HIV self-testing: an optimal approach for HIV diagnosis during COVID-19 pandemic

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Abstract

Human immunodeficiency virus self-testing (HIVST) has gained popularity as a last-mile option for achieving UNAIDS 95-95-95 targets by 2030. HIV testing has been a serious concern since the start of COVID-19 pandemic, and enhanced measures were needed to improve access to promote testing. This study aimed to review the evidence related to HIVST program during COVID-19.

In this narrative review, a literature search was performed in English databases, including Cochrane Library, PubMed, Scopus, and Science Direct as well as in Persian databases, such as Magiran and Scientific Information Database. In addition, World Health Organization, Joint United Nations Programme on HIV and AIDS, and reports of Centre for Disease Control and Prevention were explored. The search was conducted up to January 8, 2022.

Kenya was the first country to publish a national HIVST policy in 2008. U.S. Food and Drug Administration licensed the first-ever fast HIV home test in July 2012. HIVST products can be delivered via various channels, including those financed by government or donor funds as well as private and public-private sectors collaborations. Service delivery models include facility-based directed, facility secondary distribution, community-based platforms, open-access platforms, virtual platforms, workplaces model, and integrated model.

Given this new situation and COVID-19's effects on people, societies, and health services, governments must resolve political and regulatory obstacles to HIV testing and universal coverage. HIVST can help by using peer-, partner-, and community-based delivery methods as well as engagement of non-governmental and civil society organizations.

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Key words: HIV testing, AIDS testing, HIV infection diagnosis, COVID-19 pandemic.

Introduction

Despite significant advances in the worldwide human immunodeficiency virus (HIV) response, the numbers of new HIV infections and AIDS (acquired immunodeficiency syndrome)-related deaths are still too high. Global commitments to reduce AIDS-related mortality and new HIV infections to under 500,000 by the end of 2020 failed last

Address for correspondence: Dr. Elham Manouchehri, Mashhad Medical Sciences, Islamic Azad University, Mashhad, Iran, e-mail: resin770@gmail.com year, as 680,000 people have died from AIDS-related diseases and 1.5 million have become infected with HIV [1]. Despite a worldwide decrease in the number of new HIV infections, the rate of HIV-infected individuals is growing in various countries [2]. Moreover, the incidence of deaths from this illness has decreased by a substantial amount in high-income nations due to appropriate infection control,

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but in developing countries, a significant number of patients have yet to be recognized or admitted into care system [3].

COVID-19 has been declared a pandemic by the World Health Organization (WHO) in 2020 [4]. It is the world's most significant public health crisis of the century, with extensive health and socio-economic effects. The epidemic appears to be worsening existing inequities and exposing weaknesses in social, political, and financial institutions, hence, intensifying the pandemic consequences [5]. Guidelines to stay at home as well as closing of numerous clinics and community-based institutions have dramatically decreased the accessibility to HIV testing and other preventive measures, including condoms distribution or pre-exposure prophylaxis (PrEP) [6, 7]. While the availability of prevention strategies, treatment, and care facilities are the top public health priorities, reaching and maintaining low HIV incidence rate worldwide by 2030 will be impossible without the above measures [8]. In recent years, HIV self-testing (HIVST) has gained popularity as a last-mile option for achieving UNAIDS' 95-95-95 targets by 2030 [9]. HIV testing has been a serious concern since the start of coronavirus disease in 2019 (COVID-19), and enhanced measures were needed to improve the access to testing and its promoting [7]. During the first COVID-19 lockdowns in 2020, the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM) stated that HIV testing fell by 41%, and referrals for diagnosis and treatment decreased by 37%, based on data gathered from 502 health centers in 32 African and Asian countries [10]. The 2021 Political Declaration on AIDS with its 2025 targets and commitments, call for the use of different models and frameworks for diagnosis and treatment, including virtual and community-based services, to address problems, such as the COVID-19 pandemic, by providing treatment and related support programs to the most vulnerable populations [11]. To overcome inequalities among people, innovative techniques are required, but, as epidemic control approaches, effective treatments costs increase. It is critical to find new and low-cost approaches to sustain and enhance testing coverage to limit testing gaps without diverting funds from other HIV healthcare facilities [12]. In the middle of the COVID-19 pandemic, the Centers for Disease Control and Prevention (CDC) has advised persons at risk of acquiring HIV to use HIVST [13]. Integrating HIV and SARS-CoV-2 testing programs could be beneficial [14], and WHO and other international organizations are now advocating for an increased focus on HIVST [15]. Despite significant progress on HIVST, it remains a neglected issue in HIV and AIDS services in some countries.

This study aimed to explain the definition, history, interpretation of HIVST results, effectiveness, limitations, and models of HIVST programs to present new perspectives based on the most recent worldwide research.

Material and methods

This review article was written using scale for assessing narrative review articles (SANRA) to examine HIVST services during COVID-19. SANRA includes six of the following components: (1) explanation of the significance of article to the reader; (2) objective of the narrative review; (3) complete description of the literature search; (4) referencing; (5) incorporation of the relevant evidence; and (6) proper data presentation.

Methods and strategies for identifying guidelines and studies in the review

Databases examined for related articles included Cochrane Library, PubMed, Scopus, and Science Direct in English as well as Magiran and Scientific Information Database (SID) in Persian. In addition, the WHO, Joint United Nations Programme on HIV and AIDS (UNAIDS), Centres for Disease Control and Prevention (CDC), and United Nations Population Fund (UNFPA) guidelines and instructions for HIVST services during the COVID-19 pandemic were examined. To identify additional recommendations, reference lists of relevant publications were also verified. The following key words were applied in the search:

"HIV Self-Test, "Test Service", "HIV Testing", "AIDS Testing", "HIV Infection Diagnosis", "AIDS Serodiagnosis", "HIV Serodiagnoses", "AIDS Serology", AND "COVID-19 Pandemic" or "Coronavirus Pandemic". To improve the search accuracy, Boolean terms (AND/OR) were utilized to segregate key words and medical subject headings (MeSH). To collect all of the relevant literature on HIVST services, the design of the study was not restricted. The search was conducted until January 8, 2022.

Study and guideline eligibility and exclusion criteria

The current study showed evidence of HIVST services during the COVID-19 pandemic, and HIVST service guidelines in non-pandemic situations. Excluded were studies and guidelines if: the language of a study and articles were not English or Persian, full text of the article was not available, or the article was released as a letter to the editor or seminar presentation.

Study management and data extraction

To confirm inclusion criteria, two writers (ML and EM) examined all retrieved publications' titles and abstracts (articles and guidelines). Data choice and their extraction were done separately. A third author was engaged in addressing discrepancies. At this point, the authors did not have any disagreements.

Results

Articles and guidelines were categorized into sections of definition, history, HIVST for various populations, interpretation of HIVST results, benefits, and limitations as well as types of care models, benefits of HIVST, and models of delivery of HIVST services.

Definition of HIVST

HIVST is a method, in which individuals obtain a sample (oral fluid or blood), execute an HIV test, and interpret the results on their own, usually in a confidential setting [16].

History of HIVST

Suggestions for HIV home testing attracted controversy in the mid-1980s, and the argument was renewed in 2012 when a rapid oral swab kit has been approved for over-the-counter (OTC) sale in the United States [17]. However, Kenya was the first country to publish a national HIVST policy in 2008 [18]. FDA licensed the first-ever fast HIV home test in July 2012. In October 2012, Ora-Quick In-Home HIV test obtained permission to access to the general public in the United States (US), enabling people to check for HIV infection in their own homes' privacy and receive results in just 20 minutes [19]. The first worldwide consultation on HIVST was held by WHO and partner organizations. WHO defined the process for issuing recommendations and pre-qualifying products as well as the research and experience required in 2013 [20]. WHO advised governments to start investigating HIVST, and conducted practical research recommendations in 2015, but no standardizing guidelines were provided [20]. In 2016, WHO published its first HIVST normative guidance [21]. The first HIVST product, initially licensed by FDA in 2012, was pre-qualified by WHO in July 2017 [22]. A second HIVST was pre-qualified by WHO, and the first bloodbased HIVST rapid diagnostic tests (RDTs) was approved in December 2018. WHO released its HIV self-testing strategic framework in October 2018 [23]. Both the third and fourth HIVST kits are based on blood HIVST RDTs, and were pre-qualified by WHO in 2019 [24].

Various nations across the globe have differing levels of acceptability for HIVST policies. According to the latest reports, as of June 2018, 59 countries have established HIVST policies. Some 53 additional countries declared working on HIVST protocols, with many finalized in 2018. Despite the policy's fast adoption, HIVST was only available in 28 countries from July 2017. Most countries undertaking HIVST (n = 18) are upper-middle or high-income countries [25]. HIVST kits are now legal in France, the United States of America, and the United Kingdom [26]. However, in Iran, the function of HIVST throughout the epidemic has not been adequately documented. Because of the COVID-19 outbreak in Iran, the massive community intervention for aided, pharmacy-based HIVST targeting women at highrisk sexual activity in many cities, was stopped. HIVST, which allows individuals to select when and where take an HIV test, offers the benefit of decongesting health facilities, while boosting HIV testing access to groups at greater

risk of infection. Burundi, Eswatini, Guatemala, and Myanmar are among the countries that have reported growing HIVST during the COVID-19 pandemic, according to UNAIDS statistics [27].

HIVST for various populations

As a result of technological advancements, transgender women (TGW), men who have sex with men (MSM), and female sex workers (FSW) are progressively relocating to virtual platforms, being inaccessible to existing HIV interventions. Vulnerable populations are hesitant to use intervention programs because they fear shame and judgment, yet participate in high-risk behaviors. WHO has sought evidence on HIVST in the following areas: (A) virtual technologies; (B) community health workers and peer counselors for integrating links; and (C) social network utilization for key groups [28]. The literature reported to improve HIVST uptake, being highly acceptable among various groups of users in diverse settings [29, 30], particularly key and priority populations [31], men [32], young people [32], general population [32], pregnant women [33] and their male partners [34], and cohabiting couples [30].

Interpretation of HIVST results

It is not sufficient to start PrEP with a negative (nonreactive) self-test result unless followed by a negative test result at a facility. Self-testing, especially with kits that use oral fluid samples, may not consistently identify an HIV infection after starting taking PrEP [35]. The WHO advises that HIVST should be offered as an alternative method of testing that complements and increases demand for current HIV testing services. An HIV-positive diagnosis is not the same as a reactive (positive) self-test result. Starting with the first test in an approved national testing algorithm, all reactive outcomes of self-tests must be followed by additional testing supported by a trained provider. Non-reactive results should be regarded as negative. People who could have been exposed to HIV in previous 6-12 weeks may be in a 'window period', during which the test can be non-reactive. In 14 days, they should repeat the self-test or seek re-testing at a facility. According to WHO, those who are at high continuous risk should be re-tested at least once a year. As a result, it is critical to carefully develop messaging that promotes re-testing among those who would benefit (for example, members of key communities), and connect it to HIV prevention strategies, such as condom use, harm reduction, voluntary medical male circumcision, and pre-exposure prophylaxis [26, 36, 37]. Generally, a health professional must validate any positive HIV result using national testing methods [20].

Effectiveness and limitations

WHO suggests HIVST as a safe, reliable, and effective method for providing test to people who could not test other-

Significant advantages	Disadvantages
Simple, convenient, and confidential procedure [44]. HIVST has the potential to enhance program outcomes, such as identification of newly diagnosed HIV patients and their linkage to care and treatment [46]. The method is widely accepted, particularly among the most vulnerable persons [45].	Costs may prevent people who need testing the most [44, 47].
Self-test kits may be ordered online for a better level of privacy and convenience than clinic-based testing, and they are appropriate and practicable [46].	False-negative findings, particularly during the window period [17].
Most individuals can perform home tests correctly, get reliable findings, and interpret them, resulting in good correlations with laboratory and healthcare professional testing [19].	HIVST may provide false confidence and may encourage sex between discordant couples at periods of peak infectivity [47].
People usually recognized the need of validating positive test findings [19]. Self-testing is related to higher testing uptake and frequency, especially among people at risk who may not otherwise be tested, implying that self-testing will likely to uncover more HIV-positive persons than routine testing services alone [43].	Counseling, referral to treatment, and identification of additional sexually transmitted diseases may go unnoticed [17, 47].
HIV home testing offers the potential to reach more individuals and to use technology-based solutions to connect them to care [48].	Concerns about pre- and post-test counseling, and accuracy of findings [44].
Self-testing empowers people and leads to the normalization of HIV testing [45]. Self-testing may appeal to persons who are concerned about HIV-related or behavior-related stigma and prejudice in healthcare settings as well as those who might benefit from more regular testing, or who reside in areas where health services are unavailable [49].	Persons who test positive without receiving counseling would feel depressed, unable to deal with their results, and will be less persuaded to seek help [50].
Additional public health advantages include a decrease in the time of undetected infection, which is known to be a period of relatively high transmissibility [49].	Misinterpretation of test findings, failure to follow directions, and inaccurate self-testing are all examples of reported mistakes [20].
Mutual partner testing can raise risk awareness and prevent condomless intercourses between disagreeing couples [47].	Self-testing can result in spouse coercion [45].

Table 1. Advantages and disadvantages of HIV self-testing (HIVST) in the literature

wise [36]. It is a new tool that empowers users and guarantees test confidentiality [38]. An error may occur in any test and can result in inaccurate test results; this can happen to both experienced and untrained users. Operator error vary from 0.37 to 5.4% in investigations of non-experienced selftesters [39]. Misinterpretation of test findings, failure to follow directions, and inaccurate self-testing are all examples of reported mistakes. HIV self-testing is a screening test for the presence of HIV-1/2 antibodies or HIV-1 p24 antigen, rather than a final diagnosis. A health professional must validate any positive HIV result using national testing methods [20]. HIVST can be less difficult in high-income countries since existing organizations assure sufficient regulations, healthcare access, and protection against exploitation [40].

Introduction and extend of HIVST, particularly outside clinics, through pharmacies, community distribution, and online or home delivery options, are to minimize providerclient interaction and reduce facility overcrowding by triaging out those who self-test negative [41]. Also, HIVST is an option for individuals who are taking post-exposure prophylaxis (PEP) or PrEP as part of their preventative strategy [41]. HIVST enables governments to increase people's access to HIV testing services, reach individuals at highrisk who may not otherwise be tested, and meet the first 90 of UNAIDS' 90-90-90 objectives, which states that 90% of all HIV-positive persons should know their status [36]. It is a cost-effective option, and complaints of societal damage resulting from HIV testing are uncommon [32, 42]. Table 1 presents the advantages and disadvantages of HIVST.

A systematic review from 2018 evaluated the reliability of HIVST based on 20 reports from 16 studies published between 1995 and 2016. In this study, 16 (80%) of the reports had a specificity higher than 98%, while 18 (90%) of them had a sensitivity greater than 80% [43]. In 2018, another global review on HIVST found that the OraQuick HIV selftest kit had a median sensitivity and specificity of 93.6% and 99.9%, respectively, and other test kits presented typically high sensitivity and specificity [44]. According to a 2021 cross-sectional study in South Africa, the average sensitivity and specificity of HIVST were 98.2% (range, 96.8-99.3%) and 99.8% (range, 99.4-100.0%), respectively [45].

Models of delivery of HIVST services

According to the WHO, offering HIVST service delivery and support choices are desired. Communities must be included in the development and adaptation of HIVST models. HIVST does not offer a conclusive diagnosis of HIV

infection. Individuals who obtain a reactive test result must be tested again by a qualified person who follows national testing procedures. HIVST kits can be provided through a variety of channels, including those supported by government or donor funds as well as public-private partnerships. RCTs indicated that a variety of service delivery and distribution approaches are successful in improving HIV testing uptake, and reaching undiagnosed or at-risk persons with HIV. Other models may be beneficial, and depending on local circumstances and community preferences [51]. While HIVST with home-testing kits is achievable, for many people, reduced or lost employment and the resulting loss of income as well as concerns about safe delivery of testing kits, can make home-testing impossible [52, 53]. If the global 95-95-95 targets are to be attained, the outreach to these critical groups must be increased as well as innovative testing methods [54]. Despite the significant expansion of HIV testing programs, many people, particularly men, adolescents, young women, and members of vulnerable populations, remain untested. WHO and UNAIDS provide explicit instructions on the important needs for all types of testing, including the necessity that all testing must be voluntary. HIV testing should never be compelled or pressured [55]. HIVST products can be delivered thru various channels, including those financed by government or donor funds, private sector, and public-private collaborations. Many settings combine virtual assistance and community-based PrEP distribution with HIVST to continue PrEP programs [56]. HIVST service delivery models are shown in Table 2.

Discussion

The current study provided general evidence of the importance of HIVST during COVID-19. HIV infection continue to spread in countries and communities, where the benefits of science and human rights are still not reaching those left behind [1]. PEPFAR (2020) emphasizes that the COVID-19 epidemic is dynamic and unpredictable, and continual caseby-case and context-specific evaluations will be required to determine whether actions should be continued, changed, or even suspended. Patient-centered, effective, and resourceefficient HIV care delivery was sparked by COVID-19, and such creative techniques should be included in common programming. PEPFAR reported a known fact that COVID-19 causes a delay in HIV testing, treatment, and preventive care; thus, HIV services will need to be not only restored but also accelerated to compensate for the time lost, and to get back on track to control the epidemic [60]. Standard HIVST methods are important and help many individuals, but current procedures ignore a significant percentage of persons with HIV and those at high-risk. The continued increase in HIV testing among males and other high-risk populations supported by HIVST might identify a more significant number of infections at an earlier stage, resulting in faster diagnosis, treatment initiation, and a reduction of HIV-related deaths [67]. Reaching out to people who may not know their HIV status is a global issue. Although HIVST will not overcome the screening gap on its own, it has the potential to reach high-risk groups who would not otherwise get tested. According to the findings on this special issue, HIVST is appropriate and even preferred by many patients. Even though several stakeholders remain concerned about the possible potential dangers of HIVST [68], many of vulnerabilities mentioned on this topic are common to all HIV testing procedures, and the risks can be reduced if HIVST is offered as follows: with adequate guidance, using high quality products, in a supervised condition, within a human rights context, and with community engagement [69]. According to qualitative studies, most users believe HIVST to be empowering, although some respondents felt "forced" to selftest by their spouses, and stated that sero-discordant HIVST reports were complex [70]. Furthermore, despite its restrictions and due to the window period, HIVST appears to be a good screening technique before sexual contact for MSM with high-risk sexual practices [71]. In Zimbabwe, a costeffectiveness analysis revealed that if HIV testing costs USD 3 per test, health services might save USD 53 million over 20 years, resulting in a major long-term health effects [16].

According to the results of a study [44], because of the privacy provided, simplicity, ease of HIVST, and non-invasive form of oral testing, HIVST acceptance was high (range, 81-100%). In most trials, oral HIVST was deemed "not at all difficult" or "simple" to perform. Trust in HIVST results was high in majority of trials (91%), and most participants thought their interpretations after HIVST were proper (87%). Still, individuals were less likely to believe that their interpretation of a blood-based test was accurate. Some individuals would buy their own HIVST kit over-the-counter (OTC) if available, and they would recommend this self-testing technique to a friend [44]. According to the findings of a research conducted in South Africa, if HIVST is to be established, actions should be made to guarantee that poor, marginalized, and hard-to-reach groups have the access to the services by making HIVST products inexpensive to buy for majority of the population. These studies showed that policy-making in South Africa must be strategically integrated with market forces, industry, advocacy, and public demand for HIVST in order to be adopted and implemented successfully [72, 73]. It may not be easy to ensure that retailers and service providers in resource-constrained countries have the appropriate policy and legal frameworks to encourage efficient HIVST, while serving and safeguarding patients from poor products. One other recent review investigating HIV policies in seven countries in Sub-Saharan Africa reported multiple areas of ambiguity and variations of HIVSTs that may be implemented differently in the commercial and governmental sectors. The right to healthcare, privacy rights, obligation, quality assurance, licenses of prescription drugs or medical equipment, stigmatization of HIV transmitting, age of consent, questions who can accomplish an HIV test and discuss the results as well as where an HIV test can be re-distributed or conducted, are all important issues in laws and regulations that have to be produced, adjusted, and reinforced. Although the process of producing, adjusting, and reinforcing rules and

Priority populations	ally Groups (particularly, males, adolescents, critical population) obtaining healthcare and services and who (based on their risk can behavior and testing histories) are odel candidates for HIV testing following pre- lility- screening (has not done the test yet or a use last test performed over a year ago). Individuals presenting (or admitted) to clinics with symptoms or signs of HIV infection. Individuals with TB, STIs, malnutrition, and early detection of infant diagnosis (EID) [60, 61]. iders itty- cility-	 : use Sexual partners of HIV-positive index s has patients diagnosed in a health institution or who are using ART. e who Partners of pregnant or lactating women who use maternity care in the public sector (secondary distribution). (2). Sexual partners of those attending STI, no visit family planning, and TB services [61, 62]. 	basedRural high-risk groups that are underserved, particularly high-risk adultcaseunderserved, particularly high-risk adultcaseunderserved, particularly high-risk adultcasemen and adolescents who are unable toityobtain routine test kits.critical groups, such as sex workers,trieeMSM, transgender individuals, and drugtrierersusers, etc. who can be accessed via HIVSTcl [61].distribution in high-risk areas.ngPartners of HIV-positive individuals (indexno getpatients) across all target groups [61, 62].64].
Advantages	HIVST at a facility might be especially effective in high-burden outpatient clinics, which are frequently overcrowded and understaffed, and where patients can face long wait periods [58]. This model could increase the efficiency of facility- based testing services: patients can use HIVST while standing in line, enhance ART initiation, when patients are already at the facility and can easily obtain additional services, improve quality assurance as patients have immediate access to qualified HIV testing providers at the facility, and decrease expenditures of HIV self-testing by distributing kits that may be readily incorporated into facility- based staff daily activities [59].	Secondary distribution through the use of index patients to sexual partners has the potential to improve HIVST uptake and diagnose more in HIV-infected people who are unaware of their status [61, 62]. Priority groups can be reached through secondary distribution to patients who visit healthcare centers (typically females) [62].	Integration with current community-based testing programs can help to increase efficiency and resource' effectiveness. As a pre-screening test, community caregivers, peer navigators, expertise users, and other providers distribute HIVST kits to index cases (sexual partners of index patients) at community level [61]. This approach is effective regarding increasing the number of persons who get tested for HIV and referred to care due in part to community workers [21, 32, 64].
Application	Distribution from facilities or other fixed locations for future use or within the facilities. HIV-positive or HIV-negative patients can be provided with kits for secondary distribution [36].	Regardless of HIV status, pregnant/lactating women are provided HIVST kits to give to their male partners. Patients receiving STI, TB, and family planning services are given HIVST kits to take to their sexual partners [61, 62].	HIVST kits may be distributed by community healthcare professionals who can offer both assisted and unassisted HIV self-screening to primary users, either through door-to-door delivery or to selected populations. They can also provide kits to those who have been tested and are willing to distribute to their sexual partners as secondary distributors [63]. Campaign distribution, event distribution, mobile outreach, or home-based (door-to-door) distribution are all options
Model Description	HIVST in healthcare facilities is self- administration of HIV self-test within the facility, usually under the control of a healthcare practitioner [57].	In this model, HIV-positive patients will receive an HIVST kit to deliver to their partners for screening outside the clinic [61, 62].	Distribution of HIVST kits to community members by volunteers or community health workers is known as community-based HIVST [21].
Model	Facility-based direct	Facility secondary distribution	Community- based platforms

Table 2. HIV self-testing (HIVST) service delivery models

Virtual platforms	Patients who go to pharmacies to purchase medications, condoms, lubricants, and other items can be provided with HIVST kits [65]. Mobile applications or web-based consultations that provide private and discreet choices effectively addressing vulnerable populations and were well-received by end-users. HIVST kits can also be delivered via mail,	ApplicationHIVST kits are available at retail outletshIVST kits are available at retail outletsin hot spots and locations where prioritypopulations may be accessed. Individualsfrom the general public will purchase kitsand do HIV testing without assistance [65].Shop owners encourage the use of HIVSTkits by demonstrating how to use themand providing additional user informationfor the kits [65].People submit their demographicinformation, choose an HIV test kit, andplace an online HIV test kit, andplace an online HIV test kit deliveryorder (mail, grab, self-pickup). HIVST kitsare supplied to users within two daysof ordering station. The customerfrom a mailing station. The customerfrom a website that leads througheach stage of the process [65].	Advantages HIVST kits can be obtained via retail shops, pharmacies, or vending machines, ensuring continuous access to HIVST. HIVST increases the number of tested people who would not be tested otherwise. This may result in a significant increase in test coverage. This model can provide the possibility of reaching to high-risk groups [62]. Making HIVST kits available to patients via online platforms (websites, social media, digital platforms) and postal delivery can be a particularly attractive solution for assuring continued access to HIVST in the context of the COVID-19 pandemic [62]. This model may be widely accepted, particularly among young people [62]. If the person desires further information, they can call a toll-free number [65].	Priority populations Adults and men at high-risk, high-risk adolescent girls, young women, and women undergoing family planning or seeking emergency contraception. Key groups that frequently go to pharmacies and retail establishments in hot spots areas [61, 62]. Key groups who obtain health-related information from the Internet. Other high-risk populations who get information online and choose to obtain an HIV test either through home delivery or drop-off at different place [61, 62].
	eliminating visiting a facility [66]. HIV self-screening can be included in workplace wellness programs, reaching males and those at high risks, such as miners and truck drivers as well as their spouses, and facilitating HIV protection uptake [63].	Workers, their families, and community Workers, their families, and community can now receive HIVST services in their workplaces according to this method. HIV testing in the workplace should be kept private, administered in secure place, and not exploited. The employee has an option of disclosing HIV status [65]. Kits can be delivered to the end-user directly through primary distribution, and the individual can be assisted or left alone. Secondary distribution can also be used in workplace programs by supporting partner deliverv of self-screening kits [63].	This model may promote HIV testing uptake by providing greater confidentiality and autonomy to employees as well as saving time for both workers and healthcare professionals [61, 62].	Adults at risk, particularly men in a workplace, and their sexual partners. High-risk adolescent girls and young women, family planning, and emergency contraception users. Key populations in hot-spots, pharmacies, and retail outlets [61, 62].

Model	Description	Application	Advantages	Priority populations
Integrated model	Distribution in	People from a prioritized group can test	This model can increase the number	Female sex workers, men who have sex
	community hot	themselves in a cubicle or tent	of people tested and more specifically,	with men (MSM), people who inject drugs
	spots in towns	at a distribution station or HIVST facility	it targets provider-initiated testing to	(PWID) [61, 62].
	and cities, where	(with supervision), or take the test kit	increase HIV positive diagnoses,	
	HIVST outreach or	home for testing. HIVST kits can also be	ART initiation, and preventative service	
	fixed site testing	ordered online [61, 62].	adoption. Also, increases the number	
	services are offered.		of people who get tested and how often	
	Individuals can		they get tested in critical populations [62].	
	select between HIV			
	testing at home or			
	testing provided by			
	a clinician (opt-in)			
	[61, 62].			

regulations may be difficult, it is critical for guiding HIVST scale-up [16].

In the present review, we investigated the articles published in English and Persian languages only; therefore, we could miss important literature published in other languages. In addition, the current study did not perform a quality evaluation of the investigated studies. We suggest that quantitative research should be performed to examine the topic better in order to recognize additional benefits of HIVST. Qualitative research might also enable to understand the obstacles and resources required to implement this method in the HIV context.

Conclusions

Given this new context and the impact of COVID-19 on individuals, communities, and health systems, governments must overcome political and regulatory barriers to HIV test implementation and universal access. HIVST could be able to help in this by using peer-, partner-, and community-based delivery methods as well as the engagement of non-governmental and civil society organizations. Due to the COVID-19 pandemic, health systems around the world have been burdened and restricted; limited access to HIV testing services and fear of contracting COVID-19 resulted in a drop in facility-based testing among people, when lockdown measures were undertaken during the COVID-19 epidemic. There is a variety of HIVST implementation strategies that may be tailored in demographics and geographic region contexts. Several nations have failed to completely implement HIVST policies, even though many countries have created and are implementing HIVST policies. Generally, HIVST offers the potential to sustain HIV testing in this setting as well as opportunities to minimize the strain on health systems beyond HIV. A combination of testing methodologies may be required at the national level, but where and which method should be used should be determined by the local situation analysis.

Disclosures

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- 4. Conflicts of interest: None.

References

- UNAIDS. 2021 UNAIDS Global AIDS Update Confronting inequalities – Lessons for pandemic responses from 40 years of AIDS. 2021. Available at: https://www.unaids.org/en/resources/documents/ 2021/2021-global-aids-update.
- 2. SeyedAlinaghi S, Taj L, Mazaheri-Tehrani E, Ahsani-Nasab S, Abedinzadeh N, McFarland W, et al. HIV in Iran: onset, responses, and future directions. AIDS 2021; 35: 529-542.

Table 2. Cont.

- GBD 2015 HIV Collaborators. Estimates of global, regional, and national incidence, prevalence, and mortality of HIV, 1980-2015: the Global Burden of Disease Study 2015. Lancet HIV 2016; 3: e361-e387. DOI: doi: 10.1016/S2352-3018(16)30087-X. Corrrection to Lancet HIV 2016; 3: e361-e387. Lancet HIV 2016; 3: e408. doi: 10.1016/S2352-3018(16)30125-4.
- Larki M, Sharifi F, Roudsari RL. Models of maternity care for pregnant women during the COVID-19 pandemic. East Mediterr Health J 2020; 26: 994-998.
- Larki M, Sharifi F, Roudsari RL. Women's reproductive health and rights through the lens of the COVID-19 pandemic. Sultan Qaboos Univ Med J 2021; 21: e166-171. doi: 10.18295/squmj.2021.21.02.003.
- Operario D, King EJ, Gamarel KE. Prioritizing community partners and community HIV workers in the COVID-19 pandemic. AIDS Behav 2020; 24: 2748-2750.
- Jiang H, Zhou Y, Tang W. Maintaining HIV care during the COVID-19 pandemic. Lancet HIV 2020; 7: e308-e309. doi: 10.1016/S2352-3018 (20)30105-3.
- 8. UNAIDS. Understanding fast-track: accelerating action to end the AIDS epidemic by 2030. Geneva: UNAIDS; 2015.
- 9. WHO. Number of countries adopting HIV self-testing policies rises sharply. 25 July 2017. Available at: https://unitaid.org/new-s-blog/number-countries-adopting-hiv-self-testing-policies-rises-sharply/#en.
- 10. The Global Fund. The impact of COVID-19 on HIV, TB and malaria services and systems for health: a snapshot from 502 health facilities across Africa and Asia. 2021. Available at: https://www.theglobal-fund.org/en/updates/2021/2021-04-13-the-impact-of-covid-19-on-hiv-tb-and-malaria-services-and-systems-for-health/.
- UNAIDS. Political declaration on HIV and AIDS: ending inequalities and getting back on track to end AIDS by 2030. 2021. Available at: https://www.unaids.org/en/resources/documents/2021/ 2021_political-declaration-on-hiv-and-aids.
- 12. Nichols BE, de Nooy A, Benade M, Balakasi K, Mphande M, Rao G, et al. Facility-based HIV self-testing strategies may substantially increase number of men and youth tested for HIV in Malawi: results from a data-driven individual-based model. medRxiv. 2021. DOI: https://doi.org/10.1101/2021.08.25.21262593.
- CDC.HIVSelfTestingGuidance.2020.Availableat:https://www.cdc. gov/nchhstp/dear_colleague/2020/dcl-042820-HIV-self-testingguidance.html.
- 14. Zang X, Krebs E, Chen S, Piske M, Armstrong WS, Behrends CN, et al. The potential epidemiological impact of coronavirus disease 2019 (COVID-19) on the human immunodeficiency virus (HIV) epidemic and the cost-effectiveness of linked, opt-out HIV testing: a modeling study in 6 US cities. Clin Infect Dis 2021; 72: e828-e834. DOI: 10.1093/cid/ciaa1547.
- Golin R, Godfrey C, Firth J, Lee L, Minior T, Phelps BR, et al. PEPFAR's response to the convergence of the HIV and COVID-19 pandemics in Sub-Saharan Africa. J Int AIDS Soc 2020; 23: e25587. DOI: 10.1002/jia2.25587.
- Johnson C, Baggaley R, Forsythe S, Van Rooyen H, Ford N, Mavedzenge SN, et al. Realizing the potential for HIV self-testing. AIDS Behav 2014; 18: 391-395.
- Myers JE, El-Sadr WM, Zerbe A, Branson BM. Rapid HIV self-testing: long in coming but opportunities beckon. AIDS 2013; 27: 1687-1695.
- National AIDS and STI Control Programme, Ministry of Public Health and Sanitation, Kenya. Guidelines for HIV Testing and Counselling in Kenya. 2008. Available at: https://www.who.int/hiv/ topics/vct/policy/KenyaGuidelines_Final2009.pdf.
- Ibitoye M, Frasca T, Giguere R, Carballo-Diéguez A. Home testing past, present and future: lessons learned and implications for HIV home tests. AIDS Behav 2014; 18: 933-949.
- 20. WHO. Report on the first international symposium on self-testing for HIV: the legal, ethical, gender, human rights and public health

implications of HIV self-testing scale-up: Geneva, Switzerland, 8-9 April 2013.

- WHO. Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services. 2016. Available at: https://iris.who.int/handle/10665/251655.
- WHO. WHO list of prequalified in vitro diagnostic products. 2019. Available at: https://extranet.who.int/prequal/sites/default/files/document_files/231120_prequalified_IVD_product_list.pdf.
- 23. WHO. HIV self-testing strategic framework: a guide for planning, introducing and scaling up. 2018. Available at: https://www.afro. who.int/publications/hiv-self-testing-strategic-framework-guideplanning-introducing-and-scaling.
- 24. WHO Prequalification of Diagnostics Programme Product: INSTI[®] HIV Self Test. WHO reference number: PQDx 0002-002-01. 2018. Available at: https://www.who.int/diagnostics_laboratory/evaluations/ pq-list/181130_pqdx_0002_002_01_pqpr_insti_self_test.pdf?ua=1.
- WHO. Market and technology landscape: HIV rapid diagnostic tests for self-testing. Geneva; 2018.
- WHO. Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services. 2016. Available at: https://iris.who.int/handle/10665/251655.
- 27. Odinga MM, Kuria S, Muindi O, Mwakazi P, Njraini M, Melon M, et al. HIV testing amid COVID-19: community efforts to reach men who have sex with men in three Kenyan counties. Gates Open Research 2020; 4: 117. DOI: 10.12688/gatesopenres.13152.2.
- 28. WHO. Innovative WHO HIV testing recommendations aim to expand treatment coverage. 2019. Available at: https://www. who.int/news/item/27-11-2019-innovative-who-hiv-testingrecommendations-aim-to-expand-treatment-coverage.
- Figueroa C, Johnson C, Verster A, Baggaley R. Attitudes and acceptability on HIV self-testing among key populations: a literature review. AIDS Behav 2015; 19: 1949-1965.
- Krause J, Subklew-Sehume F, Kenyon C, Colebunders R. Acceptability of HIV self-testing: a systematic literature review. BMC Public Health 2013; 13: 735. DOI: 10.1186/1471-2458-13-735.
- 31. Chanda MM, Ortblad KF, Mwale M, Chongo S, Kanchele C, Kamungoma N, et al. HIV self-testing among female sex workers in Zambia: a cluster randomized controlled trial. PLoS Med 2017; 14: e1002442. DOI: 10.1371/journal.pmed.1002442.
- 32. Choko AT, MacPherson P, Webb EL, Willey BA, Feasy H, Sambakunsi R, et al. Uptake, accuracy, safety, and linkage into care over two years of promoting annual self-testing for HIV in Blantyre, Malawi: a community-based prospective study. PLoS Med 2015; 12: e1001873. DOI: 10.1371/journal.pmed.1001873.
- 33. Sarkar A, Mburu G, Shivkumar PV, Sharma P, Campbell F, Behera J, et al. Feasibility of supervised self-testing using an oral fluid-based HIV rapid testing method: a cross-sectional, mixed method study among pregnant women in rural India. J Int AIDS Soc 2016; 19: 20993. DOI: 10.7448/IAS.19.1.20993.
- 34. Thirumurthy H, Masters SH, Mavedzenge SN, Maman S, Omanga E, Agot K. Promoting male partner HIV testing and safer sexual decision making through secondary distribution of self-tests by HIV-negative female sex workers and women receiving antenatal and post-partum care in Kenya: a cohort study. Lancet HIV 2016; 3: e266-e274. DOI: 10.1016/S2352-3018(16)00041-2.
- 35. Curlin ME, Gvetadze R, Leelawiwat W, Martin M, Rose C, Niska RW, et al. Analysis of false-negative human immunodeficiency virus rapid tests performed on oral fluid in 3 international clinical research studies. Clin Infect Dis 2017; 64: 1663-1669.
- WHO. Policy brief: WHO recommends HIV self-testing. 2016. Available at: https://www.paho.org/en/documents/policy-brief-whorecommends-self-testing-hiv.
- WHO. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. 2021. Available at: https://www.who.int/ publications/i/item/9789240031593.

- 38. Njau B, Covin C, Lisasi E, Damian D, Mushi D, Boulle A, et al. A systematic review of qualitative evidence on factors enabling and deterring uptake of HIV self-testing in Africa. BMC Public Health 2019; 19: 1289. doi: 10.1186/s12889-019-7685-1.
- 39. Pant Pai N, Sharma J, Shivkumar S, Pillay S, Vadnais C, Joseph L, et al. Supervised and unsupervised self-testing for HIV in high-and lowrisk populations: a systematic review. PLoS Med 2013; 10: e1001414. DOI: 10.1371/journal.pmed.1001414.
- Ontario HIV Treatment Network, Rapid Response Service. The risk of coercion in the context of HIV self-testing. 2019. Available at: http://www.ohtn.on.ca/rapid-response-the-riskof-coercion-in-thecontext-of-hiv-selftesting/ (Accessed: 08.01.2022).
- WHO. Country & Technical Guidance Coronavirus disease (COVID-19). 2020. Available at: https://www.who.int/emergencies/ diseases/novel-coronavirus-2019/technical-guidance.
- 42. Cambiano V, Ford D, Mabugu T, Napierala Mavedzenge S, Miners A, Mugurungi O, et al. Assessment of the potential impact and costeffectiveness of self-testing for HIV in low-income countries. J Infect Dis 2015; 212: 570-577.
- 43. Figueroa C, Johnson C, Ford N, Sands A, Dalal S, Meurant R, 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-e290. DOI: 10.1016/S2352-3018(18)30044-4.
- Stevens DR, Vrana CJ, Dlin RE, Korte JE. A global review of HIV self-testing: themes and implications. AIDS Behav 2018; 22: 497-512.
- 45. Majam M, Fischer AE, Rhagnath N, Msolomba V, Venter WD, Mazzola L, et al. Performance assessment of four HIV self-test devices in South Africa: a cross-sectional study. South Afr J Sci 2021; 117. DOI: https://doi.org/10.17159/sajs.2021/7738.
- 46. Johnson CC, Kennedy C, Fonner V, Siegfried N, Figueroa C, Dalal S, et al. Examining the effects of HIV self-testing compared to standard HIV testing services: a systematic review and meta-analysis. J Int AIDS Soc 2017; 20: 21594. DOI: 10.7448/IAS.20.1.21594.
- Wood BR, Ballenger C, Stekler JD. Arguments for and against HIV self-testing. HIV AIDS (Auckl) 2014; 6: 117-126.
- Steehler K, Siegler AJ. Bringing HIV self-testing to scale in the United States: a review of challenges, potential solutions, and future opportunities. J Clin Microbiol 2019; 57: e00257-19. DOI: 10.1128/ JCM.00257-19.
- UNAIDS. Prevention gap report. 2016 Available at: https://www.unaids.org/sites/default/files/media_asset/2016-prevention-gap-report_ en.pdf.
- 50. Wirtz AL, Clouse E, Veronese V, Thu KH, Naing S, Baral SD, et al. New HIV testing technologies in the context of a concentrated epidemic and evolving HIV prevention: qualitative research on HIV selftesting among men who have sex with men and transgender women in Yangon, Myanmar. J Int AIDS Soc 2017; 20: 21796. DOI: 10.7448/ IAS.20.01.21796.
- WHO. WHO recommends HIV self-testing: evidence update and considerations for success: policy brief. 2019. Available at: https:// iris.who.int/handle/10665/329968.
- 52. Vizcarra P, Pérez-Elías MJ, Quereda C, Moreno A, Vivancos MJ, Dronda F, et al. Description of COVID-19 in HIV-infected individuals: a single-centre, prospective cohort. Lancet HIV 2020; 7: e554e564. DOI: https://doi.org/10.1016/S2352-3018(20)30164-8.
- 53. Gervasoni C, Meraviglia P, Riva A, Giacomelli A, Oreni L, Minisci D, et al. Clinical features and outcomes of HIV patients with coronavirus disease 2019. Clin Infect Dis 2020; 71: 2276-2278.
- 54. Stover J, Bollinger L, Izazola JA, Loures L, DeLay P, Ghys PD, et al. What is required to end the AIDS epidemic as a public health threat by 2030? The cost and impact of the fast-track approach. PLoS One 2016; 11: e0154893. DOI: 10.1371/journal.pone.0154893.
- 55. WHO. Statement on HIV testing and counseling: WHO, UNAIDS re-affirm opposition to mandatory HIV testing. 2012. Available at: http://www.who.int/hiv/events/2012/world_aids_day/hiv_testing_ counselling/en.2012.

- 56. Marley G, Fu G, Zhang Y, Li J, Tucker JD, Tang W, et al. Willingness of Chinese men who have sex with men to use smartphone-based electronic readers for HIV self-testing: web-based cross-sectional study. J Med Int Res 2021; 23: e26480. DOI: 10.2196/26480.
- Van Dyk AC. Client-initiated, provider-initiated, or self-testing for HIV: what do South Africans prefer? J Assoc Nurses AIDS Care 2013; 24: e45-e56. DOI: 10.1016/j.jana.2012.12.005.
- Yeatman S, Chamberlin S, Dovel K. Women's (health) work: a population-based, cross-sectional study of gender differences in time spent seeking health care in Malawi. PLoS One 2018; 13: e0209586. DOI: 10.1371/journal.pone.0209586.
- 59. Dovel K, Shaba F, Offorjebe OA, Balakasi K, Nyirenda M, Phiri K, et al. Effect of facility-based HIV self-testing on uptake of testing among outpatients in Malawi: a cluster-randomised trial. Lancet Glob Health 2020; 8: e276-e287. doi: 10.1016/S2214-109X(19)30534-0.
- PEPFAR. PEPFAR Technical Guidance in Context of COVID-19 Pandemic. 2020. Available at: https://hivpreventioncoalition.unaids. org/resources/pepfar-technical-guidance-context-covid-19-pandemic.
- 61. Considerations for HIV self-testing in the context of the COVID-19 pandemicandits response: an operational update. 2021 Available at: ht-tps://www.psi.org/project/star/resource-library/considerations-for-hiv-self-testing-in-the-context-of-the-covid-19-pandemic-and-its-response-an-operational-update/.
- 62. HIV self-testing operational guide for the planning, implementation, monitoring and reporting of HIV self-testing. 2022. Available at: https://www.fhi360.org/sites/default/files/media/documents/epic-hiv-self-testing-guide.pdf.
- 63. National Department of Health. National HIV Self Screening Guidelines. 2018. Available at: https://knowledgehub.health.gov.za/ elibrary/national-hiv-self-screening-guidelines-2018.
- 64. Mulubwa C, Hensen B, Phiri MM, Shanaube K, Schaap AJ, Floyd S, et al. Community based distribution of oral HIV self-testing kits in Zambia: a cluster-randomised trial nested in four HPTN 071 (PopART) intervention communities. Lancet HIV 2019; 6: e81-e92. DOI: 10.1016/S2352-3018(18)30258-3.
- 65. Ministry of Health AIDS Control Program. Addendum to the HIV testing services policy & implementation guidelines. HIV self-testing & assisted partner. 2018. Available at: https://www.health.go.ug/wp-content/uploads/2021/05/Uganda-HIVST-APN-Addendum-2018_-Signed.pdf.
- 66. Rosengren AL, Huang E, Daniels J, Young SD, Marlin RW, Klausner JD. Feasibility of using Grindr[™] to distribute HIV self-test kits to men who have sex with men in Los Angeles, California. Sex Health 2016; 13: 389-392.
- 67. Guy RJ, Prestage GP, Grulich A, Holt M, Conway DP, Jamil MS, et al. Potential public health benefits of HIV testing occurring at home in Australia. Med J Australia 2015; 202: 529-531.
- Brown AN, Djimeu EW, Cameron DB. A review of the evidence of harm from self-tests. AIDS Behav 2014; 18: 445-449.
- 69. WHO. March 2014 supplement to the 2013 consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach. 2014. Available at: https://www.paho.org/fr/node/69612.
- Kumwenda M, Munthali A, Phiri M, Mwale D, Gutteberg T, Mac-Pherson E, et al. Factors shaping initial decision-making to self-test amongst cohabiting couples in urban Blantyre, Malawi. AIDS Behav 2014; 18: 396-404.
- Carballo-Diéguez A, Frasca T, Balan I, Ibitoye M, Dolezal C. Use of a rapid HIV home test prevents HIV exposure in a high risk sample of men who have sex with men. AIDS Behav 2012; 16: 1753-1760.
- Chen W, Liu F, Ling Z, Tong X, Xiang C. Human intestinal lumen and mucosa-associated microbiota in patients with colorectal cancer. PLoS One 2012; 7: e39743. DOI: 10.1371/journal.pone.0039743.
- 73. Makusha T, Knight L, Taegtmeyer M, Tulloch O, Davids A, Lim J, et al. HIV self-testing could "revolutionize testing in South Africa, but it has got to be done properly": perceptions of key stakeholders. PLoS One 2015; 10: e0122783. DOI: 10.1371/journal.pone.0122783.