

*Policy Brief*

# **HIV Self-testing: Opportunities for Improving the HIV Diagnosis in North Macedonia**



A Member Association of



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HIV self-testing is a procedure in which a person collects their own saliva or blood sample, and then performs the HIV test and interprets the result. This would typically take place in a home setting, that is, in a private environment. Basically, the HIV self-testing kits are quite similar to the rapid diagnostic tests for other conditions, such as the COVID-19 virus, which are also performed independently.

This significantly simplifies the HIV testing as it can be performed at one's own home, more discreetly, avoiding the physical contact with the HIV testing service providers, as is the case with health facilities or the civil society organisations' stationary or mobile clinics.

## Self-testing as part of the HIV testing services

When HIV infection is concerned, rapid tests intended for an independent personal use do not serve for establishing a definitive diagnosis, rather, they are a mere indication of the human immunodeficiency virus (HIV) being present in the body of a person. The reactive, i.e. positive result received from one such rapid test, which has been performed independently, needs to be verified by other laboratory tests. Therefore, the HIV self-testing is considered a triage testing, requiring the persons with reactive results to be administered further testing performed by authorised professionals in compliance with the national procedures for establishing the HIV infection diagnosis. [1]

Tests used for self-testing purposes usually include collecting one's own finger-prick blood sample or saliva sample from one's own mouth, and they typically detect the HIV antibodies which may be found in these body fluids.

The World Health Organisation recommended in 2016, for the first time, that HIV self-testing be offered as an *additional access* to the HIV testing services. The objective of this recommendation was to seek out new ways of reaching out to the people who are at higher risk from HIV infection, and which would otherwise not get tested. With their 2019 Consolidated Guidelines on HIV Testing Services, WHO reiterated their self-testing recommendation, which is now to be offered as *one of the accesses to HIV testing services*, [1, 3]

This HIV testing method opens up a new opportunity for a greater availability of HIV infection diagnosis: delivery options can make the self-testing kit arrive at the home of the person wishing to make the test, anywhere in the country, unlike the classical testing, which imposes geographic restrictions, leaving a large portion of the country not covered by the service.

World Health  
Organisation, 2019:

*“HIV self-testing should be  
offered as an additional approach  
to HIV testing services.”  
(strong recommendation,  
moderate quality of evidence)*

Thanks to its possibility to be widely available, HIV self-testing has the potential to contribute to achieving the global objectives of ending the HIV epidemic, that is, diagnosing the largest share of people living with HIV. This would be achieved by also covering the persons who had never made an HIV test before.

Furthermore, the World Health Organisation believe that HIV rapid diagnostic tests may prove particularly appropriate for persons exposed to prolonged higher risk from HIV infection, such as the key populations, who may benefit from a more frequent testing. The introduction of this measure is expected to create a greater demand for HIV testing and enable a greater number of persons to perform the test, especially the ones with undiagnosed HIV infection and those who require more frequent testing on account of their continuous risk exposure, without them needing to see an organisation or an institution. [1]

*“Less stressful and more confidential. I feel encouraged  
to do it more often.”*

*(A statement by a user from Macedonia)*

At the same time, in their Consolidated Guidelines on HIV Testing Services, WHO underline that it is desirable to offer appropriate options for delivering the self-testing as a service, and that the affected communities should be involved in developing and adapting the HIV self-testing options [3].

WHO self-testing recommendations build up on the 2015 recommendation for demedicalisation of the HIV testing, so as to increase the access to HIV testing services, as well as their acceptability, by members of the key populations and priority groups, which may otherwise be prevented from using the services in health facilities. Demedicalisation means that trained non-medical staff may independently provide safe and effective HIV testing services by using the rapid diagnostic tests. This should be made possible through policies which will allow the trained non-medical staff carry out all elements of the service, including the collection of blood sample, performing the test, reading and communicating the result, providing pre-test information and counselling, as well as providing support in linking the person to other prevention, care and treatment services [2].

## Epidemiological status of HIV in North Macedonia and national priorities

Although anyone can become affected by HIV, in most parts of the world, this infection has a disproportionate effect on particular marginalised populations, which frequently have poorer or even inadequate access to preventive healthcare. Professional assessments about North Macedonia indicate that people who inject drugs, male and female sex workers, as well as men who have sex with men, are exposed to greater risks from HIV, and the virus prevalence is higher with them than among the general population [4]. Different data categories, including the regular epidemiological monitoring, prevalence assessment through biobehavioural studies, and mathematical modelling assessment, indicate that HIV epidemic in Macedonia is under control with the first two specified groups, but is rather active and growing among the population of men who have sex with men [5]. According to the inter-

national standards, this population is facing a *concentrated epidemic*, with the last prevalence assessment standing at 5.4% (in 2017) [11]. Although there is limited information about epidemiological trends among transgender persons, based on the trends in the wider region and globally, it can be assumed that this population is also disproportionately affected by the HIV epidemic.

Countries' success in responding to the HIV epidemic is assessed through the concept known as HIV care continuum (or: HIV testing and treatment cascade), which includes methodologically based assessments of the following major parameters (which comprise the cascade):

- ➔ total number of people living with the virus,
- ➔ from them – percentage of those aware of this (diagnosed),
- ➔ percentage of those receiving therapy, and
- ➔ percentage of those who, resulting from the successful treatment, have a fully suppressed viral load in the blood.

When the virus becomes fully suppressed by the therapy, it can no longer harm the person's immunity and can no longer be transmitted sexually. The analyses of the HIV care continuum in North Macedonia indicate that the so-far diagnosed people living with HIV represent 70% of the total number of persons who have the virus [6]. Contrary to this, on a global scale, the percentage of those diagnosed at the end of 2021 was as high as 85% [7]. The global targets adopted by the United Nations General Assembly include, by 2025, to have 95% of the total number of people living with HIV diagnosed – from those diagnosed, 95% to be administered therapy; and from those receiving the therapy, 95% to have a suppressed viral load. In other words, the achievement of these targets will mean that *out of the total estimated number of people living with HIV* – 95% will be diagnosed; 90% will receive therapy; and 86% will have suppressed viral load. This target will contribute to a drastic drop in the number of the newly infected, and will make it possible to end the HIV epidemic by 2030.

Chart 1:

HIV testing and treatment cascade in North Macedonia, 2021 – progress made against the 2025 global targets

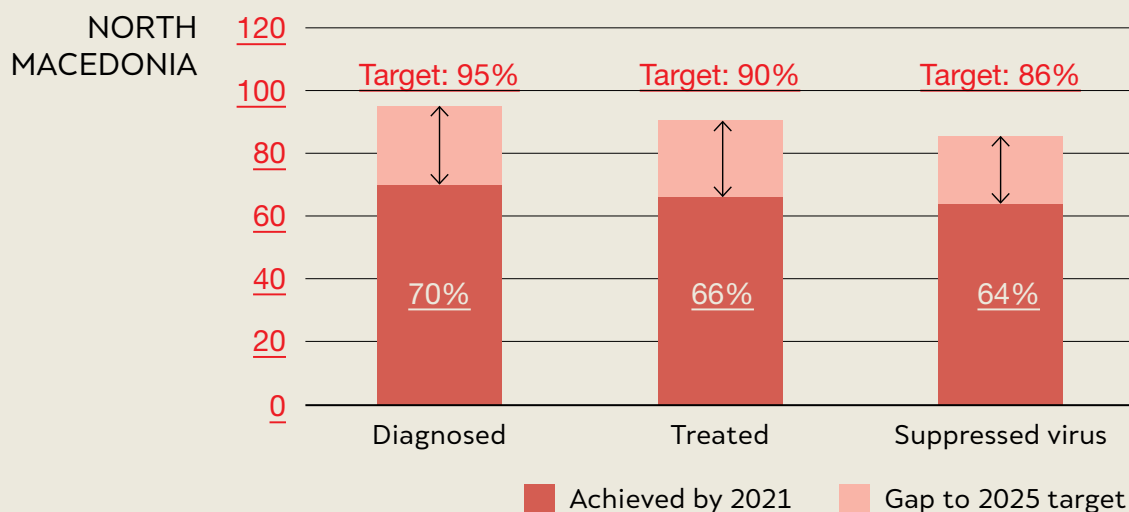
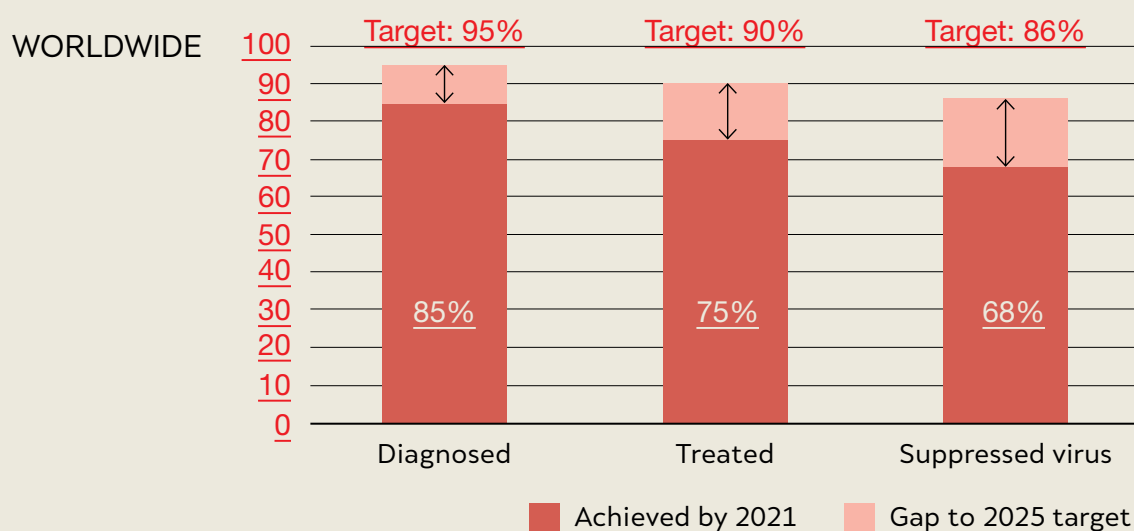


Chart 2:

HIV testing and treatment cascade in the world, 2021 – progress made against the 2025 global targets



Comparing the HIV care continuum in the world and in North Macedonia highlights the HIV testing as the major priority in the national HIV response.



The annual analyses of the HIV testing and treatment cascade for the period between 2017 and 2021 based on the methodology recommended by the European Centre for Disease Prevention and Control also indicate that Macedonia has demonstrated a very slow progress in achieving the global target of diagnosing 95% of the people living with HIV. The percentage of people living with HIV who were aware of their HIV infection, from the estimated 64% at the end of 2017, has risen to only 70% by the end of 2021, estimations shows [6, 8, 9]. Moreover, the estimated number of the newly occurred infections in the course of the year has remained approximately the same, and even greater than the number of people diagnosed annually [6, 9]. Therefore, the key priority for the national HIV response should become exactly testing – meaning, to diagnose the people infected with the virus as soon as possible, so as to sooner connect them with the appropriate healthcare and HIV treatment.

By the end of 2021, 548 cases of HIV were registered in the country, with a lethal outcome reported in 117 cases [10]. Over the last 5 years, 46 new cases a year have been registered on average [17].

## HIV self-testing in North Macedonia: Policies

Despite the clear recommendations from the World Health Organisation, HIV self-testing, as a service, was not available in Macedonia until recently. The need for introducing this opportunity in the HIV infection diagnosis process was first identified on the national level in the recommendations given by the World Health Organisation's technical assistance mission regarding the national HIV response, which was carried out in 2018 [12]. The 2019 National HIV Prevention Programme [Programme for Protection of the Population against HIV infection] stipulated, for the first time, the “design of a protocol for and introduction of HIV self-testing”, as part of the measures to improve the availability of HIV testing to members of the key populations; and with the next year's, 2020 Programme, the Ministry of Health earmarked the first ever allocation from the Programme's budget to the procurement of self-testing kits [13, 14]. However, the specified measures were never implemented.



## Civil sector initiatives

In 2019, HERA – Health Education and Research Association conducted a **research into the attitudes, acceptability and the required information regarding the self-testing of gay men and other men who have sex with men in North Macedonia**, when majority of the respondents expressed high level of willingness to independently perform the HIV self-testing from their saliva sample (75.2%) or blood sample (57.1%) – having first seen the video-material on how the tests is performed. A high share of respondents preferred to be able to obtain the self-testing kit from the local pharmacies (77.8%), or through the civil society organisations (72.2%). [15]

Based on this research, in the course of 2021 and 2022, the Association HERA implemented a pilot programme involving a demonstration project that offered web-based HIV self-testing services. The pilot programme made use of rapid tests for independent use by collecting oral samples (saliva). The primary objective of introducing this measure was to increase the coverage of HIV prevention measures among men who have sex with men, as one of the groups exposed to the greatest risk from HIV infection in the Republic of North Macedonia. In addition to men who have sex with men, in a narrower sense of the expression, the pilot programme also covered the transgender women in Macedonia. The pilot programme was implemented in the period between October 2021 and July 2022, with a total duration of 9 months, in the course of which data were collected from the respondents, which were then analysed, and based on which an evaluation was made. [16] The key findings of this evaluation will be presented below.

# Key findings from the self-testing pilot programme (2021-2022)

## Effectiveness of the self-testing service

One of the most important findings from the self-testing pilot programme implemented by HERA in 2021-2022 was that, for as many as 41.18% of the service users (49 out of the 119 respondents), members of the population most affected by HIV, self-testing through the pilot programme was their first ever HIV test. One third (32.77%) of the respondents had previously done an HIV test, in the civil society organisations' facilities; 15.71% in a public clinic; and 20% in a private laboratory.

Table 1:

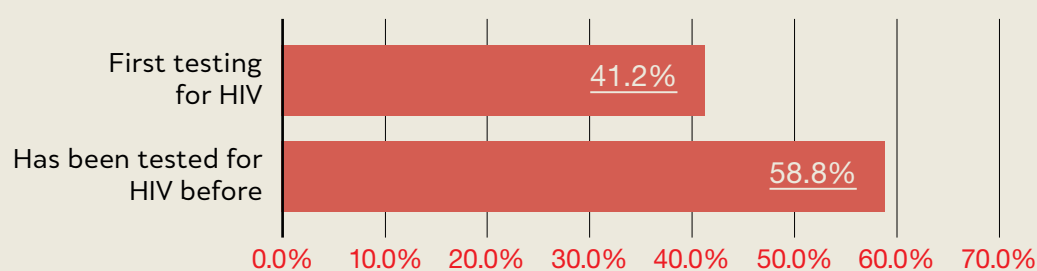
Number of newly tested men who have sex with men and transgender persons involved in HERA's pilot programme that have never used other HIV testing services in the country before

VARIABLE	FREQUENCY	PERCENTAGE
Persons for whom the self-testing was the first ever HIV test in their life	49	41.2%

In comparison, in a similar pilot in Georgia implemented in the first half of 2020, the share of users from the population of men who have sex with men for whom the self-testing was their first ever HIV test stood at 17% – with a three times greater total coverage (n=371) [17]. Another study, in Africa, showed that the share of persons who were for the first time tested for HIV by self-testing methods ranged between 20% and 30%, indicating that the self-testing service has the potential to significantly increase the coverage of persons from the affected populations who have never before done an HIV test [18].

Chart 3:

Have they made an HIV test before



In this sense, the high share (41.2%) of the newly tested persons in the Macedonian piloting of the web-based self-testing services indicates that this service was undoubtedly a significant addition to the national HIV response and may contribute to achieving the targets from the national HIV response.

These findings are in line with the findings from the global qualitative comprehensive overview of the experiences in using and in organising the HIV self-testing that, generally taken, self-testing can increase the capacity of reaching out to the priority populations and can expand the opportunities for service provision. Thereby, home-based self-testing was preferred before institutional testing on account of its comfort and confidentiality, particularly among the stigmatised populations. [18]

It is important to note that the self-testing service was popular among the younger members of the target groups, with almost half of the users (49.58%) were under 29 years of age, and as many as 83.19% were under 39 years of age.

Table 2:

Newly diagnosed HIV cases among men who have sex with men and reported reactive tests within the pilot

VARIABLE	FREQUENCY	PERCENTAGE
Newly diagnosed HIV cases among men who have sex with men	2	1.68%
Reported reactive tests	3	2.5%

The share of reported reactive results within this pilot was significant and stood at 2.5%, that is, 3 cases with reactive result from the 119 tests performed. In two of these cases (1.68%), the HIV diagnosis was verified; and for the third case, we are not aware whether the user has seen an appropriate institution to have the diagnosis verified. The importance of this result could be illustrated if we compare the share of positive HIV tests made in the public health centres in the course of 2021, which is only 0.02%, that is, only 2 positive results were reported from the 8,929 tests performed [10, 17]. This indicates that the approach applied in this pilot, by focusing on the groups exposed to greater risk from HIV, was adequate and yielded results.

Even in the single case of a reactive result for which it is not known whether the verification test was made, it is important to underline that for this client, who was aged between 40 and 49, the web-based self-testing was the first ever HIV test they have performed in their life. For persons of this category, which – if indeed HIV positive – are anyway outside the treatment system, it bears repeating that it is more so better for them to learn this information about their probable HIV positive status, rather than not have the information at all.

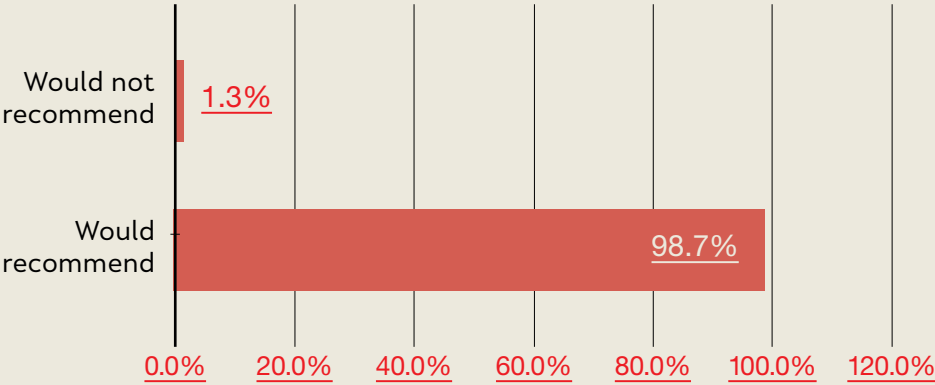
### Service acceptability and user satisfaction

With 98.67% of the users who have answered the question about their satisfaction in the follow-up questionnaire – who have declared to be very (94.59%) to somewhat (4.05%) satisfied – with as many people willing to recommend the test to others, the method in which the service was designed and delivered by HERA was hugely responsive to the needs of the users.

Table 3:  
Number and percentage of satisfied clients from the ones that have answered the question about satisfaction (n=74)

VARIABLE	FREQUENCY	PERCENTAGE
Very satisfied or somewhat satisfied with the service	73	98.65%

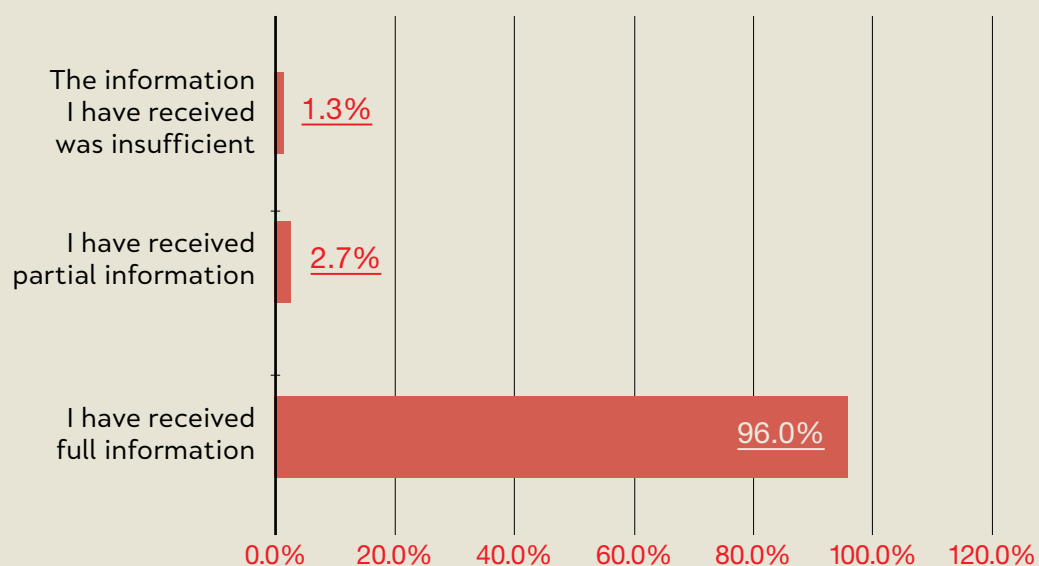
Chart 4:  
Would you recommend the HIV rapid test to friends or acquaintances (n=75)



The acceptability of the self-testing service, and of the method in which it was provided, is reflected in the fact that 96% of the persons that have answered the corresponding question reported that they have fully received all the required information about the test from the materials (i.e. how to perform it, what to do if the test returns positive or negative, and where to obtain further support). Only 2 persons (2.67%) have only partially received the required information; and 1 person reported that the information received was insufficient (1.35%).

Chart 5:

Answer to the question “Have you received all the necessary information about the rapid HIV test in the materials, as to how to perform it, what to do if the test returns positive or negative, or where to obtain further support?” (n=75)



Half (49.33%) of those who answered (n=75) the question about the reasons for their satisfaction, specified the speed with which the results are received; 32 persons (42.67%) specified the discretion, or anonymity of the test; and 29 (38.67%) – the simplicity of using the test, including the fact that the method of performing the test was well explained. 22 persons (29.33%) mentioned the other aspects, such as practicality, that is, the fact that the test is home-based, and it does not require going anywhere, nor traveling to other towns, nor being tied to a scheduled appointment.

*"I am satisfied because no one can see me or know that I am getting tested. Discretion is what matters the most to me."*

(A user from Macedonia)

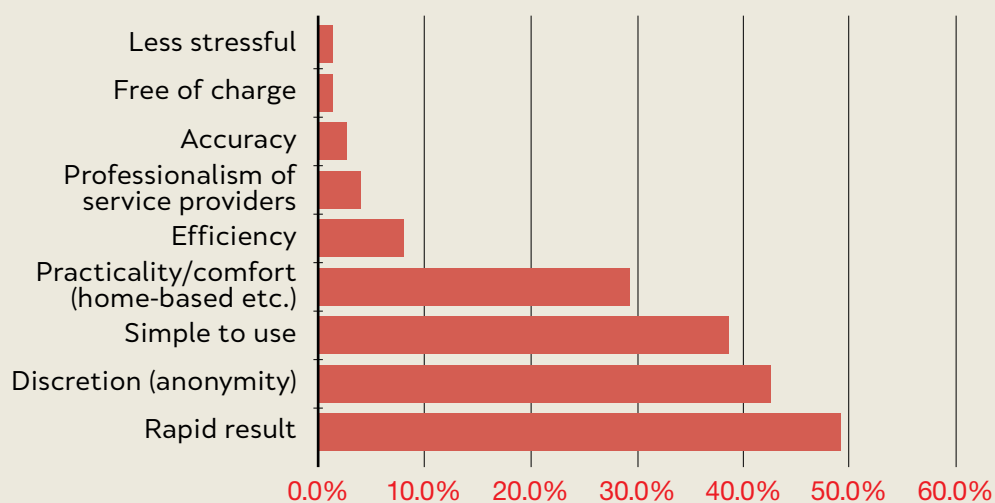
To the open question as to the reasons for their satisfaction, the most frequently mentioned ones included the speed with which the results were returned (49.33%, n=37); discretion, or anonymity (42.67%, n=32); and the simplicity of using the test, including the fact that the method of performing the test was well explained (38.67%, n=29). To a lesser extent, yet significant (29.33%, n=22), the aspects of practicality/comfort were mentioned – the fact that the test is home-based and it does not require going anywhere or travelling to another town, nor being tied to a scheduled appointment. Less frequently mentioned reasons were efficiency and accuracy – 8 (10.67%); professionalism – 3 (4%); the test being free of charge – 1 (1.33%); and the fact that this method of HIV testing proved to be less stressful – 1 (1.33%).

*"The service and its delivery were very fast. When I spoke on the phone to a lady, she was very nice and responsive. The test was simple and easy to use, and of course – free of charge. Thanks a lot!"*

(A user from Macedonia)

Chart 6:

Reasons specified for satisfaction with the HIV self-testing service



Emphasising the confidentiality so highly is in line with the findings from other similar research, including the 2019 research into the

attitudes, acceptability and the required information. Confidentiality and comfort of the HIV self-testing, in contrast to institutional testing, were indicated by majority of persons who have performed the HIV self-testing worldwide [18].

## Statements of user satisfaction with the service

*“I’m satisfied because the test can be performed in a home setting, for persons living far away from the capital. Any physical person can obtain the test and learn their HIV status at home, with greater discretion.”*

*“A good and discreet thing for us, the people who live far away from Skopje.”*

*“You are not tied to an appointment, you can do the test whenever you want.”*

*“I’m satisfied because it arrived at my home address. Efficient, exactly as it is presented. Practical. It reminded me of the COVID-19 rapid tests which can be obtained in pharmacies. If the HIV test was available also in pharmacies, that would be ideal.”*

*“Easy to use, with simple and clearly defined steps, and the informative brochure.”*

*“I’m satisfied because the test arrives fast, through a delivery service, and it is secret and safe.”*

*“Easy to use, with clear instructions, and fast results.”*

*“Because it is fast, and I can order it any time I want.”*

In the evaluation of the pilot programme, the members of the team who conducted the pilot noted that the self-testing service could be promoted also through persons for promotion and availability of the kits in other organisations (in addition to the regular promotion via the internet), and that the home-based test should also be made available in the



pharmacies. A smaller share of the users, on the other hand, indicated the following approaches: selling the tests in pharmacies at affordable prices; availability at particular points, e.g. stations at LGBT parties or through the general practitioners. Several users also mentioned the need for a greater media coverage; presentations in high schools and universities, youth organisations, sports clubs and other places frequented by young people; as well as disseminating self-testing flyers among the younger MSM population. From the specified approaches, the largest support was given to the availability of self-testing kits in pharmacies, based on the 2019 research into the attitudes, acceptability and the required information, with 77.8% of the respondents replying in this direction.

The team members emphasised that it is very important that the kits include particularly prominent information on how to get in touch with the HIV Department of the Infectious Disease Clinic; as well as – when a positive result is received – that the clients can obtain all the important information.

## Conclusion

The web-based HIV self-testing pilot programme focused on men who have sex with men and transgender people has accomplished its objective by reaffirming the exceptionally high level of acceptability of this service among the target group. It is particularly important that this programme managed to reach out to a significant share of persons that have never had an HIV test before. Considering the high level of user satisfaction, it may be expected that this model of providing the service will stimulate the other users from the target group, too, to get tested more frequently – which is desirable considering their greater exposure to the risk from HIV infection.

The self-testing pilot programme proved to be particularly successful in identifying the undiagnosed people living with HIV, which becomes particularly prominent if the results are compared to other HIV testing services in the country.

The findings from the pilot programme evaluation indicate that self-testing, as an approach in HIV testing services, has the potential to make an even greater contribution to the national HIV response, above all by addressing the major gap – the high share of people living with HIV that are not aware of their HIV status. Therefore, web-based HIV self-testing services need to be given priority in and receive funding from the national HIV programmes. In addition to this approach, HIV self-testing needs to be made available in other ways as well, including the possibility to be obtained privately in pharmacies.

## Recommendations

- The Ministry of Health should take measure to expand the HIV testing opportunities and make them more accessible to key populations affected by HIV.
- The funding for the HIV self-testing services, in the various modalities of providing this service, should be secured from the National HIV Prevention Programme [Programme for Protection of the Population against HIV Infection], and possibly from other domestic sources, such as the local self-government units.
- It is necessary that the Ministry of Health secures continuous provision of HIV rapid tests, including the self-testing kits, as part of the Programme for Protection of the Population against HIV Infection, thus guaranteeing their continuous free availability to persons exposed to greater risks.
- The availability of the self-testing option should be further expanded through the network of the civil society organisations working on HIV service provision, harm reduction from drug use, LGBTI organisation, and other organisations that provide any healthcare or social service to groups disproportionately affected by HIV.
- The Ministry of Health should take measure to stimulate and enable the HIV self-testing kits become more available for private procurement in pharmacies.
- Taking into consideration the success of the implemented HIV testing pilot programme, which was fully initiated by the civil sector, the Ministry of Health should strengthen their support and improve the mechanisms for including the civil society organisations in the healthcare system.
- The Ministry of Health should adopt National Guidelines on HIV Testing, including the rapid test and HIV self-testing services, as part of the health facilities and civil society organisations.
- In compliance with the World Health Organisation recommendations, the HIV testing services, as well as similar diagnostic procedures which require the involvement of medical professionals, should become demedicalised by introducing the corresponding amendments to the Law on Health Protection.

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