SURVEILLANCE & MONITORING

Audit of standards of care for HIV testing

September 2026

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

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Table of contents

Tables

Figures

Abbreviations

ART	Antiretroviral treatment
CHIP	Centre of Excellence for Health, Immunity and Infections
EACS	European AIDS Clinical Society
ECDC	European Centre for Disease Prevention and Control
HIV	Human immunodeficiency virus
IC	Indicator condition
MSM	Men who have sex with men
PWID	People who inject drugs
SoC	Standards of Care
REDCap	Research Electronic Data Capture
WHO	World Health Organization

Executive summary

The European Centre for Disease Prevention and Control (ECDC), in collaboration with the European AIDS Clinical Society (EACS), has developed standards of HIV care that define key quality statements, indicators and targets to support improvements in, access to, and quality of HIV services. These include a dedicated module on HIV testing, covering quality statements describing best practice based on current guidelines, and measurable, auditable indicators for outcome, structure and processes.

Outcome and structural indicators are routinely collected through the HIV monitoring, coordinated by ECDC within the framework of the Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia [1]. However, process indicators, particularly those relating to clinical practice, are not captured systematically. A pilot clinical audit was therefore conducted to assess selected process indicators and examine the implementation of HIV testing standards at the individual clinic level.

This report presents findings from both data sources for three participating countries: Greece, Poland and Romania. Country-level data were drawn from the Dublin Declaration monitoring, while clinic-level data were collected through a retrospective audit, conducted between October 2025 and January 2026 at 12 clinics (three HIV clinics and one tuberculosis (TB) clinic per country). The audit collected aggregated clinic information and individual patient-level data from medical records.

The participating clinics varied considerably in size and patient populations. At HIV clinics, HIV positivity among those tested ranged widely, and the characteristics of those diagnosed with HIV differed by clinic, including the key populations represented. TB clinics reported high levels of HIV testing among those diagnosed with TB, although performance varied.

At the country level, none of the three participating countries had achieved the UNAIDS target (95% of people living with HIV should be aware of their status). At the individual clinic level, substantial variation was observed in the proportion of people diagnosed with HIV late or very late, indicating ongoing challenges in timely diagnosis in all settings.

With regard to testing policies, there are still significant shortcomings. While community-based testing is included in national strategies to varying degrees, none of the three countries includes home testing or self-testing in national guidelines. This suggests that there are missed opportunities to expand testing approaches to reach populations who may face barriers to facility-based services.

In terms of testing strategies, most HIV clinics reported implementing targeted HIV testing promotion activities for key populations. In TB services, HIV testing coverage among those diagnosed with TB was generally high, with most clinics meeting or approaching the recommended target of 85%, although variation among clinics was observed.

For consent practices, all three countries report policies supporting voluntary HIV testing. However, requirements for pre-test counselling and written consent remain in some settings. At the individual clinic level, practices varied, with only around half of clinics fully aligned with standards that no longer recommend these requirements. These findings highlight inconsistencies between policy and practice, as well as potential barriers to scaling up routine testing.

With regard to diagnosis and linkage to care, most clinics reported having documented care pathways to HIV treatment and support services. However, performance against key timeliness indicators was variable. No clinic reached the target for confirmatory testing within five working days of a reactive test, and only a minority achieved the target for timely specialist assessment. Time to initiation of antiretroviral therapy (ART) also varied widely. Documentation of partner notification discussions was also incomplete in several settings, indicating further gaps in implementation.

For monitoring and evaluation, most clinics reported submitting HIV testing data to national surveillance systems. However, reporting practices differed, with some clinics reporting only positive tests and others reporting all testing activity. While most HIV clinics reported core indicators using key demographic variables, incompatibility of reporting practices may limit comparability and completeness of data.

Overall, the findings from this pilot audit highlight variability in the implementation of HIV testing standards both between and within countries. While some clinics and national systems meet specific targets, shortcomings persist in a number of areas, particularly in the expansion of testing approaches, the streamlining of consent procedures and improvement of timeliness in the area of diagnosis and linkage to care.

This audit demonstrates the feasibility of combining country-level monitoring data with clinic-level audit data to provide a more detailed understanding of how HIV testing standards are implemented in practice. Although the results of this audit are not intended to be generalisable beyond the clinics included, they do provide valuable insights which can be used to inform future audits and quality improvement efforts.

The audit findings have been shared with participating clinics to support local reflection and improvement. Expanding the number of participating clinics in future audits would strengthen the robustness and representativeness of findings. Further development of the audit process, including increased automation and stronger institutional support, could facilitate regular, cyclical assessments and contribute to ongoing improvements in HIV testing services.

1 Background

With the overall goal of improving HIV service access and standards of care, ECDC, in collaboration with EACS, has developed a set of modules for standards of HIV care [2]. These standards are based on existing EACS and World Health Organization (WHO) guidelines and provide a reference point against which to benchmark the quality of care and services in the context of people's changing needs and challenges of financing healthcare [3, 4]. The Standards of Care (SoC) module on HIV Testing was one of the first modules to be developed [5].

The SoC for HIV testing is divided into topics under which quality statements, indicators, and targets have been developed:

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.

The indicators in the SoC modules are either outcome indicators, structural indicators or process indicators. Many of the outcome and structural indicators are collected annually through HIV monitoring within the framework of the Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia. To evaluate performance against the process indicators, in particular at the clinical service level, cyclical audits can generate results to form recommendations for improving the quality and provision of care. Clinic-level audits can therefore supplement data collected through the Dublin Declaration HIV monitoring.

The aim of this audit was to collect information on a selection of priority indicators (identified in bold within the SoC module) using two complementary data sources. At the country level, selected data were drawn from the Dublin Declaration HIV monitoring process for the three participating countries included in this audit (Greece, Poland and Romania), covering the indicators presented in Table 1. At the individual clinic level, additional data were obtained through a clinical audit (Annex 1), conducted in the same three countries, involving three HIV clinics and one TB clinic per country, addressing the indicators outlined in Table 2. HIV clinics addressed questions regarding HIV testing strategies and policies and recruited the participants diagnosed with HIV, while TB clinics addressed questions regarding HIV testing in the context of an indicator condition, irrespective of HIV diagnosis status.

The findings from the clinical audit are not intended to be generalisable to all clinics in Europe, but rather to serve as a pilot for future audits related to HIV testing. Audits that combine country-level data with clinic-level data allow for an assessment of the practical implementation of HIV testing guidelines, showing performance at both levels, and identifying areas where action is needed. These audits are useful for public health institutions by informing policy and resource allocation, for clinics by highlighting areas for quality improvement, and for the community of people living with HIV by ensuring access to timely and effective HIV testing services.

Table 1. Quality statements and indicators covered by Dublin Declaration HIV monitoring

General		
Quality statement	**Indicator**	**Question as in Dublin Declaration**
Everybody living with HIV should be aware of their status in order to access timely treatment and care.	Percentage of people living with HIV who are aware of their status (target: 95%).	Q 18.23 Percentage (%): People living with HIV who know their HIV status (First 95).
Testing policies		
Quality statement	**Indicator**	**Question as in Dublin Declaration**
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.	Percentage of national HIV testing strategies that include community-based testing for at least one key population (target: 100%).	Q 13.4 (2023 data) Which of the following HIV testing approaches are included in national testing guidelines? Options: Community-based HIV testing and counselling (by a medically trained professional) AND community-based HIV testing and counselling (by a lay provider).
HIV self-testing and self-sampling should be offered as additional approach to HIV testing services.	Percentage of national testing strategies that include self-testing and self-sampling (target: 100%).	Q 13.4 (2023 data) Which of the following HIV testing approaches are included in national testing guidelines? Options: Home-testing AND self-testing.
HIV 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.	Percentage of national testing strategies with HIV testing algorithms that follow WHO recommendations (target: 100%).	Q 13.13 Is Western blotting and line immunoassays recommended for use in your national testing HIV guidelines or included within HIV testing strategies and algorithms?
Consent		
Quality statement	**Indicator**	**Question as in Dublin Declaration**
HIV testing should be voluntary in all situations.	Proportion of national HIV testing strategies, guidelines or policies that state HIV testing should be voluntary (target: 100%).	Q 13.14 Is there a national testing strategy, guidance or other recommendation or legal document in your country stating that HIV testing should be voluntary in all circumstances?* **(excluding situations where a person is unable to provide informed consent due to physical or mental incapacity and excluding anonymous testing for research purposes)*
Individualised pre-test counselling and written consent for HIV testing should no longer be required when undertaking HIV testing.	Proportion of national HIV testing strategies, guidelines or policies that do not recommend pre-test counselling or written consent (target: 100%).	Q 13.15 Is written consent required as part of HIV testing in your country? Q 13.16 Is individualised pre-test counselling required as part of HIV testing in your country?

Table 2. Quality statements and indicators covered by clinical audit

General	
Quality statement	**Indicator**
Everybody living with HIV should be aware of their status in order to access timely treatment and care.	Percentage of people diagnosed late (CD4 cell count <350 cells/μL) or very late (CD4 cell count <200 cells/μL or AIDS diagnosis) (target: decrease in total number of people diagnosed late by 2% per annum).
Testing strategies	
Quality statement	**Indicator**
HIV testing should be routinely offered and recommended for all people presenting with indicator conditions (ICs) or with symptoms where an IC is included in the differential diagnosis.	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 (target: 85% or annual improvement 5% from baseline/previous year).
HIV testing promotion messages and communication 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 risk.	Percentage of national HIV testing promotion strategies that are targeted to key populations (target: 95%).
Consent	
Quality statement	**Indicator**
HIV testing should be voluntary in all situations.	Proportion of national HIV testing strategies, guidelines or policies that state HIV testing should be voluntary (target: 100%).
Individualised pre-test counselling and written consent for HIV testing should no longer be required when undertaking HIV testing.	Proportion of national HIV testing strategies, guidelines or policies that do not recommend pre-test counselling or written consent (target: 100%).
Diagnosis and transfer to care	
Quality statement	**Indicator**
All HIV testing services, including those in the community, self-sampling and self-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	Proportion of HIV testing services with documented care pathways to HIV treatment and support services (target: 95%).
A confirmatory test should be offered within five working days of a reactive HIV test, in order to facilitate timely access to treatment, care and support.	Proportion of people having a confirmatory test within five working days of a reactive HIV test (target: 90%).
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 of two weeks after the result of the confirmatory test is available.	Proportion of newly diagnosed patients attending an HIV specialist appointment within two weeks of their initial HIV diagnosis (Exclusion: people offered an appointment within two weeks who decline) (target: 90%).
Antiretroviral therapy (ART) initiation should occur as soon as possible following a confirmed HIV diagnosis, taking into account patient preference and clinical condition.	Median time for newly diagnosed individuals to commence ART (no target).
Partner notification should be voluntary, offer anonymity and provider-assisted referral and be mindful of a patient's personal safety. Partner notification should be initiated in a timely manner by the service confirming the HIV diagnosis.	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 this was initiated at the reactive result appointment) (target: 95%).
Monitoring and evaluation	
Quality statement	**Indicator**
All HIV testing services should report testing data through standard national monitoring and surveillance systems.	Proportion of HIV testing services reporting testing data through national monitoring and surveillance systems (target: 95%).
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.	Proportion of countries reporting core European level testing indicators by key demographics and population (target: 100%).

2 Methods

Country-level data

Country-level data (outcome and structural indicators) were obtained from the Dublin Declaration HIV monitoring process for the three participating countries included in this audit, with information collected by ECDC in REDCap, a secure, web-based application designed for data collection and management [6, 7]. Relevant questions corresponding to the indicators listed in Table 1 were extracted from the 2025 database, or from the 2024 cycle when 2025 data were not available. These data were analysed and are presented within the appropriate results sections and summarised in Annex 2. The country-level data provide benchmarks against which individual clinics can compare themselves.

Clinical audit

The clinical HIV testing 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 SoC module (Table 2).

The audit was entered into REDCap [6, 7]. Before implementing the audit across the selected clinics, the tool was piloted in four clinics and subsequently revised. The audit was designed to be completed by both HIV clinics and TB clinics, with the latter included to address questions related to HIV testing in the context of an indicator condition.

The audit was structured in two parts:

- **Part One** (the same for both HIV and TB clinics, with some exceptions) provided background information on the clinics' aggregated data on HIV testing, their policies, guidelines and monitoring processes. This section was completed once for each HIV and TB clinic participating in the audit.
- **Part Two**
  - **HIV clinics:** were required to provide HIV testing information drawn from the medical records of the last 40 patients (≥18 years of age) prior to 1 October 2025 (date of audit launch) who tested positive for HIV at their clinic or tested positive for the first time elsewhere and were referred to their service for their first clinic visit related to HIV care and treatment[1].
  - **TB clinics:** were required to provide HIV testing information drawn from the medical records of the last 20 patients (≥18 years of age) prior to 1 October 2025 who were newly diagnosed with TB at their clinic, excluding patients already living with HIV prior to attending any service in relation to new TB diagnosis.

Between October 2025 and January 2026, 12 clinics from three countries were invited to complete the audit: Greece (country A), Poland (country B), and Romania (country C). This included three HIV clinics and one TB clinic per country. The selection of the three countries and 12 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 clinical audit will be presented using an anonymous clinic ID (A1-A4, B1-B4, C1-C4, where codes 1–3 denote HIV clinics and code 4 denotes the TB clinic).

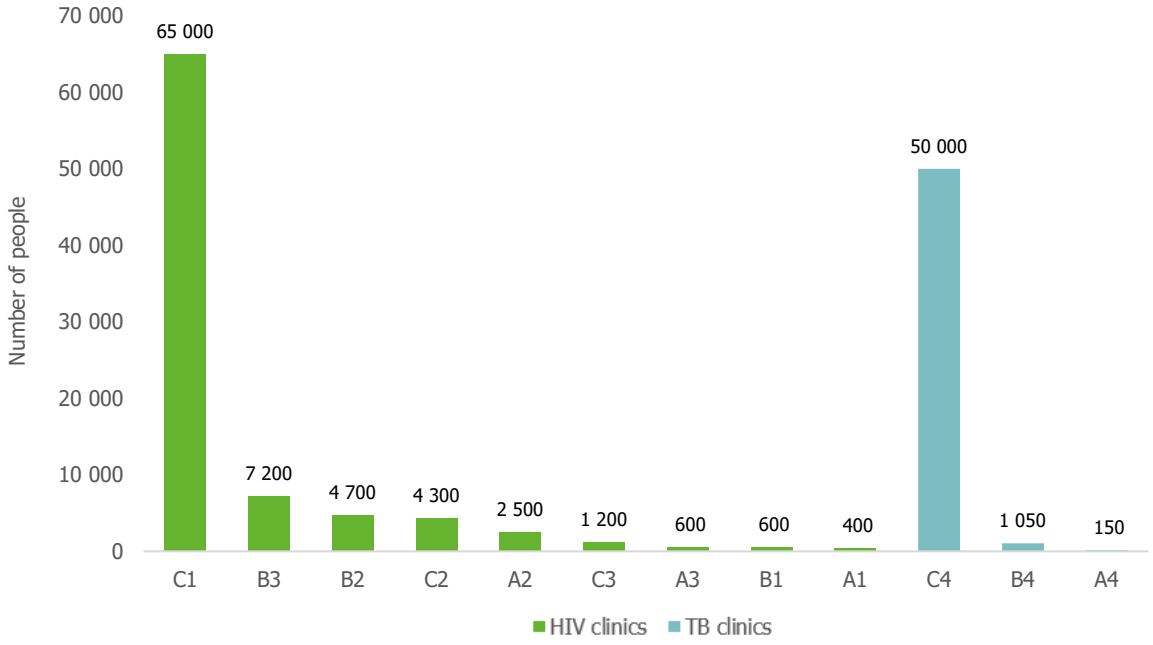
Audits that combine country-level data with clinic-level data allow for an assessment of the practical implementation of HIV testing guidelines, showing performance at both levels, as well as identifying shortcomings where action is needed. These audits are useful for public health institutions by informing policy and resource allocation, for clinics by highlighting areas for quality improvement, and for the community of people living with HIV by ensuring access to timely and effective HIV testing services.

[1] While most clinics selected the last 40 patients who tested positive for HIV prior to 1 October 2025, a couple of clinics misunderstood the selection process and either: 1) randomly selected 40 patients from scheduled annual appointments during the data collection period (clinic A2); or 2) selected the last 40 patients from the infectious disease specialist's (rather than the clinic's) patient register (clinic A1).

3 Clinic characteristics and characteristics of selected people in clinical audit

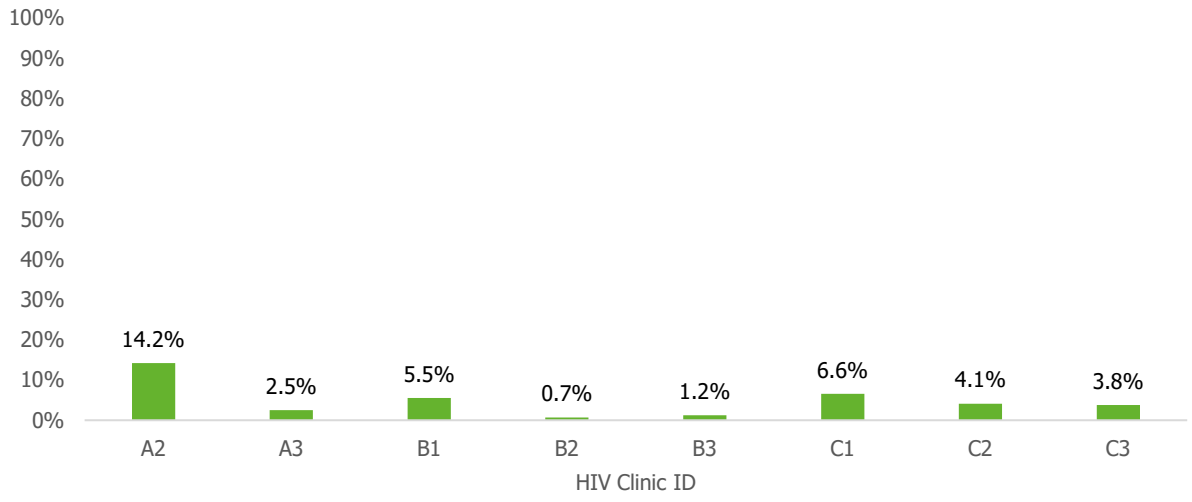
The 12 clinics participating in the audit had seen a wide range of people in 2024, with the number ranging from 400 to 65 000 in the nine HIV clinics, and from 150 to 50 000 in the three TB clinics (Figure 1), reflecting the wide variation in clinic sizes.

Figure 1. Estimated number of people seen in service in 2024, per HIV and TB clinic (n=12)



In the eight HIV clinics with available data[2], in 2024 the estimated percentage of people tested for HIV who tested positive ranged from 0.7% to 14.2% (Figure 2).

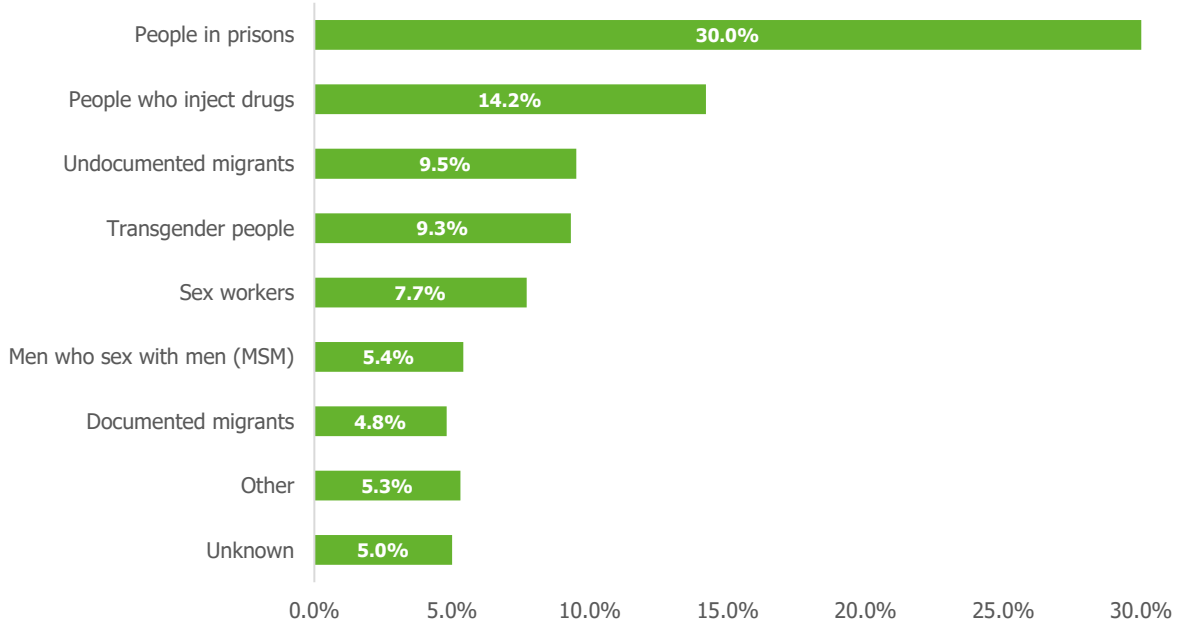
Figure 2. Estimated percentage of people tested for HIV who tested positive in 2024, per HIV clinic (n=8)



Among these, the key populations most likely to be tested positive for HIV were people in prisons (30.0% estimated positivity rate), people who inject drugs (14.2% estimated positivity rate) and undocumented migrants (9.5 positivity rate), while the least likely to be tested positive for HIV were men who have sex with men (MSM) and documented migrants (with 5.4% and 4.8% estimated positivity rate) (Figure 3).

[2] Clinic A1 was unable to provide data on individuals tested for HIV in their service in 2024.

Figure 3. Estimated percentage of people, by key population, tested for HIV who tested positive in 2024, per HIV clinic (n=8)



Overall, in the three TB clinics the percentage of people diagnosed with TB who were tested for HIV in 2024 ranged from 92.4% (in clinic C4) to 100.0% (in clinic A4) (Figure 4). Of these, the percentage of people who tested positive for HIV ranged from 0.0% (in clinic C4) to 50.0% (in clinic A4).

For Part Two of the clinical audit, all HIV clinics reported data on 40 individuals each, corresponding to a total of 360 participants who tested positive for HIV. Of these, 289 participants were male (80.3%) and their average age was 39.1 years (range: 19–75 years). In total, 354 participants were white (98.3%). While 305 participants (84.7%) were born in the same country as the clinic in which they were followed, 55 participants (15.3%) were born in various other countries around the world. Some of the participants belonged to key populations, such as MSM (152 participants), people who inject drugs (31 participants), transgender people (three trans women), people in prisons (five participants), migrants (36 participants), and other key populations defined by the clinics (20 participants). More information on the selected participants can be found in Annex 2a.

Two out of three TB clinics submitted data on 20 individuals each (Clinic A4 reported 10 participants due to it being a small clinic), resulting in a total of 50 participants who were newly diagnosed with TB. Of these, 37 participants were male (74.0%), and their average age was 49.5 years (range: 25–85 years). Overall, 44 participants were white (88.0%), and 40 participants (80.0%) were born in the same country as the clinic in which they were followed. Some of the participants belonged to key populations, such as MSM (one participant), sex workers (two participants), people who inject drugs (three participants), migrants (four participants), and other key populations defined by the clinics (five participants). More information on the selected participants can be found in Annex 2b.

4 General standard of care for HIV testing

With regard to the general standard of care for HIV testing, this audit focused on the quality statements and indicators outlined in Table 3.

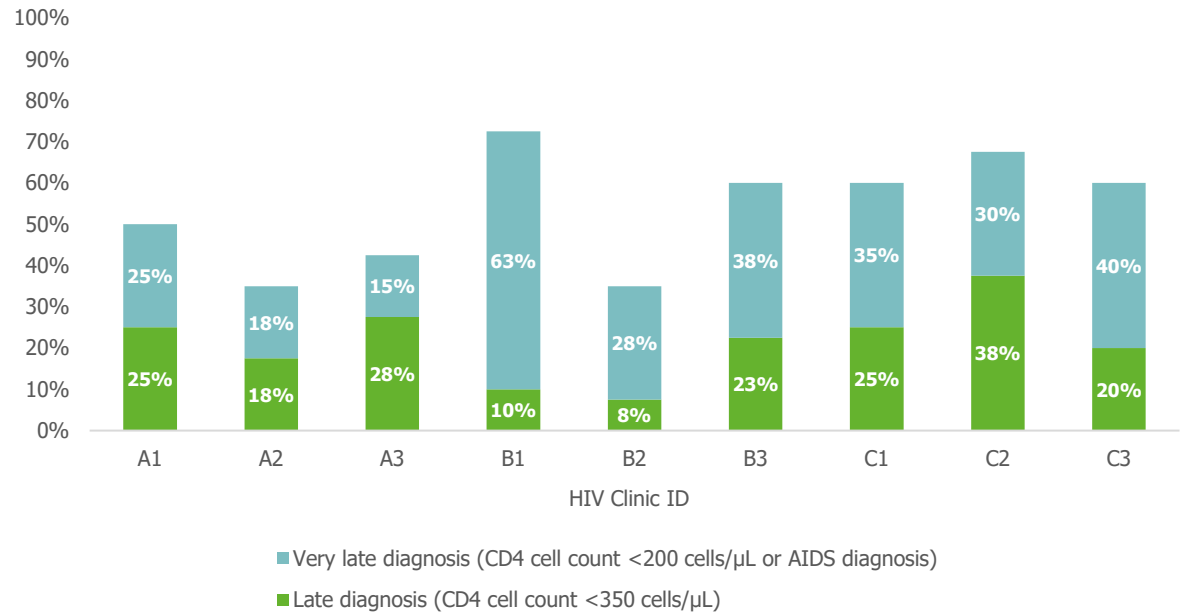
Table 3. General standard of care for HIV testing: quality statements and indicators selected for this audit

General standard of care for HIV testing		
Quality statement	**Indicator**	**Source**
Everybody living with HIV should be aware of their status in order to access timely treatment and care.	Percentage of people living with HIV who are aware of their status (target: 95%).	Dublin Declaration HIV monitoring
Everybody living with HIV should be aware of their status in order to access timely treatment and care.	Percentage of people diagnosed late (CD4 cell count <350 cells/μL) or very late (CD4 cell count <200 cells/μL or AIDS diagnosis) (target: decrease in total number of people diagnosed late by 2% per annum).	Clinical audit

According to the first standard, which is based on the 'first 95' UNAIDS target, 95% of people living with HIV should be aware of their status. With regard to the three countries where the clinical audit was conducted, 91.2% of people living with HIV in Greece know their status, compared with 81.3% in Poland and 89.2% in Romania. None of the three countries has therefore achieved the 95% target.

The target 'Percentage of people diagnosed late (CD4 cell count <350 cells/μL) or very late (CD4 cell count <200 cells/μL or AIDS diagnosis) should decrease by 2% every year' aims to improve timely access to treatment and care. This audit did not look at performance over time but can provide a baseline measure for this indicator for future audits. Overall, at the individual clinic level, the percentage of people diagnosed late or very late ranged from 35.0% (clinic B2) to 72.5% (clinic B1), highlighting the need for some clinics to focus on reducing late HIV diagnoses. Specifically, the number of people diagnosed late (CD4 cell count <350 cells/μL) ranged from three out of 40 (7.5%, in clinic B2) to 15 out of 40 (37.5%, in clinic C2), while the number of people diagnosed very late (CD4 cell count <200 cells/μL or AIDS diagnosis) ranged from six (15%, in clinic A3) to 25 (62.5%, in clinic B1) (Figure 4). In Poland, Clinic B2 appeared to diagnose patients earlier than the other two clinics, with 35.0% diagnosed late or very late, compared to 72.5% and 60.0% in clinics B1 and B3 respectively.

Figure 4. Percentage of people diagnosed late (CD4 cell count <350 cells/μL) or very late (CD4 cell count <200 cells/μL or AIDS diagnosis), per HIV clinic (n=9)



5 Standards for HIV testing policies

To assess standards for HIV testing policies, this audit focused on the quality statements and indicators detailed in Table 4. These standards were assessed at the national level.

Table 4. Standards for HIV testing policies: quality statements and indicators selected for the audit

Standards for HIV testing policies		
Quality statement	**Indicator**	**Source**
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.	Percentage of national HIV testing strategies that include community-based testing for at least one key population (target: 100%).	Dublin Declaration HIV monitoring
HIV self-testing and self-sampling should be offered as additional approach to HIV testing services.	Percentage of national testing strategies that include self-testing and self-sampling (target: 100%).	Dublin Declaration HIV monitoring
HIV 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.	Percentage of national testing strategies with HIV testing algorithms that follow WHO recommendations (target: 100%).	Dublin Declaration HIV monitoring

The standards set a 100% target for including community-based testing of at least one key population in HIV testing strategies, as well as including self-testing and self-sampling. Greece includes community-based HIV testing by medically-trained professionals and by lay providers in national testing guidelines. Poland only includes community-based testing by medically-trained professionals, while Romania does not include any community-based HIV testing.

With regard to the standard of including self-testing and self-sampling in 100% of national testing strategies, Greece, Poland and Romania do not include home testing or self-testing in national testing guidelines.

Finally, there is a standard that 100% of national testing strategies with HIV testing algorithms should follow WHO recommendations [8]. The Western blotting and line immunoassay methods set out in the WHO recommendations are recommended by Greece, Poland and Romania as part of their HIV testing strategies.

6 Standards for HIV testing strategies

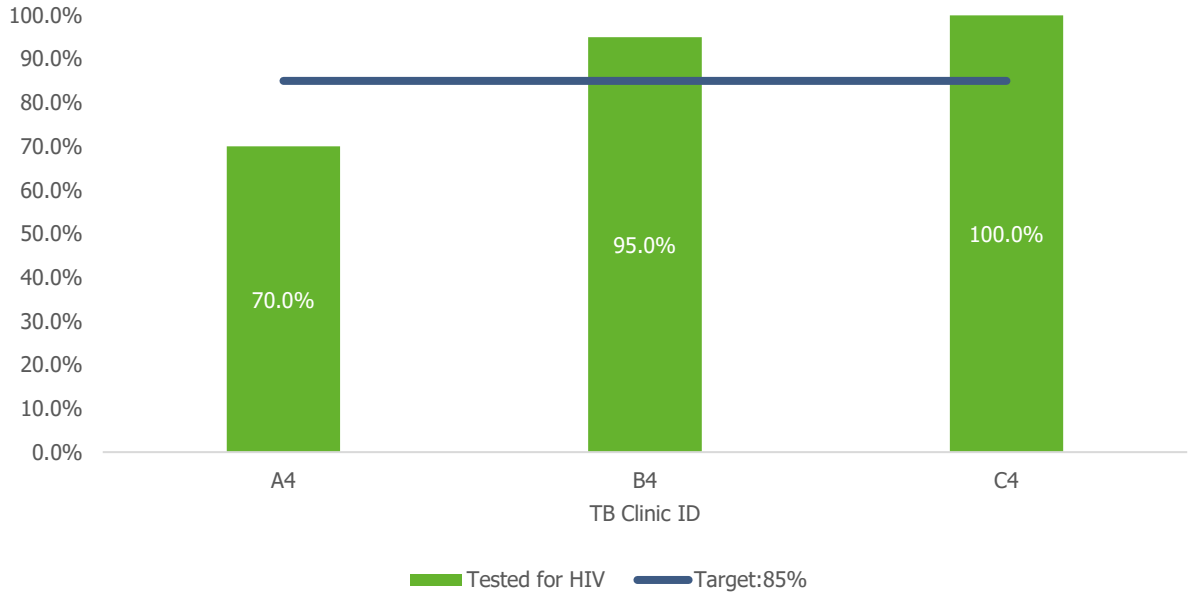
In evaluating standards for HIV testing strategies, this audit referred to the quality statements and indicators detailed in Table 5.

Table 5. Standards for HIV testing strategies: quality statements and indicators selected for the audit

Standards for HIV testing strategies		
Quality statement	**Indicator**	**Source**
HIV testing should be routinely offered and recommended for all people presenting with indicator conditions (ICs) or with symptoms where an IC is included in the differential diagnosis.	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 (target: 85% or annual improvement 5% from baseline/previous year).	Clinical audit
HIV testing promotion messages and communication 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 risk.	Percentage of national HIV testing promotion strategies that focus on key populations (target: 95%).	Clinical audit

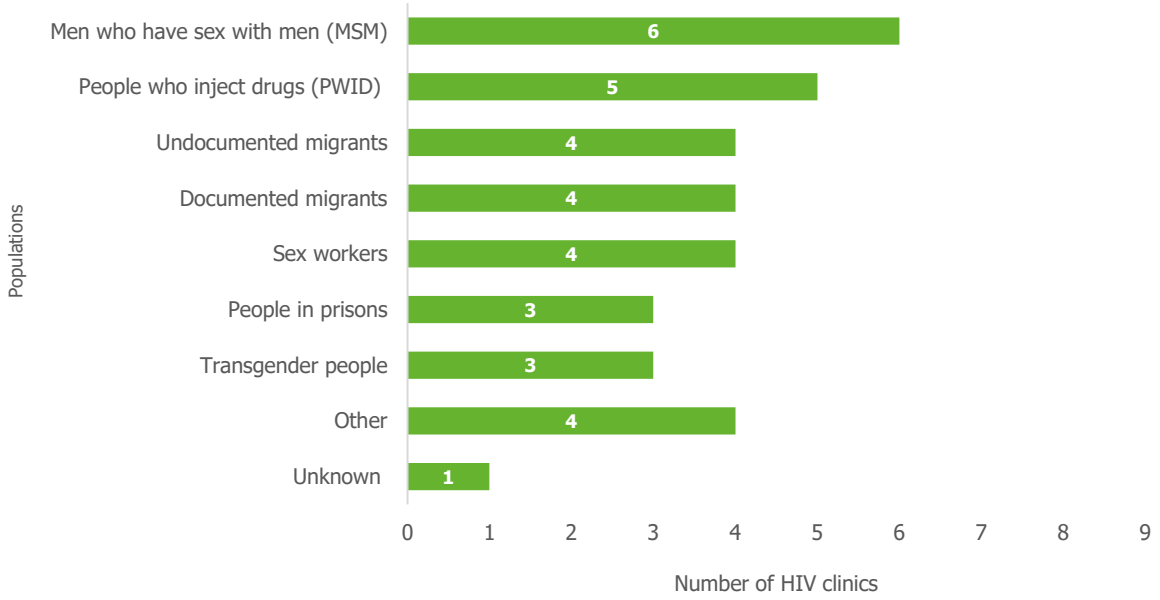
The standards set an 85% target for people presenting with indicator conditions who are tested for HIV. In the three TB clinics, the percentage of people diagnosed with TB who were tested for HIV ranged from 70% (clinic A4) to 100% (clinic C4), with two out of three clinics achieving the 85% target (Figure 5). Of those tested for HIV, the range of reactive results was from 0.5% (clinic C4) to 71.4% (clinic A4).

Figure 5. Percentage of people diagnosed with TB who were tested for HIV, per TB clinic (n=3)



The target for national HIV testing promotion strategies targeting key populations is 95%. This target was assessed at individual clinic level, as this information is not collected through the Dublin Declaration monitoring. All HIV clinics, except for clinic A3 that selected 'Unknown', responded positively to having HIV testing promotion strategies targeting key populations (88.9% of clinics). Specifically, the most targeted key populations were MSM and people who inject drugs, with variations between clinics from the same country (Figure 6). Four clinics that selected the 'Other' option stated that the focus for their HIV testing promotion strategies was on all individuals who may be at risk.

Figure 6. Number of HIV testing promotion strategies focusing on key populations, per HIV clinic (n=9)



7 Standards relating to consent for HIV testing

This audit evaluated the standards relating to consent for HIV testing with reference to the quality statements and indicators detailed in Table 6.

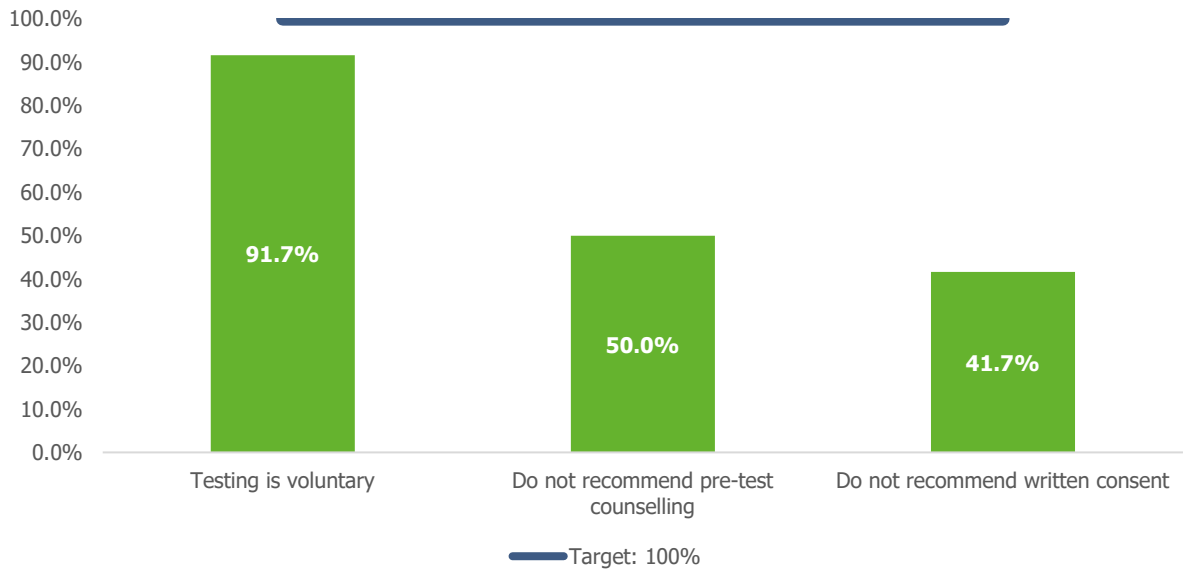
Table 6. Standards relating to consent for HIV testing: quality statements and indicators selected for the audit

Standards relating to consent for HIV testing		
Quality statement	**Indicator**	**Source**
HIV testing should be voluntary in all situations.	Proportion of national HIV testing strategies, guidelines or policies that state HIV testing should be voluntary (target: 100%).	Dublin Declaration HIV monitoring (country level) Clinical audit (clinical level)
Individualised pre-test counselling and written consent for HIV testing should no longer be required when undertaking HIV testing.	Proportion of national HIV testing strategies, guidelines or policies that do not recommend pre-test counselling or written consent (target: 100%).	Dublin Declaration HIV monitoring (country level) Clinical audit (clinical level)

The standards set a 100% target, requiring HIV testing policies to state that testing is voluntary and does not require pre-test counselling or written consent. Greece, Poland and Romania report voluntary testing. In Greece and Poland, pre-test counselling and written consent are required in some settings, while in Romania these are required in all settings.

Similarly, at the individual clinic level, the targets relating to standards for consent are not reached. While clinics reported that HIV testing is voluntary in all clinics except one TB clinic (Clinic A4), only about half of clinics do not recommend pre-test counselling (six clinics) or written consent (five clinics) (Figure 7). For pre-test counselling and written recommendations, responses varied between clinics within the same country, highlighting differences in clinical practice even within national settings.

Figure 7. Proportion of clinics with standards for consent (voluntary testing, pre-test counselling, written consent), per clinic (n=12)



8 Standards for HIV diagnosis and transfer to care

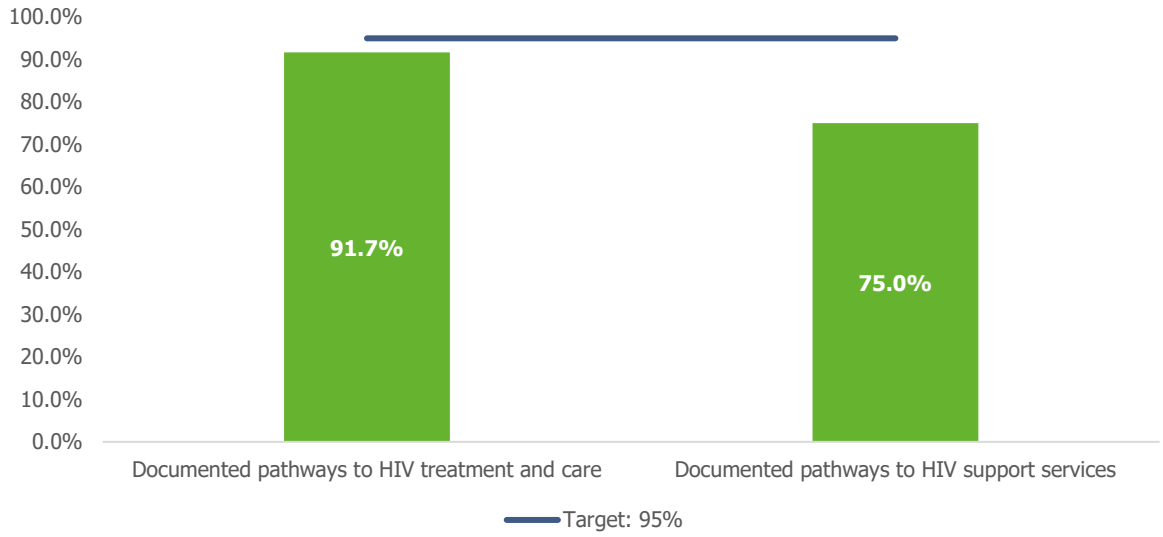
To assess standards for HIV testing policies, this audit focused on the quality statements and indicators detailed in Table 7. These standards were assessed at the individual clinic level.

Table 7. Standards for HIV diagnosis and transfer to care: quality statements and indicators selected for the audit

Standards for HIV diagnosis and transfer to care		
Quality statement	**Indicator**	**Source**
All HIV testing services, including those in the community 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.	Proportion of HIV testing services with documented care pathways to HIV treatment and support services (target: 95%).	Clinical audit
A confirmatory test should be offered within five working days of a reactive HIV test, in order to facilitate timely access to treatment, care and support.	Proportion of people having a confirmatory test within five working days of a reactive HIV test (target: 90%).	Clinical audit
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 of two weeks after the result of the confirmatory test is available.	Proportion of newly diagnosed patients attending an HIV specialist appointment within two weeks of their initial HIV diagnosis (Exclusion: people offered an appointment within two weeks who decline) (target: 90%).	Clinical audit
Antiretroviral therapy (ART) initiation should occur as soon as possible following a confirmed HIV diagnosis, taking into account patient preference and clinical condition.	Median time for newly diagnosed individuals to commence ART (no target).	Clinical audit
Partner notification should be voluntary, offer anonymity and provider-assisted referral, and be mindful of a patient's personal safety. Partner notification should be initiated in a timely manner by the service confirming the HIV diagnosis.	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 this was initiated at the reactive result appointment) (target: 95%).	Clinical audit

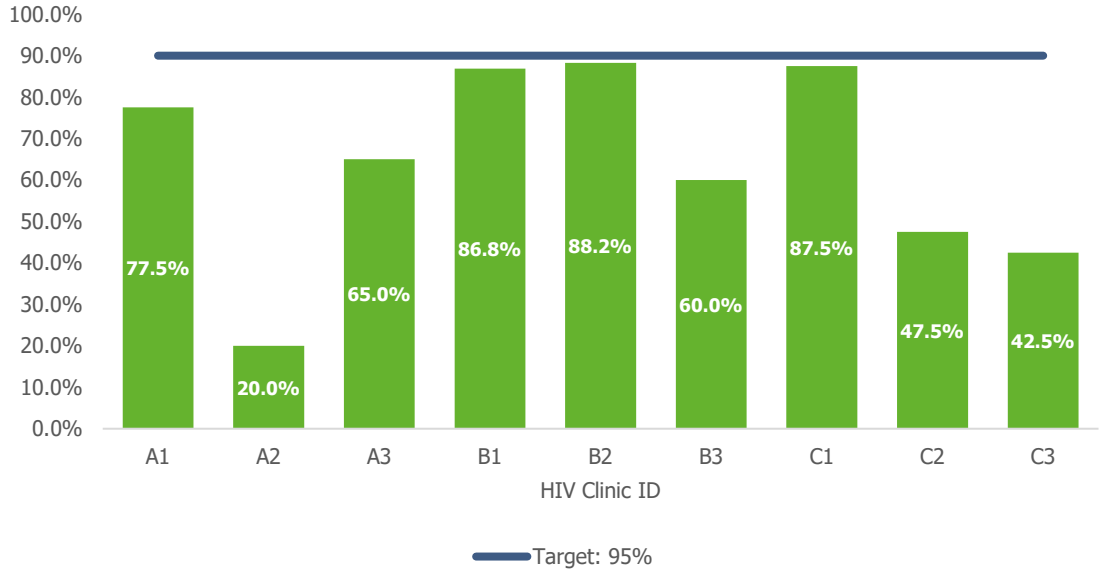
The 95% target for documented HIV care pathways was reached in the HIV clinics, with all HIV clinics and two TB clinics (clinics A4 and B4) having these pathways (Figure 8). Nine clinics, seven HIV clinics (all except for the Greek clinics B2 and B3) and two TB clinics (clinics A4 and C4) have documented pathways to HIV support services.

Figure 8. Percentage of clinics with documented care pathways to HIV treatment and support services (n=12)



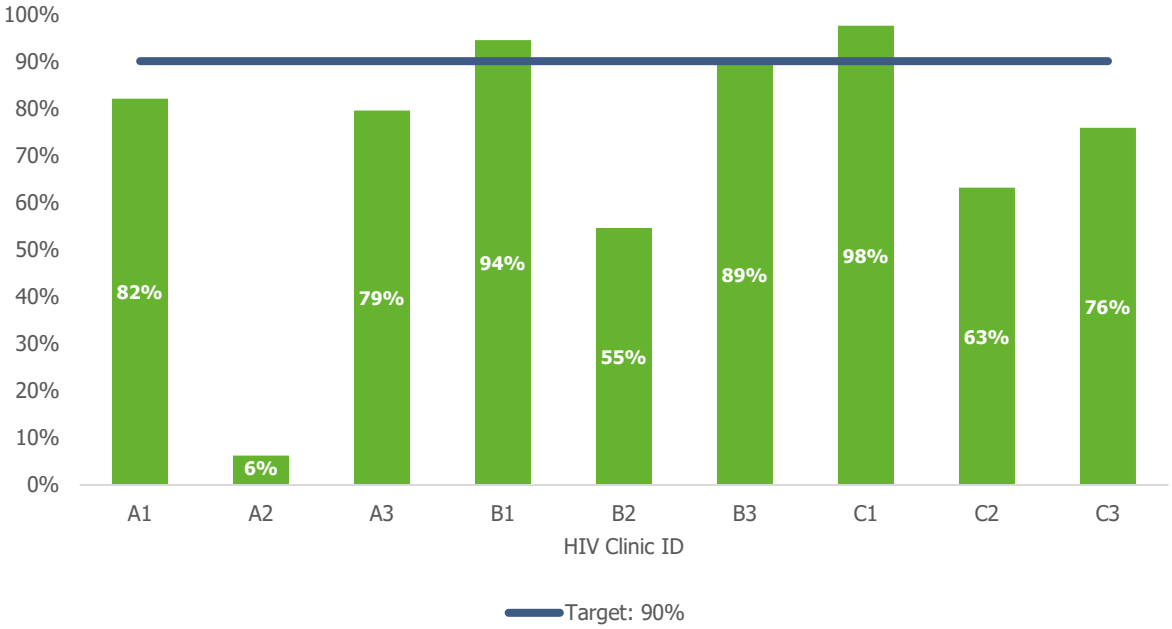
None of the nine HIV clinics met the 90% target for providing a confirmatory test within five working days of a reactive HIV test (Figure 9). The proportion ranged between 20.0% (clinic A2) and 88.2% (clinic B2). Variations in clinic performance were also observed within the same country. This highlights the need to improve timely access to confirmatory testing in order to meet recommended standards and ensure prompt linkage to care.

Figure 9. Proportion of people having a confirmatory test within 5 working days of a reactive HIV test, per HIV clinic (n=9)



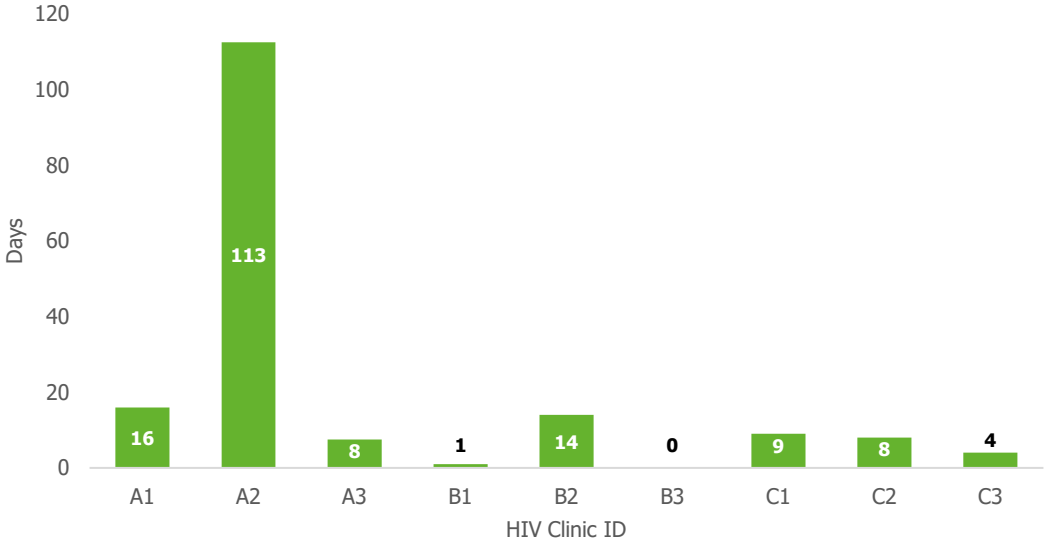
In a similar pattern, with the exclusion of people who were offered an HIV specialist appointment within two weeks but declined, two clinics (clinics B1 and C1) achieved the 90% target of newly diagnosed patients attending an HIV specialist appointment within two weeks (10 days) of their initial HIV diagnosis, with the proportion ranging between 6.3% (clinic A2) and 97.5% (clinic C1) (Figure 10).

Figure 10. Proportion of newly diagnosed patients attending an HIV specialist appointment within two weeks of their initial HIV diagnosis, per HIV clinic (n=9)



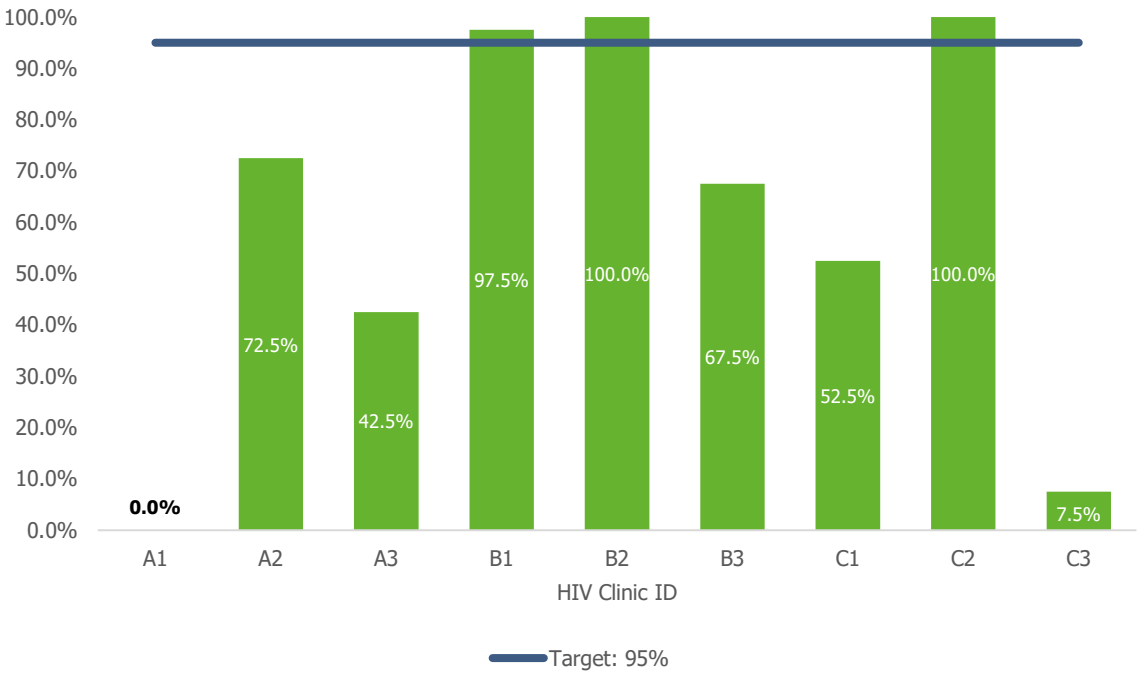
The median time for newly diagnosed individuals to commence ART ranged from 0 days (clinic B3) to 113 days (clinic A2) (Figure 11). The reasons for potential delays in commencing ART were: patient choice (45 patients overall), limited appointment availability (20 patients overall), delays in obtaining results (20 patients overall), other issues such as administrative issues (in the case of migrants), and following guidelines in effect at the time suggesting that ART should be started when CD4 cell count dropped below 350 cells/μL (in Greece in particular).

Figure 11. Median time (in days) for newly diagnosed individuals to commence ART, per HIV clinic (n=9)



Three clinics (clinics B1, B2 and C2) achieved the 95% target of newly diagnosed patients with a documented discussion of, or referral for partner notification, with the proportion ranging from 0.0% (clinic A1) to 100.0% (clinics B2 and C2) (Figure 12). Variations in clinic performance were also observed within the same country, indicating differences in clinical practice. Ensuring documented discussion or referral for partner notification is essential, as it promotes timely testing and treatment for partners and contributes to broader HIV prevention efforts.

Figure 12. 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, per HIV clinic (n=9)



9 Standards for monitoring and evaluation

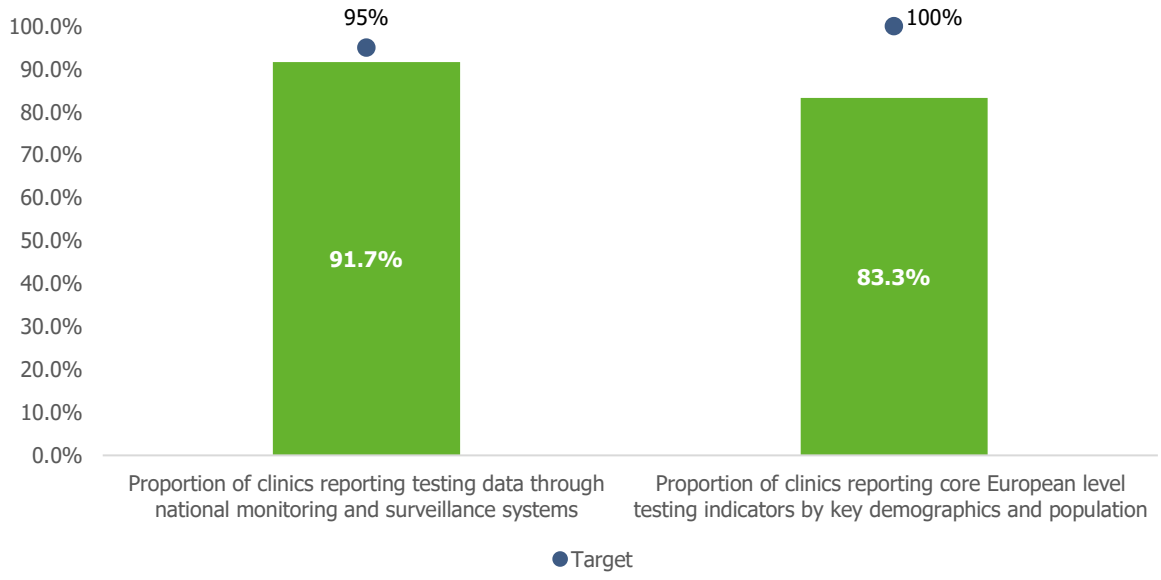
In evaluating standards for the monitoring and evaluation of HIV testing, this audit referred to the quality statements and indicators detailed in Table 8. These standards were assessed at the individual clinic level.

Table 8. Standards for monitoring and evaluation: quality statements and indicators selected for the audit

Standards for monitoring and evaluation		
Quality statement	**Indicator**	**Source**
All HIV testing services should report testing data through standard national monitoring and surveillance systems.	Proportion of HIV testing services reporting testing data through national monitoring and surveillance systems (target: 95%)	Clinical audit
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.	Proportion of countries reporting core European-level testing indicators by key demographics and population (target: 100%).	Clinical audit

All clinics, including the TB clinics, were asked about reporting testing data through national monitoring and surveillance systems. While one TB clinic (clinic B4) selected 'Unknown', all other clinics (91.7%) report testing data through national monitoring and surveillance systems (Figure 13). Of these eleven clinics, six HIV clinics and two TB clinics only report positive HIV tests, while three clinics (clinics B3, C1 and C2) report the total number of tests (both negative and positive). All HIV clinics and one TB clinic (clinic C4) reported the core European-level testing indicators by key demographics (83.3% of clinics).

Figure 13. Proportion of clinics reporting testing data through national monitoring and surveillance systems, per clinic (n=12)



10 Conclusions

This is the first audit of the Standards of Care module on HIV testing. While the Dublin Declaration HIV monitoring collects data on many of the outcome and structural indicators in the HIV Testing Standards of Care module, cyclical audits at the individual clinic level can provide information on many of the process indicators in the module.

While some countries and clinics included in this audit have achieved specific targets, improvements at both the national and clinic levels are still required in many areas of the standards of care to consistently meet these targets. Expanding community-based HIV testing is essential, as it can reach populations who may face barriers to accessing traditional healthcare, including stigma, limited access, or concerns about confidentiality. Similarly, wider implementation of home testing and self-testing can lower structural and psychological barriers to testing, promote earlier diagnosis, and increase overall testing uptake. With regard to consent standards, revisions to pre-test counselling and written consent requirements are needed at both the country and clinic level. Simplifying these procedures can help normalise HIV testing as part of routine healthcare, reduce missed testing opportunities, and support more rapid and widespread identification of undiagnosed infections, while still ensuring informed and voluntary participation.

At the individual clinic level, late and very late HIV diagnoses remain a major challenge. Reducing late diagnosis is critical, as individuals diagnosed at advanced stages of infection experience significantly worse health outcomes, including higher morbidity and mortality, and require more complex and costly medical care. Furthermore, undiagnosed individuals are more likely to unknowingly transmit HIV, meaning that earlier diagnosis is essential not only to improve individual health outcomes, but also to reduce onward transmission at the population level. Although documented care pathways are in place, further improvements are needed in confirmatory diagnosis, timely linkage to care, and documentation of partner-notification discussions. Strengthening these processes is important to ensure that individuals who test positive are rapidly connected to treatment and support services, which improves clinical outcomes and contributes to viral suppression at the population level. Interestingly, variations in clinical performance were observed even within the same countries, suggesting that differences in local clinical practices, resources, or implementation of guidelines may influence outcomes. This highlights the importance of sharing best practices and strengthening efforts for quality improvement across clinical settings.

Overall, this audit report has proven to be a useful tool to assess whether priority indicators and targets set by the standards of HIV testing are being met at the country level, as well as at clinic level. This report demonstrates the added value of audits using clinic-level data to assess HIV testing guideline implementation, reveal shortcomings, support policy and clinic improvement, and advocate for better access for people living with HIV. This audit tool is now available and countries and clinics are encouraged to conduct such audits independently and on a regular basis.

The results from the clinical audit are specific to the participating clinics and not generalisable to the broader European context. This and possible selection bias of the clinics should be considered when interpreting the results.

Next steps

The results have been shared with the participating clinics to allow them to contextualise their findings and identify potential areas for improvement.

Participation in the clinical audit may be expanded to a larger number of clinics to strengthen the representativeness of findings and enhance the robustness of future audits. In addition, future audits would benefit from greater automation and stronger support from public health institutions, particularly for the clinical components, to streamline implementation, enable continuous and cyclical monitoring and improvement of HIV testing, and establish a formal mechanism for sharing and addressing results.

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Annex 1. Clinical audit questionnaire

Part One (for both HIV clinics and TB clinics)

Clinic ID (country code-clinic code): _____
Estimated number of individuals seen in your service annually: _____

a. For HIV clinics:

- *How many individuals were tested for HIV in your service in 2024? (please estimate if you do not know the exact number)*

Men who have sex with men (MSM): _____
Sex workers: _____
People who inject drugs (PWID): _____
Transgender people: _____
People in prisons: _____
Documented migrants: _____
Undocumented migrants: _____
Other (please specify): _____
Unknown: _____

- *How many of these tested positive for HIV? (please estimate if you do not know the exact number)*

Men who have sex with men (MSM): _____
Sex workers: _____
People who inject drugs (PWID): _____
Transgender people: _____
People in prisons: _____
Documented migrants: _____
Undocumented migrants: _____
Other (please specify): _____
Unknown: _____

b. For TB clinics:

- *How many individuals were diagnosed with TB in your service in 2024? (please estimate if you do not know the exact number)* _____
- *How many of these were tested for HIV? (please estimate if you do not know the exact number)* _____
- *How many of these tested positive for HIV? (please estimate if you do not know the exact number)* _____

Policy questions:

- Does your clinic have HIV testing promotion strategies targeting the following key populations? (more than one option can be ticked) *(Note: this question was not asked to TB clinics)*

  - ☐ Men who have sex with men (MSM)
  - ☐ Sex workers
  - ☐ People who inject drugs (PWID)
  - ☐ Transgender people
  - ☐ People in prisons
  - ☐ Documented migrants
  - ☐ Undocumented migrants
  - ☐ Other (please specify)
  - ☐ Unknown.

- Regarding policies on HIV testing in your service:

	True	False	Other (specify)	Unknown
HIV testing is voluntary				
HIV testing requires pre-test counselling				
HIV testing requires written consent				
Your clinic/service has documented pathways to HIV treatment and care				
Your clinic/service has documented pathways to HIV support services*				

**HIV support services: peer support, community support, psychological support, etc.*

Monitoring and evaluation:

- Does your clinic/service report testing data through national monitoring and surveillance systems?
    - Yes
    - No
    - Other (please specify)
    - Unknown

If yes/other:

What data does this include? (more than one option can be ticked)

- ☐ Positive HIV tests
- ☐ Total number of tests (negative and positive)
- ☐ Other (specify)
- ☐ Unknown

Is testing data reported broken down by demographics?

- Yes
- No
- Other (please specify)
- Unknown.

Part Two (for HIV clinics)

Case audit number (ClinicID-PatientID): _____

Demographic information

- Gender of patient:
    - Male (including transmen)
    - Female (including transwomen)
    - Nonbinary
    - Other (please specify)
    - Unknown
- Is this the same as their sex at birth?
    - Yes
    - No
    - Unknown
- Age: _____(if unknown write 999)
- Ethnicity:
    - White
    - Black African
    - Black Caribbean
    - Asian
    - Mixed race (please specify)
    - Other (please specify)
    - Unknown
- Country of birth: _____(if unknown select 'unknown')
- Is the patient part of any of the following key populations? * (select at least one option)
    - ☐ Men who have sex with men (MSM)
    - ☐ Sex workers
    - ☐ People who inject drugs (PWID)
    - ☐ Transgender people
    - ☐ People in prisons
    - ☐ Documented migrants
    - ☐ Undocumented migrants
    - ☐ Other (please specify)
    - ☐ None of the above
    - ☐ Unknown

Audit data

- Date of first reactive HIV test: _____ (DD-MM-YYYY) *

**This includes home testing and sampling, rapid point of care testing, routine blood serology.*

Did the patient receive a confirmatory* positive HIV test?

* *A second blood sample tested for HIV*

- Yes
- No
- Other (specify)
- Unknown

If yes/other,

- Date of confirmatory positive HIV test: _____(DD-MM-YYYY)
- Is there documentation of discussion of or referral for partner notification?
  - Yes
  - No
  - Other (please specify)
  - Unknown

- Did the patient attend an HIV specialist appointment?*

  **This refers to an appointment where an HIV specialist clinician assesses clinical status, undertakes relevant investigations, and discusses HIV and its management.*

  - Yes
  - No
  - Patient was referred to an HIV specialist centre, but it is not known if they attended
  - Other (specify)
  - Unknown

If yes/other:

- Date of HIV specialist appointment: _____ (DD-MM-YYYY)

- Is measurement of CD4 count available (first measurement since diagnosis)?
  - Yes
  - No
  - Other (specify)
  - Unknown
  - If yes/other:

If yes, CD4 cell count, first measurement since diagnosis:

Date: _____ (DD-MM-YYYY)
Measurement: _____ cells/µl

If no,

- Reason for no CD4 cell count measurement: _____
- Did the patient commence antiretroviral treatment (ART)?
  - Yes
  - No
  - Other (specify)
  - Unknown

  If yes/other

  - Date of ART commencement: _____ (DD-MM-YYYY)

- If the time between the diagnosis and ART commencement was greater than 2 weeks (10working days), what was the specific reason for this?

  - ☐ There was no delay
  - ☐ Results were delayed
  - ☐ Patient choice
  - ☐ Less appointment availability
  - ☐ Other (specify)
  - ☐ Unknown

Any further comments:

_____

Part Two (for TB clinics)

Case audit number (country-clinic-patient): _____

Demographic information

- Gender of patient:
  - Male (including transmen)
  - Female (including transwomen)
  - Nonbinary
  - Other (please specify)
  - Unknown
- Is this the same as their sex at birth?
  - Yes
  - No
  - Unknown
- Age: _____ (if unknown write 999)
- Ethnicity:
  - White
  - Black African
  - Black Caribbean
  - Asian
  - Mixed race (please specify)
  - Other (please specify)
  - Unknown
- Country of birth: _____
- Is the patient part of any of the following key populations? (select at least one option)
  - Men who have sex with men (MSM)
  - Sex workers
  - People who inject drugs (PWID)
  - Transgender people
  - People in prisons
  - Documented migrants
  - Undocumented migrants
  - Other (please specify)
  - None of the above
  - Unknown

Audit data

- Date of attendance (either with diagnosed TB or for investigations related to TB): _____ (DD-MM-YYYY)
- Date of TB diagnosis: _____ (DD-MM-YYYY)
- Was the patient tested for HIV in relation to the attendance for TB?
  - Yes
  - No
  - No but had been tested prior to attendance at referring service –if select this ask for result
  - Unknown

  Only if yes/second no option,
  - Date of HIV test: _____ (DD-MM-YYYY)
  - Result of HIV test:
    - Reactive
    - Non-reactive
    - Unknown.

  Only if reactive:
  - Did the patient receive a confirmatory* positive HIV test?

    ** A second blood sample tested for HIV*
    - Yes
    - No
    - Other (specify)
    - Referred to HIV service
    - Unknown

  If yes/other,
  - Date of confirmatory positive HIV test: _____(DD-MM-YYYY)

Any further comments: _____

Annex 2a. Demographic information of participants at HIV clinics (n=9)

Clinic ID	Total	Male, including transmen (% of total)	Same sex as birth (% of total)	Average age (range)	Ethnicity (% of total)	Same country as clinic (% of total)	Key population (% of total)	Other' key population (free text)
A1	40	33 (82.5%)	40 (100.0%)	44.8 (23–75)	White: 39 (97.5%) Black African: 1 (2.5%)	37 (92.5%)	MSM: 17 (42.5%) PWID: 5 (12.5%) People in prisons: 2 (5.0%) Other: 1 (2.5%)	Heterosexual partner (1)
A2	40	34 (85.0%)	40 (100.0%)	47.6 (25–73)	White: 40 (100.0%)	37 (92.5%)	MSM: 21 (52.5%) PWID: 9 (22.5%) Other: 1 (2.5%)	Seropositive heterosexual partner (1)
A3	40	36 (90.0%)	39 (97.5%)	38.1 (22–66)	White: 39 (97.5%) Black African: 1 (2.5%)	32 (80.0%)	MSM: 29 (72.5%) PWID: 5 (12.5%) Transgender: 1 (2.5%) Migrant: 1 (2.5%)	
B1	40	29 (72.5%)	40 (100.0%)	39.3 (19–59)	White: 38 (95.0%) Black African: 2 (5.0%)	25 (62.5%)	MSM: 14 (35.0%) PWID: 2 (5.0%) Migrants: 13 (32.5%) Other: 1 (2.5%)	Bisexual (1)
B2	40	33 (82.5%)	40 (100.0%)	38.3 (22–56)	White: 39 (97.5%) Black African: 1 (2.5%)	30 (75.0%)	MSM: 22 (55.0%) PWID: 3 (7.5%) People in prisons: 3 (7.5%) Migrants: 9 (22.5%) Other: 1 (2.5%)	Former war prisoner (1)
B3	40	30 (75.0%)	38 (95.0%)	35.6 (21–63)	White: 40 (100.0%)	26 (65.0%)	MSM: 17 (42.5%) PWID: 2 (5.0%) Transgender: 2 (5.0%) Migrants: 12 (30.0%)	
C1	40	34 (85.0%)	40 (100.0%)	37.5 (21–66)	White: 39 (97.5%) Asian: 1 (2.5%)	39 (97.5%)	MSM: 2 (5.0%) PWID: 5 (12.5%) Migrants: 1 (2.5%) Other: 11 (27.5%)	Multiple sexual partners (11)
C2	40	36 (90.0%)	40 (100.0%)	31.9 (19–75)	White: 40 (100.0%)	39 (97.5%)	MSM: 26 (65.0%) Other: 1 (2.5%)	Pregnant woman (1)

Clinic ID	Total	Male, including transmen (% of total)	Same sex as birth (% of total)	Average age (range)	Ethnicity (% of total)	Same country as clinic (% of total)	Key population (% of total)	Other' key population (free text)
C4	40	24 (60.0%)	39 (97.5%)	39.1 (20–66)	White: 40 (100.0%)	40 (100.0%)	MSM: 4 (10.0%) Other 4 (10.0%)	Bisexual (4)
Total	**360**	**289 (80.3%)**	**356 (98.9%)**	**39.1 (19–75)**	**White: 354 (98.3%)** **Black African: 5 (1.4%)** **Asian: 1 (0.3%)**	**305 (84.7%)**	**MSM: 152 (42.2%)** **PWID: 31 (8.6%)** **Transgender: 3 (0.8%)** **People in prison: 5 (1.4%)** **Migrants: 36 (10.0%)** **Other: 20 (5.6%)**	

Annex 2b. Demographic information of participants in TB clinics (n=3)

Clinic ID	Total	Male, including transmen (% of total)	Same sex as birth (% of total)	Average age (range)	Ethnicity (% of total)	Same country as clinic (% of total)	Key population (% of total)	Other' key population (free text)
A4	10	9 (90.0%)	10 (100.0%)	46.3 (29–85)	White: 5 (50.0%) Asian: 5 (50.0%)	4 (40.0%)	MSM: 1 (10.0%) Sex workers: 2 (20.0%) PWID: 2 (20.0%)	
B4	20	13 (65.0%)	20 (100.0%)	49.8 (25–74)	White: 19 (95.0%) Asian: 1 (5.0%)	16 (80.0%)	Migrants: 4 (10.0%) Other: 5 (25.0%)	Alcohol abuse (4) Homeless (1)
C4	20	15 (75.0%)	20 (100.0%)	50.9 (30–79)	White: 20 (100.0%)	20 (100.0%)	PWID: 1 (5.0%)	
Total	**50**	**37 (74.0%)**	**50 (100.0%)**	**49.5 (25–85)**	**White: 44 (88.0%)** **Asian: 6 (12.0%)**	**40 (80.0%)**	**MSM: 1 (2.0%)** **Sex workers: 2 (4.0%)** **PWID: 3 (6.0%)** **Migrants: 4 (8.0%)** **Other: 5 (10.0%)**	

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