







CONSIDERATIONS FOR HIV SELF-TESTING INTHE CONTEXT OF THE COVID-19 PANDEMIC AND ITS RESPONSE: AN OPERATIONAL UPDATE























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Editing by Bandana Malhotra

Acronyms

AGYW	Adolescent girls and young women
ANC	Antenatal care
ART	Antiretroviral therapy
ATLAS	AutoTest VIH, Libre d'Accéder à la connaissance de son Statut (HIV self-testing
	project in Mali, Côte d'Ivoire and Senegal)
CLW	Community lay worker
COVID-19	Coronavirus 2019
EID	Early infant diagnosis
FSW	Female sex worker
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
HIVST	HIV self-testing
HTS	HIV testing services
IPC	Infection prevention and control
LMICs	Low- and middle-income countries
M&E	Monitoring and evaluation
MCH	Maternal and child health
MSM	Men who have sex with men
NGO	Nongovernmental organization
OPD	Outpatient department
PEPFAR	US President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV
PPE	Personal protective equipment
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
PWTB	People with TB
RDT	Rapid diagnostic test
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SOP	Standard operating procedure
STAR	Self-Testing AfRica
STI	Sexually transmitted infection
TROA	Total remaining on ART
USAID	United States Agency for International Development
VMMC	Voluntary male medical circumcision
WHO	World Health Organization

Executive Summary

HIV testing services in the context of COVID-19

The coronavirus disease 2019 (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a major global health threat. It has caused worldwide disruptions, such as economic slow-downs, travel restrictions, interruptions to the global supply of medical, diagnostic and infection prevention commodities, and has severely impacted public health in many countries. As of 14 June 2020, it was estimated that there were at least 7.98 million cases of and over 434 000 deaths attributed to COVID-19.

There is limited evidence to suggest that the risk of infection or complications of COVID-19 among people living with HIV (PLHIV) who are clinically and immunologically stable on antiretroviral therapy (ART) may be comparable with the general population. However, people with HIV who are not on ART and those with advanced disease have an increased risk of infection and related complications in general. Moreover, some people with HIV have comorbidities that are known risk factors for the complications of COVID-19, such as lung disease (e.g. due to active or previously treated tuberculosis), diabetes, cardiovascular disease, chronic kidney and liver disease, chronic obstructive pulmonary disease (COPD), certain other noncommunicable diseases and pregnancy. As such, they may be at increased risk for COVID-19 not directly related to HIV.

To control the pandemic and prevent the spread of SARS-CoV-2 infection, many national and local governments are implementing measures such as physical distancing, travel restrictions and stay-athome orders. Such changes have had important implications, particularly for maintaining health services, including HIV services.

The World Health Organization (WHO) has recently issued key updates, which include information on <u>HIV</u>, antiretroviral therapy and <u>COVID-19</u> as well as <u>operational guidance for maintaining</u> <u>essential health services in response to COVID-19</u>. As part of this guidance, **WHO** highlights the importance of ensuring continuing access to essential HIV services – including HIV testing services (HTS) and linkage to prevention, treatment and care services – in all settings. These include areas where there is community transmission and measures of physical distancing and restricted movement are being implemented within the public health response to the COVID-19 pandemic.

During this time, it remains critical to **support people with undiagnosed or untreated HIV to get tested and linked to ART**. While access to HTS followed by linkage to care must be maintained, evidence-based measures need to be implemented for both clients and providers to reduce possible transmission when adapting services. These include environmental surface cleaning, practising hand hygiene and respiratory hygiene such as the use of face masks, and physical distancing measures. Additionally, for health-care workers and providers, including lay and community workers, it is essential to practice infection prevention and control (IPC) measures and use appropriate personal protective equipment (PPE) when delivering services. Maintaining existing HTS with these measures and at current scale is challenging for many settings, however, and innovative strategies and tools are urgently needed.

HIV self-testing in the COVID-19 context

Since 2016, WHO has recommended HIV self-testing (HIVST) as a safe, accurate and effective way to deliver HTS and to reach people who may not otherwise get tested. Given the possibility that general health services may be overburdened due to the number of patients with COVID-19, as well as reduced access to HIV services in many settings, HIVST — whereby a person who wants to know their status collects their specimen (oral fluid or blood), performs a rapid test and interprets their result — has many advantages.

First, HIVST provides a way to maintain access to HTS while adhering to physical distancing guidance and helping to reduce the number of people attending and in need of HTS in health facilities. Following HIVST, those with a reactive result can be directed to appropriate service sites and tools including confirmatory testing, ART access and support. Self-testers with a non-reactive result may also benefit by avoiding an unnecessary health facility visit and reduce the risk of exposure to SARS-CoV-2. People at high ongoing HIV risk may also be able to utilize HIVST as a way to test more frequently and as part of their ongoing HIV prevention efforts, such as those taking pre-exposure prophylaxis (PrEP). It is important to strategically implement HIVST, **prioritizing geographical settings, clinics and populations** with the greatest need and where there are gaps in testing coverage.

Second, implementation of HIVST can be easily adapted to the COVID-19 context. It can be used in facilities and community settings, and test kits delivered through the Internet, mail-order systems and the private sector. Strategies include personal use of HIVST kits, as well as secondary distribution of HIVST kits to a sexual or drug-injecting partner among PLHIV and social contacts among key populations. In some high HIV burden settings, pregnant women may also provide HIVST kits to their male partners. Where access to facility-based testing is limited due to COVID-19, several programmes are evaluating the use of HIVST as a way to maintain PrEP programmes and caregiver testing for children (≥18 months of age) of people with HIV (e.g. an approach which is not self-testing, but whereby a parent, guardian or community outreach worker uses an HIVST kit to provide follow-up HTS).

Objectives and aims

This document provides an operational update to countries and implementers on the use of HIVST during the COVID-19 response. Through this update, WHO and Self-testing Africa (STAR) aim to highlight the importance of HIVST in the context of the COVID-19 response. It is a key way to maintain access to and uptake of HTS and onward services for those at high ongoing risk of HIV.

As the COVID-19 response evolves, countries and programmes will need to be flexible and adapt to specific contexts and epidemics. Thus, this guide provides key considerations for implementing and monitoring implementation of HIVST in the COVID-19 context and illustrates this with country examples and experiences.

While many countries have developed and are implementing HIVST policies, several countries have yet to fully introduce HIVST. Considering this new context and the effect of COVID-19 on individuals, communities and health systems, countries should urgently overcome policy and regulatory barriers to HIVST implementation and enable widespread access to HIVST. Such efforts are key to ensuring the continuity of HTS and access to prevention, treatment and care services, which are public health priorities, and are critical to global goals to achieving and maintaining low HIV incidence by 2030.

Table 1. Brief reference guide: HIV self-testing (HIVST) in the context of COVID-19

When should HIV selftesting (HIVST) be used in the context of COVID-19?

HIVST continues to be a safe, effective and acceptable HIV testing approach. As part of the COVID-19 response, it is an important tool and acceptable way to maintain access to HIV testing services (HTS) while adhering to physical distancing guidance and efficiently triaging HTS clients seeking services at health facilities. It is critical to use HIVST where there is access to further confirmatory testing and linkage to prevention, treatment and care services.

Who are the populations that should be reached with HIVST specifically in the COVD-19 context?

Priority populations in need of access to HIVST will vary by context. While wide-scale access to HIVST may be beneficial for physical distancing and for reducing client volumes at facilities, it remains critical to reach those at ongoing risk, such as:

- key populations^a and their partners who may not be able to access HIV testing services routinely or as frequently as needed;
- sexual and drug-injecting partners of a person with HIV;
- people with HIV-related symptoms;
- individuals who are sexually active and have not tested in the past 12 months in high HIV burden settings.

What does adequate HIVST service delivery require and what needs to be considered in the context of COVID-19?

Demand creation/mobilization: adapted, user-centred communication and demand creation tools that increase awareness and demand among priority populations should be available. These engage with key stakeholders and also provide information about COVID-19 and its potential risks for PLHIV who are not on treatment.

Testing process: distribution is either direct (offered to the client who will use it) or indirect (secondary distribution) and should be largely unassisted to reduce inperson contact with the provider. Adequate information and demonstration videos should be provided through the social media or user-friendly inserts. Self-testers may have the option to test on-site or take the test kit home.

Linkage: tools that support testers' links to information, counselling, treatment and/or prevention after a self-test should be available. Linkage information should be updated to inform clients about health facilities that provide safe services, which might require booking and scheduling due to COVID-19. Tools should allow the tester to opt-in, use the highest level of technology available to the target population (e.g. phone, Internet, smartphone), offer the option of speaking to a human and allow for direct community follow up, and protect the privacy and confidentiality of the self-testing experience.

Tools should not pressurize self-testers to disclose their test results nor compromise the privacy of the testing experience. Linking self-testers who test off-site is more challenging, so innovative follow-up approaches might be required, such as calls, SMS, WhatsApp contact, or community outreach.

What HIVST approaches can be applied in the context of COVID-19?

- Facility-based direct distribution of HIVST kits and drop-off sites at health facilities
- Secondary distribution through PLHIV to their sexual or drug-injecting partners, pregnant women to their male partners, and social, sexual or drug-injecting contacts of key populations
- Pick up or purchase at kiosks, pharmacies or vending machines
- Internet or mail-order system (e.g. e-commerce)

^a WHO defines key populations as: men who have sex with men, people who inject drugs, people in prison or closed settings, sex workers and transgender people.

Table 1. Brief reference guide: HIV self-testing (HIVST) in the context of COVID-19 Integrating HIVST into SARS-CoV-2 testing and COVID-19 contact tracing and/or screening at facilities or community settings Due to disruptions in services following the COVID-19 pandemic, some countries are evaluating: HIVST use in PrEP programmes. While HIVST is not being promoted over HTS, when available, it is important to carefully consider and monitor implementation. caregiver HTS, whereby a parent, guardian or community outreach worker uses an HIVST kit to provide follow-up HTS for children of PLHIV. While this approach is not self-testing, high HIV burden countries considering this approach will need to carefully monitor implementation. Where and how can HIVST There are currently four WHO-prequalified HIVST products, including both oral-fluid kits be procured? and blood-based rapid diagnostic tests: https://www.who.int/diagnostics_laboratory/evaluations/pq-list/selftesting public-report/en/. All manufacturers have local distributors at country level in selected countries in Africa, Asia and Latin America through whom HIVST kits can be locally purchased at affordable prices. A list of local distributors can be obtained from each of the manufacturers. HIVST kit orders can also be placed directly with the manufacturers or through the procurement mechanisms of major donors, e.g. PEPFAR and the Global Fund. **How should HIVST** Several indicators are recognized by WHO and PEPFAR for monitoring HIVST and are outcomes and impact be available at: https://www.who.int/hiv/pub/self-testing/strategic-framework/en/. measured and reported? Many of these metrics can be obtained using routine clinic data. In the context of COVID-19, it might be necessary to adapt data collection processes to limit the time of direct interaction between the provider and the beneficiary. Additional process indicators may be useful to also identify bottlenecks in implementation and to ensure fidelity of the planned HIVST service delivery approaches.

COVID-19: coronavirus disease 2019; HIVST: HIV self-testing; HTS: HIV testing services; PEPFAR: US President's Emergency Plan For AIDS Relief; PLHIV: people living with HIV; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

1. Background

The coronavirus disease 2019 (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a major global health threat. It has caused widespread disturbance of international travel, economic slow-downs, country lockdowns, severe supply chain interruptions of medical, diagnostic and infection prevention commodities, and has severely impacted the health delivery system in many countries. As of 21 June 2020, it was estimated that there were at least 8.7 million cases of and over 461 000 deaths attributed to COVID-19¹. In many low- and middle-income countries (LMICs), the health infrastructure is neither equipped nor prepared to care for large numbers of severely ill COVID-19 patients.

To control the pandemic and prevent the spread of SARS-CoV-2 infection, many national and local governments are implementing measures such as physical distancing, travel restrictions and stay-athome orders. Efforts to minimize unnecessary gatherings in and patient contact with health facilities are important for reducing the burden on and transmission risk in these facilities. In many settings, group-based activities have also been paused or restricted. Such changes have had important implications, particularly for maintaining health services, including HIV services.

Interventions that ensure access to HIV testing and treatment to protect people living with HIV (PLHIV) and people with tuberculosis (PWTB) are a public health priority. While evidence on the interaction of SARS-CoV-2 and HIV or TB is still limited, PLHIV, PWTB and/or people with other viral infections are at higher risk of becoming infected or suffering the more serious effects of COVID-19.^{2,3} To contain and mitigate the spread of COVID-19 in communities particularly affected by HIV and TB, programmes need to promote procedures that properly identify (triage) patients seeking care for COVID-19 and minimize exposure to it.

Initiation and continuity of antiretroviral therapy (ART) for all PLHIV, as well as access to HIV prevention services, is the foundation of HIV programmes during the COVID-19 pandemic. It is important to support governments to maintain PLHIV who are already on treatment, ensure that PLHIV not yet on treatment are started as soon as possible, and establish the best possible infection control procedures at sites where HIV services are offered, so that the risk of transmission of SARS CoV-2 among providers and clients is reduced or prevented. As a result, efforts are needed for HIV treatment services to become more easily accessible through differentiated care, such as multimonth dispensing and decentralized delivery of ART. Likewise, community programming and digital tools can be used to provide information, support and maintain contact while following physical distancing.

The World Health Organization (WHO) has recently issued key updates such as information on <u>HIV</u>, antiretroviral therapy and COVID-19⁴ as well as operational guidance for maintaining essential health services in response to COVID-19.⁵ As part of this guidance, **WHO** highlights the importance of ensuring continuing access to essential HIV services – including HIV testing services (HTS) and linkage to prevention, treatment and care services – in all settings. These include areas where there is community transmission and measures of physical distancing and restricted movement are being implemented within the public health response to the COVID-19 pandemic.

2. HIV Testing Services in the Context of COVID-19

Considering the potential risks of serious complications related to COVID-19 among PLHIV who do not know their status and who might be severely immunosuppressed, it is critically important to **continue** to support people with undiagnosed or untreated HIV to get tested and linked to ART.

While access to HTS followed by linkage to care must be maintained, evidence-based measures for both clients and providers should be implemented to reduce possible transmission when adapting services. These include environmental surface cleaning, practicing hand hygiene and respiratory hygiene such as the use of masks, and physical distancing measures. Additionally, for health-care workers and providers, inclusive of lay and community workers, it is essential to practice infection prevention and control (IPC) measures and use appropriate personal protective equipment (PPE) when delivering services. Innovations are needed to reduce face-to-face contact, increase efficiency, and reduce the burden and workload on staff during the COVID-19 pandemic.

To adapt to these new considerations, HIV programme managers need to optimize HTS programming, such as linkage to prevention and care, and follow government directives or policies on physical distancing. For community-based HTS, this may mean adapted outreach strategies using greater caution and fewer outreach visits and client participation in outreach sessions and altered pattern of participation (e.g. staggered visits to minimize contact), depending on the local context and guidance from authorities. For facility-based testing, this may mean prioritizing HTS in certain settings and for specific population groups, such as (i) those presenting for antenatal care (ANC)/postnatal care (PNC) and at maternal and child health (MCH) services, as well as their partners and families; (ii) those requiring early infant diagnosis (EID); (iii) individuals reporting (or admitted) to facilities with illness suggestive of HIV infection (for diagnostic testing); (iv) individuals with TB, sexually transmitted infections (STIs), malnutrition; (v) partners and biological children of PLHIV presenting at facilities or through offering HIV self-test (HIVST) kits; (vi) key populations and their partners.

HIV self-testing, whereby a person who wants to know their status collects their specimen (oral fluid or blood), performs a rapid test and interprets their result, has many advantages for adapting existing HTS approaches to maintain essential services. Furthermore, expansion of HIVST may contribute to reducing the health facility burden and crowding that can lead to SARS-CoV-2 transmission.

3. HIV Self-Testing in the Context of COVID-19

WHO recommends HIVST as a safe, accurate and effective way to deliver HTS and reach people who may not otherwise get tested.^{6,7} HIVST can also contribute to efforts to increase HTS programme efficiency and effectiveness by focusing limited HIV resources, space and staff time towards individuals with a reactive self-test in need of further confirmatory testing and linkage to prevention, treatment and care services. ^{8,9}

Given the current COVID-19 context, HIVST is quickly becoming a critical tool for maintaining access to existing HTS as it can reduce the influx of clients and patients seeking HTS at health facilities and thereby reduce unnecessary health facility visits and the risks of exposure to SARS-CoV-2.

Self-testers with a non-reactive result may also benefit by avoiding unnecessary health facility visits and reducing their risk of exposure to SARS-CoV-2. People at high ongoing HIV risk may also be able

to utilize HIVST to overcome service disruptions and to test more frequently as part of their ongoing HIV prevention efforts, such as those taking pre-exposure prophylaxis (PrEP).

While many countries have developed and are implementing HIVST policies, several countries have yet to fully introduce HIVST. Considering this new context and the effect of COVID-19 on individuals, communities and health systems, it is urgent for countries to overcome policy and regulatory barriers to implementation of and enable widespread access to HIVST. Such efforts are key to ensuring the continuity of HTS. Access to prevention, treatment and care services are public health priorities, and are critical to global goals to achieve and maintain low HIV incidence by 2030.¹⁰

In addition to the WHO guidelines on HIVST, there is a substantial body of evidence and lessons learnt on HIVST implementation to guide programmes. In particular, the Self-Testing Africa (STAR) Initiative has been leading the largest evaluation and implementation of HIVST for the past five years across 13 countries in Africa and Asia: http://www.psi.org/project/star.9

Recently, WHO and STAR have been quickly learning how to adapt and focus HIVST implementation in the context of COVID-19. The following sections draw from the lessons learnt by WHO and STAR and provide key considerations for how to select and adapt HIVST implementation, including demand creation, service delivery, and linkage to prevention and care in the context of the COVID-19 response.

4. Considerations for HIV Self-Testing in the Context of COVID-19

4.1 General Conditions

WHO recommends HIVST as a key approach for delivering HTS.¹¹ Evidence to date has demonstrated that it is a safe, accurate and effective way to increase the uptake and frequency of testing among populations missed by existing services. Detailed guidance on HIVST implementation is available in the WHO strategic framework: https://www.who.int/hiv/pub/self-testing/strategic-framework/en/.¹²

The following principles should be considered when introducing or scaling up HIVST implementation in the context of COVID-19.

- HIVST can improve access to and uptake of HTS among PLHIV who do not know their status as well as those at high ongoing risk in need of more frequent testing. Globally, focusing HIVST toward reaching and linking PLHIV who do not know their status to ART is a priority.
- HIVST can create a demand for, and improve linkages to, HIV prevention services (e.g. voluntary medical male circumcision [VMMC], PrEP, condom use), and testing and treatment for people who have a non-reactive self-test result, such as those with STIs, and those requiring contraceptive/family planning services and sexual and reproductive health services.^b
- HIVST can increase efficiencies for those who test HIV-negative (non-reactive). Those with a
 negative self-test result will not immediately need further testing, but HIVST is an opportunity
 to direct these people to access prevention services as described above and, consequently,
 unnecessary testing or facility visits can be avoided, saving time and resources on the part of

^b Note that most countries and PEPFAR-supported programme have stopped the provision of VMMC services, as male circumcision is an elective procedure and bears the risk of medical adverse events that might be difficult to resolve in the context of restricted health services.

both the clients and the health system, ensuring physical distancing and preventing individuals from visiting health facilities during the COVID-19 epidemic.

- HIVST can improve testing coverage through integration in facilities where HTS is needed but not routinely offered or is poorly implemented. For example, offering HIVST at high-volume clinics in high HIV burden settings and at STI or family planning clinics while clients wait for other clinical services makes beneficial use of their waiting time and ensures that they have their test results on-site. When relevant, they can be offered further testing and treatment initiation. Facility-based testing, followed by linkage to prevention and care, remains an important part of the HIV response and should be continued with appropriate precautions for COVID-19 prevention.
- HIVST can facilitate partner testing and social network testing. HIVST has been shown to facilitate couples and partner testing in high HIV burden settings or among partners of PLHIV. HIVST may also be used to support disclosure where beneficial and provide HIV prevention to serodiscordant couples (where one partner is HIV-positive and the other is HIV-negative). PLHIV can be provided with HIVST kits to distribute to their sexual and/or drug-injecting partners, particularly in settings where provider-assisted referral is not feasible or is limited due to COVID-19. Key populations, whether HIV-positive or HIV-negative, can be provided HIVST kits to distribute to their sexual and/or drug-injecting partners, peers or social contacts. To maintain community-based HTS, the use of social networks for HIVST distribution can be considered among key populations (with appropriate caution to clients on physical distancing when distributing HIVST kits). HIVST is a way to reach hidden/hard-to-reach populations and those who do not access health services through this HIVST social network or secondary distribution.

4.2 Populations that May Need Increased Access to HIVST

HIVST should be offered to selected groups of populations who are at increased risk of HIV infection and have the greatest need for testing coverage, as well as in areas where there are gaps in coverage.

Table 4.1 outlines the populations that may need increased access to HIVST and for whom there is evidence that HIVST can improve HIV testing coverage and consequently linkage to care, treatment and prevention. There may be other groups of populations, depending on the country context and specific testing and ART gaps.

Table 4.1. Populations in need of increased access to HIV self-testing and considerations regarding COVID-19

Priority population	Rationale	Distribution during the COVID-19 pandemic
Key populations (i.e. men who have sex with men, people who inject drugs, sex workers, transgender people and people in prison)	HTS coverage is disproportionally low among key populations globally. Maintaining and increasing HTS coverage among key populations is critical to preventing new HIV infections and achieving low incidence.	Delivering HIVST kits through virtual online distribution with home delivery or delivery at dropoff sites, social network or distribution through peers, free distribution at pharmacies or retail outlets that are accessible during the COVID-19 pandemic or health facilities and drop-in centres that reach key populations represent excellent opportunities for HIVST distribution. In settings where PrEP is being disrupted by COVID-19, HIVST

Priority population	Rationale	Distribution during the COVID-19 pandemic
		with close monitoring can be considered to maintain services.
Men	HIV testing coverage and knowledge of HIV status among men living with HIV is substantially lower than among women worldwide. Men in southern Africa and from key population groups are an important population to reach. Men have lower rates of health-care utilization in general. This reduces their opportunities to test for HIV through routine services. ¹³	Several HIVST access points could be considered for reaching men during the COVID-19 pandemic, especially those offered through secondary distribution, by sex workers to their clients, female partners who access health facilities or who access pharmacies where HIVST kits are offered through promotions. Men can also be reached through workplaces and the private sector, including pharmacies and the Internet. Internet-based and mail-order delivery of HIVST may be options in many settings.
Couples and partners, including partners of people with HIV	Couples and partner HIV testing, particularly for sexual and drug-injecting partners of PLHIV, is highly beneficial but under-implemented.	Offer HIVST to PLHIV for secondary distribution. This offers an opportunity to integrate HIVST distribution within adapted ART distribution at community level (3–6 months – WHO recommendation in the COVID-19 context). This is currently implemented in several countries.
Pregnant and postpartum women in high HIV burden settings	Offering HIVST during this heightened period of HIV risk has increased couples and partner testing in studies conducted through STAR and is currently being scaled up in most countries that have adopted HIVST as part of their testing programmes.	Provide HIVST kits to pregnant women to encourage their male partners to test. Countries implementing maternal retesting can also consider providing HIVST kits to implement retesting in late pregnancy or in the postpartum period. Such approaches should be prioritized for high HIV burden settings or for women living with HIV or with a partner from a key population.
Adolescents and young people (aged 15–24 years)	Approximately one third of new HIV infections in the world occur among young people in southern Africa. Young key populations are especially vulnerable to and affected by HIV. For adolescents and young adults, their status as dependents can limit their ability to consent or pay for HIV services or generate fears of social and economic marginalization from families. 14,15 Concerns around implicit revelation of sexual debut and stigma and discrimination from health-care providers can also limit uptake. 16	Virtual online distribution with home delivery or delivery at drop-off sites and free distribution at pharmacies or retail outlets that are accessible during COVID-19 or drop-off distribution at health facilities represent excellent opportunities for young people to access HIVST kits.

4.3 Key Considerations for Delivery of HIV Self-Testing in the Context of COVID-19

Providers need to consider the specific restrictions and conditions that are prevailing with COVID-19 when planning HIVST interventions.

As with conventional facility-based HTS, where this may still be offered, e.g. testing of pregnant women, all HIVST programmes need to ensure that confirmatory HIV testing and easy access to ART for those with a reactive test are available and that information on how and where to access those services, especially in the context of COVID-19, is provided at the time of distribution of the test kit.

This might also require additional follow-up services that self-testers can access digitally (e.g. telephone helpline, WhatsApp, SMS, mobile applications). Access to HIV prevention, such as condoms, and PrEP, should also be assured where possible for those provided with HIVST kits. Equally important is information on and access to other sexual health services, including contraceptives, emergency contraception and STI services.

Community-based HIVST services need to be amended to comply with national authorities' recommendations on physical distancing and use of PPE. The frequency of community or outreach visits, and the number of clients participating in outreach sessions can be adapted to the local context and in conformity with guidance from ministries of health and other national authorities. The pattern of participation in group education or lining up in queues at HIVST distribution points needs to be staggered to prevent potential exposure and transmission. Essential measures and appropriate use of PPE to protect health-care providers, distributors and peer distributors need to be put in place to protect them from exposure and transmission. PPE includes wearing of face masks, provision of water and soap, and hand sanitizer before and after delivering the kit, disinfection of the kit package before handing over to the client and strict implementation of physical distancing. Information should be provided to self-test users on how to safely dispose of used oral-fluid and blood-based HIVST kits at home. It is important to train staff adequately in these prevention measures and their proper use and provide job-aids and reminders.

Facilities and other fixed health services sites offering HIVST services need to implement standard precautions such as triage, early recognition of infection and source control, ensure adequate ventilation; maintain physical distancing among patients and providers in the waiting areas and consultation rooms; provide information and standard operating procedures (SOPs), and job-aids for correct and consistent cleaning and disinfection procedures; and ensure appropriate use of PPE by health-care workers. Further guidance is available through WHO: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance¹⁷.

Procurement and Supply Chain Management of HIVST Kits in the Context of COVID -19

Countries implementing and scaling up HIVST in the COVID-19 context will need to carefully plan procurement and how to address potential challenges to supply chain management. It is key to quantify the need for HIVST based on the context, and ensure that other essential commodities stay in stock, including HIV rapid diagnostic tests (RDTs), ART and PrEP.

It is important for programmes implementing HIVST to utilize quality-assured products designed for self-testing. WHO does not recommend the use or distribution of standard professional-use HIV RDTs for self-testing. Countries should consider procuring available WHO-prequalified HIVST kits. It is also important to consider the benefits of providing different options to individuals, particularly the choice

of using oral fluid- or blood-based test kits. Implementation studies have highlighted that user preferences do vary and offering options may encourage HIVST uptake. 18,19

As of June 2020, there were four WHO-prequalified HIVST products. Countries should review the WHO HIVST public reports to determine which products to select: http://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/.

Manufacturers of the four WHO-prequalified HIVST products have local distributors at country level in selected countries in Africa, Asia and Latin America, through whom HIVST can be locally purchased. A list of local distributors can be obtained from each of the manufacturers. Alternatively, orders for HIVST kits can be placed with the manufacturers directly or through the procurement mechanisms of major donors, such as the US President's Emergency Plan For AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). It is critical that programmes enquire about language options for instructions for use, as most manufacturers have translated their instructions into multiple languages.

During the COVID-19 pandemic, when planning for HIVST procurement, as with all commodities, it is important to place orders promptly to avoid potential disruptions to service delivery. The following resources provide additional guidance.

- Global Fund list of eligible diagnostic products: https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/²⁰
- COVID-19 response: health product supply: https://www.theglobalfund.org/en/sourcing-management/updates/2020-04-22-covid-19-response-health-product-supply-update-for-principal-recipients/21
- Update for Principal Recipients Unitaid HIVST market and technology landscape: https://unitaid.org/assets/HIVST-landscape-report.pdf²²
- WHO IVD field safety notices: http://www.who.int/diagnostics_laboratory/procurement/complaints/en/²³

Considerations for Adaptation of HIVST Service Delivery for Infection Prevention and Personal Protection in the COVID-19 Context

HIVST can be provided in community settings (e.g. through online distribution, targeted outreach and workplace settings) and facilities (e.g. drop-in clinics, pharmacies, key population clinics, public and private sector hospitals and other clinical settings, such as antenatal care, STI clinics and contraceptive/family planning clinics).

Whether operating at health facilities or at community level, active prevention of SARS-CoV-2 transmission and preparedness for a possible surge of patients with symptoms of COVID-19 needs to be considered. Both prevention and preparation will have an impact on HIVST services.

The following steps should be followed to prepare providers and facilities:

1. Communication and education of HIVST kit distributors and other community and health-care providers.

Information and national strategies to control COVID-19 transmission continue to evolve. All providers, including those distributing or providing HIVST kits, need to be trained on IPC and

recommendations for COVID-19²⁴. Screening and triage tools and guidelines for clinical management of COVID-19 need to be provided.²⁵

2. Optimize infection prevention and ensure supply of protective equipment and commodities for disinfection and infection prevention.

All providers need to be trained on optimized infection prevention and staff supervised and monitored. Infection prevention guidelines need to be made available and job-aids used to remind providers to use hand sanitizers after each client visit, to carry out frequent handwashing and appropriate use of face masks. Adequate supplies of protective equipment and commodities should be ensured. Donors might have provided guidance on how funds can be used to procure infection prevention and protective equipment. At facilities, the availability of running water, soap and disposable towels at all handwashing facilities should be ensured for providers and clients. If running water is not available, hand sanitizer must be available, and instructions provided on how to use it. Appropriate ventilation should be ensured, and windows kept open, unless privacy and confidentiality would otherwise be compromised. All clients, patients and providers entering facilities or consultation rooms should use hand sanitizer before entering the facility and consultation room. Clients with a cough and sneezing should be provided with face masks.

3. Triage of patients with respiratory illness, including COVID-19, at health facility and community outreach sites

Train providers and develop protocols on how to manage client flow to ensure optimal maintenance of physical distance, triaging and efficient service provision, and develop client flow diagrams. Arrange seating to ensure at least 1 metre distance between seats and from providers. Create zones of working and waiting spaces to separate clients with respiratory symptoms from those without any symptoms. Fast-track suspected, probable and symptomatic clients (with cough, fever). Identify a screening area for all patients in a well-ventilated area (ideally covered, outdoor areas if feasible) for screening and triaging prior to entering the facility.

Identify a dedicated space in the facility for temporary isolation of suspected COVID-19-infected clients awaiting referral to designated isolation or treatment centres. Ensure that all patients presenting at facilities aged ≥60 years are immediately fast-tracked and prioritized in the hope of limiting the effects of COVID-19. Consider staggering clinical appointments to avoid crowding and streamlining clinic flow, so that clients do not interact with multiple health-care workers (e.g. avoiding multiple points of contact between PLHIV and health-care workers). Optimize space to reduce close contact. See patients with HIV in clinics that have dedicated spaces for HIV treatment services. Provide visual alerts (signs, posters) at the entrance of the site or facility and in strategic places with instructions on hand hygiene, respiratory hygiene and cough etiquette, and triage procedures (screening for symptoms/contacts, exposure) throughout the duration of the visit. Ensure that supplies are available (tissues, waste receptacles, alcohol-based hand sanitizer) as well as face masks for staff at triage areas for patients with respiratory symptoms.

4.4 Approaches to Distribution of HIV Self-Testing Kits

Facility-Based Distribution

Distribution of HIVST kits at health-facility level can either be through direct distribution to clients and patients accessing the health-care facility for any medical reason (outpatient department [OPD]) or admitted in the hospital and who have been pre-screened and found eligible for HIV testing as an alternative to routinely offering HTS in facilities. Alternatively, secondary distribution of HIVST kits can be done to sexual partners of pregnant and postpartum women (or women accessing family planning and sexual and reproductive health services, etc.) or through HIV-positive index clients, who have been newly diagnosed or who are accessing ART services at the health facility (including HIV-positive pregnant women). Key population clinics can also be used for primary and secondary distribution of HIVST kits.

Facility-Based Direct Distribution and Drop-Off Points

In this model, facility-based counsellors and health-care workers directly promote HIVST at entry points to the health-care delivery system. This model can be beneficial in terms of cost and time saved for the health system and users, and can be a good fit for health facilities with limited HIV-testing capacity and where physical distancing should be enhanced as in the current COVID-19 situation. These entry points can include: outpatient and inpatient departments, clients accessing family planning, STI or other sexual and reproductive health services, among others. HIVST is then offered to individuals who are eligible for HTS based on their testing history and sexual risk behaviour. Individuals from priority populations can test themselves during their waiting time in a cubicle/tent at the health facility or outside of the health-care facility, which is preferred in the COVID-19 situation. Clients can also access HIVST at drop-off points outside of health-care facilities and conduct the test at home. If clients are testing at the facility, they should present their HIVST test result to the provider at the health facility. If the self-test is non-reactive, clients receive counselling and information on the HIV prevention services available and are referred and linked to HIV prevention services (e.g. PrEP). Self-testers with a reactive result receive confirmatory testing on-site and, if feasible and acceptable, are initiated on ART immediately (test and treat) (Table 4.1. and Fig. 4.1).

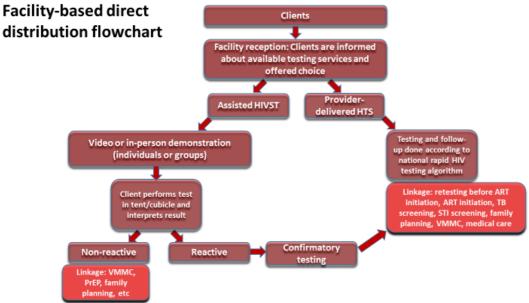
Table 4.2. Facility-based direct distribution of HIV self-test kits

Facility-based direct distribution		
Model description	 Facility-based counsellors and health-care workers directly promote HIVST at entry points to the health delivery system, for example, to outpatients, inpatients, clients accessing family planning services. Individuals from priority populations can test themselves in a cubicle/tent at the health facility. Individuals present their HIVST test result to the provider at the health facility. If the self-test is negative, the client is referred to prevention services (such as PrEP). Self-testers with a reactive result receive confirmatory testing on-site and are initiated immediately on ART (test and treat). 	
Rationale	 Maintains HTS at facilities offering physical distancing Increases testing capacity and coverage at health-facility level 	

	 Allows fast-track pre-screening, triaging out those who self-test HIV-negative unless confirmatory testing desired Providers can shift attention to those most in need, for example, those needing provider-assisted referral/index testing and confirmatory testing followed by initiation on ART Increases the demand for HTS if mobile or fixed HTS clinic services are promoted as outlets for HIVST kits
Priority populations	 Individuals (priority – men, adolescents, key populations) accessing health-care facilities and who are eligible after pre-screening for HIV testing due to their risk pattern and testing history (never tested, tested more than 12 months ago)
Mobilization strategy	Awareness creation and promotion at health facility, routine offer/opt-out approach after pre- screening
Linkage strategy	On-site confirmatory testing and linkage to on-site treatment services, VMMC and PrEP services provided on site if HIV-negative.

ART: antiretroviral therapy; HIVST: HIV self-testing; HTS: HIV testing services; PrEP: pre-exposure prophylaxis; VMMC: voluntary male medical circumcision

Fig. 4.1. Client flow following distribution of HIV self-test kits in facilities



Secondary Distribution of HIV Self-Test Kits through PLHIV (Index Testing) and Pregnant and Post-Partum Women in High HIV Burden Settings

HIVST can be used in different ways to potentially increase (i) the uptake of HIV testing among sexual partners of HIV-positive index clients, (ii) coverage of provider-assisted referral/index testing, and (iii) efficiency and convenience through screening of index cases at community level using HVST offered by community health-care workers and lay providers. The different approaches can potentially enhance client referral options for index testing (client referral and contact referral) as well as provider

referral options (provider referral and dual referral). Evidence has shown that HIVST can facilitate disclosure of status from an HIV-positive individual to their sexual partners²⁶.

In this model, HIVST kits are offered to HIV-positive clients to take to their sexual partner(s) for testing (screening) outside the facility. Index clients are shown how to perform the self-test and receive information material and user guides to give to their sexual partners to facilitate the HIVST process without the assistance of a trained provider. Referral and linkage are also facilitated to confirmatory testing, care and treatment in case of a reactive self-test, and to prevention services in case of an HIV-negative self-test. Follow up after HIVST is either conducted with the index client or directly with the sexual partner, with the client consent. Partners with a reactive result are encouraged to return to the health facility for confirmatory testing and referral/linkage into care and treatment.

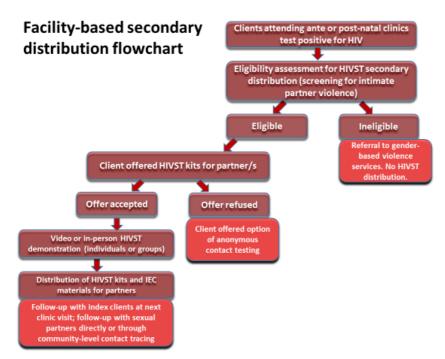
HIVST kits can also be offered to pregnant and lactating mothers at ANC/PNC and MCH services or to women attending family planning services at public and private sector health-care facilities in high HIV burden settings, irrespective of their HIV status, to reach their sexual male partners. As described above (index testing), HIVST kits are offered to female clinic attendees to give to their male partners at home. Women receive advice on how to approach their sexual partners and how to demonstrate HIVST use. Information on how to access post-test support services, either for confirmatory testing after a reactive result and consecutively treatment and care, or how and where to access HIV prevention options, is included in the additional HIVST kit package for the partners. At subsequent clinic visits, women will be asked whether the test kit had been used by their sexual partner. Follow up with the sexual partner can be arranged through telephone, if consent has been provided (Table 4.2).

Table 4.2. Facility-based secondary distribution of HIV self-testing kits

Facility-based secondary distribution	
Model description	 HIVST kit offered to HIV-positive clients to take to sexual partner(s). Follow up with index patient or partner for outcome and, if required, confirmatory testing HIVST kit is offered to pregnant/lactating women to take to male partner, irrespective of HIV status. Follow up with women or partners for outcome and, if required, confirmatory testing HIVST offered to STI patients, TB patients, family planning clients to take to sexual partner(s). Follow up with client or partner for outcome and, if required, confirmatory testing
Rationale	 Secondary distribution through clients accessing health-care facilities (often women) can reach priority populations. In high HIV burden settings, as there is increased risk of HIV infection during pregnancy and breastfeeding period due to infection acquired by the sexual male partner during this time, it is important to reach male sexual partner for testing who might not visit the health facility. Secondary distribution through index client to sexual partners can increase HTS uptake and diagnose more people with HIV who do not know their status. Requires follow-up methods with sexual partner or index client for confirmatory testing.
Priority population	 Sexual partners of HIV-positive index client diagnosed at health facility or taking ART (secondary distribution) Partners of pregnant/lactating women using public sector maternity services (secondary distribution)

	Sexual partners of those attending STI, family planning and TB services (secondary distribution)
Mobilization strategy	 Health-care providers actively promote HIVST at health facilities, with option for individuals to take test kit for partner home testing Index clients offer HIVST to sexual partners Pregnant women offer HIVST to sexual partners
Linkage strategy	Referral form included in information materials when HIVST is handed to sexual partner. Referral information provided via index client

Fig. 4.2. Client flow following secondary distribution of HIV self-testing kits



GBV: gender-based violence; HIVST: HIV self-testing; IEC: information, education and communication; IPV: intimate partner violence

Pharmacies and Private Sector Distribution of HIV Self-Test Kits

Private and community pharmacies are often the main sources of drugs and medicines in many LMICs due to frequent shortage of drugs in public health facilities. Community pharmacies in urban and rural areas are readily available and accessible by the majority of the general public and are where most people obtain their medicines, information about medication and counselling on medical care. During the COVID-19 lockdown, pharmacies represent a part of grocery shops, with limited opening hours offering the only opportunity to buy essential items, personal protection, condoms and other family planning products, and are therefore an excellent distribution point for HIVST kits. Community pharmacies are already involved in HIV-related dispensing of rapid test kits and antiretrovirals (ARVs), which would make introduction of HIVST kits much more expedient. A dispenser at the community pharmacy can promote HIVST kits to pharmacy clients who are also purchasing condoms, family

planning products, including emergency contraceptives, or filling prescriptions for STI treatment. The dispenser should provide guidance and information to clients purchasing HIVST kits and show videos demonstrating HIVST. The information provided would also include a referral card for the different referral options available, depending on the outcome of the HIVST. Clients with a reactive HIVST result will be referred to treatment and care centres, while clients with non-reactive HIVST results will receive referral information for PrEP and encouraged to use condoms.

Special time-limited campaigns for free HIVST kits could run during the COVID-19 lockdown targeting high-risk individuals. Promotion of HIVST kits should also include information on COVID-19 prevention and the potential risk of COVID-19 in PLHIV not on ART.

Table 4.3. Private sector and pharmacy-based distribution of HIV self-test kits

Private sector and	pharmacy-based distribution of HIV self-test kits
Model description	 HIVST kits are offered to clients accessing pharmacies to buy drugs or condoms, lubricants, etc. Pharmacists prompt and promote HIVST (especially in combination with family planning products, emergency contraception, condoms, STI treatment) and offer test kits to the client (test kits can be provided for free, or at a nominal subsidized price). Pharmacists are trained in HIVST use and can conduct a demonstration and provide referral information. HIVST kits are offered at retail outlets in hotspots and areas where priority populations can be reached. Shop owners promote the use of HIVST kits, demonstrate their use and provide additional user information together with the HIVST kits.
Rationale	 Pharmacies are good entry points during lockdown due to COVID-19. They attract many clients and can offer HIVST to clients who present for sexual and reproductive health products. It increases testing coverage among populations that would otherwise not seek testing services. Could potentially rapidly increase testing coverage. Provides a good opportunity to reach high-risk populations and those who would otherwise not test.
Priority population	 High-risk adults, men High-risk adolescent girls and young women, and women attending family planning or accessing emergency contraceptive services in southern Africa Key populations who access pharmacies, retail outlets in hotspots
Mobilization strategy	 Free HIVST campaign during CVID-19 lockdown at pharmacies to promote open-access model Pharmacists and shop owners promote HIVST General advertisement and community mobilization near pharmacies HIVST campaigns
Linkage strategy	 Referral form included in information materials given when HIVST kit is offered Call-in line to provide information on referral sites for confirmatory testing and treatment and prevention services such as PrEP Potential for direct follow up via telephone, WhatsApp and SMS

Case Study 1: Distribution of HIV Self-Testing through Pharmacy Networks in South Africa in the COVID-19 Context

In South Africa, HIVST is being provided in partnership with the Independent Community Pharmacy Network (ICPA). **ICPA** spans all nine provinces and has over 1100 member pharmacies. This extensive network allows HIVST to be readily available in the far reaches of the country. In 2019, STAR partners piloted the feasibility of provision of HIVST through a group of ICPA pharmacies in the city of Tshwane, in Gauteng.



In total, the capacity of 11 pharmacies was built to provide HIVST to the community through targeted demand creation activities. The community was able to redeem a test using a voucher provided during secondary distribution in the community programme, or by simply requesting a test kit directly from the pharmacist. STAR partners trained the pharmacists on correct usage of the test kit for demonstration purposes, as well as how to handle frequently asked questions. An online data capture platform was used to ensure real-time collation of data through this channel Clients in the pharmacy were offered support through WhatsApp for linkage and for self-reporting their results. Linkage officers were then able to actively follow up those reporting positive results or seeking assistance.

During the COVID-19 pandemic, this model was able to quickly make HIVST kits available to more members of the ICPA Network. This was to counteract the shutdown or slowdown of HIVST in communities. In total, 40 pharmacies across South Africa have been capacitated to distribute HIVST kits to clients and thereby ensure continued access.

Case Study 2: Pharmacy Distribution through Pick-Up Points of the Central Chronic Medication Dispensing and Distribution (CCMDD) Unit

STAR, in collaboration with the National Department of Health (NDoH) and the CCMDD unit, distributes HIVST kits to beneficiaries who visit retail pharmacies of Clicks and Dischem to receive their medications. This initiative was branded in line with the "Cheka Impilo!" national wellness campaign. HIVST kits are provided free of charge to beneficiaries. Distribution at pharmacies is at the discretion of the pharmacist, therefore pharmacy selection criteria used were based on district-level data focused on key indicators:

- PLHIV, total remaining on ART (TROA), HIV testing and treatment gap, and HIV incidence;
- ranked districts as high, moderate and low priority in terms of HIV testing and treatment gap;
- mapped all pharmacies in the areas selected;
- narrowed down to the busiest pharmacies frequently accessed by targeted population (adolescent girls and young women [AGYW], men, men who have sex with men [MSM] and transgender persons [TG]).

To create basic awareness of the availability of the HIVST kit in store to other pharmacy customers, we proposed minimal communication through specific touch points. These included *floor stickers* leading to the pay point, *posters* and *decals*.

Support package and tools that accompany the HIVST kits are issued to all clients. The tools support correct HIVST usage and facilitate linkage to care in the context of the COVID-19 pandemic. They include:

- standard, manufacturer-provided instructions for use;
- HIVST user guide and frequently asked questions guide;
- information brochure on prevention of COVID-19;
- instructions for call-in line and WhatsApp for Business, HIVST App;
- information on linkage to online counsellor for those clients requiring additional psychosocial support.



Case Study 3: Extending Safe HIV Testing Services to Pharmacies During the COVID-19 Pandemic in the Democratic Republic of the Congo

Following the two-day lockdown orders in Lubumbashi in the Democratic Republic of the Congo (DRC) at the start of the COVID-19 outbreak, attendance at health facilities dropped due to fears of contracting the virus at health-care settings, slowing down provision of HTS. To maintain provision of and reach at-risk individuals with safe HTS outside of health facilities, PATH introduced delivery of assisted HIVST services at eight pharmacies and two alternative medicine centres (AMCs) through the Integrated HIV/AIDS Project in Haut-Katanga (IHAP-HK) funded by United States Agency for International Development (USAID).



Client wearing a face mask waiting outside MukaPharma – a pharmacy offering assisted HIVST services – in Lubumbashi, DRC. PATH/Raphael

- Pharmacists or alternative healers at selected outlets provide information on HIVST to individuals
 who come to pharmacies/AMCs seeking medication for treating STIs, fever and/or dermatosis.
 Those interested in self-testing are provided with an informal HIV risk assessment, and those who
 screen positive are offered on-site assisted HIVST. For individuals with reactive self-test results, the
 pharmacist/alternative healer contacts a community health volunteer to schedule a same-day or
 next-day escorted referral to a nearby project-supported health facility, where the client is fasttracked for confirmatory testing services and treatment initiation.
- During the first three weeks of this pilot, 55% of eligible individuals who were offered assisted HIVST accepted, among whom 33% received reactive HIVST results. Of these, 70% were successfully referred for confirmatory testing, all of whom were confirmed HIV-positive and initiated on treatment (23% yield).

Online Distribution of HIV Self-Test Kits

Virtual online ordering of HIVST kits with home delivery or drop-off at conveniently accessible distribution points has been successful in reaching key populations, especially MSM, in selected countries. (i) The client clicks on an HIVST advertisement and completes an online risk assessment;

(ii) next, through a quick and easy process, individuals can order the HIVST kit of their choice (blood-based or oral fluid-based test).

They enter their demographic information, choice of HIVST kit and select/fill out an online HIVST delivery order (mail, grab, self-pick up); (iii) HIVST kits are delivered to clients within two days of placing the order through a peer, a courier service or post, depending on the distance of the client from the mailing point; and (iv) the client confirms receipt of the HIVST kit through the website, and then performs the HIV self-test using the instructions for use and, if needed, sees the video on the website, which guides each step of the process. Clients are invited to provide feedback via the website, a telephone call with the distributor or via SMS/WhatsApp. Follow-up reminders are sent to clients if they do not respond.

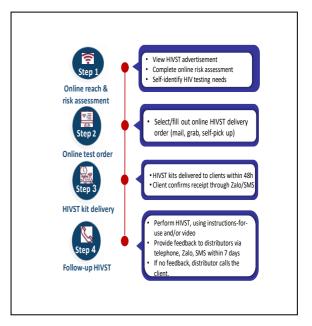


Table 4.4. Virtual and online distribution of HIV self-testing kits

Virtual and online distribution	
Model description	 Client clicks on an HIVST advertisement and completes an online risk assessment. Next, through a quick and easy process, individuals can order the HIVST kit of their choice (blood-based or oral fluid-based). They then enter their demographic information, choice of HIVST kit and select/fill out an online HIVST kit delivery order (mail, grab, self-pick up). HIVST kits are delivered to clients within two days of placing the order through a peer, a courier service or post, depending on the distance of the client from the mailing point. The client confirms receipt of the HIVST kit through the website, and then performs HIVST using the instructions for use and, if needed, sees the video on the website, which guides each step of the process. Clients are invited to provide feedback via the website, a telephone call with the distributor or via SMS/WhatsApp. Follow-up reminders are sent to clients if they do not respond. HIVST can be co-packed with STI self-sampling or family planning commodities, depending on the need of clients in a given location.
Rationale	 Provides a safe and fast means of ordering an HIV self-test kit Increases testing in populations that may not otherwise seek HIV testing services. Could potentially rapidly increase testing coverage
Priority population	 Key populations that seek health information online Other high-risk populations that are online and prefer to seek an HIVST through home delivery or drop-off at another location.
Mobilization strategy	 Online campaign to promote availability of free HIVST kits during the COVID-19 lockdown at pharmacies to promote the open-access model Advertisements posted on Facebook, Grindr and other platforms
Linkage strategy	 Referral form included in information materials given when HIVST kit is offered Direct follow up via telephone, WhatsApp, Zalo or FaceTime Real-time video-assisted HIVST and follow-up support to link to confirmatory testing and ART or PrEP.

Case Study 4: Online Ordering and Distribution of HIVST Kits in South Africa

The STAR project in South Africa responded to the national lockdown by offering online ordering of HIVST kits. The project targeted MSM, TG, young women (18–25 years) and older men (30–49 years). Social media platforms such as Grindr, Tinder, Facebook, Instagram, Bumble, Google ads and GaySA Radio were used for targeting. The communications messaging focused on this unique audience owning their individuality in taking charge of their health during the COVID-19 pandemic, by firstly finding out their HIV status. The call to action was *"#OrderNow #StayHome"*



Demand generation for the project was achieved by using digital marketing techniques that included search engine optimization (SEO) for specific keywords related to



the online behaviours of key populations, associating them with sexual risk activities. Google Banner advertising was also targeted through dating applications such as Grindr and Tinder, online radio station and their social pages GaySA radio and Facebook.

Clients were directed from the relevant social media platform to the https://www.hivselfscreening.co.za/ webpage to place an order for their HIVST (OraQuick/Insti) kit to be delivered to their private homes or an alternative convenient private point of delivery. Interested clients had to register on the online platform, provide their individual demographic data, consent for follow up and physical address to which the test kit was to be delivered within three working days.



The package included the relevant IEC materials with frequently asked questions (FAQs), condoms, lubricant and additional contact information. If the client consented to follow up, a WhatsApp message with the appropriate guidance on "how to use video" was sent to their phone. Some clients returned to the HIVST Facebook page to confirm that they had successfully received the kit or requested additional support.

Case Study 5: Virtual Ordering Platforms for HIV Self-Test Kits in Viet Nam During COVID-19

During the COVID-19 outbreak period, the USAID/PATH Healthy Markets project in Viet Nam ramped up client-directed online HIVST to maintain provision of HTS for MSM, TG women, and people who inject drugs (PWID). The project launched promotional campaigns with integrated HIVST and COVID-19 messaging (#Stayhome #Self-test) on a variety of virtual media, ranging from the project's *Rainbow Village* and *Be Me. Be Sexy* Facebook pages for MSM and TG women, respectively; dating apps, such as Grindr, Blued, and Hornet; and WhatsApp discussion boards.



The online HIVST kit ordering process begins with an interested client linked from the HIVST

advertisement to an online risk assessment tool that helps them self-identify HIV testing needs. Based on the results of the risk assessment, the client can place an online order for an HIVST kit, with multiple options provided for delivery – either by mail, courier service, or pick-up at a key population-led clinic or community-based organization – and type of self-test, OraQuick HIV Self-Test or INSTI HIV Self-Test (both WHO prequalified HIVST products).

Once the HIVST order is placed, the distributor prepares the HIVST package (comprising instructions-for-use materials, HIVST videos and resources, and contact information of the clinic or community-based organization) for client pick-up or home delivery through courier or mail. Clients receive HIVST packages within a maximum of two days, with kits generally received by clients within a few hours (for courier deliveries) or in one day (for mail deliveries). Clients confirm receipt of the kit through SMS or Zalo. Clients are directed to share their self-test result within seven days; if there is no response from the client, the distributor will follow up to confirm the self-test result and ensure linkage to follow-on testing and treatment or prevention services.

Social Network-Based Testing

HIVST has been shown to be highly acceptable and often preferable to provider- or clinic-based testing among key populations and is more likely to result in partner testing. Furthermore, HIVST was found to double the testing frequency among MSM and is now recommended as an effective strategy. Network-based strategies have demonstrated that peers are better than traditional medical clinics in locating members of marginalized, underserved or hidden populations. Peers have access to broader networks of key populations who may be untested or who rarely test, and can access these networks outside clinic hours and in venues often not accessible to traditional outreach workers. Peer-driven approaches have been demonstrated to be highly effective in identifying persons with undiagnosed HIV infection in high-risk networks. Network-based strategies can overcome some of the structural barriers encountered by vulnerable populations and may be an efficient vehicle for the distribution of HIVST. Peer-driven approaches through social network distribution can be increased in the context of COVID-19 if precautions of physical distancing and protective measures are taken to prevent any transmission.

Table 4.5. Integrated HIV self-testing services for key populations

HIVST integrated with	h HTS services for key populations (e.g. female sex workers, MSM, PWID)
Model description	 HIVST offered as alternative to HTS to clients accessing sex worker clinics or health services for men who have sex with men (MSM) HIVST distribution through social networks of female sex workers and their sexual partners (and clients), MSM or people who inject drugs (PWID)
Rationale	 Test-for-triage approach. The HTS clinic can shift attention to other tasks. Increases the numbers tested and offers more targeted provider-initiated testing to maximize HIV-positive diagnoses, ART initiation and uptake of prevention services Increases uptake and frequency of testing among key populations, especially among hidden key populations with limited access to conventional testing and health services
Priority population	Female sex workers and MSM, PWID
Mobilization strategy	 Health-care providers actively promote HIVST at health facilities and drop-in centres for key populations Peers of key populations promote HIVST among their peers and social networks.
Linkage strategy	 Self-testers with reactive results receive confirmatory testing on-site, followed by initiation on ART (test and treat) Referral form included in information materials given with HIVST kit Referral facilitation through peer after direct follow up with self-tester

Case Study 6: Leveraging HIVST to Continue Index Testing During the COVID-19 Pandemic in Ukraine

PATH, through the PEPFAR/USAID-funded Serving Life project in Ukraine, is leveraging the use of oral HIVST to continue partner notification services for sexual or injecting partners of HIV-positive PWID residing in communities.

Clients are reached by case finders who are former or current PWID, or are ex-prisoners or recently released, who conduct outreach to their social networks. The index client opts for HIVST as part of the index testing and partner notification counselling process, following a risk screening for intimate partner violence. Those opting for self-testing services are then offered the option for the self-test kit to be delivered to their home or dropped off at a public location by a social worker from a nongovernmental



organization (NGO). Clients either contact social workers with their HIVST result, or social workers follow up with clients if they do not hear back within the agreed-upon period. In some cases, an NGO social worker provides an HIVST kit to an index partner in a private setting and offers guidance on how to use the test and interpret the result. For partners with reactive self-test results, an NGO social worker provides an accompanied referral to an AIDS centre for confirmatory diagnosis and treatment initiation.

Wider community-based distribution of HIVST kits through door-to-door distribution or distribution at hotspots in densely populated areas, such as taxi stands and workplaces, might not be feasible as

governments have limited the size of gatherings due to the risk of exposure to distributors to COVID-19 transmission.

Since the pandemic, the government has engaged community health-care workers to support COVID-19 response activities, such as reaching out to communities to inform them about COVID-19 and the risk of transmission, ensuring that communities have adequate resources and commodities to reduce transmission and conduct COVID-19 contact tracing. Adequately equipped with PPE and sensitized and trained on HIVST, these community health-care workers can also carry HIVST kits and distribute them to populations in need. STAR partners in South Africa have been engaged in the COVID-19 response in populations and provide both COVID-19 prevention services and HIVST kit distribution.

Case Study 7: Using HIVST to Strengthen HTS Uptake During Covid19: A Case Study from Zambia DOD-Funded Project, Cross Cutting in Military Settings

The JHPIEGO Project *Cross Cutting in Military Settings*, with funding from PEPFAR/US Department of Defense HIV/AIDS Prevention Program, and based on guidance from Ministry of Health (MoH) and PEPFAR, quickly developed strategies to continue reaching communities at high risk for HIV with HTS and link them to ART. HIVST was used as a modality to make sure that HTS continued through the use of community lay workers (CLWs).

HIVST kits are distributed through trained CLWs at community level, who are given basic PPE from facilities in order to prevent SARS-CoV-2 transmission. The CLWs observe preventive measures by wearing face masks, frequently washing their hands and using hand sanitizer, and observe physical distancing when in the community. Index clients give details about their recent sexual contacts, who are then traced by phone call, SMS or physical contact, and offered HIVST kits by the CLW during community visits. Alternatively, HIVST kits are offered to index clients to give to their sexual partners; it may facilitate disclosure of status to the partner and client referral; this approach is particularly popular with female sex workers (FSWs).

The CLWs are supported by the project's Provincial and National Technical Advisors, who check in with them daily or weekly by WhatsApp message or video call, to ensure that HIVST kits are distributed to the contacts of HIV-positive index clients, FSWs, workforce, and other contacts of PLHIV. The CLWs also use the HIV risk screening tool to identify other risk factors of the sexual partners and contacts, such as low or no condom use, which helps ensure that client-tailored services reach populations most at risk.

Many index clients and contacts reach out to the CLW who gave them the HIVST kit within two days to report their HIVST results, but for those who delay, CLWs follow up with them directly within 3–7 days, with the consent of the index client. CLWs collect the HIVST results, and facilitate linkage to the health facilities for confirmation (using the national HIV testing algorithm) and initiation on ART for those who test positive, and to prevention services, including VMMC for men, and pre-exposure prophylaxis (PrEP) where available for those who test negative. CLWs work closely with the health facility laboratory and clinical staff when linking a client to the facility, so that clients are supported to access services and data are recorded accurately. Some clients are physically escorted to the health facility, while others are linked with facility clinical staff by phone. Once the client has been initiated on ART, the clinician sends the ART number to the CLW as a sign of confirmation, and the CLW also contacts the client to verify that he/she has started ART and offer support.

Case Study 8: Integrating HIVST into SARS-CoV-2 Testing and COVID-19 Contact Tracing in South Africa

Two weeks after the COVID-19 lockdown started, the National Department of Health (NDoH) requested all partners (NGOs, faith-based organizations [FBOs], private sector) to assist with COVID-19 contact tracing and screening in communities. The National Institute of Communicable Diseases conducted training for trainers across the country. Each organization was responsible for training their

own teams in preparation for activities. As new organizations join the COVID-19 response team, they are paired with partners who have been in the field for a while to ensure that practical expertise is effectively transferred. Each district develops context-specific plans.

Heat maps are generated depending on where the cases and contacts solicited reside. Based on cases, districts decide to either embark on *mass* screening and testing or symptomatic screening.



Mass screening and testing is a combination of door-to-door screening (using a screening tool), mobilization through loud hailers to inform about the screening point, information provided by local newspapers and radio stations about the upcoming screening, notices to the community by the ward councillor and at select screening points. All teams are escorted by the South African Police Services for set-up and support.

Symptomatic screening consists of door-to-door screening (using a screening tool); however, only individuals who screen positive are escorted for testing. Testing is conducted in the mobile van parked near the teams who conduct screening.

HIVST distributors who conduct contact tracing and screening first assess whether clients *know their HIV status and use this as an entry point* for screening. Emphasis is on the importance of testing and early initiation of ART. Post distribution of HIVST kits, where applicable, HIVST distributors continue with COVID-19 screening and refer accordingly. In areas where teams do not have any trained HIVST provider, details are shared with distributors and HIVST kits delivered to clients.



Case Study 9: Maintaining Access to HIV Testing Services in Kenya During the COVID-19 Pandemic through Community-Based Distribution of HIVST

In western Kenya, the PATH-led PEPFAR/USAID-funded Afya Ziwani project is maximizing the use of oral-fluid-based HIVST at home to mitigate the impact of COVID-19 on HTS for both partners and contacts of PLHIV as part of index testing as well as adolescent girls and young women (AGYW) enrolled in the project's DREAMS programme, which provides a layered package of interventions to reduce HIV risk and increase the agency of AGYW.



During the COVID-19 outbreak, AGYW who request HIV testing services are first

provided with an HIV risk assessment and then offered options for accessing testing services, including the option to self-test at home. DREAMS mentors or ambassadors distribute HIVST kits to AGYW who opt for home-based HIVST, either providing assisted self-testing services for adolescent girls under 18 years of age or delivering self-test kits for young women who opt for unassisted HIVST or request one for their partners. Under the index testing entry point, the project has been increasing the use of remote means (phone calls or video) to provide assisted partner notification services, with home-based HIVST now being promoted as part of this process as a safer testing option during the COVID-19 pandemic.

For both AGYW or partners or contacts of index clients who opt for unassisted HIVST, community health volunteers or DREAMS mentors follow up with individuals to confirm self-test results after a mutually agreed-upon period. Those who have a reactive self-test result are provided with an accompanied referral by a community health volunteer or DREAMS mentor to a health facility for confirmatory diagnosis and linkage to treatment or prevention services.

Case Study 10: HTS Continuity in the Context of COVID-19 Lockdown and Physical Distancing in Eswatini

The Prime Minister of Eswatini announced a national lockdown at the end of March 2020 following the initial identification of residents who tested positive for SARS-CoV-2. Industries and businesses that were deemed to be non-essential were instructed to stop operating, and residents were told to leave their homes only to access health care, medicines and food. Subsequently, the Ministry of Health announced a halt of community HTS, including index contact tracing and rapid diagnostic testing outside of facilities. The focus shifted to providing HIVST kits near to those businesses that continued operating, including pharmacies and food stores.

Population Services International (PSI) reassigned duties to its employees to distribute HIVST kits in front of food stores, pharmacies and in their own home communities. This would enable the organization to have access to clients in public, and to even more eligible clients through secondary distribution of HIVST kits.



up, during which they are provided with further support and linked to HIV prevention or treatment services. Additionally, free condoms are also available on offer at distribution stations. These efforts ensure that HTS continue to be provided to the public. Client feedback is positive and preliminary programme data suggest that these efforts are also reaching populations that are not usually reached through standard community HTS provision.

This service is provided in the context of social distancing and regular sanitizing of the workspace as well as employees and clients.

Eligibility screening and risk assessment are conducted for each client, as well as screening for sexual partners or family members who are eligible for receiving an HIV self-test.

As there are no self-tests conducted onsite, contact details are collected from consenting clients for telephone follow



Case Study 11: Adapting HIVST Distribution and Support to Users in the Context of the COVID-19 Pandemic in Senegal: Ambulatory Treatment

Since 2018, the ATLAS project is supporting the introduction and large-scale deployment of HIVST in Côte d'Ivoire, Mali and Senegal. In close collaboration with ministries of health and implementing partners, specific distribution channels have been designed to reach the project's target populations (key populations, partners of PLHIV, patients with STI and their partners) in a context of low prevalence in the general population but high prevalence in key populations and significant gaps in achievement of the first 90 target- diagnosing 90% of PLHIV by 2020.

In Senegal, HIVST targeting partners of PLHIV and those of patients with STI is provided through partnerships with 20 public health centres. In Dakar, the Ambulatory Treatment Center (ACT) plays a crucial role in following more than 1400 PLHIV and hosting the free HIV national hotline to provide counselling and support to HIVST users.

From mid-March, the COVID-19 crisis and related transport restrictions decided by the authorities impacted the overall capacity and willingness of PLHIV to attend their medical

follow up and receive their treatment at the hospital. To ensure treatment continuity to patients and therefore mitigate the risk of resistance and increase in viral load, ACT adapted its strategy by implementing three months' ART distribution at community level through home visits in particular, thanks to the support of the ATLAS project through the provision of protective equipment.

As HIVST kits were already accessible in the assisted partner notification process at facility level, it was decided to integrate distribution of HIVST kits during community ART distribution to maintain access to HIV index testing, provide support for sharing the status and minimize contact with health providers, and therefore reduce the risk of SARS-CoV-2 transmission.

To support HIVST users in accurately using the test kit, interpreting the result and referring them to prevention and care services, the Senegal national hotline number hosted by ACT has been included by ATLAS in each and every HIVST kit distributed.

4.5 Linkages Post-HIV Self-Testing in the COVID-19 Context

Protocols must be in place prior to distribution of HIVST kits to ensure that individuals are referred and linked to counselling, treatment and/or prevention services, as appropriate, following a self-test.

Users who receive a reactive result must be immediately referred and linked to confirmatory testing using conventional, professionally administered approaches according to national standards. If follow-up testing confirms the HIV-positive status, appropriate counselling and treatment options should be provided, including ART and other care options. As with all HIV testing, users who receive a non-reactive result should be encouraged to retest at least every year, depending on their individual risk exposure.

Prevention options should also be recommended. These include condom use, uptake of PrEP and other sexual and reproductive health services. Care must be taken to develop clear messages for each contingency tailored to each priority population. Following up of self-test users who chose to test off-site and for users who received the HIVST kit through their sexual partner or peers can be more challenging, and innovative approaches might be required, such as direct voluntary telephonic follow up or follow up via SMS, WhatsApp or through community outreach. Nevertheless, without active follow up and linkage facilitation, it would be very difficult to measure the impact of HIVST programmes according to the HIVST impact framework. It is also important to link follow-up data to individual HIVST kit distribution.

There are many possible ways to improve linkages to prevention, treatment and care following HIVST. See the WHO guidelines and strategic framework for additional information: https://www.who.int/hiv/pub/self-testing/strategic-framework/en/12

Both facility-based and community linkage models and follow up will continue to be critical for following up HIVST, even during the COVID-19 pandemic. In facilities, on-site health workers or peers can help triage and direct those with reactive tests to further testing and care services. In

community settings, support for post-HIVST linkage, access to confirmatory testing and ART initiation can be integrated into existing differentiated models of care, such as through ART pick-up points.

Where feasible, strategies that utilize digital and remote support may be preferable as they can efficiently direct clients to services outside of facilities and without face-to-face contact. Follow up using hotlines and telephone calls, text messages or social media counselling messages and reminders (e.g. through WhatsApp and WhatsApp for business) and other digital platforms can be utilized to facilitate linkage, such as Internet-based tools, apps, videos and telemedicine. Such tools can be used to deliver pre-test information and counselling messages, including where and how to access further testing to confirm a reactive result and access ART or available HIV prevention services such as PrEP. These tools may also be used to help individuals communicate with local health systems and schedule appointments for follow-up services either in a facility or community setting.

Case Study 12: Digital Platforms to Support Linkage after Unassisted HIV Self-Testing

Several digital platforms have been developed through the STAR program in South Africa to assist HIVST clients to perform the test and to facilitate linkage into care and treatment after obtaining a

reactive result. These digital follow-up and linkage platforms have been further developed and adapted in the context of COVID-19. In the pharmacy models described in case study 1 and 2 above, HIVST clients receive information on accessing a data free app that assists them to go through the whole process from receipt of the test kit, performing the test, interpretation of results, reporting back and receiving information on linkage to health care facilities for confirmative testing and treatment and care. The WhatsApp



chat bot allows for result reporting, testing support and troubleshooting. In addition, a toll-free call-in number to report results and seek additional assistance is provided. Follow up is voluntary and only consenting participants are followed up by telephone. Clients reporting reactive results through the mHealth channel and the helpline are receiving information through a linkage officer. Confirmative testing is recommended at the pharmacy at which the HIV Self-Test was received. In case of a confirmed positive result, clients are linked to health care facilities or outreach services, where care and treatment services can be accessed through prior appointment to avoid long waiting times and potential exposure to COVID-19.

4.6 Monitoring and Evaluation of HIV Self-Testing and Tools

Monitoring and evaluation (M&E) are critical aspects of any public health intervention, including HIVST. The M&E framework has a core function as part of the implementation process to ensure that the programme is proceeding as planned; it provides routine information for decision-making at all levels; and helps to highlight areas where there are challenges or unexpected delays so that these can be identified and resolved quickly.

Regular reports of programme performance are required by donors and government representatives and other stakeholders according to a pre-determined schedule to keep all relevant partners informed about progress and any necessary changes to the initial roll-out plan and in the HIVST models chosen to reach priority populations. However, for the system to function effectively, it is crucial that the right indicators are chosen for monitoring to ensure that data reflect the actual status of operations, that there are mechanisms for collecting reliable figures on a routine basis, and that review and checking processes are in place to ensure consistent data quality.

In the context of the COVID-19 pandemic, it might be necessary to adapt data collection processes to limit the time of direct interaction between the provider and the beneficiary. At open-access distribution points such as pharmacies and drop-off points in hospitals or at community level, beneficiaries can be asked to fill data collection tools for their demographic information and previous testing history as they receive the HIVST kits. Data can then be entered electronically for each test kit distributed by the providers and M&E officers.

HIV Self-Testing Indicators and Data Collection

There are a number of established indicators recognized by WHO and PEPFAR to track the success of HIVST in particular, along with linkage to prevention and treatment. Many of these metrics can be obtained using routine clinic data. For more information on M&E for HIVST, see the WHO HIVST strategic framework: https://www.who.int/hiv/pub/self-testing/strategic-framework/en/.

To adapt to the COVID-19 context, efforts to collect data will need to adhere to physical distancing guidance. For example, surveys that would typically be implemented door-to-door or through inperson outreach can be adapted and implemented using telephone surveys or through other apps or short messages.

Resources

HIV and COVID-19 information

- WHO COVID-19 website: https://www.who.int/emergencies/diseases/novel-coronavirus-2019.
- WHO Q&A on HIIV, antiretroviral therapy and COVID-19: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q-a-on-covid-19-hiv-and-antiretrovirals
- Operational guidance for maintaining essential health services in response to COVID-19: https://www.who.int/publications-detail/covid-19-operational-guidance-for-maintaining-essential-health-services-during-an-outbreak
- Advice on the use of point-of-care immunodiagnostic tests for COVID-19: https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19
- Technical guidance hub: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications
- Strategic considerations for mitigating the impact of COVID-19 on key population-focused HIV programmes:

https://www.unaids.org/en/resources/presscentre/featurestories/2020/june/20200604 covi d19-key-population-focused-hiv-programs

- Maintaining and prioritizing HIV prevention services in the time of COVID-19: https://www.unaids.org/en/resources/documents/2020/maintaining-prioritizing-hiv-prevention-services-covid19
- Prioritizing the continuity of services for adolescents living with HIV during the COVID-19 pandemic: http://childrenandaids.org/node/1342

WHO HTS and HIVST guidance

- WHO recommends HIV self-testing evidence update and considerations for success: https://www.who.int/publications/i/item/who-recommends-hiv-self-testing-evidence-update
- HIV self-testing strategic framework: https://apps.who.int/iris/bitstream/handle/10665/275521/9789241514859-eng.pdf?ua=1
- Consolidated guidelines on HIV testing services for a changing epidemic: https://www.who.int/publications/i/item/consolidated-guidelines-on-hiv-testing-services-for-a-changing-epidemic

WHO HTS info: https://www.who.int/hiv/mediacentre/news/hts-info-app/en/#:~:text=WHO%20HTS%20Info%3A%20new%20app,you're%20online%20or%20offline

References

¹ WHO Coronavirus Disease (COVID-19) dashboard: https://covid19.who.int/?gclid=EAlalQobChMIlpC96u-T6gIVBWHmCh3yFAFvEAAYASAAEgLwZ D BwE, accessed, last updated: 2020/6/21, 12:54pm CEST

² Vizcarra P, Pérez-Elías M-J, Quereda C, et al. Description of COVID-19 in HIV-infected individuals: a single-centre, prospective cohort. *Lancet HIV* 28 May 2020: ePub DOI:https://doi.org/10.1016/S2352-3018(20)30164-8

³ World Health Organization. Guidelines for Managing Advanced HIV Disease and Rapid Initiation of Antiretroviral Therapy. Geneva: WHO, July 2017. https://www.who.int/hiv/pub/guidelines/advanced-HIV-disease/en/, accessed 19 June 2020.

⁴ World Health Organization (Western Pacific Region). Information note on HIV and COVID-19. Manilla: WHO Regional Office for the Western Pacific, March 2020. https://apps.who.int/iris/handle/10665/331919, accessed 19 June 2020.

⁵ World Health Organization. Maintaining essential health services: operational guidance for the COVID-19 context. Geneva: WHO, 1 June 2020. https://www.who.int/publications/i/item/covid-19-operational-guidance-for-maintaining-essential-health-services-during-an-outbreak, accessed 19 June 2020.

⁶ World Health Organization. Policy Brief: Who Recommends HIV Self Testing – Evidence Update and Considerations for Success. Geneva: WHO, November 2019. https://www.who.int/publications/i/item/who-recommends-hiv-self-testing-evidence-update, accessed 19 June 2020.

⁷ Figueroa C, Johnson C, Ford N, et al. Reliability of HIV rapid diagnostic tests for self-testing compared with testing by health-care workers: a systematic review and meta-analysis. Lancet HIV 2018; 5: e277–90.

- ⁸Choko AT, Corbett EL, Stallard N, et al. HIV self-testing alone or with additional interventions, including financial incentives, and linkage to care or prevention among male partners of antenatal care clinic attendees in Malawi: An adaptive multi-arm, multi-stage cluster randomised trial. PLoS Med 2019; 16(1): e1002719. https://doi.org/10.1371/journal.pmed.1002719.
- ⁹ The STAR Initiative, Unitaid, World Health Organization. Knowing your status—then and now realizing the potential of HIV self-testing. Geneva: Unitaid, 1 December 2018. https://www.psi.org/publication/knowing-your-status-then-and-now-realizing-the-potential-of-hiv-self-testing/, accessed 19 June 2020.
- ¹⁰ United Nations Joint Programme on HIV/AIDS. Understanding Fast-Track: Accelerating action to end the AIDS epidemic by 2030. Geneva: UNAIDS, June 2015. https://www.unaids.org/sites/default/files/media_asset/201506_JC2743_Understanding_FastTrack_en.pdf, accessed 19 June 2020.
- ¹¹ World Health Organization. Policy Brief: Consolidated Guidelines on HIV Testing Services for a Changing Epidemic. Geneva: WHO, November 2019. https://www.who.int/publications-detail/consolidated-guidelines-on-hiv-testing-services-for-a-changing-epidemic, accessed 19 June 2020.
- ¹² World Health Organization. HIV Self-Testing Strategic Framework: A Guide for Planning, Introducing and Scaling Up. Geneva: WHO, October 2018. https://www.who.int/hiv/pub/self-testing/strategic-framework/en/, accessed 19 June 2020.
- ¹³ Musheke M, Ntalasha H, Gari S, McKenzie O, Bond V, Martin-Hilber A, et al. A systematic review of qualitative findings on factors enabling and deterring uptake of HIV testing in sub-Saharan Africa. BMC Public Health. 2013;13(1):220.
- ¹⁴ Strauss M, Rhodes B, George G. A qualitative analysis of the barriers and facilitators of HIV counselling and testing perceived by adolescents in South Africa. BMC Health Serv Res. 2015;15:250.
- ¹⁵ Sam-Agudu NA, Folayan MO, Ezeanolue EE. Seeking wider access to HIV testing for adolescents in sub-Saharan Africa. Pediatr Res. 2016;79(6):838–45.
- ¹⁶ Chikwari CD, Dringus S, Ferrand RA. Barriers to, and emerging strategies for, HIV testing among adolescents in sub-Saharan Africa. Curr Opin HIV/AIDS. 2018;13(3):257–64.
- ¹⁷ World Health Organization. Country & Technical Guidance Coronavirus disease (COVID-19). https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance, accessed 19 June 2020.
- ¹⁸ Kumwenda M, Indravudh P, Johnson C, et al. Uptake and performance of blood-based self-testing versus oral fluid-based self-testing in Blantyre district, Malawi. 10th International AIDS Society Conference on HIV Science; Mexico City, Mexico; 21-24 July 2019.
- ¹⁹ Lippman SA, Gilmore HJ, Lane T, et al. Ability to use oral fluid and fingerstick HIV self testing (HIVST) among South African MSM. PLoS ONE 2018; 13(11): e0206849. https://doi.org/10.1371/journal.pone.0206849
- ²⁰ The Global Fund to Fight AIDS, Tuberculosis and Malaria. Sourcing and Management of Health Products: Diagnostic Products. https://www.theglobalfund.org/en/sourcing-management/ quality-assurance/diagnostic-products/, accessed 19 June 2020.
- ²¹ The Global Fund to Fight AIDS, Tuberculosis and Malaria. Sourcing and Management of Health Products: COVID-19 Response: Health Product Supply Update for Principal Recipients. https://www.theglobalfund.org/en/sourcing-management/updates/2020-04-22-covid-19-response-health-product-supply-update-for-principal-recipients/, accessed 19 June 2020.

²² Unitaid, World Health Organization. Market and Technology Landscape. HIV Rapid Diagnostic Tests For Self-Testing, 4th Edition. Geneva: WHO, July 2018. https://unitaid.org/assets/HIVST-landscape-report.pdf, accessed 19 June 2020.

²³World Health Organization. In vitro diagnostics and laboratory technology: Complaints and Product Alerts. https://www.who.int/diagnostics laboratory/procurement/complaints/en/, accessed 19 June 2020.

²⁴ World Health Organization. Infection Prevention and Control guidance for Long-Term Care Facilities in the context of COVID-19 https://apps.who.int/iris/bitstream/handle/10665/331508/WHO-2019-nCoV-IPC long term care-2020.1-eng.pdf, accessed 21 June 2020.

²⁵ World Health Organization. Operational considerations for case management of COVID-19 in health facility and community. https://apps.who.int/iris/rest/bitstreams/1272399/retrieve, accessed 21 June 2020.

²⁶ Johnson C, Kennedy C, Fonner V, Siegfried N, Figueroa C, Dalal S, Sands A, Baggaley R. Examining the effects of HIV self-testing compared to standard HIV testing services: A systematic review and meta-analysis. J Int AIDS Soci. 2017; 15;20(1):21594. https://pubmed.ncbi.nlm.nih.gov/28530049/, accessed 21 June 2020.

Annex 1. Table summarizing HIV self-testing in the context of COVID-19

- HIVST models suggested in the context of COVID-19 Strategic facility-based testing remains an important HTS approach and should be continued with appropriate precautions. HIV testing using rapid diagnostic tests at facilities can provide same-day results and facilitate prompt initiation of ART or relevant prevention services to clients.
 - Facilities and other fixed health services sites continuing to offer HIV testing and HIVST services should develop standard operating procedures and implement standard precautions. These include triage, early recognition and source control (isolating patients with suspected SARS-CoV-2 infection/COVID-19); adequate ventilation; maintaining recommended physical distance among patients and providers; correct and consistent cleaning and disinfection procedures; and appropriate use of personal protective equipment (PPE) by health-care workers and other providers.
 - Clients seeking HTS at facilities can be given HIVST kits for use within the facilities or for later use to reduce facility burden and minimize contact with health-care workers.
 - o In high HIV burden settings, HIVST kits can be given to women presenting for antenatal care (ANC) so that they can provide a kit to their male partner.
 - People with HIV can be provided with HIVST kits to distribute to their sexual and/or drug-injecting partners.
 - Key populations, whether HIV-positive or HIV-negative, can be provided HIVST kits to distribute to their sexual and/or drug-injecting partners, peers or social contacts.
 - People taking pre-exposure prophylaxis (PrEP) can be given HIVST kits where access to routine facility-based HTS is limited to prevent disruption of services.
 - Consider easy-to-access HIVST kits and other prevention materials (condoms, lubricants and relevant educational materials) for distribution in pre-packaged bags at health-care facilities or outside in proximity of health-care facilities for clients to take to minimize contact.
 - Consider the use of digital tools for delivering pre-test information and post-test counselling, including videos, social media, applications and other media.
- HIVST kits can be targeted and distributed through community-based fixed sites or through mobile or community outreach. However, community-based, mobile and outreach distribution models should be managed with greater caution and adapted to comply with national authorities' recommendations on physical distancing. The frequency of community or outreach visits, number of clients participating in outreach sessions, contact tracing associated with partner services and pattern of participation (e.g. staggered to minimize contact) can be adapted depending on local context. Additionally, consider the use of social networks for HIVST distribution among key populations (with appropriate caution to clients on physical distancing when distributing HIVST kits) to maintain community-based HTS. HIVST kits can be provided to HIV-positive clients to distribute to their sexual and/or drug-injecting partners.
- HIVST availability through online platforms. Making HIVST kits available to clients
 through online platforms (websites, social media, digital platforms) and distribution
 through mail can be a particularly attractive option in the context of the COVID-19
 pandemic, ensuring ongoing access to HTS. HIVST kits through this model typically come

at a price to clients; however, efforts should be made to provide kits to those in need for free or at an affordable price.

HIVST availability through retail outlets, pharmacies and vending machines. HIVST
 availability through retail outlets, pharmacies or vending machines can ensure ongoing
 access to HTS in settings where restrictions on movement are being implemented.
 Efforts are needed to ensure supply at an affordable cost and through innovative
 financing initiatives such as through public—private partnerships and distribution of
 coupons or vouchers to those at increased risk.

All programmes using HIVST, as with standard HTS, need to ensure that confirmatory HIV testing is available for those with a reactive test. This is essential for diagnosing and treating all people with HIV. Access to HIV prevention, such as condoms and lubricants, and PrEP should also be assured where possible for those provided HIVST kits. Information and access to other sexual health services will continue to be important, including contraceptive services.

Special attention and provisions for key populations and other populations vulnerable to both HIV and COVID-19 will need to be considered and supported.

Support package and tools for HIVST

In collaboration with civil society organizations, countries and programmes can develop a support package and tools that accompany HIVST kits. Some tools that can be considered to support correct HIVST usage and facilitate linkage to HIV confirmation testing (if needed) and care in the context of COVID-19 pandemic are as follows:

- standard, manufacturer-provided instructions for use (and local adaptations or translations where appropriate) and manufacturer-provided telephone hotline or other customer support;
- virtual real-time support through online platforms (such as messaging, social media, videos):
- new digital, social media, clear print media and video or messaging platforms tailored for different audiences (such as young persons, key populations). These may be readily acceptable, especially to young people.

Considerations for successful HIVST implementation

- Develop simple, clear and supportive policies, regulations and standard operating
 procedures and disseminate them to distribution sites and providers. These should
 ensure the registration and availability of quality-assured HIVST products and adequate
 post-market surveillance. The most up-to-date list of WHO-prequalified HIVST kits can
 be accessed on the WHO website at:
 - https://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/
 - Empower and effectively engage communities in developing and adapting HIVST delivery and support models, including information about where people can link to further testing for diagnosis and ART services. The meaningful participation of community members and people from key populations in HIVST services in the context of COVID-19 can also be ensured using virtual platforms and simple, clear print media.

- Create messages and communication strategies for dissemination HIVST with key stakeholders, including communities and civil society organizations. It is important to ensure that messages and materials provide accurate information and raise awareness about HIVST, minimize misuse and eventual harms in relation to HIVST, and offer information on ways of reporting and addressing complaints and adverse events through the national post-market surveillance system. It will be important for these messages to also provide correct information on COVID-19 and address misinformation and myths at the community level. Community action plans may be an important tool to develop and utilize.
- Ensure that messaging reinforces the fact that a positive HIVST result does not confer a positive HIV diagnosis until a confirmatory test is conducted that also yields a positive result.
- If possible, offer a choice in HIVST service delivery options and type of test kit (such as kits using oral fluid or blood).