Policies, Regulations and Practice of HIV Rapid Testing / Self-testing in Four SEE Countries, North Macedonia, Albania, Montenegro, and Serbia

ASSESMENT REPORT

AUTHORS: MAKA GOGIA, TAMAR ZURASHVILI

Disclaimer

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Contents

Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
BBSS	Bio Behavioral Surveillance Survey
CBO	Community Based Organization
CCM	Country Coordinating Mechanism
CSO	Civil Sociality Organization
EECA	Eastern Europe and Central Asia
EU	European Union
GF	Global Fund
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
HIVST	HIV self-testing
HTS	HIV testing services
IDI	In-depth Interview
IPH	Institute of Public Health
KP	Key Population
LGBTI	Lesbian, Gay, Bisexual, Transgender, and Intersex people
M&E	Monitoring and Evaluation
MoH	Ministry of Health
MSM	Men who have Sex with Men
NGO	Non-Governmental Organization
PHC	Primary Health Care
PLHIV	People Living with HIV
PreP	Pre-Exposure Prophylaxis
PWID	People Who Inject Drugs
RCT	Randomized Controlled Trial
RDT	Rapid Diagnostic Test
STI	Sexually Transmitted Infection
SW	Sex Worker
TG	Transgender
VCCT	Voluntary, Confidential Counselling and Testing
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

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Introduction

The current document provides information about an assessment conducted in four countries of Balkans, including North Macedonia, Albania, Montenegro, and Serbia to evaluate country-specific policies, regulations, and practical factors that are currently facilitating or affecting community-level access to HIV rapid diagnostic tests, including self-testing.

Structure

This document is structured as following:

- Firstly, it provides a brief background on approaches to delivering HIV testing services (HTS) to better reach PLHIV, including community-based testing and HIV self-testing (HIVST)
- Secondly, gives a brief review of the methodology used; and
- Finally, provides summary of key findings on HIV rapid testing / self-testing policies and practices and recommendations for each country separately.

Background

Globally, one in five people with HIV are unaware of their status[1], despite considerable scale up of HIV testing, treatment, and prevention services. Number of people living with HIV by 2021 was more than 38 million with 1,500,000 people newly infected with HIV. In terms of UNAID 95-95-95 strategy, of all people living with HIV (PLHIV) globally, 85% [75–97%] knew their status, 75% [66–85%] were accessing treatment and 68% [60–78%] were virally suppressed in 2021[2]. For Eastern Europe and Central Asia (EECA) data indicates that the region is failing to reach those targets with estimated 63% [56 - 69] of PLHIV who know their status, 51% [46 - 56] on ART and 48% [43 - 53] with viral suppression[3].

WHO's 2022–2030 global health sector strategy on HIV aims to reduce HIV infections from 1.5 million in 2020 to 335 000 by 2030, and deaths from 680 000 in 2020 to under 240 000 in 2030[4]. Key populations at higher risk of HIV infection include gay men and other men who have sex with men, transgender people, people who inject drugs, sex workers and their clients, and people in prisons and other closed settings are more likely to be exposed to HIV or are living with HIV[5]. HIV testing, prevention and treatment service coverage remains insufficient at global and Eastern and Central Europe level, including countries of Balkan.

[1] https://www.unaids.org/en/resources/fact-sheet
[2] UNAIDS, Global HIV & AIDS statistics — Fact sheet, 2021
[3] Ibid
[4] https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/strategies/global-health-sector-strategies
[5] UNAIDS Global AIDS Update 2022, https://www.unaids.org/sites/default/files/media_asset/2022-global-aids-update_en.pdf

Following the development of the first HIV antibody tests in 1985, ways of offering and providing HTS have continuously evolved[6,7], which led to the development of HIV testing service (HTS) delivery modes. Apart from facility-based testing, WHO recommends some other approaches to delivering HTS to better reach all PLHIV, including community-based testing and HIV self-testing (HIVST).

Many of those unreached by HIV testing services need targeted tools and interventions that increase the demand for HTS that are needed to reach people who are uninformed about HTS options and advances in treatment and prevention, people who are not motivated to seek HTS and those who are hesitant to test because of fear of an HIV diagnosis or other reasons[8]. HIV self-testing, as a convenient and confidential option for HIV testing, is one of the promising testing strategies to reach persons most affected by HIV.

HIV self-testing is a process in which a person collects his or her own specimen (oral fluid or blood) and then performs a test and interprets the result, often in a private setting, either alone or with someone he or she trusts[9]. WHO recommends HIVST as a safe, accurate and effective way to reach people who may not test otherwise, including people from key populations, men, and young people. Lay users can perform HIVST reliably and accurately and achieve performance comparable to that of trained health-care workers[10].

A reactive (positive) HIVST result is not equivalent to an HIV positive diagnosis. All reactive HIVST results need to be followed by further testing by a trained provider to confirm HIV status, starting with the first test in the national testing algorithm and if diagnosed HIV should be encouraged and supported to initiate ART. Nonreactive HIVST results should be considered HIV-negative, with no need for immediate further testing except for those starting pre-exposure prophylaxis (PrEP). Any person uncertain about their HIVST result should be encouraged to seek testing from a trained provider. Retesting following a negative self-test result is necessary only for those at ongoing risk, such as people from key populations and those reporting potential HIV exposure in the preceding 12 weeks.

Globally, many countries have developed HIVST policies, and implementation is growing rapidly. Different countries developed their guidance to effectively adopt and utilize HIVST testing strategy, including effective service delivery models, linkage to care and support tools. In many places, HIV testing that requires face-to-face contact has been scaled back or suspended because of the COVID-19 pandemic response[11].

WHO conducted a systematic review to update the guidance on HIVST[12]. Key findings from HIVST systematic review of 32 randomized controlled trials (RCTs) showed that, compared with standard facility-based HIV testing: HIVST increases the uptake of HIV testing; Proportions of people diagnosed and linked to care with HIVST are comparable to those with facility-based testing; Misuse of HIVST and social harms associated with HIVST are rare. No suicides were reported; HIVST does not increase

[6] Klarkowski D, Glass K, O'Brien D, Lokuge K, Piriou E, Shanks L. Variation in specificity of HIV rapid diagnostic tests over place and time: an analysis of discordancy data using a Bayesian approach. PLoS One. 2013;8(11):e81656.

[7] Klarkowski DB, Wazome JM, Lokuge KM, Shanks L, Mills CF, O'Brien DP. The evaluation of a rapid in situ HIV confirmation test in a programme with a high failure rate of the WHO HIV two-test diagnostic algorithm. PLoS One. 2009;4(2):e4351.

[8] https://www.who.int/publications/i/item/WHO-CDS-HIV-19.33

[9] https://sahivsoc.org/Files/HIVST-Policybrief-Globalversion.pdf

[10] https://www.who.int/publications/i/item/978-92-4-155058-1

[11] https://www.cdc.gov/nchhstp/dear_colleague/2020/dcl-042820-HIV-self-testing-guidance.html

[12] https://apps.who.int/iris/bitstream/handle/10665/251655/9789241549868-eng.pdf

sexual risk behaviors among men who have sex with men; A range of HIVST service delivery models and support tools are found to be effective; Many people are willing and able to perform HIVST with minimal support; HIVST is acceptable and feasible in a range of populations and settings.

Depending on local context and HIV prevalence among KP groups, countries choose different models of HIVST delivery, although demand creation is the main activity to scale up and maximize efficiency of HIV self-testing, specifically to reach those who are unable or reluctant to access services and remain undiagnosed or those at ongoing HIV risk who would benefit from prevention services. Demand creation includes activities that directly improve an individual's knowledge, attitudes and motivation, and eventually lead them to seek testing[13]. Countries have different policies, regulations, and Operational considerations that are currently facilitating or affecting community-level access to rapid diagnostic tests, including self-testing.

HIVST service delivery models HIVST kits can be distributed through various channels, including those supported by public or donor funding or in the private sector, as well as through public–private partnerships. A range of service delivery and distribution models are effective in increasing uptake of HIV testing and reaching people with HIV who are undiagnosed or those at ongoing HIV risk[14]. Other models may be effective and can be considered depending on the local context and community preferences. Where feasible, offering choice in HIVST service delivery options and type of test kits (such as between kits using oral fluid or blood) can help to reach more people.

The purpose of this assessment was to evaluate country-specific policies, regulations, and practical factors that are currently facilitating or affecting community-level access to rapid diagnostic tests, including self-testing of HIV in four countries of Balkan region: North Macedonia, Albania, Montenegro, and Serbia.

Methodology

The currents assessment was conducted between August-November 2022 and was accomplished through two main objectives:

1. To conduct desk review to provide baseline information in understanding the overall country-specific policies, regulations, landscape, and trends in community-level access to RDTs for HIV self-testing in 4 countries of Balkan
2. To qualitatively examine the views and perceptions towards HIV self-testing through conducting in-depth interviews (IDIs) among key informants in 4 countries of Balkan

The main documents used for the desk review included country strategies and strategic plans on HIV/AIDS, state and GF HIV programs, relevant laws regulating issues of testing procedure and ensuring confidentiality of tested clients and national HIV testing guidelines and protocols.

The key informants participating in IDIs from all four countries included the following groups: (1) Decision makers, including representatives of Ministry of Health, HIV State programs and Principal Recipients of the Global Fund; (2) representatives of HIV services providers including both prevention and treatment services from governmental and non-governmental sectors; and (3) representatives of KP community members (MSM, PWID, SW, Trans* people).

[13] https://www.who.int/publications/i/item/WHO-CDS-HIV-19.36
[14] https://apps.who.int/iris/bitstream/handle/10665/329968/WHO-CDS-HIV-19.36-eng.pdf

The data collection was conducted online via Zoom platform. Oral informed consents were obtained from all members of IDIs. The average duration for IDI was 1 hour. The IDIs were audio recorded without identification of the participants. The report does not include identifiable information of IDI participants. The recorded information was used to prepare transcripts. The obtained information was organized and followed by contextual analysis, presented below separately for each country.

North Macedonia

North Macedonia - a small country located in Southeastern Europe on the Balkan region bordered by Kosovo, Serbia, Bulgaria, Greece and Albania.

The population of North Macedonia is estimated at 2,083,169 people as of November 2022 to UN data. 58.6% of the population is urban and the median age of population is 39.1 years[15]. The largest city and the capital is Skopje.

Overview of the HIV epidemic in North Macedonia

The Republic of North Macedonia has a low-level, concentrated HIV prevalence. Main epidemiological trend is nearly the same, as in other countries in the European region. Several categories of data suggest that the epidemic is under control among people who inject drugs and female sex workers, but prevalence is rising among men who have sex with men (MSM)[16].

The first case of HIV infection in North Macedonia was reported in 1987. Since then, there is an increasing trend of new HIV diagnoses registered in the last years. By the end of 2021, 548 HIV cases have been officially recorded. Over the last decade, the number of new HIV diagnoses has not been stable with considerable decrease during the years of pandemic (2020-2021).

Figure 1: New HIV diagnosis 1987-2021

Source: Institute of Public Health

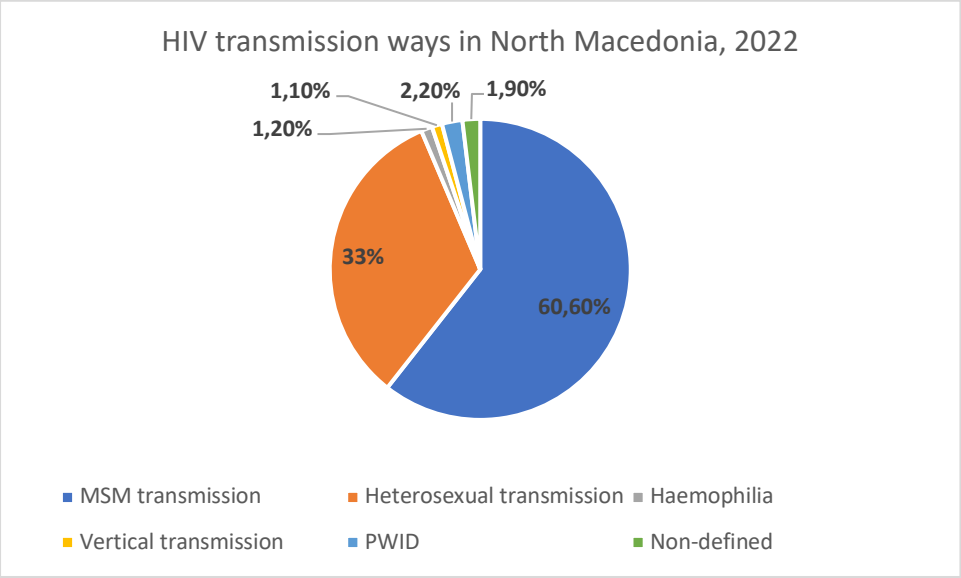
Cumulatively, by the end of 2021, among all reported HIV cases, sex between men was the most frequently reported mode of transmission at 60.6%. Heterosexual contact was reported in 33 % of the cases and injecting drug use was reported in 2,2 % of the cases. For 1.9 % of the new cases, the mode

[15] https://www.worldometers.info/world-population/montenegro-population/

[16] Vladimir Mikikj et al. The Continuum of HIV Care in North Macedonia: Assessment Report for 2017 with a Special Focus on Men Who Have Sex with Men. Available at: https://zp.mk/wp-content/uploads/2020/08/thecontinuum-of-hiv-care-in-north-macedonia-in-2017.pdf

of transmission was not reported17. 64% of people living with HIV in North Macedonia are aged 20-39. 2019 HIV Incidence rate was 2.8 in 100.000 population in 2019[18].

Figure 2: HIV transmission ways in North Macedonia, 2022



Source: Institute of Public Health

Country official data show an increasing proportion of MSM among newly diagnosed HIV cases; during the period of 2013 to 2020, this proportion ranges between 58 % and 90 % on an annual basis[19]. In 2018, 82 % of newly diagnosed cases were MSM. The last IBBS surveys also suggests the same increasing trend of HIV prevalence in MSM population in the capital city 1.9% in 2013/2014 and 5.4% in 2017/2018[20].

Bio-behavioral study conducted among MSM revealed risky sexual practices, 47.2% of MSM have not used condoms during their last anal intercourse, while 47.2% believe they are exposed to small risk (44.2%) or no risk at all (3%)[21]. According to the BBSS data the HIV epidemic is concentrated among MSM with the growing trend.

Table 1. HIV prevalence among KPs, BBSS data, 2008-2021

KP	HIV Prevalence (%)		
	2010	2014	2017
MSM	0.5	1.9	5.4
PWID	0.0	0.0	0.0
FSW	0.0	0.0	0.0
Prisoners	0.0	0.0	0.0

[17] Source: Institute of Public Health of North Macedonia
[18] Source: Institute of Public Health of North Macedonia, https://www.iph.mk/en/overview-of-the-epidemiological-situation-with-hiv-in-north-macedonia-and-the-results-achieved-under-the-2019-hiv-population-protection-program-up-to-december-1/
[19] https://www.aidsactioneurope.org/sites/default/files/2022-09/North%20Macedonia.pdf
[20] IBBS study among MSM in Skopje, Macedonia and estimation of population size, 2017-2018 http://iph.mk/wp-content/uploads/2019/03/RDS-MSM-2018.pdf
[21] Bio-behavioral study among men having sex with men in Skopje, Macedonia

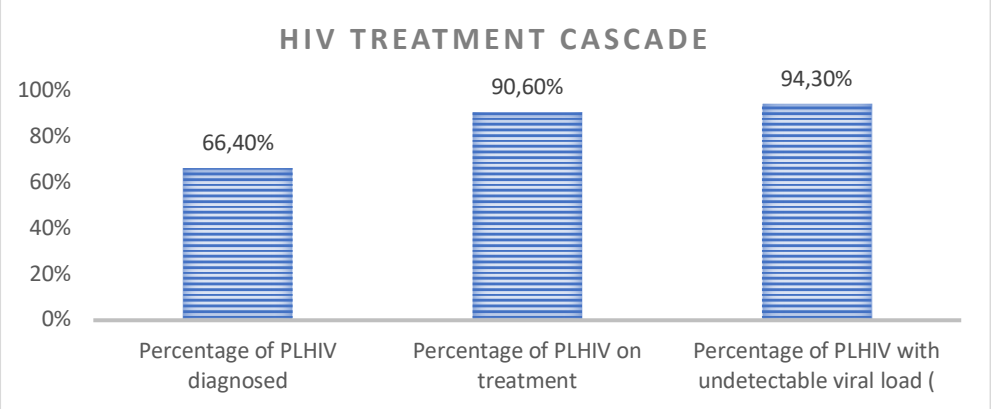
Number of provided HIV testing for key populations by VCT centers was hampered during the pandemic, the most challenging was first semester of 2020 when the strict restrictions and lockdowns does not allow CSOs to operate on a regular base. Public health institutions were closed to HIV testing due to pandemic as well. Low threshold programs modified the mode of service delivery and adjusted to new circumstances. NGOs moved to online counselling mostly, making an appointment after defining the rational to do HIV testing. Later in 2021, CSOs continued HIV testing and reached the same level, as before pandemic. Overall HIV detection level was also decreased during 2020-2021 (see the figure above).

> *'"During COVID or other emergencies, this is a good chance to promote HIV ST, but we did not have it during COVID pandemic, unfortunately. They should be available for key population and general population as well..."*
>
> AIDS center representative

Late diagnosis also represents a challenge to the National HIV response in North Macedonia. In 2019 63.6% of PLHIV were diagnosed with the initial CD4 cell count <350 cells/mm3 and 18.2% of PLHIV presented with the initial CD4 cell count <200 cells/mm3.

Figures 3 below shows that the rather weakest part of National HIV Test and treatment cascade in 2020 is number of people diagnosed with HIV 66.4%. HIV treatment and care part of the Cascade looks pretty good as they are more than 90% (Percentage of PLHIV on treatment 90.6%; Percentage of PLHIV virally suppressed 94.3%). The increased number of people aware of their HIV status among all key populations but with particular attention to MSM, is one of the most important national prevention objectives for HIV National strategy in the country.

Figure 3: Test and treatment cascade, 2020, North Macedonia



HIV testing rate is low among all key populations according to last IBBS studies. Percentage of key population who tested for HIV in the past 12 months, or who know their current HIV status are as follow: Sex workers 47.7%, PWID – 38.9% and MSM – 28.8%[22], although 63.4% of MSM know where confidential HIV testing can be done in Skopje. Of those who did not make an HIV test (71.2%), 36.6% did not make a test because they think they did not have risky behaviour, 23.6% did not know where to do HIV testing, 10.5% had done the test before, and only 3, 7% did not make an HIV test because of fear of stigmatization.

[22] Country progress report of North Macedonia (Global AIDS Monitoring report 2020) https://www.unaids.org/sites/default/files/country/documents/ALB_2020_countryreport.pdf

Table 2. Coverage of KPs with HIV testing services

Key populations	BBSS data
MSM	28.8%
FSW	47.7%
PWID	38.9%

HIV rapid testing – policy and practice

The leading role of national HIV response implements Ministry of Health with meaningful involvement of Institute of Public Health in Skopje, Municipal Institute of Public Health, Infectious Diseases clinics and of course SCOs/NGOs/CBOs with major experience in HIV service delivery. MoH of North Macedonia is responsible for HIV prevention, coordination of national HIV response, HIV testing, designing of HIV prevention policy, preparation HIV and related strategic documents. Besides to state program and NGOs, private hospitals and lab facilities provide HIV testing. The country was a recipient of Global Fund support for its national response to HIV between November 2004 and 2017. While this support has allowed North Macedonia to maintain a low-level HIV epidemic and provide continuous HIV prevention services to key affected populations, the country is now facing a challenge to sustain those interventions as the Government struggles to allocate sufficient funding to provide services to people in need, according to epidemiological trends[23].

VCT for HIV for the key affected population is accessible at stationary and mobile ambulances. In total 13 NGOs and 10 healthcare institutions provide HIV screening in 11 towns across the country[24], including at the Clinic for Infectious Diseases and several other institutions and organisations in Skopje. Opioid agonist therapy (OAT) centres have also been integrated within the public health care system. Other HIV prevention services for MSM, PWID and SW, such as HIV testing, needle exchange programmes and condom and lubricant distribution, have been almost exclusively delivered by CSOs during the past 15 years. To cover rather small towns and villages, 2 mobile vans provide HIV testing across the country. The targeted groups for HIV testing are young population, men who have sex with men and LGBTI community, people who inject drugs, male and female sex workers and male and female prisoners. Non-governmental organization ,,HERA" as pioneer and umbrella organization/NGO in HIV, sexual and reproductive health coordinates HIV testing services of NGOs at national level. The Global Fund supports HIV testing targeted to key populations.

Table 3. List of organizations/facilities providing HIV testing

Name of the organization	Legal status (state/hospital/PHC/NGO/Community based organization/other)	Beneficiaries (general population / KP, including MSM, SW, TG, PWID, Prisoners/ migrants/blood donors/health care workers/pregnant women/youth/other)
HERA – Health Education and Research Association	NGO	MSM, SW, TG
EGAL	NGO/CBO	MSM

[23] North Macedonia: Benchmarking sustainability of the HIV response among Key Populations in the context of transition from Global Fund support to domestic funding, EHRA https://harmreductioneurasia.org/wp-content/uploads/2022/06/North-Macedonia-TMT-assessment-report-EHRA-2021-ENG.pdf

[24] Contact information and List of services with providing VCT services in North Macedonia https://hera.org.mk/wp-content/uploads/2021/07/Partnerski-organizacii-i-institucii-za-HIV-testiranje-2021.pdf

HOPS	NGO	PWID, SWs
Stronger Together	NGO/CBO	MSM
Clinic for Infectious Diseases	State hospital	MSM; general population
Institute of Public Health	Public health institution	General population

HIV testing is confidential and free of charge except of the testing performed by private hospitals and lab facilities. VCT services toward key populations are comprehensive and includes all essential component of it: provide information about HIV transmission ways, HIV risk counselling (pre and post-test), psycho-social support, referral of screened HIV positive individuals and linkage to care. Offering HIV prevention commodities including sterile injecting equipment, condoms, lubricants, and information materials is also part of provided HIV VCT services by NGOs. ,,Confidentiality of the conversation and of the test results are guaranteed, and everybody is offered equal treatment irrespectively of their HIV status, social status, education, gender identity, sexual orientation, age, ethnic or religious affiliation, disability or any other characteristics"[25].

In Macedonia stigma and discrimination toward gay and other men who have sex with men is still present, which may lead to avoidance of public health services by this population, or in order to avoid discrimination or stigma they may hide their sexual orientation while using these services. As consequence, part of this population remains "hidden" for regular surveillance and public health in general[26.] Stigma is considerable toward other key populations as well.

We also asked community representatives (MSM, PWID, SW/TG) to talk about the rapid HIV testing barriers and provide suggestions/recommendations for improvement to policy makers in North Macedonia. All the interviewed community members together with CSO representatives noted that stigma reveals to be one of the barriers in HIV testing for all key populations as well. Community members prefer to do HIV testing at low threshold programs where testing is anonymous confidential, but they have fear of breach of confidentiality and judgmental attitude if doing testing in hospitals or other health care settings.

> *"PWID in Skopje can get info regarding HIV/AIDS, HCV or STI's whenever they want, also we are having trainings, educations about HIV, Safer injection, Overdose etc. Only one disadvantage as far as I understand my population, psychological impact in the moment of realizing that somebody is HIV positive, and all things that come together with HIV, stigma, discrimination, judgmental looks because of addiction. But with more coverage from all parts, we can overcome this problem in time".*
>
> PWID community representative

> *"Stigma attached to drug users is enormous, and after all these years I can't stand it anymore, mostly their judgmental look, that Doctors/" Professionals" don't even try to hide it".*
>
> PWID community representative

National response to HIV in North Macedonia was threatened by major budget cuts in the beginning of 2022 that considered 40% reduction of the budget allocated to civil society organisations to deliver essential services to key affected populations, including PWIDs, MSM, SW, PLHIV). Local Civil society and community-based organisations together with international partners, reached out to the

[25] https://hera.org.mk/servisi/mobilni-ambulanti-za-hiv-testiranje/?lang=en
[26] IBBS study among MSM in Skopje, Macedonia and estimation of population size, 2017-2018 http://iph.mk/wp-content/uploads/2019/03/RDS-MSM-2018.pdf

government to ask it to reverse the decision to cut the HIV budget allocation[27]. So far, budget restrictions are being still in place till the end of 2022, with no promise to increased SCO funding for 2023.

"I would recommend to people who make decisions regarding health issues, it's better to spend some money and not to have HIV/AIDS positive people, especially between PWID, MSM, Roma population, SW etc., and to have small programs, like Needles Exchange, good and balanced methadone and buprenorphine treatments, best medicine or ARV for HIV, because its practical, make less damage, better and cheap compared for treatments, health care, social stigma, psychological issues, discrimination and other socio economic problems related with HIV positive people and their psychological and socio-economic status".

PWID community representative

"Funding is low this year, we can't expect much increase so far as whole state HIV program for HIV testing was decreased this year and this influences HIV testing uptake in the country. We decreased volume of outreach testing, fuel, vehicles, ambulances, all parts were affected with budget cut…"

CSO representative

"At this stage we can't include procurement of HIV Self tests into state program, we have restricted budget in 2022. Even we are not sure for 2023. Community did a lot of advocacy, still waiting for the results of advocacy, maybe for the next year they will have better budget…"

State HIV program representative

Country has prepared draft of HIV National Strategy for 2017-2021 with a strong commitment to maintain and scale up the response to HIV in the country, although it is not formally adopted. Strategy preparation work was organized by Ministry of Health, WHO and with the support of UNFPA CO. The aim of the strategy is to achieve 90-90-90 targets with a clear focus to maintain and enhance services provided to key populations by civil organizations[28].

National HIV testing protocol and guideline on HIV Rapid testing is outdated and have not been officially updated during the recent years according to WHO recommendations. According to current practice, HIV screening is conducted mainly with drop of blood (Finger prick) or dry blood specimens. HIV testing algorithm for HIV confirmatory testing includes Eliza and then Western Blot. The most confirmatory tests are done at the Infectious Diseases clinic in Skopje, some are done at the laboratory of MANU academy of science and art.

NGOs are performing VCT according to HIV testing protocol prepared by HERA in 2012 (so called ,,internal protocol"). There happened periodic review and update of this protocol, according to each review HERA carries out targeted training for VCT staff on HIV testing. Public health center and other facilities also have their own internal protocols for HIV rapid screening. HIV testing is anonymous (using a unique code) and provided by NGOs through the GF program. Every NGO apply the same coding system to avoid duplication of clients. According to internal protocol, NGO that send HIV screened positive individuals for confirmatory diagnostics, receive feedback from AIDS center whether HIV confirmed cases are linked to treatment services.

[27] https://www.eatg.org/press-releases-and-statements/national-response-to-hiv-in-north-macedonia-is-threatened-by-major-budget-cuts/

[28] Country progress report of North Macedonia (Global AIDS Monitoring report 2020) https://www.unaids.org/sites/default/files/country/documents/ALB_2020_countryreport.pdf

"I think that in Macedonia we have a lot of experts and organizations who can make good impact on target population, face to face, through social media, podcasts, same coffee places where key population is gather, Pharmacies, etc."

PWID community representative

In north Macedonia, it is not clear who is legally allowed to do HIV screening test. According to the practice that NGOs and other institutions have, HIV testing should be performed with clinical supervision and participation of a lab worker or trained nurse who are trained by the Institute for Public Health. VCT counselors both at stationary service sites and at outreach perform HIV testing based on guided principles based on informed consent, confidentiality, correct results, and connection, considered by WHO recommendation[29]. The community outreach worker is the key figure to attract and conduct risk reduction, pre and post-test counseling (Peer-to-Peer HIV testing service delivery model) at outreach.

"According to local regulations, rapid HIV tests are made by Lab technician (for getting blood), but questionaries' and all other info's regarding HIV are done by trained Counselors. It's very easy to make rapid testing at NGOs who work with some of the more marginalized groups…"

MSM community representative

The availability of testing is not an issue in North Macedonia, but some concerns regarding accessibility were noted by the respondents who participated in interviews for this assessment. They mostly talked about the geographical accessibility barrier for KPs, especially in regions, where NGO drop-in centers are not available and community members do not want to go to VCT centers with the fear that somebody might recognize them. Besides to this, HIVST is not available for Migrants (Migrants who are nationals of another EU state; Migrants from outside the EU (but not refugees, asylum seekers or undocumented); Migrants from outside the EU applying for asylum/refugee status ('documented'); Migrants from outside the EU who are undocumented ('illegals).

"For PWUD/PWID there aren't barriers for rapid testing, but I can speak only for Skopje, and NGOs that I know. Also, I don't have enough information about other places in Macedonia…"

PWID community representative

PreP program among MSM in North Macedonia started in 2021 during COVID pandemic within the Global Fund Regional SoS project. HIV screening and Eliza testing is offered to all potential beneficiaries and for MSM already involved in PreP. Besides, all PreP clients are screened on viral hepatitis and STIs (chlamydia, gonorrhea, and syphilis). HIV self-testing is not part of PreP program.

NGOs have their internal monitoring and evaluation system for VCT, as there is no national regulatory document that contains the frames for M&E or controls the quality of its performance. HERA, as an organization who carries out HIV testing coordination among different NGOs, conducts monitoring in all 12 NGOs/service providers according to its internal HIV testing protocol and prepares joint reports to the Institute of Public Health on a quarter level. Representatives of Institute of Public Health conduct on-site monitoring visits once a year and HERA conducts on-site monitoring visits of outreach VCT.

[29] Consolidates guidelines on HIV Testing services 5Cs: consent, confidentiality, counselling, correct results and connection https://apps.who.int/iris/bitstream/handle/10665/179870/9789241508926_eng.pdf?sequence=1&isAllowed=y

The Criminal Code of North Macedonia does not specify HIV but sets out sanctions for the intentional transmission of infectious disease in Article 205. The intentional transmission of a sexually transmitted infection (STI) is punishable with imprisonment of up to three years, while unintentional transmission incurs up to 6 months[30]. Sex work is criminalized, there is no criminalization of trans people, no laws, or policies restriction the entry, stay and residence of people living with HIV[31].

There is no specific law on HIV. Protection of confidentiality of HIV positive persons and individuals tested on HIV is specifically mentioned as a protected discriminatory ground: the Law on Protection of Patients' Rights[32], the Law on Health Protection[33], and the Law on Social Protection[34] . Legislation applies equally to the state funded facilities and NGOs providing HIV testing and prevention services.

HIV testing is mandatory for donors of blood, blood products, tissue, and organs. As well as for some doctors and for people, who do in vitro fertilization.

VCT protocol does not apply to pregnant women, mostly they don't receive pre and post testing counselling, although VCT for HIV infection among pregnant women is a public health priority given the ability of potent antiretroviral therapy to prevent HIV infection in infants and preserve the mother's health during pregnancy[35]. HIV testing in prison settings is not voluntary in practice, besides to it, confidentiality issue is also concerning. CSO representatives and KP members also expressed their concerns regarding HIV testing performed in some hospitals/clinics, where the patients are not given information about diagnostics, they do for them. No pre and post HIV test counseling is ensured for them.

> *"In some cases medical clinics do HIV testing not notifying patient, this is more shocked information for patient, they should know when HIV testing is done for them, we may miss such patients, they google what AIDS means, they have 2-3 years to live and they can do suicide, without proper counseling this should not be done…"*
>
> AIDS center representative

Since 2010 there has been introduced an Anti-Discriminatory law in North Macedonia[36]. Although the purpose of this law is to ensure the right of every person equality before the law and equal protection by the law, the civil societies were lobbying for amendments which will more explicitly protect rights of key populations. In October 2020, North Macedonia's parliament readopted the country's previously scrapped Anti-Discrimination Law, which among other things guarantees protection from gender-based discrimination[37].

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[30] HIV Justice network https://www.hivjustice.net/country/mk/

[31] UNAIDS GLOBAL AIDS UPDATE 2022 https://www.unaids.org/sites/default/files/media_asset/2022-global-aids-update_en.pdf

[32] Law on Protection of Patients' Rights (Official Gazette of the R. of North Macedonia No. 82/08, as amended). Available at: http://zdravstvo.gov.mk/zakon-za-zashtita-na-prava-na-pacienti/

[33] 6 Law on Health Protection (Official Gazette of the R. of North Macedonia No. 43/12, as amended). Available at: http://zdravstvo.gov.mk/zakon-za-zdravstvenata-zashtita/

[34] Law on Social Protection (Official Gazette of the R. of North Macedonia No. 104/19, as amended). Available at: https://mtsp.gov.mk/zakoni.nspx

[35] Voluntary HIV Counseling and Testing of Pregnant Women -- An Assessment of Compliance With Michigan Public Health Statutes https://www.medscape.com/viewarticle/475007#:~:text=Voluntary%20counseling%20and%20testing%20(VCT,the%20mother's%20health%20during%20pregnancy.

[36] Law on Prevention of and Protection Against Discrimination https://www.refworld.org/pdfid/5aa12ad47.pdf

[37] https://balkaninsight.com/2020/10/28/north-macedonia-reinstates-anti-discrimination-law/

There is no restriction in laws, regulations, and policies for Community-led HIV service Delivery in the country. Ministry of Health supports a wide network of NGOs and CSOs working on HIV prevention with key populations such as MSM, SW and PWID. HIV services for key populations (condom/lubricants distribution, IEC, harm reduction/needle exchange, community-based voluntary counselling, and testing (at stationary points and through mobile testing vans), as well as peer and psychosocial support services) are provided by CSOs/CBOs in collaboration with state agencies in North Macedonia. During interviews CSO representatives noted that their great contribution resulted to zero HIV prevalence in PWID and SW population.

"I wanted to point out that the zero prevalence in SW and PWID, especially in PWID is due to long term efforts of well-established network of CSO preventive and harm reduction programs across the country".

SCO representative

HIV self-testing – policy and practice

To improve the HIV prevention, particularly among the most stigmatized MSM population, North Macedonia started to introduce a new model of HIV testing service - HIV self-testing (HIVST) is a convenient and confidential option for HIV testing in a private environment, that gives possibility to people to perform the test and interpret the results from the HIV rapid test on their own.

Self-test kits for HIV are not legally registered as medical products in North Macedonia. The firstly HIV self-test kits were available in the country in 2021 within pilot-study Project "Sustainability of Services for Key Populations in Eastern Europe and Central Asia", funded by ICF "Alliance for Public Health" within the Global Fund Regional project. Only HIV saliva-based ST is available currently in the country.

There is no national level protocol or guideline on HIV Self-testing. HIV self-testing as kind of intervention targeted to key populations is mentioned in HIV state prevention program. NGOs work according to guidance prepared by NGO HERA "Operational protocol for piloting HIV self-testing via the Internet". This document was prepared according to WHO recommendation in 2021 Before the launch of HIV ST pilot project in North Macedonia[38].

The study for assessing the HIV self-testing attitudes and acceptability among gay men and other men who have sex with men was conducted in 2020. The survey looked into the needs and concerns MSM regarding the possible introduction of HIV self-test kits in the country, it made an assessment of the advantages and disadvantages of using oral fluid versus blood specimen, and identified the HIV self-testing distribution, promotion and support strategies for this population[39]. This survey had restriction in terms of providing community perspectives of HIVST based on their practical experience, it illustrates findings resulted from the respondents' perception of the HIV self-testing, rather than from their experience with using this type of tests. Results of this study findings contributed to further introduction of this testing model in the national prevention programmes and in developing first HIV ST guideline for the upcoming pilot among MSM and TG in 2021.

The internal HIV ST guideline includes specific recommendations form testing of MSM and TG population. HIV self-test kits are mostly considered to be distributed via internet platforms through special dating (Grindr) applications and promoted Facebook adds. If the person is interested to obtain

[38] https://hera.org.mk/hiv-samotest/

[39] HIV self-testing among gay men and other men who have sex with men in the republic of North Macedonia: attitudes, acceptability and required information https://hera.org.mk/wp-content/uploads/2020/07/HERA-istrazuvanje-Samotestiranje-za-HIV-en-web.pdf?fbclid=IwAR26z8nEakoSysjpviLHM7VhSr_TjP6rk7KUFG-WGXSKP8x1bDCbV2wL3Dw

HIV ST, he/she is offered to fill an online questionnaire[40]. The questionnaire includes 20 questions; the community members are asked to indicate how they would like to receive test kits. According to the feedback received from MSM community there is a need to edit questionnaire, minimize the questions from 20 to 8.

"Shorter questionnaire may reduce barriers to filling them…"

MSM community representative

There are two modes of ST delivery: 1) Via user friendly services/VCT services, where are other type of screening testing available. After filling online questionnaire, they can come to ST test-kits. This model of HIV ST delivery designed for key populations is being served with or without additional support of HIV counselor by hot line. This is the most common method of HIV ST distribution in the country. 2) receiving test kits by home delivery service, with no geographic barrier. The clients have to appoint their telephone numbers only, not the addresses. When the delivery company contact them by phone, they will schedule the location for delivery. This can be any place that is suitable for the clients. Leaflets with illustrations/pictures and detailed manufacturer-provided instructions translated into local language are available in the test-kits. Leaflets also contain QR codes with video link https://www.youtube.com/watch?v=8NbS0YhjaHU. Video instruction on HIV ST is also available online to help potential users to understand the ways for its correct use. According to internal protocol, clients can use virtual real-time support or supervision through online platforms, such as phones Viber, but this service has not been requested by clients so far.

"We have online questionnaire on site, community members are advised to use them. Still, we don't have many responses, as well as not many people are ordering HIV self- test kits, we are just thinking how to make ST more popular in our country…"

CSO representative

Boosting of online advertisements had great impact in terms of increased recruitment for HIV ST. Based on the practice SCO representatives mentioned that the Peer-to-Peer HIVST distribution model was much more successful than internet-based model. In October 2022, based on increased efforts among peers, there were distributed nearly the same amount of test kits (229) as during the whole pilot – 6 months. Among the tested, 3 were diagnosed as positive and are currently involved on ART.

Besides to this, there are focal points per difference HIV service sites, appointed by NGO HERA, who distribute HIV ST kits via their networks among MSM and TG groups at LGBT cafeterias, some LGBT events, at stationary HIV prevention service sites, for people who feel uncomfortable to do blood test. HIV ST kits are also available to people who wants assisted HIV testing.

Representatives of all these organizations who participated in interviews for this assessment stated that as the HIV testing reveals to be rather weakest part of National HIV Test and treatment cascade for the country, HIV ST approach should be scaled up and adopted by the state funded HIV program as appropriate strategy to reach those stigmatized and marginalized key affected population in North Macedonia. Community members also noted about missed opportunities to identify new HIV cases at earlier stages among different key population groups. They mentioned that it will be useful to use some motivational packages to facilitate their interest in HIV ST at the beginning stage of introduction HIVST among PWID and SWs.

[40] https://docs.google.com/forms/d/e/1FAIpQLSdB-q-k2z7wYp8tns_1IM4xobkC4yryvxAtpyDMbfVn-EBQgA/viewform

,,I have heard about HIV/ST, from another organization HERA, and I took little part for implementation of self-testing kits among PWID. I like a lot, because I had lost a lot of chances for testing my clients, because of factor time, but if I had Self-Testing kits, I would give one and mission accomplished. If every person with HIV get test, know their statuses, and be on ARV, eventually HIV will not be transmitted to other people…"

PWID/PWUD community representative

"HIV ST should be considered for general population to some extent. Because of high stigma, they are hidden, they hide the risky behavior, mainly their MSM practice…"

MSM community representative

"I think that acceptance wouldn't be problem for HIV ST for PWID, maybe in some cases who are hard to reach, and because they have double stigmatization or as women, or as Sex Workers or like Roma PWID etc, and because of totally different ways of life. Lot of PWID last decade became homelessness, in very bad socio-economic status. It should be great, at the beginning of introduction non HIVST, to give some motivational package, food, or hygiene to our clients in need, and getting possibilities for distribution and explanation of self-testing procedures, peer to peer…".

PWID community representative

As the pilot has ended and there are considered a meaningful scale up of HIV ST intervention among other key groups (PWID, SWs, general population to some extent), there is a need to update the existing internal protocol that will be in line to new interventions.

Self-tests are donated from Alliance for Public Health within the Global Fund regional SoS program. Part of program costs are funded by IPPF project that includes scaling up continuation and finalization of pilot results. This model is ensured till the end of 2022. For the next year, CSOs expect that HIV ST-kits will be procured by state program.

,,A transition from donors to state funding is happening now. State program should do more to scale up HIV ST…"

CSO representative

"We have only pilot project for now, HIV ST is being delivered in limited number for community members, only for MSM and TGs. During the last months it became available for female SWs. it depends on foreign funding only, but it has limited capacity. If HERA doesn't success to manage the funds, we will not have HIV ST…"

PWID community representative

"HIV ST should be accessible for people in rural areas, who don't live in Skopje, who have self-stigma because of their risky behavior. In the past we wanted to make it pilot to include HIV ST in vending machines, together with condoms and syringes, but this was postponed, because no funding to buy these machines…"

MSM community member

HIV service providers and community members noted that sustainability issue of HIV ST is not clear, at this stage they try to do advocacy activities. The main purpose of advocacy is to include HIV ST into national HIV and integrate it in existing HIV service delivery model. In this case they will not be dependent on donor funding, but government will ensure procurement of HIV ST that is the most challengeable currently.

"In future, after the donor withdraws, it must be funded by state program, by MoH, as HIV ST is combination of HIV prevention tool, currently incorporated in HIV prevention, HIVST should be included in all means of prevention programs at national level…"

MSM community representative

"In order to ensure all marginalized community affected by HIV, to have easier access to HIV testing, on a regular basis HIV ST should be distributed to all communities by outreach team and by all service providers. For now, ST is only managed by one organization, by HERA. Thanks to them ST is available…"

MSM/TG community representative

"Finally, the most important is to note that HIV ST funding responsibility is on MoH not for the CSO. Country is responsible for HIV prevention, we are partners as service providers, all the service funding should be provided by MoH and HIV ST is within the frame essential tool kits…"

SW community representative

NGOs that were involved in HIV ST preparation process, are aware about WHO guidance and other international experiences on ST, in comparison to those NGOs and community members who are involved only in HIV ST delivery.

All the interviewed participants from state and non-governmental entities, as well as community members noted that HIV ST increases the uptake of HIV testing among different key populations.

"If the person is HIV positive after using self-test and they are not prepared for confirmatory testing, they would not come. We may lose him in this case, if he has not any implication in health. They should be prepared mentally risk counsellors, for all kind of outcome of testing… Still there is no case of lost to follow up in our country…"

AIDS center representative

Community members consider that HIV ST has both advantages and disadvantages in general. They noted that flexibility in access of this test lies in the fact that it removes the geographical barrier to HIV testing.

,,HIV ST can remove geographic barrier as most HIV services are in the capital, ST should be very accessible to all community throughout the country, online order should include all regions, cities, but HERA now has very limited resources, and only self-test kits are not enough, but operational costs, to overcome geographic barrier…"

CSO representative

Another positive side is the fact that people who wants to avoid stigma at healthcare facility can do HIV testing at home. Community members also noted that self-testing may facilitate access to HIV prevention services for the hidden population. If those, firstly tested on HIV, were unaware of these services, after reading the instructions on HIV ST leaflets, they have information about referrals and where to get the services they might need.

"I think it is great, because have a lot advantages, especially possibility to stay home and to test yourself alone, whenever you want, and I think its good idea, and it's good for demystification of HIV/AIDS…"

PWID community member

"I think, most interesting people to reach are those with no HIV testing experience, they don't go to testing to public spaces, once they are offered HIV ST, they accept this. We have that kind of people who got HIV testing first time. Community assistance, for the people who are not notable about this testing, we explain how the ST is being done. Some people, like PWID and street SW mostly need our us assistance…"

SW community representative

"The people who don't know about our organization and can't receive info what to do and where to go (if they tested HIV negative, they will continue risky behavior), their clients can be luckier. They can be engaged in HIV preventions services, counseling and contribute to their risky behavior decrease…"

MSM community member

"Yes, of course, HIV ST could reach to never tested people, this is important… Yes, for rural places it can support. It can be home based testing or at some certain locations, we had one positive case of young man from rural place. This is more comfortable for them to be screened at home…"

AIDS center representative

Community members discussed some negative sides of HIV ST. Some people form key population don't have high education to understand the instructions, besides, there are different myths about HIV ST. Another bigger threat, as CSO representatives noted, is related to harmful behavior or negative psychological impact of a reactive/positive result when a person is performing self-testing alone. Absence of VCT counselor and lack of professional psychological support may lead to mental health crises.

"If being alone during testing, HIV positive results can lead to suicide, impressions, it will affect their mental health, it is a sensitive issue, that may be a risk". There was one case of SW who did home self-testing and was in panic as she tested HIV positive. She applied to this service, we helped her to follow next steps…"

MSM community member

"It will take time to raise awareness about positive sides of HIV ST, among key population, especially among PWIDs and SWs, they are more stigmatized. They don't have high level education, living in patriarchal surroundings, Roma people easily accept dogma… "

FSW community member

"I am not sure how they will understand the way how to accept testing result, how to accept false negative HIV test results. There was one case, when HIV ST screened positive and it was not confirmed after. This makes some uncertainty…"

MSM community member

"I think this is reason why our outreach workers are essential, they are in really close connection with the community, to my experience HIV positive person, our community member is psychologist who accompanied one HIV screened positive client to private clinic and after to infectious disease clinic. Before getting final result, during one month he was in uncertainty, our community worker supported him, that is why our support it essential".

SCO representative

In terms of existing barriers, community members noted that sometimes NGO staff don't promote HIV ST, they prefer to offer key population other HIV rapid tests. They suggest that maybe some HIV service organizations do not believe much in this intervention, or they perceive these tests as somewhat competitive services, they think that existing VCT services may not be needed in the future and people will directly apply HIV self-tests.

Service providers were asked whether HIV ST increases linkage to care of people diagnosed with HIV or it is similar to that in standard facility-based HTS. They noted that during the pilot project linkage to care was the similar to standard rapid testing, but still, it is too early to assess quality of linkages, it may decrease, as VCT counselor is not participating in pre and post testing according to assessment of service providers. To overcome this potential threat, HIV ST service providers considered adding 2

hotlines where VCT counselors provide comprehensive information and counseling with needed psychological and social support to clients, in case they need some assistance.

"Personally, I am not sure if HIV ST increases linkages to care of people screened HIV positive. Still it is a new practice, lots of stigma, people don't trust health institutions, fear of breach of privacy..."

MSM community member

"If the client calls us, we can give them some advice how to do ST, about HIV in general. If they are screened as HIV positive, we are giving them telephone number of the clinic to get psychological and social support, we help them with referral to make appointment. Leaflets are available in the kits and instruction and pictures, also they have video instruction and QR code with video link inside the kit…"

CSO representative

"HERA developed very good methodology, how to reach healthcare centers if screened positive after HIV ST, I reached 3-4 sex workers as a focal point to support them in linkage to care. These focal points distribute but also motivate to use ST. This function is good, I like it. I don't think there is a lack of complementary approach to HIV confirmation and linkage…"

CSO representative

"HIV positive cases were found by HIV ST among those who were tested before as negative during recent years. As a result of risky behavior they got HIV. They found HIV ST more convenient for them, for some people ST is easier to know their HIV status, if that person refused to do HIV testing at mobile lab or drop-in center, they have this option. As I am aware, still there is no case of lost to follow up…"

CSO representative

Service providers and community members were asked whether a meaningful participation of community members and people from key populations was ensured in designing and delivering services. They noted that during the preparation of pilot project targeted to MSM, HERA underwent consultations with some community organizations to create a new model relevant to local context.

"I know that MSM community were asked, and focus groups were made, but also I believe that also a lot of NGO's or governmental organizations are just spending money, if they don't ask targeted community and don't consider their opinion…"

PWID community member

"I have been involved on behalf of SW community. I have no concerns regarding it…"

SW/TG community member

Community members provided their suggestions about the activities that should be undertaken by service delivery organizations for demand creation for HIV testing. According to their opinion Peer-led interventions should be undertaken at festivals and Chem-sex parties, key populations should have access to HIV ST. CSO representatives, as well as KP members highlighted importance of advertisement via digital platforms and social media, as well dating applications.

They talked about missed opportunity to use Paralegals in dissemination of HIV ST related information. Vending machine was also noted as one of the important way to reach those unreached among MSM and SW/TG population. However, one PWID community member noted the opposite:

"I don't give a lot of faith on vending machines because PWID are people in need of human emotion and non-judgmental look towards them… My experience told me, PWID need human touch, warm smile, shake hands, hugs, smile, something that vendor machine cannot offer…"

PWID community member

"If trained properly, outreach Paralegals team can reach difficult groups, they have access to most marginalized groups who mostly have low access to healthcare and testing services..."

CSO representative

"There are several ways to increase awareness and access to HIV ST. Vending machine is good idea, toilets of the parties at festivals is great idea as well, people can take it home and do testing when applicable…"

MSM community member

"In Macedonia we don't have digital platforms, for escort women, we should develop such kind of digital platforms or some specific interventions for them too…"

SW community member

Community members also noted that some innovative approaches like fixed financial and lottery-based incentives for HIV ST can work affectively, especially for SWs.

"Still, we don't have any financial and lottery-based incentives, but it will definitely increase motivation, especially among SW…"

SW community member

Both service providers and community members noted importance of HIV ST availability at pharmacies. Currently HIV ST are available in the pharmacy, the price per unit it 5-10 euro. All the interviewed respondents expressed dissatisfaction due to high price, they consider that this is an important obstacle for people who don't have access to free HIVST, it should be affordable for general population. From the other hand, pharmacies currently have no business interest to HIV ST, as the demand on among general population it has not been created so far. KP and CSO representatives mentioned, that although there can be some stigma related issues toward HIV ST at pharmacies, some effective ways can be elaborated there to avoid stigma related barrier.

"The price should be accessible for all communities however some community members can afford it. For street SWs it is too expensive, as they get 5 euro per client, no sense to pay 10 euro for HT at pharmacy. it should be available in the pharmacies for free even. If we want to have much more people tested, we should have more access to HIV ST and more availability…"

SW community member

"Advertisements about this testing option and availability of test kits in pharmacies should be done in shopping malls, where number of consumers is big enough there every day…"

MSM community member

"Decision makers should concentrate HIV ST related activities only toward MSM population, as HIV prevalence is higher in this group, but we should also increase awareness among general population, they should know what it is, where to buy it, as we sometimes cannot reach ,,classic gay men" directly, they don't declare often, there is risk behavior…"

AIDS center representative

KP and CSO representatives discussed the importance of increasing awareness about HIV ST among sero-discordant couples. Introducing of HIVST may facilitate in-home, self-guided couples testing[41].

"Motivational messages on HIV ST during couples counselling (among sero-discordant couples) - this is a good way too, especially if trusted people do such counselling, they (key population) should understand that HIV diagnose is not fatal, it can be managed, and you can still have good quality of life…"

CSO representative

Representatives of all KPs stated that HIV self-testing would increase testing coverage, it would be convenient for them to perform test alone, they would be free from unpleasant feelings that they experience during accompanied testing, especially at health care facilities in a stigmatized environment. However, they also mentioned that without proper education, supportive material (such as instructions for use and contact information where beneficiaries can address in case of positive results) and adequate follow-up services it might lead to even worth consequences. Sensitization of staff at follow-up services is also an important aspect for consideration.

"Together with promotion of HIV ST informational-awareness campaigns should be carried out. This will lead to de-stigmatization of HIV issue, as people are not familiar about HIV transmission and where to test on HIV. Social media, NGOs are doing a lot – especially for young people, but for older population who less use Facebook and social platforms, we need to work more. We should educate journalists how to inform about HIV…"

CSO representative

"We should focus on MSM more, as HIV prevalence is higher. Besides, we need to reach young people with risky behavior, to prepare community for PreP and other HIV related services and outreach…"

CSO representative

Key populations as well as CSOs were asked about their experience regarding quality of HIV ST. They noted that no individual case of dislike was revealed during the pilot period. They had a case, person who tested HIV positive based on HIV ST, but after he screened as HIV negative in a private clinic. Finally, this case was confirmed as HIV positive at the University clinic of infectious diseases.

"We had a case when HIVST came out as positive, person went to private clinic and did HIV screening but got HIV negative result. We insisted to accompany us to University clinic of infectious diseases, HIV positive status was confirmed. HIV ST delivered by HERA was much more quality than those test that was used by private clinic here. I have no problem with the quality of STs…"

CSO representative

Recommendations

- Consider HIV self-testing as an important part of next National HIV Strategy for 2023-2027 with a strong commitment to scale up HIV testing among key affected population that reveals rather weakest part of National HIV Test and treatment cascade for the country.
- Update National Guidelines/Protocols for HIV testing, outlining clear HIV testing algorithm in line with WHO recommendation. Community based testing and HIV self-testing should also be a part of this guideline. Removing any possible restrictions that require all testing to be conducted by

[41] The term "sero-discordant couple" refers to an intimate partnership in which one person is HIV-positive and the other is HIV-negative, Advances in HIV Prevention for Serodiscordant Couples, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4267973/#:~:text=I.,the%20other%20is%20HIV%2Dnegative.

medical professionals at community settings; The development process should ensure engagement of representatives of target populations.

- Update the existing internal protocol on HIVST in line to new interventions for other key groups (PWID, SWs, general population to some extent) to support the meaningful scale up of HIV ST intervention, minimize the number of online questions to be filled in before order by communities.
- Develop effective National level monitoring and evaluation system for HIV testing (including HIV ST), that includes frames for M&E, responsible entities ensuring quality of VCT services (governmental and non-governmental facilities), with special focus to ensure pregnant women, prisoners and patients of hospitals and private clinics with pre and post HIV test counseling. The data of monitoring and evaluation of HIV testing and linkages enables decision makers to better plan and increase efficiency of interventions targeted each KPs.
- Ensure sustainability of HIVST after donor-funding by developing long-term funding mechanisms for NGOs/CSOs as implementers of community-led HIV prevention and support services for KPs. Ensure adequate funding of HIV self-testing within state HIV program for 2024-2025, funding should include procurement of HIV self-test kits, as well as costs for demand creation activities that are in line with WHO recommendations. Project designs for scale up for other key populations (FSWs, PWID, Young key population and their sex partners) should be developed by meaningful participation of communities, as well as HIVST delivery services.
- Develop an integrated information and communication strategy with sufficient activities to raise awareness on HIV transmission ways, HIV testing for both the general population and KPs. Regular implementation of these activities is essential. The informational-awareness campaign development process should ensure engagement of representatives of target populations. As well as to educate journalists how to inform about HIV. Ensure adequate funding for information and communication activities.
- Integrate HIV self-testing intervention into existing HIV service delivery models in the country (part of HIV prevention package for key populations) including OST programs.
- Plan and implement HIV stigma and discrimination research activities and develop policy and advocacy recommendations for reducing HIV-related stigma and discrimination
- Address stigma related HIV testing barriers (including human rights violations, homophobia, direct and indirect discrimination, stigma and discrimination by care providers) by prioritizing activities aimed facilitating formation of friendly healthcare environment towards PLHIV and KPs in line with local context.
- Ensure broader participation of HIV service providers in HIVST delivery, prepare NGO staff to promote HIVST among their clients; Training and sensitization of staff both at NGOs and state/primary healthcare facilities on HIVST and follow-up services.
- Foster collaboration between HIV service providers and different medical providers, including primary health care centers to disseminate information about HIV ST to improve the coverage of HIV self-testing.
- State agencies together with NGOs negotiate with HIVST producers/dealers to decrease price for increasing accessibility to ST at pharmacies.
- To develop some effective ways to minimize stigma related barrier for customers during procuring HIVST in pharmacies.
- Support licensing or official registration of self-test kits as medical products in the country licensing and registration.
- To remove policy and legislative barriers to realize right to health of key affected population, as Punitive and discriminatory laws and policies are undermining the AIDS response by pushing people

away from services and undermining public health efforts to reach those most at risk of new infection or death[42].

- Develop list of innovative approaches for demand creation in order to scale up HIVST **for all key affected groups:** a) CSO/NGO Community-based, Peer to Peer secondary distribution b) medical facility-based c) Develop digital platforms for HIV ST distribution, develop video-based information, targeted messages for counselling to reach designated key populations and use chat-bots in online spaces; boosting advertisements in social media, as well dating applications ordering online and receiving via mail; d) Distribution of HIV ST during special events, like music festivals, night clubs, Chem-sex parties.
- To maximize benefit, demand creation efforts on HIV ST should be focused: a) on people who do not know their status/never tested individuals and b) on people with risky sexual and injecting behavior to promote re-testing. Demand creation can also address stigma and discrimination issues towards KPs.
- Monitor and evaluate effectiveness of HIV ST demand creation activities and the results regularly to ensure that demand creation works correctly and does not increase stigma. Based on results, review the strategies and action plans toward HIV ST by meaningful participation of communities and modify/develop new evidence-based interventions.
- To develop fixed financial, other motivational (food or hygiene) and lottery-based incentives as potential ways to pilot HIV ST interventions in the country. Although while considering incentivization for demand creation, benefits and risks should be carefully weighed, to avoid potential negative effects related to equity, due to prioritization of some populations and diseases; besides some issues can come due to sustainability of such interventions after pilot and dissatisfaction of community members if incentives quite.
- Ensure funding to scale up HIV prevention and testing services by developing vending machines distributing HIVSTs, condoms, syringes, other sterile paraphernalia, informational materials.
- Promote and increase awareness about HIV ST among sero-discordant couples. Introducing of HIVST may facilitate in-home, self-guided couples testing.
- Consider using HIVST for PrEP program when facility-based services and in-person patient-clinician contact is limited.

[42] UNAIDS GLOBAL AIDS UPDATE 2022 https://www.unaids.org/sites/default/files/media_asset/2022-global-aids-update_en.pdf

Albania

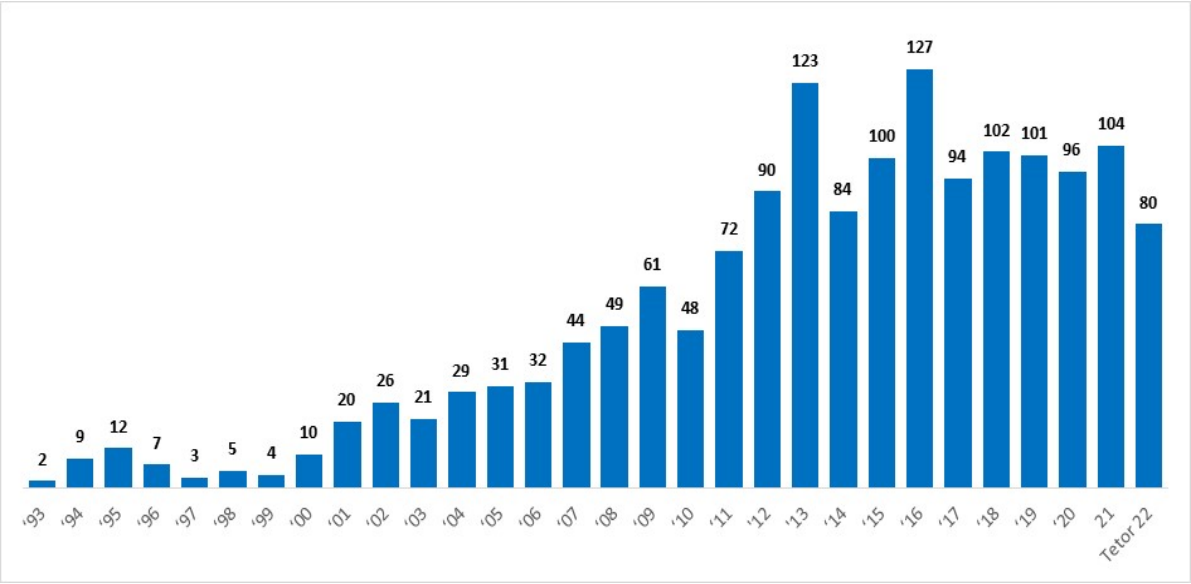
Albania, on Southeastern Europe's Balkan Peninsula, is a small country with Adriatic and Ionian coastlines with a total of 2,877,797 people at mid year according to UN data. The country is bordered by Greece, North Macedonia, Kosovo and Montenegro. Albania is considered an upper-middle-income (UMI) country. 63.5 % of the population is urban, The median age in Albania is 36.4 years. The largest city and the capital is Tirana.

Overview of the HIV epidemic in Albania

Albania remains to be a low HIV prevalence country with concentrated epidemics in key populations, mainly among MSM (2.0%) and PWID (1.4%). However, the increasing trend of positive cases and the assessment studies suggest higher numbers. The latest IBBS study (2019) indicated high-risk behaviours among all KPs, particularly among PWID and MSM.

At the end of 2019, HIV prevalence was estimated at 0.04%, while the incidence was 3.6 per 100,000 people. At the end of October 2022, a total of 1588 HIV cases had been reported. In 2016 marked the highest figure ever report, since the beginning of HIV / AIDS in our country (1993). According to Country progress report of Albania[43] (Global AIDS Monitoring report 2020) the available data are likely to be an underestimation of the actual number of HIV cases. The available data are based on HIV testing data, while only a very small proportion of the population is being tested for HIV, especially among key populations.

Figure 4. Distribution of HIV cases in years in Albania, 1993-2022



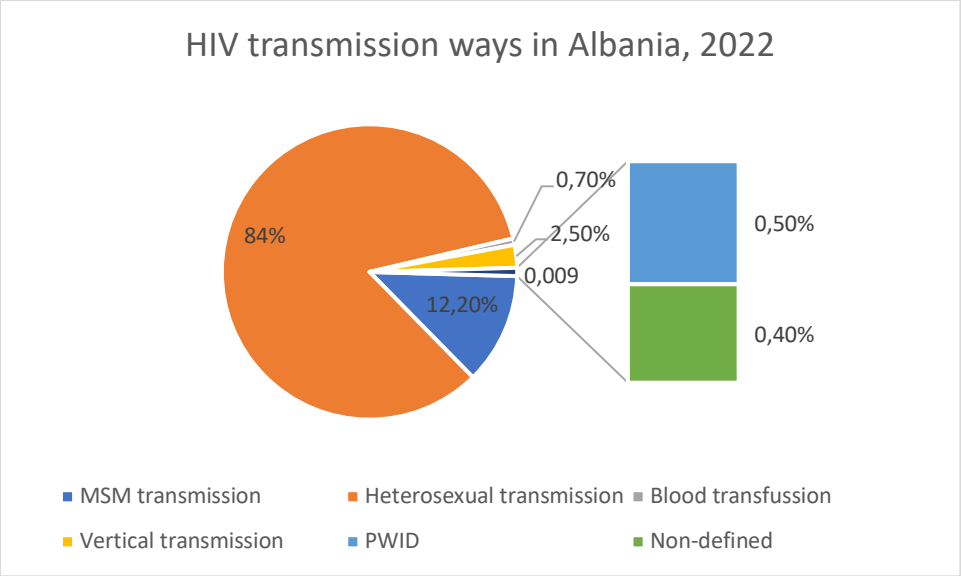
Source: Institute of Public Health, Albania

Majority of PLHIV are living in the capital Tirana, where HIV epidemic is concentrated.

[43] Country progress report of Albania (Global AIDS Monitoring report 2020) https://www.unaids.org/sites/default/files/country/documents/ALB_2020_countryreport.pdf

In 2022, the main mode of transmission was self-reported as heterosexual contact, it is considered by the experts that due to strong stigma and discrimination toward MSM, male-to-male sexual transmission can be the important route as almost three-quarters of HIV cases were males, as well as there was a relatively high number of sero-discordant couples.

Figure 5. Distribution of HIV cases according to the route of transmission (n=1586).



Source: Institute of Public Health, Albania

According to UNAIDS Spectrum 2017, the number of people living with HIV in Albania was 1400. Nearly 25% of PLHIV don't know about their HIV status. 2019 IBBS study shows that there are low HIV testing rates among key populations. Nearly 60% of the new HIV reported cases are being revealed in late stages of infection44. According to last IBBS data in 2019 HIV testing rate in the past 12 months among PWID is nearly 51%, among MSM – 39% and among SW – 31%. The difference between the 2011 and 2019 IBBS results show a positive trend as in 2011 24% of MSM reported tesing on HIV in comparison to 2019 where MSM HIV testing rate was 50%.

Late diagnosis also represents a challenge with 47,7% of PLHIV presented with the initial CD4 cell count <200 cells/mm3 and 61.4% with the initial CD4 cell count <350 cells/mm3 during 2019[45].

Figures 6, 7 and 8 below show that the country progress to reaching the 90-90-90 targets, with an overall test-treatment cascade of 80% – 61% – 83% in 2020. The "Second 90" is the most problematic part of the cascade, especially among males, with only 59% having been in treatment while knowing their status, compared to 69% of the female population in 2020.

Figure 6: Test and treatment cascade among adults, ages 15+, both sexes, 2017-2021[46]

[44] Country progress report of Albania (Global AIDS Monitoring report 2020) https://www.unaids.org/sites/default/files/country/documents/ALB_2020_countryreport.pdf
[45] Country progress report of Albania (Global AIDS Monitoring report 2020) https://www.unaids.org/sites/default/files/country/documents/ALB_2020_countryreport.pdf
[46] UNAIDS HIV estimates. Available at: https://www.unaids.org/en/resources/documents/2022/HIV_estimates_with_uncertainty_bounds_1990-present

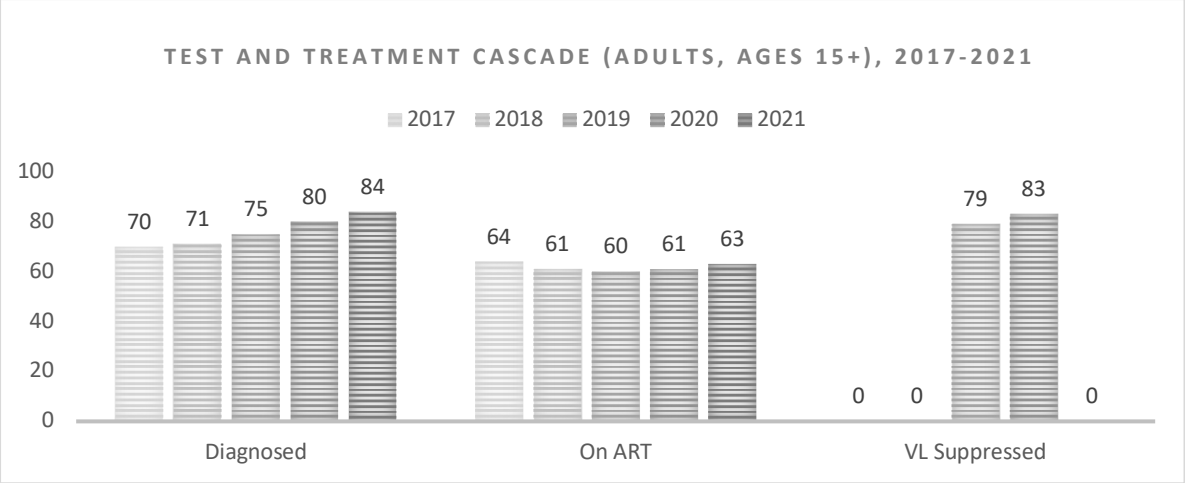


Figure 7: Test and treatment cascade among adults, ages 15+, males, 2017-2021[47]

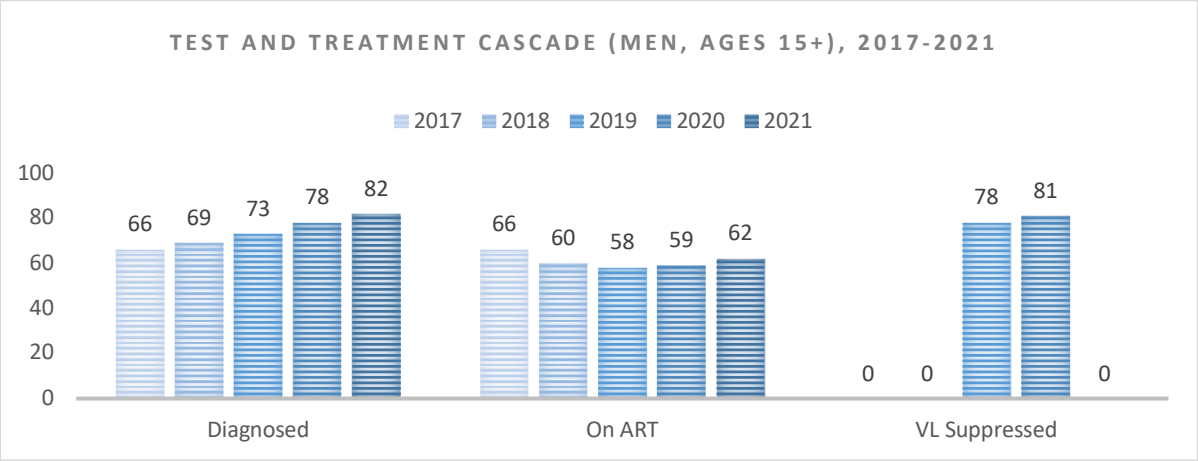
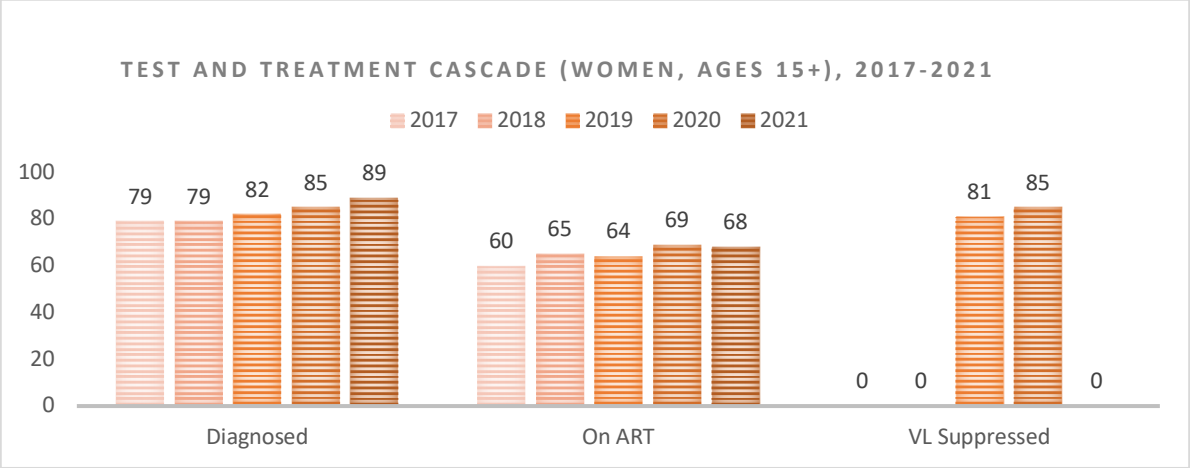


Figure 8: Test and treatment cascade among adults, ages 15+, females, 2017-2021[48]



[47] ibid
[48] ibid

HIV testing – policy and practice

The leading role of national HIV response implements the Institute of Public Health (IPH), under the Ministry of Health, in department of Epidemiology and Infectious diseases control. This unity is responsible for HIV prevention, coordination of national HIV response, HIV testing, designing of HIV prevention policy, preparation HIV and related strategic documents. Accordingly, they are working with all key population groups: men who have sex with men, sex workers, people who use drugs, TG.

University hospital centre, in the capital city Tirana, as a separate entity, is responsible for HIV treatment. There is one reference laboratory which performs HIV confirmatory testing. Every single HIV positive test that is detected in Albania (VCT centres, NGOS private lab, etc) is confirmed at the Institute of Public Health, and then is referred to University hospital centre in Tirana for treatment. HIV confirmation can be conducted even without Personal ID number, based on Unique code.

Currently, PreP is not available in Albania. The introduction of PreP is under discussion and according to the plan it might be started in 2023.

In Albania, people are tested/screened for HIV infection through Voluntary Counselling and Testing (VCT). HIV testing is available in all major cities (13 regions throughout the country). VCT testing as "recommended testing" is also provided in University hospitals and main pulmonary disease centres in Tirana. HIV testing is also provided at the Institute of public health (National Reference Centre). 6 districts of the country with its IPH centres provide Eliza testing as well. HIV testing is also provided by private hospitals and clinics and laboratories.

Table 4. List of VCTC centers in Albania

Facilities	Legal status (state/hospital/PHC/NGO/Community based organization/other)	Beneficiaries (general population / KP, including MSM, SW, TG, PWID, Prisoners/ migrants/blood donors/health care workers/pregnant women/youth/other)
National HIV/AIDS Laboratory	Institute of Public Health	General population / KP, including MSM, SW, TG, PWID, Prisoners/ migrants/blood donors/health care workers/pregnant women/youth/other)
Regions: Tiranë, Durrës, Elbasan, Lushnjë, Fier , Vlorë, Berat, Lezhë, Shkodër , Kukës, Korçë dhe Gjirokastër.	Regional PHC	General population / KP, including MSM, SW, TG, PWID, Prisoners/ migrants/blood donors/health care workers/pregnant women/youth/other)
National and regional blood centers	State/Hospital	General population / KP, including MSM, SW, TG, PWID, Prisoners/ migrants/blood donors/health care workers/pregnant women/youth/other)
Institute for Health, Social Policy and Research Development (former STOP AIDS NGO)	NGO	KP, including MSM, SW, TG, PWID, Prisoners, young people including sexual/injecting partners of target population

Aksion Plus	NGO	KP, including MSM, SW, TG, PWID, Prisoners, young people, including sexual/injecting partners of target population
ACPD	NGO	KP, including SW, pregnant women and young people
ALEANCA	NGO	KP, including MSM, SW, TG, young people and other vulnerable groups
ALGA	NGO	KP, including MSM, SW, TG, young people and other vulnerable groups.
PLWHIV (olimbi)	NGO	KP, including MSM, SW, TG, young people and other vulnerable groups.
Prisons 6 male and one female prison)	State/Ministry of Justice/General Prison Administration	General prison population, including the ones coming from the MSM, SW, TG, PWID subgroups.

VCT centres for key populations were established as stand-alone centres, in 2007 within the Global Fund (GF) program. From 2009 all the VCT centres were funded by the government program. These centres are already integrated into healthcare system of Albania. HIV testing is free of charge to everyone who needs HIV testing but is also available at private clinics as paid one. Apart from HIV, VCT centres provide screening on other STIs (HCV, HBV, Syphilis, Gonorrhoea) for key populations.

Since the underwent healthcare system reform in 2020-2021, VCT centres don't function as stand-alone centres, they work under the departments of public health. Non-governmental organizations (NGOs) and community-based organizations (CBOs) provide HIV testing and prevention services to key affected population: MSM, PWID, TG, SWs and their sex partners (Needle and Syringe program in 6 districts, HIV prevention services for MSM in 5 districts and for SWs there is one centre in Tirana). Community based testing includes provision of testing in fixed sites (stationary service points for PWIDs, MSM and SW), through mobile vans/outreach in "hot Spots", and special testing campaigns and events (e.g. for university students). There are 2 mobile vans that serve PWID and MSM population at outreach. There is no syringe or condom vending machine in the country. Counselling and testing for Hepatitis B, C, Syphilis, Gonorrhoea and Chlamydia has been provided at all established centres.

HIV testing for key population is free and anonymous (using a unique code) and provided by NGOs through the GF program. Every NGO apply the same coding system to avoid duplication of clients. Besides, all key populations can come for rapid testing to state funded VCT programs. In terms of prisoners, HIV testing is provided in prison settings through mini-VCT centres, that were established in prisons by UNFPA support in 2019. The availability of testing is not an issue in Albania, but some concerns regarding accessibility was noted by the respondents who participated in interviews for this assessment. They mostly talked about the geographical accessibility barrier for KPs, especially in regions, where NGO drop-in center are not available and community members do not want to go to VCT centers with the fear that somebody might recognize them.

HIV testing is freely available for general population as well, everyone who wishes to do HIV testing, can get it free of charge. Besides, all migrants can receive free HIV testing in the country. HIV testing is free of charge for refugees as well. HIV testing in voluntary for most cases, except of certain groups that are defined by the Law on the "Prevention and Control of HIV/AIDS" (Article 29). These groups are ,,Blood donors, tissue and organ donors for transplantation, donors for artificial insemination are obliged to undergo HIV testing. This testing is also mandatory for persons who are officially required,

by court decision or at the request of the prosecutor. The Minister of Health approves regulations for mandatory testing, in certain cases, for diagnostic and treatment purposes". HIV testing is also mandatory for military participating in NATO missions but is not mandatory to be carried out before marriage or to obtain a work or residence permit in Albania[49].

HIV testing is being considered one of the most important components of National AIDS strategy for 2020-2025 of Albania that was approved in 2019. The aim, objectives and activities of HIV/AIDS national strategy have become the part of National HIV/AIDS Program, which is supplemented with the National Action Plan (NAP) for 2020-2025. The NAP outlines objectives, indicators, and activities for increasing HIV testing rates in the country and includes different directions for HIV testing, education, testing promotion, collaboration, etc. One of its strategic objectives includes to increase coverage and utilization of HIV-testing services by the general population and key populations, ensure that all PLHIV know their HIV status and can have access to life-saving treatment[50]. Besides, NAP includes another Strategic objective to support integration and better coordination of HIV services, e.g. by the integration of HIV testing in a range of health services (provider-initiated HIV testing), and stronger involvement of local governments in the coordination and implementation of HIV services at the municipal level.

National HIV testing algorithm in Albania was updated in 2020 and is being considered to be in line with the recent WHO´s HIV testing guidelines, although it has not been approved yet (it is submitted to MoH for approval). At this stage all organizations performing VCT and HIV testing (governmental, non-governmental) work according previous "Provider-Initiated HIV testing protocol for Albania", approved in 2019. This protocol was developed by the Global Fund Project Management Unit in Albania. The protocol development process was initiated with a desk review of published and unpublished relevant documents including previous reports on technical missions related to HIV in Albania and the current literature and guidelines on HIV testing[51]. This document offers basic operational guidance on provider-initiated HIV testing and counselling in healthcare settings in Albania.

The need for and importance of updating National HIV Testing Guideline/Protocols was unanimously confirmed by all respondents participating interviews for this assessment. IPH is taking proactive steps and trying to provide relevant recommendation to the Ministry of Health and decision makers to support this process.

According to current HIV testing practice HIV screening is being carried out by participation of a laboratory personnel/nurse and VCT counsellor/psychologist. All the screened positive blood samples from VCT centers are sent to Institute of Public Health for confirmatory testing. HIV confirmatory testing includes Eliza and then Western Blot testing, while WHO recommends that western blotting and line immunoassays should not be used in HIV testing algorithms[52]. Although there was intense discussion to adopt three rapid tests for confirmatory testing, it has not been established so far. Due to small number of newly diagnosed cased per each year, it is agreed at national level to keep the existing Western Blot model for confirmatory diagnostics.

[49] Country progress report of Albania (Global AIDS Monitoring report 2020) https://www.unaids.org/sites/default/files/country/documents/ALB_2020_countryreport.pdf
[50] National Action Plan (NAP) for 2021-2025
[51] Provider Initiated HIV Testing Protocol Albania, Deniz Gökengin, 2019
[52] Consolidated guidelines on HIV testing services, 2019. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

"We still use the same testing algorithm on HIV, all screened positive blood should proceed Eliza and then Western Blot testing. We had a lot of discussion with WHO experts on new model of confirmatory testing. As Albania has small number of new HIV cases per year (nearly 100 cases), we consider that Western Blot is not difficult to do. Still, we want to keep this model…"

IPH representative

HIV rapid testing is done by medical personnel, trained lab personnel at government structures. As regarding to NGOs, they have trained mainly nurses or lab workers to perform HIV screening. According to Provider-Initiated HIV testing protocol there is no specific restrictions for trained outreach worker to do HIV screening at outreach work, but according to current practice, only medical staff should provide it.

"If we are talking about government structure, HIV rapid testing is done by medical personnel, trained lab personals. If we are talking about NGOs, they have trained nurses to perform HIV testing. HIV screening practically can perform outreach workers, we don't have special restrictions on it in guidelines, but according to policy trained medical staff should provide it…"

IPH representative

All the VCT centers, governmental facilities and NGOs, as well private clinics, provide reporting about the performed work to the management team of National AIDS program. According to preliminarily defined schedule monitoring and verification visits at VCT centers (governmental facilities and NGOs) are being carried out twice per year.

The delivery of testing services by VCT centers during COVID pandemic was greatly affected in Albania, like in other countries worldwide. It should be noted that the lockdowns and social distancing has greatly affected the personal well-being and mental health of many people affected by HIV, including representatives of Key Populations. Lockdowns and other pandemic related restrictions have significantly affected access to testing and face-to-face consultations. Accordingly, the number of HIV screening was dramatically decreased, especially first 3 months after pandemic (For example, number of HIV testing of MSM in 2019 before COVID-19, 411, in 2020 this number of 69). Due to absence of HIV self-testing intervention, service providers could not provide home delivery HIV ST to key populations.

"We were really in difficult situation because of restriction during COVID time. HIV testing rate was dramatically decreased. If we had ST, it would increase HIV testing…"

IPH representative

CSOs/CBOs in Albania, being at the forefront of service provision have not stopped operation and continue HIV service delivery in compliance with COVID regulations and all measures of infection control. Over time, service centers have been able to increase HIV testing to the same level as before the pandemic.

The law "Prevention and Control of HIV/AIDS in Republic of Albania[53] (No. 9952) was lastly revised and adopted in 2008. The HIV Law includes 48 specific articles on the principles of HIV/AIDS prevention and control; defines entities responsible for HIV/AIDS prevention and control; and rights and obligations of persons living with HIV/AIDS, as well as includes articles about protection of confidentiality to be ensured by the organization providing VCT.

According to the law everyone has the right to have access to information, education and communication, for the prevention and control of HIV/AIDS. There are defined specific groups

[53] Law No. 9952/14.07.2008, "Prevention and Control of HIV/AIDS in Republic of Albania

interested in information, education, and communication, for the prevention and control of HIV/AIDS (Article 12). These groups are: a) persons living with HIV/AIDS and their family members; b) drug users; c) persons who have sexually transmitted infections; ç) men who have sexual relations with men; d) sex workers; h) mobile population groups; e) pregnant women; e) young people.

Since 2010 there has been introduced an Anti-Discriminatory law[54] in Albania. The purpose of this law is to ensure the right of every person to: a) equality before the law and equal protection by the law; b) equality of opportunities and possibilities to exercise rights, enjoy freedoms and participate in public life; c) effective protection from discrimination and from every form of conduct that encourages discrimination. Anti-Discriminatory law ensures the following legal protections for key populations[55]:

- constitutional prohibition of discrimination based on any grounds
- Hate crimes based on sexual orientation considered an aggravating circumstance
- Incitement to hatred based on sexual orientation prohibited
- Prohibition of discrimination in employment based on sexual orientation
- Other non-discrimination provisions specifying sexual orientation

Transgender people are Neither criminalized nor prosecuted, as well as Laws penalizing same-sex sexual acts have been decriminalized or never existed. Selling or buying sexual services is criminalized, as well as ancillary activities associated with selling or buying sexual services or profiting from organizing and/or managing sexual services are criminalized (Articles 113, 114 and 115). Criminalization of sex work in Albania means that male and transgender sex workers hesitate to take an HIV test or to "carry condoms". Community members from SW population talked about the importance to remove criminalization of sex work, as a barrier to HIV testing and healthcare services.

> *"SW is illegal in Albania. It will be better for me if I will be allowed by the law and the police to provide income for myself and my child. I have no other profession, and no one hires a drug user like me. So, I have sex work as a means of living… We are restricted by law and the police is chasing us, the only possibility for us remain services offered at community center. For us this is the main barriers, being illegal…"*
>
> SW community representative

> *"The data on sex workers is very limited and is mostly based on street-based SWs. Although being identified as KPs, SWs we're not included in any of the BBSS. HIV prevalence among sex workers is reported as 0%. However, the accuracy of this result is controversial due to lack of reliable data…"*
>
> CSO representative

There is a need to obtain parental consent for adolescents to access HIV testing. In terms of PWID, drug use or possession for drugs for personal use is not subject for an offence. No laws or policies restrict the entry, stay and residence for people living with HIV[56].

SCO and community representative who participated in interviews for this assessment noted that HIV stigma is a huge problem for Albania, especially in regions. Stigma together with Structural barriers creates obstacles for LGBT and PWID community to be tested and retested time to time. Discrimination and stigmatization of people because of their sexual orientation or their gender identity makes it harder to engage people in HIV prevention and treatment. Young MSM and

[54] Law No. 10 221 dated 4.2.2010 On Protection from Discrimination, https://equineteurope.org/wp-content/uploads/2021/04/Law-on-Protection-from-Discrimination-Albania_amended-1.pdf
[55] Country progress report of Albania (Global AIDS Monitoring report 2020) https://www.unaids.org/sites/default/files/country/documents/ALB_2020_countryreport.pdf
[56] UNAIDS GLOBAL AIDS UPDATE 2022 https://www.unaids.org/sites/default/files/media_asset/2022-global-aids-update_en.pdf

transgender people are at increased risk of HIV and therefore require targeted, rights-based interventions.

> *"Structural barriers that exist in Albania, including human rights violations, homophobia, direct and indirect discrimination, and shortcomings in the implementation of policies and laws; all of which limit the effectiveness of HIV intervention programs, hinder or reduce service delivery, compromising the quality of services; Stigma, homogeneity and discrimination by care providers; stigma from Health care personnel often discourage KAP community members from seeking and receiving basic HIV prevention, testing, and counseling services…"*
>
> TG community representative

> *"Outside the walls of this community center, I would not prefer to go to be tested. There are many barriers and stigma in the provision of HIV testing, as in general for the members of the MSM Community, the behavior and services offered to us by the medical staff are not always very friendly and without stigma…"*
>
> MSM community representative

> *„Although in Albania there are legal frameworks for access to healthcare, they are not yet a reality and the gap between policy and practice needs to be bridged; In Albania, public awareness of the principles of discrimination and the fight against it, is still very low; Sexual Orientation in society is considered a moral crime and the public perception of homosexual orientations is associated with the constant weight and pressure of prejudice, discrimination, and even abuse and physical violence…"*
>
> LGBTQ community representative

It is important to note that in spite of no restrictive legislation, MSM are the most hidden key population in Albania. PWID can be considered as stigmatized key population as well. The results are from IBBS 2019 shows rate of avoidance of health care among key populations because of stigma and discrimination: PWID - 11.6% for avoidance of Health Care and 5.3% for avoidance of HIV Testing; MSM – 6.7% for avoidance of Health Care and 8.5% for avoidance of HIV Testing.

> *"Discrimination and stigmatization of people because of their sexual orientation or Transgender people face intense levels of violence because their appearance does not conform to gender expectations. A report on human rights violations of transgender people reported high levels of discrimination against transgender people in schools, bars and streets. Many homeless transgender people are forced into street sex work to make a living, and because sex work is criminalized, they are at high risk of being exploited. Because the police do not provide protection, transgender sex workers are subject to rape and other forms of brutal sexual violence, stalking and sexual harassment. In interviews with transgender people, they reported a high level of threats and physical violence from unknown people…"*
>
> LGBTQ community representative

> *"Health and well-being, including HIV and access to public health services, are real concerns for LGBTI people. For transgender people, access to gender-confirming surgery is a concern. Conversely, intersex is often forced into unnecessary medical interventions. In-vitro fertilization (IVF) and assistive reproduction technology (ART) are not available to LGBTI people. A lack of LGBTI-friendly healthcare facilities and services is coupled with discriminatory attitudes and practices by the medical professional…"*
>
> LGBTQ community representative

Stigma from healthcare professionals against key population was noted among other barriers to HIV services. They talked about some cases, where transgender people who were attacked and beaten to death were left without help and medical treatment. Discrimination from medical personnel because of risky behavior was mentioned towards PWID and MSM population as well.

> *"Persisting patriarchal and hetero-normative discourse, lack of wider institutional support, fear of emotional and physical violence associated with the HIV positive status, stigma and discrimination play a*

significant role in preventing members of key affected populations accessing HIV testing for earlier diagnosis and treatment of HIV infection…"

TG community representative

We also asked community representatives (MSM, PWID, SW, TG) to talk about the barriers of rapid HIV testing and provide community perspectives for improvement to be recommended to policy makers in Albania. They mentioned stigma as the biggest barrier to HIV testing. Lack of information and communication on HIV prevention is another issue that concern KPs. More resource investment in HIV prevention is needed from the state to ensure adequate access of KPs to essential HIV services.

"All the time since I started Methadone Therapy, I have been tested on HIV here at the center, otherwise I didn't know other places than offer testing for HIV. I know, as a drug user I'm not so much pleasant for the medical staff, some other people working there are not so friendly with me…"

PWID community representative

"As a drug user I'm not so much welcome in society or at healthcare settings, and people working at hospitals are not all the time so friendly with me. I feel they look at me with disrespect and I always try not to be in contact with them, only when I urgently need it…"

PWID community representative

There is no restriction in laws, regulations, and policies for Community-led HIV service Delivery in the country. Registration of HIV civil society organizations or community-based organizations is easily possible. HIV services for key populations (condom/lubricants distribution, IEC, harm reduction/needle exchange, community-based voluntary counselling, and testing (at stationary points and through mobile testing vans) are provided by CSOs/CBOs in collaboration with state agencies in Albania. Community-based testing services are commonly recognized as a good model to improve access to most-at-risk populations by promoting early HIV diagnosis in Albania. It was clearly revealed that the representatives of KPs do not want to be tested at state VCT centers, the most acceptable and convenient place to receive HIV prevention services is NGO/CSO. Community members noted that low threshold and friendly environment created by peers at community sites are the main facilitators to HIV prevention and testing services for them.

"Community-based HIV testing can be offered in many ways such as home-based testing or by door-to-door outreach ad in many settings such as schools and other educational establishments and in workplaces, places of worship, parks, bars and other venues. Community-based testing may be offered and run by healthcare professionals who work for NGOs or by trained lay-providers…"

PWID community representative

"Here at PWID NGO's Center, me or other people like me, can make HIV rapid test all the times, by the nurse who is here for us. Here we have a doctor, psychologist and peer counselors who assist and help me when I need. When I have a problem, I share and discuss it with them…"

PWID community representative

"Yes, at the at LGBT community center we have welcome environment, people easily can test on HIV, by the nurse who is staff there all the time. Also, there are psychologist and peer counselors who assist all the time…"

TG community representative

"It is a very easy to access a quick test for HIV and other STDs at our community center. We are in a friendly environment, without stigma and, above all, educational support…"

MSM community representative

CSO and community members provided some recommendation towards decision makers in Albania to change and improve HIV rapid testing. They talked about importance of sustainability after donor

funding for KPs and more investment in innovative programs to reach most hidden key population. Community members mentioned the need of more comprehensive services, that includes mental health services and some living support, like food, medicines, hygienic items, and financial support as well. These needs are more crucial towards more marginalized community like TG, WS and PWID. They also mentioned the need of investment in community strengthening to increase their influence in restrictive policy change towards stigmatized and marginalized population and their active participation in programs planning and service delivery.

"There is insufficient access to psychological and mental health services, particularly considering the immense pressures of discrimination, stigma, social ostracism and internalized homophobia faced by LGBTI people…"

TG community representative

"Sometimes at the center we are offered some healthy packages, but not all the time. I prefer to have some mechanism to support me monthly. I am abandoned by my family, barely manage to pay the rent and often I have nothing left to eat…"

PWID community representative

"There is a need to strengthen TG and PLHIV community work and also identify the best community leaders – agents in local and regional level of change to take on a cross boarder leadership role to promote and facilitate community involvement within the health system…"

TG community representative

"It is imperative that our community be considered as partners and involved in the design and implementation of public policies and intervention programs…"

MSM community representative

Taking care about the quality of HIV testing services was also mentioned by community members to be addressed by decision makers of HIV programs. They talk about trainings/re-trainings that are needed for VCT staff to keep and improve the quality of HIV testing.

"Staff involved in the testing process must be trained and re-trained from time to time to provide quality services such as consulting and testing. Health care providers and other workers engaged in the testing process for HIV and other STDs must adopt a friendly, non-stigmatizing approach to us regardless of background and respect and maintain confidentiality…"

MSM community representative

HIV self-testing – policy and practice

HIV self-testing protocol is part of national AIDS strategy and national HIV testing guideline that was approved in 2019. But there is a lack of practical experience using HIV ST in the country. There has not been provided any studies on HIV ST acceptability and feasibility in Albania.

HIV Self-test kits, as medical products are not legally registered in the country. To facilitate initiation of HIVST in the country, more than 10,000 saliva self-test kits were procured for the first time within the Global Fund regional SoS program in October, 2022. The procurement was accomplished via Wambo platform under the GF program. The cost of one HIV self-test kit is 2 USD. Self-test kits are not still available for purchase (other than GF program ones) in the country.

According to existing plan the pilot project of HIV self-testing among key population will be launched till the end of 2022. During the piloting of HIV ST intervention, there are budgeted costs only for test-kits, no additional funding to support HIV testing activities is considered in the GF program. HIV ST activities will be fully incorporated into existing HIV prevention programs that are foreseen only for key affected populations.

According to plan, there will be different strategies developed for HIV ST service delivery within GF funded pilot project. So far there are considered distribution of HIV ST kits online, via stationary service sites and mobile vans through NGOs. Firstly, HIV ST will be launched for MSM population in Tirana, as this is the most stigmatized and hidden group in the country. Depending on the success of the pilot and demand, created by the community/SCOs, HIV ST will be developed for other key populations as well.

During the interviews with state program representatives, it was noted that implementing HIV self-testing would definitely contribute to the increase in overall testing coverage.

"Albanian national AIDS strategy considers ambitious plan to increase HIV testing coverage. HIV ST can help HIV testing uptake in the country, especially to reach those key population groups, that are never tested and hidden for HIV prevention programs. We want to attract and keep those people at our prevention centers…"

IPH representative

Although HIV state program representatives noted that there are no restrictions regarding who can legally carry out/distribute the HIV self-test in the country, service delivery organizations still consider that HIV ST intervention might include participation of special staff (lab worker/nurse, medical doctor/counselor). This might be the result of misinformation of service representatives about HIV ST intervention, which requires special educational activities for them.

Community members (PWID, MSM, TG, SW) have different level of knowledge about HIVST, due to absence of this practice in the country. Some of them (mostly MSM) noted that they heard about it via internet, at international events/webinars. Most of interviewed community members have no practical knowledge on HIVST (SW, TG and PWID).

"Yes, I have knowledge on HIVST, as I have been part of some training sessions and community discussions. But in Albania, It's not available yet for community…"

TG community representative

All the study respondents (state representatives, service providers and community members) noted that international policies support countries to develop new interventions and have a great influence on the local HIV context. According to their notes, new HIV self-testing strategy and interventions will strongly promote and strengthen community-based HIV testing, as an approach to achieve high coverage of testing and linkage to care particularly among key affected population. They consider that alongside with the existing HIV-testing services, HIV self-testing will increase a yield of HIV among MSM and other KPs, as it can reach most hidden risk groups.

"For me it will be easier, not to spend a lot of time waiting for results…"

PWID community representative

"MSM community will benefit in a variety of ways from Self-Testing. The main thing is the privacy and securing confidentiality, as well as the flexibility in time… It is more private, saves time and preserves anonymity, therefore it will be more preferred by the community…"

MSM community representative

„In my opinion I think it's great to provide Self-Testing for HIV based on a lot of advantages, especially the possibility to do it at home and alone, whenever you want, I think it's a good idea, and it's a good approach…"

TG community representative

According to the expectations of all study participants, HIV self-testing will contribute to develop more friendly and non-judging HIV services, reducing stigma and discrimination for KPs. The collaboration of NGO/CSOs and VCT/Health facilities will be strengthened through capacity building at both sites.

Study participants consider, that after piloting HIV self-testing intervention in Albania, the new approach should be integrated into existing HIV prevention service delivery models for KPs to ensure its sustainability after donor funding.

Few respondents from community mentioned about possible negative psychological impact while testing alone. Besides, they noted that there is a potential risk that HIV ST will not be followed with effective linkage to care and screened positive cases can be lost to follow up. All the screened positive cases should be accompanied to health care facilities as they might meet stigmatized environment there. Besides, they consider that a proper education and supportive materials written in easy and understandable way are important factors for effective linkage to care. Training and sensitization of staff both at NGOs and state facilities on HIVST and follow-up services are also important aspects for consideration.

"In my opinion, the only problem remains psychological impact in the moment of performing the test if the result is suspicious or positive. This requires studied strategies and interventions on how to motivate this individual with this test result to follow the referral systems to start therapy…"

TG community representative

"People should know exactly what to expect from this testing. What screened positive cases mean, who to contact for questions and needed follow up… Who can monitor if HIV screened positive cases go to confirmation? They may be lost to follow up, not knowing where to go, whom to trust…"

PWID community representative

Concerns were discussed by SCO/service providers as well, some of them consider that performing self-testing alone can contain little threat for person, their assumption is that no one can predict what a person should do after the test result is positive.

"They can do some harmful behavior while there is no one is around to provide counselling, we may see this in practice…"

SCO representative

Service providers mentioned the importance of collaboration with different medical providers, including primary health care centers to disseminate information about HIV ST in order to improve the coverage of HIV self-testing. Their involvement can contribute to reach those key populations who remains uncovered by existing HIV prevention services.

"Health care providers should collaborate with NGO members representing KPs to reach out to KP members and find better ways to promote HIV testing…"

SCO representative

Community representatives were also asked about the most acceptable HIV self-test service delivery models they would like the most. All of them stated that receiving self-tests through NGOs/CSOs would be the best option for them and at the initial stage they would prefer assisted testing. Ordering online, getting in pharmacies and via vending machines were also listed as suitable options. They consider that saliva test-kits are more acceptable for them. Peer-led interventions, vending machines together with safe boxes, digital platforms, advertising, brief messaging, and information, fixed financial and lottery-based incentives were listed as main activities needed for demand creation for HIV self-testing.

"In my opinion Community-based, facility-based centers are more suitable. I am not sure about a machine… I like to be offered HIV ST in the same way, and distribution should be offered here, through organization

who provide me methadone therapy, since I find more easily, friendly services and without prejudice, discrimination, or stigma…"

PWID community representatives

"I prefer to have Self-Testing here at our community center where I have been assisted and supported for my needs. We are subject of law and the police, so the only possibility for us remain services offered at the center. Being illegal in our work, for us this is the main barriers… I prefer Peer-led interventions…"

SW community representative

"I'll prefer through: Community-based, Facility-based centers, pharmacies and vending machines, together with safe boxes…"

MSM community representative

As HIV ST is a new intervention in national HIV response in Albania, NGOs and international organizations are not still active and influential in the sphere of HIV self-testing, neither they participate in the development of targeted HIV ST models. Although community members consider that meaningful participation of people from key populations is important in designing and delivering services order to create a new model relevant to the local context. They also talked about their participation in redesigning of HIV ST program after pilot project. They can contribute (round tables, forums) to provide community-based perspectives of scale up HIV ST in their populations.

"Undoubtedly, the involvement of community members in the process is very important. KP education and information as well as the way of performing Self-Testing should be part of the promotion and delivery of this new approach…"

MSM community representative

"I think all HIV services and especially new services should not have been offered for us without our involvement at all stages…"

TG community representative

"The pilot results may lead to unification of forces among state and NGO stakeholders in future…"

SCO representative

Although the pilot project of HIVST test has not yet started in Albania, we asked CSO and community members about possible barriers to this intervention. CSO representatives noted, that pilot will review all the obstacles and facilitators to this, but community members mentioned that stigma can be one of the barriers in HIVST as well. Apart to this, community talked about possible constraints of geographical access for KPs in other cities, especially in regions.

"There are different factors, the main is a stigma. I think HIV ST will increase HIV testing uptake. We can't say anything about other barriers as the intervention is in pilot phase… Pilot will bring some evidence and we will navigate how the ST will go. We can mitigate some risks or problems step by step I am sure… new intervention will increase our coordination among state and community organizations…"

IPH representative

Recommendations

- Update National Guidelines/Protocols for HIV testing, outlining clear HIV testing algorithm in line with WHO recommendation. Community based testing and HIV self-testing should also be a part of this guideline. Removing any possible restrictions that require all testing to be conducted by medical professionals at community settings; Review the regulation to obtain parental consent

for adolescents to access HIV testing; The development process of national guidelines should ensure engagement of representatives of target populations.

- Develop a protocol on HIVST that considers focused interventions for all key groups (MSM, PWID, SWs, general population to some extent). To carry out targeted training for VCT and HIV prevention staff on HIV ST testing according to new protocol.
- Ensure broader participation of HIV service providers in HIVST delivery, prepare NGO staff to promote HIVST among their clients; Training and sensitization of staff both at NGOs and state/primary healthcare facilities on HIVST and follow-up services.
- Foster collaboration between HIV service providers and different medical providers, including primary health care centers to disseminate information about HIV ST to improve the coverage of HIV self-testing.
- To review and change restrictive legislative policies that criminalize risky behavior and hampers effective implementation of HIV testing and prevention services.
- Develop effective National level monitoring and evaluation system for HIV testing (including HIV ST), that includes frames for M&E, responsible entities ensuring quality of VCT services (governmental and non-governmental facilities), with special focus to ensure pregnant women, prisoners and patients of hospitals and private clinics with pre and post HIV test counseling. The data of monitoring and evaluation of HIV testing/HIV self-testing and linkages enables decision makers to better plan and increase efficiency of interventions targeted each KPs.
- Integrate HIV self-testing intervention into existing HIV service delivery models in the country (part of HIV prevention package for key populations) including OST programs.
- Ensure sustainability of HIVST after donor-funding by developing long-term funding mechanisms for NGOs/CSOs as implementers of community-led HIV prevention and support services for KPs. Ensure adequate funding of HIV self-testing within state HIV program for 2024-2025, funding should include procurement of HIV self-test kits, as well as costs for demand creation activities that are in line with WHO recommendations. Project designs for scale up for all key populations (MSM, FSWs, PWID, Young key population and their sex partners) should be developed by meaningful participation of communities, as well as HIVST delivery services.
- Develop list of innovative approaches for demand creation in order to scale up HIVST **for all key affected groups:** a) CSO/NGO Community-based, Peer to Peer secondary distribution b) medical facility-based c) Develop digital platforms for HIV ST distribution, develop video-based information, targeted messages for counselling to reach designated key populations and use chat-bots in online spaces; boosting advertisements in social media, as well dating applications ordering online and receiving via mail; d) Distribution of HIV ST during special events, like music festivals, night clubs, Chem-sex parties.
- To maximize benefit, demand creation efforts on HIV ST should be focused: a) on people who do not know their status/never tested individuals and b) on people with risky sexual and injecting behavior to promote re-testing. Demand creation can also address stigma and discrimination issues towards KPs.
- Monitor and evaluate effectiveness of HIV ST demand creation activities and the results regularly to ensure that demand creation works correctly and does not increase stigma. Based on results, review the strategies and action plans toward HIV ST by meaningful participation of communities and modify/develop new evidence-based interventions.
- To develop fixed financial, other motivational (food or hygiene) and lottery-based incentives as potential ways to pilot HIV ST interventions in the country. Although while considering incentivization for demand creation, benefits and risks should be carefully weighed, to avoid potential negative effects related to equity, due to prioritization of some populations and

diseases; besides some issues can come due to sustainability of such interventions after pilot and dissatisfaction of community members if incentives quite.

- Develop an integrated information and communication strategy with sufficient activities to raise awareness on HIV transmission ways, HIV testing for both the general population and KPs. Regular implementation of these activities is essential. The informational-awareness campaign development process should ensure engagement of representatives of target populations. As well as to educate journalists how to inform about HIV. Ensure adequate funding for information and communication activities.
- Plan and implement HIV stigma and discrimination research activities and develop policy and advocacy recommendations for reducing HIV-related stigma and discrimination.
- Address stigma related HIV testing barriers (including human rights violations, homophobia, direct and indirect discrimination, stigma, and discrimination by care providers) by prioritizing activities aimed facilitating formation of friendly healthcare environment towards PLHIV and KPs in line with local context.
- Promote and increase awareness about HIV ST among sero-discordant couples. Introducing of HIVST may facilitate in-home, self-guided couples testing.
- Support licensing or official registration of self-test kits as medical products in the country licensing and registration.
- Ensure funding to scale up HIV prevention and testing services by developing vending machines distributing safe boxes with HIVSTs, condoms, syringes, other sterile paraphernalia, informational materials.
- Consider using HIVST for PrEP program when facility-based services and in-person patient-clinician contact is limited.

Montenegro

Montenegro - a small country located in Southeastern Europe on the Balkan Peninsula bordered by Albania, Bosnia and Herzegovina, Croatia, and Serbia.

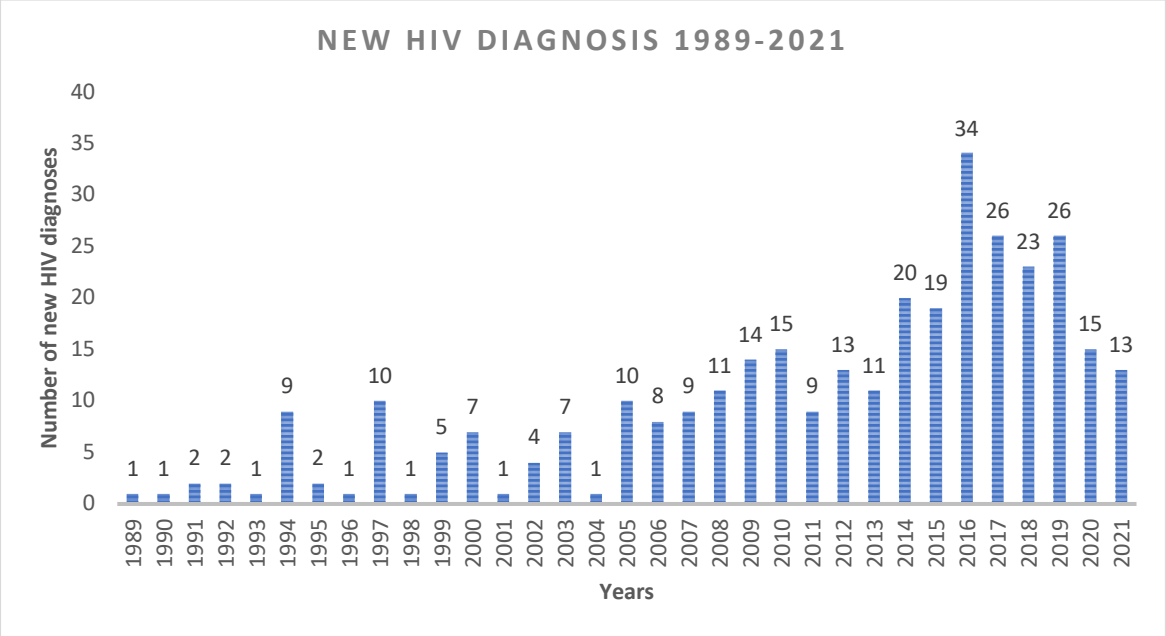
Montenegro 2020 population is estimated at 628,066 people at mid-year according to UN data; 67.6 % of the population is urban and the median age is 38.8 years[57]. The largest city and the capital is Podgorica.

Overview of the HIV epidemic in Montenegro

Montenegro is a low HIV prevalence country (0.04%) with growing trends, especially among men having sex with men (MSM).

The first case of HIV infection in Montenegro was reported in 1989. Since then, until the end of 2021, 331 HIV infections had been recorded, out of which 65 have died. Over the last decade, the number of new HIV diagnoses has not been stable with considerable decrease during the years of pandemic (2020-2021).

Figure 7: New HIV diagnosis 1989-2021



Source: Institute of Public Health, Montenegro

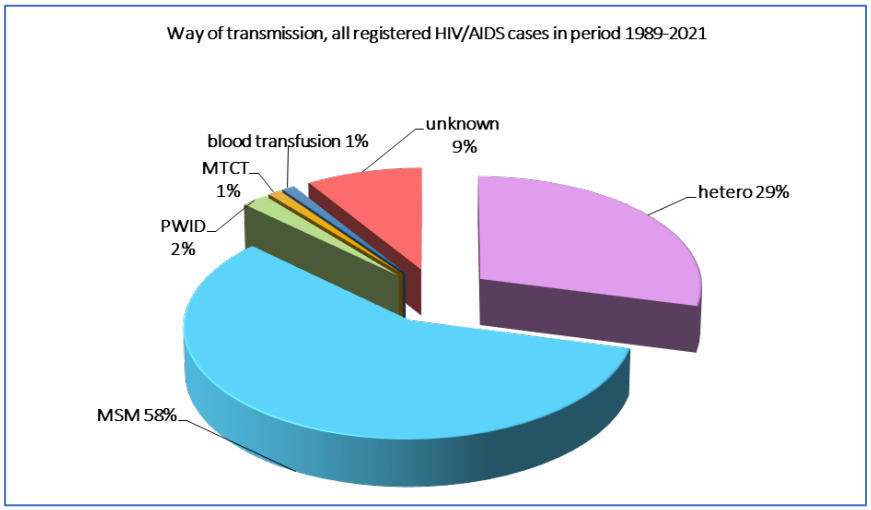
Montenegro has one of the highest male-to-female ratios of HIV cases among countries in WHO European region[58]. Of all cases, 88% are males and 12% females. Most HIV infections are diagnosed at

[57] https://www.worldometers.info/world-population/montenegro-population/

[58] European Centre for Disease Prevention and Control/WHO Regional Office for Europe. HIV/AIDS surveillance in Europe 2021 – 2020 data. Stockholm: ECDC; 2021.

age 20-39 years (76%)[59]. In more than half of the cases the root of transmission is through homosexual contact between men, followed by heterosexual transmission.

Figure 8: Ways of HIV transmission, all registered cases of HIV/AIDS, 1989-2021



Source: Institute of Public Health, Montenegro

According to the BBSS data the HIV epidemic is concentrated among MSM with the growing trend.

Table 5. HIV prevalence among KPs, BBSS data, 2008-2021

KP	HIV Prevalence (%)								
	2008	2010	2011	2012	2013	2014	2015	2020	2021
MSM			4.5			12.4			
PWID	0.4		0.3		1.1			0.5	
FSW	0.8	1.1		0.0			0.5		0.9
Prisoners				0.0					0.0

Late diagnosis also represents a challenge with 36.4% of PLHIV presented with the initial CD4 cell count <200 cells/mm3 and 63.6% with the initial CD4 cell count <350 cells/mm3 during 2019[60].

Figures 9, 10 and 11 below show that the country overall is making progress to reaching the 90-90-90 targets, with an overall test-treatment cascade of 76% – 77% – 98% in 2021. The "first 90" is the most problematic part of the cascade, especially among females, with only 69% having been diagnosed and knowing their status, compared to 76% of the male population in 2021.

Figure 9: Test and treatment cascade among adults, ages 15+, both sexes, 2017-2021[61]

[59] Country Progress Report – Montenegro, 2020
[60] Ibid
[61] UNAIDS HIV estimates. Available at: https://www.unaids.org/en/resources/documents/2022/HIV_estimates_with_uncertainty_bounds_1990-present

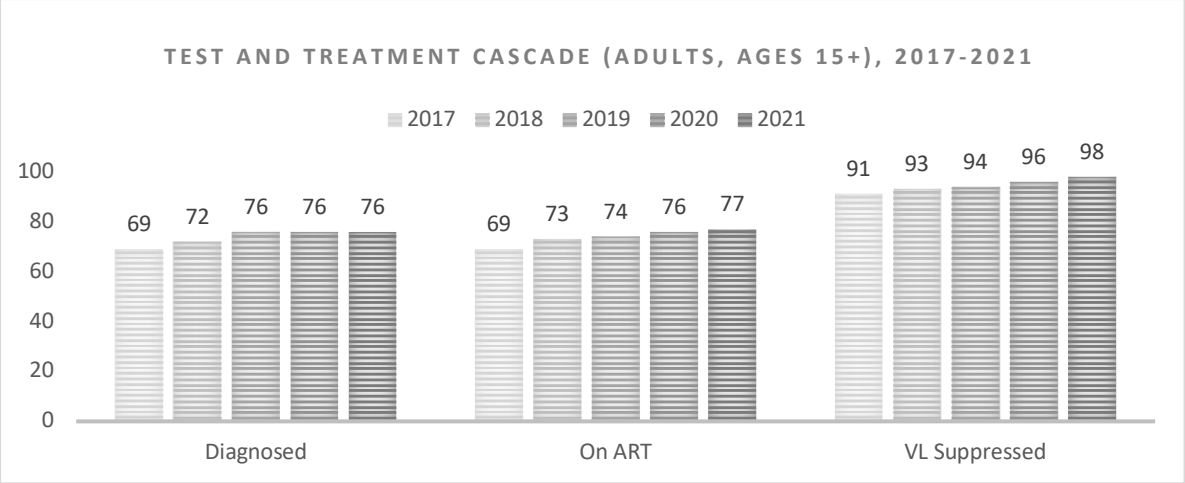


Figure 10: Test and treatment cascade among adults, ages 15+, males, 2017-2021[62]

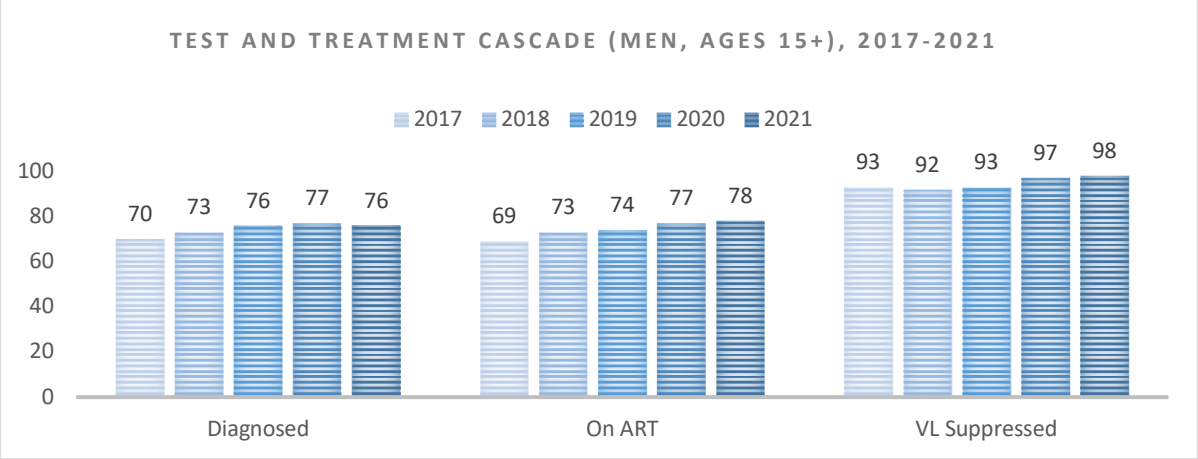
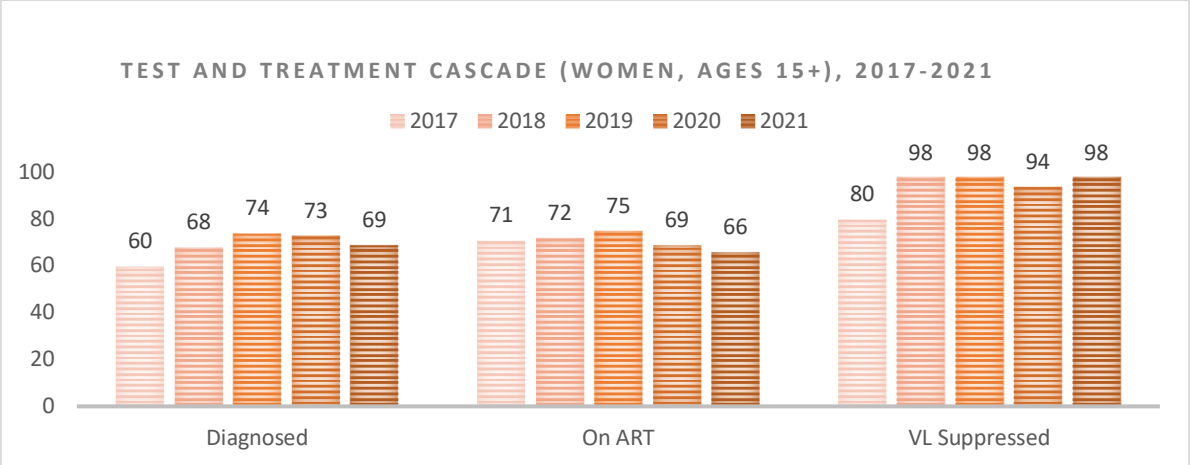


Figure 11: Test and treatment cascade among adults, ages 15+, females, 2017-2021[63]



[62] ibid
[63] ibid

HIV rapid testing – policy and practice

Montenegro employed the practice of developing and guiding the HIV/AIDS national response according to the HIV/AIDS National Strategy. There were three such documents developed and operational, covering the following years: 2005-2009, 2010-2014 and 2015-2020. Since 2021, the aim, objectives and activities of HIV/AIDS national strategy have become the part of National HIV/AIDS Program, 2021-2023, which is supplemented with the Action Plan for 2021-2022. **The testing rate in Montenegro is** 10.6 per 1,000 inhabitants (excluding voluntary blood donors), making it **one of the lowest** testing rates **in Europe**[64]. Thus, the Action Plan outlines objectives, indicators and activities for increasing HIV testing rates in the country and includes different directions for HIV testing, education, testing promotion, collaboration, etc.

There are no National HIV Testing Guideline or Protocols available in Montenegro. Institute of Public Health (IPH), which is the main body to implement and oversee testing activities in the country, guides these activities based on the internal documents (standard operating procedures) and WHO and ECDC recommendations. The need for and importance of elaborating National HIV Testing Guideline/Protocols was unanimously confirmed by all respondents participating interviews for this assessment. IPH is taking proactive steps and trying to provide relevant recommendation to the Ministry of Health and decision makers to support this process. In addition, plans regarding elaborating the National HIV Testing Guideline/Protocols are included in the National HIV/AIDS Program, 2021-2023. There are favorable conditions to accomplish this task in the country: there are experts with relevant technical expertise to prepare Guideline/Protocols; this is not a huge investment and there are funding alternatives, such as the current grant of the Global Fund HIV program (under the savings), the regional grant of the Global Fund and/or the CCM funds.

> *"For sure, having national HIV testing guidelines/protocols would be very beneficial… It is good to follow all WHO recommendations, but for sure we need to adjust them to our reality..."*
>
> IPH representative

While WHO recommends that western blotting and line immunoassays should not be used in HIV testing algorithms65, Montenegro is practicing the algorithm that includes initial testing with rapid diagnostic HIV test (RDT), followed by two ELISA or PCR test, sometimes western blot test is also used to confirm a positive HIV diagnosis. Montenegro is low HIV prevalence country, thus moving to the three RDT is not in the future plans of the country's HIV response.

PreP is not available in Montenegro, but there are efforts to scale up the national dialogue in the upcoming period and the National HIV/AIDS Program for 2021-2023 includes some related activities under the strategic area of HIV prevention, namely to develop an analysis on the possibility of PreP, to adjust organizational–normative framework for PrEP and to conduct an informational and educational campaign on innovative preventive methods, such as PrEP and community testing.

Rapid HIV testing in Montenegro is available through different institutions operating in the country.

Table 6. Institutions providing HIV testing

Name of the organization	Legal status (state/hospital/PHC/NGO/Community based organization/other)	Beneficiaries (general population / KP, including MSM, SW, TG, PWID,

[64] National HIV/AIDS Program 2021-2023

[65] Consolidated guidelines on HIV testing services, 2019. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

		Prisoners/ migrants/blood donors/health care workers/pregnant women/youth/other)
Institute of public health (IPH)	State	All (without blood donors)
Clinic for Blood transfusion	State	All (donors)
VCT Kotor	PHC	All (without blood donors)
VCT Herceg Novi	PHC	All (without blood donors)
VCT Bar	PHC	All (without blood donors)
VCT Nikšić	PHC	All (without blood donors)
VCT Berane	PHC	All (without blood donors)
VCT Pljevlja	PHC	All (without blood donors)
VCT Bijelo Polje	PHC	All (without blood donors)
Drop in for MSM	NGO JUVENTAS	MSM/collaboration with IPH outreach
Drop in for IDU	NGO JUVENTAS /CAZAS	IDU/collaboration with IPH outreach
Drop in SW	NGO JUVENTAS	SW/collaboration with IPH outreach
Montenegro HIV and Viral Hepatitis Foundation	NGO	Partners and family members of PLHIV, General Population
Privat labs	Private	All (without blood donors)

HIV testing is available through IPH VCT center (in Podgorica, first established in 2005) and 7 other VCT centers throughout the country. Organizationally these 7 VCT centers are part of the prevention departments at Primary Health Care (PHC) centers. Three of them are in the south, two in the central part and two in the coastal region. Operation of VCT centers is fully state funded. Rapid testing at VCT centers is free and anonymous (through generating the codes for each client) and available for all citizens of Montenegro including general population, KPs, and migrants. However, it was noted by all respondents participating in interviews for this assessment that representatives of KPs are reluctant to going to VCT centers for testing due to widespread stigma in the country. Due to the latter, people also avoid visiting regional VCTs and mostly go to the VCT center in Podgorica. It was also noted that KPs avoid talking about their risky behaviors and present as members of general population at VCT centers and this is reflected in low testing rates there - out of all people tested in VCTs in Montenegro in 2021 (408 persons), 28% were members of key populations (MSM, PWID, SW)[66]. IPH has the only laboratory conducting HIV testing by referral from chosen doctor (Primary Health Care unites) or doctor from the hospital for hospitalized patients, as well as conducting HIV confirmatory testing. Testing by referral also lacks information on testing reasons and respective risky behaviors.

HIV rapid testing is also available at private laboratories (worth around 15 EU), but they do not report to IPH (the main body responsible for HIV surveillance), thus no data is available about on the number of HIV tests conducted at private laboratories. They even do not report HIV positive results, although the law obliges them to do so. However, since Montenegro is a small country with good connections between institution, they mostly use oral communications between laboratories, IPH and infectious disease specialists to address the needs of particular patients. IPH is currently taking the first steps in

[66] Information provided by Institute of Public Health, Montenegro

preparing reporting forms and conducting conversations/negotiations with the private sector on HIV/HCV testing reporting.

Testing on HIV for pregnant women is not a part of routine program, it is not mandatory, it may or may not be offered to pregnant women at antenatal clinic and thus the data on testing coverage among this population is not available.

HIV testing is mandatory for blood, blood products, tissue, and organs donors.

Decentralization of HIV rapid testing in general health institution (at PHC level in general practitioners' offices, as well as gynecological offices) could contribute to the increased testing coverage in Montenegro.

> *"We need to decentralize HIV rapid testing in health institution, it should be available in general practitioners' offices, gynecological offices, that would support reaching our testing goals…"*
>
> IPH representative

Apart from VCT centers, HIV rapid testing for KPs is also available at civil social organizations (CSO) providing HIV prevention services: JUVENTAS (MSM, SW, PWID, LGBTIQ, Roma), CAZAS (PWID, youth, Roma, PLHIV), the Montenegrin HIV and Viral Hepatitis Foundation (PLHIV and members of their families and partners) and Queer Montenegro (LGBTIQ). Representatives of all these organizations who participated in interviews for this assessment stated that they have excellent collaboration between each other, with VCT centers and other health institution. According to the Law on Health Care only health worker at a health institution is obliged to do any procedures that are concerned with blood and blood sampling. Therefore, NGOs conduct so called "community-based testing" in collaboration with VCT centers and infectious disease clinics, based on the memorandums between these institutions. NGOs have dedicated working hours when medical workers from VCT centers come to NGO facilities to test KPs mobilized by community workers (who are mostly representatives of community), who are also involved in pre and post-test counseling. Some NGOs have medical doctors available at their drop-in centers for general health counseling of beneficiaries, but those medical staff cannot conduct testing since drop-in centers are not recognized as health care institutions. This organizational arrangement does not allow the full implementation of the community-based testing model. Firstly, mostly counseling and testing are carried out by different individuals that might be inconvenient for KPs due to stigma. Secondly, considering the existing legislation, social workers do not have the opportunity to conduct testing during outreach. Outreach typically involves reaching out to hidden populations, informing them about risks, providing them with preventive materials and explaining the importance of testing, but at the same time cannot offer testing on-site. Instead, the beneficiaries are invited to the facility (NGO or VCT center) at a specific time dedicated for testing, which greatly increases the likelihood that the beneficiaries will change their mind and miss opportunity of testing for HIV or other infections. There is an urgent need for making decentralization of HIV rapid testing services; making legislative changes that will support full scale implementation of community-based testing by recognizing SCOs as public health service providers and allowing ley providers (social workers/community workers) to conduct testing services.

> *"Among the barriers I would mention that community-based testing is not implemented here, yes NGOs do it with cooperation with IPH, but we don't have real community-based testing… This is the area where we should work actively. The law needs to be adjusted somehow…"*
>
> IPH representative

"Finding these hidden populations and then bringing them for testing is an issue of course, so if we could offer the testing at place once found during the outreach (especially outside Podgorica) would be a great opportunity for us… Another factor is stigma and discrimination and prejudices that people have in medical personnel that affects the reach with testing services..."

SCO representative

"We really put a lot of effort in mobilization of beneficiaries for testing and then when we refer them to VCT centers, they might be closed when they go there, especially in regions… Beneficiaries would never go there for the second time…"

SCO representative

HIV testing services for KPs are free and anonymous. The availability of testing is not an issue in Montenegro, but some concerns regarding accessibility was noted by the respondents who participated in interviews for this assessment. They mostly talked about the geographical accessibility barrier for KPs, especially in regions, where NGO drop-in center are not available and community members do not want to go to VCT centers with the fear that somebody might recognize them.

HIV stigma is a huge problem for Montenegro, especially in regions. Some of the NGO representative who participated in interviews for this assessment were also concerned about confidentiality issues that are violated mostly by medical staff outside HIV care services. Again, due to stigma such cases are not reported officially, documented or followed-up. Therefore, response mechanisms fail to be used properly despite laws regulating confidentiality and personal data protection.

"And one of the main barriers for people not coming for testing is of course stigma. We are small country, we are all relatives, we all know each other. Self-stigma exists among our KPs, it is not addressed well and is one of the main barriers for HIV testing…"

IPH representative

"Breaking the confidentiality is definitely a problem in Montenegro. We have law on that but it's not in the practice. Officially we don't have any complains like that because patients need to give their names and they don't want it, because then everybody will know their names… Our organization ensures confidentiality, as well as VCT centers, other NGOs and infectious disease specialists… but not other doctors and health care workers. PLHIV have other health problems as well and they need to go to other doctors, so there it is a problem…"

SCO representative

Like every other population, prisoners are also tested on HIV upon their request, it is not mandatory. For this they should go to their health center at the prison facility where medical staff takes blood, which then is transported to IPH for testing. Testing for prisoners is also available during the European testing weeks (in Spring and Winter), when IPH and NGOs representatives go to prison and conduct testing.

Lack of awareness about and insufficient promotion of HIV testing was mentioned as one of the barriers by the interviewees for this assessment. NGOs and VCT centers are conducting sporadic promotion activities, but it's not sufficient and adequate to reach all target populations and increase testing coverage.

"Many doctors at many PHC don't know that there are VCT centers… We have some promotion activities to inform population about VCT centers and NGOs work on this issue as well… And I think this is the space for improvement, education for HCWs, population, testing promotion…"

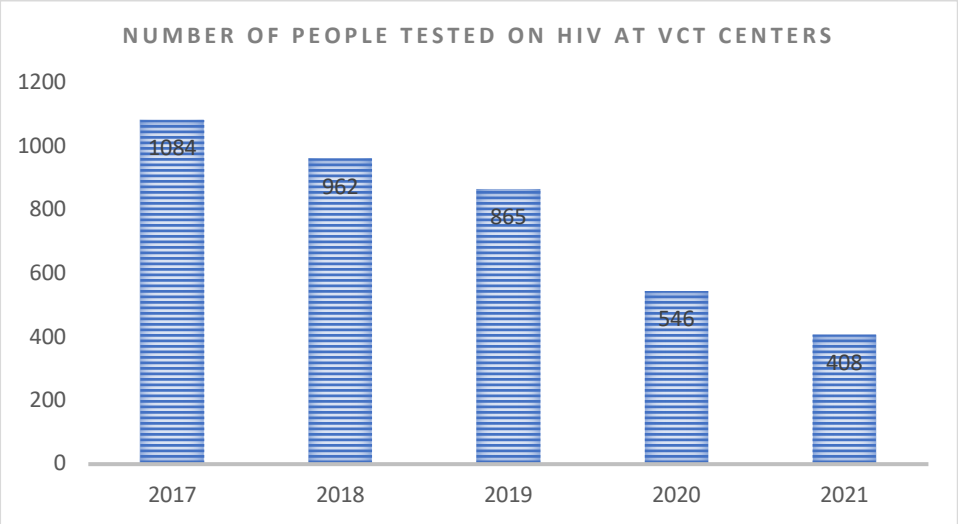
IPH representative

"I think we (NGOs) don't do enough promotion of HIV testing. I cannot remember of any serious campaigns for HIV or testing done besides December the 1st. And I think we should talk much more on HIV, HIV testing and PLHIV on the media… Media would have a huge role for stigma, testing promotion…"

SCO representative

COVID-19 pandemic has affected HIV testing rates in Montenegro, and it is reflected in case detection (see Figure 1.) and in testing coverage as well:

Figure 12. Number of people tested at VCT centers, 2017-2021



The delivery of testing services by VCT centers has not been suspended during the pandemic, although the service hours have changed. If before the pandemic the centers worked for a full working day, during the COVID pandemic the health force was shifted to COVID response, and this time was halved. The latter coupled with strict lockdown measures and lack of social interactions has significantly affected the access of KPs to testing services.

"We changed our working hours during COVID, and it has negatively affected testing. In addition, the entire COVID situation had negative impact on people, and they did not want to come and test at VCT centers. Social media was full about stories on COVID and nothing on HIV and I think HIV was pushed away to some small corner at this time and now we see its impact, many people come for testing, and they test positive..."

IPH representative

"Testing rates also severely dropped during pandemic, people did not have social interaction of any kind, SWs were afraid to work, different communities faced different problems and issues. Nobody from those was speaking about HIV testing... COVID also showed that certain communities are been forgotten when crisis arises, especially communities that have not been taken care of during peaceful times."

SCO representative

Although not a current issue, but financial sustainability for HIV testing services and other CSO-led HIV services and activities was named as a threat by the respondents participating in interview for the present assessment. Currently, within the HIV testing services all but the community-based testing for KPs is fully funded by the state (at VCT centers, blood donors, IPH laboratory), and no one has talked about its sustainability risks; while community-based testing for KPs is almost 50-50% covered by the state and the Global Fund. This is where concerns about sustainable funding arises and there is a need

to enhance efforts and prioritize the further increase of domestic investments in the CSO-led HIV prevention and support services in the upcoming years[67]. Full takeover of funding HIV prevention services for KPs by the government after the GF withdrawal will be essential. Moreover, sustainable funding should not be doubted in parallel with changes of Governments.

We also asked community representatives (MSM, PWID, SW, TG) to talk about the rapid HIV testing barriers and provide suggestions/recommendations for improvement to policy makers in Montenegro. It was clearly revealed that the representatives of KPs do not want to be tested at VCTs and the most acceptable and convenient place to receive HIV prevention services is NGO/CSO. This is very closely tied with stigma and discrimination towards KPs. They also talked about the infrequent testing opportunities that should be addressed based on their needs. Lack of information and communication on HIV prevention is another issue that concern KPs. More investment in HIV prevention is needed from the state to ensure adequate access of KPs to essential HIV services.

> *"Testing conducted by NGOs should be accessible more frequently… it should be there… at NGO… I would never go to VCT… we pay taxes, and we pay for health insurance and government should invest more, so we have adequate access to HIV prevention services…"*
>
> MSM community representative

> *"And I still can't imagine that there is a possibility that you go to the health center, tell them that you are PWID/MSM/TG and that they welcome you nicely…"*
>
> PWID community representative

> *"I have only been tested three times in my life, at the drop-in center. At hospitals and health centers, they often look at you as if you are below them, and then you feel uncomfortable. I think that's why people who are into this don't get tested very often. The environment should be there like it in drop-in centers…"*
>
> SW community representative

> *"I believe that Trans* people are not sufficiently targeted through testing campaigns in our country, and also Trans* women are not sufficiently aware of the risks, especially when they engage in sex work…"*
>
> TG community representative

HIV self-testing – policy and practice

No policies and practice on HIV self-testing exist in Montenegro. During the interviews with country representatives, it was noted that implementing HIV self-testing would definitely contribute to the increase in overall testing coverage, but sound preparation and planning should precede the implementation process. The main concerns that arose during discussions were high cost of self-test kits and no plans regarding HIV self-testing implementation within National HIV response. It was noted that existing regulatory framework does not prohibit NGO staff to conducted testing on saliva sample, so it would be a great opportunity for social/community workers to use this kind of tests during the outreach. However, registration, licensing and importing HIV self-test kits by NGOs might be an issue since they are not recognized as health care institutions. Thus, adequate support and commitment from the state and heath care sector is necessary to deal with barriers at policy and regulatory levels.

> *"This oral HIV self-tests during the outreach and even taking at home, would be a breakthrough for us in civil society sector... And I think implementation of self-testing, whatever mode we use, will definitely increase*

[67] Golubovic V. Montenegro: Benchmarking sustainability of the HIV response among Key Populations in the context of transition from Global Fund support to domestic funding. Vilnius, Lithuania; Eurasian Harm Reduction Association, 2021.

the coverage with testing, those how are afraid of testing in front of somebody or coming to medical or any other facility would benefit the most…"

CSO representative

"Main barriers include that we don't have self-testing and it's not in the plans for 2021-2023. It is actually the policy and regulatory barrier. When we start thinking about self-testing on a policy level, then we will need identify and consider or other barriers at regulatory, pricing, registration, and procurement levels…"

IPH representative

"Law on Health Care states that testing on blood sample is allowed only for health care workers, so NGOs cannot do anything that include blood. But there is no statement that they cannot use tests from oral fluids, but these kinds of tests are not registered in Montenegro, they are expensive, price is almost 10 times higher per test. We are now working on exploring some possibilities to import such kind of tests. We will need saliva tests if we want to improve testing at NGOs, at their drop-in centers or during the outreach..."

IPH representative

"I think self-testing will work in Montenegro; I am for that. And I think if we carefully plan implementation process, then it will work and increase testing coverage… We really need to change something, and I really support for self-testing, because the current ways of testing are not working so well…"

CSO representative

Concerns were expressed about people's attitude towards HIV self-test in general. In addition, psychological impact of a reactive/positive result when a person is performing self-testing alone was also mentioned as an individual level barrier. Thus, it is important to focus on needs assessment, acceptability, and feasibility of HIV self-tests as a very first step in preparation processes for implementation of HIV self-testing in the country. Educational component will also be essential. The next preparatory work would include development of appropriate follow-up and linkage to care services after self-testing. Pilot projects among different populations would be the logical next sept before the full-scale implementation of HIV self-testing in the country.

"In this case we will need to have good education of population, not only the NGO staff. And education on how to continue care after positive results… We have not done any surveys among populations, if they have any will to do that, what does population think about that, etc. it's really necessary first to conduct acceptability study to get some ideas what people think about HIV self-testing…"

IPH representative

"But we need to do that job very smartly. Because positive result may negatively affect people and they even may want to kill themselves, rather than go to the infectious disease specialist…"

NGO representative

"For us it will be very important to prepare very good first steps, educate NGOs, educate KPs and general population about self-testing, because I'm afraid that if they don't have enough knowledge, we will get much more bad results then good. We need to do many things for preparation in advance. And if we are well prepared for implementation of self-testing, I think overall it will increase testing coverage…"

IPH representative

KP representatives participating in interviews for this assessment also provided their views on HIV self-testing. Representatives of all PKs stated that HIV self-testing would increase testing coverage, it would be convenient for them to perform test alone, they would be free from unpleasant feelings that they experience during accompanied testing, especially at health care facilities in a stigmatized

environment. However, they also mentioned that without proper education, supportive material (such as instructions for use and contact information where beneficiaries can address in case of positive results) and adequate follow-up services it might lead to even worth consequences. Sensitization of staff at follow-up services is also an important aspect for consideration.

> *"Well, the obvious advantage would be availability right away, you get it and do the test yourself in your own space. But again, if the test is positive, it can be dangerous, because if you don't have a good support system, who to refer to, and you don't have any knowledge about HIV, and you think that's the end, you remain isolated and scared…"*
>
> MSM community representative

> *"Lack of education would be a huge barrier… Majority of PWID do not know anything about HIV, hepatitis, they just don't care. When you are addicted, you don't think that you can get sick from something. I'm shocked at how many people there are who are completely uneducated when it comes to injecting drugs and HIV…"*
>
> PWID community representative

KP representatives were also asked about the most acceptable HIV self-test service delivery models if self-testing would be implemented in Montenegro in the future. All of them stated that receiving self-tests through NGOs/CSOs would be the best option for them and at the initial stage they would prefer assisted testing. Ordering online, getting in pharmacies and via vending machines were also listed as suitable options. Both finger prick and saliva test-kits are acceptable for them. Peer-led interventions, digital platforms, advertising, brief messaging, and information, fixed financial and lottery-based incentives were listed as main activities needed for demand creation for HIV self-testing.

Recommendations

- Develop National Guidelines/Protocols for HIV testing, outlining clear HIV testing algorithm in line with WHO recommendation. Community based testing and HIV self-testing should also be a part of this guideline. The development process should ensure engagement of representatives of target populations.
- Ensure full scale implementation of community-based testing. The latter requires changing the legislation/regulations and enabling NGOs/CSOs to conduct full scale community-based testing, enabling NGO/CSO staff conducting the testing. Using the saliva HIV self-tests during the outreach activities can also be considered (assisted self-testing).
- Decentralize HIV rapid testing, enable testing at NGO/CSO facilities, at PHC level in general practitioners' offices, as well as gynecological offices.
- Ensure adequate funding for and implementation of demand creation activities in line with WHO recommendations to increase HIV testing uptake. Demand creation and mobilization should be developed together with communities and tailored to the specific interests, concerns and needs of each priority community.
- Develop an integrated information and communication strategy with sufficient activities to raise awareness on HIV testing for both the general population and KPs. Regular implementation of these activities is essential. The development process should ensure engagement of representatives of target populations. Ensure adequate funding for information and communication activities.
- Ensure sustainable and long-term funding mechanisms for NGOs/CSOs as implementors of community-led HIV prevention and support services for KPs.
- Prioritize and implement activities aimed at reducing stigma and discrimination towards PLHIV and KPs and ensuring confidentiality of PLHIV.

- Plan and implement HIV stigma and discrimination research activities and develop policy and advocacy recommendations for reducing HIV-related stigma and discrimination in Montenegro.
- Plan and conduct research activities regarding acceptability of HIV self-testing among KPs; the results should be considered during its scale-up.
- Introduce HIV self-testing for KPs through small-scale pilot project before full scale implementation. Priority should be given to assisted HIV self-testing. Pilot projects should be planned based on the results from acceptability studies and should include all organizational arrangements that are required for smooth implementation: namely, test-kits should be distributed together with supporting material, including pre and pos-test counseling leaflets, detailed instructions for use on local language, contact information of focal points in case of positive test results, hot line numbers, etc. Appropriate follow-up and referral services should be in place to ensure timely linkage to treatment and care services in case of positive test results.

Serbia

Serbia – is a landlocked country in the west-central Balkans. Bounding the country to the west are the Bosnia and Herzegovina and Croatia. Serbia adjoins Hungary to the north, Romania and Bulgaria to the east, North Macedonia and Kosovo to the south, and Montenegro to the southwest.

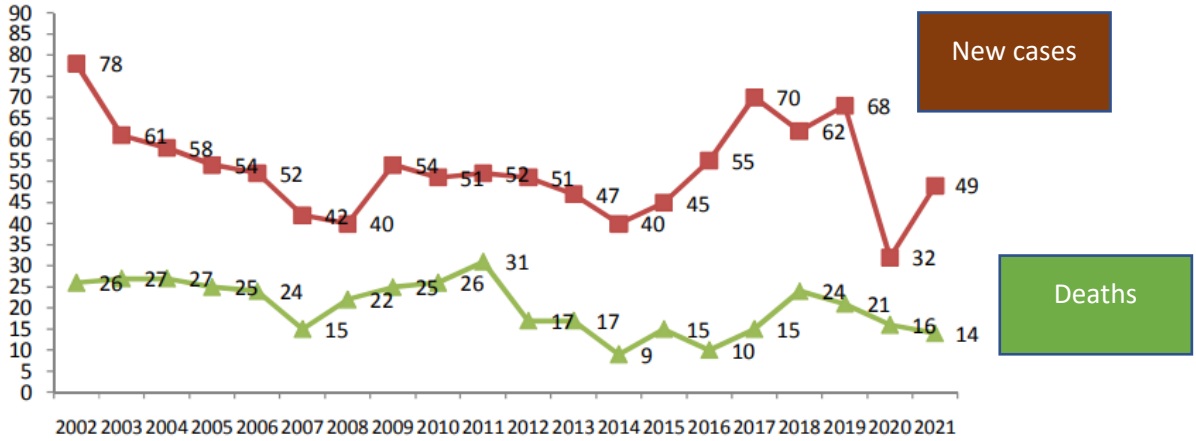
Serbia 2020 population is estimated at 8,737,371 people at mid-year according to UN data; 56.2 % of the population is urban and the median age is 41.6 years[68]. Its capital Belgrade is also the largest city.

Overview of the HIV epidemic in Serbia

The estimated prevalence of all PLHIV in the population aged 15 and over is less than 0.1% in Serbia, although there is a growing trend, especially among men having sex with men (MSM).

In the Republic of Serbia in the period from 1985, when the first cases were registered, as of 31 December 2021, there were 2119 reported cases of HIV/AIDS of which 1186 (56%) persons died[69].

Figure 1: New HIV diagnosis and deaths 2002-2021



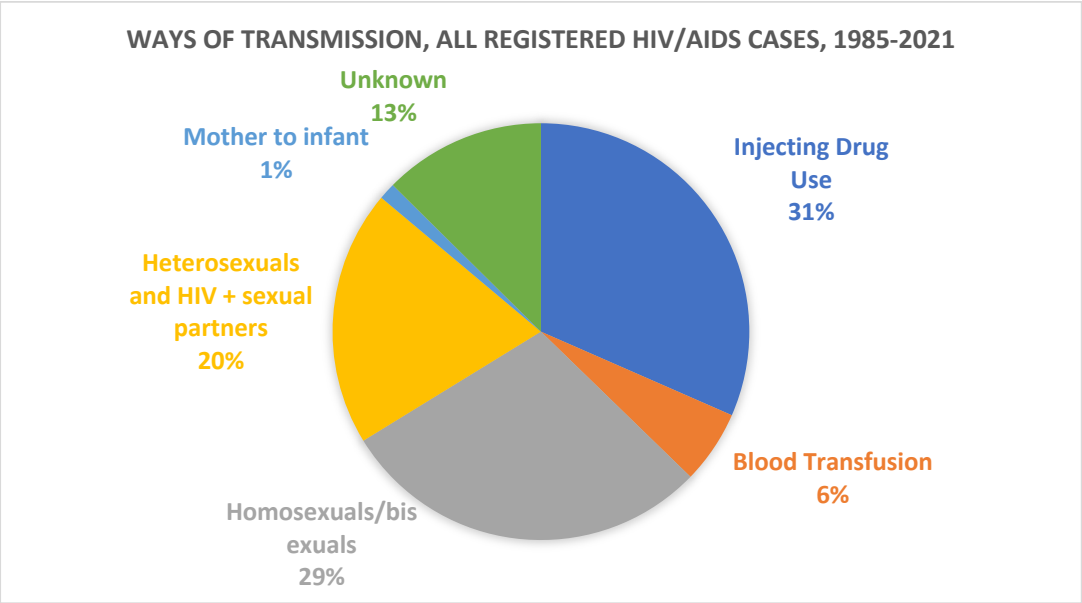
Source: Health statistical yearbook of Republic of Serbia, 2021

Serbia has one of the highest male-to-female ratios of HIV cases among countries in WHO European region[70]. Of all cases, 78% are males and 22% females; most HIV infections are diagnosed at age 20-49 years (80%)[71]. Since the beginning of HIV epidemic, the main root of transmission among all registered cases is related to injecting drug use, although in recent years the share of injecting drug use is decreasing while transmission through homo and heterosexual contacts has an upward trend[72]. Late diagnosis presents a challenge in Serbia with almost 58% of so called "let presenters" (CD4 count

[68] https://www.worldometers.info/world-population/serbia-population/
[69] Health statistical yearbook of Republic of Serbia, 2021
[70] European Centre for Disease Prevention and Control/WHO Regional Office for Europe. HIV/AIDS surveillance in Europe 2021 – 2020 data. Stockholm: ECDC; 2021.
[71] Health statistical yearbook of Republic of Serbia, 2021
[72] National Strategy for Fight against HIV/AIDS, 2018-2025

less than 350 cells/ml) in 2020[73].

Figure 2: Ways of HIV transmission, all registered cases of HIV/AIDS, 1985-2021



Source: Health statistical yearbook of Republic of Serbia, 2021

According to the BBSS data the HIV epidemic is concentrated among MSM with the growing trend.

Table 1. HIV prevalence among KPs, BBSS data, 2008-2013, Belgrade

KP	HIV Prevalence (%)			
	2008	2010	2012	2013
MSM	6.1	4	4	8.3
PWID	4.7	2.4	1.7	1.5
FSW	2.2	0.8	2	1.6

Source: National Strategy for Fight against HIV/AIDS, 2018-2025

By 2021, there were estimated 3600 [2700 - 4500] PLHIV in Serbia out which 85% knows about their status, meaning that country is almost reaching the UNAIDS target for the first step of the test-treatment cascade, however only 64% of PLHIV are on ARV treatment. The data for viral suppression is not available[74].

HIV rapid testing – policy and practice

National efforts to combat the HIV epidemic in Serbia is guided by National Strategy for fight against HIV/AIDS. The first comprehensive Strategy was developed for the period of 2005-2010, followed by the second one for the period of 2011-2015. Currently, the country leads its HIV/AIDS response based on the latest Strategy adopted for the period of 2018–2025. During 2018, a new Monitoring and Evaluation Plan was developed that emphasizes the monitoring of outcome, impact indicators, and coverage indicators in order to monitor the successful implementation of the Strategy. The main mechanism for coordinating the implementation of the Strategy is the Commission for the fight against HIV/AIDS and Tuberculosis, a multidisciplinary consultative body of the Government that includes representatives of relevant ministries, experts working in the field of prevention and control

[73] Report on Infectious Diseases in the Republic of Serbia, 2020
[74] UNAIDS, Country factsheet, Serbia, 2021

of HIV infection, representatives of associations, representatives of people living with HIV and others interested parties[75]. One of the main components of the Strategy is built around strengthening the programs for the prevention of HIV infection and underlines the necessity of provide HIV testing through different modalities.

GF supported HIV prevention programs for KPs were functional in Serbia till 2014. After the end of these programs, activities for KPs were reduced and some programs even closed. However, during 2018, the Ministry of Health implemented the application process for GF grant funds to co-finance HIV infection prevention programs in key populations and PLHIV. This grant was approved and at the end of 2019, the Ministry of Health started its realization.

The first guideline for VCT on HIV was developed and published in 2006. The guideline included provision of VCT in the communities of KPs provided mainly by the CSOs. In 2018 the country started updating and developing of the new guideline on VCT for HIV and other infections important for integrated approach. It was almost finalized but due to the COVID pandemic the process of its sharing with all key stakeholders and adoption by the Commission was postponed. It is anticipated that the process will resume, and the guideline will be put in practice soon.

While WHO recommends that western blotting and line immunoassays should not be used in HIV testing algorithms[76], Serbia is practicing the algorithm that includes initial testing with rapid diagnostic HIV test (RDT) conducted at health care institution or community-based setting, followed by ELISA or PCR test (PCR test is preferable, but available in reference labs and in labs of larger health institutions), some labs also perform western blot test to confirm a positive HIV diagnosis. Considered to be a low HIV prevalence country, moving to the three RDT for HIV diagnosis was not mentioned in the future plans of the country's HIV response by the interviewees participating in this assessment.

PreP is available at pharmacies in Serbia upon prescription from the infectious disease specialists, although it was noted by some interview participants that there are cases when certain pharmacies sell PreP medications without prescription. The country doesn't have official guidelines for PreP implementation but preparations for its development are underway. One of the organizations working with LGBTI community mentioned that they have recently started PreP counselling and provision of testing at their organization in collaboration with the Institute for Student's Health Care and infectious disease clinic.

> *"Officially we still do not have guide for PreP… it is available in pharmacies… officially it is forbidden to sell it without prescription, but from practice we know that pharmacies sometimes sell it without prescription… Now we started PreP counseling in corporation with the doctor from students' policlinic, and also with cooperation with infectious disease clinic, so we have counseling with people who want to have prep and all needed analysis can be done at our check point in corporation with lab technician who comes every Thursday in our center and takes blood, we conduct counselling and provide prescription…"*
>
> CSO representative

Rapid HIV testing in Serbia is available through different institutions operating in the country.

HIV rapid testing is available for all citizens, including general population, KPs, and migrants of Serbia at 24 VCCT (Voluntary Confidential Counseling and Testing) centers at regional public health

[75] National Strategy for Fight against HIV/AIDS, 2018-2025

[76] Consolidated guidelines on HIV testing services, 2019. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

institutions. In Belgrade, apart from the city Institute of Public Health, testing on HIV is also available at Institute for Student's Health Care. Testing services are anonymous (through generating the codes for each client) and free of charge. If clients are referred to the VCCT center by the physicians, the costs of testing are covered by the Republican Health Insurance Fund, otherwise if they voluntarily present to the health institution, testing services (for HIV/HCV/HBV) are covered by the state budget (through the budget of Ministry of Health).

HIV testing is also available at private laboratories, but they rarely report to IPH (the main body responsible for HIV surveillance, monitoring and evaluation), so to what extent populations utilizes the private lab sector is unknown. It should also be noted that testing at private labs is missing an important part such as counselling and no information is available on referral and linkage to care practices from these private institutions.

Migrants have access to HIV testing at all VCCT centers, CSOs and migrant centers.

Specific programs for the prevention of HIV infection in prisons are not implemented systematically. Poisoners receive HIV testing services within ad hoc activities organized by CSOs and some VCCT centers. These activities were seriously affected during the COVID pandemic.

Although recommended by number of laws and by-laws, voluntary HIV testing of pregnant women is still not a routine practice in Serbia.

Mandatory HIV testing is performed during blood donation, also when donating tissues and organs, as well as during preparations for artificial insemination.

Apart from VCCT centers, HIV rapid testing for KPs is also available at civil social organizations (CSO) providing HIV prevention services. These services are free and anonymous. Implementation of the community-based testing started since 2019 with the support of the GF and co-financing by the government. CSOs are contracted by the Ministry of Health to provide HIV prevention services, including counselling and testing on HIV/HCV and Syphilis for MSM, PWID and SWs. Since epidemic is mainly concentrated among MSM, the reach with testing services is largely focused on this population. These services are available mainly in the big cities (Belgrade, Novi Sad, Nis and Kragujevac) at SCO check-in points and via mobile medical units in the surroundings. Limited funding for expending geographical coverage, as well as access to quality counselling and testing services outside Belgrade was named as one of the barriers to HIV testing by the interviewees participating in this assessment. According to the Law on Health Protection only health worker at a health institution is obliged to do any procedures that are concerned with blood and blood sampling. Therefore, NGOs conduct so called "community-based testing" in collaboration with VCCT centers or other health institution based on the contracts between these institutions. The contracted health care representative (who undergoes special training and is considered to be sufficiently sensitized to work with KPs) is responsible for conducting testing, overall supersession, and support and also for entering the VCT data (collected by the NGO staff on paper) into the National VCT database. NGOs have dedicated working hours when medical workers from health institutions come to NGO facilities to test KPs mobilized by community workers (who are mostly representatives of community), who are also involved in pre and post-test counseling. These medical workers/lab technicians are usually at the same time working at other institutions and are not available for the full-time employment at NGOs. These organizational arrangements do not allow the full-scale implementation of the community-based testing, which offers access to care for individuals who may typically be missed by the healthcare system and allows providers to meet patients where they are, regardless of time, geography, health literacy, or financial

barriers[77]. Furthermore, complicated pathway of linkage to care after reactive HIV screening test during the community-based testing was named as one of the barriers by CSO representatives participating in interviews for this assessment. Since CSOs are not allowed to issue any kind of document on the results of the reactive screening test, they have to refer or accompany such clients to the health institution to perform the same test and get a printed copy of the result in order to go for confirmatory testing. All representatives of CSOs participating in interviews for this assessment consider it essential to allow the full-scale implementation of community-based testing and they considers their competences to be sufficiently developed to accomplish these activities on their own. Thus, it is recommended to decentralize HIV rapid testing services, make legislative and/or organizational changes that will support full scale implementation of community-based testing.

"MSM population is the key KP at risk in our country because we have very concentrated epidemic among MSM. We have very few PWID who are HIV reactive, one or two per year, so this is not a big problem, and among SWs it is almost no one. So, the focus and reach with testing is mostly on MSM… Services for KPs are mainly in the big cities or the certain geographical areas… It is very desirable to provide services in a broader geographic area, but it depends on the capacity and money for NGOs to provide these services… HIV testing is as a medical intervention as defined by our law on Health Protection, so HIV testing should be done only by the health care staff, medical technician, any doctor or nurse but not ley providers… so NGOs need to have contracts with regional institute of public health or other health institution to implement testing services…"

IPH representative

"We do not have real community-based testing, the law does not allow to conduct testing outside the medical institution… Officially we have to have cooperation memorandum with the health institution, and we have to engage lab technicians from health institution, so we can only provide community-based counseling… It's a complicated model, because people who are engaged, they also have their regular jobs, so they are not always available for us, and it would be good to have such full time staff… It will be easier if we could also provide testing because it's not a hard job, it's a blood from the finger, we might undergo some kind of training and that's all… Even the current situation is kind of illegal according to the existing regulations, because we perform testing outside the medical institution, so there are problems and discrepancies between regulations and practice…"

SCO representative

"Not every municipality have health institutions where people can get tested, in big cities where we have such services an issue would be the quality of counselling and testing and confidentiality issue, that's why most people come to Belgrade for testing…"

SCO representative

"This is [linkage to care], I think, also complicated because if we have for example reactive results during the outreach work or in our check-point center, we cannot directly link patient to infectious disease clinic, because we do not have any kind of document, we don't issue printed results… so we need to refer client to do the same kind of testing within the public health institution, so that he/she can be referred to the infectious disease clinic for confirmatory tests. It's complicated for us and clients as well. This pathway from rapid testing to inclusion in treatment sometimes takes more than 7 days… "

SCO representative

[77] Schaffer DH, Sawczuk LM, Zheng H, Macias-Konstantopoulos WL. Community-Based, Rapid HIV Screening and Pre-Exposure Prophylaxis Initiation: Findings From a Pilot Program. Cureus. 2022 Jan 2;14(1):e20877. doi: 10.7759/cureus.20877. PMID: 35145784; PMCID: PMC8806132.

"We have to pay to lab technicians, to those who enter the data, which we collect on paper, and we have a lot of paperwork… you need to have some cooperation with institutions, we could do it easy by ourselves, but it is not allowed…"

SCO representative

Protection of confidentiality of HIV positive persons and individuals tested on HIV is regulated by number of laws in Serbia, including law on protection of people with communicable diseases, law on protection of patients' rights, law on protection of personal information, etc. Even the medical doctor is not allowed to share personal health information with family members or any other people or other doctors if the patient or client did not give them permission for that. They are not allowed to put information on HIV status on the front side of the medical record. In addition, the Criminal Law defines the penalty for those who break the confidentiality. It is only allowed to report (through the very protected system) the case of HIV/AIDS to the defined institution. Some of the interview participants still mentioned about cases of breaking confidentiality of PLHIV, mainly at health care institutions. Although documentation and follow-up of such cases is not a routine practice in Serbia, thus drawing conclusions on its extent is not possible. Evidence suggests[78,79] that HIV stigma and discrimination is definitely an issue in Serbia, hindering access to HIV testing and other prevention services, especially among KPs.

"We provide anonymous testing, but after testing positive, the issue of anonymity goes out of the agenda because every institution who finds the positive HIV case is obliged by the law to report it as a case of infective disease… In our organization we did not have such case of breaking confidentiality, but we know that at the state level, mostly in health institutions there are such cases that status is disclosed to others…"

SCO representative

"At our organization we have internal procedures for protecting confidentiality… We had such issues concerning breaking the confidentiality in the past, especially among dentists… IPH conducts trainings on this issue, but I don't know if there are still such cases… People will rarely make individual complains, they do not document such cases. This is very much tied to stigma…"

SCO representative

"Stigma is definitely an obstacle for people to get tested, especially at public institutions… This is the main reason why people do not go to VCT centers, especially in small cities of Serbia, they prefer community-based centers, they don't trust public institution that their information will be confidential there… Even if the staff of VCT centers are well sensitized to work with KPs, people do not want to go there because of fear that someone will see them…"

SCO representative

"We have very strict and very good laws, which protects disclosure of HIV, or any other sensitive information related to health. We had some cases of breaking confidentially in the past, but we used that examples to highlight during continuous medical education for the health care providers… Maybe there are some cases, but I am pretty sure that during the last 10 years they are very rare…"

IPH representative

[78] Goran Opačić. Survey of knowledge, attitudes and behavior of health workers in the field of HIV. (Belgrade: Institute for Public Health of Serbia "Dr. Milan Jovanović Batut", 2015) http://www.batut.org.rs/index.php?content=1330 (January 31, 2018)

[79] Aleksandra Božinović Knežević, Violeta Anđelković and Radoš Keravica. Monitoring of human rights of persons living with HIV/AIDS in Serbia. (Belgrade: Humanity, Charitable Foundation of the Serbian Orthodox Church, 2016)

COVID-19 pandemic has seriously affected HIV testing rates in Serbia. Although VCT centers were available for interested clients during the period of pandemic, testing rates at public health institutions were very low. There were several main factors contributing to this reduction as stated by the by the interviewees participating in this assessment: people's fear of getting infected by COVID and therefore avoiding visits to health institutions, other priorities related to the social and economic conditions, and the shift of medical personnel to COVID activities. The delivery of testing and other HIV prevention services by some NGOs were stopped at the beginning of the pandemic and during the lockdowns, while others continued their effort and remained as the only source for delivering HIV preventive services to KPs. Currently, the overall testing situation is normalizing and there are increasing trends in HIV testing coverage, especially among KPs.

"In 2020, during COVID, NGOs within the MoH projects provided services to KPs, VCT services in the regional institutes of public health were also available... But we notified sharp decrease in HIV testing, almost third less that it was in 2019… But in 2021 the people are actually more willing to be tested, numbers are increasing, and we are satisfied… in 2021 we have a lot of those from KPs who are tested, for instance we had more than 10000 MSM tested in the community, which is a very large number…"

IPH representative

"In our organization we stopped our activities when COVID started, we did not work for two months. Everything was closed, we had a state of emergency in Serbia from March to May 2020 and in that time, we did not work, nor testing nether anything else. After that it was not easy to start program again and find clients… but now the situation is improving…"

SCO representative

"The situation changed a lot during COVID pandemic… during that 2 years when health staff was shifted to COVID activities and they did not do testing, testing numbers were really low… community-based organization were the only option for people to get tested at that time, and also the private labs… At some point actually we were the only organization that could provide community-based testing for the whole country…"

SCO representative

Financial sustainability of HIV rapid testing services at health institution is not considered to be an issue in Serbia, unlike the one conducted at community level. The latter is supported by the GF and is anticipated to be functional by the end of 2025. Some NGOs receive additional funding from pharmaceutical companies and other donors, which is also a problematic issue in terms of sustainability. It should also be mentioned that some local municipal authorities are committing resources for implementation of programs by NGOs. Moreover, some NGOs are currently working on accreditation of their outreach work with the aim of institutionalization of these services within the social system and thus ensuring sustainable funding.

"When we are talking about the rapid testing, there are no big barriers, there is governmental support, tests are licensed and registered, procurement is going well, costs are not so big… but in the future, the HIV prevention program provided by the NGOs in the community for the KPs supported by the GF will be ended at the end 2025. And then if we do not have additional support from the GF, it is expected that the MoH should cover these costs… So, we will see after 2025 what will happen... Actually, for the next three years we have very good chance to successfully control and eliminate HIV/AIDS as the public health issue. Because at this moment we have, based on the estimates, more than 85% of estimated PLHIV diagnosed, so we need to find that 10-15% more in the next three years and put them on the treatment, this is our top goal, and we will try to reach that goal… we expect that the MoH will support in the future activities in the community because it is really needed…"

IPH representative

"Outreach work in mobile unites is covered by MoH project through the money of GF and checkpoint center activities by Gilead. This the third year we have support form Gilead. Sustainability of funding is always a problematic issue generally for NGOs, because our activities are mainly covered by the GF… We also have some part of funding covered by local municipality. Now we are working on accreditation of our outreach, we are trying to be established in the system so that after the state will have to pay us… That's one more way how we actually want to make services sustainable…"

SCO representative

We also interviewed community representatives (MSM, PWID, SW, TG) on the rapid HIV testing barriers and asked to provide suggestions/recommendations for improvement to policy makers in Serbia. KPs prefer to receive HIV prevention services at community-based organizations in use-friendly environment and are mostly satisfied with these services. Expanding geographical availability of HIV rapid testing at community level was suggested by KPs participating in this assessment, since representatives of KPs feel more comfortable receiving services at community-based organization rather that at health care institutions.

"When testing in health institutions, it bothers me that the wait is longer for the result, and I don't feel comfortable talking to the doctor about my sexual orientation, so it would be good to have greater availability…"

MSM community representative

"The testing process itself is free, fast, accessible and is performed in a pleasant atmosphere - good staff and excellent relations with users..."

MSM community representative

"More frequent and more widely available, free testing services would be better…"

PWID community representative

"The process [of receiving testing services at SCOs] is user-friendly. It mostly corresponds to community needs…"

MSM community representative

HIV self-testing – policy and practice

HIV STs were available at pharmacies about more then 10 years ago, but some serial false negative cases reported, made the health authorities to investigate the quality of those self-tests and consequently they were removed from the market.

Currently, no policies and practice on HIV self-testing exist in Serbia. Although, country plans to develop a pilot project on HIVST, submit it to the GF and in case of availably of funding within the current allocation, implement it within the next two years. The results of the pilot project will be used for its future scale-up. In addition, one of the CSO representatives participating in the interview for this assessment mentioned that their organization is planning to conduct HIVST acceptability survey (currently mobilizing funding from different donors, otherwise will be accomplished on a voluntary basis) among their beneficiaries. During the interviews with country representatives, it was noted that implementing HIV self-testing would definitely contribute to the increase in overall testing coverage, but sound preparation and planning should precede the implementation process. It should be an additional option offered to those willing to be tested and preference should be given to assisted testing, especially at the initial stage. The main concerns about HIVST that arose during discussions

were its high price, availability of funding for its implementation, linkage to care for those who test positive, and psychological impacts of a reactive/positive result when a person is performing self-testing alone. Sound preparation, proper education and political will would facilitate the implementation of HIVST in Serbia.

"Using self-tests during the outreach would be something new for us and maybe we need more time to think about it, all its pros and cons of this method. Some pilot project to evaluate acceptance would be useful… Currently in Serbia we have estimated 1000 more PLHIV who do not know their status and maybe it is a good solution to find these 1000 PLHIV who are not motivated to go to institutions or NGOs for testing to check their status…"

SCO representative

"More than 10 years ago HIV self-tests were available in some pharmacies. Some people used it for self-testing, during some parties… HIV positive people tested negative on these tests... we investigated the case, and the conclusion was that these tests were of bad quality, also maybe there were also problems with storage and then the Ministry of Health put the ban for these self-tests in our country… It [HIVST] is not a practice in our country currently, but actually, together with the GF, within current allocation we want to conduct demonstration project, then to implement and monitor results and effects, and also the acceptability… At the moment we have not defined yet what will be the setting for HIV self-testing, but actually we plan… We have prepared the outline of the demonstration project and shared it with the global fund portfolio manager, and they are very willing, but it depends on the funding, it is planned to be implemented in the next two years… If the project gives us good results, it could become part of our strategic approach in our country… In terms of HIVST we think that it will be a challenge to properly monitor and evaluate utility, acceptability, and final linkage to care of those who are self-tested… Hight price could be a barrier, also the psychological impacts when test is positive…"

IPH representative

"In the nearest future we want to make some kind of survey (we applied for some small funding but if we do not get, we can do it without funding) among our KPs we are working with, to see if it's OK for them, how they would like to receive it and so on… I think that it should be an option for those who would like to use it. It should be an option, but I think with some kind of assistance and proper preparations..."

SCO representative

When talking about HIVST with community members, they mostly expressed positive attitude towards its implementation, they think it could facilitate the reach of most hidden and reluctant beneficiaries, but some concerns were expressed regarding follow-up and linkage to care after positive test results. The importance of participation of community members in planning processes for HIVST implementation in the country was also underlined. Participants also highlighted the importance of general education of population on HIV/AIDS, its prevention, stigma reduction, testing importance and implementation of demand creation activities for both community-based and HIVST. In terms of HIV ST delivery modes, community members think that there should be various options, so that clients use the most convenient possibilities based on their preference. Both finger prick and saliva test-kits are acceptable for them.

"Main issue will be that individuals lack trust and will be reluctant to report and follow up positive results… it should be widely available and though different delivery modes… In general, there is lack of community participation in national policies… more public education regarding HIV and importance of testing is needed… there should be motivational messages for demand creation…"

PWID community representative

"People will not willingly always report positive result due to stigma regarding HIV… The public needs to be informed on self-testing or other HIV related services, they are not publicly advertised… Not aware that there is any participation of community members in creating service models, rarely do members of the community have any impact on national policies and practice. … The advantage of wider self-test availability would clearly include reach to otherwise reluctant members of the community… there should be adequate psychological support to increase linkage to care after self-testing… we need major public campaign before implementation… Lack of trust, general fear and upset, fear of stigmatization could be barriers for implementation..."

PWID community representative

"It would have a positive effect on the number of people tested, as some people do not even want to go to organizations for privacy reasons… All tests should have leaflets with information about support and who to contact for further procedure…"

MSM community representative

Recommendations

- Ensure that updated National Guidelines/Protocols for HIV testing are in line with WHO recommendation, include provision of full-scale community-based testing and HIV self-testing. The development process should ensure engagement of representatives of target populations.
- Ensure full scale implementation of community-based testing. The latter requires changing the legislation/regulations and enabling NGOs/CSOs to conduct full scale community-based testing, enabling NGO/CSO staff conducting the testing. Using the saliva HIV self-tests during the outreach activities can also be considered (assisted self-testing).
- Decentralize HIV rapid testing, enable testing at NGO/CSO facilities and other relevant health institutions.
- Ensure adequate funding for and implementation of demand creation activities in line with WHO recommendations to increase HIV testing uptake. Demand creation and mobilization should be developed together with communities and tailored to the specific interests, concerns and needs of each priority community.
- Develop an integrated information and communication strategy with sufficient activities to raise awareness on HIV testing for both the general population and KPs. Regular implementation of these activities is essential. The development process should ensure engagement of representatives of target populations. Ensure adequate funding for information and communication activities.
- Ensure sustainable and long-term funding mechanisms for NGOs/CSOs as implementors of community-led HIV prevention and support services for KPs after GF withdrawal from the country.
- Ensure adequate governmental support to CSOs in accreditation of outreach and other community-based services in order to institutionalize them in the entire health/social system and thus ensure its sustainable funding from state and local municipalities.
- Prioritize and implement activities aimed at reducing stigma and discrimination towards PLHIV and KPs and ensuring confidentiality of PLHIV.
- Plan and implement HIV stigma and discrimination research activities and develop policy and advocacy recommendations for reducing HIV-related stigma and discrimination in Serbia.
- Ensure mobilization of funding for piloting HIVST. Conduct the pilot, evaluate it and consider the results during its scale-up. Pilot project should include all organizational arrangements that are required for smooth implementation: namely, test-kits should be distributed together

with supporting material, including pre and pos-test counseling leaflets, detailed instructions for use on local language, contact information of focal points in case of positive test results, hot line numbers, etc. Appropriate follow-up and referral services should be in place to ensure timely linkage to treatment and care services in case of positive test results.

- Consider using HIVST for PrEP when facility-based services and in-person patient-clinician contact is limited.