

HIV Self-Testing in Southern Africa: Progress and Challenges

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Abstract: Pitfalls of HIV testing in health care facilities include fears over loss of privacy and confidentiality. HIV self-testing represents an innovative strategy to expand access to HIV testing services in the general population and also to reach individuals at high risk for HIV who may not otherwise submit to HIV testing, including young people and key populations. We conducted a systematic review of observational studies done in southern African countries between the 1st January 2016 to 15th March 2018 on HIVST with focus on progress made and challenges observed. Thirteen (13) observational studies satisfied the inclusion criteria. These studies were published between January 2016 and March 2018 across five southern African countries namely Zambia (3), Malawi (2), South Africa (5), Zimbabwe (1), Botswana (1). There was also a study done in both Malawi and Zimbabwe (1). HIVST is highly acceptable in southern Africa despite challenges ranging from gender differences, acquisition of test kits, lack of pre-test and post-test counseling, potential social harm and inadequate ability to following user's instructions.

Keywords: HIV self-testing, progress and challenges, observational studies, systematic review, southern Africa.

Introduction

The World Health Organization (WHO) (2018) estimated that only 75% of people living with HIV know their HIV status. Countries are looking for ways to rapidly increase uptake of HIV testing services, especially for populations with low access and those at higher risk that would otherwise not get tested. HIV testing has always been seen as the “keystone” of the HIV response [1]. While this view of HIV testing has not changed significantly over the years, the linkages between testing, prevention, treatment and care have. Emphasis on HIV testing as a gateway to prevention, treatment and care has grown tremendously over the past decade.

In turn, this emphasis on testing has created a demand for governments, public health agencies, and HIV organizations to develop new policies, programs, and approaches [2-3]. These efforts include the 90-90-90 strategy proposed by the Joint United Nations Programme on HIV/AIDS (UNAIDS) as well as many national strategies that target high coverage of diagnosis, treatment and viral suppression among people living with HIV in attempts to reduce HIV mortality and morbidity and ultimately end the HIV epidemic [4].

The strategy entails that proposing that by 2020 90% of all people living with HIV will know their status; 90% of all people diagnosed HIV infection will receive sustained antiretroviral therapy (ART); and 90% of all people receiving ART will have viral suppression.

Pitfalls of HIV testing in health care facilities include fears over loss of privacy and confidentiality, as well as potential stigma and discrimination, especially in young people and marginalized high-risk groups, such as female sex workers and homosexual men [5-7]. HIV self-testing (HIVST) represents an innovative strategy to expand access to HIV testing services in the general population and also to reach individuals at high risk for HIV who may not otherwise submit to HIV testing, including young people and key populations. In 2012, oral HIVST was approved by the US Food and Drug Administration [8].

HIV self-testing is a process in which a person collects his or her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone he or she trusts [9]. HIV self-testing does not provide a definitive HIV-positive diagnosis. All reactive (positive) self-test results need to be confirmed by a trained tester using a validated national testing algorithm. Non-reactive (negative) self-test results are considered negative. In 2016, WHO published the first global guidelines on HIV self-testing, in which HIV self-testing was recommended to be offered as an additional approach to HIV testing services [7].

In 2015 the UNITAID Self-Testing Africa (STAR) Initiative began the largest evaluation of HIV self-testing. At end 2014, just before the STAR Initiative began, it was estimated only 45% of people with HIV in sub-Saharan Africa knew their status [4]. The STAR Initiative's first phase generated crucial information about how to distribute HIVST products effectively, ethically and efficiently. Implemented initially in Malawi, Zambia and Zimbabwe, the first phase of the STAR Initiative was designed to address critical challenges to the development of the HIVST market. The STAR Initiative's second phase built on the evidence generated in the first phase to scale access to HIVST across sub-Saharan Africa and expanded implementation to three additional countries, Eswatini, Lesotho and South Africa with the aims of generating large-scale experience and evidence, contributing to reaching the first 90 target. By November 2018 STAR Initiative had distributed 2.3 million HIV self-test kits in Eswatini, Lesotho, Malawi, South Africa, Zambia and Zimbabwe. As a result HIV testing coverage has increased, with HIV self-testing reaching many men, young people and first-time testers. Now it is estimated 81% of people with HIV in sub-Saharan Africa are aware of their status.

In this study, we conducted a systematic review of observational studies done in Southern African countries between the 1st January 2016 to 15th March 2018 on HIVST with focus on progress made and challenges observed.

Methods

Database search

The electronic search of relevant publications was conducted between 1st January 2016 and 15th March 2018. Pubmed, Google scholar were searched for English language on human studies about AIDS. The medical terms used in different combinations in the search included the following:

- ✓ 'HIV self testing southern Africa',
- ✓ 'HIV self testing challenges', and
- ✓ 'HIV self testing OR challenges'.

Inclusion and exclusion criteria

The studies included satisfied the following criteria:

- (1) All were observational studies;
- (2) Conducted between January 2016 to March 2018;
- (3) Conducted in southern African countries

The studies which did not satisfy the inclusion criteria were excluded. Two reviewers assessed the eligibility for inclusion of the studies independently.

Data extraction

Data was obtained using a predesigned data collection form. The information extracted was the name of the author, year of publication, country of study, study design, sample size, gender and age of participants, situational analysis of HIV self testing exercise and challenges observed.

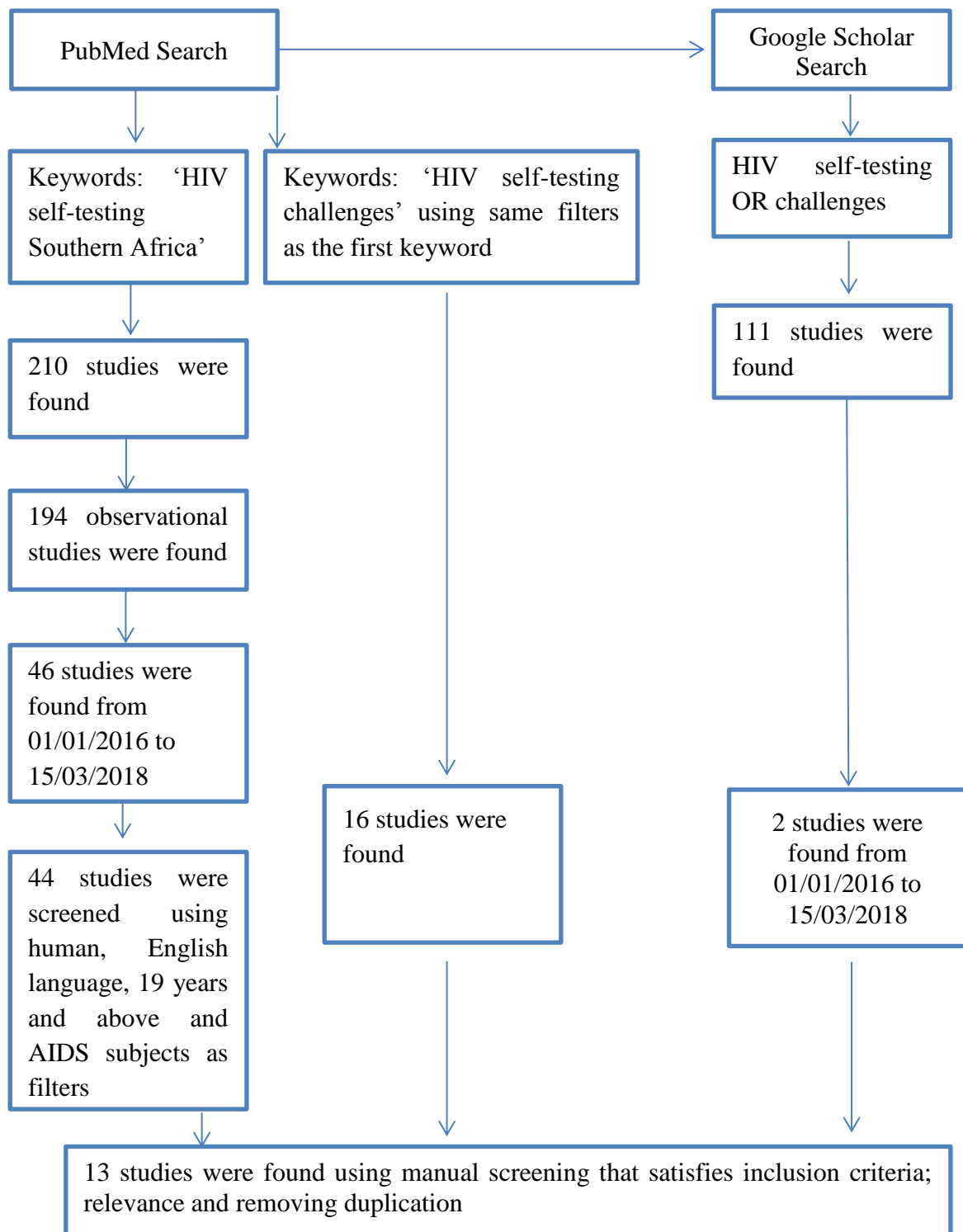


Figure 1. Flowchart of studies selection

Results

Description of included studies

Thirteen observational studies satisfied the inclusion criteria as indicated in Figure 1 above. These studies were published between January 2016 and March 2018 across five southern African countries

namely Zambia (3), Malawi (2), South Africa (5), Zimbabwe (1), Botswana (1). There was also a study done in both Malawi and Zimbabwe (1). The details of the studies are summarized in Table 1 below.

Assessment of progress on HIVST

Seven observational studies reflected on progress made in southern Africa about HIVST. The progress assessment is summarized in Table 2 below. The progress is compiled in terms of findings of each study and implications as well as future plans emanating from the findings. The progress covers (1) acceptability of HIVST by population groups, (2) preference of HIVST over other HIV testing technologies, (3) willingness to link to care following positive result of HIVST (4) testing with sex partners, and (5) willingness to purchase self-test kit.

Observed challenges to HIVST

Ten observational studies outlined several challenges to HIVST reflected by users. The compilation of the challenges is summarized in Table 3 below. In each study, identified challenges were presented, they cover (1) gender differences in willingness to self-test, (2) financial resources to acquire test kits, (3) potential for social harms (4) ability to follow user’s instructions for use of the HIVST kit, (5) commercially available kits versus their accuracy, (6) demand for ARVs and (7) threat to HCW jobs.

Table 1. Characteristics of studies included in the review

Author(s)	Country(s)	Study aim	Study design	Sample size	Age group (years)
Chipungu <i>et al.</i> (2017)	Zambia	Examination of the intention to link to care amongst potential HIVST users and the suitability of three linkage to care strategies in Lusaka Province, Zambia	Cross sectional survey	1,617 (60% females)	16-49
Gotsche <i>et al.</i> (2014)	Zambia	Investigation of ability of intended users of the OraQuick® HIV rapid self-test in Zambia to understand and follow the instruction for use.	Cognitive interviews	17 (77% males)	15+
Indravudh <i>et al.</i> (2017)	Malawi & Zimbabwe	Identifying young people’s preferences for HIV self-testing (HIVST) delivery, determining the relative strength of preferences and exploring underlying behaviors and	mixed methods	463	20 median age

		perceptions to inform youth-friendly services in southern Africa			
Indravudh <i>et al.</i> (2017)	Malawi	Assessment of user understanding of packaged HIVST kits and instructions-for-use and methods to optimize comprehension; and investigating feasibility, acceptability and accuracy of semi-supervised HIVST	Cognitive interviews and cross-sectional feasibility	360	16+
Kelvin <i>et al.</i> (2016)	South Africa	Providing pre-approval baseline data about potential users of the self-test	Qualitative descriptive study	20 (50% females)	Not provided
Kumwenda <i>et al.</i> (2018)	Malawi	Describing factors dissuading individuals in couples from self-testing with their partner	Qualitative descriptive	33 (61% female)	Not provided
Madanhire <i>et al.</i> (2016)	Zimbabwe	Exploration of health care workers' views on HIVST	Qualitative descriptive	43	Not provided
Mokgatle & Madiba (2017)	South Africa	Investigating the acceptability of HIVST among students in Technical Vocational Education and Training colleges in two provinces in South Africa	Cross-sectional survey	3,605 (57% females)	21.9 mean age
Moyo <i>et al.</i> (2017)	Botswana	Assessment of opinions and acceptability of HIVST amongst tertiary students	Qualitative descriptive	45 (56% females)	most were between 21-25 years
Nkuna & Nyazema (2016)	South Africa	Assessing the potential of HIVST to increase access to and uptake of HIV testing among health sciences	Qualitative descriptive	300 (51% females)	Not provided

		students, University of Limpopo			
Perez <i>et al.</i> (2016)	South Africa	Exploring reasons for declining provider-initiated counseling and testing or counseling and testing among community members of an informal settlement, and to ascertain the healthcare workers' and community members' perspectives on the acceptability of home O-HIVST as an alternative to clinic-based modes of testing.	Qualitative	20 (55% females)	20-47
Perez <i>et al.</i> (2016)	South Africa	Describing implementation of counsellor-introduced supervised OralST in a high HIV prevalent rural area	Cross-sectional	2,198 (66% females)	Mostly between 18-25 years
Zanolini <i>et al.</i> (2018)	Zambia	Assessing attitudes and preferences toward HIV self-testing (HIVST) among Zambian adolescents and adults	Population-based survey	1,617 (60% females)	16-49
Total Number of Participants				10,338 participants	

Table 2. Assessment of progress on HIVST

Author	Findings	Remarks
Chipungu <i>et al.</i> (2017)	<p>(1) Respondents were asked to imagine that they had taken an HIV self-test and their result was positive. Out of the 1,617 respondents, 85% (95%CI 83±86) said they would be willing to link to care within a week of having a positive result</p> <p>(2) Overall 53% (95%CI = 50 to 55) of respondents reported preferring a home visit from a health care worker, and 30% preferred a phone call,</p>	<p>In the first study of HIVST in Zambia, 85% of those participating in a representative survey reported that they would intend to link to care within a week if they used an HIVST and found they were positive.</p> <p>In order to encourage linkage to care, half of the respondents preferred to be followed up through home visits and one third</p>

	followed by 13% who preferred SMS	preferred phone calls. SMS was the least preferred because it was difficult to establish a relationship using this platform
Indravudh <i>et al.</i> (2017)	<p>(1) HIVST is highly acceptable to young people in Malawi and Zimbabwe as it empowers them to choose the location and timing of the test and control disclosure around their results.</p> <p>(2) Confidentiality was one of the main reasons why young people preferred HIVST. Young people's lack of trust of health workers and desire for confidentiality has motivated young people's preference for HIVST in this study</p> <p>(3) In the context of a gap between biological and psychosocial maturity, as well as discrepancies in cultural, social and legal definitions of maturity, promoting HIVST in young people may not be without conflicts, including denied or forced testing.</p>	<p>Being empowered to control one's own HIV testing process seems to be particularly appealing to young people</p> <p>Appropriate training of distributors and sensitization of parents and the wider community would therefore be needed.</p>
Mokgatle & Madiba (2017)	<p>(1) The acceptability of HIVST as a testing option was 87.1%.</p> <p>(2) The willingness of participants to purchase a self-test kit was 74.7%, while the willingness to submit HIVST results at a local clinic for inclusion in the HCT statistics which is necessary for the targets of the HCT uptake campaign was at 14.8%,</p> <p>(3) The willingness to confirm HIV positive self-test results at a local health facility was 75.6%.</p> <p>(4) Logistic regression showed that college students who were willing to uptake HIVST were at most four times more likely to test using HIVST with their sexual partners at unadjusted odd ratio (OR = 3.99; CI: 2.84±5.62). At adjusted odd ratio statistics show that college students who had ever tested for HIV within the HCT program were twice as likely to</p>	<p>The majority (87.1%) considered HIVST to be acceptable, and 84% would uptake HIV self-testing with partners. Being sexually active, having multiple sexual partners, and having been tested for HIV was associated with acceptability of HIVST.</p> <p>The HIVST is regarded as safe if implemented correctly to ensure the accuracy of the tests, and there is confirmation testing and referral for counseling and care</p> <p>HIV self-testing is acceptable in South Africa as an HIV testing option, and self-tests kit are available over the counter in pharmacies. Nonetheless, the high acceptability of HIVST among the students calls for extensive planning and preparation for the scaling up of HIVST beyond its availability in pharmacies</p>

	accept HIVST (OR = 2.13; CI:1.72±2.63).	
Moyo <i>et al.</i> (2017)	<p>(1) Most of the students were not aware of HIVST before the interviews, most found HIVST to be acceptable as an alternative testing option</p> <p>(2) The students indicated that they would utilize HIVST because it assures confidentiality and privacy, and would reduce the stigma concern that is associated with facility-based HCT</p>	HIV self-testing is an alternative testing option that can complement available HCT methods such as VCT and PITC provided in public health facilities in Botswana
Nkuna & Nyazema (2016)	<p>(1) There were a significant number of students who supported the introduction HIVST and did not seem concerned about possible risk associated with self-testing.</p> <p>(2) Interestingly, female students seemed concerned more about being pregnant than contracting HIV infection and appeared to be ready to know their HIV status</p>	<p>The investigation on the sale of HIVST kits found that they were indeed available at some pharmacy retail outlets.</p> <p>Self tests for HIV should fall under the definition of a ‘medical device’ in the Medicines and Related Substances Control Act (Act 101) of 1965, as amended).</p>
Perez <i>et al.</i> (2016)	(1) This research adds evidence of the need for self-testing service providers to ensure the five ‘Cs’ as outlined by the World Health Organization are guaranteed: consent, confidentiality, the opportunity for counselling, correct results, and linkage to care	In applying the knowledge this research contributes to programme implementers must consider that efforts are necessary in ensuring that future documented evidence of harms and benefits informs the counselling, support, and monitoring components of home self-testing.
Zanolini <i>et al.</i> (2018)	<p>(1) HIVST was found to be highly acceptable and participants expressed relatively few concerns regarding the introduction of HIVST. Importantly, those who had not recently tested reported strong willingness to learn their HIV status through a self-test</p> <p>(2) Participants also expressed a strong preference for counseling to be made available with HIVST as well as a willingness to pay US\$3–5 out-of-pocket for test kits.</p>	<p>Zambian adults expressed preference for HIVST over current HIV testing approaches and on average expressed a strong preference that counseling should accompany HIVST.</p> <p>HIVST scale-up should therefore be accompanied by adequate information about how and where to access confirmatory testing services in the event of a positive result, as well as innovative ways to access pre- and post-test counseling through services such as phone-based hotlines</p>

Table 3. Observed challenges to HIVST

Author	Findings
Gotsche <i>et al.</i> (2014)	(1) Participants struggled to open the test kit easily (2) Difficulty in instructions on collection of oral fluid by swabbing the gums (3) Understanding and interpreting images and particular terms (e.g. pouch, press firmly) was perceived challenging
Indravudh <i>et al.</i> (2017)	(1) 4 participants did not know where instructions began (2) 8 participants did not recognize symbols for cutlery prohibiting eating (3) 7 participants did not know how to tear open the package (4) 15 participants struggled to slide tube into stand (5) 15 participants did not understand steps to take after self-test
Kelvin <i>et al.</i> (2016)	(1) Associated with risk of mental distress and even suicide (2) Gender differences in willingness to use the self-administered test, with slightly more men reporting willingness than women (3) Women were also less confident that their partner would continue the relationship if they tested HIV-positive
Kumwenda <i>et al.</i> (2018)	(1) The community-based approach found women at home much more often when HIVST was offered through door-to-door approach (2) Conflicting work schedules between male and female sexual partners made one of the partners, particularly men, not available to receive HTC together with their partners
Madanhire <i>et al.</i> (2016)	(1) While they generally believed that HIVST can increase testing uptake among men, well-to-do clients and those living in hard-to-reach areas, a recurrent theme was that HIVST poses a threat to HCW jobs (2) The potential for social harms (domestic violence, suicide, and forced-testing) was widely discussed (3) HCW described fear that devices showing negative results could be "traded" and used to deceive partners of HIV-positive individuals
Perez <i>et al.</i> (2016)	(1) In spite of high accuracy, it must be noted that fourteen of our 2,198 study participants read their Oral-Quick™ as negative but had a positive Determine™ test. (2) There are several different oral rapid diagnostics devices currently available commercially; however, many of them have not yet been pre-qualified by WHO for self-testing
Indravudh <i>et al.</i> (2017)	(1) Given young people's low access to financial resources and strong aversion to price, the findings also show that uptake of HIVST may be limited if kits are not provided for free or at extremely low prices.
Mokgatle & Madiba (2017)	(1) There were significance gender differences for acceptability of HIVST among the students, with more females showing acceptability versus males ($p = 0.000$), more female students willing to confirm HIV-positive test results at a health facility, more female students citing willingness to submit HIVST test results at the nearest health facility ($p = 0.03$), more females willing to use HIVST with their sexual partners ($p = 0.000$), and willing to buy HIVST kits ($p = 0.000$). (2) The cost of an HIV self-test kit has been identified as a potential barrier to adoption, willingness to use, purchase, and the uptake of HIVST, particularly among people in poor-resource settings. Despite the students being from poor-resource settings, we found

	that three quarters (75%) reported the willingness to purchase self-testing kits
Moyo <i>et al.</i> (2017)	(1) The students in the current study who were against HIVST, indicated that they would not utilize HIVST because of the lack of post-test counseling support. They indicated that they might harm themselves because of a positive HIVST results. (2) HIVST will also require the purchase of the test kits over the counter at a pharmacy or from other retailers depending on how the policy of distribution is developed. This will introduce a cost to HIV testing; the concern for the argument against HIVST is that not everyone will be in a position to afford the self-testing kit.
Nkuna & Nyazema (2016)	(1) The student Health Centre seemed not to be ready for the introduction of HIVST. Their main concerns were possible self-stigmatization and increased demand of ARVs.

Discussion

The current systematic review involved 10, 338 participants consisting of mainly females aged between 15-49 years. The review was made thirteen observational studies conducted on five countries (Zambia, Malawi, South Africa, Botswana and Zimbabwe). Majority of the studies qualitative studies (9/13) aimed at exploring users' perspectives about HIVST. HIV self-testing was implemented in different phases in these countries. Malawi, Zambia and Zimbabwe come from the first pilot phase of implementation while South Africa was covered on expansion of implementation in the second phase. Botswana was not part of the UNITAID Self-Testing Africa (STAR) Initiative which was the largest evaluation of HIV self-testing in southern Africa started in December 2015.

HIV self-testing is highly acceptable by adolescents and young adults in southern Africa [11, 18-20, 15, 22]. Most people who test for HIV using HIVST are willing to refer themselves to nearby health facilities for confirmation of positive test results and to link themselves to care and treatment of HIV infection [15-16 & 18]. In comparison with other rapid HIV testing technologies, HIVST is regarded as an acceptable alternative to HIV testing [11, 16, & 19-20]. Although HIVST kits are currently available commercially in most settings, users are willing to purchase the self-test kits [18, 22].

A scoping study conducted in sub-Saharan Africa (SSA) revealed that similar to global rates, there is a broad range of acceptability rates for HIVST in SSA; ranging between 22% and 95% [23]. HIVST is acceptable and feasible, can be disseminated through high-risk peer networks, and increases testing frequency and partner testing. A longitudinal HIVST study conducted in South Africa among men who have sex with men (MSM) indicated an extremely high uptake and acceptability of HIVST following distribution of HIV self-testing kits [24].

Despite the fact HIVST is a highly acceptable HIV testing technology; gender differences pose mixed perspectives to testing [12-14, & 18]. More females showed more acceptability to HIVST than males ($p > 0.001$) and willingness to confirm HIV-positive test results at a health facility ($p = 0.03$) [18]. In some settings, more females are willing to use HIVST with their sexual partners ($p > 0.001$), and willing to buy HIVST kits than males ($p > 0.001$) [18] and other settings reveal that more men than women said that they would test with their partner, and women were less certain that their partners would be willing to self-test with them. Women were also less confident that their partner would continue the relationship if they tested HIV-positive [12].

Another key issue identified with gender differences was gender unavailability. The social positions of men and women shaped by the normative gender roles and gender stereotypes made it difficult for men to access HIVST delivered through a community-based approach. HIVST was mostly offered during the normal working hours, the community counselors found women at home more often, as

men had gone to work. Women commonly stated that they self-tested without a partner because the male partner was at work when HIVST was offered [13].

Furthermore on the scoping review done in SSA, there is a more unique pattern of gender disparities in HIVST acceptability rates was observed; with acceptability rates of HIVST being much higher for men compared to women. Men prefer HIVST as it does not require for them to present at medical facilities for testing, often associated with loss of income due to absence from work [23]. The disparity was consistent even in situations whereby women attending maternal and child health (MCH) and family planning (FP) services were requested to distribute HIVST kits to their men counterparts. Most women reported that their partners accepted and used self-test [26].

Although HIVST is highly acceptable, the cost of self-test kit has been identified as a potential barrier to adoption, willingness to use, purchase, and the uptake of HIVST, particularly among people in poor-resource settings [11 & 18-19]. In some settings participants revealed that even if the test kits were subsidized, the fact that there would be a cost attached to the testing might be prohibitive to the potential users [19]. HIVST was highly accepted by young people, if provided at no or very low cost since young people are also rarely financially independent [11].

Although HIVST was found to reduce costs of reduced travel, clinical costs and time away from work, purchasing of HIV self-test kit also becomes a barrier to testing. Some participants expressed concern about potentially high fees and preferred to use existing free clinic-based HCTS than purchase HIVST kits in a qualitative study done in Tanzania [25].

It has been noted in this review that HIV testing without adequate counseling stands a potential to harm due to psychological distress [12, 14, & 20]. Participants indicated that they might harm themselves because of a positive HIVST result [20]. The potential for social harms such as domestic violence, suicide, and forced-testing were widely perceived [14].

In a public opinions and perspectives quantitative study done in Nigeria on HIV self-testing concerned raised were that counselors are no longer concerned about suicide and self-harm after testing since the treatment is widely available. However, these are still potential risks and there is still the need to provide adequate messaging and information to prevent potential harm [27].

The user's ability to perform the HIVST correctly is important to obtain a valid test result. Incorrect usage usually results in a negative result rather than an invalid one, which may falsely reassure the user [10-11]. HIVST pilot studies conducted in Malawi and Zambia on user ability to follow the manufacturer's instructions for use revealed that literacy may not guarantee ability to follow instructions for use.

The key findings of challenge to participants in following instructions for use were test preparation, specimen collection, timing, misinterpretation of universal symbols and illustrations, understanding purpose and use of each equipment of the kit and challenges with result interpretation [10-11]. Consistently, there were minor and major errors observed using the oral fluid (OF) and fingerstick (FS) HIV self test kits respectively. The errors included conducting procedures randomly without following the correct order [24].

Despite the fact that HIVST is highly acceptable with some challenges to users, it calls for preparation and readiness for countries to implement HIVST especially in resource-limited settings. The integration of HIVST into existing provider-initiated HIV diagnosis initiatives poses a threat to healthcare work jobs that primarily provide testing and counseling [14]. It was perceived that while HIVST might be cheaper, this was likely further justification for job losses. However, many of oral rapid diagnostics devices currently available commercially have not yet been pre-qualified by WHO

for self-testing [15]. In addition the staff mentioned that HIVST might lead to the demand for more ARVs which would not be met by current consumption based procurement systems [20].

In conclusion, HIVST is highly acceptable in southern Africa despite challenges ranging from gender differences, acquisition of test kits, lack of pre-test and post-test counseling, potential social harm and inadequate ability to following user's instructions. It is further recommended that for optimization of acceptability of the test, the issues of obtaining test kits at a cost, lack of associated counseling and frequent public education on how to use the kit be addressed.

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