Integrate

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HIV self-testing and self-sampling in Europe: Situation Report to January 2021

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Executive Summary

This document outlines the current progress across Europe in implementing HIV self-testing and self-sampling as an HIV testing strategies. Provision of these testing strategies are largely dependent on the countries local legal situation and support from the relevant governmental body through national policy. This helps organizations to provide tests through these mechanisms and facilitate the monitoring of these tests. Publication of data related to these testing strategies will recognize their contribution to the testing landscape but will also help make the case for increase implementation in the country itself or in other countries.

The published literature suggests there self-testing is highly acceptability in studies from Europe. Self-testing was found to reduce barriers to testing, offering convenience and anonymity, whilst increasing the autonomy of the user. However, studies had limited generalisability due to the small of studies based in Europe and small sample sizes in these studies.

When reviewing the legality of self-testing and self-testing policies across Europe, in 23 countries self-testing was legal and 14 countries had dedicated, national self-testing policies. Supporting the use of self-testing in this way can encourage access and normalise testing. There were 7 countries where testing was illegal and 21 countries that had no self-testing policy. The patchy availability of HIV self-tests across Europe means there is a risk that individuals in countries where tests are not legal or available, will resort to procuring self-tests online or through illegal means, and using them with limited guidance and lack of regulation or quality assurance. In some countries, the situation is not as clear as self-testing being either illegal or legal. Instead, self-testing may be available, e.g. for online purchase, however, the resultant guidance or linkage to care is then compromised due to a lack of clear guidance. On top of this, even where countries where self-testing is both legal and has a national policy, self-tests must be privately purchased, at a cost of €25-30 which creates an additional barrier to access.

There is limited uptake of self-sampling across Europe, where it is legal in only six countries. As with self-testing, self-sampling can reduce barriers to testing especially for those experiencing stigma and discrimination, by encouraging testing autonomy and privacy. Barriers to implementing self-sampling strategies and use of self-sampling kits are both structural and individual. Structural barriers include legal barriers, such as restrictions around sending biological specimens in the post, the cost and resource required to establish an end-to-end system that includes test order, laboratory testing and results reporting. Despite these, the scale up of self-sampling should still be considered as a mode to increase access to testing.

As an important element of a comprehensive HIV combination response, access to testing should be facilitated at the national and local level. Self-testing and self-sampling are critical strategies to encourage testing and broaden access, with supportive laws and policy an essential part of this. Though a number of countries have made progress in these spheres, there is still work to be done to ensure access to self-testing and self-sampling. Post-testing, linkage to care pathways are vital and should be clearly defined. For those who test positive or reactive this will include links to a confirmatory test and treatment. For those who test negative, signposting to other HIV prevention resources should be offered. Though critical, linkage to care is one of the major shortcomings of self-testing. In order to overcome this, relationships between manufacturers, distributers, non-governmental organisations (NGOs) and public health bodies should be strengthened.

Finally, the needs of key populations need to be considered and consulted throughout these recommendations, with a clear focus on the structural barriers and inequalities experienced that can limit access and positive health outcomes and a rigorous assessment of the unmet needs of the key populations being served.

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Abbreviations and terminology

ECDC: European Centre for Disease Prevention and Control
Europe: EU/EEA Countries (as of end of December 2019)
HCW: Health care worker
MSM; Gay, bisexual and other men who have sex with men
NGO: Non-governmental organization
PHE: Public Health England
Positive result: A HIV test result that indicates that the individual does have HIV infection
PrEP: Pre-exposure prophylaxis
PWID: People who inject drugs
Reactive result: A HIV test result which requires further confirmation as to whether or not it is positive
Self-sampling HIV kits/test: A test in which the specimen to be tested is taken by the individual and sent to a laboratory or clinic for processing.
Self-testing HIV kit: A test carried out and interpreted by the individual undergoing the test.
WHO: World Health Organization

1. Introduction: HIV self-testing and self-sampling in Europe

In Europe, there were 136,449 new HIV diagnoses made in 2019, an increase of 19% over the past 10 years. However, it is likely that the number of people living with an undiagnosed HIV infection in Europe is increasing [1].

HIV testing is crucial to ensuring that people living with HIV infection are diagnosed and subsequently offered prompt, effective treatment. This is imperative to improve the individual's own health outcomes and achieve viral suppression whilst also reducing the risk of onwards HIV transmission.

Throughout Europe, there is substantial variation in the legality, administration and provision of HIV self-testing and self-sampling kits. There has been continued diversification of the testing pathways and modalities are available including the provision of self-sampling kits [2] and the legalization self-testing kits [3]. This diversification helps to broaden access to HIV testing and increases the autonomy of the tester [4, 5].

As there is a paucity of published data specific to a European context, this report sought to outline the situation in the region.

1.1 Self-testing

HIV self-testing is a HIV test carried out the tester themselves and the result is interpreted by the tester. There are several benefits to self-testing. It has been suggested that self-testing will help key populations who may experience stigma, to test for HIV in a confidential setting [6, 7] for example gay, bisexual and other men who have sex with men (MSM). It has also been hypothesized that self-testing has value in allowing people to have more ownership over where they would like to test and it is able to reach people who might not be able to access or travel to current services, such as those who live rurally.

This report outlines the legal situation for the provision of self-tests, investigating if there laws that permit or prevent their sale and use and whether self-testing is included in the national policy or strategy for HIV prevention. The first HIV self-test approved for public use was in the United States of America in 2012 [8] and since then, many countries have incorporated this testing strategy into their national policies and have authorized legislation to permit their use.

Despite self-testing kits first coming to the market nearly 10 years ago, several structural barriers continue to contribute to limit the uptake of self-testing. Both prohibitive laws and a lack of national policy can restrict access to self-tests where prohibitive laws could criminalise the use of a self-test kit and a lack of national policy can limit accountability, guidance, and vision around self-testing.

1.2 Self-sampling

Self-sampling involves a test in which the specimen to be tested is taken by the individual and sent to a laboratory or clinic for processing and interpretation. As with self-testing, self-sampling can offer privacy whilst testing, with the potential to reduce barriers to accessing testing, such as stigma and discrimination. This mode of testing is also beneficial as it is free to the tester at the point of use and can be used to supplement existing clinic based testing.

In addition to these benefits, self-sampling has been found to be an acceptable testing method and can facilitate testing in populations at an increased risk of HIV infection [9]. However, uptake of self-sampling has been much poorer compared to self-testing and less is known about its acceptability in a European context. It is not widely

adopted in Europe, and as such there are few national policies and few countries where it is legal. This is explored further in section 7.

2. HIV self-testing: Acceptability, Positivity and Uptake

Since the introduction of self-testing, there have been several studies assessing its acceptability to key populations. Acceptability is considered both the willingness to use and actual use of self-testing [10, 11]. However, there have been very few published studies in a European context. From the published literature, five systematic reviews have been published on the acceptability and uptake of HIV self-testing [10-14], which included only four European studies [15-18]. Most studies demonstrated that acceptability of self-test kits was high. Only two European studies assessed acceptability: encouragingly it was high at 78% and 83% [15, 16]. Overall, the reviews found there was no significant differences in acceptability between key population groups, test type, education level and whether someone had previous experience carrying out a self-test. It was also reported that this testing approach has not been associated with any harms or unintended consequences [14].

in the European studies, reactivity of self-tests ranged between 0% to 20%. The high test positivity suggests that self-testing is successful in reaching groups at risk of HIV. However, it is difficult to accurately ascertain an overall positivity for self-testing. This is due to a combination of the lower test sensitivity of self-tests compared to other types of HIV tests [14] and the confidential nature of self-testing, where the user interprets the test results themselves and not in a healthcare setting. This means all reactive test results require confirmatory testing, and not all those people who receive a reactive result will disclose that they have previously tested before using a self-test or disclose their result to the relevant people.

Most of the studies included were demonstration projects. However, for studies where uptake figures were presented, most people offered an HIV self-test accepted the offer, with uptake ranging from (69-90%). In the instances where testers concerns were recorded, users were concerned they would use or interpret the test incorrectly [11].

The evidence summarized above is based on research studies rather than real-life scenarios. This may limit the generalizability of the findings as study contexts may not capture the real-life barriers to accessing HIV self-testing, There is also an issue of generalizability to the European context, for two main reasons; primarily only four studies were carried out in European countries, and the European studies had small sample sizes, making it difficult to draw rigorous conclusions. Another limitation of this review is that three studies used an oral swab as the method for sample collection, rather than a blood sample. Currently, there are no self-tests using oral fluid authorized for use or sale in the European region, and as the testing process is less invasive it is possible that using salvia may be more acceptable compared to a blood sample [19, 20].

While these studies demonstrate high acceptability, there is a considerable lack of awareness about self-tests. Further work is required to understand the motivation to use this testing modality and how much people are willing and able to pay for a test. This latter point is particularly important as it has been suggested that people who are motivated to purchase and use a self-test are likely to have less errors when using a self-test [12].

Following the review of the published data, a desk review was commissioned to assess the current situation of HIV self-testing in Europe using grey literature and reports from organisations engaged in international surveillance of HIV self-testing, including European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO).

3. Methods

We reviewed and compiled data from of several recently published reports and resources on HIV self-testing and self-sampling. The primary publications and data sources used for this report are described in **Table 1**.

Table 1: Primary data sources

SOURCE	ABOUT	YEAR	OWNER
HIVST website [21]	A repository of information on HIV self-testing which monitors country-level policy and regulatory data.	Continuously updated	Collaborative
Dublin Declaration monitoring [22]	An annual survey of all 55 countries in EU/EEA to monitor health system and political progress toward ending the HIV epidemic.	2018	ECDC
Legal barriers website [23]	Database of the most common legal and regulatory barriers to HIV testing, linkage to care and treatment across Europe and in individual European countries, including key populations.	2016	OptTEST by HIV in Europe
Public health guidance on HIV, hepatitis B and C testing in the EU/EEA [24]	Technical testing guidance for European countries, based on systematic literature reviews, including HIV self-testing and self-sampling.	2018	ECDC
Guidelines on HIV self-testing and partner notifications: supplement to consolidated guidelines on HIV testing services [3]	Support the implementation and scale-up of ethical, effective, acceptable and evidence-based approaches to HIV self-testing.	2016	WHO
Market and Technology Landscape: HIV Rapid Diagnostic Tests for Self-Testing [25]	Technical guidance for all countries about the current availability of self-tests available.	2018	UNITAID
HIV self-testing strategic framework: a guide for planning, introducing and scaling up [26]	Brief guide for countries and implementers that are planning, starting or scaling up HIV self-testing implementation. It provides key considerations for: 1) preparing for HIV self-testing; 2) implementing HIV self-testing; 3) monitoring and optimizing HIV self-testing implementation.	2018	WHO

[1] Croatia, Estonia, Greece, Hungary, Ireland, Italy, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, United Kingdom

Published documents were retrieved from their respective websites in March 2020and reviewed by a senior epidemiologist. Websites with databases of information about HIV self-testing and self-sampling were searched. Information pertaining to the current situation of HIV self-testing and self-sampling in individual European countries was extracted into an Excel spreadsheet and categorised by country.

Due to the rapidly changing landscape of HIV self-testing and self-sampling, an internet search was also undertaken in March 2020 (and updated in January 2021) to identify recent news articles, press releases or other websites about HIV self-testing and self-sampling. A Google (UK) search was performed using the terms “HIV self-test”, “HIV home-

test", "HIV self-sampling" and "HIV rapid test" combined with each of the 32 European countries[1], was conducted. Data for each country was extracted into an Excel spreadsheet, including a lay summary of the results retrieved, the date of release, type of test used, and links to websites of interest. These data were used to validate results from the aforementioned resources or to provide updates where newer information was available.

The final Excel database was split into four categories: legal, policy, barriers and implementation. The available data was reviewed and synthesized to determine the most up to date situation in each country. In the case of discrepancies, these were discussed with a second reviewer to determine a final answer, with most priority given to the most recently published documents and resources in Table 1.

4. Legal environment of HIV self-testing in Europe

The legal availability of self-testing allows for testing to be more widespread within a country as individuals can order a test online or visit a pharmacy. For some people, the convenience and privacy of HIV self-testing make it preferable to visiting a clinic, such as people who are part of marginalised groups or who live in rural areas. HIV self-tests are legal in most countries in Europe 72% (23/32) and a further two countries have legislation under development. In the majority of countries where it is currently legal, self-tests are available for use, sale and distribution (50%, 11/22). However, in 6 countries self-tests are only available for use, meaning they cannot be purchased legally from private vendors, limiting access to HIV self-tests.

HIV self-testing is a strategy which can overcome other prohibitive testing regulations or laws in countries where testing is only carried out by healthcare workers (HCWs) or at certain locations. Legality of who can administer an HIV test varies across Europe: clinical supervision is required in 69% (22/32) of countries and just over half of countries (59%, 19/32) allow testing to be carried out by non-governmental organisations (NGOs).

There are seven countries where self-tests are explicitly illegal. In addition, there are seven countries where the legality surrounding their use is ambiguous as there is no legislation preventing or aiding HIV self-testing and three countries where the legal status is unknown (Figure 1).

Despite HIV self-testing being illegal in some countries, local stakeholders have acknowledged that an individual could purchase a self-test kit online from another country and get it delivered to their home. The situation in these countries is concerning there is unlikely to be any creditable regulation of test kits, little or no support available to people wishing to carry out a self-test and no formalised linkage to care pathways for those with a reactive result.

Ensuring that there is the legal basis to permit self-testing is crucial. Even if their use is not legalised, this does not ensure that their use is prevented as they can be ordered online from other countries and without the thorough authorisation and approval of the test kit, these unregulated tests could cause harm to those using them.

[1] Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom

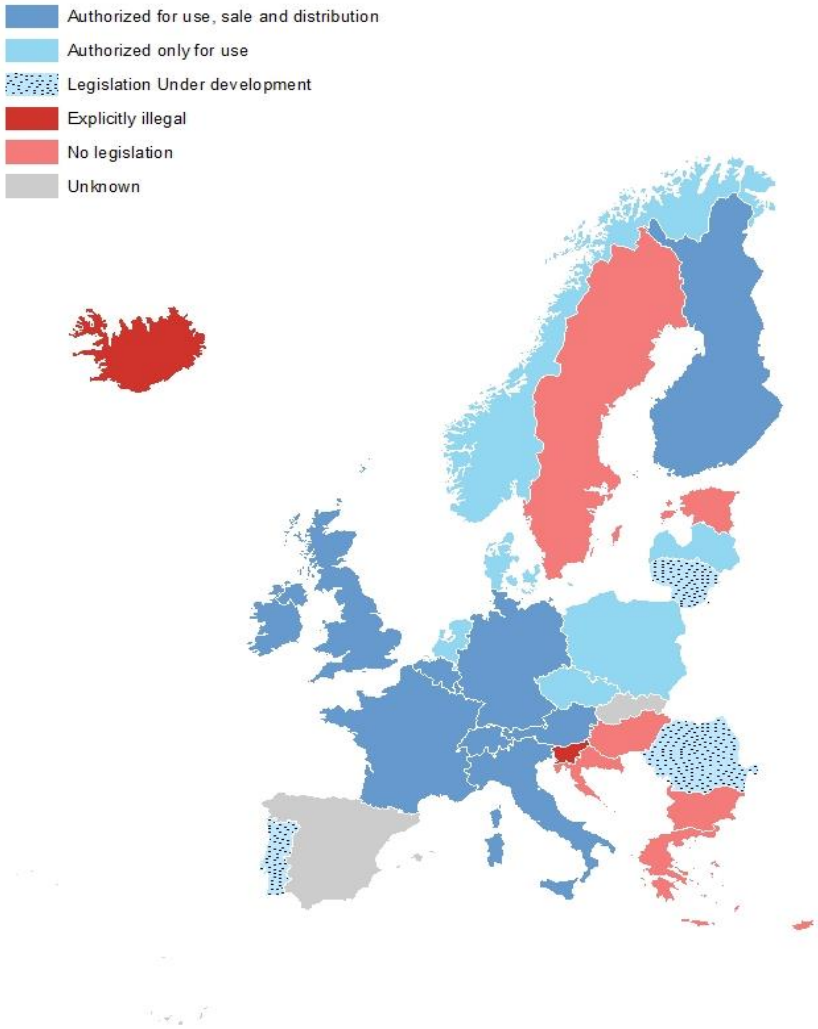

Figure 1: Map of countries classified according to their legal situation for the provision of HIV self-tests

5. Policy environment of HIV self-testing in Europe

Across European countries, self-testing policy is at varying stages. Most European countries (78%, 25/32) have a national HIV testing policy, just over half of these include self-testing (56%, 14/25). Of the remaining 7 countries where it is not currently included in national policy, only four (13%) countries have reported that its inclusion is in development. National policy is a clear way to signal the importance of HIV self-testing, through indicating that it is a priority and by providing guidance and generating accountability, both for its efficacy and safety. A self-testing national policy can also support in normalizing self-testing. Including HIV self-testing in national policy does not mean that there is a legal obligation for the government or any organization to provide HIV self-tests. However, support from governmental or public health body will help facilitate their introduction. In addition, if it is included in national policy it creates a better platform for it to be monitored.

Eight of the countries where it is included in national policy also stated that the policy only permits the use of HIV self-tests that are CE marked and require the test to be nationally registered. For countries that do not included this aspect in their policy, they have been encouraged to include this to ensure regulation and quality assurance of the tests being used, to ensure that the test meets the necessary standards of accuracy [3].

Four countries have not included self-testing in their national policy but stated HIV self-tests are available either through pilot studies or for purchase online and in pharmacies.

Further to this, six countries do not have a HIV testing policy at all and in one country it is unknown whether they have one. Creation of a policy is imperative to ensure that HIV testing is available to all people at risk of HIV, to ensure regulation of all HIV tests available and to facilitate monitoring of the implementation of the testing policy itself. Each of these efforts help to reduce the number of people living with undiagnosed HIV infection and improve the outcomes of people living with HIV.

6. Progress towards implementing HIV self-testing in Europe

Fewer than half of the countries in Europe (47%, 15/32) report having fully implemented HIV self-testing. Many countries have adopted HIV self-testing very recently in the past three years. For example, the ban on HIV self-testing in Germany, Austria and Switzerland was lifted simultaneously in all three countries in June 2018. In these countries, HIV self-tests are available for purchase in pharmacies, but online purchase remains illegal in Germany and Austria. Encouragingly, HIV self-testing pilots are currently underway in four countries; Czech Republic, Netherlands, Romania and Slovakia.

Self-testing is unique in that it allows users to both purchase and take the test from the comfort of their home. In 38% (12/32) of countries HIV self-tests are available for purchase online. Purchasing online helps the user to overcome concerns about confidentiality and privacy. However, this anonymity means that there is no opportunity for the individual to receive any pre-test counselling from trained professional or to be informed or signposted to other relevant HIV prevention interventions (i.e. condoms or pre-exposure prophylaxis (PrEP)). A greater proportion of countries (44%,14/32) offer self-tests in pharmacies, where most are available for purchase over the counter or on the shelf. However, tests are not always easily accessible in the pharmacy, for example requiring ordering into store or retrieval from a warehouse which can take a day or more, which can become a barrier to access and defeat a key benefit of selling self-tests in a pharmacy which is immediate access.

The cost of self-testing kits remains high across the region ranging between €20-35. Research has shown that only a minority of people are willing and able to pay for a HIV self-test at the current cost level, further creating a barrier to their use and limiting the groups able to use this testing strategy. There are two known countries where NGOs regularly offer free or subsidized HIV self-testing (France and UK). However, due to the high cost, many organisations are unable to afford to offer HIV self-testing. In some countries, self-tests are only offered through pilot schemes and short term interventions or research studies, which are unsustainable strategies long-term.

The legality of who can administer an HIV test varies across the region and clinical supervision is required in most countries (69%, 22/32). Most countries (59%, 19/32) allow testing to be carried out by NGOs. However, most countries (63%, 12/19) legally require clinical supervision to carry out medical tests and some countries have reported that not even all clinical staff are able administer an HIV test. Restrictions in who can administer an HIV test present a key barrier to the widespread provision of HIV testing generally. However, self-testing offer a potential solution to overcome barriers associated with the legality of who can administer tests. If the legal situation permits the use of self-testing, then any laws about test administration need not be changed as an individual cannot be restricted for tests they perform on themselves.

It is difficult to accurate estimate the number of countries where self-testing is legal but not being fully implemented. Estimates can be made through accessing sales data or calculating the number of people who first had a reactive self-test before their diagnosis. The former point relies on the distributor providing sales data through the private

market, which they may be hesitant to provide, particularly if the data is commercially sensitive and there is sales competition with another distributor on the market in the same area. Data from online sales may also be difficult to quantify given the number of retailers and distributors based outside the country. Thus data on sales of private tests prove difficult to add to existing national surveillance systems.

A summary of each European country's HIV self-testing situation is available in Table 2 below.

Table 2: Summary of HIV self-testing situation by country

COUNTRY	IS IT LEGAL?	YEAR LEGALISED	IS THERE A NATIONAL POLICY?	IS IT IMPLEMENTED?	WHERE IS IT AVAILABLE?	HOW MUCH DOES IT COST?	WHAT TEST IS AVAILABLE?	WHAT ARE THE RECOGNISED BARRIERS?
Austria	Yes	2018	Yes	Yes	Pharmacy			Illegal to buy online
Belgium	Yes	2017	No	Yes	Pharmacy	€25	INSTI (Bioyltica), Autotest VIH (Mylan)	
Bulgaria	Unknown		No	No				Absence of national policy or legal regulations
Croatia	No		No	No				Absence of legal regulations; small market
Cyprus	No		No	No				Absence of national policy or legal regulations
Czechia	Yes	2018	No	Being piloted	Online		Autotest VIH (Mylan)	
Denmark	Yes		Yes	Yes	Pharmacy			
Estonia	Yes		No	Yes	Pharmacy, Online		Autotest VIH (Mylan)	High cost; no process for linkage to care
Finland	Yes	2018	Yes	Yes				
France	Yes	2015	Yes	Yes	Pharmacy		Autotest VIH (Mylan), Exacto	
Germany	Yes	2018	Yes	Yes	Pharmacy		Autotest VIH (Mylan)	Illegal to buy online
Greece	No		No	No				Absence of national policy or legal regulations
Hungary	No		No	No				Lack of support from clinicians
Iceland	No		No	No				Absence of national policy or legal regulations
Ireland	Yes	2018	No	Yes	Pharmacy, Online			No process for linkage to care
Italy	Yes	2016	Yes	Yes	Pharmacy, Online	€25	Autotest VIH (Mylan)	Lack of information; no process for linkage to care
Latvia	Yes		No	No				Absence of national policy
Liechtenstein	Unknown		No	Yes				
Lithuania	Yes	2016	Yes	Yes	Pharmacy	€25		Hard to access
Luxembourg	Yes		No	No	Online			Absence of national policy
Malta	Yes	2017	Yes	Yes	Pharmacy			Not available online; not available in all pharmacies.
Netherlands	Yes	2017	Yes	Being piloted	Online		Autotest VIH (Mylan)	

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COUNTRY	IS IT LEGAL?	YEAR LEGALISED	IS THERE A NATIONAL POLICY?	IS IT IMPLEMENTED?	WHERE IS IT AVAILABLE?	HOW MUCH DOES IT COST?	WHAT TEST IS AVAILABLE?	WHAT ARE THE RECOGNISED BARRIERS?
Norway	Yes		No	No				
Poland	Yes		No	No	Online		Autotest VIH (Mylan)	Absence of national policy; no monitoring systems
Portugal	Yes	2018	Yes	No	Online		Autotest VIH (Mylan)	
Romania	Yes	2017	Yes	Being piloted	Pharmacy, Online	€24,95	Autotest VIH (AAZ)	Lack of information; Lack of regulation; High cost
Slovakia	Unknown		No	Being piloted				Lack of information; High cost
Slovenia	No		No	No				Absence of national Policy; not available for purchase
Spain	Yes	2018	Yes	Yes	Pharmacy, Online		Autotest VIH (Mylan)	Absence of national policy; no process for linkage to care
Sweden	No		No	No			Oraquick	Hard to access
Switzerland	Yes	2018	Yes	Yes	Pharmacy, Online			High cost
United Kingdom	Yes	2015	Yes	Yes	Pharmacy, Online	£29.95	BioSure INSTI (Bioyltica)	High cost

7. HIV self-sampling

HIV self-sampling is another testing strategy that has become available in recent years. Self-sampling has the benefit of allowing a user to collect the sample themselves conserving the testers autonomy, then sending the sample off to a laboratory for testing, providing a the laboratory confirmed result. Furthermore, it allows for greater contact between the tester and the clinic or organization delivering the test which enables that those test positive to be easily linked to care. However, use of self-sampling has not been widely adopted in Europe, with only six countries (19%, 6/32) having legalized the use of self-sampling kits. Reassuringly, six further countries have stated that they plan to include self-sampling in their national guidelines. However, this still means more than half of European countries do not offer, nor have plans to offer, this testing strategy in their national guidelines. Although six countries have legalized use of self-sampling, there remains a lack of information about how many self-sampling kits are delivered across the region. The only country that has published information about the number of self-sampling tests carried out is England where in 2019, 232,738 people tested using a self-sampling kit accessed through local sexual health clinics [27]. Further to this, 24,342 people also tested using a self-sampling kit accessed through a national scheme targeted at key populations between November 2018 and October 2019 [28].

There are many advantages to using of self-sampling, as with self-testing, the sample collection can be carried out at the user's convenience. As individuals do not need to travel to a clinic to obtain the test, it may help to those who may experience stigma or those who are not able to travel to a clinic. It may also have financial benefits for both the testers and the provider, as it can be offered free at the point of access which could contribute to greater uptake. Additionally, it may more cost-effective to provide a self-sampling kit by post compared to testing in person at a clinic, particularly for asymptomatic individuals, as it removes costs involved with clinical staff time and overheads. In turn, it can increase clinic capacity for people who are symptomatic or have complex needs. Self-sampling kits can also include tests for other STIs as well (i.e. chlamydia, gonorrhoea and syphilis), potentially improving testing integration and sexual health screening access. It is also easier to monitor testing through this process and patient information could easily be linked to their clinic records.

As there are very few countries using self-sampling as part of their HI testing strategy. There is less evidence about its acceptability and the barriers to its use in Europe, in comparison to other testing strategies. Globally, the more commonly known barriers are both structural and at the individual level. There may be legal barriers such as laws that do not permit the posting of blood samples or biological specimens. A key structural barrier is the high costs and resources associated with establishing and delivering a self-sampling programme. For example, laboratory systems need to be organized to process the samples, the logistics of sending and receiving kits will need to be set up, a safe and efficient result reporting system established, and a clearly defined linkage to care pathway need to be organized.

Individual level barriers include poor return rates where people order the kit but then do not return it. Although this could be an issue for self-testing, with individuals never using their test kit, with self-sampling is possible to follow individuals who have not returned their sample using the contact details provided at the time the test kit is ordered. Further barriers include fear or discomfort collecting the sample themselves, they may struggle to collect an adequate sample or samples may become hemolyzed leading to a lack of result for the patient.

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8. COVID-19 pandemic

Starting in 2020, the COVID-19 pandemic caused severe disruption to the running of many healthcare services, including face-to-face sexual health services, due to social distancing measures and lockdown restrictions [29].

As a result, declines have been observed in the number of HIV tests carried out at a face-to-face testing services [30] with a knock-on effect on testing modalities. This has brought self-testing and self-sampling to the fore, and a side effect has expediting the upscaling HIV self-tests, changes in law/policy, due to their ability to be carried out by the person testing. Supporting testing in this manner is of a particular priority given the impact of COVID-19 and some countries have used it to help lobby further for its implementation [31].

A global survey found that self-testing availability had been maintained or improved, and in some areas self-testing had become available for the first time during the COVID-19 pandemic [32]. Throughout this time, self-test kits have been provided by NGOs, pharmacies, and online, and roll out has been supported by campaigns to increase awareness. The impact had been found beneficial in some cases. For example, self-testing in Bulgaria encouraged more individuals to test for HIV [33].

However, there have been some barriers to upscaling testing, including the availability of test kits, and further research is needed to fully understand the impact of COVID-19 on self-testing and self-sampling, and HIV testing and diagnoses more broadly.

9. Conclusions and recommendations

In the era of HIV elimination, self-testing and self-sampling are key elements in the combination HIV prevention response. As such, ensuring that individuals have easy access to a HIV test and are offered different testing methods is imperative for several reasons. Not only does it help to ensure people have autonomy over how they would like to test, but the offer of self-test and self-sampling kits also widens access to people who may not be able to or who do not wish to attend health care settings. Self-testing provides confidentiality and anonymity to those who may feel stigmatized or do not feel comfortable attending local testing services in person. Ensuring that HIV prevention programmes are comprehensive is vital and should facilitate prompt linkage to care for those who are diagnosed with HIV and support those who test negative by signposting them to appropriate HIV prevention interventions and services.

This review found that the use of self-sampling was extremely limited in Europe and there were more barriers to its use compared to self-testing, which was available in most countries. The key barriers to the use of self-sampling included the cost and resource required to establish an end-to-end system that includes test order, laboratory testing and results reporting. Legal restrictions around sending biological specimens by post, and specific restrictions on HIV self-sampling exists In some countries. There can also be a lack of political will to challenge any legal barriers that are preventing self-sampling use. Self-testing is attractive to policy makers as little input is required from the government and public health sector, both in terms of introducing self-tests and facilitating their use as their role primarily centers on ensuring there is the appropriate legal basis to permit their use and/or sale. The manufacturer is responsible for producing the tests and distributor organizes the distribution to either individuals directly (i.e. for sale online) or to businesses where they can be purchased (i.e. pharmacies).

The legality of who can administer an HIV test varies across the region and clinical supervision is required in most countries (69%). Additionally, some countries have reported that not all clinical staff are able administer an HIV test.

However, as self-testing has the potential to bypass the legal barriers associated with test administration, if the law permits self-testing then any laws about test administration does not need to be changed.

Despite the well-known benefits and high acceptability of self-testing, this review has identified that, while it may be legal in some countries, self-testing is not fully implemented due to both structural and individual level barriers. These barriers include the high cost of the test and limited availability to access or purchase. The combination of small market size in each country and the high cost of the test ultimately contributes to poor availability. This is compounded by lack of marketing and campaigns that promote HIV self-testing, leading to low public awareness of self-testing. This could potentially be overcome by either initiating a joint multi-country procurement agreement or facilitating subsidised test costs, either paid for by the supplier or government to help increase supply. Other initiatives could include an NGO or public health body using HIV self-testing marketing as part of their HIV Testing Week or other promotional materials to raise awareness and increase demand.

While access for key populations must be improved, it should be recognised that not all people will want to use a HIV self-test. There is value is targeting key risk groups to increase awareness and help overcome any personal barriers they may face. For example, HIV self-testing has been used to effectively target: MSM to provide convenience or anonymity, particularly where homosexuality is highly stigmatised, partners of people with a confirmed diagnosis to overcome fear or stigma and those living in rural areas or areas where the health service is weak or testing coverage is poor. Self-tests should be made available in a variety of ways including vending machines, online and in pharmacies.

A drawback to the use of self-tests is the reliance on self-referral to facilitate linkage to care for those who have a reactive test result. Therefore, the information included in the test kit about accessing a confirmatory test needs to be optimised and specific to the local context. This can be achieved through strengthening the relationships between manufacturers, distributors, NGOs and public health bodies. This is mutually beneficial for all parties involved as it ensures that the information included with the test is correct, improves the utility of the test and it ensures there is specific and relevant support available. Such information could be provided in the form of a helpline or website signposting to pathways to care and contact details for local NGOs or clinics.

As self-testing is confidential, anonymous and often provided by private companies, it can be difficult to monitor its implementation, measure positivity rate and facilitate linkage to care. Improving surveillance data may be facilitated by the sharing of sales data, which would also be supported by the maintenance of good relationships with manufacturers and distributors of HIV self-tests. The use of self-testing could also be monitored by clinicians through the inclusion of “setting of first positive test” in new diagnosis reporting forms which could be then reported to the public health body. The use of a patient survey would provide another option to collect this data by asking individuals “Where did you first test positive?”. Together these would allow countries to understand self-test use in their country and to report aggregate numbers of tests. This is pertinent as there is currently paucity of data specific to a European context and it is essential to obtain and publish this data to give formal recognition that the testing has been carried out and to help make the case for this strategy to be successfully implemented in other countries.

Policy makers and service commissioners should consider how they can implement self-testing and self-sampling schemes, if not already offered. For those countries, that do already offer these testing strategies they should consider how these schemes can be optimised so that barriers to their use are removed or reduced.

Key recommendations include:

- Promote HIV self-sampling as a testing strategy to reach underserved popualtion, particualry in countries where only healthcare providers are permitted give HIV test results.

- Routinely assess local and national level structural barriers that may hinder their implementation, such as laws that prohibit an individual performing a test on themselves. Supervised HIV self-testing could be used where lay provider testing is not legal.
- National agencies and non-governmental organisations work together with manufacturers and distributors to provide tests at lowest possible costs and ensure that the information included in test kits are correct and relevant to the local context.
- Improve access to self-testing through enabling their sale online, in shops and vending machines.
- Faciliatate training of staff wherever self-tests are sold; such as pharmacies.
- Establish clear linkage to care pathways and collaborate with NGOs on how to effectively provide support to those self-testing, including contact points in case of reactive results and detialed information how to obtain a confirmatory test
- Explore the use of self-sampling across sexually transmitted infections and hepatitis, including acceptability and feasibility.
- Facilitate access to self-testing and self-sampling for key populations, particularly those that experience stigma and discrimination.

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