ASSESSMENT

Final report from the audit of the HIV pre-exposure prophylaxis standards of care

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

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Abbreviations

ART	Antiretroviral treatment
CHIP	Centre of Excellence for Health, Immunity and Infections
EACS	European AIDS Clinical Society
HBsAb	Hepatitis B Surface Antibody
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
PrEP	Pre-exposure prophylaxis
REDCap	Research Electronic Data Capture
STI	Sexually transmitted infection
TDx/FTC	Tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC)
WHO	World Health Organization

Executive summary

ECDC, in collaboration with EACS (the European AIDS Clinical Society), is developing modules of HIV care standards to improve service access and quality. The pre-exposure prophylaxis (PrEP) Standards of Care module was among the first developed. Each module includes quality statements with indicators and targets, categorised as structural or process indicators. Many of the structural indicators are monitored annually via the Dublin Declaration monitoring framework, while the process indicators require clinical audits to assess service performance. The current report presents findings from a clinical audit conducted on the PrEP Standards of Care module, which also serves as a model for future audits on other care standards.

The PrEP audit involved developing a questionnaire based on selected key quality statements in the Standards of Care module, focusing on Standards for PrEP safety, Standards for continuum of PrEP care, and Standards for PrEP delivery, integrated services, and combination prevention. Created by the Centre of Excellence for Health, Immunity and Infections (CHIP) and hosted in Research Electronic Data Capture (REDCap), the audit had two parts: Part One assessed clinic policies and guidelines, while Part Two evaluated their implementation through a review of up to 40 randomly selected people. In December 2024, 10 clinics from eight countries participated.

The clinics completed Part One of the audit, reporting a total of 8 311 PrEP users in 2023, mostly male. Most clinics followed national or EACS guidelines, with eligibility primarily for gay men, transgender people, and anyone who might benefit from PrEP. PrEP was fully funded in seven clinics, while HIV and STI testing was covered in all 10 and eight clinics respectively. The clinics completed Part Two for a total of 366 people, 99.5% of whom were male. PrEP use varied by clinic, with daily and on-demand regimens based on risk.

Six out of 10 clinics met the target of reliably excluding HIV infection before initiation. Users over 50 are required to have their glomerular filtration rate measured annually, with most clinics meeting this target. The HBV status target of 80% was met by all clinics except one. Additionally, most clinics have clear pathways for rapid HIV diagnosis and timely ART initiation. The standards require 80% of PrEP users to have annual adherence assessments. All but two clinics met this, with at least 80% of users receiving two assessments within 14 months. The audit assessed HIV and STI testing in PrEP programs, with a target of 80% testing rate. All clinics had policies for regular HIV and STI testing. Most clinics met the target for HIV and syphilis testing. Testing for gonorrhoea and chlamydia was lower, with five out of 10 clinics meeting the 80% target. The lower rates may be due to PCR tests being done at different clinics or only being performed on symptomatic individuals. Further investigation is needed to understand these issues.

The audit demonstrated that most participating clinics are meeting the process indicators and targets set by the ECDC/EACS standards for PrEP safety, continuum of care, and for PrEP delivery, integrated services, and combination prevention. Policies for HIV testing, HBV status determination, adherence assessments, and regular HIV and syphilis testing are largely followed. However, improvements are needed in HIV testing timing and gonorrhoea and chlamydia testing rates. The audit also highlighted areas for improvement of the audit, such as including questions on PrEP interruptions, specifying HBV testing types, and adjusting timeframes for 12-month assessments. Participating clinics found the audit useful for identifying areas of improvement, and future audits could be automated to streamline the process and ensure continued monitoring.

1 Background

An estimated 2.6 million people are living with HIV in Europe and Central Asia [1]. In 2023, 112 883 new HIV diagnoses were reported in 47 of the 53 countries in the World Health Organization (WHO) European Region [1]. Pre-exposure prophylaxis (PrEP) with antiretroviral medications is a highly effective tool in preventing new HIV infections [2–5]. Roll-out of oral tenofovir disoproxil/emtricitabine (TDx/FTC) as PrEP effectively reduces incidence among key populations at substantial risk of HIV acquisition through sexual exposure [6–8]. The implementation of HIV PrEP has improved substantially since 2016, but there is still a great deal of variation in the implementation and access across countries. A wider scale-up in the implementation of PrEP is necessary to accelerate progress towards the UN Sustainable Development Goal 3.3 of ending the HIV/AIDS epidemic by 2030.

With the overall goal to improve HIV service access and standards of care, ECDC, in collaboration with EACS, is developing a set of modules of standards of HIV care [9]. These standards are based on existing EACS and WHO guidelines and provide a reference point against which to benchmark the quality of care and services in the context of the changing needs of people and healthcare financing challenges [7,10]. The PrEP Standards of Care module was one of the first modules to be developed [11].

Previous ECDC guidance indicates that people at risk and living with HIV need equitable access to high quality HIV prevention, treatment, and care services irrespective of who they are and where they live in Europe [12]. It is important to understand the specific barriers that prevent the implementation of PrEP programmes in individual countries to facilitate improvements in availability. For this purpose, each module contains a set of quality statements with corresponding indicators and specific targets. The indicators listed in the standards are either: 1) structural or 2) process indicators. Many of the structural indicators are collected annually through Dublin Declaration HIV monitoring coordinated by ECDC [13]. Some of the structural indicators included are: 1) the percentage of countries offering PrEP; 2) the percentage of countries across Europe providing system-funded PrEP; and 3) the percentage of countries with PrEP available in at least one non-medical (community) setting.

On the other hand, to evaluate performance against the process indicators, particularly 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 HIV monitoring. This report presents the results of a clinical-level audit conducted in a few selected clinics in Europe in relation to the PrEP Standards of Care module. The findings are not intended to be generalisable to all clinics in Europe, but rather to serve as a pilot for future audits related to PrEP and other Standards of Care modules. Active feedback on the audit tool will be collected from participants. The report aims to demonstrate the added value of audits for public health institutions, clinics, and the community of people living with HIV, and to encourage countries and clinics to carry out similar audits independently.

Process indicators in the PrEP Standards of Care module

A clinical level audit can collect data on some of the process indicators listed in the PrEP Standards of Care module. The findings could be used to identify areas of underperformance to produce specific clinic recommendations and drive quality improvement. On a broader scale, the audit can assess the quality-of-care people receive in Europe, guide service commissioning, and support the development of public health, clinical, and community guidelines. The audit collects anonymised clinical data to measure service provision against a unified set of standards and compares the extent to which different countries and clinics meet these standards. Specifically, the focus for this audit is three areas outlined in the PrEP Standards of Care module, and targeted specific quality statements and process indicators (Table 1).

Table 1. Audit focus areas from the PrEP Standards of Care module

Standards for PrEP safety	
Quality statement	**Indicator**
PrEP should be initiated with full consideration of clinical safety, including reliable exclusion of HIV infection.	Percentage of PrEP users with reliable exclusion of HIV infection prior to initiating PrEP (target: 95%).
	Percentage of PrEP users older than 50 years and with baseline eGFR <90 with kidney function assessed at least annually (target: 90%).
All PrEP users should be tested for hepatitis B and, if non-immune, effectively immunised.	Percentage of PrEP users with HBV status verified using a) HBsAg (active replication) (target: 90%) or b) anti-HBc (past/active infection) (target: 80%).
	Percentage of PrEP users tested HBsAb negative immunised with HBV vaccination (target: 80%).
Clear pathways for rapid and reliable diagnosis of HIV and timely antiretroviral treatment initiation should be ensured for PrEP users.	Percentage of PrEP services with established pathways for rapid identification of HIV infection among PrEP users (target: 80%).
	Percentage of PrEP users with recently acquired HIV infection (no target).
	Percentage of PrEP users with recently acquired HIV infection initiated on ART (target: 95%).
Priority resistance testing for PrEP users recently infected with HIV should be available.	Percentage of PrEP users with recently acquired HIV infection who undergo resistance testing prior to ART initiation (80%).
Standards for continuum of PrEP care	
Quality statement	**Indicator**
PrEP adherence and other influencing factors should be assessed and addressed routinely whenever PrEP is dispensed.	Percentage of people on PrEP with documentation of adherence assessment (80%).
Standards for PrEP delivery, integrated services, and combination prevention	
Quality statement	**Indicator**
In PrEP users, HIV and STI testing should be performed at regular intervals in line with national and international guidelines.	Percentage of PrEP users being tested for HIV at least every six months (target: 80%).
	Percentage of PrEP users tested for syphilis and STI (gonorrhoea, chlamydia) at least annually (target: 80%).

anti-HBc: hepatitis B core antibody; ART: antiretroviral therapy; HBsAg: hepatitis B surface antigen; HBV: hepatitis B virus.

2 Methods

The PrEP audit (Annex 1) consisted of developing a questionnaire based on and worded according to a subset of areas and relative quality statements and indicators in the Standards of Care module: 1) Standards for PrEP safety; 2) Standards for continuum of PrEP care; and 3) Standards for PrEP delivery, integrated services, and combination prevention (Table 1).

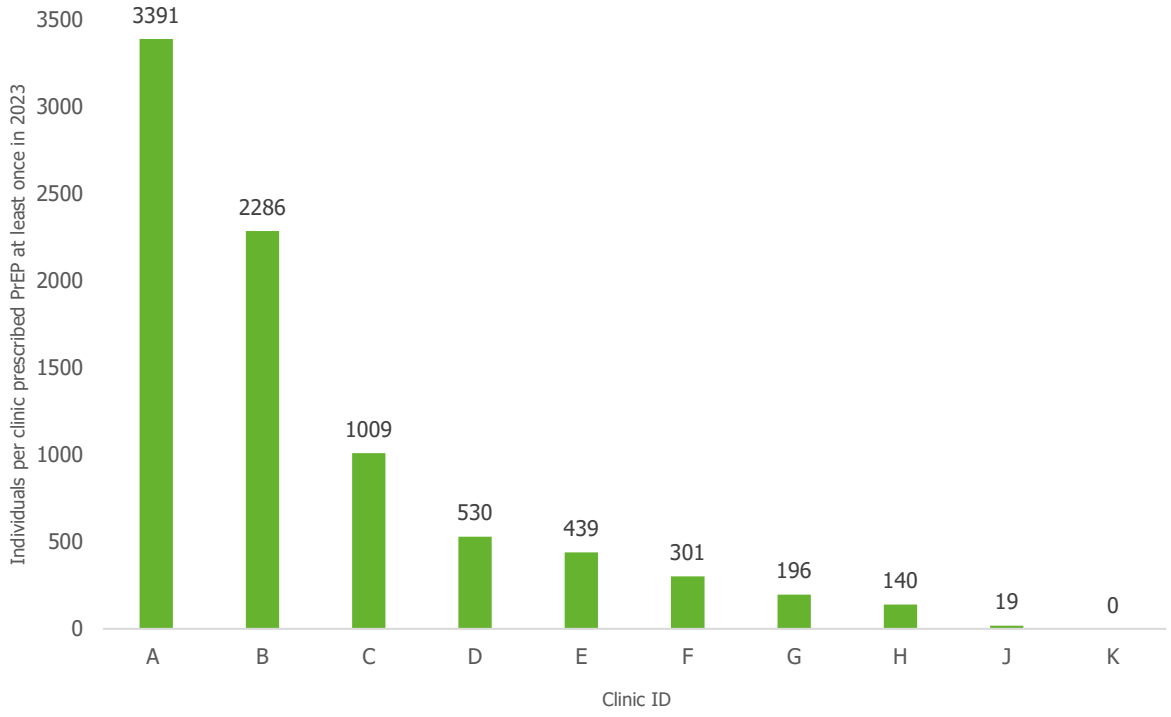
The audit was developed by the team at the Centre of Excellence for Health, Immunity and Infections (CHIP) and entered into REDCap, a secure, web-based application designed for data collection and management [14,15]. Before implementing the audit across all clinics, the tool was piloted in one clinic and subsequently revised. The audit was structured in two parts. Part One provided background information on the clinic's aggregated data on PrEP, as well as the clinic's/country policies and guidelines. This section was completed once for each HIV or infectious disease clinic participating in the audit. For Part Two, a subset of up to 40 people per clinic were selected randomly, meeting the following criteria: (1) they were over 18 years old, and (2) they had been prescribed PrEP at least once before 18 December 2022, to allow for two years of follow-up. Their medical records were reviewed for the completion of Part Two. While Part One aimed to review the policies and guidelines followed by the clinics, Part Two was designed to assess whether these policies and guidelines were being implemented in practice.

In December 2024, 10 clinics from seven countries (Croatia, Estonia, France, Georgia, Italy, Spain, and Poland) were invited to complete the audit. Of these, one clinic did not fully participate in both parts of the audit and therefore was excluded from this analysis. In addition to these nine clinics, an additional clinic (Clinic K) from Greece, a country where PrEP is not yet prescribed but can be purchased online, also participated in the audit. The selection of clinics was based on factors such as interest, availability, and geographical representation. Each clinic was anonymised, and the participant data were collected retrospectively and extracted from medical files. Throughout this report, the results of the audit will be presented using an anonymous clinic ID (from A to K) and ordering the clinics in the figures by clinic size (i.e. number of people with a PrEP prescription at the clinic).

3 Clinic characteristics and characteristics of people on PrEP

The 10 clinics participating in the audit had a varied range of people on PrEP, with the number of those prescribed PrEP at least once in 2023 ranging from zero to 3 391, for a total of 8 311 people across the clinics (Figure 1)[1]. In 2023, most people were male (8 213; range: 0–3 349), with only a small number of females (50; range: 0–20), trans women (44; range: 0–32), trans men (2; range: 0–1), and non-binary individuals (2; range: 0–2). Twenty-three of those prescribed PrEP in 2023 seroconverted in 2023.

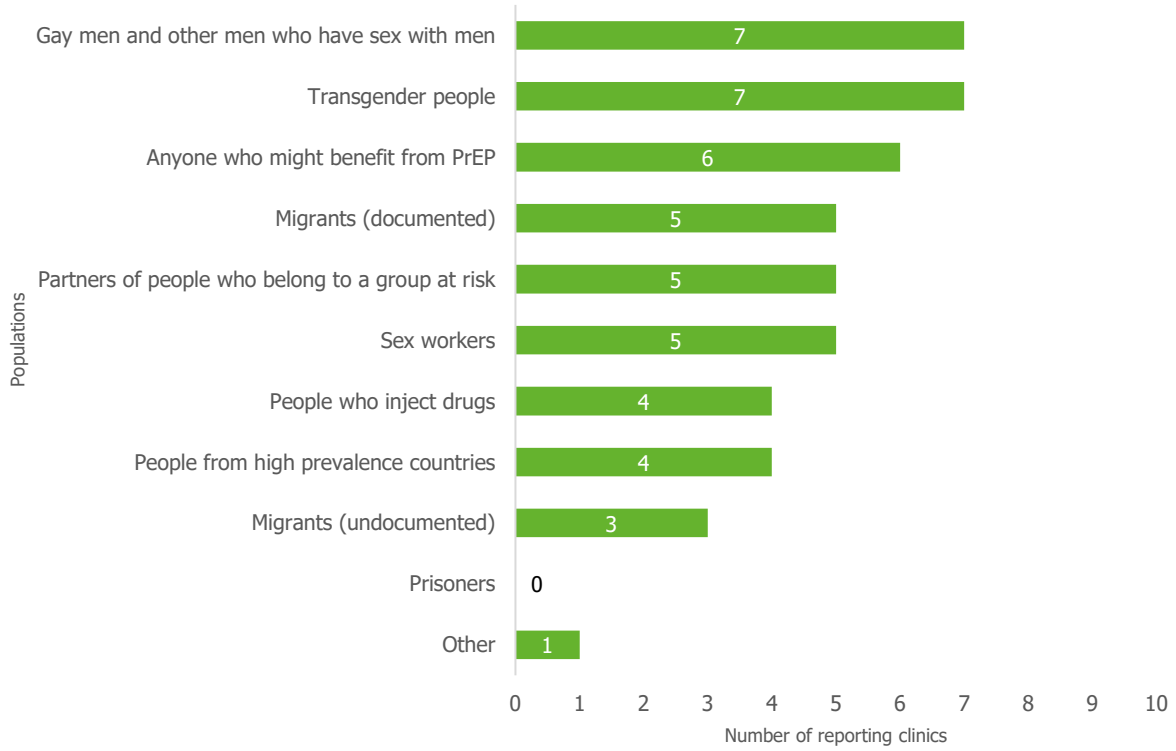
Figure 1. Individuals per clinic prescribed PrEP at least once in 2023 (n=10)



Seven clinics reported following national PrEP guidelines and recommendations and/or EACS PrEP guidelines. The populations most eligible to access PrEP were gay men and other men who have sex with men (seven clinics)[2] and transgender people (seven clinics), followed by all individuals who could benefit from PrEP (six clinics), and documented migrants (five clinics) (Figure 2). Undocumented migrants, people from high prevalence countries, and people who inject drugs were eligible to access PrEP in only a few clinics.

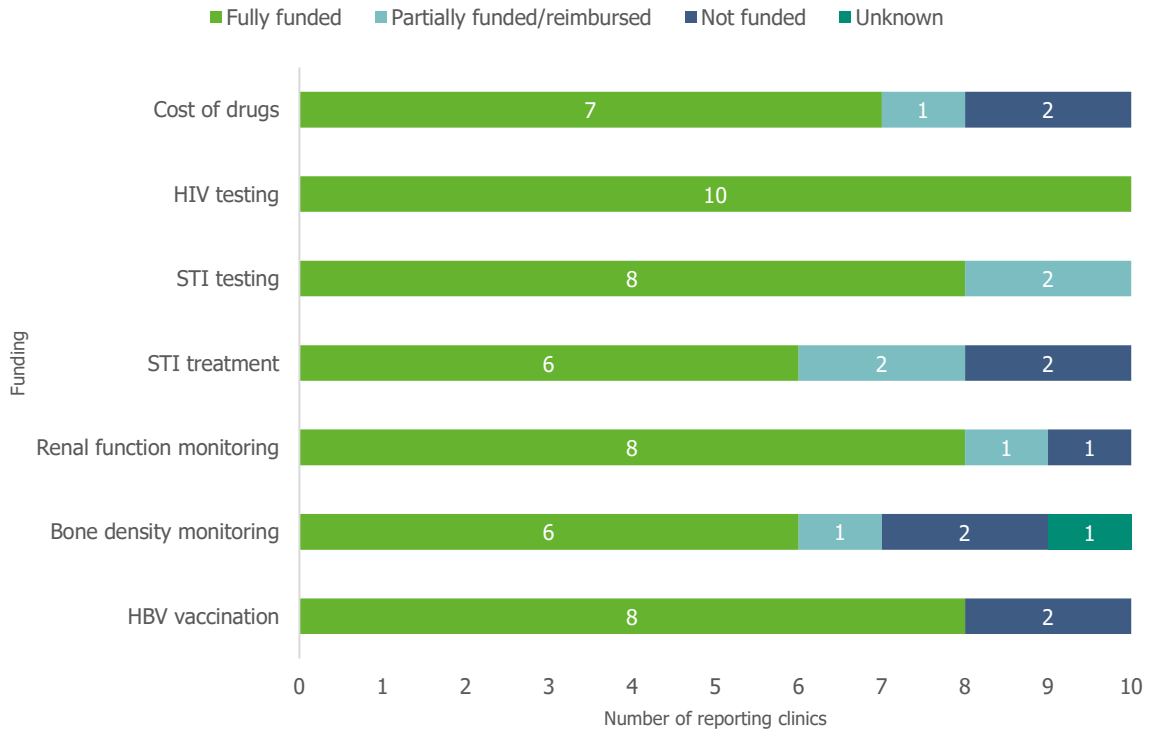
[1] Clinic K is the clinic from the country where PrEP can only be purchased online.
[2] The three clinics that did not select 'Gay men and other men who have sex with men' were Clinic K (where no one is eligible for PrEP), and Clinics G and H (which answered that 'anyone who might benefit from PrEP' is eligible for PrEP).

Figure 2. Key populations eligible to access PrEP, per clinic (n=10)



The cost of PrEP was fully funded/reimbursed by seven clinics, while HIV and STI testing was fully funded by 10 and eight clinics, respectively (Figure 3). Vaccination against HBV was reported as being fully funded by eight clinics. These factors are likely to affect access to PrEP services, as financial barriers may limit access for certain populations. Furthermore, three clinics reported having a waiting list for PrEP, ranging from two to 12 months.

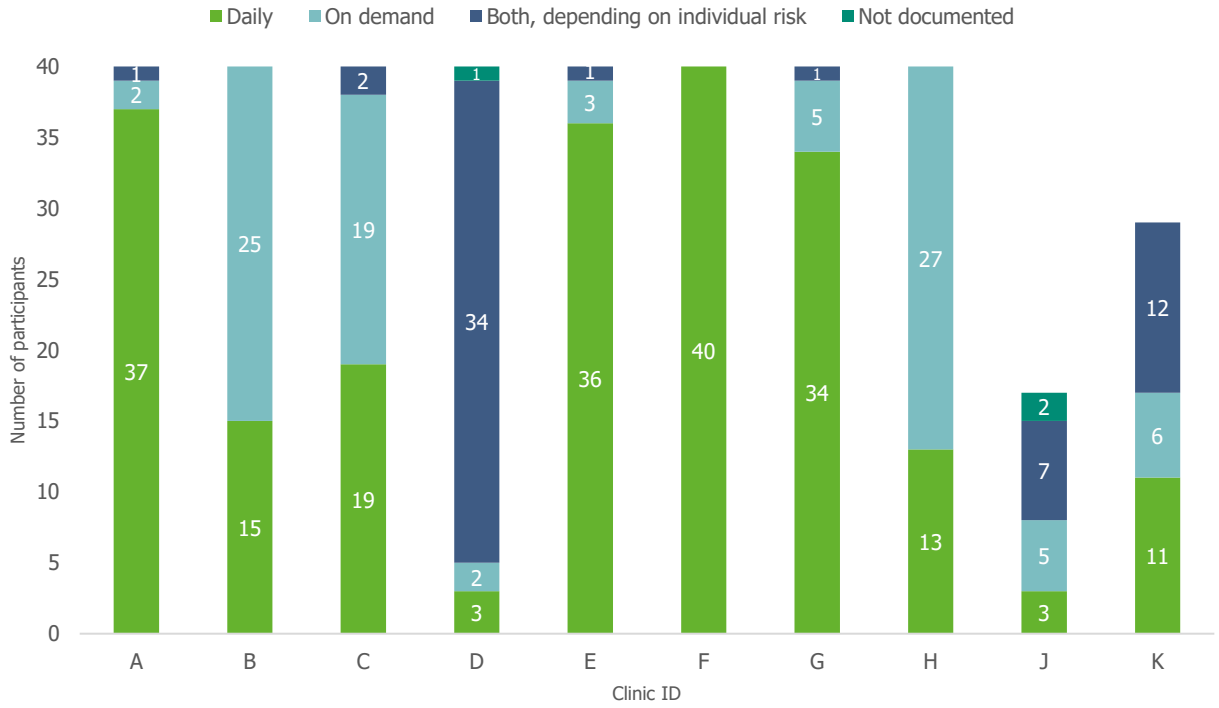
Figure 3. Funding of PrEP by national government, health system, or health commissioners, per clinic (n=10)



Ten clinics completed Part Two, with all clinics reporting data for 40 people, except for two (clinics J and K), which only reported data for 17 and 29 people, respectively, due to the small number of people on PrEP. Clinic K reported information about people who were taking PrEP acquired online. Consistent with the clinics' aggregated data, 364 of 366 participants were male (99.5%). Two participants were trans women, making up 0.5% of the total. The participants' average age was 39 years (range: 19–76 years). In total, 334 participants were white (91.3%). While 304 participants (83.1%) were born in the same country as the clinic in which they were followed, 62 participants (16.9%) were born in various countries around the world. More information on the selected participants can be found in Annex 2.

Depending on the clinic where people received PrEP, they took it either daily, on demand, or both, based on their individual risk (Figure 4).

Figure 4. Type of PrEP prescribed, per clinic



4 Standards for PrEP safety

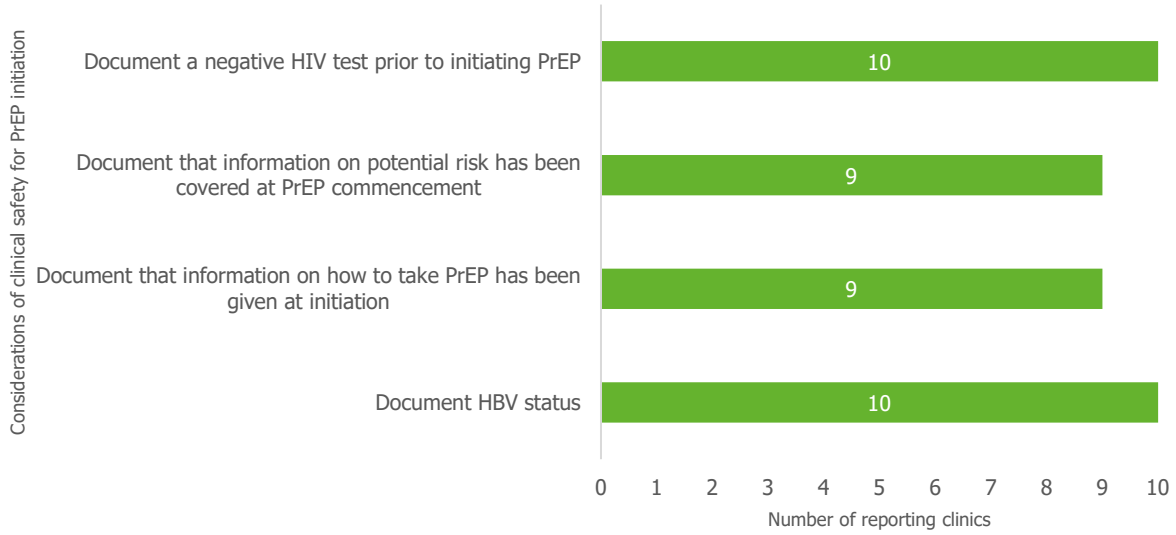
Regarding standards for PrEP safety, the audit focused on the quality statements and indicators outlined in Table 2.

Table 2. Standards for PrEP safety: quality statements and indicators selected for the audit

Quality statement	Indicator
PrEP should be initiated with full consideration of clinical safety, including reliable exclusion of HIV infection.	Percentage of PrEP users with reliable exclusion of HIV infection prior to initiating PrEP (target: 95%).
	Percentage of PrEP users older than 50 years and with baseline eGFR <90 with kidney function assessed at least annually (target: 90%).
All PrEP users should be tested for hepatitis B and, if non-immune, effectively immunised.	Percentage of PrEP users with HBV status verified using a) HBsAg (active replication) (target: 90%) or b) anti-HBc (past/active infection) (target: 80%).
	Percentage of PrEP users tested HBsAb negative immunised with HBV vaccination (target: 80%).
Clear pathways for rapid and reliable diagnosis of HIV and timely antiretroviral treatment initiation should be ensured for PrEP users.	Percentage of PrEP services with established pathways for rapid identification of HIV infection among PrEP users (target: 80%).
	Percentage of PrEP users with recently acquired HIV infection (no target).
	Percentage of PrEP users with recently acquired HIV infection initiated on ART (target: 95%).
Priority resistance testing for PrEP users recently infected with HIV should be available.	Percentage of PrEP users with recently acquired HIV infection who undergo resistance testing prior to ART initiation (80%).

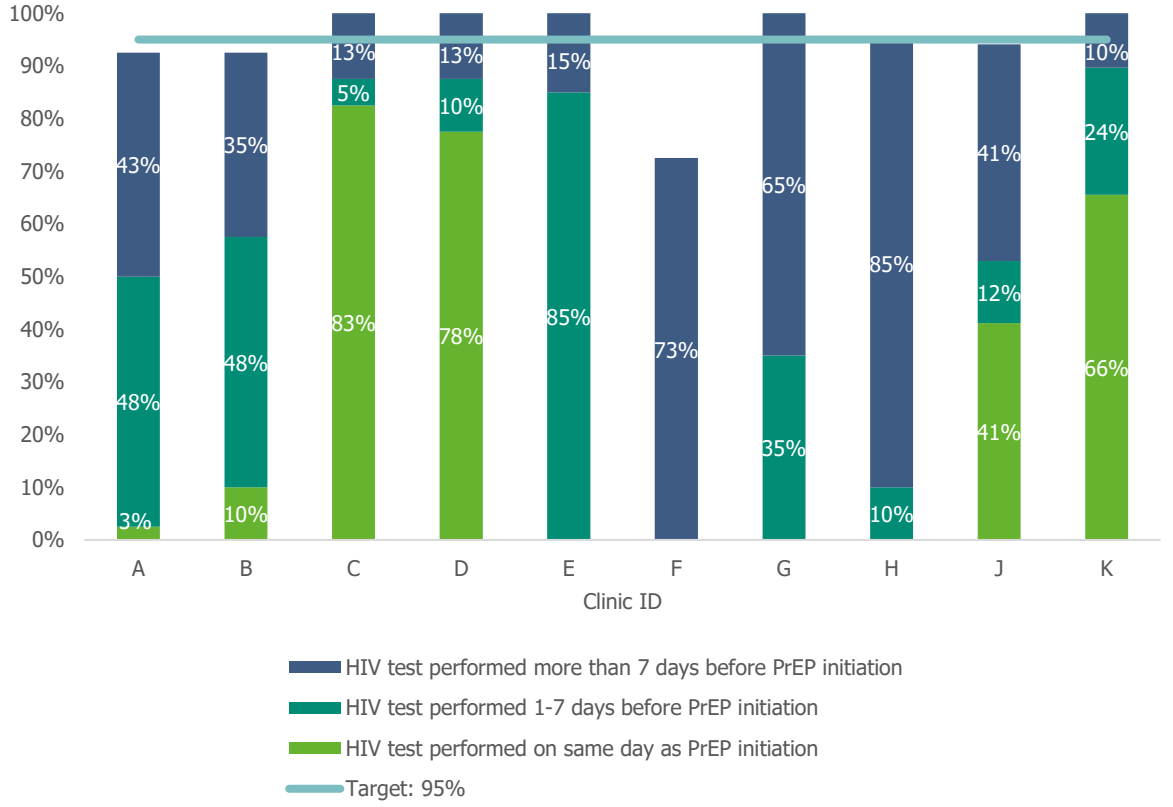
All 10 clinics reported that it is their policy to document a negative HIV test prior to initiating PrEP, as well as determine HBV status (*Figure 5*). Nine of the 10 clinics reported covering potential risk at PrEP commencement and documenting that information on how to take PrEP has been given at initiation.

Figure 5. Considerations of clinical safety for PrEP initiation, per clinic (n=10)



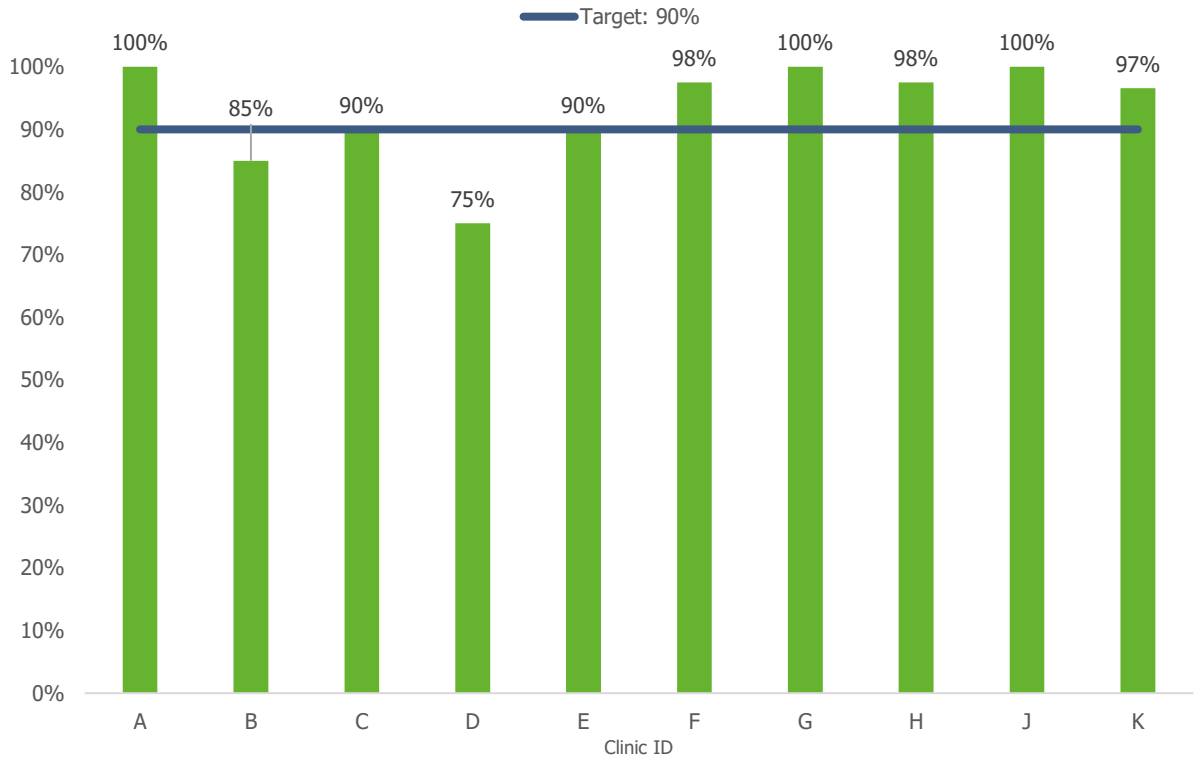
The standards set a 95% target for reliably excluding HIV infection in PrEP users before initiation. While six clinics met the target (Figure 6), it is also crucial to perform the HIV test as close to PrEP initiation as possible to ensure reliable exclusion of infection.

Figure 6. Percentage of participants per clinic with HIV test performed prior to initiating PrEP



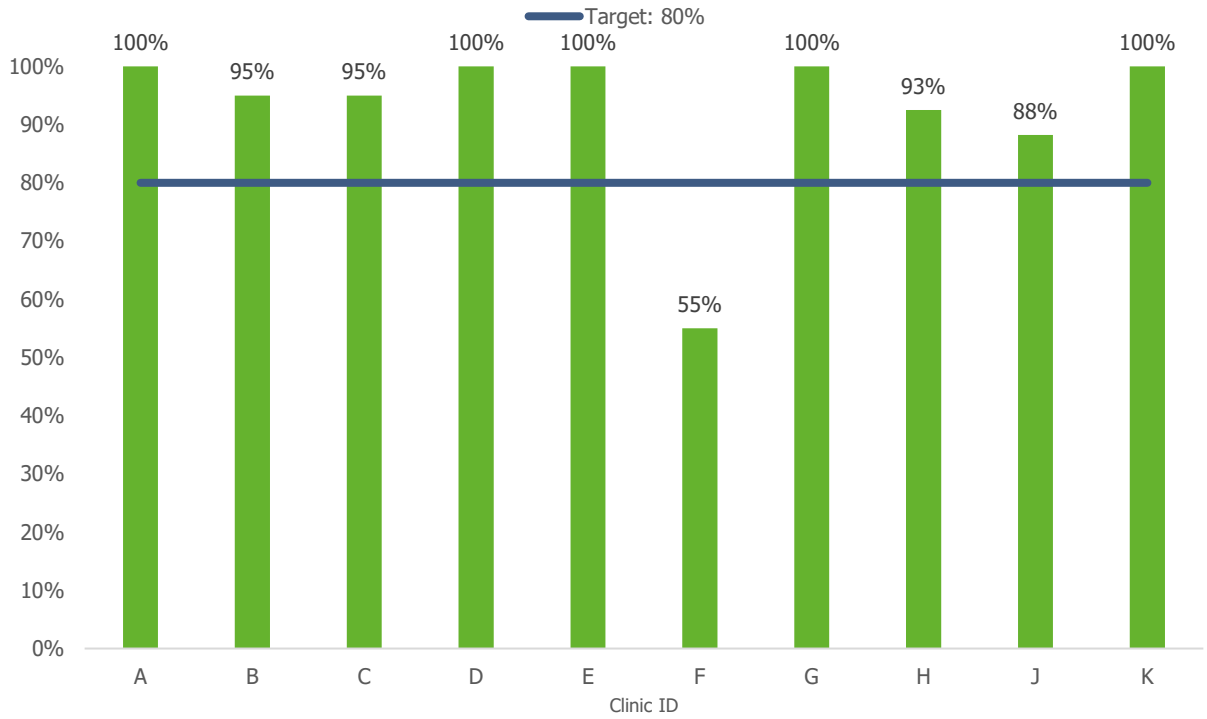
The standards indicate that PrEP users over 50 years should have their glomerular filtration rate measured at least once a year (target: 90%). Only two clinics (clinics B and D) failed to achieve the standard in relation to all people (Figure 7). However, when considering people aged over 50 years, both clinics achieved the target.

Figure 7. Percentage of people per clinic with glomerular filtration rate measurement while on PrEP



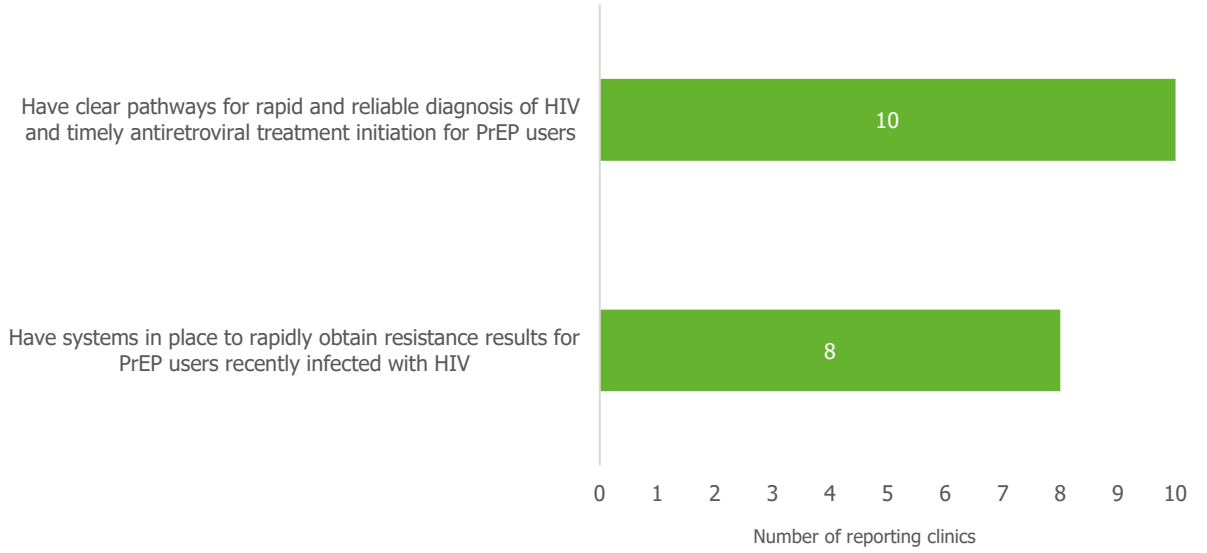
The standards' hepatitis B indicator is that 80% of people should have their hepatitis B status assessed prior to the initiation of PrEP. All clinics except for one (Clinic F: 55%) achieved the target (Figure 8). The questionnaire did not differentiate between specific tests to determine HBV status.

Figure 8. Percentage of people per clinic with HBV status determined prior to PrEP initiation



The standards set indicators for having clear pathways for rapid and reliable diagnosis of HIV and timely antiretroviral treatment initiation (target: 80%), as well as for having systems in place to rapidly obtain resistance results for PrEP users recently infected with HIV (target: 80%). All clinics reported having rapid and reliable diagnosis for HIV and timely ART initiation for PrEP users, and eight (all except clinics J and K) reported having access to rapid resistance results for PrEP users recently infected with HIV (Figure 9).

Figure 9. Presence of clear pathways for rapid diagnosis of HIV and timely antiretroviral treatment initiation for PrEP users, per clinic (n=10)



Among the people included in Part Two of the audit, five tested positive for HIV. ART was initiated within a median of seven days from diagnosis (range: 3–15 days), and three people had a resistance test prior to ART initiation. One person was later reported by the clinic to have stopped PrEP prior to seroconversion.

5 Standards for continuum of PrEP care

To assess standards for continuum of PrEP care, the audit focused on the quality statement and indicator detailed in Table 3.

Table 3. Standards for continuum of PrEP care: quality statement and indicator selected for the audit

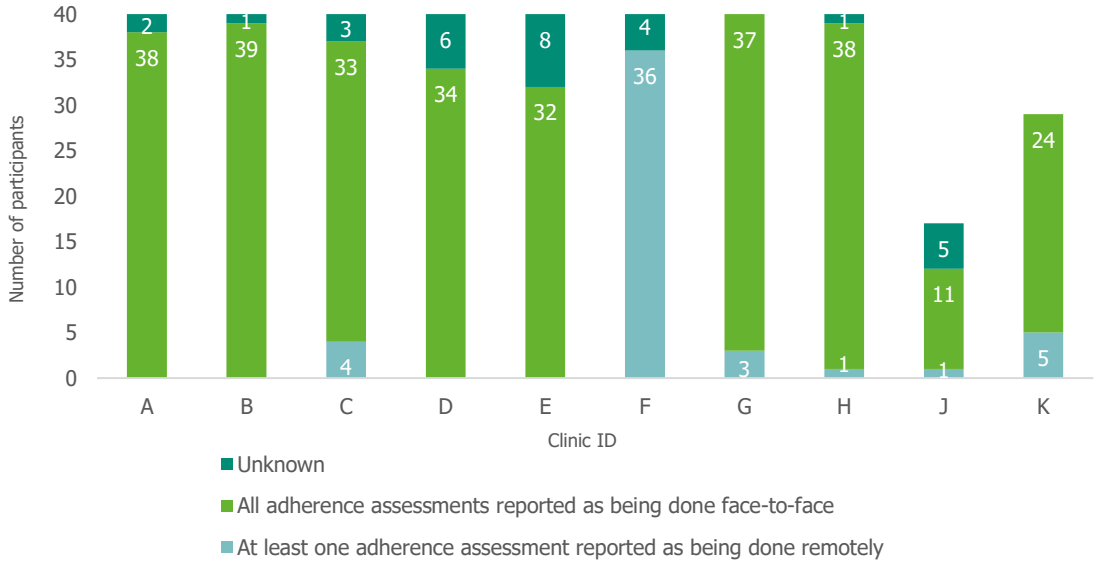
Quality statement	Indicator
PrEP adherence and other influencing factors should be assessed and addressed routinely whenever PrEP is dispensed.	Percentage of people on PrEP with documentation of adherence assessment (80%).

The standards state that 80% of people on PrEP should undergo annual adherence assessments. All clinics except two (Clinic A: 75%, and Clinic J: 65%) documented two adherence assessments performed within 14 months of each other for at least 80% of their PrEP users in the audit (Figure 10). Clinic D reported that some PrEP users missed follow-up visits because they required a formal referral from their general practitioner (GP). For those who preferred not to disclose their PrEP use to their GP, this sometimes became a barrier.

Figure 10. Percentage of people per clinic with at least two adherence assessments performed within 14 months of each other

Six clinics reported carrying out some of the adherence assessments documented in the audit remotely (Figure 11).

Figure 11. Distribution of adherence assessment methods (face-to-face, remote, and unknown) per clinic



6 Standards for PrEP delivery, integrated services, and combination prevention

In evaluating standards for PrEP delivery, integrated services, and combination prevention, the audit referred to the quality statement and indicators detailed in Table 4.

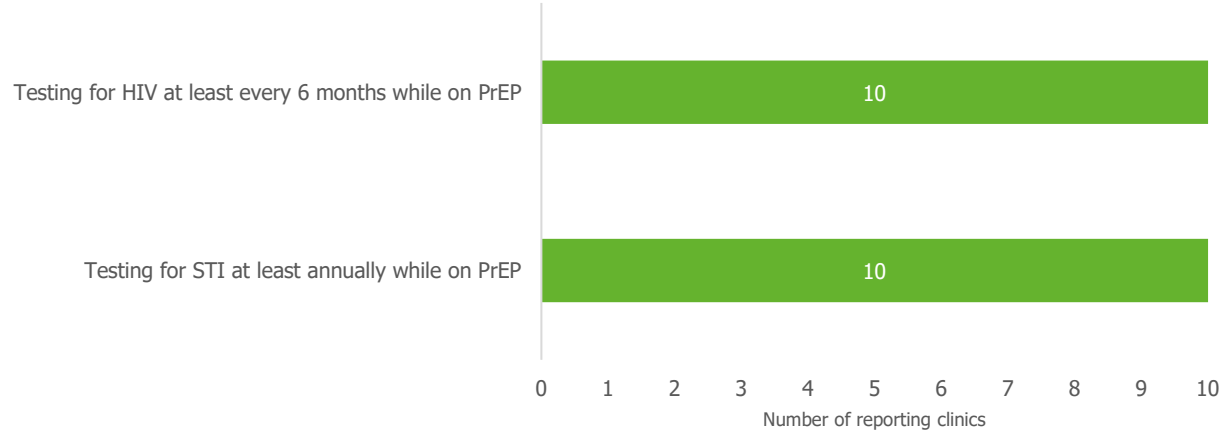
Table 4. Standards for PrEP delivery, integrated services, and combination prevention: quality statement and indicators selected for the audit

Quality statement	Indicator
In PrEP users HIV and STI testing should be performed at regular intervals in line with national and international guidelines.	Percentage of PrEP users being tested for HIV at least every 6 months (target: 80%).
	Percentage of PrEP users tested for syphilis and STI (gonorrhoea, chlamydia) at least annually (target: 80%).

Comprehensive HIV and STI testing, prophylaxis, and vaccinations (e.g. HAV, HBV) should be included in PrEP programmes to optimise health outcomes. This audit focused on evaluating whether HIV and STI testing (syphilis, gonorrhoea, and chlamydia) were being conducted at regular intervals, specifically every six months for HIV and every 12 months for STIs, with a target of achieving an 80% testing rate as set by the standards.

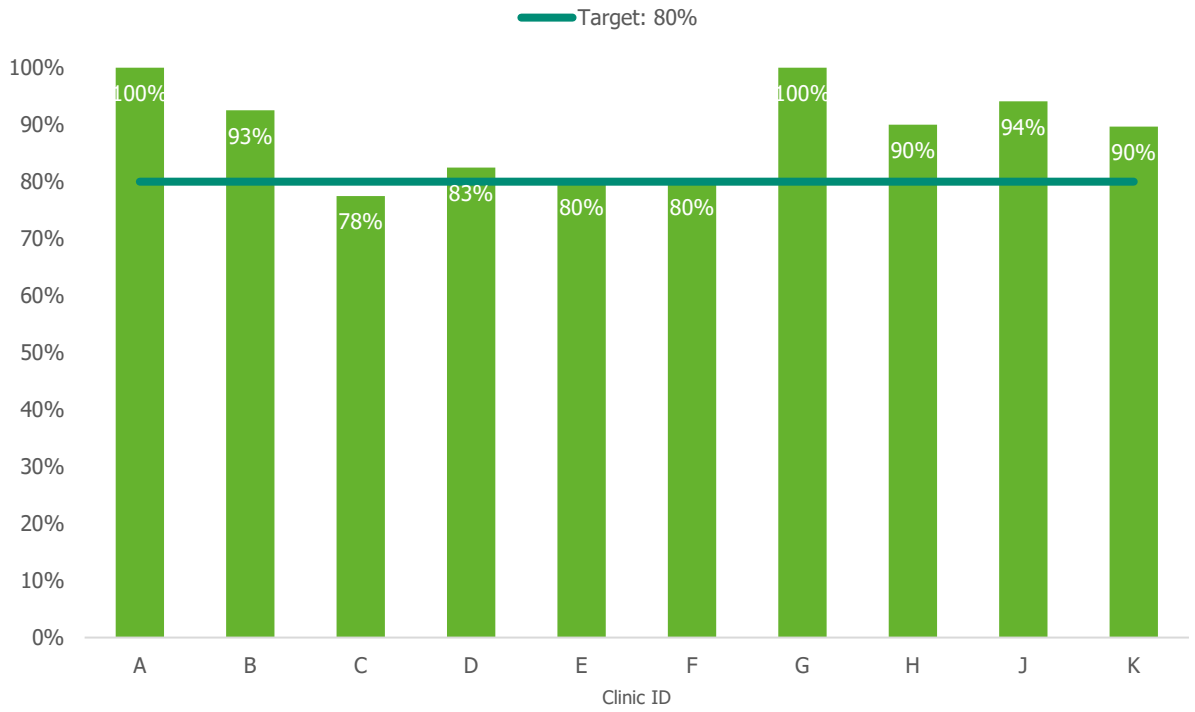
All clinics reported having established policies and systems for conducting regular HIV and STI testing for people on PrEP (Figure 12).

Figure 12. Policies for regular HIV and STI testing while on PrEP, per clinic (n=10)



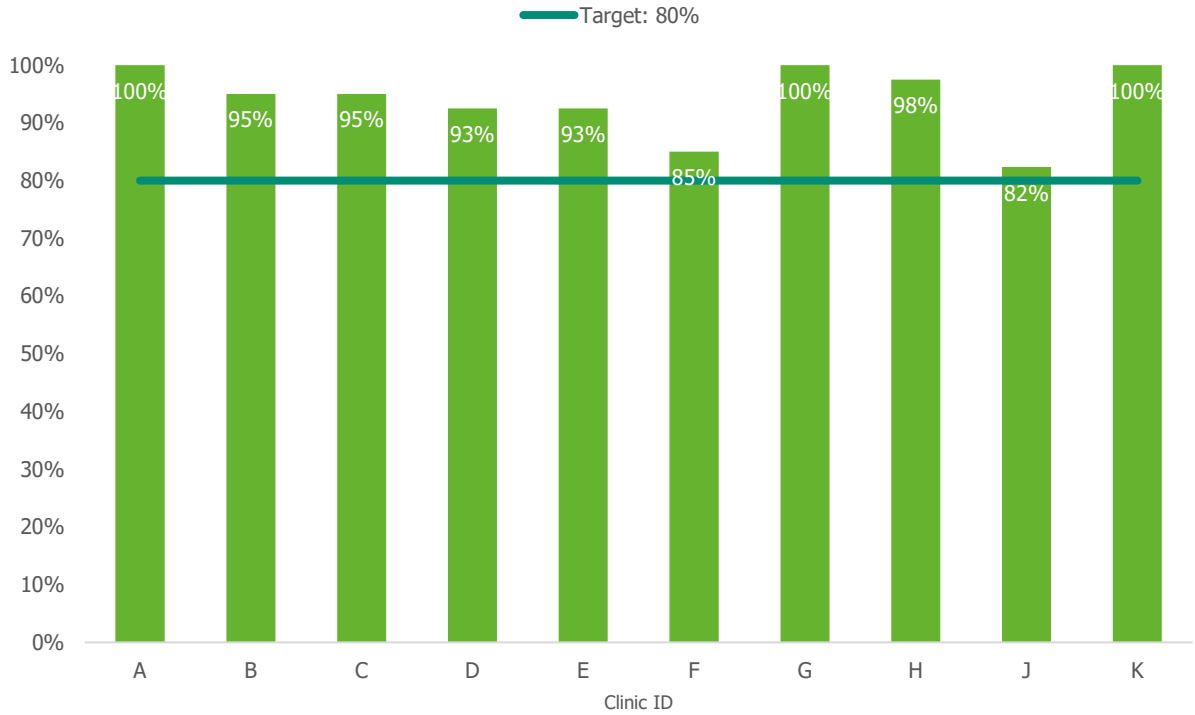
To account for minor delays, the audit checked whether at least two HIV tests were conducted within 14 months of PrEP initiation, and at least one STI test (syphilis, gonorrhoea, and chlamydia) was completed within 14 months of PrEP initiation. With regards to HIV, all clinics except one (Clinic C: 78%) achieved the 80% target (Figure 13).

Figure 13. Percentage of people per clinic with at least two HIV tests performed within 14 months after PrEP initiation



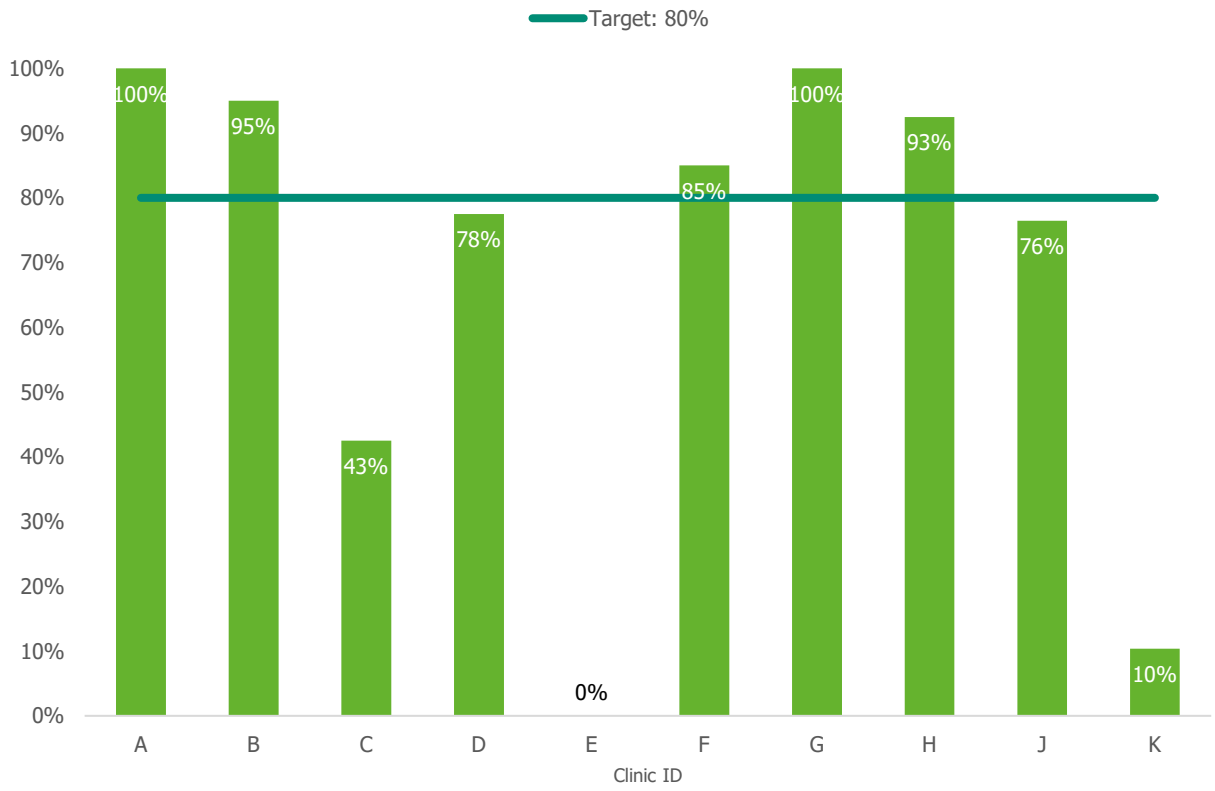
Similarly, all clinics conducted regular syphilis tests and met the target of having at least 80% of tests performed within 14 months of PrEP initiation (Figure 14).

Figure 14. Percentage of people per clinic with at least one syphilis test performed within 14 months after PrEP initiation



However, at some clinics performance in testing for gonorrhoea and chlamydia was lower. Five out of 10 clinics met the 80% target of performing at least one gonorrhoea and chlamydia test per PrEP user within 14 months of PrEP initiation (Figure 15). This could suggest that PCR tests for gonorrhoea and chlamydia are taken in a different clinic than the one in which people are prescribed PrEP. It could also suggest that, since PCR tests are more costly, clinics only test symptomatic individuals, and not on a regular basis as recommended. One clinic also noted that some PrEP users are not keen on taking swabs if they have no symptoms. Further investigations are needed to explore the reasons behind the lower rates of gonorrhoea and chlamydia testing.

Figure 15. Percentage of people per clinic with at least one gonorrhoea and chlamydia test performed within 14 months after PrEP initiation



7 Conclusions

While the Dublin Declaration HIV monitoring can collect data on many of the structural indicators in the PrEP Standards of Care module, cyclical audits at the clinic level can populate many of the process indicators in the module. This is the first audit on PrEP implementation in clinics across a number of diverse European countries. Generally, the audit demonstrates that, in the selected clinics, policies are in place to effectively achieve the targets set by the ECDC/EACS standards of PrEP implementation with regards to PrEP safety, continuum of PrEP care, and integrated testing services. The patient-specific data also show that these targets are being reached for most indicators. For example, most participating clinics reached the targets for HIV testing and determining of HBV status before PrEP initiation, regular adherence assessments during PrEP, and regular HIV and syphilis testing. These results might also be influenced by the fact that the clinics participating in this audit were selected based on interest and availability, potentially making them higher performing than others.

However, given that the clinic policies were not reflected in practice, some improvements should be made in the following areas:

- For PrEP safety, HIV tests should be performed as close as possible to PrEP initiation, preferably within seven days of starting PrEP.
- In terms of testing for HIV and STIs, there should be improvements in gonorrhoea and chlamydia testing, along with an exploration of potential reasons for the lower testing rates.

The results from this report are specific to the participating clinics and not generalisable to the broader European context. The primary purpose of the report was to test the feasibility and utility of the audit process itself, and to assess whether it could be scaled up and rolled out more widely across Europe in the future.

Lessons learned from this audit

The delivery of this audit, along with feedback from the participating clinics, has highlighted some areas within the audit that need to be modified to ensure more accurate reporting and comprehension, in particular in Part Two of the audit. For example:

- A question should be included to determine whether and when PrEP was interrupted for the selected people. This would provide clearer understanding, such as whether seroconversion occurred after PrEP interruption.
- More specific information on HBV testing prior to PrEP initiation should be gathered, such as the type of test used to determine HBV status. There is also a need to review the indicators, as they do not allow for positive HBsAb test in previously vaccinated individuals.
- Information on chlamydia and gonorrhoea testing was collected in two separate questions. Based on a clinic's suggestion and the identical results for both, these questions can be combined in future audits.
- For all 12-month timepoints (e.g. glomerular filtration measurements, adherence assessments, and testing while on PrEP), the questions should allow for data within a 14-month period to accommodate minor delays. While most clinics reported data beyond 12 months, this would make the instructions clearer.
- It would also be useful to add a section where clinics can explain any exceptions or discrepancies. While clinics were presented with the results and invited to provide comments or considerations for this report, a dedicated section for clarification would enhance transparency.

Overall, this audit has proven to be a useful tool to assess whether process indicators and targets set by the standards of PrEP implementation are being met at a clinical level. As reported by some clinics, the audit was highly beneficial in helping them identify areas for improvement. This report aimed to demonstrate the added value of audits for public health institutions, clinics, and the community of people living with HIV, and to encourage countries and clinics to conduct such audits independently and on a regular basis. Future audits could benefit from increased automation and support from public health institutions, helping to streamline the process, facilitate continuous monitoring and improvement of clinical PrEP services, and establish a formal mechanism for sharing results and incorporating feedback from participating clinics into subsequent audit cycles.

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Annex 1. Audit data

Part One

Aggregated data:

1. How many individuals at your clinic **have been prescribed** PrEP at least once **in 2023**?*
   - Total: _____
   - Males: _____
   - Females: _____
   - Trans women: _____
   - Trans men: _____
   - Non-binary: _____
   - Unknown: _____

2. How many people with a history of PrEP use in 2023 have been diagnosed with HIV **in 2023**?* _____ (if unknown write: -1)

Guidelines and Policies:

3. Which guidelines/recommendations on PrEP are recommended be followed in your clinic?*
   - EACS guidelines
   - WHO guidelines
   - National guidelines
   - Other
   - None
   - Unknown

3a. If 'national guidelines', specify: _____

3b: If 'other', specify: _____

3c: If 'none', please give more detail as to guideline choice by clinicians: _____

4. Does your clinic have a protocol/policy to (can select multiple options):*
   - Document a negative HIV test prior to initiating PrEP?
   - Cover potential risk at PrEP commencement?
   - Testing for HIV at least every 6 months while on PrEP?
   - Testing for STI at least annually while on PrEP?
   - Document HBV status?
   - Document that information on how to take PrEP has been given at initiation?
   - Have clear pathways for rapid and reliable diagnosis of HIV and timely antiretroviral treatment initiation for PrEP users?
   - Have systems in place to rapidly obtain resistance results for PrEP users recently infected with HIV?
   - None of the above
   - Unknown

5. Which key populations are able to access PrEP at your clinic?*
   - Gay men and other men who have sex with men
   - Sex workers
   - People who inject drugs
   - Transgender people
   - Prisoners
   - People from high prevalence countries
   - Partners of people who belong to a group at risk
   - Migrants (documented)
   - Migrants (undocumented)
   - Anyone who might benefit from PrEP
   - Other (specify)
   - Unknown

5a. If 'other', please specify: _____

6. Is PrEP funded by your national government/health system/health commissioners?*

	Yes	No	Partially funded/reimbursed	Unknown
Cost of drugs	○	○	○	○
STI testing	○	○	○	○
HIV testing	○	○	○	○
STI treatment	○	○	○	○
Renal function monitoring	○	○	○	○
Bone density monitoring	○	○	○	○
HBV vaccine	○	○	○	○

7. Does your clinic have a waiting list for access to PrEP?*
   - Yes
   - No
   - Unknown

7a. If yes, how long is it approximately? _____

Part Two (to be filled out for 40 people)

1. Gender of individual:*
   - Male (including trans men)
   - Female (including trans women)
   - Non-binary
   - Other
   - Not documented

2. Is this the same as their sex at birth?*
   - Yes
   - No
   - Unknown

3. Age: _____*

4. Ethnicity:*
   - White
   - Black African
   - Black Caribbean
   - Asian
   - Mixed race (please specify)
   - Other (please specify)
   - Unknown

5. Country of birth: _____* (if unknown, select 'unknown')

Audit data

6. Documented date of first contact with individual to discuss PrEP (if available): _____

7. Date of PrEP prescription: _____*

8. Was the individual prescribed/recommended PrEP daily or event-driven/on demand?
    - Daily
    - On demand
    - Both, depending on individual risk
    - Not documented

9. Was an HIV test performed prior to initiating PrEP?*
    - Yes
    - No
    - Not recorded

9a. If yes, date of HIV test: _____

10. Prior to PrEP initiation, was hepatitis B status determined?*
    - Yes
    - No
    - Unknown

11. In the 12 months after the first PrEP prescription, was the individual tested for:*

	Yes	No	Unknown
HIV	○	○	○
Gonorrhoea	○	○	○
Syphilis	○	○	○
Chlamydia	○	○	○
Other (please specify)	○	○	○

11a. If yes, specify date(s) for: HIV: _____

Gonorrhoea: _____

Syphilis: _____

Chlamydia: _____

Other: _____

12. While on PrEP, was the glomerular filtration rate calculated? _____ *
    a. Yes
    b. No
    c. Unknown

12a. If yes, date(s): _____

13. While on PrEP, is there documentation of adherence assessments with the individual over time?*
    a. Yes
    b. No
    c. Unknown

13a. If yes, date(s): _____

13b. Were any of these assessments carried out remotely?
    d. Yes
    e. No
    f. Unknown

14. Has the individual tested positive for HIV since the first PrEP prescription?*
    a. Yes
    b. No
    c. Not recorded

14a. If yes, date of first positive HIV test: _____

15. If yes, was the individual initiated on antiretroviral treatment?*
    a. Yes (specify date)
    b. No
    c. Care was transferred to an HIV treatment centre
    d. Not recorded

16. If yes, did the individual have a resistance test prior to initiating ART?*
    a. Yes (specify date)
    b. No
    c. Unknown

** Required field*

Annex 2. Demographic information of selected participants in the auditing clinics (n=10)

Clinic ID	Total	Male, including trans men (% of total)	Same sex as birth	Average age (range)	Ethnicity (% of total)	'Other' ethnicity (free text)	Same country of origin as clinic (% of total)
A	40	40 (100%)	40 (100%)	42 (31–63)	White: 29 (72.5%) Other: 11 (27.5%)	Latinoamerican (11)	65.0%
B	40	40 (100%)	40 (100%)	46 (24–76)	White: 23 (57.5%) Unknown: 17 (42.5%)		82.5%
C	40	39 (97.5%)	39 (97.5%)	35 (22–57)	White: 40 (100%)		95.0%
D	40	40 (100%)	40 (100%)	40 (27–75)	White: 40 (100%)		97.5%
E	40	39 (97.5%)	39 (97.5%)	32 (22–59)	White: 39 (97.5%) Unknown: 1 (2.5%)		92.5%
F	40	40 (100%)	40 (100%)	37 (19–62)	White: 40 (100%)		57.5%
G	40	40 (100%)	40 (100%)	35 (23–55)	White: 40 (100%)		77.5%
H	40	40 (100%)	40 (100%)	45 (23–66)	White: 38 (95%) Black African: 2 (5%)		95.0%
J	17	17 (100%)	17 (100%)	40 (30–51)	White: 17 (100%)		88.2%
K	29	29 (100%)	29 (100%)	41 (28–60)	White: 28 (96.6%) Other: 1 (3.4%)	Arab (1)	82.8%
Total	**366**	**364 (99.5%)**	**364 (99.5%)**	**39 (19–76)**	**White: 334 (91.3%) Black African: 2 (0.6%) Other: 12 (3.3%) Unknown: 18 (4.9%)**		**83.1%**

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