance testing	Process indicator	Healthcare providers	Number of people living with HIV initiating ART with a documented baseline resistance test	Number of people living with HIV who initiated ART during the measurement period	90%	Audit
2.3 People living with HIV about to initiate ART should be provided with sufficient information and support to successfully initiate ART and readiness to start ART should be documented	2.3a Percentage of people living with HIV initiating ART who have documented readiness to initiate therapy	Process indicator	Healthcare providers	Number of people living with HIV initiating ART with documented readiness to initiate to successfully initiate ART	Number of people living with HIV initiating ART during the measurement period	2.3a 95%	Audit
	2.3b. Percentage of people living with HIV who were provided with sufficient information and support to successfully initiate ART	Process indicator	Healthcare providers	Number of people living with HIV initiating ART with sufficient information and support to successfully initiate ART	Number of people living with HIV initiating ART during the measurement period	2.3b 95%	Audit

3. Initiating ART

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
3.1 People living with HIV should be offered, where no contra-indication, first line regimen	**3.1** **Percentage of people living with HIV initiating ART who are offered EACS guideline first line regimen, where no contraindications exist**	**Process indicator**	**Healthcare providers**	**Number of people living with HIV initiating ART who are offered the EACS guideline first line regimen, where no contraindications exist**	**Number of people living with HIV initiating ART during the measurement period**	**95%**	**Audit**
3.2 Where there is a contraindication or there is patient-preference for a different regimen, people living with HIV should be offered the best suitable regimen for them	3.2 Percentage of people living with HIV initiating non-EACS guideline first-line regimen whose regimen choice is justified by valid clinical indication and/or patient choice	Process indicator	Healthcare providers	Number of people living with HIV initiating non-EACS guideline first-line regimen whose regimen choice is justified by valid clinical indication and/or patient choice	Number of people living with HIV initiating non-national first-line regimen	95%	Audit

4. Integrated care for key populations

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
4.1 All services providing HIV care should have processes in place to support key populations' (men who have sex with men, people who inject drugs, migrants, sex workers, people in prison) access to services	**4.1.1 Percentage of HIV care services that have processes, including policies or designated personnel in place to address issues in key populations' access to services**	**Structural indicator**	**Policy/public health**	**Number of HIV care services with policies to address access issues for key populations**	**Number of HIV care services**	**100%**	**Audit**
	4.1.2 Percentage of people from key populations initiating ART within seven days of an HIV diagnosis (unless of specific contraindication)	Process indicator	Healthcare providers	Number of people from key populations who start ART within seven days of an HIV diagnosis (unless of specific contraindication)	Number of people from key populations eligible to start ART	95%	Audit
4.2 Difficulties in taking ART should be identified, monitored, and should be addressed allowing patients to receive effective ART	4.2.1 Percentage of institutionalised people living with HIV (e.g. in prisons, nursing homes) receiving ART who have access to care equivalent to that provided to people living with HIV outside such settings	Structural indicator	Healthcare providers	Number of institutionalised people living with HIV receiving ART with documented access to care equivalent to that provided to people outside such settings	Number of institutionalised people living with HIV	95%	Audit / Dublin declaration (only denominator for people in prisons and institutional
	4.2.2 Percentage of people living with HIV unable to take oral ART who are offered alternative treatment options (e.g. injectable ART, but not only limited to LAI)	Process indicator	Healthcare providers	Number of people living with HIV unable to take oral ART who were offered alternative treatment options	Number of people living with HIV identified as unable to take oral ART	95%	Audit
4.3 Women of reproductive age contemplating pregnancy should have a specific discussion about ART regimen and pregnancy plans/fertility	**4.3.1 Percentage of women of reproductive age diagnosed with HIV who have documented discussions about ART regimen and pregnancy plans/fertility**	**Process indicator**	**Healthcare providers**	**Number of women of reproductive age contemplating pregnancy diagnosed with HIV who have documented discussions about ART regimen and pregnancy plans/fertility**	**Number of women of reproductive age diagnosed with HIV during the measurement period**	**90%**	**Audit**
4.4 Pregnant women about to initiate ART should have the same access to ART and outcome as the non-pregnant general population	4.4.1 Percentage of pregnant women about to initiate ART who have the same access to ART as non-pregnant women	Process indicator	Healthcare providers	Number of pregnant women initiating ART	Number of pregnant women about to initiate ART during the measurement period	95%	Audit
	4.4.2 Percentage of pregnant women about to initiate ART who achieve comparable outcomes as non-pregnant women	Process indicator	Healthcare providers	Number of pregnant women initiating ART who achieve a viral load below the limit of detection by six months or pre-delivery whichever comes first	Number of pregnant women about to initiate ART during the measurement period	95%	Audit
4.5 For pregnant women on ART, discussion around risks and benefits of breastfeeding taking into account cultural, social and personal circumstances should be documented	4.5 Percentage of pregnant women diagnosed with HIV who have a documented discussion about breastfeeding to make an informed decision	Process indicator	Healthcare providers	Number of pregnant women diagnosed with HIV who have documented discussions about breastfeeding	Number of pregnant women diagnosed with HIV during the measurement period	95%	Audit

5. Community and support services

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
5.1 Individuals initiating (or on) ART should have access to community-based support services (such as peer support services, substance-use organisations, social and psychological support organisations)	**5.1** **Percentage of HIV care services that have documented involvement of community members in services**	**Structural indicator**	**Policy/public health**	**Number of HIV care services with documented involvement of community members and key populations in service development and access pathways**	**Number of HIV care services**	**95%**	**Audit**
5.2 For people living with HIV specific needs in terms of mental health, substance abuse treatment, requirement of social services should be assessed, and help should be offered to those who need it	**5.2.1** **Percentage of people living with HIV who have a documented assessment of mental health**	**Process indicator**	**Healthcare providers / Healthcare providers at community level**	**Number of people living with HIV who have a documented assessment of mental health needs**	**Number of people living with HIV in care**	**90%**	**Audit**
	5.2.2 Percentage of people living with HIV who have a documented assessment of substance abuse treatment needs	Process indicator	Healthcare providers / Healthcare providers at community level	Number of people living with HIV who have a documented assessment of substance abuse treatment needs	Number of people living with HIV in care	90%	
	5.2.3 Percentage of people living with HIV who have a documented assessment of social service requirements	Process indicator	Healthcare providers / Healthcare providers at community level	Number of people living with HIV who have a documented assessment of social service requirements	Number of people living with HIV in care	90%	

6. Continuum of care

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
6.1 All people living with HIV should receive clinical follow-up in line with EACS guidelines until established on treatment with an undetectable viral load	6.1.1 Percentage of people living with HIV receiving follow-up clinical assessments in line with the EACS guidelines	Process indicator	Healthcare providers	Number of people living with HIV who received follow-up visits according to EACS guidelines until achieving an undetectable viral load	Number of people living with HIV initiating ART during the measurement period	95%	Audit
	6.1.2 Percentage of people living with HIV with an undetectable HIV RNA on ART six months after initiating ART	**Structural indicator**	**Healthcare providers**	**Number of people living with HIV on ART who have suppressed viral load at six months after initiating ART**	**Number of people living with HIV newly initiating ART during the measurement period**	**95%**	**Audit**
6.2 All people living with HIV should have HIV viral load testing to ensure undetectability six months after initiating ART	**6.2 Percentage of people living with HIV having a viral load test at a minimum of six months after initiating ART**	**Process indicator**	**Healthcare providers**	**Number of people living with HIV initiating ART who have undergone at least one viral load test at minimum of six months after initiating ART**	**Number of people living with HIV newly initiating ART during the measurement period**	**95%**	**Audit**
6.3 People living with HIV who fail to achieve viral suppression at six months should have a genotypic resistance test, an adherence check and potential drug-interactions assessed	6.3.1 Percentage of people living with HIV who fail to achieve viral suppression six months after initiating ART with a documented genotypic resistance test result	Process indicator	Healthcare providers	Number of people living with HIV on ART six months after initiation who have not achieved viral suppression who have documentation of a genotypic resistance test being performed	Number of people living with HIV on ART six months after initiation who have not achieved viral suppression	95%	Audit
	6.3.2 Percentage of people living with HIV who fail to achieve viral suppression six months after initiating ART who have documented discussion of adherence to therapy	Process indicator	Healthcare providers	Number of people living with HIV on ART six months after initiation who have not achieved viral suppression who have clear documentation of an adherence-focused clinical discussion	Number of people living with HIV on ART six months after initiation who have not achieved viral suppression	95%	Audit
6.4 All people initiating on ART should have potential drug interactions recorded and communicated to other caregivers	**6.4.1 Percentage of people living with HIV initiating ART who have documentation of potential drug interactions and all co-medications (including over-the-counter medications) recorded in their medical records**	**Process indicator**	**Healthcare providers**	**Number of people living with HIV initiating ART with documented potential drug interactions and all co-medications recorded**	**Total number of people living with HIV initiating ART during the measurement period**	**95%**	**Audit**
	6.4.2 Percentage of people living with HIV initiating ART whose potential drug interactions have been communicated to their primary care team or other relevant healthcare providers	**Process indicator**	**Healthcare providers**	**Number of people living with HIV initiating ART with documented communication of potential drug interactions to other healthcare providers**	**Total number of people living with HIV initiating ART during the measurement period**	**100%**	**Audit**

7. Monitoring and evaluation

Quality statements	Indicator	Type of Indicator	Key audience	Numerator	Denominator	Targets	Source
7.1 Every country should have standardised national protocols for monitoring ART provision	7.1 Proportion of countries collecting, analysing, and reporting data on key European level ART initiation indicators in line with national protocols for monitoring HIV treatment provision	Process indicator	Healthcare providers	Number of countries collecting, analysing, and reporting data on key European level ART initiation indicators in line with national protocols for monitoring HIV treatment provision	Number of countries	95%	National level data sources or Dublin Declaration / TESSy
7.2 ART initiation indicators/metrics should be standardised with core European level HIV treatment indicators (and should be reported by key demographics and populations	7.2 Proportion of countries reporting core European level HIV treatment indicators (by key demographics and populations)	Process indicator	Policy/public health	Number of countries reporting ART initiation data (by key demographics and populations) at the European level	Number of countries	100%	National level data sources or Dublin Declaration / TESSY
7.3 HIV care services should report ART initiation data through standard national monitoring and surveillance systems	7.3 Proportion of HIV care services that report ART initiation data through standard national monitoring and surveillance systems	Process indicator	Healthcare providers	Number of HIV care services that report ART initiation data through standard national monitoring and surveillance systems	Number of HIV care services	95%	Audit

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