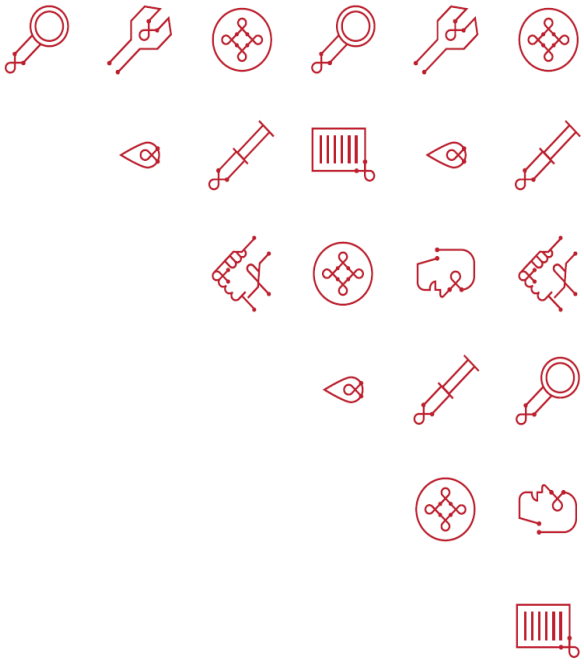
Legal and Policy Barriers to Community HIV testing services and HIV self-testing

A comparative 28-country report



COBATEST NETWORK

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List of Abbreviations

AAE:	AIDS Action Europe
AIDS:	Acquired Immune Deficiency Syndrome
ART:	Antiretroviral therapy
CBVCT:	Community-based voluntary counselling and testing
CSO:	Civil society organization
ECDC:	European Centre for Disease Prevention and Control
GBQMSM:	Gay, bisexual, queer men and other men who have sex with men
HIV:	Human immunodeficiency virus
LGBTQI+:	Lesbian, gay, bisexual, transgender, queer, intersex and others
NGO:	Non-governmental organisation
PLHIV:	People living with HIV
PrEP:	Pre-exposure prophylaxis
STI:	Sexually transmitted infection
TB:	Tuberculosis
UN:	United Nations
UNAIDS:	The Joint United Nations Programme on HIV/AIDS
UNDP:	United Nations Development Programme
UNGASS:	United Nations General Assembly Special Session
U=U:	Undetectable = Untransmittable
VH:	Viral hepatitis
WHO:	World Health Organization

Acknowledgments

The authors would like to thank and acknowledge the COBATEST Network and AIDS Action Europe, their members and other organisations who were partners in this project, provided invaluable information on their national situation regarding community HIV testing and HIV self-testing, and helped identify major issues and barriers to their availability and accessing these services.

Furthermore, the authors would like to thank the staff of AIDS Action Europe and CEEISCAT for their support during the writing of this report, especially Megi Gogishvili from CEEISCAT and Nina Tumanyan and Ferenc Bagyinszky from AIDS Action Europe for their feedback and suggestions that helped shaping this final version of the report.

Should you wish to contact one or more of these organisations for further information on community HIV testing in their national context, please send an inquiry to the COBATEST Secretariat.

Background

The COBATEST Network links community-based voluntary counselling and testing services (CBVCT) across Europe and Central Asia. Established in 2009 within the HIV-COBATEST project under the European Union Public Health Programme, its mission is to promote HIV and other STI testing and linkage to care and treatment, to improve CBVCT services across Europe and Central Asia, to share good practices, procedures and information to improve CBVCT activities, and to provide tools to strengthen collaborative work between professionals. The Secretariat of the COBATEST Network is provided by AIDS Action Europe (AAE) and by the Centre for Epidemiological Studies on HIV/AIDS and STI of Catalonia (CEEISCAT).

AAE is a regional network of more than 370 NGOs, national networks and community-led and -based groups, most of which are HIV service organisations, in 47 countries spanning the WHO European Region. AAE´s mission is to strengthen civil society to work towards a more effective response to the HIV and AIDS, TB and viral hepatitis epidemics in Europe and Central Asia.

CEEISCAT is a structural service of the Catalan Institute of Oncology (ICO). CEEISCAT acts as a reference body for the epidemiological surveillance and monitoring of HIV, STIs and viral hepatitis. The research activity is managed by the Germans Trias i Pujol Research Institute (IGTP), a public research centre dedicated to increasing scientific knowledge and transferring it to improve the care and lives of patients.

Aligned with this objective, AAE and COBATEST Network developed the current report, which explores legal and policy barriers to community HIV testing services and HIV self-testing. The aim of this report is to support CSOs, community organisations and activists, and governmental representatives and policy makers in planning advocacy campaigns, for promoting the access to sexual health services for PLHIV and other key populations, and for overcoming barriers that limit their access to testing.

Definition of CBVCT:

"CBVCT is any program or service that offers HIV counselling and testing on a voluntary basis outside the formal health facilities and that has been designed to target specific groups of the population most at risk and is clearly adapted for and accessible to those communities.

Moreover, these services should ensure the active participation of the community with the involvement of community representatives either in planning or implementing HIV testing interventions and strategies."[1]

Community-led organisations and community-led HIV responses

Community-led HIV responses, including testing, are clearly differentiated from community-based HIV services. According to UNAIDS: *"(a) community-led organizations, groups and networks, whether formally or informally organized, are entities for which the majority of governance, leadership, staff, spokespeople, membership and volunteers, reflect and represent the experiences, perspectives, and voices of their constituencies and who have transparent mechanisms of accountability to their constituencies. Community-led organizations, groups and networks are self-determining and autonomous, and not influenced by government, commercial, or donor agendas. Not all community-based organizations are community-led; and (b) community-led responses are actions and strategies that seek to improve the health and human rights of their constituencies that are specifically informed and implemented by and for communities themselves and the organizations, groups and networks that represent them."*[2]

Lay provider HIV testing

WHO uses the term lay provider for any HIV testing performed by a person trained to use rapid HIV-testing technology. Lay provider HIV testing can take place in a variety of settings.

In this report we will use the term "community HIV testing" to refer to testing conducted in a community-led or –based setting or by a lay provider, unless quoting the original text from guidelines, strategies or reports.

As both the COBATEST Network and AAE have a very diverse membership, we use the term "civil society organisations" (CSOs) when referring to them. We understand and acknowledge that besides HIV testing, they are engaged in providing many other services,

[1] This definition has been developed as part of EURO HIV EDAT Project
[2] UNAIDS. *Community-led AIDS responses: Final report based on the recommendations of the multistakeholder task team.* Available at: https://www.unaids.org/sites/default/files/media_asset/community-led-aids-responses_en.pdf

from STI testing to prevention, mental health and other support services, and also other activities from policy and advocacy work to community strengthening that serve the interest of the communities they are working for.

Introduction

The early diagnosis and treatment of HIV is crucial for reducing infection rates and improving the health outcomes of individuals and communities. PLHIV on effective ART have their viral load suppressed to an undetectable level, which means that they cannot pass on the virus even if other safer sex methods (e.g. a condom) are not used.[3] Community HIV testing has proven effective to detect new HIV cases, especially in communities where access to health care services is limited. "*Based on the WHO's guidelines on HIV Testing Services (HTS) and with the introduction of rapid and self-sampling testing options for HIV, […] CBVCT services are an essential and indispensable element of the responses to [the HIV pandemic].*"[4]

The critical role of community leadership in the HIV response has been reconfirmed in the *Global AIDS Strategy 2021-2026 - End Inequalities* and the 2021 *Political Declaration on Ending AIDS: Ending Inequalities and Getting on Track to End AIDS by 2030*. In the 2021 Political Declaration on Ending AIDS, the United Nations (UN) member states affirmed the key role of communities in advocacy, participation in the coordination of HIV and AIDS responses and service delivery. The Political Declaration has identified priority targets to be achieved by member states by 2025 in relation to HIV services, community leadership, integration,[5] and societal enablers. In the context of **HIV services,** this includes reaching the 95–95–95 testing, treatment and viral suppression targets within all demographics and groups and geographical

[3] Prevention Access Campaign. *Resources*. Available at: https://preventionaccess.org/resources/
[4] AAE. *AIDS Action Europe Strategic plan 2022-2026.* 2021, p. 23. Available at: https://www.aidsactioneurope.org/sites/default/files/2022-07/Work%20ENG%20web%20final.pdf
[5] "Invest in robust, resilient, equitable and publicly funded systems for health and social protection that provide 90% of people living with, at risk of or affected by HIV with people-centred and context-specific integrated services for HIV" UNAIDS. *Summary: Let Communities Lead – UNAIDS World AIDS Day report.* 2023, p. 7. Available at: https://www.unaids.org/sites/default/files/media_asset/2023WADreport-summary_en.pdf

settings.[6] The **community leadership** targets entail the commitment to increase the proportion of community-led HIV services and to ensure that community-led organisations deliver: 30% of testing and treatment services; 80% of HIV prevention services for people from populations at high risk of infection, and 60% of programmes to support societal changes that enable an effective and sustainable HIV response.[7] **Societal enablers** are realised through the 10–10–10 targets, which aim at removing punitive laws against PLHIV and other key populations, including GBQMSM and transgender people, people who use drugs, sex workers, and people from other populations often facing punitive legal environments. These targets also aim at reducing and eliminating HIV-related stigma and discrimination, gender inequality, and violence experienced by PLHIV and people from key populations.[8]

The 2022-2030 WHO Europe strategy on HIV and viral hepatitis (VH) draws attention to the region being off track to meet the **95–95–95** targets, primarily due to the high percentage of late HIV diagnosis and insufficient access to antiretroviral treatment.[9] As highlighted in the WHO Europe Regional action plan, the full range of existing evidence, tools and strategies to address HIV, VH, and STIs do not seem to be utilised by all countries.[10] The availability of community HIV testing services and the level of support provided to them is one of such examples.

Community HIV testing offers a possibility to reach the most vulnerable groups and ensure they learn their HIV status early and have timely linkage and access to treatment and care. During the COVID-19 pandemic, community HIV services played a crucial role in ensuring uninterrupted access to testing, care, treatment and support to everyone, even amid lockdowns that restricted access to treatment and care services and HIV testing in healthcare centres. It also became evident that improved availability and provision of HIV self-test kits,

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[6] United Nations General Assembly. *Political declaration on HIV and AIDS: Ending inequalities and getting on track to end AIDS by 2030.* 2021, p. 14. Available at: https://www.unaids.org/en/resources/documents/2021/2021_political-declaration-on-hiv-and-aids

[7] ibid. p. 18.

[8] UNAIDS. *Let Communities Lead – UNAIDS World AIDS Day report.* 2023, p. 8; p. 93. Available at: https://www.unaids.org/sites/default/files/media_asset/2023WADreport_en.pdf

[9] WHO. *Regional action plans for ending AIDS and the epidemics of viral hepatitis and sexually transmitted infections 2022–2030.* Available at: https://iris.who.int/bitstream/handle/10665/369243/9789289058957-eng.pdf?sequence=7

[10] ibid.

encouraged and supported by communities and their organisations, facilitated the early detection of one's HIV status during these challenging times. However, in many countries of the WHO European Region, such services receive little, unreliable or no funding from national institutions, and community HIV service providers struggle to sustain their activities.

Following consultations with the COBATEST Network member and partner organisations, it became evident that the challenges they face are not limited to the sustainability of funding of services, but extend to policy and legal obstacles. In response to that, AIDS Action Europe and COBATEST Network decided to conduct a survey and develop a report to explore and reflect this situation. **The objectives of this report** are to provide an overview of the landscape in which the COBATEST Network member and partner organisations operate and define legal and policy barriers to community HIV testing and HIV self-testing. In addition, the report provides recommendations and shares new approaches and good practices on how to eliminate the barriers and enable the provision of community HIV testing and HIV self-testing.

Methodology

In the autumn of 2022, a survey was carried out among COBATEST Network and AIDS Action Europe member and partner organisations. The survey covered several areas, including the overall availability of community HIV testing and other services, the legal and policy situation regarding community HIV testing, and the legal and policy situation regarding HIV self-testing as experienced by the COBATEST Network member and partner organisations. The survey was widely disseminated within the network. 38 organisations from 28 countries in Europe and Central Asia submitted their responses. The information provided is based on information publicly available and information requested from different relevant institutions. It reflects the experience of COBATEST Network member and partner organisations during the data collection period. The questionnaire included in Annex 1 to this report contains the following sets of information:

- GENERAL INFORMATION REGARDING COMMUNITY HIV TESTING AND OTHER SERVICES
- LEGAL AND POLICY SITUATION OF COMMUNITY HIV TESTING

- LEGAL AND POLICY SITUATION OF HIV SELF-TESTING

The 38 organisations represented the following 28 countries:

1. Armenia	2. Austria	3. Belgium	4. Croatia	5. Cyprus	6. Czechia
7. Denmark	8. Estonia	9. Georgia	10. Germany	11. Hungary	12. Ireland
13. Italy	14. Kyrgyzstan	15. Latvia	16. Malta	17.Moldova	18. Poland
19. Portugal	20. Romania	21. Russia	22. Serbia	23. Slovakia	24. Slovenia
25. Spain	26. Sweden	27. Turkey	28. Ukraine		

These countries can be assumed to be representative of the epidemiological, political, geographical, and economic diversity, as well as show a diversity of community HIV testing and other services in the WHO European Region, therefore they allow this analysis to approach the presented topic through multiple perspectives.

International and European Guidelines and Policies

In addition to the survey among COBATEST Network and AAE member and partner organisations, the authors of the report undertook desk research in order to produce an overview and create a framework of relevant international and European policies, guidelines, and strategies in the field of community HIV testing and other community HIV services and HIV self-testing.

This section provides an overview of the guidance provided by the WHO Consolidated guidelines[11] on HIV prevention, testing, treatment, service delivery and monitoring, and recommendations for a public health approach.

As defined by the WHO Consolidated guidelines, HIV testing and diagnosis processes as part of the differentiated approach consist of a combination of facility-based HIV testing, community HIV testing, and HIV self-testing. **Facility-based HIV testing** refers to testing in healthcare facilities or in laboratory settings. **Community HIV testing** services are offered within and/or by communities outside of healthcare facilities. **HIV self-testing** is a process in which people collect their own oral fluid or blood sample using a simple HIV rapid diagnostic test and interpret the result themselves.

Community HIV testing

Community HIV testing approach has been recommended by WHO since 2013[12,13] with the aim of expanding testing frequency and coverage, particularly among key populations and their partners. It can be delivered in many forms – testing at fixed locations, mobile outreach at hotspots, community sites and events, etc.

As for training of individuals in charge of performing community HIV testing services, WHO recommendations state that trained lay providers and peers are most suitable for conducting

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[11] WHO. *Consolidate guidelines on HIV testing services.* 2019. Available at: https://www.who.int/publications/i/item/978-92-4-155058-1

[12] WHO. *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection.* 2013, p. 27. Available at: https://www.who.int/publications/i/item/9789241505727

[13] WHO. *Consolidate guidelines on HIV testing services.* 2019, p. 100. Available at: https://www.who.int/publications/i/item/978-92-4-155058-1

HIV rapid diagnostic tests and shall be allowed to do so by the national regulations and policies. These recommendations are in line with the task-sharing approach to HIV testing, where lay providers perform selected tasks instead of the clinical healthcare professionals, alleviating the overload of the healthcare system.

Regarding the role of community HIV testing services within the national settings, the WHO recommendations are as follows[14]:

- In high-HIV-burden settings, lay provider HIV testing services are recommended (in addition to routine facility-based HIV testing) for all populations, particularly key populations.
- In low-HIV-burden settings, lay provider HIV testing services are recommended (in addition to routine facility-based HIV testing) for key populations.
- Lay providers trained and supervised to use rapid HIV tests can independently conduct safe and effective community HIV testing services.

Improving access to HIV testing services

In addition to recommending the implementation of community HIV testing, WHO also outlines several strategies to make HIV testing services more accessible. These strategies include integration, decentralization and task sharing.[15]

Integration of HIV services involves offering HIV testing, prevention, treatment and care services alongside other relevant health services such as services for TB, VH, STIs, sexual health care, primary health care, harm-reduction programmes, etc. Decentralization aims at providing HIV testing in places closer to people's homes in order to increase uptake (and reduce transport costs and waiting times) by conducting HIV testing at health facilities such as primary healthcare clinics.[16] This of course, only if the WHO's essential five Cs for HIV testing

[14] WHO. *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach*. July 2021, p. xv – xvii. Available at: https://www.who.int/publications/i/item/9789240031593

[15] WHO. *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach*. July 2021, p. 30. Available at: https://www.who.int/publications/i/item/9789240031593

[16] Decentralized approach to HIV testing may not always be appropriate. For instance, key populations may fear being seen at a decentralized HIV testing site due to the persisting stigma and discrimination. The desirability of

services are ensured: consent, confidentiality, counselling, correct test results, and connection or linkage to prevention, care and treatment.[17] Task-sharing once again refers to the role of trained lay providers who are able to conduct HIV testing independently, thus address the shortage of medical professionals many countries are currently facing.

HIV self-testing

The third component of the differentiated approach to HIV testing is HIV self-testing that has been recommended by WHO since 2016 as an "additional HIV testing approach"[18] and since 2019 as a "strongly recommended approach to HIV testing" [19]. Over the past few years, the use of HIV self-testing has increased globally, helping countries achieve national a global targets and objectives.[20]

It is necessary to emphasize, however, that although HIV self-testing is an effective tool to reach individuals who would otherwise not have accessed an HIV test; its reactive result is not equivalent to a definitive HIV diagnosis. Individuals with a reactive HIV self-test result must undergo further confirmatory testing by a trained provider. Nonetheless, non-reactive HIV self-test results should be considered negative, and no immediate further testing is necessary (with the exception for those starting PrEP).[21]

When compared to the standard facility-based HIV testing, the WHO points out in its systematic review that the proportion of people diagnosed and linked to care through HIV

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decentralization of HIV testing is therefore situational and such a step must first be properly planned and assessed.

[17] WHO. *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach*. July 2021, p. 10. Available at: https://www.who.int/publications/i/item/9789240031593

[18] WHO. *Guidelines on HIV self-testing and partner notification.* December 2016, p. xvii. Available at: https://www.paho.org/en/documents/guidelines-hiv-self-testing-and-partner-notification-supplement-consolidated-guidelines

[19] WHO. *Consolidated guidelines on HIV testing services*. 2019, p. 100. Available at: https://www.who.int/publications/i/item/978-92-4-155058-1

[20] Muhammad S. Jamil et al*. Examining the effects of HIV self-testing compared to standard HIV testing services in the general population: A systematic review and meta-analysis.* The Lancet. 2021. Available at: https://doi.org/10.1016/j.eclinm.2021.100991

[21] WHO. *Policy Brief: WHO recommends HIV self-testing.* 2016. Available at: https://iris.who.int/bitstream/handle/10665/251549/WHO-HIV-2016.21-eng.pdf?sequence=1

self-testing is comparable to those through facility-based HIV testing.[22] The uptake of HIV self-testing has increased in recent years especially among key populations. Furthermore, according to the WHO review, misuse, adverse events, and social harms often associated with HIV self-testing were rare (and comparable to standard facility-based HIV testing services).

Regarding the role of HIV self-testing in the national HIV response plans and guidelines, the WHO recommendations are as follows[23]:

- HIV self-testing should be offered as an approach to HIV testing;
- Communities need to be engaged in developing and adapting effective HIV self-testing models.

Questionnaire Analysis

Community HIV Testing Services and Practices

Availability of community HIV testing and other related services

All 38 organisations from the 28 countries that submitted the responses to the survey confirmed that they offer community HIV related services to some extent, at least in the form of counselling. In 26 of the 28 countries, community HIV testing is reported to be legal or legal with some exceptions.[24] In the remaining two countries, Turkey and Hungary, the local CSOs are only able to provide community HIV services in the form of counselling. People who are seeking to be tested are referred to healthcare facilities.

Even though the CSO from Hungary does not carry out community HIV testing, some (although limited) options for anonymous HIV testing are available in the country through the

[22] WHO. *Consolidated guidelines on HIV testing services*. 2019, p. 106. Available at: https://www.who.int/publications/i/item/978-92-4-155058-1
[23] WHO. *Consolidated guidelines on HIV testing services*. 2019, p. 109. Available at: https://www.who.int/publications/i/item/978-92-4-155058-1
[24] Such exceptions relate mainly to confirmatory testing and the necessity for a medical worker to be present in every facility that performs HIV testing. See below for more details on the topic of guidelines and rules on testing.

Anonymous AIDS Association (Anonym AIDS Tanácsadó Szolgálat). Booking of appointments is available to the public online.[25] In Turkey, anonymous testing can be performed by municipality-based public health clinics which hold a licence from the Ministry of Health to provide such testing. In practice, only clinics located in geographic areas with a higher representation of the LGBTQI+ community have such a licence. The Turkish CSO then closely cooperates with these municipalities in order to ensure availability of testing for individuals from key populations.

Although the results showed differences in the range and practical use of the community HIV testing services between the countries, all participants considered them invaluable to the HIV response in reaching prevention, testing and treatment targets.

Two countries where no legal framework for community HIV testing exist, reported that it has different effect on the work of organisations. The lack of framework does not necessarily have a limiting effect on the work as reported by the CSOs, but they can create additional barriers not only to performing community HIV testing but also to accessing local funding for this work.

Range and reach of community HIV testing services

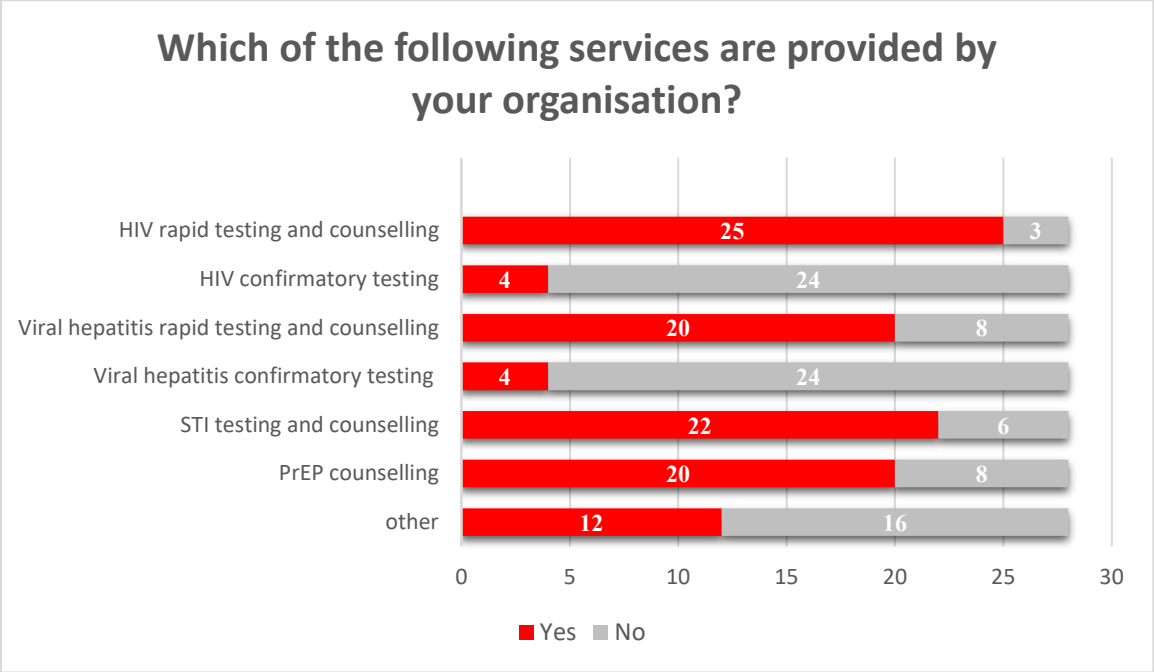
Community HIV testing sites and the services they provide vary greatly in the WHO European Region, including their monthly reach. The data and information on the number of tests performed (and not number of persons tested) by the COBATEST Network member and partner organisations showed that, despite community HIV testing services being legal and available in most of the 28 countries included in this report, there are considerable differences in the practical reach of community HIV testing.

The reasons for these differences vary and include legal barriers encountered by the 38 participating CSOs, the level and sustainability of funding for the services they provide, the scope of these services, the overall access to healthcare, the existence of stigma-free testing options in healthcare facilities, and the availability of self-testing kits.

[25] The Anonymous AIDS Association (AATSZ). Available at: https://anonimaids.hu/en/

The countries with the highest reported average number of community HIV tests per month per 100.000 inhabitants (performed by the CSOs participating in the survey) were Armenia, Denmark, Georgia, Latvia and Portugal.

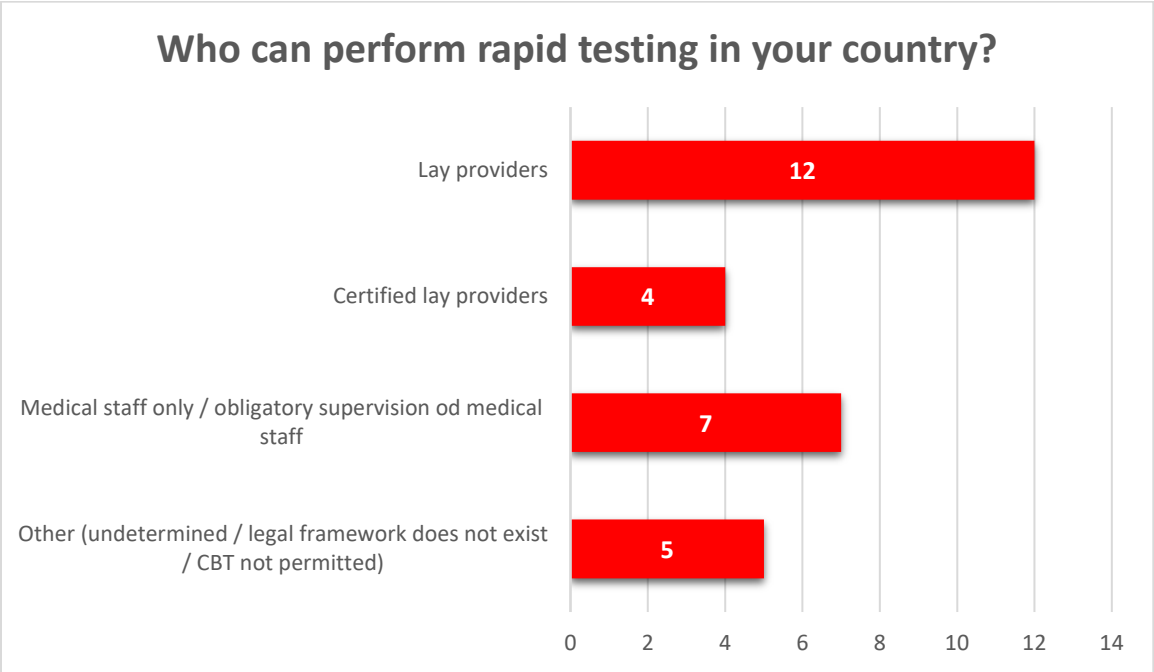
Out of the countries in which community HIV testing is legal, Malta reported the lowest number of tests performed per month per 100.000 inhabitants under available community HIV testing programmes. However, this low number coincides with the wide availability of HIV self-testing kits in the country, which is a preferred method of HIV testing for key populations in Malta. HIV self-testing kits are available for purchase in pharmacies, through CSOs, and online.



Concerning different testing options, there is great variety between the countries in this report. Only 4 out of the 28 participating countries allow CSOs to collect blood samples for confirmatory HIV testing. Even in these cases, the evaluation of the blood sample is predominantly carried out outside the community setting, usually by a lab in a healthcare institution. Moreover, blood sampling can only be performed by medical professionals, i.e. only the CSOs who employ or otherwise directly cooperate with medical professionals may do so; otherwise, persons with reactive rapid tests are referred to a healthcare facility for a confirmatory test.

Qualifications and training

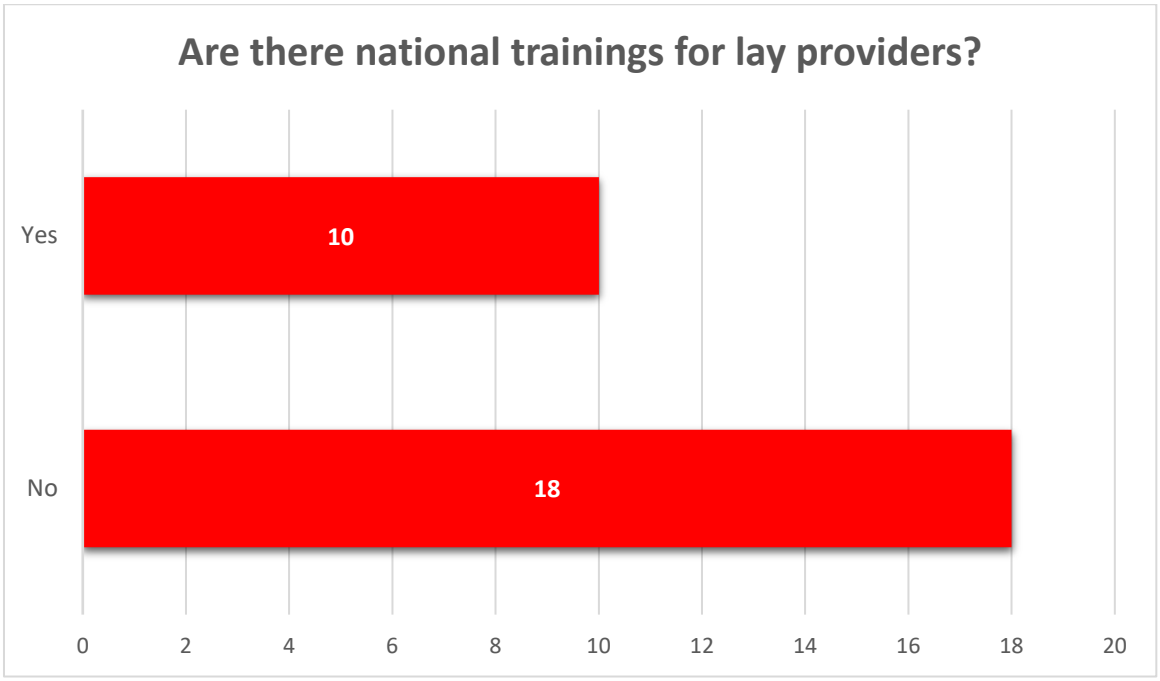
Qualifications necessary for the performance of rapid HIV testing



Qualifications needed to legally perform rapid HIV testing is largely dependent on the level of attention given to the HIV response in each country, i.e. the existence, thoroughness and effective implementation of national HIV plans or guidelines. In countries, where there is a strong focus on HIV and STI prevention (Belgium, Germany, Italy, Poland), official national training for lay providers is available. Following the training, lay providers are legally allowed to perform rapid HIV testing. In other countries, training is provided by the CSOs themselves and is considered to be sufficient (e.g. Ireland, Portugal).

In several of the countries, however, the necessary qualifications of the person performing HIV testing depends on the licence held by the CSO or facility where the rapid HIV testing is performed. The requirements vary between organisations and regions (e.g. Denmark, Sweden).

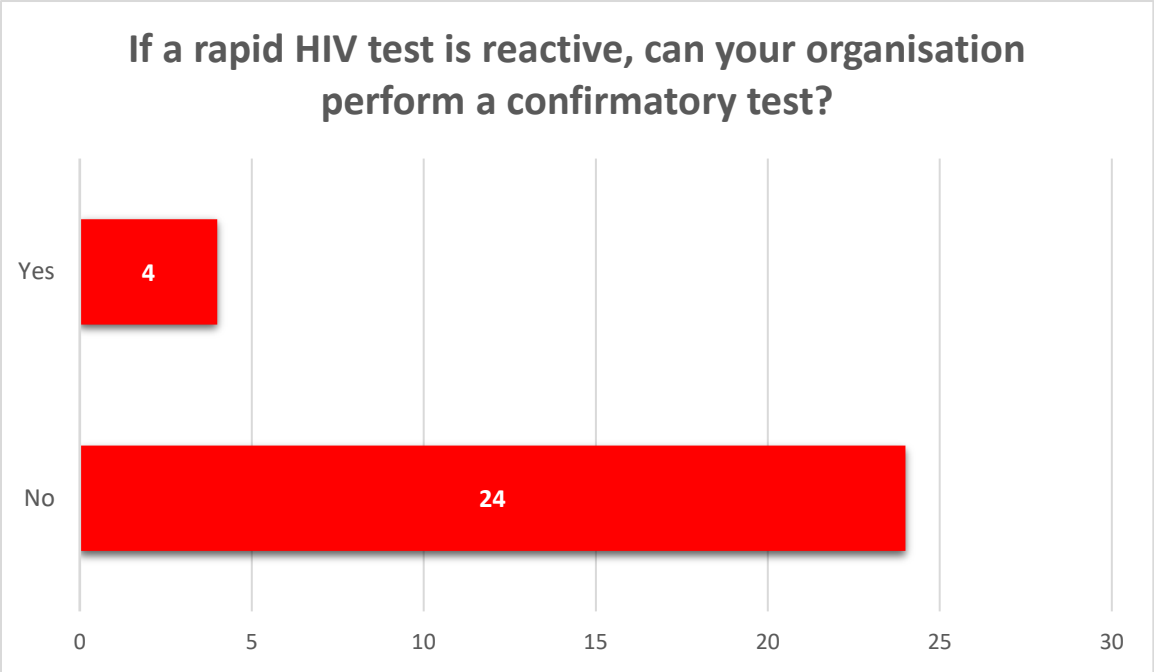
Availability of national training for lay providers



Official national training (i.e. training organized by a public/state body) is indicated to be available in 10 out of the 28 respondent countries. Such training was reported to be available for instance from national HIV centres / national infectious diseases institutes / institutes of public health.

In the remaining countries where rapid HIV tests may be performed by lay providers or certified lay providers, the training is usually one of the core activities of the local CSOs – training is available within the organisation offering HIV rapid testing.

Confirmatory HIV testing

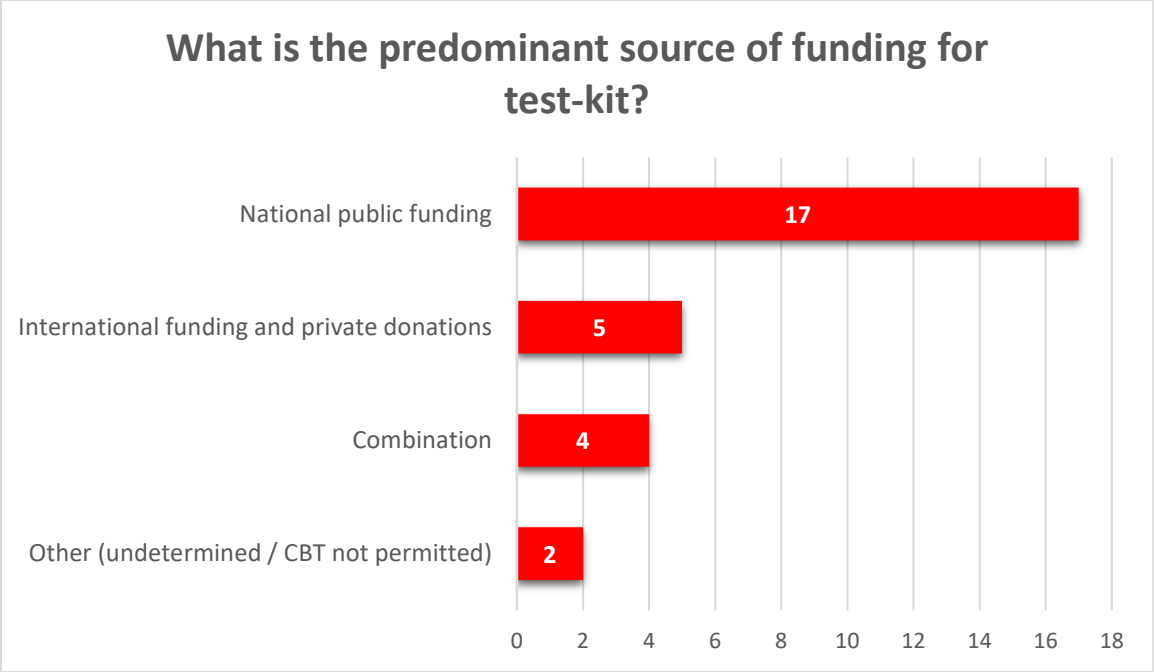


In the vast majority of the countries (24 out of the 28 countries), participating CSOs reported not having a permission to carry out a confirmatory test if the HIV rapid test result was reactive. These CSOs have to refer the respective client to a local healthcare provider, infectious disease clinic or hospital for a confirmatory test. In the four countries, where CSOs can perform confirmatory tests (Austria, Germany, Poland, Spain), they are required to own the equipment necessary to perform confirmatory tests. If they do not own such an equipment, they can still collect blood samples and send them for confirmatory testing.

In Austria, if a rapid HIV test shows a reactive test result, another blood sample is taken by the CSOs after which the sample is sent to a laboratory for evaluation. Similarly to Austria, CSOs from Poland also collect additional blood samples and send them directly to a laboratory for confirmatory evaluation. In Germany, blood sampling for the purpose of confirmatory testing is possible if a medical doctor is present on the CSOs premises (CSOs without a medical doctor must refer their patients to local healthcare providers). In Spain, one of the participating CSOs, 'Apoyo Positivo', utilizes a confirmatory PCR test (GenXpert) after a reactive rapid HIV test. However, confirmatory tests can still only be performed by healthcare professionals.

The general prevailing practice among responding CSOs was that even if a community centre can employ an in-house doctor to draw blood for confirmatory testing, the evaluation is done at an external medical facility.

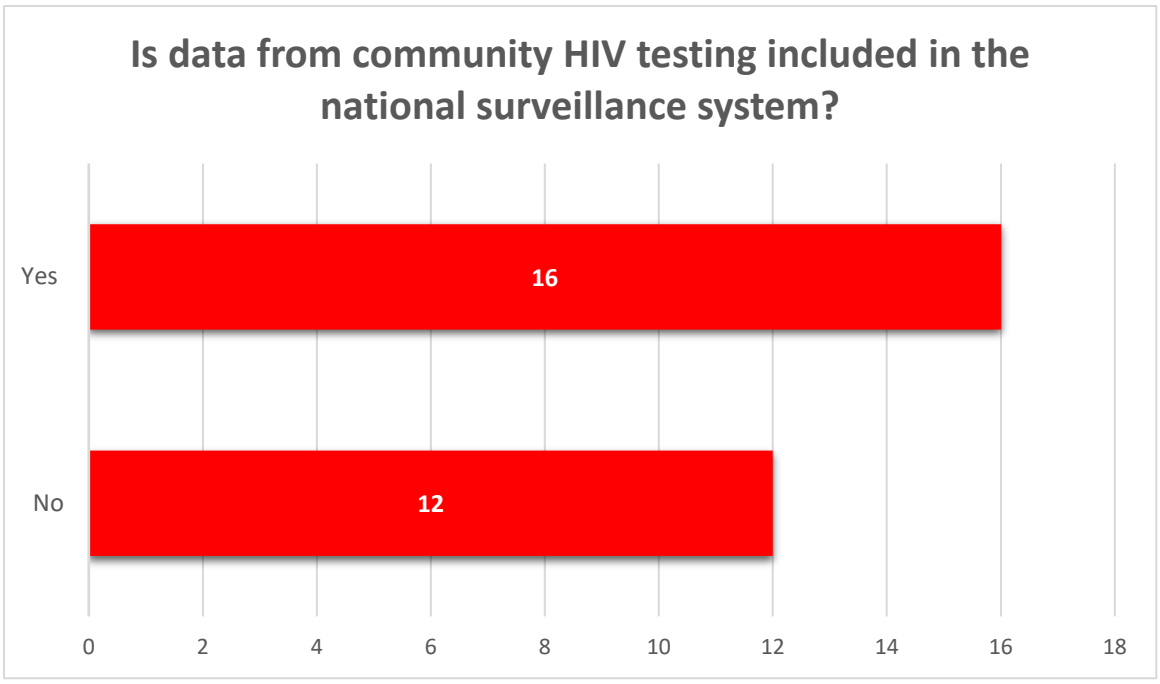
Funding and resources – funding for test-kits



The overall funding for services provided by the CSOs varies from country to country. The majority of survey responses indicate that a large part of the CSOs' budget comes from the public sector (e.g. governmental, ministerial and regional sources). However, many of the CSOs reported that they have to apply for grants annually or biannually (10 out of the 28 countries). This practice often poses difficulties for the CSOs, as applying for grants yearly is a time-consuming, albeit often only formalistic, process.

Although the survey responses show that CSOs in almost all countries receive public funding for their activities, the costs of HIV test-kits is not always fully covered. Therefore, some CSOs obtain their test-kits as donations from pharmaceutical companies, or they purchase them from budgets funded by other private sources (Italy, Malta, Ukraine and Russia). In Kyrgyzstan and Russia, it is reported that test-kits are partly financed by international funds, such as funds of UNDP.

Inclusion of community HIV testing results in the national surveillance system



In 16 out of the 28 countries, data obtained from the community HIV testing activities are reported to the national bodies at least in an anonymised form (given that community HIV testing is often offered as an anonymous service). Since most of the CSOs are not legally allowed to perform confirmatory testing, which has to be performed in clinical settings, it can be assumed that in the remaining 12 countries community HIV testing results are at least to some extent (when reactive) reflected in the national surveillance system.

Identified barriers and advocacy topics – community HIV testing

Although the range and practical use of the community HIV testing services in each country varies, there were several recurrent advocacy topics mentioned in the questionnaire by participating CSOs. These topics were grouped into three major themes – financial, legal, and systemic.

Concerning the availability of financing for community HIV testing services, two main points of interest emerged throughout the questionnaire. In countries where CSOs are dependent on private donations or international funding, the problem of non-inclusion of community HIV testing services in the national HIV plan / guidelines was repeatedly raised as a fundamental issue. Where public funding is available for community HIV testing, the issue of sustainability

of funding and consequently the services has come to the fore, due to the necessity to undergo annual grant application procedures.

Regarding legal barriers, the number one issue is the prohibition of performing tests by lay providers. This issue has gained even more attention during the COVID-19 pandemic due to the congestion of the healthcare sector and the shortage of medical personnel in general.

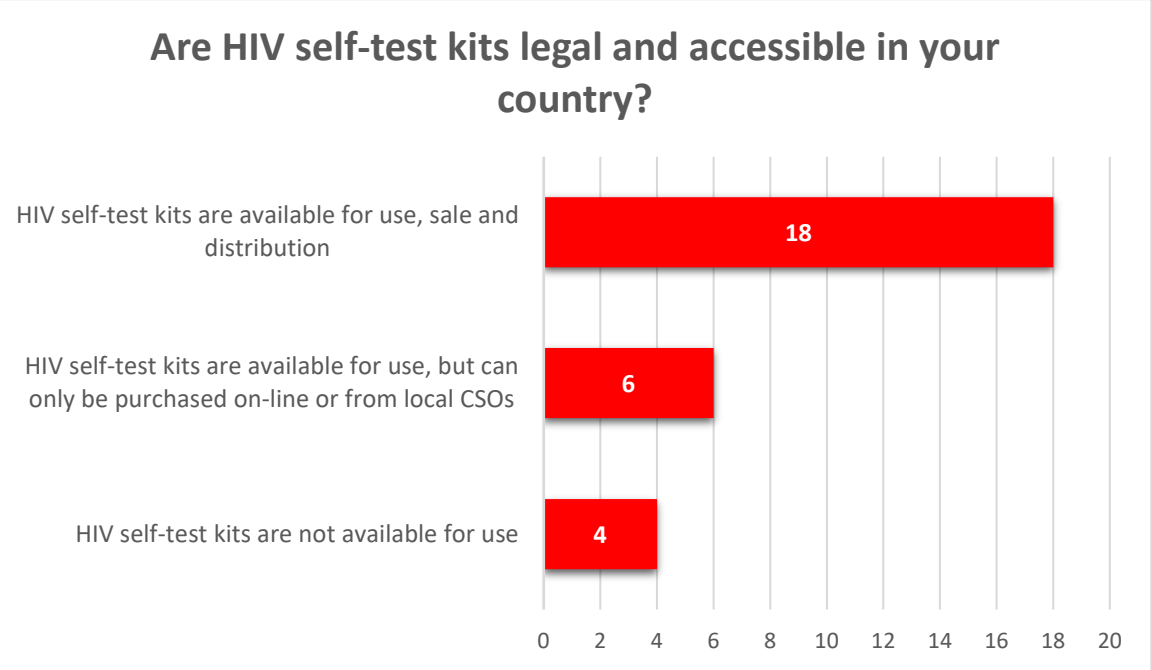
In this respect, Italy can be considered as a prime example of the significance given to community HIV testing services and its potential for practical application. During the COVID-19 pandemic, the Italian CSOs were provided with an opportunity to participate in a nationally organised training for lay providers to perform rapid HIV testing without medical supervision. This possibility proved to be an essential tool to maintain the HIV response in Italy throughout the COVID-19 pandemic.

Another legal barrier described in the questionnaires is the limited access to or complete lack of anonymous and/or free HIV testing. This issue disproportionately affects migrants in irregular situations who may not possess the necessary documentation to access an HIV or STI test.

The need for systemic changes was also widely mentioned in the questionnaires. Given the growing practical importance of the CSOs in both the national and global HIV responses, calls for better recognition and support for community testing centres and their work were frequent among the respondents. Other emerging calls for systemic change relate to the necessity for greater focus on awareness raising programmes, campaigns to promote testing and full implementations of existing national HIV plans and guidelines. Furthermore, as community HIV testing services can be expected to become more widespread in line with the international standards and recommendations, the inclusion of the obtained HIV testing data in the national surveillance systems shall be one of the main advocacy topics.

HIV Self-testing

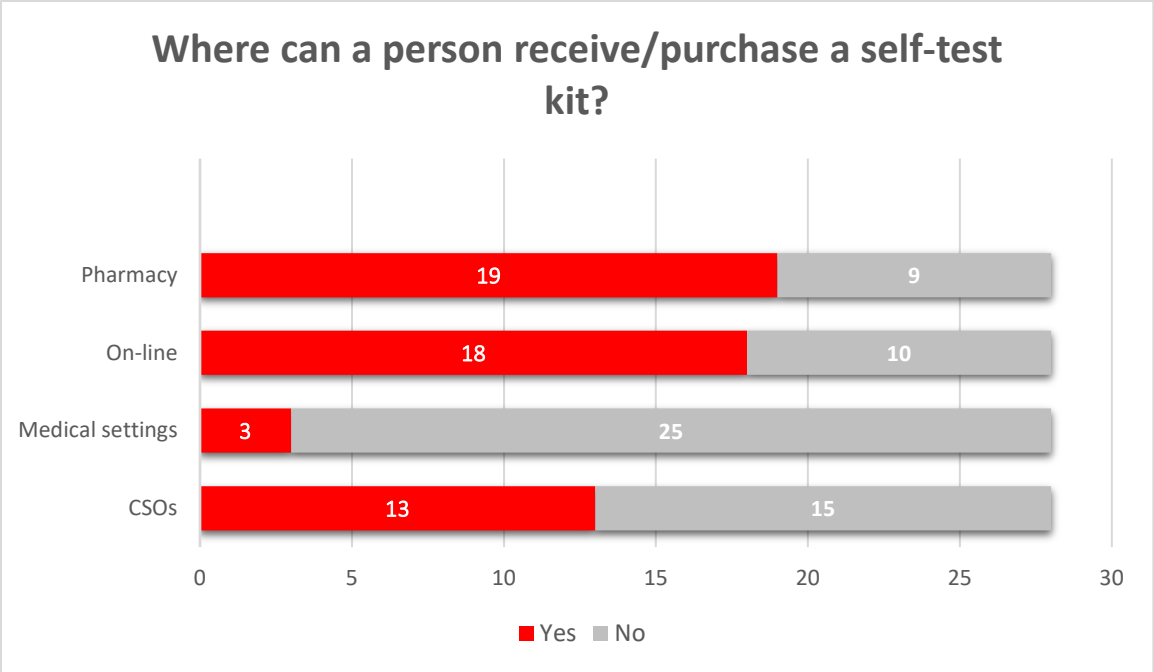
Legality of HIV self-testing



In 18 out of the 28 countries, it was reported that HIV self-test kits are not prohibited by the law and they can be purchased without major difficulties. In 6 out of the 28 countries, HIV self-test kits can only be purchased online or from a local CSO. In 4 out of the 28 countries, self-testing kits were said not to be available for purchase through any vendor.

Although it was stated that in 24 out of the 28 countries HIV self-test kits can be legally used, their practical availability differed. Furthermore, 4 out of these 24 countries reported HIV self-test kits not to be addressed in the national legal systems, i.e. self-testing is neither reportedly prohibited nor explicitly allowed by the law.

Possible ways of obtaining HIV self-test kits



HIV self-test kits were reported to be accessible in a pharmacy (in 19 out of the 28 countries) or online (in 18 out of the 28 countries). However, HIV self-test kits are only available for purchase and not covered by the national health insurance. The practical accessibility of HIV self-test kits is questionable due to their high cost, ranging on average between €20 and €30. HIV self-testing in most countries therefore remains supplementary to the community HIV rapid testing conducted by CSOs.

Identified barriers and advocacy topics – HIV self-testing

According to the respondents of the survey, the biggest barriers for the expansion of HIV self-testing are the lack of practical availability of HIV self-testing kits and (in countries in which HIV self-testing kits are accessible) their high cost. Another perceived barrier is the lack of active promotion and awareness raising regarding HIV self-testing by national policies. Raising awareness about the availability of HIV self-testing should be included in the national HIV programmes and guidelines.

Main Findings and Recommendations

This report provides an overview of the situation regarding the availability and practical use of community HIV testing and other related services in 28 countries of Europe and Central Asia. The information provided by the local CSOs suggests that although community HIV testing services are legal and available in most countries, their implementation and effective execution differs from country to country.

In the course of the questionnaire analysis, several key advocacy points were identified.

First, it became clear that despite international guidelines and recommendations, not all countries have fully implemented policies and legal changes concerning community HIV testing and HIV self-testing.

Second, the integration of testing and linkage to care data collected by CSOs in the national HIV surveillance should be improved.

Third, international organisation and agencies, such as WHO or ECDC have long been recommending HIV testing performed by trained lay providers. Yet, only 16 out of the 28 countries from the survey have policies allowing testing performed by lay providers. Moreover, at a time when most countries face a shortage of medical professionals, enabling lay providers to perform rapid HIV testing shall become one of the main priorities for health systems, as it may relieve some of the strain the healthcare sector is currently under as a consequence of the COVID-19 pandemic.

Fourth, the issue of insufficient or difficult to obtain funding has been a recurrent topic raised by the responding CSOs. Although many of the CSOs involved in this project reported that a large part of their budget comes from the public sector, they often have to apply for grants annually or biannually.

Fifth, in line with WHO recommendations[26], HIV self-testing should be offered as part of the differentiated approach to HIV testing. When implementing HIV self-testing into the national HIV response, linkage to appropriate post-testing services is critical to achieve its full benefits.

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[26] WHO. *Policy Brief: WHO recommends HIV self-testing – evidence update and considerations for success.* 2019. Available at: https://www.who.int/publications/i/item/WHO-CDS-HIV-19.36

In developing and adapting models of HIV self-testing delivery and support, communities and CSOs should be involved; this should include using their platform to raise awareness about the practical use of HIV self-testing and to minimize its misuse.

In addition, it should be emphasized that all modalities of HIV testing shall adhere to the WHO's 5 Cs: consent, confidentiality, pre-test and post-test counselling, correct test results and connection or linkage to prevention, care and treatment. Mandatory and/or coerced testing is never appropriate. HIV testing must always be voluntary, and consent must be informed and given prior to testing.

In light of the main findings, this report proposes the following recommendation for the reviewed countries:

- Revise national HIV plans and guidelines in order to ensure the inclusion of the necessary framework for a differentiated approach to HIV testing in accordance with WHO and ECDC recommendations.
- Expand modalities of HIV testing in order to increase testing frequency and coverage.
- Streamline standardized HIV testing data collection processes to include data from community HIV testing in the national surveillance system.
- Enable lay providers to independently perform rapid HIV testing and introduce either an appropriate national training or an approved CSO-led training to ensure provision of the necessary level of expertise to these lay providers.
- Review the public funding available to CSOs performing HIV testing and other services and the frequency of submission of such funding applications.
- Make HIV self-testing kits available, accessible and affordable to all as part of the differentiated approach to HIV testing to increase uptake of HIV testing and early diagnosis.
- Ensure that the WHO's five Cs for HIV testing services (consent, confidentiality, counselling, correct test results and connection or linkage to prevention, care and treatment) are adhered to regardless of the testing modality.

Annex 1 – Questionnaire

COBATEST NETWORK

AIDS ACTION EUROPE

Rapid assessment of legal and policy barriers to the provision of community based and –led testing services, uptake of HIV self-testing and experience of organisation with HIV self-testing

GENERAL INFORMATION			
1. *Name of the organisation*			
2. *Does your organisation provide community based voluntary counselling and testing?*	☐ Yes ☐ No	3. *Is your organisation a member of the COBATEST Network?* Learn more about the COBATEST Network	☐ Yes ☐ No
4. *Which of the following services is provided by your organisation*			
☐ HIV rapid testing and counselling ☐ HIV confirmatory testing ☐ Viral hepatitis rapid testing and counselling ☐ Viral hepatitis confirmatory testing ☐ STI testing and counselling ☐ PrEP counselling ☐ other		*Please add any additional information here*	
5. *On average, how many tests a month is performed in your organisation?*			
6. *What tests are available for your organisation? What is the price for each of the tests?*			

HIV		*Viral Hepatitis*		*STI*	
Name	*Price in €*	*Name*	*Price in €*	*Name*	*Price in €*

Additional comments:

COBATEST NETWORK AIDS ACTION EUROPE 1

LEGAL AND POLICY SITUATION OF THE COMMUNITY BASED TESTING AND COUNSELLING

In this part, we would like to ask you about the legal situation of CBVCT in your country and how it is regulated.

7. Is community based testing legal in your country?

☐ Yes, it is legal ☐ Yes, it is legal with some exceptions ☐ No, it is not legal ☐ I don't know	*Please add any additional information here*

8. Please describe below what is the official national stand on community based and led counselling and testing, is there a national plan or strategy and is CBVCT acknowledged as part of the system?

Please describe…

9. Who can perform rapid testing in your country?

HIV	*Viral Hepatitis*	*STIs*
☐ Lay provider ☐ Certified lay provider ☐ Only medical staff ☐ Certified lay provider only under supervision of medical staff ☐ Other (please describe in the field below)	☐ Lay provider ☐ Certified lay provider ☐ Only medical staff ☐ Certified lay provider only under supervision of medical staff ☐ Other (please describe in the field below)	☐ Lay provider ☐ Certified lay provider ☐ Only medical staff ☐ Certified lay provider only under supervision of medical staff ☐ Other (please describe in the field below)

10. Are there national trainings for lay providers?	☐ Yes ☐ No

If yes, who provides it?

11. If rapid test is reactive, can your organisation perform a confirmatory test?	☐ Yes ☐ No

How is it organised?

12. Please describe below how does your organisation arrange linkage to care.
13. How is the funding of test kits organised? Please describe below.
14. Please describe below how overall funding of the services is organised. (Is it reimbursed by the government, are only test costs reimbursed or staff costs as well etc.)

15. Is the data from CBVCTs included into national surveillance system?	☐ Yes ☐ No
Please describe...	

16. What are the needs for support and advocacy in your national context to improve lthe legal situation of CBVCT centres?
Please describe...
17. Do policies introduced as a result of the COVID-19 Pandemic currently affect CBVCTs and how?
Please describe...

18. We would like to collect any good practices (guidelines, protocols etc) that could be helpful to CBVCT centers in other countries. If there are any, please share them here (links etc).	

LEGAL AND POLICY SITUATION OF SELF-TESTING ON HIV

In this part, we would like to ask you about the legal situation of self-testing in your country and how it is regulated.

19. Are HIV self-test kits legal in your country?

☐ Yes, HIV self-tests are available for use, sale and distribution ☐ Yes, HIV self-tests are available to use, but cannot be purchased legally from private vendors ☐ No	*Please add any additional information here*

20. Is there a national policy on HIV self-testing and is it implemented? If yes, are CBVCT sites included into the national policy?

☐ Yes, there is national policy and it is implemented ☐ Yes, there is national policy but it is not fully implemented ☐ Yes, there is national policy and it is not implemented ☐ No, there is no national policy	*Please add any additional information here*

21. Where can a person receive a self-test kit?	☐ Pharmacy ☐ Online ☐ Medical settings ☐ NGOs ☐ Other	***22. What is the average price of the HIV self-test kit?***	
23. Which tests are available on the market?			

24. What are, in your opinion, barriers to the roll out of self-testing in your national context?

Annex 2 – Comparative tables

TABLE 1: COMMUNITY BASED VOLUNTARY TESTING AND COUNSELLING – AVAILABILITY

Country	Availability of community HIV testing and other related services							Community based testing legality
	HIV rapid testing and counseling	HIV confirmatory testing (blood sampling)	Viral hepatitis rapid testing and counselling	Viral hepatitis confirmatory testing	STI testing and counselling	PrEP counselling	Other	
1. Armenia	✓	✗	✗	✗	✓	✓	✓	✓ (With some exceptions)
2. Austria	✓	✓	✓	✗	✓	✓	✓	✓
3. Belgium	✓	✗	✓	✗	✓	✓	✓	✓
4. Croatia	✓	✗	✓	✗	✓	✓	✓	✓

5.	Cyprus	✓	✗	✗	✗	✓	✓	✓	Legal framework does not exist
6.	Czechia	✓	✗	✓	✗	✓	✓	✗	✓
7.	Denmark	✓	✗	✓	✗	✓	✓	✓	✓
8.	Estonia	✓	✗	✓	✗	✓	✗	✗	✓ (With some exceptions)
9.	Georgia	✓	✗	✓	✓	✓	✓	✗	✓
10.	Germany	✓	✓	✓	✓	✓	✓	✗	✓
11.	Hungary	✗	✗	✗	✗	✗	✗	✗	Undetermined**
12.	Ireland	✓	✗	✓	✗	✗	✓	✗	✓
13.	Italy	✓	✗	✓	✗	✓	✗	✗	✓
14.	Kyrgyzstan	✓	✗	✗	✗	✓	✓	✗	✓
15.	Latvia	✓	✗	✓	✗	✓	✗	✗	✓

16.	Malta	✓	✗	✗	✗	✗	✗	✗	✓
17.	Moldova	✓	✗	✓	✗	✓	✓	✗	✓
18.	Poland	✓	✓	✓	✗	✓	✓	✗	✓
19.	Portugal	✓	✗	✓	✓	✓	✓	✓	✓
20.	Romania	✓	✗	✓	✗	✓	✓	✗	Legal framework does not exist
21.	Russia	✓	✗	✓	✗	✓	✓	✗	✓ (With some exceptions)
22.	Serbia	✓	✗	✓	✗	✓	✓	✗	Legal framework does not exist
23.	Slovakia	✓	✗	✓	✗	✓	✗	✗	✓
24.	Slovenia*	✗*	✗	✗	✗	✗	✓	✓	✓
25.	Spain	✓	✓	✓	✓	✓	✓	✓	✓
26.	Sweden	✓	✗	✗	✗	✗	✗	✓	✓

27.	Turkey	✗	✗	✗	✗	✗	✗	✓	✓** (With some exceptions)
28.	Ukraine	✓	✗	✓	✗	✓	✓	✓	✓

* Although the Slovenian CSO Legebitra does not provide rapid testing, it does provide standard laboratory testing

** See section “Questionnaire Analysis” for more details

TABLE 2: COMMUNITY BASED VOLUNTARY TESTING AND COUNSELLING – ORGANISATION AND FUNDING

Country	Legality of lay providers performing rapid HIV testing – minimal qualification			Availability of national training for lay providers (i.e. training organised by a public body)	Permission to perform blood sampling for confirmatory testing (CSOs)	Indication of frequent accompaniment of individuals to confirmatory testing appointments	Predominant source of HIV test-kit funding		
	Lay providers	Certified lay providers	Medical staff only / obligatory supervision of medical staff				National public funding	International funding and private donations	Combination
1. Armenia	✓			✓	×	×	✓		
2. Austria			✓	×	✓	×	✓		
3. Belgium		✓		✓	×	✓	✓		
4. Croatia			✓	×	×	×			✓

5.	Cyprus	Legal framework does not exist			✗	✗	✓			✓
6.	Czechia			✓	✗	✗	✗	✓		
7.	Denmark	✓*			✗	✗	✗	✓		
8.	Estonia			✓	✓	✗	✗	✓		
9.	Georgia	✓			✓	✗	✓			✓
10.	Germany		✓		✗	✓	✗	✓		
11.	Hungary	Undetermined			✗	✗	✗	Undetermined		
12.	Ireland	✓			✗	✗	✗	✓		
13.	Italy		✓*		✓	✗	✓		✓	
14.	Kyrgyzstan	✓			✗	✗	✓		✓	
15.	Latvia			✓	✓	✗	✗	✓		
16.	Malta	✓			✗	✗	✗		✓	
17.	Moldova	✓			✓	✗	✓	✓		

18.	Poland		✓*		✓	✓	✗	✓		
19.	Portugal	✓			✗	✗	✗	✓		
20.	Romania			✓	✗	✗	✓			✓
21.	Russia	✓			✗	✗	✗		✓	
22.	Serbia	Legal framework does not exist			✓	✗	✓	✓		
23.	Slovakia	✓			✗	✗	✓	✓		
24.	Slovenia	Legal framework does not exist			✗	✗	✗	✓		
25.	Spain	✓*			✗	✓	✗	✓		
26.	Sweden	✓*			✗	✗	✗	✓		
27.	Turkey	N/A			✗	✗	✗	CBT not performed by CSOs		
28.	Ukraine			✓	✓	✗	✓		✓	

* The requirements differ between organisations or regions / municipalities

TABLE 3: SELF-TESTING

Country	Self-testing legality	Availability of self-test kits				Average price of self-test kits
		Pharmacy	Online	Medical settings	CSOs	
1. Armenia	✓*	✗	✗	✓	✓	N/A
2. Austria	✓	✓	✓	✗	✗	30 €
3. Belgium	✓	✓	✓	✗	✓	28 – 30 €
4. Croatia	✓*	✗	✗	✗	✓	N/A
5. Cyprus	Legal framework does not exist*	✗	✓	✗	✗	N/A
6. Czechia	✓	✓	✓	✗	✓	25 €
7. Denmark	✓	✓	✓	✗	✗	26,8 €
8. Estonia	✓*	✗	✓	✗	✗	27,9 – 29,9 €

9. Georgia	✓	✗	✓	✗	✓	N/A
10. Germany	✓	✓	✓	✓	✓	28 €
11. Hungary	✗	✗	✗	✗	✗	-
12. Ireland	✓	✓	✓	✗	✓	40 – 75 €
13. Italy	✓	✓	✓	✗	✓	20 €
14. Kyrgyzstan	✗	✗	✗	✗	✗	-
15. Latvia	✓	✓	✗	✗	✗	30 €
16. Malta	✓	✓	✓	✗	✓	25 – 30 €
17. Moldova	✓	✓	✗	✗	✓	20 €
18. Poland	✓*	✗	✓	✗	✗	25 – 32 €
19. Portugal	✓	✓	✗	✗	✗	25 €
20. Romania	✓*	✗	✗	✗	✓	14 € (As purchased by the local CSOs from France)

21. Russia	✓	✓	✓	✗	✓	4 €
22. Serbia	✗	✗	✗	✗	✗	-
23. Slovakia	✓	✓	✓	✗	✗	20 – 30 €
24. Slovenia	✓	✓	✓	✗	✗	25 €
25. Spain	✓	✓	✓	✓	✓	10 – 30 € (Dependant on the region)
26. Sweden	✓	✗	✓	✗	✗	N/A
27. Turkey	N/A	N/A				N/A
28. Ukraine	✓	✓	✓	✗	✓	N/A

*Limited availability