ASSESSING THE POWER OF HIV SELF-TESTING IN UNREACHABLE POPULATIONS IN SUB-SAHARAN AFRICA

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Editorial: Assessing the power of HIV self-testing in unreachable populations in sub-Saharan Africa

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HIV self-testing, unreachable populations, sub-Saharan Africa, key populations, men

Editorial on the Research Topic
Assessing the power of HIV self-testing in unreachable populations in sub-Saharan Africa

Introduction

HIV self-testing has been touted as the game-changer in HIV testing uptake with high HIV testing rates reported in studies conducted in low and middle-income countries, a majority of which were conducted in sub-Saharan Africa (1). In this highly successful Research Topic, we assessed the power of HIV self-testing in reaching unreachable populations in sub-Saharan Africa. Overall, 17 papers have been published in response to this Research Topic from eight countries (Mali, Senegal, Cote d'Ivoire, Ghana, South Africa, Uganda, Zimbabwe, and the Democratic Republic of Congo); 14 papers in volume 1 and three papers in volume 2. The papers published as part of this Research Topic demonstrate that HIV self-testing has the power to reach a diversity of unreachable populations including men who have sex with men (MSM), female sex workers (FSW), people who use drugs (PWUDs), truck drivers, men in the general population, and other unreachable populations. This Research Topic has received a high level of visibility with over 41,000 views by October 23, 2022.

Key and priority populations

Evidence shows that HIV testing uptake among key populations (KPs) remains sub-optimal despite the fact that these populations contribute up to 51% of new

HIV infections in sub-Saharan Africa (2). Four studies reported on different approaches used to reach KPs with HIV self-testing services. Abubakari et al. used community-based interventions, enhanced with mobile platforms and digital technology, as opportunities to increase HIV self-testing and linkage to HIV care among MSM in Ghana. Abubakari et al. worked with community-based organization partners to implement three interventions that successfully engaged and retained MSM which provided an opportunity for linkage to HIV self-testing and medical care. d'Elbee estimated the cost of integrating HIV self-testing into 23 civil society organization (CSO)-led models for key populations in Senegal, Cote d'Ivoire, and Mali and found that providing HIV self-test kits to KPs through CSOs was not only cost-effective but had varying levels of cost-effectiveness. The team found that the cost of reaching female sex workers with HIV self-testing services was much lower than that for reaching MSM and PWUDs (FSW: $13–17; MSM: $15–28; PWUDs: $16–144). Okoboi et al. found that the cost per new HIV-positive MSM identified ($325 vs. 914) and the cost per HIV transmission averted ($6,253 vs. 17,567) through HIV self-testing was much lower than the cost per new HIV-positive MSM identified and new HIV transmissions averted through conventional HIV testing services. The team concluded that HIVST was not only cost-effective but also identified more undiagnosed HIV infections than standard-of-care HIV testing. Kra et al. described the adaptations that the HIV self-testing teams used to navigate the challenges posed by the COVID-19 pandemic including the use of social networks by MSM peer educators to maintain contact with their peers, promote HIV prevention and testing, and organize face-to-face or small group meetings, as needed. These adaptations were essential for the continued provision of HIV self-testing services during the COVID-19 lockdown in Mali, Senegal, and Cote d'Ivoire.

Truck drivers

Mantell et al. and Kelvin et al. found that truck drivers preferred blood-based HIV testing over oral-based HIV self-testing. In the study by Kelvin et al. 305 truck drivers were randomized to receive oral HIV self-test kits or stand-of-care HIV testing and followed up for 6 months. At the end of the follow-up period, HIV testing uptake was similar [56.3% in the intervention arm and in the standard-of-care arm (55.6%)], with those who did not test for HIV in both arms citing reasons related to lack of time to test for HIV, low HIV risk behavior, fear of knowing their HIV status and recent HIV testing. When asked to choose between blood-based and oral HIV self-testing, 69.4% preferred blood-based HIV testing. Similar results were reported by Sithole et al. who found that of the men who were given the option to choose between oral or blood-based HIV self-test kits, 62% (1,624) preferred to use the blood-based kits while 38% (1,010) selected to use the oral fluid kits; suggesting a growing interest in blood-based HIV self-test kits. This interest is usually driven by beliefs, particularly among men, that since HIV is found in blood, then, blood-based HIV self-testing strategies could yield the most realistic results (3).

Men in the general population

Men in the general population have been dubbed as the missing link in HIV prevention programming. Three studies assessed approaches for reaching men with HIV self-testing services. Sithole et al. used community-based recruitment procedures, including distributing HIV self-test kits at venues where men were likely to congregate, e.g., taxi pranks, to reach men with HIV self-testing services in KwaZulu-Natal, South Africa. The team found that reaching men in places where they congregate was not only feasible but also highly effective in reaching men, including those who had not previously tested for HIV. However, Tonen-Wolyec et al. found that linkage to HIV care was much lower in men than women, suggesting that despite the increasing HIV testing rates and identification of new HIV-positives as a result of HIV self-testing, additional innovative approaches are still needed to improve linkage to HIV care among men who self-test HIV-positive. Muwanguzi et al. found that the use of phone reminders; consistent, open and regular communication with the research team; providing HIV-positive men with an enabling, non-stigmatizing health environment; the ease with which HIV-positive men with referral forms were attended to by health workers, and trust that health workers would keep their HIV-positive status confidential, facilitated HIV-positive men to link to HIV care. Future studies should assess the extent to which a combination of these interventions can help to enhance linkage to HIV care among men who are reluctant to link to HIV care or if they do so, they link to HIV care late, usually with advanced HIV disease.

Other populations

Amstutz et al. assessed the cost of reaching absent or refusing individuals through provision of HIV self-testing services in the intervention arm, as part of a home-based, randomized controlled HIV testing intervention in rural Lesotho. The team concluded that adding HIV self-testing to conventional HIV testing services not only increased HIV testing coverage by 21% but also reduced the cost per person tested. Sithole et al. used 63 men and women living with HIV participating in an HIV treatment trial in KwaZulu-Natal, South Africa, as HIV self-test kits distributors to reach their social and sexual networks. HIV self-test kits distributors took 218 kits; of these, 143 (65.6%) were reported as used by their recipients. Forty-two per cent of the testers were first-time testers. However, linkage to HIV care remained low with only 9% of the 11 HIV-positive individuals identified were linked to HIV care. McGowan et al. explored

PrEP naïve and PrEP-experienced adolescent girls and young women's (AGYW) willingness to engage in a peer-delivered HIV self-testing and referral model for PrEP initiation in Kiambu County, Kenya. Study findings show that PrEP-experienced AGYW were willing to initiate discussions about HIV self-testing and PrEP use among their peers, to deliver HIV self-test kits to them, and to refer them to appropriate HIV prevention, care and treatment services, based on their HIV status. PrEP-naïve AGYW were also willing to receive and use HIV self-test kits delivered to them by their peers and to link to appropriate HIV prevention, care and treatment services based on their HIV test results. Muchedzi et al. distributed 11,983 kits between 2018 and 2020 in Zimbabwe; of these, 99.5% (11,924/11,983) were used and results were returned to the health care workers. Of the returned HIVST results, 22.3% (2,658/11,924) were reactive and, of these, 2,610 (98.2%) results were confirmed HIV positive by a trained health care worker using the national testing algorithm. The highest positivity rate was reported among users aged 35–49 years (25.5%, $n = 667$). The prevalence of HIV in the study population was nearly twice as high as the prevalence reported among adults 15 years or older in the 2020 Zimbabwe Population-based HIV Impact Assessment survey (22.3 vs. 12.9%) (4).

Moving the HIV self-testing agenda forward

Evidence from two papers, published as part of this Research Topic, shows that policymakers and other key stakeholders consider HIV self-testing to be an opportunity to reduce stigma; preserve anonymity and confidentiality; reach key populations that do not access HIV testing *via* conventional HIV testing strategies; remove spatial barriers; save time for users and providers; and empower users with autonomy and responsibility (Nagai et al.; Ky-Zerbo et al.). However, as Ky-Zerbo et al. reported, stakeholders doubted potential HIVST users' autonomy regarding their ability to use HIVST kits correctly; to ensure quality secondary distribution; to accept a reactive test result; and to use confirmation testing and care services. Similar sentiments have been reported in other settings where HIVST interventions are being introduced for the first time (5–7) and suggest a need for pre-project implementation stakeholder meetings to identify and address such fears as part of HIVST project initiation activities. Due to the low partner HIV status disclosure among PLHIV (Boye et al.), future interventions will need to enhance HIV disclosure as part of HIV self-testing promotional strategies, especially in populations with traditionally low HIV disclosure rates. As Hamilton et al. have argued, probably there is no one intervention strategy that will work universally to increase HIV testing uptake and linkage to appropriate HIV prevention or care and treatment services. Multiple interventions will be needed to reach men and other unreachable populations with HIV self-testing services including peer-to-peer distribution, use of community health counselors, use of trained lay distributors selected by the community, and integration of HIV self-testing services into other HIV services. Also, multiple interventions will be needed to enhance linkage to HIV care including home-based ART initiation, use of phone reminders, and community-based ART initiation.

Author contributions

JKBM wrote the initial draft. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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SYSTEMATIC REVIEW
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HIV Self-Testing Uptake and Intervention Strategies Among Men in Sub-Saharan Africa: A Systematic Review

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Background: HIV testing is an essential gateway to HIV prevention and treatment services. However, HIV testing uptake remains low among men due to stigma, discrimination, and confidentiality concerns. HIV self-testing (HIVST) is an alternative HIV testing method that can address many of these barriers for men. We conducted a systematic review to examine HIVST uptake and intervention strategies among Men in Sub-Saharan Africa.

Methods: We used a systematic approach to survey literature published from January 2010 to June 2020 using five electronic databases (PubMed-Medline, CINAHL Complete, PsychINFO, Google Scholar, and Web of Science) and a manual search. Studies were included if they were peer-reviewed, published in English, and examined HIVST willingness, uptake, and/or linkage to care and included men in Sub-Saharan Africa.

Results: Sixty-three articles related to HIVST were reviewed. Of the included articles, 37 discussed HIVST uptake/acceptability and 24 discussed intervention strategies. Both oral swab and finger-prick methods had high acceptability with ease of access and availability of the test cited as important by men. Free HIVST kits were preferred by men. Secondary distribution of kits via peers, sexual partners, and female sex workers were successful.

Conclusion: HIV self-testing is highly acceptable to men. More efforts are needed to develop policies to implement HIVST programs targeting men in Sub-Saharan Africa, including a focus on linkage to care in sub-Saharan Africa. Future interventions should

directly target men independently in tandem with using peers and their romantic partners to promote self-testing among men in sub-Saharan Africa. HIVST kit distribution strategies should be combined with services that can offer confirmatory tests and counseling for men as well as linkage to care.

Keywords: HIV, self-testing, men, Sub-Sahara Africa, systematic (literature) review

INTRODUCTION

As of 2018, almost 37.9 million people worldwide were infected with HIV (1), with only 75% of people living with HIV (PLWH) globally being aware of their HIV status (1). The Joint United Nations Programme on HIV/AIDS (UNAIDS) responded by developing an ambitious treatment plan to end the HIV/AIDS epidemic. The objective was for 90% of all PLWH to become aware of their HIV status, 90% of those be linked to sustained antiretroviral treatment (ART) so that 90% of people receiving ART could achieve viral suppression (2). HIV testing is an essential gateway to initiate HIV prevention and treatment services. Yet, most individuals who are at high risk of contracting HIV or who are already infected with HIV are not accessing HIV testing at a high enough rate due to fear of stigmatization, inadequate treatment by healthcare workers, and/or confidentiality concerns (2). In sub-Saharan Africa, the increasingly widespread availability of HIV testing remains hindered by the perceived psychological burden of having to live with HIV, financial barriers, as well as gender inequality (3). Furthermore, men in sub-Saharan Africa are less likely to be self-aware of their HIV status compared to their female counterparts (3). This can be attributed to the exposure of women to HIV testing through antenatal services as well as to misguided masculinity norms (4, 5). In nations like Uganda and Tanzania, a lack of knowledge of HIV status is the limiting factor in getting people to engage in prevention and treatment programs (6). The 2016–2017 Tanzania HIV Impact Survey showed that only 45% of men living with HIV (MLWH) were aware of their positive HIV status (7). Eighty-six percent of MLWH who knew their HIV status reported initiation of ART, and 84% of those undergoing ART had been virally suppressed and were significantly less likely to transmit HIV to others (6). HIV screening is a hallmark in being able to provide linkage to care and in turn halt the transmission of HIV. Various interventions have been employed throughout the last decade to determine the most effective way of encouraging men to get tested for HIV, including antenatal clinic-based testing for upcoming fathers, community-based testing, workplace testing, home-based testing, and most promising of all, self-testing.

HIV self-testing (HIVST) is an alternative HIV testing method that can overcome many barriers to testing, including stigma, privacy concerns, time and expense associated with traveling and waiting at the clinic for men. In HIVST an individual can use a kit to collect a specimen, perform the test (usually a rapid diagnostic test) which screens for HIV-1/2 antibodies or the HIV-1 p24 antigen (8), and interpret the test results for themselves. A positive result requires confirmatory testing at a clinical facility which allows for more accurate diagnoses as well as for those persons to easily become linked to ART (8). This promising approach overcomes the initial stigmatization of HIV testing by promoting privacy and security (8). In 2018, the World Health Organization (WHO) reported that 59 countries worldwide had taken up HIVST and 53 additionally were developing policies (8). However, around two thirds of these nations have upper middle- or high-income status, including Australia, Brazil, France, Moldova, the UK, and USA (8). HIVST pricing in low- to middle-income countries, like those in sub-Saharan Africa, is expected to decrease significantly thanks to the Bill & Melinda Gates Foundation's recent agreement to support the affordable sale of Oraquick Self-Testing Kits in order to continue the scale-up of HIV testing in these higher risk areas (9). In November 2018, the UNITAID Self-Testing Africa Initiative distributed nearly 2.3 million HIVST kits in East and South Africa, with a significant number given to countries like South Africa, Zimbabwe, Malawi, Zambia, eSwatini, and Lesotho (9). Between 2015 and 2017, nearly 628,700 self-test kits were distributed to Malawi, Zambia, and Zimbabwe, with close to half of all people self-testing being men and between 14 and 27% not having previously tested for HIV (9). One study in Kisumu, Kenya that distributed self-test kits to women receiving antenatal services for their male partners, discovered that 90.8% of male partners had tested for HIV in the self-testing group compared to only 51.7% of partners in the facility-based testing group (10). Another study performed by PopART in Zambia that observed the rate of uptake when HIVST were distributed door-to-door showed success in increasing awareness of HIV status among men (11).

We conducted a systematic review to examine the HIVST literature focusing on men in Africa. While past research has presented findings from a global review regarding HIVST (12–17), there are currently no systematic reviews published for HIVST uptake and intervention strategies among men in sub-Saharan Africa. In this review, we aim to systematically identify relevant articles to address this gap and to provide implications for future research.

METHODS

This review adopted and followed the guidance provided by the Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA) (18) and was registered with PROSPERO (registration number: CRD42020138729). A literature search was completed by a trained librarian for articles which matched the criteria for inclusion. To ensure ample coverage in the search process, the following electronic databases were

surveyed: CINAHL, PsycINFO, PubMed, Web of Science, and Google Scholar. Both Boolean-paired keywords and controlled vocabulary pertaining to HIVST strategies for men in sub-Saharan Africa were used. Search strategies included terms, such as HIV, HIV self-testing, HIVST, HIV testing, Self-Testing, Men, Male(s), Willingness, Uptake, Intervention(s), Africa, Sub-Saharan Africa, West-Africa, East Africa, southern Africa, and all sub-Saharan African country names.

Inclusion Criteria

Articles were included in this review if they met the following criteria: (1) the research was conducted in sub-Saharan Africa, (2) reported findings on HIVST, among men aged 16 years or older, (3) the research was peer-reviewed and published in English. Articles were excluded if the research was unpublished, if they were written in languages other than English, or if they were not published between January 2010 and June 2020. Articles were considered to be "current literature" if they were published within the past 10 years; therefore, articles published prior to this time were not included in this review. The included articles focused on men who were deemed as being at-risk for HIV infection and living in sub-Saharan Africa.

Data Extraction

Two research team members independently reviewed the results of the database search in an Endnote file. The team members first reviewed the titles and abstracts of all articles, after duplicate articles were removed, in order to assess the relevance of each article. The articles were grouped into one of two categories, either "Selected for Full-Text Review" or "Does Not Meet Inclusion Criteria." Data were then extracted from the articles categorized as selected for full-text review. Ninety-seven articles were selected to be reviewed in full. The two research members summarized the selected articles according to their methods and findings with the aim of assessing if they met the full inclusion criteria. The research members also independently read the included articles in their entirety and summarized their methods, design, and results in order to confirm the appropriateness for being included in the final sample of included articles. Any discrepancies or confusion pertaining to the included articles for which consensus could not be reached by the two research members, was settled by a third research team member.

Quality Assessment

In order to assess the methodological and research quality of each article that is included in this review, appropriate quality assessment tools were used. Two team members independently rated each included article using a pre-determined and agreed upon acceptable scoring requirement for each assessment. The Critical Appraisal Skills Programme (CASP) (19) was used to evaluate qualitative studies; included articles had to meet at least seven of ten listed criteria. Included articles evaluated using the Quality Assessment Tool for observational cohort and cross-sectional studies (20) were required to meet at least eleven of fourteen listed criteria. Included articles evaluated using the Cochrane Risk of Bias Tool for randomized trials (21) were required to have a low level of assessed bias in the four domains (selection, performance, attrition, and other). Studies that scored poorly on either of the quality assessment tools were removed from inclusion.

Chosen Methodology

A narrative synthesis approach was used to present the results of this review. Narrative synthesis allows for the synthesis of the findings of multiple studies in a qualitative manner (22). We organized each article by themes, such as HIVST uptake and intervention strategies. The findings of each article were matched with their appropriate theme; however, some articles were included in multiple themes.

RESULTS

The results of the database searches yielded 7,620 articles; following the removal of duplicate articles, 5,368 articles remained (**Figure 1**). Articles ($n = 5{,}271$) were then excluded for multiple reasons, such as not discussing HIVST, study populations not being in sub-Saharan Africa, article not being written in English, or the article was not a peer-reviewed original article. Ninety-seven articles were selected for full-text review. Thirty-six articles were excluded because they did not meet the full-inclusion criteria. Sixty-one articles met the full-inclusion criteria and are presented in this review (see **Figure 1**). Fourteen sub-Saharan countries were represented in included studies (**Table 1**). The frequency of represented countries in included articles were as follows: Botswana (1), Ethiopia (1), Kenya (14), Lesotho (1), Malawi (12), Mozambique (1), Nigeria (1), Rwanda (2), Senegal (1), South Africa (21), Tanzania (4), Uganda (9), Zambia (5), and Zimbabwe (4). The designs of the articles included: cluster randomized trial (2), cohort study (4), cross-sectional survey (7), demonstration study (4), discrete choice experiment (3), experimental exploratory design (1), feasibility study (1), implementation project (1), individual-based scholastic model (1), longitudinal study (1), mixed methods (1), multiple models of distribution (e.g., community based, mobile outreach, workplace, public health facilities, etc.) (1), non-experimental descriptive study (1), prospective study (2), qualitative (e.g., in-depth interviews, focus groups, etc.) (26), randomized clustering (1), randomized controlled trial (RCT) (9), single-arm pilot trial (1), and three-phase trial (1). Of the included articles, 37 focused on HIVST uptake/acceptability, and 24 focused on intervention strategies; however, data extracted from each article is presented under its appropriate subsection regardless of study focus.

HIVST Knowledge

Regarding knowledge of HIVST, in Uganda, researchers found that most participants had never heard of HIVST (23). In Tanzania, A lack of knowledge was found for HIVST with only 22% of participants having heard of HIVST (27). In another study, most healthcare users (HCU) (69.9%), consisting of both men and women reported having heard of HIVST in South Africa (30). Additionally, in South Africa, only 3.9% of men had ever heard of oral HIVST prior to the study (47). Lastly, less than half of students (46.2%) knew what HIVST was prior to the administration of a survey in South Africa (50).

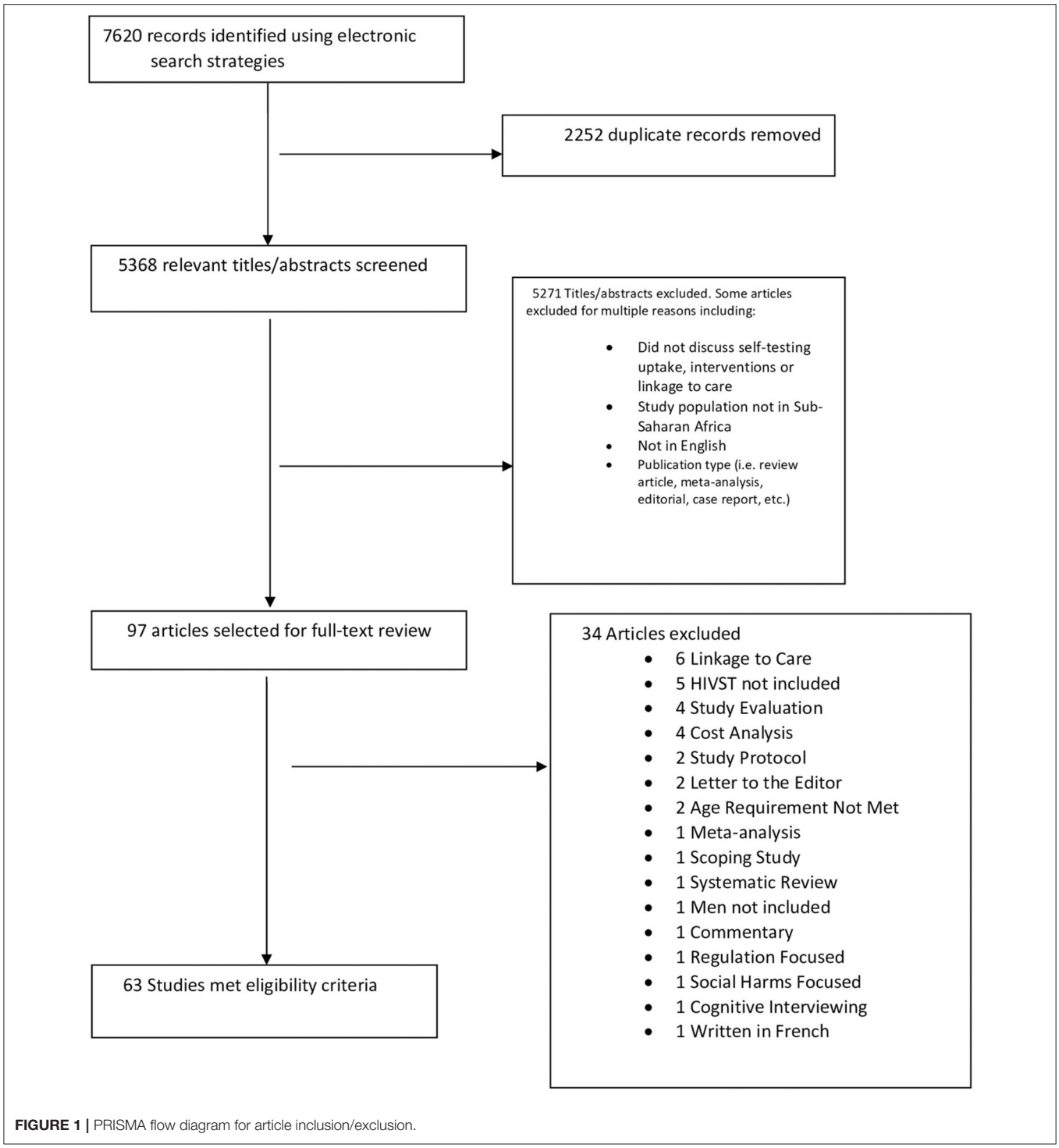

FIGURE 1 | PRISMA flow diagram for article inclusion/exclusion.

Acceptability and HIVST Benefits

In South Africa, preferences of testing were associated with patient autonomy, violation of human rights, confidentiality and privacy, fear of discrimination and stigma, and an aversion to mandatory face-to-face counseling with participants favoring HIVST for these reasons (57). One cross-sectional study from Malawi, Kenya, and South Africa reported that participants were in support of the idea of an accurate, easy-to-use, rapid HIVST and believed that this could increase testing across all populations (58). Furthermore, in Uganda, both men and women believed HIVST was a strategy that could address men's lack of time to go to the health facilities to test for HIV (49). In South Africa, in support of the testing method, HIVST was deemed acceptable (55). In Kenya the acceptability rate for

TABLE 1 | Included articles.

Theme	References	Included countries	Study population	Study design	Sample size	Main findings
HIVST uptake/ Acceptability	Burke et al. (23)	Uganda	Healthcare providers and community members in high-risk fishing communities	In-depth interviews and focus groups	30 men; 25 women	Most participants were not familiar HIVST but believed there were benefits associated: privacy, convenience, and being able to test before sex. Perceived barriers included absence of professional support, poor disposal of kits, and delayed linkage to care.
	Cambiano et al. (24)	Botswana, Lesotho, Malawi, Nigeria, Rwanda, Tanzania, Uganda, Zambia, Zimbabwe	Women having transactional sex, young people, adult men	Individual-based scholastic model	Not specified	Community-based HIVST had the greatest impact with adult men with an average of 1,500 HIV infections averted.
	Choko et al. (25)	Malawi	Men and women	Formative qualitative study	8,643 men; 8,017 women	76.5% of residents self-tested during months a 12-month period. Persons aged 16–19 were most likely to test.
	Choko et al. (26)	Malawi	Pregnant women and their male partners	Formative qualitative study	18 men; 20 women	Male partners reported a preference for HIVST due to its perceived privacy and reduction of associated stigma.
	Conserve et al. (27)	Tanzania	Men	In-depth interviews	23 participants	Seventy-eight percent of participants had never heard of HIVST; sixty-five percent of participants were willing to use HIVST in the future.
	Conserve et al. (28)	Tanzania	Men	In-depth interviews	23 men	HIVST willingness was highly acceptable among both male ever-testers and never-testers. Some 72% of ever-testers vs. 67% of never-testers reported being willing to self-test.
	Dzinamarira et al. (29)	Rwanda	Key stakeholders	In-depth interviews	10 men; 3 women	Key stakeholders perceived HIVST as an effective initiative that may be used to increase uptake of testing services for underserved populations in Rwanda.
	Gumede and Sibiya (30)	South Africa	Men and women	Quantitative, non-experimental descriptive study	442 healthcare users	Most healthcare users (HCU) (69.9%), consisting of both men and women, reported having heard of HIVST in South Africa. Most HCU (81.2%) perceived HIVST as a strategy that could lead to more people knowing their HIV status.
	Harichund et al. (31)	South Africa	Men and women	Qualitative comparative cross-over	12 men; 28 women	Naïve testers were confident in performing unsupervised HIST but reported desiring more counseling support during the testing process.
	Harichund et al. (32)	South Africa	Men and women	Qualitative comparative cross-over	12 men; 28 women	Men deemed HIVST acceptable because of its convenience and efficiency.
	Harichund et al. (33)	South Africa	Men and women	Focus groups and individual interviews	63 participants	HIVST is advantageous when provided in combination with existing services. All distribution models had high male participation in the country.
	Hatzold et al. (34)	Malawi, Zambia, Zimbabwe	Adults and adolescents	Multiple models of distribution (e.g., community based, mobile outreach, workplace, public health facilities, etc.)	294,508 men; 130,223 women	Male partners believed secondary distribution of HIVST kits to be acceptable due to its convenience, confidentiality, privacy, and its ability to allowed men to avoid the clinic
	Hector et al. (35)	Mozambique	Adolescents	Demonstration study	496 students	Over 80% of participants selected directly assisted HIVST compared to standard FS testing and of those who selected HIVST, 20% opted to perform HIVST at home. More than three-fourths of participants (76%) preferred to do HIVST at the health center due to the presence of a counselor.
	Hershow et al. (36)	Malawi and Zambia	Male partners; pregnant and postpartum women	Qualitative formative study	28 male partners; 80 pregnant/	Of three male partner HIV testing strategies (HIV partner notification, partner HIV self-testing, and partner home-based HIV testing) the majority of participants (both men and women) accepted all three partner testing modalities; however, male

(Continued)

TABLE 1 | Continued

Theme	References	Included countries	Study population	Study design	Sample size	Main findings
					post-partum women	partners were split in their preferences for the three partner testing modalities. Most women and male partners thought home-based testing and secondary distribution of HIV self-test kits were acceptable. Secondary distribution of HIVST kits was thought to be convenient, ensured confidentiality, allowed men to avoid the clinic, and allows for couples testing privately. Home-based testing was thought to be convenient and would provide savings in time and transport money, and helpful to have health workers present to provide counseling.
	Janssen et al. (37)	South Africa	Men and women	Observational cohort study	14 men; 16 women	A smartphone app used in tandem with an oral HIVST was able to help people through the self-testing process by providing counseling and care and simplifying the process of self-testing. The app was able to multiple common HIV testing barriers, such as lack of confidentiality, wait times and testing locations. The app also enabled testing services outside a clinic context or within a clinic; however, an additional layer of privacy was added by using the app. Participants were able to use the app-based HIVST strategy unsupervised at home, unsupervised alone at the Kiosk around the clinic, or supervised under direct supervision of staff at the clinic.
	Kebede et al. (38)	Ethiopia	HCWs	Cross-sectional study design triangulated with qualitative method	307 HCWs	Both oral swab and finger-prick methods had high acceptability. Ease of access and the availability of the test were cited as being of importance.
	Knight et al. (39)	South Africa	Men and women	In-depth interviews	50 lay users	Individual motivations for HIVST included perceived benefits of access to treatment. HIVST was regarded as convenient, confidential, reassuring and an enabling new way to test with one's partner.
	Kumwenda et al. (40)	Malawi	Cohabitating couples	Analysis of baseline data within a 12-month qualitative longitudinal cohort study nested into a cluster randomized trial	17 couples (34 participants)	Men sometimes required persuasion even though they believe HIVST is more flexible than traditional testing.
	Kurth et al. (41)	Kenya	Men and women	Prospective validation study	161 men; 78 women	The acceptability rate for HIVST was 94%. The main theme in the behavioral study was affordability; participants were willing to pay up to 111 Ksh (around $1.25 USD) for an HIVST kit.
	Lebina et al. (42)	Uganda	Men and women	HIV self-screening demonstration project	808 men; 809 women	Some 68.7% of participants selected unsupervised HIVST while 25% opted for supervised HIVST and 6.3% chose semi-supervised.
	Lyons et al. (43)	Senegal	Men and women	Experimental design	1,959 participants	Most participants (74.5%) were comfortable using HIVST, 86.1% found the instructions easy to follow, and 94.4% believed their family or friends would use it.
	Majam et al. (44)	South Africa	Lay users	Cross-sectional study	777 men; 633 women	Participants had a high average usability index of 93.8% for HIVST; some 96.6% of participants found HIVSTs easy to use.
	Makusha et al. (45)	South Africa	Key stakeholders	In-depth interviews	12 participants	Stakeholders expressed high enthusiasm regarding HIVST, its scale-up, and the development of HIVST policies and programming. Perceived barriers included a lack of counseling and Difficulty in ensuring linkages to care among those with positive results.
	Martínez-Pérez et al. (46)	South Africa	Men and women	Mixed-methods research	9 men; 11 women	Participants believed that home O-HIVST uptake would not necessarily lead to higher uptake. It was also believed that men that would show the most interest in using home O-HIVST compared to their female counterparts.
	Martínez-Pérez et al. (47)	South Africa	Men and women	Cross-sectional study	741 men; 1,457 women	Only 3.9% of men had heard about oral HIVST prior to the study. Uptake of oral HIVST was 25.4%

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TABLE 1 | Continued

Theme	References	Included countries	Study population	Study design	Sample size	Main findings
	Matovu et al. (48)	Uganda	Pregnant women and their male partners	Cross-sectional qualitative study	62 FGD participants with pregnant women and 30 IDI with male partners of pregnant women	Most women were willing to take the kits to their male partners and male partners reported being willing to use HIVST kits provided to them by their female partner. Women believed that HIVST could help to improve couples' HIV testing.
	Matovu et al. (49)	Uganda	Pregnant women and their male partners	In-depth interviews	32 participants	Men reported skepticism regarding HIVST and whether or not the kits could actually test for HIV, but this was not a deterrent to its use. Both men and women believed HIVST is a strategy that could address men's lack of time to go to the health facilities to test for HIV.
	Mokgatle and Madiba (50)	South Africa	Technical vocational education and training college students	Cross-sectional survey	1,565 male and 2,040 female students recruited from 13 colleges	Less than half of students (46.2%) were knowledgeable of what HIVST is prior to the administration of the survey. Still, HIVST acceptability was high among the students (87.1%); three-quarters of students were willing to purchase an HIVST kit and many reported being willing to self-test with their partners.
	Njau et al. (51)	Tanzania	Individuals, community leaders, experts	Focus groups and in-depth interviews	21 men; 33 women	Participants reported positive attitudes toward HIVST, supportive perceived norms, and self-efficacy.
	Peck et al. (52)	Kenya, Malawi, South Africa	Lay users	Formative usability research—In-depth interviews	150 Participants	Users found instructions for HIVST to be confusing and/or difficult to follow. Less than 25% of participants completed the test successfully without errors. Results interpretation was difficult for participants.
	Ritchwood et al. (53)	South Africa	Young adults	Focus groups and direct observation	19 men; 16 women	Participants deemed HIVST acceptable due to its privacy, ease of use, and trustworthiness.
	Sibanda et al. (54)	Zimbabwe	Men and women	Discrete choice experiment	128 men; 168 women	The strongest preference for kits was price—every $1 increase in price increased disutility. Door-to-door delivery of kits was highly preferred compared to kit distribution to batch deliveries.
	Spyrelis et al. (55)	South Africa	Men and women	Focus group discussions	118 participants	HIVST was deemed acceptable; however, men had concerns (potential suicidality) regarding the lack of HIV counseling associated with HIVST. Privacy and confidentiality were perceived benefits of HVST.
	van Dyk (56)	South Africa	Men and women	Semi-structured questionnaire	147 men; 319 women	Preferences of testing were associated with patient autonomy, violation of human rights, confidentiality and privacy, fear of discrimination and stigma, and an aversion to mandatory face-to-face counseling.
	van Dyk (57)	South Africa	Men and women	Semi-structured questionnaire	147 men; 319 women	Twenty-two percent of participants preferred HIVST; however, 66% of participants (mostly men) preferred client-initiated testing. Participants reported being willing to use HIVST if it included telephone counseling and if it were available in their communities.
	van Rooyen et al. (58)	Kenya, Malawi, South Africa	Government policy makers, academics, activists, donors, procurement specialists, laboratory practitioners, and health providers	In-depth interviews	54 participants	Participants were in support of the idea of an accurate, easy-to-use, rapid HIVST and believed that this could increase testing across all populations.
	Zanoli et al. (59)	Zambia	Households	Structured survey questionnaire	1,617 Participants	After being informed about HIVST, 91% of participants reported being comfortable with using a self-test; 87% believed that HIVST would increase their likelihood of testing.

(Continued)

TABLE 1 | Continued

Theme	References	Included countries	Study population	Study design	Sample size	Main findings
Intervention strategies	Asiimwe et al. (60)	Uganda	Men and women	Un-blinded randomized non-inferiority trial	141 men; 105 women	Participants were randomized to either an unsupervised HIVST group or a provider supervised HIVST group. Unsupervised HIVST was able to identify 90% of HIV-infected persons.
	Chang et al. (61)	Zimbabwe	Men and women	Randomized clinical trial	1,155 men; 2,841 women	Participants were provided vouchers to be redeemed for HIVST within 1 month at prices between $0 and $3 at multiple sites. A high sensitivity to price for HIVST was realized among men, rural residents, and persons who had never tested for HIV. Reduced-priced or free tests increased demand
	Choko et al. (25)	Malawi	Men and women	Prospective study nested within a cluster-randomized trial	6,124 men; 7,868 women	Participants received pre-test counseling, instructions on how to perform HIVST, and were asked to demonstrate their understanding of how to use the kit; 10% of participants required help or made errors while using the kits. The estimated uptake of HIVST was >80%. Uptake was greater among women than men.
	Choko et al. (62)	Malawi	Adult members of 60 households and 72 members of community peer groups	Population-weighted randomized clustering	298 adult participants	Participants were offered self-testing plus confirmatory HTC (parallel testing with two rapid finger-prick blood tests), standard HTC alone, or no testing. Some 91.9% of participants chose to self-test following a demonstration and illustrated instructions.
	Choko et al. (63)	Uganda	Men	Single-arm pilot-trial of secondary distribution of HIVST kits	116 men	Seeds (peer distributors) distributed HIVST kits to men. Eighty-two percent of men accepted HIVST kits. Ninety-seven percent of recruited men and 100% of seeds reported being willing to recommend HIVST to their friends and family.
	Choko et al. (64)	Malawi	Pregnant women and male partners	Adaptive multi-arm, multi-stage cluster randomized trial	676 men; 2,349 women	Secondary distribution of HIVST kits provided by women to their male partners increased the proportion of men who tested and linkage to care and prevention services if accompanied by financial incentives and reminder calls.
	Gichangi et al. (65)	Kenya	Pregnant women and male partners	Randomized controlled trial	362 men; 387 women	Three-arm randomized control study of participants randomized to receive either standard-of-care plus standard information card, an information card referencing male HIV testing, or two oral HIVST kits, and HIV testing information. In the intervention group (arm 3), 82% of men reported HIV testing as a couple, compared with 28% in arm one and 37%in arm two.
	Hensen et al. (66)	Zambia	Men and women	Randomized controlled trial	3,677 men; 5,428 women	PopART intervention used door-to-door delivery of HTS and included HIVST. Uptake of secondary distribution of HIVST was 9.1%, of which, 55.8% of kits were reported to have been used.
	Kalibala et al. (67)	Kenya	HCWs	Semi-structured pretested questionnaire and in-depth interview	842 HCWs	Thirty-four of surveyed HCWs used the kit on themselves; seventy-three percent provided a kit to their partner.
	Kelvin et al. (68)	Kenya	Truck drivers	Randomized controlled trial	305 male truck drivers	Participants were recruited from two roadside wellness clinics in Kenya. Participants were randomized on a 1:1 basis to either the SOC arm (provider-administered FS test) or the Choice arm (choice of SOC test or self-administered oral rapid test). The Choice arm had significantly greater odds of testing uptake. Of those in the Choice arm who tested, 26.9% selected the SOC test, 64.6% chose supervised self-testing in the clinic, and 8.5% took a test kit for home use. Participants varied in the HIV test they selected when given choices.
	Kelvin et al. (69)	Kenya	Truck drivers	Randomized controlled trial	2,262 male truck drivers	Texting about the availability of HIVST kits increased testing rates from 1.3 to 3.5%.
	Kisa et al. (70)	Uganda	Pregnant women and male partners	Cross-sectional study nested within a cluster randomized HIVST trial	51 women; 44 men	Most participants (94.7%) underwent repeat HIVST with a returned 2.1% positivity rate.

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TABLE 1 | Continued

Theme	References	Included countries	Study population	Study design	Sample size	Main findings
	Kumwenda et al. (71)	Malawi	Men and women	In-depth interviews nested in a cluster randomized trial	33 participants	Community counselors provided HIVST to community members through a community-based model prior to the interviews. More men than women declined joint HIVST due to fear of their infidelity being exposed.
	Lippman et al. (72)	South Africa	MSM	Three-phase trial	133 MSM	Men were recruited over three phases (different locations) of which they were given HIVST kits. Errors were committed by persons in both the OF and FS group; however, participants successfully performed the OF test while FS was less consistent. FS was a more preferred option than OF.
	Lippman et al. (73)	South Africa	MSM	Longitudinal study	127 MSM	Men were given up to nine test kits, either OF or FS, to use themselves or to provide to their social networks. Almost all MSM (91%) self-tested. A majority of men (80%) preferred HIVST to testing at a clinic.
	Marwa et al. (74)	Kenya	Pregnant women and male partners	Randomized controlled trial	1,107 couples	Three-arm RCT of participants randomized to either arm one (SOC), arm two (letter of invitation for partner to test, and arm three (letter and instructions on how to use HIVST and two HIVSTs with counseling). Men in arm three were twelve times more likely to test when compared to arm one. improved male invitation letter increased the likelihood of male partner testing by twelve times.
	Masters et al. (10)	Kenya	Men and women	Randomized controlled trial	600 women	Participants were randomized in a 1:1 ratio using balanced block randomization to an HIVST group or a comparison group. Participants in the HIVST group received two oral-fluid-based rapid HIV tests alongside written instructions and a brief demonstration of how to use the test. Male partner HIV testing was higher (90.8 vs. 51.7%) among participants in the HIVST group. Couples testing was also more likely in this group (75.4 vs. 45.8%).
	Moore et al. (75)	South Africa	Men and women	Cohort study	33 men; 606 women	The sending of short message service (SMS) to participants aided participants in reporting HIVST results.
	Mugo et al. (76)	Kenya	Pharmacy clients	Exploratory feasibility study	225 men; 238 women	Staff at five pharmacies recruited clients and offered participants HIVST kits for $1 USD. Participants were contacted for post-test data collection and counseling. Almost all testers stated they would like to use HIVST again in the future, and that they were likely (19%) or very likely (80%) to recommend self-testing to a friend, partner or family member.
	Pintye et al. (77)	Kenya	Women and their male partners	Implementation project	3,620 women	Some 93% of women offered an HIVST to their male partner. Of those women, 95% of male partners used a self-test.
	Schaffer et al. (78)	Uganda	Men	Discrete choice experiment	203 men	When presented as a choice, distribution of HIVST kits at local pharmacies reported the lowest predicted uptake and was higher among men who perceive a higher relative risk of having HIV.
	Strauss et al. (79)	Kenya	Truck drivers	Discrete choice experiment	305 male truck drivers	Participants were presented with hypothetical options of making trade-offs between different characteristics of HIV testing services delivery models by making hypothetical choices in a series of paired HIV testing scenarios to identify which HIV testing characteristics influenced the selection of preferred options. Drivers who had previous testing experience preferred oral testing and counseling via telephone while drivers with no testing experience preferred clinic-based testing.
	Strauss et al. (80)	Kenya	Truck drivers	Randomized control trial	150 male truck drivers	Cost drove the preference of between self-testing and provider administered testing. Self-testers preferred oral-testing vs. finger-prick testing.
	Thirumurthy et al. (81)	Kenya	Women	Cohort study	280 participants	Study staff instructed one arm of women on how to use OF based rapid HIV tests and provided them multiple test kits. The other arm was given three test kits each and FSW IPs were given five test kits each. Ninety-one percent of women in antenatal care and 86% in post-partum care distributed HIVST kits to their primary sexual partners. Seventy-five percent of female sex workers distributed HIVST kits to their clients.

HIVST was 94% (41). Both oral fluid (OF) and finger-stick (FS) methods had high acceptability of which ease of access and the availability of the test were cited as being of importance (38) and FS was preferred to OF tests, both in South Africa (72). In Kenya, self-testers preferred OF vs. FS (80). However, South African participants believed that the acceptability of home OF uptake would not necessarily lead to higher uptake of the test (46). Furthermore, participants also believed that men would show the most interest in using home OF compared to their female counterparts (46). In Zimbabwe, door-to-door delivery of kits was highly preferred compared to kit distribution to batch deliveries (54). After being informed about HIVST, 91% of participants reported being comfortable with using a self-test; 87% believed that HIVST would increase their likelihood of testing in Zambia (59). Still, naïve testers were confident in performing unsupervised HIVST but reported desiring more counseling support during the testing process in South Africa (32). South African men deemed HIVST acceptable because of its convenience and efficiency (33). In South Africa, participants deemed HIVST acceptable due to its privacy, ease of use, and trustworthiness (53). HIVST acceptability was high among the students (87.1%) (50). In South Africa, researchers found that participants had a high average usability index of 93.8% for HIVST (44). In Tanzania, participants reported positive attitudes toward HIVST, supportive perceived norms, and self-efficacy (51). In Malawi and Zambia, most women and male partners thought home-based testing and secondary distribution of HIV self-test kits were acceptable (36). In Uganda, women believed that HIVST could help to improve couples' HIV testing (48). In Kenya, truck drivers, who had previous testing experience, preferred oral testing and counseling via telephone while drivers with no testing experience preferred clinic-based testing (79). In Malawi and Zambia, of three male partner HIV testing strategies (HIV partner notification, partner HIV self-testing and partner home-based HIV testing) most participants (both men and women) accepted all three partner testing modalities; however, male partners were split in their preferences for the three partner testing modalities (36). Key stakeholders perceived HIVST as an effective initiative that may be used to increase uptake of testing services for underserved populations in Rwanda (29).

In South Africa, some 96.6% of participants found HIVST easy to use (44) and Individual motivations for HIVST included perceived benefits of access to treatment. HIVST was regarded as convenient, confidential, reassuring and an enabling new way to test with one's partner (39). In Senegal, most participants (74.5%) were comfortable using HIVST, 86.1% found the instructions easy to follow, and 94.4% believed their family or friends would use it (43). Participants in Uganda believed there were benefits associated with HIVST, such as privacy, convenience (55), and being able to test before sex (23). In Rwanda, most HCU (81.2%) perceived HIVST as a strategy that could lead to more people knowing their HIV status (30). In Malawi, individual motivations for HIVST included perceived benefits of access to treatment; HIVST was regarded as confidential, reassuring and as a novel way to test with one's partner (40). South African stakeholders, consisting of two government officials, four non-governmental organization stakeholders, two donors, three academic researchers, and one international stakeholder, expressed high enthusiasm regarding HIVST, its scale-up, and the development of HIVST policies and programming (45). Secondary distribution of HIVST kits was thought to be convenient, ensured confidentiality, allowed men to avoid the clinic, and allows for couples testing privately in Malawi and Zambia (36). Home-based testing was thought to be convenient and would provide savings in time and transport money, and helpful to have health workers present to provide counseling (36). In South Africa, 22% of participants preferred HIVST; however, 66% of participants (mostly men) preferred client-initiated testing (56). In Malawi, male partners reported a preference for HIVST due to its perceived privacy and reduction of associated stigma (26). In Kenya, almost all testers stated they would like to use HIVST again in the future, and that they were likely (19%) or very likely (80%) to recommend self-testing to a friend, partner or family member (76). Also, 97% of recruited men and 100% of seeds (peer distributors) reported being willing to recommend HIVST to their friends and family in Malawi (63).

In South Africa, a smartphone app used in tandem with an oral HIVST was able to help people through the self-testing process by providing counseling and care and simplifying the process of self-testing (37). The app was able to multiple common HIV testing barriers, such as lack of confidentiality, wait times, and testing locations (37). The app also enabled testing services outside a clinic context or within a clinic; however, an additional layer of privacy was added by using the app (37). Participants were able to use the app based HIVST strategy unsupervised at home, unsupervised alone at the Kiosk around the clinic, or supervised under direct supervision of staff at the clinic (37).

Willingness to Use HIVST

In Tanzania, 65% of participants were willing to use HIVST in the future (27) and HIVST willingness was high among both male ever-testers and never-testers with 72% of ever-testers vs. 67% of never-testers reported being willing to self-test (28). Most women were willing to take the kits to their male partners and male partners reported being willing to use HIVST kits provided to them by their female partners in Uganda (48). Participants reported being willing to use HIVST if it included telephone counseling and if it were available in their communities in South Africa (56). Three-quarters of students were willing to purchase an HIVST kit and many reported being willing to self-test with their partners in South Africa (50).

Uptake

Broadly, several community-based HIVST interventions throughout sub-Saharan Africa reported that the most significant impact has been with adult men, with an average of 1,500 HIV infections averted (24). HIVST was found to be advantageous when provided in combination with existing services, which resulted in several distribution models having high male participation in Malawi, Zambia, and Zimbabwe (34). Uptake of oral HIVST was reported as 25.4% in South Africa (47). One study conducted in Malawi reported that 76.5% of residents self-tested during a 12-month period (25). In South Africa, almost all men who have sex with men (MSM) (91%) self-tested

and most men (80%) preferred HIVST to testing at a clinic (73). Furthermore, an overall estimated uptake of HIVST >80% was reported with uptake being greater among women than men (25). Also, 91.9% of participants chose to self-test following a demonstration and illustrated instructions (62). Both accessibility and availability to HIVST were influential to uptake as described in a study from Ethiopia (38).

Finally, both unsupervised and supervised HIVST were preferred across sub-Saharan populations for varying reasons. In Johannesburg, South Africa, it was reported that 68.7% of participants selected unsupervised HIVST, while 25% opted for supervised HIVST and 6.3% chose semi-supervised (42). In Mozambique, when asked to choose a test to be administered, over 80% of participants selected to perform directly assisted HIVST compared to standard FS testing and of those who selected HIVST, 20% opted to perform HIVST at home (35). Still, more than three-fourths of participants (76%) opted to perform HIVST at the health center due to the presence of a counselor (35).

HIVST Barriers

In Uganda, perceived barriers for HIVST included the absence of professional support, poor disposal of kits, and delayed linkage to care (23). Participants in Malawi sometimes required persuasion even though they believe HIVST is more flexible than traditional testing (40). Perceived barriers included a lack of counseling and difficulty in ensuring linkages to care among those with positive results in South Africa (45). Participants had concerns (potential suicidality) regarding the lack of HIV counseling associated with HIVST in South Africa (55). Participants from Central Uganda reported skepticism regarding HIVST and whether the kits could actually test for HIV, but this was not a deterrent to its utilization (49). Also, in a cross-sectional study from Malawi, Kenya, and South Africa, it was reported that participants found instructions for HIVST to be confusing and/or difficult to follow (52). Less than 25% of participants completed the test successfully without errors (52). Results interpretation was difficult for participants (52). In South Africa, errors were committed by participants in both the oral fluid (OF) and finger stick (FS) group; however, most participants successfully performed the OF test while FS was less consistent. Lastly, in 10% of participants needed help or made errors while using HIVST kits in Malawi (62).

INTERVENTION STRATEGIES

Twenty-four articles reported various intervention strategies regarding HIVST. Strategies included choices of testing strategies, cost/financial incentives, distribution strategies, and miscellaneous strategies.

Choices/Options of Testing

In Kenya, participants were presented with options of making trade-offs between different characteristics of HIV testing service delivery models by making hypothetical choices in a series of paired HIV testing scenarios to identify which HIV testing characteristics influenced the selection of preferred options (79). In Uganda, when presented as a choice, distribution of HIVST kits at local pharmacies reported the lowest predicted uptake and was higher among men who perceive a higher relative risk of having HIV (78).

Participants were recruited from two roadside wellness clinics in Kenya and were randomized on a 1:1 basis to either the standard of care (SOC) arm (provider-administered FS test) or the Choice arm (choice of SOC test or self-administered oral rapid test) (68). The Choice arm had significantly greater odds of testing uptake. Of those in the Choice arm who tested, 26.9% selected the SOC test, 64.6% chose supervised self-testing in the clinic, and 8.5% took a test kit for home use. Therefore, participants varied in the HIV test they selected when given choices (68). In South Africa, MSM were recruited over three phases (different locations) when they were given HIVST kits (72). Still, texting about the availability of HIVST kits increased testing rates from 1.3 to 3.5% in Kenya (69). Furthermore, the sending of short message service (SMS) to participants aided participants in reporting HIVST results in South Africa (75).

Cost/Financial Incentives

Free HIVST kits were preferred compared to kits available to be purchased by male and female regular testers to overcome the financial burden associated with obtaining HTS, a prominent deterrent for linkage to care in several developing sub-Saharan nations (15). Cost (free vs. paid) drove the preference between self-testing and provider administered testing in Kenya (80). In Zimbabwe, participants were provided vouchers to be redeemed for HIVST within 1 month at prices between $0 and $3 at multiple sites (61). A high sensitivity to price for HIVST was realized among men, rural residents, and persons who had never tested for HIV, while reduced-priced or free tests increased HIVST demand (61). Also, in Zimbabwe, the strongest preference for kits was price—every $1 increase in price increased disutility (54). Staff at five pharmacies recruited clients and offered participants HIVST kits for $1 USD in Kenya (76). In one paper, the main theme in the behavioral study was affordability; participants were willing to pay up to 111 Kenyan shillings (Ksh) (around $1.25 USD) for an HIVST kit (41).

HIVST Distribution Strategies

In Uganda, seeds (peer distributors) distributed HIVST kits to men; 82% of men accepted HIVST kits from their peers (63). Community counselors provided HIVST to community members through a community-based model prior to the interviews in Malawi (71). More men than women declined joint HIVST due to fear of their infidelity being exposed (71). In South Africa, MSM were given up to nine test kits, either OF or FS, to use themselves or to provide to their social network (73). In Kenya, 93% of women offered an HIVST to their male partner and of those women, 95% of male partners used a self-test (77). Hospitals were randomly selected from each region of Kenya (67). Thirty-four of surveyed HCWs used the kit on themselves; 73% provided a kit to their partner in Kenya (67). Also in Kenya, staff instructed two arms of women from antenatal and postpartum clinics on how to use OF based rapid HIV tests and provided them multiple test kits; the women were given three test kits each and FSWs were given five test kits

each (81). Ninety-one percent of women in antenatal care and 86% in post-partum care distributed HIVST kits to their sexual partners. Seventy-five percent of female sex workers distributed HIVST kits to their clients (81). Secondary distribution of HIVST kits provided by women to their male partners increased the proportion of men who tested, linkage to care, and prevention services if accompanied by financial incentives and reminder calls (64). In Zambia, door-to-door delivery of HIV Testing Services (HTS) was offered to participants and included HIVST (66).

In a three-arm RCT, participants were randomized to either arm one [standard of care (SOC)], arm two (letter of invitation for partner to test), and arm three (letter and instructions on how to use HIVST and two HIVSTs with counseling) in Kenya (74). Men in arm three were twelve times more likely to test when compared to arm one; improved male invitation letter increased the likelihood of male partner testing by twelve times (74). Also, in Kenya, a three-arm RCT of participants randomized to receive either SOC plus standard information card, an information card referencing male HIV testing, or two oral HIVST kits, and HIV testing information (65). In the intervention group (arm 3), 82% of men reported HIV testing as a couple, compared with 28% in arm one and 37% in arm two (65). Uptake of secondary distribution of HIVST was 9.1%, of which, 55.8% of kits were reported to have been used (66).

Miscellaneous Strategies

In Malawi, participants received pre-test counseling, instructions on how to perform HIVST, and were asked to demonstrate their understanding of how to use the kit (25). Participants were also offered self-testing plus confirmatory HTC (parallel testing with two rapid finger-prick blood tests), standard HTC alone, or no testing (62). In Uganda, participants were offered HIVST or standard of care in a cluster randomized HIVST trial; most participants (94.7%) underwent repeat HIVST with a returned 2.1% positivity rate after having used the kits (70) In Uganda, participants were randomized to either an unsupervised HIVST group or a provider supervised HIVST group; unsupervised HIVST able to identify 90% of HIV-infected persons (60).

DISCUSSION

We completed a systematic review to assess published articles regarding HIVST uptake and intervention strategies among men in sub-Saharan Africa. Though more attention and research has been paid to HIVST in recent years, men in sub-Saharan Africa are still not testing at rates consistent with their female counterparts. The intervention strategies found in this review aimed to increase HIV testing for men in some capacity. Novel approaches, such as the targeting of truck drivers who are at high risk of HIV infection at truck stops in Kenya (80) offer the chance of accessing such a hard-to-reach niche group. Still, other strategies have been used successfully as well. In a study ineligible for inclusion in this review, community health counselors have been used to target hard-to-reach populations as well as reported in a recent a study (82). To sustain awareness of the availability of HIVST, counselors consistently sensitized their communities through the distribution of flyers and regular interaction with potential clients (82). Over a 12-month period, counselors achieved over 80% adult uptake of HIVST within their respective cluster (82). Neuman et al. (83) developed a protocol for HIVST to be provided by trained lay distributors selected by the community. Trials evaluated the effectiveness of distribution of HIVST kits by community-based distribution agents on uptake of HIV testing (83). Strategies, such as these are necessary for increasing the uptake of HIVST. There is no one intervention strategy that will work universally for meeting the needs of all men in the sub-Saharan Africa region. It is important that multiple strategies be employed in several locations in order to better locate men and provide what they need to be tested for HIV.

Overall, HIVST was found to be acceptable and when surveyed, most participants reported being willing to either use HIVST kits themselves and/or recommend it to family and friends. Research has provided further evidence of the acceptability of HIVST. A study, not included in this review, found that 96% of participants reported that they would use a self-test if it were available to them and 95.5% would recommend a self-test to their sexual partners (84). Secondary distribution of HIVST kits to men by peers or their partners were highlighted in this review and are advantageous ways to reach some men. These avenues of HIVST kit distribution should continue to be utilized. HIVST kit distribution via female sex workers should also be prioritized. Testing kits should also be provided for free to all users in order to address the barriers of cost that play a role in men not utilizing HIVST.

One of the major findings of this review is that HIVST is deemed to be more convenient than traditional testing. Yet, there were also findings of some men being skeptical of HIVST and were not convinced of the accuracy of the kits (49). There were also issues identified with persons being unable to complete their HIVST without errors (52). These findings suggest that there is a great need for more health information pertaining to HIVST and its benefits as well as its accuracy to be provided in the region. There is also a need for the instructions which accompany each HIVST kit to be reviewed (85) and tested among diverse populations in the region. Pre-test counseling, as mentioned in Choko et al. (25) article, is also worthy of further exploration in order to minimize user error. Overall, HIV counseling in general is still needed and should be provided to men who opt to use HIVST. In the context of self-testing, HIV counseling is necessary for addressing concerns around testing, stressing the importance of confirmatory testing, and achieving linkage to care for those testing positive. HIV counseling may also be completed via SMS or a mobile app in order for testers to report their HIVST results and schedule a convenient date and time for in-depth counseling, receive a confirmatory HIV test, and be linked to care (86). Using home visits or phone, or through a mobile app, HIVST can be better promoted as convenient and efficient. Lastly, as pre-exposure prophylaxis (PrEP) becomes more available in the region, men who engage in risky-sexual behaviors should be provided PrEP to add to the current toolbox of HIV prevention methods.

Further research should investigate the use of HIVST and linkage to care in tandem for men in sub-Saharan Africa. Linking men to care is paramount to reducing HIV incidence in the region. Past research reported some 85% of respondents being willing to link to care following a positive test (86). Respondents also preferred home visits or phone calls to SMS for linking to care (86). Another study reported that linkage to care for participants was estimated to be 56.3% (524/930) (25). Furthermore, it was reported that over 97% of men reported using the HIVST kit at 3-month follow up (87). All participants who tested positive (5.6%) sought a confirmatory test and began HIV treatment (87). Linkage to care was confirmed by participants via 8.7% receiving counseling, 16% initiated ART, and 5.3% CD4-tested (42). Future research should also investigate the use of multiple venues as a means for reaching men in sub-Saharan Africa. Past research has reported uptake of HIVST being high for both the home-based (64.9%) and facility-based groups (52.7%) (88). Significantly, more adults reported positive HIVST results in the home group (6.0%) vs. the facility group, (3.3%) (88).

This systematic review is subject to limitations that should be considered. First, only full-text peer-reviewed articles that were written in English were included. Also, while this review aimed to review published articles pertaining to HIVST uptake and intervention strategies among men in sub-Saharan Africa, articles meeting our criteria included both men and women. Furthermore, country specific names and truncated regional names were not used during the database search; this search strategy may have omitted relevant articles. Study evaluations, and cost analyses were also not included. Articles which fit into the categories may have provided salient strategies for increasing HIVST uptake. One article was omitted due to it not meeting the required age restriction of participants being 16 years or older; the population of interest included participants as young as. Finally, only articles which were published between 2010 and 2020 were included in this review. Still, this review has multiple strengths which is necessary to highlight. First, the various quality assessment tools used for article evaluation ensures that included articles' design, analysis, and reporting has been properly considered and carried out and indicates the quality of included studies. Also, the rigor of the methodology used in this review presents an accurate and comprehensive account of articles pertaining to HIVST uptake and intervention strategies among men in sub-Saharan Africa.

CONCLUSION

HIVST is highly acceptable to men. More efforts are needed to develop policies to implement HIVST programs targeting men in Sub-Saharan Africa, including a focus on linkage to care in sub-Saharan Africa. Future interventions should directly target men independently in tandem with using peers and their romantic partners to promote self-testing among men in sub-Saharan Africa. HIVST kit distribution strategies should be combined with services that can offer confirmatory tests and counseling for men as well as linkage to care. The continuation of implementing health education, promotion, and the offering of HIVST at multiple venues and target areas where men in each country are known to congregate is necessary. Country-specific HIVST intervention strategies and methods are also necessary to achieve the greatest reach. Lastly, PrEP strategies for men in tandem with HIVST should developed and implemented in countries where PrEP is available.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

AH and NT completed the data extraction quality assessment, and manual searches for articles. AC, MH, PJ, JK, and DC reviewed, edited, and provided the insight for the development of the manuscript. All authors contributed to the article and approved the submitted version.

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Cost-Effectiveness of Peer-Delivered HIV Self-Tests for MSM in Uganda

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Introduction: Distribution of HIV self-testing (HIVST) kits through MSM peer networks is a novel and effective strategy to increase HIV testing coverage in this high-risk population. No study has evaluated the cost or cost effectiveness of peer distribution of HIVST strategies among MSM in sub-Saharan Africa.

Methods: From June to August 2018, we conducted a pilot study of secondary MSM peer HIVST kit distribution at The AIDS Support Organization at Entebbe and Masaka. We used an ingredients approach to estimate the cost of MSM peer HIVST kit distribution relative to standard-of-care (SOC) hotspot testing using programme expenditure data reported in US dollars. The provider perspective was used to estimate incremental cost-effective ratios per HIV infection averted using the difference in HIV annual transmission rates between MSM with HIV who knew their status and were not virologically suppressed and MSM with HIV who did not know their status.

Results: We enrolled 297 participants of whom 150 received MSM peer HIVST kit distribution (intervention group) and 147 received TASO standard of care HIV testing (control group). Provider cost for the intervention was $2,276 compared with $1,827 for SOC during the 3-month study period. Overall, the intervention resulted in higher HIV positivity yield (4.9 vs. 1.4%) and averted more HIV infections per quarter (0.364 vs. 0.104) compared with SOC. The cost per person tested was higher for the intervention compared to SOC ($15.90 vs. $12.40). Importantly, the cost per new HIV diagnosis ($325 vs. $914) and cost per transmission averted ($6,253 vs. $ 17,567) were lower for the intervention approach relative to SOC. The incremental cost per HIV transmission averted by the self-testing program was $1,727. The incremental cost to providers per additional HIV-positive person identified by the intervention was $147.30.

Conclusion: The intervention strategy was cost-effective, and identified more undiagnosed HIV infections than SOC hotspot testing at a cost-effectiveness threshold of US $2,129. Secondary distribution of HIVST kits through peers should further be evaluated with longer duration aimed at diagnosing 95% of all persons with HIV by 2030; the first UNAIDS 95-95-95 target.

Keywords: MSM, HIV, self-testing, peers, cost-effectiveness, Uganda

INTRODUCTION

Key populations in Uganda, including sex workers, fisher folk, prisoners, and Men having sex with Men (MSM), are disproportionately affected by HIV and account for more than a third of new HIV infections (1, 2). The risk of HIV acquisition is estimated to be 28 times higher among MSM than heterosexual men (3). In 2012, HIV prevalence among MSM (13.2%) (3) was thrice that of heterosexual adult men aged 15–49 years (4.3%) in Uganda (4). A mathematical model suggests that the biggest reductions in HIV incidence in Sub-Saharan Africa will occur through increased coverage of HIV testing and effective treatment of people living with HIV (5). In Uganda, HIV testing uptake among men is low (55%) compared to 82% among women (6). No data are available regarding HIV testing coverage among MSM in Uganda where same sex relationships are criminalized through colonial-era laws (7, 8). The Anti-Homosexuality Act was passed in 2014 but subsequently overturned by the Constitutional Court of Uganda (7, 8). However, social and healthcare stigma and discrimination still hamper key population access to HIV prevention services (6) despite the fact that the Uganda Ministry of Health prohibits discrimination of key populations (7, 8).

Scaling up cost effective strategies for HIV testing and counseling services is paramount in order to effectively reach individuals unaware of their HIV status and/or embedded in risky sexual networks. HIV self-testing (HIVST) is the process by which a person performs an HIV test by themselves to know their HIV sero-status (9). OraQuick is approved by the Ministry of Health, and HIVST is recommended in national guidelines as an additional approach to HIV testing services (9). It is an accessible prevention tool that can empower MSM to overcome stigma and discrimination and increase access to HIV testing. Delivering HIVST through peer and sexual networks (9) could be synergistic to existing MSM HIV prevention programmes by reaching MSM, a high-burden population with limited access to HIV testing services, with user-friendly technology (10–13). Prior studies suggest that most MSM would be willing to distribute HIVST kits as well as to self-test in the presence of a peer or sexual partner (9, 14–18).

An internet peer MSM HIVST kit distribution strategy in the United states averted 3.34 HIV transmissions among 1,325 MSM over 12 months and saved 14.86 QALYs and $1.6 million in lifetime HIV treatment costs with an incremental cost effectiveness ratio (ICER) of $63,400 for cost-effectiveness at $100,000 cost per QALY threshold (10). To our knowledge, no prior study in sub-Saharan Africa has estimated the cost-effectiveness of peer distributed HIV oral fluid self-test kits in MSM sexual and social networks. Understanding cost effectiveness of HIVST kits peer distribution is important to inform programmes and policy makers as HIVST is scaled up. This study aimed to estimate the cost per person tested, incremental cost per HIV infection averted, and cost effectiveness of MSM peer distribution of HIVST kits in Uganda.

METHODS

Study Design

We conducted a cost effectiveness analysis of a non-randomized study using a provider perspective (9). We compared the cost-effectiveness of an intervention consisting of MSM peer HIVST kit distribution strategy in identifying undiagnosed HIV infection with the standard of care (SOC) HIV testing approach (hotspot HIV testing) used at The AIDS Support Organization (TASO).

Study Setting

TASO is the largest and oldest indigenous non-governmental HIV care provider in sub-Saharan Africa. It was founded in 1987 by a group of people living with, or deeply affected, by HIV/AIDS in order to provide psychosocial support and basic medical care to people living with HIV and AIDS. TASO Entebbe and Masaka are two of the 11 TASO HIV care centers of excellence located in Central region of Uganda. By June 2018, TASO Entebbe and Masaka had active client populations of >6,000 and >8,000, respectively. The study was conducted in two urban sites, located in Entebbe and Masaka, in Central Uganda.

Description of HIV Testing Strategies

The TASO SOC HIV testing models included hotspot HIV testing and counseling for key populations, and highly stigmatized persons (9). From January-March 2018, TASO healthcare workers performed hotspot HIV testing fortnightly at MSM hotspots identified in partnership with MSM civil society organizations; MSM were mobilized for HIV testing through social networks, social media and word-of-mouth. They were eligible to receive an HIV test if they were: (i) aged >18 years or older, and (ii) a member of the identified hotspot. For the intervention, we identified 15 MSM peers, eight in Entebbe and seven in Masaka. Each peer (a person with or without HIV and trusted by MSM community) received 10 serialized HIVST kits (Oraquick® Rapid HIV-1/2 Antibody Test, Orasure Technologies, Bethlehem, PA) to distribute to individuals (henceforth referred as participants) in their social and sexual networks who had not tested in the previous 6 months. OraQuick® is a U.S. Food and Drug Administration and Uganda Ministry of Health approved in-home test for HIV-1 and HIV-2 that uses oral fluids. The kit consists of a test swab to collect oral fluid from the user's gums, which is then placed in buffered developer solution and results read after 20–40 min. Peers trained the participants on how to use the HIVST kit and interpret the results. Peers provided pre- and post-test HIV counseling, followed up participants through phone calls and face-to-face meetings, collected used kits, and linked those who tested positive to a blood-based confirmatory HIV testing and ART initiation as previously reported (9) (**Table 1**). To be eligible for MSM peer HIVST kit distribution, participants: (i) were identified by peers, (ii) aged 18 years or older, (iii) had receptive or insertive anal sex with men in the past year.

Cost Data Collection and Analysis

We used an ingredients approach to estimate the cost of MSM peer HIVST kit distribution and hotspot SOC approaches

TABLE 1 | Comparison of MSM peer HIVST kits distribution (intervention) and hotspot HIV testing (standard of care) at the AIDS support organization in Uganda.

Variable	Standard of care hotspot HIV testing	Intervention (Peer HIVST distribution)
Type of test kit	Blood based HIV rapid test kits (Determine® and Uni-Gold®)	Oral fluid based OraQuick® HIV self-test kit
Mobilization of participants	Healthcare workers and drop in center leadership	Peers (MSM either HIV infected or not, identified by MSM community)
Performer	Healthcare worker	Self or peer assisted or HIVST
Where	Hotspots where MSM meet	Place of participant's choice
Linkage to care	Referral letters given by the healthcare workers	Peers used phone calls, face to face meeting including physically linking MSM to confirmatory testing and care
HIV counseling	Healthcare worker	Peers (both HIV-positive and negative MSM)
Sample size	147 participants	150 participants
Completed the test	147 participants	143 participants
Duration	January–March 2018	June–August 2018

TABLE 2 | Estimated costs (US dollars) of the intervention (MSM peer HIVST distribution) and standard of care.

Programme activities	Intervention	Standard of care
	Peer HIVST distribution provider cost ($)	Hotspot HIV testing provider cost ($)
Programme start-up costs		
MSM peer identification and training	148.90	N/A
Venue identification and facilitation	N/A	82.80
Personnel and Administration cost		
Project coordinator	449.30	N/A
Counselor coordinator	N/A	720
Laboratory technician	N/A	619.20
Research assistants	168	N/A
Data manager	151	N/A
Variable costs		
Transport	250	46
Mobilization of MSM to hotspots	N/A	155
HIV testing	1,008.80	204
Follow up and reporting	99.0	N/A
Total cost	**$2,276**	**$1,827**

The counselor at TASO also works as a Coordinator. The laboratory technician performs HIV testing, manages the data and enters it into the HIV testing register. MSM peers provided pre- and post-test HIV counseling including linkage to a confirmatory test and ART initiation. Transport costs, is for peer transport reimbursement (stipend) for the intervention arm and TASO staff transport to the hotspot for the control arm. HIV testing, is cost for purchasing HIVST kits for the interventional arm and control arm.

(11). For intervention cost estimation, we retrieved and reviewed 2020 intervention expenditures reported in US dollars which included formative research, administrative, overhead costs, and intervention implementation costs from financial records and reports. We extracted research project expenditure including both costs for formative research and peer HIVST kit distribution. Thereafter, we identified MSM peer HIVST kit distribution (intervention) ingredients, estimated costs likely to be provider costs using the expenditure report, and excluded formative research costs. We categorized costs as fixed costs that remained unchanged over the short-term regardless of the number of participants, and variable costs likely to increase or decrease according to the number of participants. Fixed costs included personnel, training, and administration. Variable costs were direct provider costs including HIV test kits, monitoring of peer HIVST kit distribution, and costs of participant tracing and peer stipends. Data collection for the SOC group (January–March 2018) was not synchronous with the intervention group (June–August 2018) (**Table 2**).

Standard of Care Costing Estimation

We reviewed TASO key population programme data and reports between January and March 2018 to identify the number of persons tested during hotspot campaigns as previously described (9). Each month, TASO staff conducted a maximum of two hotspot testing sessions. A total of nine hotspot-testing activities were conducted during the study period, five in Entebbe and four in Masaka. We interviewed TASO staff to estimate time (in hours) spent during hotspot testing. We identified ingredient activities to identify provider costs of hotspot testing. We used the 2018 public sector cost of $1.02 to estimate the total cost of Determine® HIV1/2 rapid test kits (Alere Medical Company, Chiba, Japan).

For both groups, we estimated: (a) the cost per person tested by dividing total costs by number of HIV tests completed, (b) the cost per new HIV diagnosis by dividing total costs by the number of new (not diagnosed before) HIV infections identified, and (c) the cost per transmission averted by dividing total programme cost by the number of HIV infections averted.

Cost-Effectiveness Analysis

Cost effectiveness was defined as the number of HIV transmissions averted using a Bernoulli model to estimate averted transmissions among MSM (12). The number of transmissions averted was estimated using the difference in HIV annual transmission rate between HIV-positive MSM who knew their status and were not virologically suppressed (6.9%) and HIV-positive MSM who did not know their status (12.1%) (12). MSM who do not know their HIV status transmit HIV infection at a higher annual rate than those who know their HIV status (12). Since all MSM who completed an HIV test in both groups received their test results and were initiated on treatment, we assumed that the HIV transmission rate dropped after HIV diagnosis and immediate initiation of treatment. We therefore estimated the number of HIV transmissions averted by

multiplying the number of new diagnoses by the difference in HIV transmission rates before and after HIV diagnosis. This was calculated for each HIV testing approach using the formula a = Nu (Tu–Ta) where a is the number of averted HIV transmissions, Nu is undiagnosed HIV infections, Tu is the average HIV transmission rate from MSM unaware of their status, and Ta is the average HIV transmission rate from MSM aware of their status (13).

The cost-effectiveness threshold was set at US $2,130, following the World Health Organization (WHO) "CHOosing Interventions that are Cost-Effective (CHOICE)" recommended threshold for cost effectiveness analysis, i.e., thrice the Uganda gross domestic product per capital of US $710 in 2018 (18–20). We used WHO threshold because we found no comparable HIV prevention (HIV testing) study estimating QALY gained or DALY averted among MSM in a similar setting and did not collect quality of life data. We calculated the incremental cost effectiveness ratio (ICER), defined as $\Delta C/\Delta E = Cb–Ca/Eb–Ea$ where **C** is total programme cost, **E** is effectiveness (averted infections), **b** is the control index, and **a** is the intervention.

Sensitivity Analysis

We tested the robustness of the intervention cost effectiveness analysis by using a weighted average transmission rate half (6.9%/2 = 3.45%) the transmission rate for MSM aware of their HIV-positive status and not virologically suppressed (12), taking into consideration participants who completed an HIV test, diagnosed HIV- positive and initiated on ART with good peer adherence support system to achieve viral suppression. For our sensitivity analysis, we assumed that newly diagnosed MSM in the intervention group were more likely to be linked to care by peers and initiate ART than those in the SOC group because the intervention participants received HIV counselling and prevention messaging from a peer who is familiar with them. Thus, we halved the proportion of MSM who engaged in risky behaviours in the intervention group. We also added the cost of confirmatory HIV testing ($1.02 per Determine® rapid test and $3.40 per Uni-Gold® rapid test (2018 market price) for the eight participants diagnosed with HIV infection using HIVST. We also included personnel costs of confirmatory testing, assuming ∼30 min of HIV testing and counseling were equivalent to 3.4% effort (mean monthly salary of $800 per TASO provider).

Ethics Approval

This study was approved by the Infectious Diseases Institute Scientific Review Committee, TASO Research Ethics Committee, The University of California, San Francisco Ethics Committee, and the Uganda National Council for Science and Technology (UNCST). The English or Luganda (local language) information sheet and the verbal informed consent tool approved by the TASO Research Ethics Committee and UNCST was explained to the participant. Those who agreed to take part in the study provided verbal consent that was not documented, consistent with guidelines from regulatory bodies concerned about the criminalization of MSM in Uganda (21).

TABLE 3 | Cost effectiveness of MSM peer HIVST kit distribution and hotspot HIV testing in Uganda.

Measure	MSM peer HIVST kits distribution	Hotspot HIV testing
a. Number of tests[a]	143	147
b. Total number testing positive	8	4
c. Number testing positive, aware	1	2
d. Number testing positive, unaware	7	2
e. Proportion testing positive, unaware	0.049	0.014
f. Transmission rate from MSM unaware HIV+	0.121	0.121
g. Transmission rate from MSM aware HIV+	0.069	0.069
h. Number of infections averted[b,c]	0.364	0.104
i. Total provider costs ($)	2,276	1,827
j. Cost per person tested	15.90	12.40
k. Cost per new diagnosis ($)	325	914
l. Cost per averted infection ($)	6,253	17,567
Incremental CE ratio (ICER), per averted infection	$1,727	

[a] *Market price of 2018 per Determine HIV test ($1.02) was used to estimate the cost of hotspot testing.*

[b] *The number of averted HIV infections was estimated by multiplying the number of MSM with HIV who became aware of their status and the difference in transmission rates before and after knowing their HIV status. h = d * [f–g].*

[c] *The average HIV transmission rate for all groups was used for the number of averted infections.*

RESULTS

Overall, 297 participants were included in the analysis of which 150 received HIVST (intervention) and 147 were reached with SOC HIV testing during the 3-month study period as previously described (9). A total of 143 participants (95%) completed HIVST, of whom 32% had never tested for HIV. All participants in the control group (100%) received SOC testing. Overall, a total of 12 participants were diagnosed with HIV infection: eight in the intervention group and four in the SOC group [5.6 vs. 2.7%, respectively; $P = 0.02$]. All participants newly diagnosed HIV-positive using HIVST received confirmatory HIV testing, were linked to care by the peers and initiated on treatment. Details about SOC and HIVST.

The total provider cost for MSM peer HIVST distribution (intervention) was $2,276 compared with $1,827 for hotspot testing (SOC). Using the HIV transmission rate averted between MSM of known status but not virally suppressed, and unknown HIV status, the intervention resulted in a higher HIV positivity rate (4.9 vs. 1.4%) vs. SOC during 3 months of implementation. Compared to the control group, the intervention strategy averted more HIV transmissions per quarter (0.364 vs. 0.104) but yielded a higher cost per person tested ($15.90 vs. $12.40). The cost per new HIV diagnosis ($914 vs. $325) and the cost per HIV transmission ($17,567 vs. $6,253) averted were higher for the SOC than the intervention. The incremental cost per

transmission averted by the self-testing program was $1,727 (**Table 3**).

In sensitivity analysis, adding the cost of confirmatory costing increased the cost per person tested from $15.90 to $16.50 and halving the the transmission rate for MSM aware of their HIV-positive status and not virologically suppressed increased the number of HIV infections averted from 0.364 to 0.602. The cost per infection averted reduced from $6,253 to $3,914. MSM peer HIVST distribution remained cost-effective (ICER $1,062) in identifying new infections and the incremental cost per transmission averted by the self-testing program remained cost effective (**Table 4**).

The incremental cost to providers per additional HIV-positive person identified by the intervention was $147.30 (**Table 5**).

DISCUSSION

To our knowledge, this is first study to examine the cost-effectiveness of peer HIVST distribution in sub-Saharan Africa. Our provider perspective analysis found that the MSM peer HIVST kit distribution strategy was cost-effective than SOC hotspot testing in identifying undiagnosed HIV infections among MSM who are a hidden, highly stigmatized population in Uganda and hard to reach with HIV services. The average cost per person tested through MSM peer HIVST kit distribution was higher than hotspot testing because of the higher cost of the Oraquick® HIVST kit relative to the Determine® HIV rapid kit ($6.72 vs. $1.02), respectively. The MSM peer HIVST kits distribution strategy averted thrice as many HIV infections as hotspot testing, potentially lowering the risk of HIV transmission from MSM unaware of their HIV status.

Previous studies have found that HIVST distribution strategies are cost-effective for heterosexual populations in sub Saharan Africa (22, 23). Our findings are in agreement with an internet MSM peer HIVST kits distribution strategy that reached 1,325 MSM over a 12 month period and found that peer based HIVST kit distribution was cost-effective in the United States (10). Furthermore, a modeling study of HIV testing interventions that included lifetime treatment, quality-adjusted life years and 12 months of implementation still found that HIVST delivered through social and sexual networks remained cost effective for identifying undiagnosed HIV infections (17). Reaching high-risk MSM with HIV testing services is key to facilitating early diagnosis of HIV infection and linkage to HIV services. Immediate initiation of antiretroviral therapy has personal health benefits (decreased morbidity and mortality) and public health benefits (prevention of sexual transmission of HIV) (24). MSM peer HIVST kit distribution could address

TABLE 4 | Cost effectiveness of MSM peer HIVST kit distribution and hotspot HIV testing for different HIV transmission rates by type of testing.

Measure	Hotspot HIV testing	MSM peer HIVST kits distribution and testing	MSM peer HIVST kits distribution and HIV testing
No risky behavior: risky behavior	**1:1**	**1:1**	**1:1/2**
a. Number of tests	147	143	143
b. Number testing positive, unique	4	8	8
c. Number testing positive, aware	2	1	1
d. Number testing positive, unaware	2	7	7
e. Portion of number testing positive, unaware	0.014	0.049	0.049
f. Transmission rate from unaware HIV+	0.121	0.121	0.121
g. Transmission rate from aware HIV+	0.069	0.069	**0.035**
h. Number of infections averted[a,b]	0.104	0.364	0.602
i. Total provider testing costs[c] ($)	1,827	2,276	2,356
j. Cost per test completed ($)	12.40	15.90	16.50
k. Cost per new diagnosis ($)	914	325.10	337
l. Cost per averted infection ($)	17,567	6253	3,914

[a] *The number of averted HIV infections was estimated by multiplying the number of MSM with HIV who became aware of their status and the difference in transmission rates before and after knowing their HIV status. h = d * [f–g].*

[b] *The average HIV transmission rate for all groups was used for the number of averted transmissions.*

[c] *We added cost of confirmatory testing using rapid test kit market rate of 2018 and provider cost of counseling and testing.*

TABLE 5 | Providers incremental cost for the peer HIVST distribution strategy.

Strategy	Provider costs	Incremental cost $	Effectiveness (HIV positive diagnosed)	Incremental effectiveness (+ve)	ICER ($)
Standard of care arm	1,827	–	4	–	
Intervention arm	2,276	449	8	4	112.3

gaps in HIV testing services by increasing testing coverage and frequency and increasing the proportion of first time testers and new HIV diagnoses in stigmatized high-risk populations such as MSM and sex workers in sub-Saharan Africa (15, 25, 26).

The cost per person tested in our study ($15.90 and $12.40 for peer distribution and hotspot testing, respectively) compares favorably with prior studies in sub-Saharan Africa in which the average cost per person tested using door to door community based HIVST distribution was $13.00 (range, $8.78–$16.42): $8.78 in Malawi, $16.42 in Zambia, and $13.84 in Zimbabwe (22). Door-to-door and peer HIVST distribution are community-based HIV testing strategies with similar costs per person tested, but only the latter approach is suitable for hidden populations like MSM. The cost per HIV kit distributed in our peer distribution programme would significantly decrease if it were integrated within the established TASO key population HIV prevention programme in which staff and peers mobilize MSM for HIV testing at hotspots and link them to HIV services. Integration would reduce personnel costs and increase the number of MSM reached with HIVST. In the FHI 360 linkage project (23), MSM peers integrated within the HIV testing programme distributed over 500 kits within 3 months, indicating that peers can efficiently distribute HIVST kits, potentially decreasing the cost per HIVST kit distributed and increasing the yield of persons testing HIV-positive. The incremental provider cost per additional HIV positive person identified by MSM peer HIVST kits distribution was $147.30 (**Table 5**). This additional cost is considered high given that it is almost thrice Uganda national health expenditure on health per capital – spending of $55 in 2017 (27). However, our current study findings show that the MSM peer HIVST kit distribution approach is cost effective in identifying HIV infection in this stigmatized population.

Scale-up of MSM peer based HIV testing approaches in sub-Saharan Africa in general, and in Uganda in particular, is hampered by criminalization of homosexual behavior and scarcity of evidence on the cost-effectiveness of peer distribution programmes (7, 8). Our results suggest that HIVST can efficiently reach a high-risk marginalized population in need of HIV services. The President's Emergency Plan for AIDS Relief (PEPFAR) is working with the Ministry of Health and HIV implementing partners in Uganda through the local capacity initiative to strengthen the national capacity of key population civil society organizations to address barriers to HIV care, support and prevention services among the MSM community and to understand how best to reach them with HIV services (28). Our results will inform HIV programmes and policy makers on key considerations when scaling up peer distribution of HIVST kits to MSM social and sexual networks. In Uganda, peer distribution of HIVST kits is being scaled up for key populations including MSM and male and female sex workers (29–31). Our findings support the cost-effectiveness of this approach. However, there is need to evaluate the cost-effectiveness of HIVST differentiated delivery models for other key populations and the cost-effectiveness of frequent testing for MSM as recommended by WHO. Quality assurance of HIVST kits is needed since products of unknown quality are available on the unregulated market, with attendant risks of false positive/negative results, and underscoring the need to strengthen consumer protections (25, 32).

Sensitivity analyses including the cost of confirmatory testing and a different set of assumptions for differences in transmission risk found that the cost per person tested increased marginally from $15.90 to $16.50. Importantly, the number of infections averted were increased from 36.4% to 60.2% and the cost per infection averted was halved from $6,253 to $3,914. MSM peer HIVST kit distribution remained cost effective in our study (ICER $1,062) (**Table 4**).

A strength of our study is the first cost-effectiveness evaluation of peer-distributed HIVST for MSM in sub-Saharan Africa. Our study has limitations. Study duration was only 3 months and mostly reached younger MSM in a setting where older MSM are harder to reach but have higher HIV prevalence. However, younger MSM are at higher risk of HIV acquisition despite lower HIV prevalence; risk of HIV infection increases with age (3). The number of HIV self-tests distributed was relatively small and the comparator was hotspot moonlight testing and not facility-based HIV testing services, thus limiting generalizability of our results. We relied on self-report of prior HIV status and some participants may incorrectly have reported their status. MSM peer HIVST kit distribution (June–August 2018) was not synchronous with programmatic SOC testing (January–March 2018); nevertheless, the 3-month offset did not influence cost estimates. The cost analysis was not specified *a priori* and relied on data from study implementation costs reported to the funder. Initial expenditures included costs of formative research and we may have under- or overestimated implementation costs. We used a provider perspective that excludes patient costs, which are a key barrier to accessing HIV testing services in Uganda. However, in our intervention, patient costs should have been minimal since HIVST kits were distributed to participants at their locations of preference. Finally, we used transmission risk data from the USA; HIV transmission risk among MSM in Uganda is unknown and is likely different (higher or lower) than the United States.

In conclusion, secondary distribution of HIVST kits by MSM peers was cost-effective and identified more undiagnosed HIV infections than SOC approaches. HIVST peer distribution should further be evaluated with longer durations aimed at underserved and hard-to-reach MSM at risk of HIV infection with the goal of expanding testing coverage to 95% of all persons with HIV (UNAIDS first 95 target).

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by this study was approved The Infectious

Diseases Institute Scientific Review Committee, TASO Research Ethics Committee, The University of California, San Francisco Ethics Committee, and the Uganda National Council for Science and Technology (UNCST). The English or Luganda (local language) information sheet and the verbal informed consent tool approved by the TASO Research Ethics Committee and UNCST was explained to the participant. Those who agreed to take part in the study provided verbal consent that was not documented, consistent with guidelines from regulatory bodies concerned about the criminalization of MSM in Uganda. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

SO designed the study and wrote the first draft along with AM. SO, YK, PO, and BC performed the statistical analyses. All authors contributed to data collection, interpretation of the results and the writing of the manuscript, and approved the final draft.

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High HIV Positivity Rates Following Large-Scale HIV Self-Testing Implementation in Zimbabwe, 2018–2020

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Introduction: HIV self-testing (HIV-ST) is an innovative strategy to increase HIV case identification. This analysis shares the outcomes of HIV-ST implementation within the Zimbabwe HIV Care and Treatment (ZHCT) project for the period October 2018–March, 2020.

Materials and Methods: We extracted HIV-ST data for the period October 2018 to March 2020 from the project database and assessed (1) the proportion of reactive HIV-ST results; (2) the concordance between reactive HIV-ST results against rapid confirmatory HIV tests using Determine™ and Chembio™ in parallel; and (3) the monthly contribution of HIV-ST to total HIV positive individuals identified within project. The Chi-square test was used to assess for statistical differences in HIV positivity between age groups, by sex and district; as well as the difference in HIV positivity between the HIV-ST and index and mobile testing strategies.

Findings: Between October 2018 and March 2020, the ZHCT project distributed 11,983 HIV-ST kits; 11,924 (99.8%) were used and 2,616 (21.9%) were reactive. Of the reactive tests, 2,610 (99.8%) were confirmed HIV positive giving a final positivity rate of 21.9%, and a concordance rate of 99.8% between the HIV-ST results and the confirmatory tests. Proportion of reactive results differed by age-groups ($p < 0.001$); with the 35–49 years having the highest positivity rate of 25.5%. The contribution of HIV-ST to total new positives increased from 10% in October 2018 to 80% at the end of March 2020 ($p < 0.001$). Positivity rates from HIV-ST were significantly different by age-groups, sex and district ($p = 0.04$). Additionally, index and mobile testing had a higher positivity rate compared to HIV-ST ($p < 0.001$).

Conclusion: The ZHCT project has successfully scaled up HIV self-testing which contributed significantly to HIV case finding. Countries should consider using the lessons to scale-up the intervention which will contribute in reaching under-served and undiagnosed populations.

Keywords: Zimbabwe, HIV, self-testing, Sub-Saharan Africa, HIV testing

INTRODUCTION

In 2016, Zimbabwe had an estimated 1.2 million PLHIV, and an adult prevalence of 14.1% (1), a huge decline from 27.2% in 1998 (2). During the same period, incidence also declined from 2.6% to 0.47%. Pivotal to the national success was the decentralization and scale-up of HIV testing and treatment services from 337 central, district, and primary hospitals in 2009 to 1,552 primary health facilities by 2016 (3). As of 2019, an estimated 76.8% PLHIV in Zimbabwe knew their HIV positive status of which 88.4% were on ART (4). These are positive milestones toward the achievement of the Joint United Nations Program on HIV and AIDS (UNAIDS) 95-95-95 Goals (5). While significant progress has been made on the 1st 95 which focuses on case finding, gaps still exist in reaching some under-served populations.

HIV self-testing (HIV-ST) is an innovative and high-impact strategy to increase HIV-case identification (6). It offers greater convenience and privacy, and has the potential to increase the proportion of the population who test regularly (6). HIV-ST has been found to be highly acceptable to young people in several African countries as it empowers them to choose the location and timing of the test and control disclosure around their results (7, 8). In pilot studies conducted in Zimbabwe, Zambia and Malawi, the highest proportions of first-time testers through HIV-ST were in young men and women in the 16–24 year age group, and men older than 50 years of age (9), population groups known to be lagging behind in the 1st 95. Unsupervised HIV-ST has also been found to be feasible in rural Africa and is non-inferior to provider-supervised HIV-ST (10), but demand has been highly price sensitive (11).

In this study conducted in Zimbabwe, HIV-ST kits were introduced within an established project, the 6-year PEPFAR/USAID funded Zimbabwe HIV Care and Treatment (ZHCT) led by FHI 360, which was implementing HIV testing through (i) mobile clinics in targeted hotspots and (ii) index case testing at homes since 2016. HIV-ST was offered to sexual contacts of newly tested HIV positive individuals referred as index cases at home, and also distributed at hotspots during targeted mobile testing. In this analysis, we assessed the proportion of self-testers screened and confirmed HIV-positive, following a multi-year, large scale implementation of HIV-ST. Results from this real-world approach to scaling up HIV-ST will help demonstrate the approaches of implementing HIV-ST in order to realize its utility in case finding.

MATERIALS AND METHODS

Using programmatic data, we evaluated HIV-ST uptake and HIV-positivity rates within the ZHCT project by month from October 2018 to March 2020.

Implementation Approach of HIV-ST Within ZHCT

Through the ZHCT project, HIV-ST was implemented in eight Districts namely Mwenezi, Kwekwe, Makoni, Gutu and Gokwe South, Zaka, Chivi and Mutasa. The project deliberately scaled up HIV-ST in a phased rollout starting with three districts (Mwenezi, Makoni, and Kwekwe) as a pilot in October 2018. Two districts were added in March 2019 (Gokwe South and Gutu) before further expansion to all eight districts in October 2019. Kwekwe and Makoni Districts are partly urban and partly rural while the rest of the districts are rural. Two of the districts, Kwekwe (HIV prevalence = 14.42%) and Chivi (14.19%) have an HIV prevalence which is higher than the national average of 14.1%. Mutasa District has the lowest prevalence of 9.46% amongst all the eight districts.

After the first 5 months, further rollout of HIV-ST was informed by early lessons from the three-district pilot. For example, because more reactive results were among males, subsequent distribution targeted men; and because most people (75%) who received tests kits during the pilot needed assistance, we offered support more during subsequent rollout. Finally because preliminary data showed that HIV-ST reduced the number of HIV tests conducted by nurse testers thereby reducing workload, we used this information to promote HIV-ST and get further buy in from staff. Prior to introduction of HIV-ST, the ZHCT project had been implementing index testing in the community and targeted mobile testing since 2016. Clients reached were tested by project nurse testers (who are qualified general nurses) using rapid HIV Type 1 antibody testing in line with the national HIV testing algorithm. To reduce the number of clients directly tested by nurse testers, the project introduced screening through HIV-ST using the OraQuick test kit (OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test, OraSure Technologies, Inc.) ahead of HIV Type 1 antibody testing within its index and mobile testing strategies.

Ahead of index testing, HIV-ST was provided at household level or at targeted hotspots to the sexual contacts of index cases that were aged 16 years and above who were followed up by community outreach workers. Index cases were clients who would have recently returned a confirmed positive HIV test and identified from HIV testing registers at health facilities within the supported districts; and any clients who newly tested HIV positive through index and mobile testing at home or targeted hotspots within the ZHCT project. All index cases whether identified at the facility or community were listed in the index case testing (ICT) register which were based at facility level. Outreach workers [community-based expert clients and described here (12)] extracted names of index cases from the facility ICT register, then elicited contacts before following them up in the community where they distributed the HIV-ST kits.

The outreach workers prepared contacts of index cases by making appointments with those who agreed to be tested for HIV, with HIV-ST being offered as the initial test. The date, time, and place for meeting for HIV-ST distribution and testing were recorded in the appointment diaries. The outreach workers, where requested, assisted clients to conduct the HIV-ST and/or interpreted the result. They also collected information on prior HIV testing, demonstrated how the test is done and how the results are interpreted. Clients who did not require direct assistance were given written instructions as well as a video which they could play for guidance for those with compatible phones. After the test, the community outreach workers obtained the results from the clients which they reported daily to the

nurse tester responsible for that community. The outreach worker will then contacted those who would have returned a reactive result and book an appointments for a confirmatory test which was done at the household level by the nurse tester. The HIV confirmatory tests are conducted in accordance with national guidelines (13), using Determine™ (Alere Determine™ HIV−1/2 Ag/Ab Combo) and Chembio™ (Chembio HIV 1/2 STAT-PAK®) rapid HIV Type 1 (HIV-1) p24 antigen (Ag) and HIV Type 1 antibody test kits in parallel. Those who tested positive on Determine™ and Chembio™ were recorded as HIV positive and referred for ART. Aggregate data on positivity and contribution to positives were reviewed weekly as part of program monitoring and lessons shared across sites.

HIV-ST is also implemented during mobile testing at targeted hot spots, mainly farming and mining communities, and long-distance truck-ins where target populations were famers, artisanal miners, female sex workers and truck drivers. Outreach workers made available HIV-ST kits to individuals who they would have considered at high risk of HIV, based on a screening tool that assessed prior HIV testing and results, assessed clinical symptoms (e.g., TB, STI), behaviors or social practices and those who belonged to specific social networks. Apart from those determined as eligible using the screening tool, HIV-ST was also made available on request to other adults found within hotspots. Outreach workers, who are expert patients used their community intelligence and their knowledge on HIV clinical symptoms to initiate conversation with targeted population groups. Targeted and consenting individuals were given HIV-ST kits, instructed how to test and those with a reactive result were confirmed by a project nurse tester as described above. However, the nurse tester was always part of the team that conducted outreaches at hotspots for testing.

Children were not offered HIV-ST but were offered HIV Type 1 antibody test conducted by nurse testers. Additionally, adults who decline HIV-ST were directly tested by nurse testers as part of index or targeted mobile testing. Service providers in this project received training on the WHO Five Cs of HIV testing to assure confidentiality (Consent, confidentiality, counseling, correct test results and connections to care). Consent was sought at the time of booking an appointment, with the client given the opportunity to suggest the best time, day, and place for HIV testing. Privacy was ensured by allowing them to choose alternative private and suitable best places for the testing.

Data Collection

During delivery of services, outreach workers compiled data on HIV-ST kits distributed and recorded all clients in the HIV-ST register. Following confirmatory testing for clients, the information was captured in the community HTS register. The district Monitoring and Evaluation Officer (MEO) aggregated data from the HIV-ST registers every month and entered it into the ZHCT project database, a DHIS 2 aggregate-based health information system.

Data for this analysis was extracted from the project DHIS 2 aggregate system. The variables extracted were number of HIV-ST kits distributed, HIV-ST results returned, HIV-ST results reactive, and HIV-ST reactive and confirmed by nurse tester. We also extracted HIV testing data for children who were not eligible for HIV-ST and data for adults who declined HIV-ST but received testing from nurse testers through index or targeted mobile testing. The data extracted was disaggregated by age and sex, and it was sent to the district MEO for validation.

Data Analysis

We started our analysis by assessing the proportion of confirmed HIV positive results following an HIV-ST screening test disaggregated by age-group, sex and district. We also assessed the changes in proportion of reactive HIV-ST results by month since the start of implementation in October 2018 until March 2020, as well as the monthly contribution of HIV-ST to overall case identification within the ZHCT project catchment area. Variables were summarized as frequencies and percentages and Chi-square tests were used for assessing differences in HIV positivity rates by age-group, sex, and month for each test modality separately as well as comparing within the groups. SPSS was used for data analysis (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp).

Ethical Review

A non-research determination was granted by the Medical Research Council of Zimbabwe (approval number MRCZ/E/159), the local institutional review board which reviews research involving human subjects in Zimbabwe. Analysis for this manuscript used aggregate data routinely collected and reported by the ZHCT project, with no personal identifying information. None of the authors accessed patient-level data. Consent with each individual person for testing was obtained following national guidelines during implementation. None of the data can be linked back to the clients. Validation of the data was through the district monitoring and evaluation officers of which none of them are co-authors.

Role of Funding Source

The ZHCT project is funded by the United States Agency for International Development under Cooperative Agreement No. AID-613-A-00009 and implemented in collaboration with the Ministry of Health and Child Care Zimbabwe. The funder did not play a role in interpretation of the results.

RESULTS

During the period October 2018–March 2020, the ZHCT project distributed a total of 11,983 HIV-ST kits, identifying 2,610 HIV positive individuals. **Figure 1** shows the HIV-ST cascade for the ZHCT project for the period October 2018–March 2020.

Of the 11,983 HIV-ST kits distributed, 99.5% (11,924/11,983) were used and had results returned to the health care workers. Among those who returned HIV-ST results, 22.3% (2,658/11,924) were reactive and 2,610 were confirmed HIV positive by a trained health care worker using the national testing algorithm. This gave a concordance rate of 99.8% (2,610/2,658) between the HIV-ST positive results and the confirmatory testing an HIV positivity rate of 21.9% (2,610/11,924).

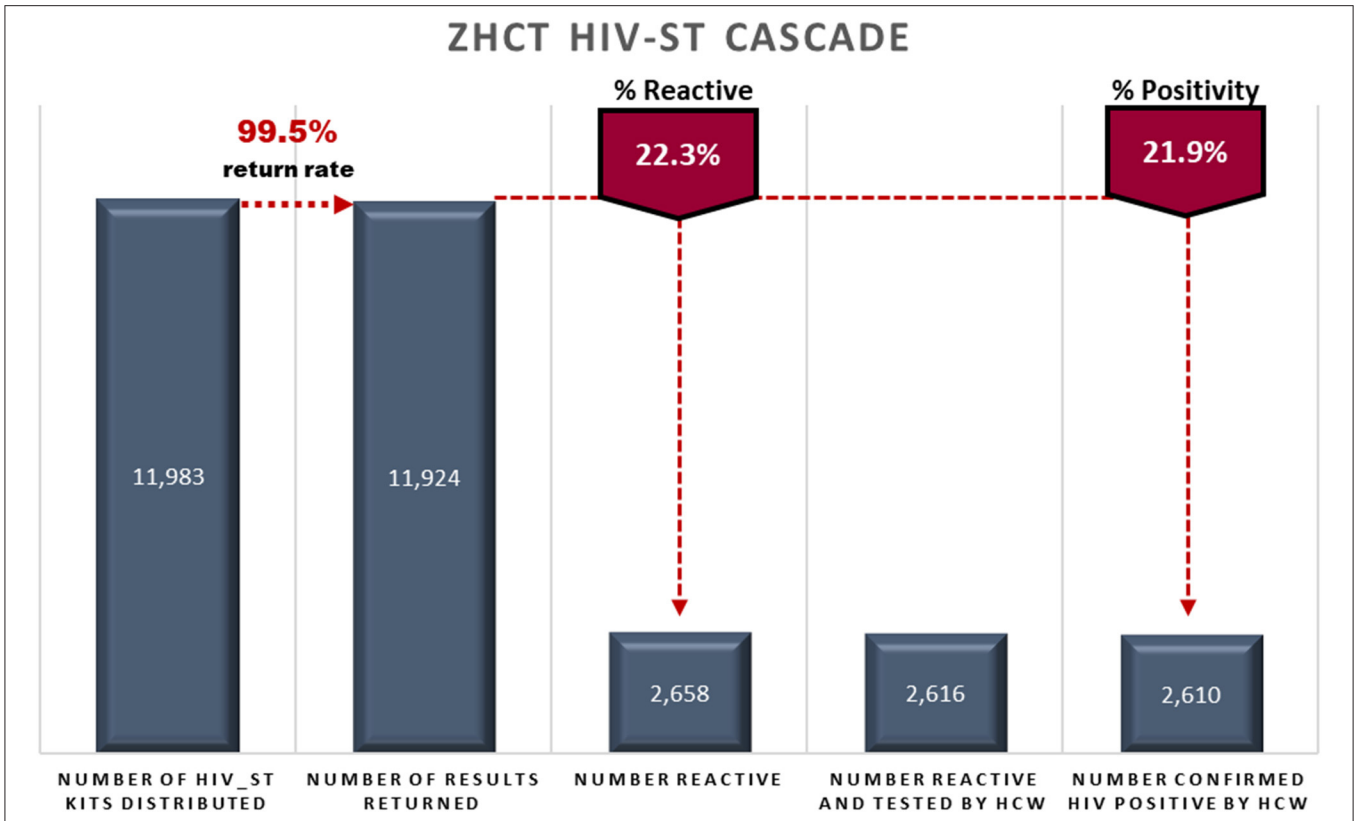

FIGURE 1 | ZHCT HIV-ST cascade.

ZHCT HIV-ST Positivity by Age, Sex, and District

Over a third (3,990) of clients who received HIV-ST were in the 35–49 age group. This age group also accounted for 39% (1,018/2,610) of the newly diagnosed HIV positive and had the highest positivity rate, 25.5% (1,018/3,990) compared to other age groups. Positivity rate varied across the different age groups, $p < 0.001$. More females ($n = 6,422$, 53.8%) accessed HIV-ST and had a significantly higher positivity rate (22.6%; 1/451/6,422) compared to males (21.1%; 1,159/5,502), $p = 0.04$. **Table 1** shows the HIV positivity rate from the HIV-ST by age, sex, and district.

When comparing districts, the highest positivity rate was reported in Zaka District (positivity 42.1%, 91/216) but more HIV positive individuals were identified in Kwekwe district (713/2,422), at a positivity rate of 29.5% during the study period. The difference in HIV positivity from HIV-ST varied across districts, $p < 0.001$.

HIV-ST Positivity Over Time

The number of HIV-ST kits distributed gradually increased from an average of 200 kits distributed per month in the first 6 months, to more than 1,000 per month in November 2019. **Figure 2** shows trends over time of HIV-ST test kits distributed and proportion which were reactive.

The proportion of reactive results averaged 20% in the first 6 months, declining in March 2019 before gradually increasing month-on-month from June 2019 to a high of 30% in March 2020.

Contribution of HIV-ST to All Positives Within the Project

Overall, positivity rates from index and targeted mobile testing were higher at 34.7% (3,653/10,524) and in some age groups nearly double those of HIV-ST during the same period. This trend was the same for both age and sex. **Table 2** shows the number of individuals tested and positivity rate for index and targeted mobile testing.

Within each age-group, index testing and mobile testing were associated with higher HIV positivity rates compared to HIV-ST. This association was statistically significant for all age-groups except among those <15 years (**Table 3**).

Over time, the contribution of HIV-ST to HIV positives within the ZHCT project increased. Between October 2018 and July 2019, HIV-ST contributed around 25% of the total newly diagnosed cases within the project per month (**Figure 3**) and increased gradually, reaching 80% in March 2020.

TABLE 1 | Demographic characteristics of HIV-ST recipients and test results outcome.

	Number of kits distributed	Number positive	Positivity		*P*-value
Age group			Positivity	95% CI	<0.001
<15 Yrs	48	3	6.3%	(0.60: 13.1)	
15–24 Yrs	2,536	419	16.5%	(15.8: 17.97)	
25–34 Yrs	3,840	918	23.9%	(22.56: 25.26)	
35–49 Yrs	3,990	1,018	25.5%	(24.16: 26.87)	
50+ Yrs	1,510	252	16.7%	(14.81: 18.57)	
Gender					<0.001
Female	6,422	1,451	22.6%	(21.6: 23.6)	
Male	5,502	1,159	21.1%	(20.0: 22.1)	
District					<0.001
Chivi District	582	207	35.5%	(31.6: 39.4)	
Gokwe South	2,507	424	16.9%	(15.5: 18.4)	
Gutu District	1,847	220	11.9%	(10.5: 13.4)	
Kwekwe District	2,422	713	29.5%	(27.6: 31.3)	
Makoni District	1,564	439	28.1%	(25.8: 30.3)	
Mutasa District	237	26	11.0%	(7.0: 15.0)	
Mwenezi District	2,549	489	19.2%	(17.7: 20.7)	
Zaka District	216	91	42.1%	(35.5: 48.7)	

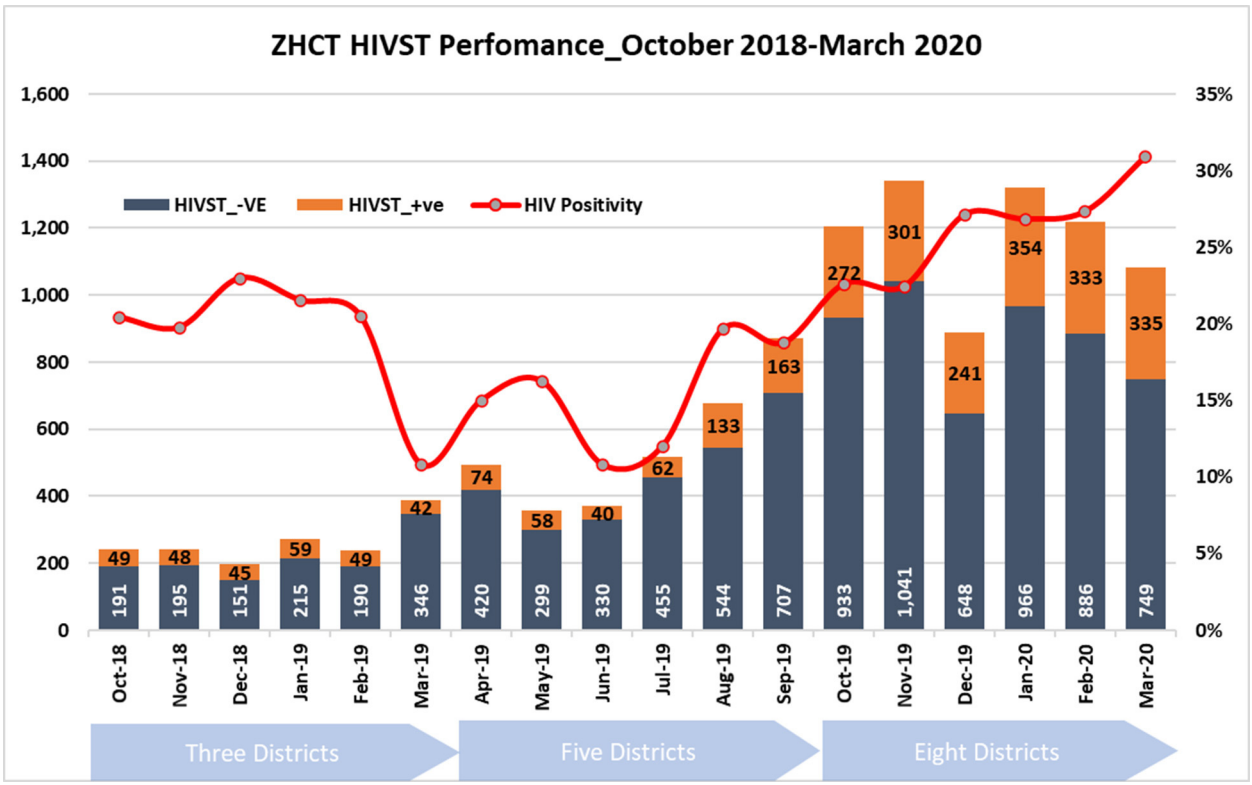

FIGURE 2 | ZHCT monthly HIV-ST positivity rates: October 2018–March 2020.

TABLE 2 | Index and mobile testing results by age group, gender, and district.

	Index and targeted mobile testing results			
	# HIV tested	**# Positive**	**% Positive**	***P*-value**
Age-group				<0.001
<15 Yrs	2,740	270	9.85%	
15–24 Yrs	1,479	559	37.80%	
25–34 Yrs	3,060	1,225	40.03%	
35–49 Yrs	2,595	1,308	50.40%	
50+ Yrs	650	291	44.77%	
Total	10,524	3,653	34.70%	
Gender				<0.001
Male	5,577	2,092	37.50%	
Female	4,947	1,561	31.60%	
Total	10,524	3,653	34.70%	
District				<0.001
Chivi	973	322	33.08%	
Gokwe	2,250	752	33.43%	
Gutu	1,098	323	29.40%	
Kwekwe	2,887	1,113	38.54%	
Makoni	737	343	46.61%	
Mutasa	672	114	16.96%	
Mwenezi	1,043	443	42.47%	
Zaka	864	243	28.16%	
Total	10,524	3,653	34.70%	

TABLE 3 | Differences in HIV positivity between HIV-ST and targeted/mobile testing.

	Positivity rates by age-group		Test results	
	HIV-ST	**Index/targeted mobile testing**	X^2	***P***
<15	6.3%	9.9%	0.589	0.443
15–24 Yrs	16.5%	37.8%	134.43	<0.001
25–34 Yrs	23.9%	40.0%	107.708	<0.001
35–49 Yrs	25.5%	50.4%	197.696	<0.001
50+ Yrs	16.7%	44.8%	105.581	<0.001

DISCUSSION

The ZHCT project successfully scaled up HIV-ST and through this approach identified many HIV positive individuals who could have previously been undiagnosed. The high concordance rate of 99.8% between HIV-ST and confirmatory testing is reassuring and goes to show that HIV-ST is an accurate and effective strategy for HIV diagnosis. HIV-ST enabled over 2,600 individuals to know their HIV positive status. These findings are important for Zimbabwe and other countries that are close to reaching or have exceeded the 1st 95, where testing approaches need to be nuanced and better targeted. For these countries, HIV-ST should be scaled-up. In Zimbabwe, a gradual implementation allowed the project teams to learn and establish systems to monitor implementation before scale-up to other districts. By so doing, HIV-ST was targeted better and as result, HIV positivity improved month-on-month, and contributed more by month and over time to the overall number of newly diagnosed HIV positive individuals within the project. HIV-ST would reduce the workload for HCW, allowing them to spend more time on those who need care.

Multi-country evidence confirms high feasibility, acceptability and accuracy of HIV-ST across many delivery approaches, venues and populations, with minimal risk of harm (6–8, 14). Evidence on the effectiveness of HIV-ST during increased testing coverage is strong, while evidence on demand generation for follow-on HIV prevention and treatment services and cost-effective delivery is emerging. Despite these developments, HIV-ST delivery remains limited outside of pilot implementation (15).

This analysis from the ZHCT project, using routinely collected data has demonstrated how HIV-ST can be optimized at project level, generating lessons over time and targeting it to high-risk individuals. Over time, HIV positivity increased as did its overall contribution to total positives identified. Although the positivity from HIV-ST was lower than from index and targeted community testing in our program, it was at par or similar to that reported in other approaches (16). We attributed the lower positivity to the fact that HIV-ST was also availed to people who requested a test unlike nurse-tester conducted index and targeted mobile testing which is restricted to those who have been exposed to an HIV positive individual or have been screened to be high risk individuals. With 77% of all PLHIV already diagnosed in Zimbabwe (17), HIV-ST is an attractive testing modality to reach undiagnosed individuals.

A major concern for HIV-ST is the major drop off between test kit distribution, return of used self-test kits and confirmatory HIV testing (18). We achieved a very high return rate of 99.5%, together with the high concordance HIV-ST rates with confirmatory testing (99.8%). We attribute this to our implementation approach that was phased and closely supervised. We were able to integrate HIV-ST as part of index testing and use of symptom and behavioral risk prescreening. By offering confirmatory testing at home, we reduced the drop off from reactive tests to confirmation. Our success shows that HIV-ST can replace or complement less efficient testing strategies such as untargeted provider-initiated and community testing.

Our findings add to the body of evidence supporting the benefits of HIV-ST in general and how it has been used successfully to reach undertested populations. The potential of HIV-ST to increase access to and uptake of HIV testing has been highlighted (19) within antenatal clinic (ANC) platforms offering a unique opportunity to increase HIV couple testing among men (14). In Kenya, HIV-ST offered at ANC increased male partner testing by twelve times (20). In South Africa, when given a choice between clinic-based HIV testing and HIV oral self-testing, the overwhelming majority of young women chose HIV-ST offering an important opportunity to significantly increase testing rates among young women, their peers and partners (21). Males are known to have the highest HIV case identification gap worldwide while adolescent girls and young women (AGYW) also account for the majority of new infections.

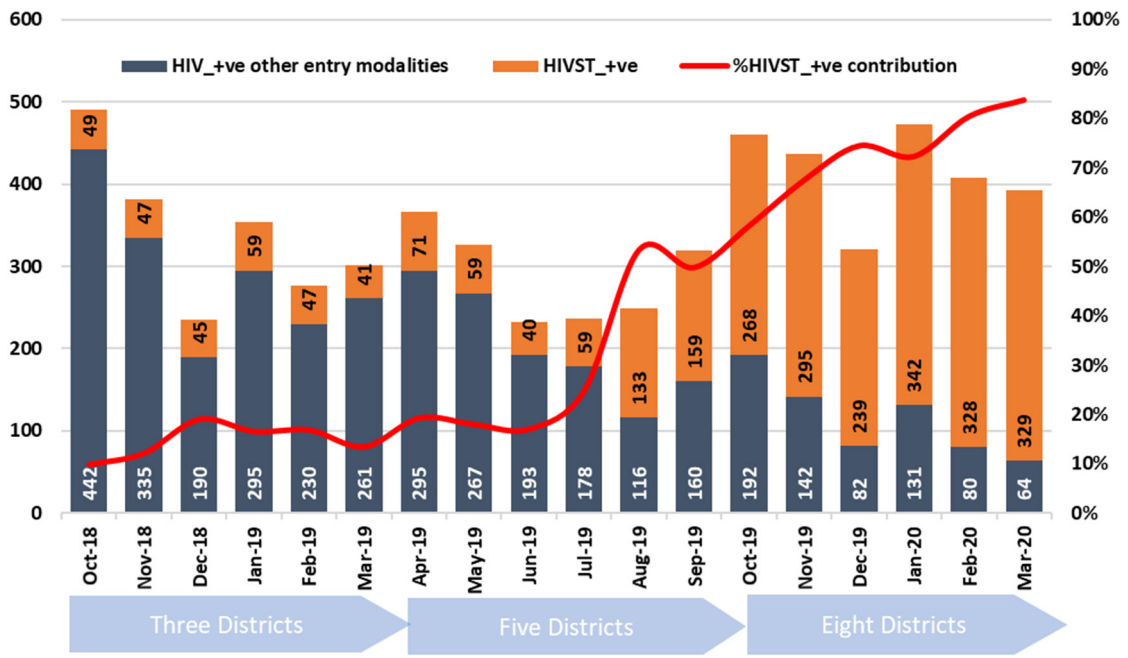

FIGURE 3 | Monthly contribution of HIV-ST to total newly identified HIV positive within the ZHCT project.

These pilot results in Kenya and South Africa, supported by performance of HIV-ST at the program level within the ZHCT project provides more evidence to support HIV-ST as an approach to finding men and AGYW, two demographic groups left behind. The utility of HIV-ST has also been demonstrated in Malawi where facility-based HIV-ST increased HIV testing among outpatients with minimal risk of adverse events (22). HIV self-testing was easily integrated into routine outpatient services and drastically reduced provider workload related to HIV testing while increasing testing coverage, including coverage among high-risk and hard-to-reach individuals (22). While in the Malawi study data were from a randomized control trial, our results provide a real-world view.

This study had some limitations. Firstly, implementation was stopped for 3 months at the start of COVID-19. We missed an opportunity to further scale-up and collect data which would have demonstrated the utility of HIV-ST during COVID-19 or similar emergencies. Secondly, we did not test any individuals who screened non-reactive on HIV-ST to determine if there were any false negatives under field conditions. However, OraQuick® HIV self-test kits have been shown to be very accurate with a specificity of 99.9% and a specificity of 93% (23). Additionally, because HIV-ST kits were only given to individuals who were identified through prescreening, we may have missed people who despite being at low risk may be HIV positive. Despite these limitations, these results offer important implementation lessons regarding HIV-ST. Lastly, the project only started disaggregating its data on distribution of HIV-ST kits by modality (home delivery vs. hotspot delivery) in November 2019 and we were not able to integrate that level of analysis in this study.

Our findings on the contribution of HIV case finding using HIV-ST have several implications during this COVID-19 period where major disruptions to healthcare delivery have occurred and health systems have become overwhelmed. Implementation of physical distancing measures and movement restrictions has further reduced access to health services (24) while the mounting fear of COVID-19 has also led to delayed health seeking (25). The WHO, UNAIDS, and the Global Network of People Living With HIV have worked collectively with national health departments and other development partners to ensure continued provision of HIV prevention, testing, and treatment services with particular efforts made to safeguard timely access to, and to avoid disruption of, routine HIV services (26). The priority, has been to ensure that PLHIV on ART continue to get their refills during the COVID-19 pandemic (27) HIV testing services, especially those requiring a blood draw and physical contact have been severely impacted. HIV-ST could offer an alternative that safeguards both clients needing to know their status and HCWs who administer tests especially during the COVID 19 pandemic when health facilities are closed, and health care workers are diverted to more critical roles. HIV-ST allows delivery of HTS while maintaining physical distancing between the patient and the HCW, be it at the healthcare facility or community level. In this context, delivery of test kits could be made even more safer by screening individuals for exposure or symptoms by phone, providing community workers distributing the kits with personal protective equipment,

giving every newly diagnosed individual HIV-ST kits to distribute to their sexual contacts together with information on COVID-19 mitigation.

CONCLUSION

FHI 360, through the ZHCT project has successfully implemented and scaled-up HIV-ST, achieving high return and positivity rates among those tested. These results demonstrate the potential of HIV-ST to supplement other testing modalities toward the achievement of the UNAIDS 95-95-95 goal. HIV-ST should be scaled-up to ensure that the trajectory for countries to reach epidemic control does not stall.

DATA AVAILABILITY STATEMENT

The data analyzed in this study is subject to the following licenses/restrictions: The data sets are available on request from the project. Requests to access these datasets should be directed to Auxilia Muchedzi, amuchedzi@fhi360.org.

ETHICS STATEMENT

Ethics approval was not required for this study, as according to United States federal guidelines and guidance from the FHI 360's Office of International Research Ethics, this analysis did not constitute human-subjects research. Additionally, a non-research determination was granted by the Medical Research Council of Zimbabwe (approval number MRCZ/E/159), the local institutional review board which reviews research involving human subjects. Written informed consent from the participants was not required to participate in this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

AM, MM, and TTaf conceived and designed the manuscript. FM, TM, HS, RD, TZ, TTap, TS, TN, and GN wrote the manuscript. MB participated in the revision of the manuscript. All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data, critically revised manuscript and approved the final version.

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frontiers in Public Health

ORIGINAL RESEARCH
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Challenges of HIV Self-Test Distribution for Index Testing When HIV Status Disclosure Is Low: Preliminary Results of a Qualitative Study in Bamako (Mali) as Part of the ATLAS Project

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Context: The rate of HIV status disclosure to partners is low in Mali, a West African country with a national HIV prevalence of 1.2%. HIV self-testing (HIVST) could increase testing coverage among partners of people living with HIV (PLHIV). The *AutoTest-VIH, Libre d'accéder à la connaissance de son Statut* (ATLAS) program was launched in West Africa with the objective of distributing nearly half a million HIV self-tests from 2019 to 2021 in Côte d'Ivoire, Mali, and Senegal. The ATLAS program integrates several research activities. This article presents the preliminary results of the qualitative study of the ATLAS program in Mali. This study aims to improve our understanding of the practices, limitations and issues related to the distribution of HIV self-tests to PLHIV so that they can offer the tests to their sexual partners.

Methods: This qualitative study was conducted in 2019 in an HIV care clinic in Bamako. It consisted of (i) individual interviews with eight health professionals involved in the distribution of HIV self-tests; (ii) 591 observations of medical consultations, including social service consultations, with PLHIV; (iii) seven observations of peer educator-led PLHIV group discussions. The interviews with health professionals and the observations notes have been subject to content analysis.

Results: HIVST was discussed in only 9% of the observed consultations (51/591). When HIVST was discussed, the discussion was almost always initiated by the health professional rather than PLHIV. HIVST was discussed infrequently because, in most of the

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consultations, it was not appropriate to propose partner HIVST (e.g., when PLHIV were widowed, did not have partners, or had delegated someone to renew their prescriptions). Some PLHIV had not disclosed their HIV status to their partners. Dispensing HIV self-tests was time-consuming, and medical consultations were very short. Three main barriers to HIVST distribution when HIV status had not been disclosed to partners were identified: (1) almost all health professionals avoided offering HIVST to PLHIV when they thought or knew that the PLHIV had not disclosed their HIV status to partners; (2) PLHIV were reluctant to offer HIVST to their partners if they had not disclosed their HIV-positive status to them; (3) there was limited use of strategies to support the disclosure of HIV status.

Conclusion: It is essential to strengthen strategies to support the disclosure of HIV+ status. It is necessary to develop a specific approach for the provision of HIV self-tests for the partners of PLHIV by rethinking the involvement of stakeholders. This approach should provide them with training tailored to the issues related to the (non)disclosure of HIV status and gender inequalities, and improving counseling for PLHIV.

Keywords: HIV self-testing, index testing, knowledge of HIV status, HIV status disclosure, Mali, partners of PLHIV, people living with HIV, screening

INTRODUCTION

For people living with HIV (PLHIV), HIV testing is the entry point for receiving life-saving treatment and care. HIV testing remains a pillar of HIV responses, as it also enables those testing negative to link to appropriate HIV prevention services. In 2019, 81% of PLHIV worldwide knew their HIV status; this proportion was estimated to be only 64% in West Africa (1). Such regional differences reflect difficulties in access to testing, which is related to stigma and discrimination against PLHIV (2). This fear of stigmatization causing difficulties related to the sharing of serological status in general and within couples has been reported in this area. This encouraged the establishment of support programs for the disclosure of HIV infection. However, few studies have been done to assess the impact of these programs (3–5).

To reach populations considered most vulnerable to HIV and with limited access to or uptake of conventional HIV testing services (which may be due to structural barriers), the World Health Organization (WHO) has recommended HIV self-testing (HIVST) since 2016 as a complementary approach. HIVST is defined as the process by which a person takes his or her own sample (oral fluid or blood); performs a test; and then interprets the results, often in a private setting, alone or with a trusted person (6).

In Eastern and Southern Africa, the HIV Self-Testing Africa Initiative (STAR), which pioneered the distribution of self-tests in this region, has tested different community-based delivery channels (door-to-door, within couples, among key populations, etc.) (7–9). Studies in other regions of Africa have also supported the efficacy, ease of use, and acceptability of HIVST (10–16).

Despite the high level of acceptability of HIVST, there has been little interest in couple testing, particularly among men. Two studies in Malawi and South Africa showed that men usually fear being in a serodiscordant relationship or being judged on their faithfulness (17, 18). A study conducted in Uganda among pregnant women showed the feasibility and effectiveness of HIVST secondary distribution to reach their male partners (i.e., giving self-tests to a pregnant woman to distribute to her partner). The study also emphasized the importance of support to minimize the risk of adverse effects such as violence or relationship breakdown (19).

Following STAR, the *AutoTest-VIH, Libre d'accéder à la connaissance de son Statut* (ATLAS) program was launched in West Africa with the objective of distributing nearly half a million HIV self-tests from 2019–2021 in Côte d'Ivoire, Mali, and Senegal. This program was initiated by a consortium composed of the non-governmental organization (NGO) *Solthis* and the *Institut de recherche pour le développement* (IRD). The ATLAS program introduced HIVST as an additional strategy in West Africa and was charged with organizing distribution, integration and scaling-up into national systems. The delivery of HIV self-tests was implemented through eight delivery channels and priority populations. Implementation plans were developed with country stakeholders (national AIDS programs/councils; international institutions, including the WHO; international and national NGO involved in local HIV programs; civil society; and community representatives). The priority groups include members of key populations (sex workers, men who have sex with men, and drug users), patients with sexually transmitted infections (STIs), and partners of PLHIV.

The ATLAS program integrates several research activities already described in detail elsewhere (20). This research component aims to generate and disseminate knowledge for the three countries and the West African region more broadly. The ATLAS program includes two qualitative studies conducted in Mali and Côte d'Ivoire to improve our understanding of the practices, limitations and issues related to the distribution of HIV self-tests to PLHIV for their partners. In these studies, "partner" is defined in a broad sense, i.e., regular or occasional,

recent or former, formal or informal, and cohabitating or non-cohabitating. This article focuses only on the data from the first study conducted in Mali in an HIV care clinic in Bamako. Findings of the whole study, examined from an anthropological lens, will be published afterward.

The overarching aim of this study was to improve our understanding of the practices, limitations and challenges related to the distribution of HIV self-tests to PLHIV for partner testing in Mali. The estimated national HIV prevalence was 1.2% in 2019, and only 43% of PLHIV knew their HIV status (1). The rate of partner notification and disclosure of serological status is low in Mali, with an estimated 42% of PLHIV not having shared their HIV status with their partners in 2019 (21). In the next sections, we present the results from a qualitative study conducted in Bamako, the economic and political capital city of Mali.

MATERIALS AND METHODS

Study Framework

The study was conducted in Bamako in a community HIV clinic with an active caseload of several thousand HIV patients (adults and children), more than two-thirds of whom were women. This clinic has good experience in community support. Since 2010, this clinic has been hosting a community empowerment program (Gundo_So: "Room of secrets" in Bambara) for women living with HIV to help them make informed choices about the disclosure of their HIV status to reduce the burden of HIV secrecy (22–24).

The clinic receives ∼100 patients a day who pass through the reception service, which is then responsible for sorting and orienting patients according to the purpose of their visits.

Medical Consultations

Medical consultations are provided by two and four health professionals according to their availability. Consultations are not loyalty-based; i.e., a patient can be taken care of by any health professionals according to their availability. The reasons for consultation are diverse and include prescription renewal, follow-up check-ups and, rarely, consultation for not HIV related. Most medical consultations take place between 8:00 a.m. and 2:00 p.m. and are generally very short, lasting an average of 5 min, with most patients coming to renew their prescriptions. In some cases, the patient delegates a close person to pick up the medication for him or her.

Social Service Activities

Social service activities revolve around the psychosocial follow-up of patients and the general screening of people who have been referred by another health facility or who have presented for voluntary testing (pre- and post-test counseling, disclosure of results, etc.). The social worker is assisted by a peer educator for HIV testing and psychosocial follow-up activities. The social workers receive an average of 10 to 12 patients per day. Interviews can last between 10 and 30 min depending on the reason for the visit (HIV testing, psychosocial follow-up, etc.).

Group Discussions

Every Friday, cooking events are organized, which include group discussions (talks) facilitated by peer educators. They are attended by ∼40 participants, two-thirds of whom are women. Talks take place before meals and last an average of ∼30 min.

Introduction of HIVST

Following the example of Côte d'Ivoire and Senegal, in July 2019, the Solthis implementation team in Mali organized training sessions that aimed at imparting knowledge on strategies and methods of HIVST distribution before the introduction of HIVST. The training focused on the role of health professionals and the practical aspects of HIVST distribution in the ATLAS project. All the health professionals who were trained received the necessary materials for HIV self-test delivery. These materials included descriptive brochures for the demonstration/use of the self-test kit and the promotion of confirmatory testing and shareable video support (Youtube/WhatsApp) in French and translated into the main local languages (Bambara and Peul/Fula).

Data Collection

We adopted a qualitative method combining observations and interviews (25–27). Data collection was carried out between September and November 2019 at the very beginning of the HIVST distribution in the facility, which started in August 2019.

The data were collected through (i) semi-structured individual interviews with health professionals who were directly or indirectly involved in HIV self-test distribution; (ii) observations of the clinical consultations of PLHIV; and (iii) observation of peer educator (psychosocial counselor)-led group talks attended by PLHIV. The data collection was carried out by the first author, who is an anthropologist, and the second author, who acted as the research assistant and interpreter (French-Bambara-French).

Semi-structured Interviews With Health Professionals

Individual interviews with health professionals were conducted in French using semi-structured interview guides (see **Supplementary Table 1**). Open questions were asked on these topics: introduction to HIVST, organization of the distribution of HIV self-tests, and practices and perceptions related to HIVST.

Observations of the Consultations

Consultations' observations included the consultations of PLHIV with two physicians, the consultations with a nurse prescribing antiretroviral drugs and the consultations with the social service office. These were routine consultations. The anthropologist and the research assistant attended consultations with various health professionals. Using an observation grid (see **Supplementary Table 3**), they observed exchanges between health care professionals and patients, noting their attitudes and the content of exchanges and specifically targeting attitudes and content related to HIVST. For all patients, they collected only age range and gender. For 51 patients whom HIVST was offered or discussed, they also collected marital status in addition to age range and gender. For the analysis, we only used observation reports and data from the 51 patients.

Observations of Group Discussions

The group discussions facilitated by peer educators involved bringing together the PLHIV who attended the clinic for a meal to discuss the benefits of local food. On this occasion, participants discussed various topics related to HIV. The discussions were conducted in Bambara (the most widely spoken local language in Bamako). We observed how the issues of HIV, AIDS, and HIVST were addressed by the facilitators and the reactions of the participants using an observation grid (see **Supplementary Table 2**).

We positioned ourselves as observers during steps (ii) and (iii) and avoided any intervention. The aim was to see how HIVST was approached by the facilitators and the participants.

Collected Data

We conducted 8 individual interviews with health professionals whose characteristics are summarized in **Table 1**. Six of the eight health professionals interviewed benefited from ATLAS' training sessions. The other two health professionals (both peer educators) did not benefit from specific training on HIVST but had training on HIV testing. HIV self-tests were provided by only two physicians, the nurse and the social worker. The third physician, who was the clinic coordinator and was responsible for supervising HIVST activities, was not involved in the distribution of HIV self-tests "due to a lack of time," according to his terms. The pharmacist oversaw the stock of HIV self-tests. The two peer educators addressed the issue of HIVST during the talks and group discussions that they delivered during cooking activities called "community meals."

We observed 556 medical consultations with the two physicians and the nurse, 35 consultations at the social service office, and seven group discussions. We toured the offices of the health personnel in charge of the dispensing of HIV self-tests for 1–5 days per office or according to the professionals' availability.

Profiles of the participants with who HIVST was discussed and/or proposed during the consultations are presented in **Table 2**. Among the 51 patients, age between 21 and 55, with whom HIVST was discussed and/or proposed during the consultations, the majority were women (42 women/nine men); 36 were married (31 women/5 men); six were in a relationship (three women/three men); three were single (two woman/one man); and five were widows (all women), only one declared have a partner.

Data Analysis

Interview Analysis

All interviews with health professionals were recorded with their consent. Then all recorded interviews were transcribed before being coded and analyzed using Dedoose qualitative data analysis software (https://www.dedoose.com/). The codes and subcodes were defined based on the themes developed in the interview guides and then refined based on the content analysis of the data (28, 29).

Observation Analysis

Observation notes taken during group discussions were subjected to content analysis. Regarding the observation notes taken during consultations with health professionals, only those where HIVST was discussed and/or proposed were considered in the content analysis ($n = 51$).

Data analysis was based on a Grounded Theory approach i.e., a theory developed by induction from a corpus of data (30). A gendered approach was used to account for the effects of gender on HIVST in the data analysis (31).

Ethical Approvals

The study protocol, including consent sheets and procedures, was approved by the WHO Ethical Research Committee (07 August 2019, reference: ERC 0003181), the National Ethics Committee of Life Sciences and Health of Côte d' Ivoire (28 May 2019, reference: ERC 0003181): 049-19/MSHP/CNESVS-kp), the Ethics Committee of the Faculty of Medicine and Pharmacy of the University of Bamako, Mali (August 14, 2019, reference: 2019/88/CE/FMPOS), and the National Ethics Committee for Health Research of Senegal (July 26, 2019, protocol SEN19/32).

RESULTS

In this section, we first describe how the issue of HIVST is addressed in medical consultations, social service consultations, and group discussions. Next, we present the reasons why it is

TABLE 1 | Profile of the health professionals, including peer educators, who participated in the survey.

Code	Category	Education level	Distributed HIV self-tests	Sex
Health professional 1	Social worker	High	Yes	Female
Health professional 2	Physician	High	Yes	Male
Health professional 3	Physician	High	Yes	Female
Health professional 4	Nurse	High	Yes	Male
Health professional 5	Psychosocial adviser (peer educator)	Secondary	No	Male
Health professional 6	Psychosocial adviser (peer educator)	Secondary	No	Male
Health professional 7	Physician	High	No	Male
Health professional 8	Pharmacist	High	No	Male

TABLE 2 | Profile of the participants with who HIVST was discussed and/or proposed during the consultations.

N°	Sex	Marital status	Age range
1	Female	Married	31–35
2	Female	Married	31–35
3	Female	Married	36–40
4	Female	Married	31–35
5	Female	Married	31–35
6	Female	Relationship	21–25
7	Female	Widow	31–35
8	Female	Married	31–35
9	Female	Married	31–35
10	Female	Married	41–45
11	Female	Relationship	21–25
12	Female	Widow, single	51–55
13	Female	Relationship	36–40
14	Female	Married	31–35
15	Female	Married	41–45
16	Female	Married	41–45
17	Female	Married	31–35
18	Male	Married	51–55
19	Female	Single	51–55
20	Female	Married	41–45
21	Female	Married	51–55
22	Male	Married	41–45
23	Male	Single	16–20
24	Female	Married	36–40
25	Female	Married	31–35
26	Female	Married	31–35
27	Male	Relationship	31–35
28	Female	Married	41–45
29	Female	Married	36–40
30	Female	Married	41–45
31	Female	Married	51–55
32	Female	Married	51–55
33	Female	Married	41–45
34	Female	Married	31–35
35	Female	Married	26–30
36	Female	Married	31–35
37	Female	Widow, single	41–45
38	Female	Widow, single	41–45
39	Female	Widow, single	51–55
40	Female	Married	31–35
41	Male	Married	41–45
42	Female	Single	21–25
43	Female	Married	41–45
44	Female	Married	36–40
45	Female	Married	51–55
46	Male	Married	51–55
47	Female	Married	21–25
48	Male	Married	31–35
49	Male	Relationship	41–45
50	Male	Relationship	31–35
51	Female	Widow, in a relationship	36–40

difficult for health professionals to discuss or propose HIVST during consultations. Finally, we present three barriers to the proposal of HIVST when disclosure of HIV status is not done within the couple.

Approach to HIVST

The approach to or presentation of HIVST differed from one health professional to another, even if all health professionals used the same tools (HIVST kits with instructions for use and videos describing how to use HIVST). Two of the health professionals (one physician and one nurse) used both the video in Bambara and the instructions to present HIVST to PLHIV, while the other two (one social worker and one physician) relied only on the instructions.

The two peer educators, on the other hand, only showed the HIVST kit without going into much detail about its use.

HIVST Was Discussed in Almost All Talks (and Group Discussions)

The issue of HIVST was raised in almost all the talk sessions (6/7) that we attended, either to provide information, to remind the participants about the existence of HIVST or to invite the participants to talk about HIV self-tests or to propose testing to their partners.

> *"I remind you that we discussed the existence of a new screening technique here. We use it in the mouth"* (from a peer educator).

Mentions of HIVST during the discussions were always followed by exchanges with and questions from the participants about how the tests are used, especially how they could be offered to partners when one's HIV status had yet to be disclosed with one's partner.

Discussion About HIVST Increased With the Length of Medical Consultations

Consultations during which HIV self-tests were provided lasted between 10 and 30 min depending on the health professionals and how HIV self-tests were offered to patients for their partners' use. The two health professionals (one physician and one nurse) who used both video and the paper instructions to explain how to use HIVST spent an average of 20–30 min per person, while the other two (social worker and 1 physician) who used only the instructions spent less time (10–15 min). Medical consultations lasted an average of 5 min, while social service consultations lasted from 10 to 30 min.

We did not notice any difference in the way HIV self-tests were delivered according to the gender of the health professional. Exchanges between health professionals and patients were conducted mostly in Bambara and rarely in French. During the 591 observed consultations, of which ∼35 were at the social service office, most PLHIV who presented were women (n = 450/591, 76%).

Proposing HIVST could affect health professionals' workload, especially during medical consultations. In some cases, the proposal of HIVST considerably lengthened waiting times, and patients complained about the delays. Although such delays were not explicitly mentioned by the health professionals responsible

for the delivery of HIVST as one of the reasons for the low rate of HIVST proposal, they nonetheless represented a non-negligible factor.

Interviewer: How long do you do [a consultation]?
Health professional: It is more than 30 min anyway.
Interviewer: ounhoun (ok). When you have to show the video, ehh.
Health professional: You have to explain. You have to show the video; you have to explain. It takes at least 30 min.
Interviewer: But does it change anything in your work? Is it additional work?
Health professional: Yes, yes. Because at the very beginning, it can often lead to a slowdown in your work. (...) often the sick will yell out there...
(Interview with a health professional).

Difficulties Discussing HIVST During the Observed Consultations

The results showed that there were difficulties for health professionals in discussing or proposing HIVST during consultations because, prior to the introduction of HIVST, the discussion of HIVST was deemed inappropriate for most consultations and some PLHIV had not disclosed their HIV status to their partners.

Indeed, according to our observations and the explanations of the health professionals in charge of providing HIVST, the following two situations could lead health professionals to avoid discussing the issue of HIVST or proposing that PLHIV give the HIVST kit to their partners:

1 It was not appropriate to dispense an HIV self-test at the consultation: e.g., if a patient with HIV was represented by a third party to renew his or her prescriptions or if the health professional knew in advance or after questioning the patient that he/she was widowed or single (without a partner) or that his or her partner was already receiving care, the issue of HIVST was not generally addressed or was just briefly mentioned.

Excerpts from exchanges between patients and health professionals during consultations where HIV self-tests were not provided:

Extract n° 1:
Health professional: Do you have a partner(s)?
Patient: No.
Health professional: The reason I asked you this is because there is a new at-home test. It is in the experimental phase.
Patient: Ok, it is (...)
(Extract from an exchange between a health professional and patient during a consultation)
Extract n° 2:
Health professional: Has your husband been tested?
Patient: Yes. He is even followed here at the XXX (clinic).
Health professional: The reason I am asking you this is because we now have a way for people to test themselves for HIV/AIDS.
Patient: Ok, I heard.
(Extract from an exchange between a health professional and patient during a consultation)

2 When the health care professional knew that the patient with HIV had not disclosed his or her status and did not wish to do so, the health care professional generally avoided offering the patient an HIVST kit for his or her partner, considering, e.g., that it might "be complicated."

Health professional: Are you married?
Young man: No.
Health professional: Do you have a sexual partner(s)?
Young man: Yes, I do.
Health professional: Has she been screened?
Young man: Not yet. She will do it when we are engaged.
Health professional: Have you shared your status with her?
Young man: Not yet.
Health professional: Ok. We have a test for that, which is done in the mouth. But since you haven't shared your status yet, it's going to be complicated.
(Excerpt from an exchange between a patient and a health professional during a consultation where HIVST was not dispensed)

Overall, HIVST was discussed during only 51 [42 women (W) and nine men (M)] of the 591 observed consultation (9%); in 49 of the consultation, the health professional initiated the discussion on HIVST, and PLHIV initiated the discussion two times. In the 49 consultations (40 W and nine M) where the discussion was initiated by the health professional, six PLHIV (5 W and 1 M) were found not to have a partner after the discussion, five (4 W and 1 M) had partners who had already been tested or followed up for HIV, 27 (22 W and 5 M) had disclosed their HIV status to their partners and 11 (9 W and 2 M) had not disclosed their HIV status to their partners. A total of 37 proposals for HIVST were made to PLHIV, of which 28 proposals (23 W and 5 M) were accepted and 9 were refused (8 W and 1 M).

The Three Main Barriers to the Distribution of HIV Self-Tests

The observations of the consultations and focus group discussions with peer educators and interviews with health professionals revealed three main barriers to the distribution of HIV self-tests in the context of low HIV status disclosure.

Health Professionals Avoided Offering HIVST to PLHIV Who Did Not Have Partners or Did Not Want to Disclose Their HIV+ Status to Their Partners

During the interviews, the four health professionals in charge of providing HIV self-tests considered the disclosure of one's HIV status to be a prerequisite for offering testing (and thus for providing HIV self-tests) of partners of PLHIV, as illustrated in this excerpt from an interview with a health professional.

Health professional: (…) it is people who are monitored at the clinic level and who wish to screen their partners. Now, it would be necessary that, first of all, the person shares his status.
Interviewer: Ounhoun (ok).
Health professional: If not, the person is offered to share [his or her HIV status with his or her partner]. Because you can't just give the test to someone who may not have shared their status.
Interviewer: Ok. So that's been said since the training.
Health professional: No, no, no. In practical terms.

Interviewer: But in relation to training, they didn't exclude this case for example?
Health professional: No, no, no.
Interviewer: A person who hasn't shared [his or her status], we can't offer the test? (. . .)
(Interview with health professional)

In our observations, the four health professionals who distributed tests avoided offering HIV self-tests for index testing when they knew that the individual's HIV status had not been disclosed to his or her partner. In two instances, the proposal of HIVST was withdrawn when the health professional realized that the patient had not disclosed his or her status—as described in the excerpt below from an observation note from a medical consultation.

Health professional: Has your husband been tested?
Woman: He is not infected.
Health professional: Has he been tested or not?
Woman: Yes, he did, and he renews it every 3 months.
Health professional: Okay. The reason I am asking is that we now have a "test" (referring to the self-test kit). It's just done with saliva, and the result can be read after 20 minutes.
Woman: Ok.
Health professional: You could bring it to him for home testing. I will show you a video explaining how to use it in Bambara.
Woman: Ok.
Health professional (after viewing): Did you understand?
Woman: Yes. Could I do it too?
Health professional: No. Those who are already HIV-positive are not allowed to do it. Only your husband could do it.
Woman: Okay. But I haven't shared my status with my husband yet.
Health professional: Then, it's going to be complicated because he might ask you questions about where the kit comes from. What could you say in that case?
Woman: Oh, that's right. I hadn't thought of that.
Health professional: Even if you told him it came from a hospital, he might ask you to specify which one?
Woman: Yes, that's right.
Health professional: Or are you going to share your status with him now?
Woman: Not at all. [He is] someone who already wants to divorce me; I'm not going to add more.
Health professional: Ok, I understand. Then I won't be able to give you a self-test kit anymore.
Woman: Ok.
(Extract from an exchange between a health professional and patient during a consultation).

PLHIV Were Reluctant to Offer HIV Self-Tests to Their Partners If They Had Not Shared Their HIV Status

Despite the position of health professionals that disclosing one's HIV status to a partner was a prerequisite for offering an HIV self-test for the partner, offers for HIV self-tests were indeed made to people who had not shared their HIV status and did not wish to do so. Of the 27 people who had already shared their status and were offered HIVST, 26 (21 W and 5 M) agreed to give HIV self-tests to their partners, while of the nine who had not shared their status, seven (6 W and 1 M) refused to so, with six (5 W and 1 M) explicitly mentioning or implicitly implying non-disclosure as the main reason for refusal. This finding shows that disclosure of one's HIV status to one's partner is a determining factor in the acceptance of the proposal of partner HIVST by PLHIV.

Example 1
Health professional: Is your husband here?
Woman: Yes, he is at home.
Health professional: Is he under treatment?
Woman: No.
Health professional: Did you share your status with him?
Woman: No. I am very afraid
Health professional: Okay. But are you going to tell him one day?
Woman: No (while lowering her head).
Health professional: Why? And yet you've been followed here for 14 years.
Woman: I'm very scared. I would like him to find out from me one day, but I am very afraid.
Health professional: Okay. But it can't go on like this. You can't keep it from him forever.
Woman: Yes, I know that.
Health professional: If you were given something, could you send it to him for testing?
Woman: No, I can't (with her head down).
Health professional: So he's going to ask you if you did it too?
Woman: Yes.
(Extract of health professional/patient exchange during a consultation)
Example 2
Health professional: Have you shared your status with your husband?
Woman: No.
Health professional: Why?
Woman: Because he's going to tell everyone (...)
Health professional: I still advise you to think about it since it would be better if he were to be screened and even followed up if necessary.
Woman: Yes, that's right.
Health professional: Otherwise, we have a way for him to do it [the test] at home.
Woman: No, it's ok.
(Extract of health professional/patient exchange during a consultation).

Strategies to Support the Disclosure of HIV Status Had Limitations

The third barrier was related to the limitations of existing support strategies for disclosing HIV-positive status when proposing HIVST to PLHIV who had yet to disclose their status to their partners. Despite the presence of a support program for disclosure called *Gundo-So* in the facility, health professionals and patients often felt powerless to overcome barriers to disclosure.

In the interviews, the health professionals acknowledged that the *Gundo-So* program is useful but has limitations regarding inclusion criteria, particularly in terms of timing (only women who have discovered their HIV status within the last 6 months to 5 years can participate). Moreover, this program, based on values of autonomy and empowerment, is not intended to force women to disclose their HIV status, which could in some cases put them at risk, but rather to accompany them in their choice of whether to share their status.

"Gundo-so" does exist. But the "Gundosso" doesn't intervene directly to tell someone to share "(...) They didn't want to take everyone. They wanted to take people who have disclosed recently (6 months to 5 years).
(Interview with one health professional)

In the peer educator-led group discussions for PLHIV, one of the first requests from patients after the mention of HIVST was tips on how to offer HIV self-tests for index testing without having to disclose their HIV status.

In the two consultations in which HIV self-tests were accepted by patients who had not yet disclosed their status to their partners, the health professional left it up to the patients to manage the disclosure themselves and did not offer them any specific support. Consequently, one patient proposed a strategy by requesting two test kits so that she and her partner could test simultaneously (i.e., without having to disclose her serological status prior to the test). The health professional accepted the request, telling the patient that the HIV self-test would probably be "indeterminate" [viral load undetectable with antiretroviral (ARV) treatment]. During the ensuing discussion, the young patient seemed very hesitant and anxious about offering her partner the HIV self-test. According to her, her partner was very smart and would certainly ask where she had received the test and why she did not test herself at the same time as him. The health professional explained to us that the patient's case was somewhat unique since she could not use the HIVST kit since she was already HIV positive and on ARV treatment. On the other hand, the health professional said he was obliged to give her the two HIVST kits since the patient considered this to be the only way for her partner to agree to be tested. After showing the video, the physician continued as follows:

Health professional: Did you get the message?
Woman: Yes.
Health professional: So he should be convinced to do it.
Woman: It's not going to be easy. He will ask me to use it first. So I would need two kits for that.
Health professional: Ok. I will give you two kits, but you should know that your result will be insignificant for us.
Woman: Ok.
Health professional: You'll know how to do it, right?
Woman: Yes (smiling).
(Excerpt from exchanges between physician and patient)

DISCUSSION

Using qualitative survey methods, we found several difficulties for health professionals to propose HIVST to their patients and for PLHIV to accept the proposal for index testing in the context of the high rate of HIV non-disclosure within couples. Specifically, we identified three main barriers to the provision of HIVST for index testing. First, almost all health professionals avoided offering HIV self-tests to PLHIV when they thought or knew that PLHIV had not shared their HIV+ status with their partners or did not wish to do so. Second, PLHIV were reluctant to offer HIV self-tests to their partners if they had not disclosed their own HIV+ status. Third, it was difficult for health professionals and PLHIV to manage the offer of HIVST and the disclosure of HIV+ status with the partner.

Difficulties in Proposing HIVST for the Partners of PLHIV Were Exacerbated by the Non-disclosure of HIV Status

The difficulties of discussing or proposing HIVST to PLHIV for health care staff notably resulted from the fact that most consultations were not appropriate for HIVST proposal to partner (e.g., when PLHIV were widowed, did not have a partner, or had delegated someone to renew their prescriptions). In addition, health care professionals were reluctant to discuss HIVST with their patients when they knew that their patients had not disclosed their HIV+ status with their partners. Other factors, such as the time-consuming nature of dispensing HIV self-tests, should not be overlooked among the underlying reasons for the low proportion of HIV self-tests dispensed in consultations.

The fears of PLHIV regarding the possible adverse consequences following the disclosure of HIV-positive status and the difficulties of health professionals in supporting PLHIV in this process were identified in this study as important barriers to the secondary distribution of HIV self-tests for index testing. In West Africa, the difficulties of disclosing HIV+ status to a partner results from a structural problem related to low self-esteem and fear of stigmatization or rejection by the partner, especially among women (32–35). Studies conducted in Malawi and Uganda on testing within couples at home attributed the low use of HIVST, especially among men, to a fear of having one's infidelity revealed, absence from home due to their professional activities, and fear of marital breakdown (18, 36). In Burkina Faso, an analysis of the effects of gender on testing showed that while fear of rejection by partners, friends or family members was cited as a reason for not using testing in general, women also cited a fear of losing their livelihoods (37). A woman's precariousness and/or financial dependence is a factor that reinforces her vulnerability to the undesirable effects of sharing HIV status within the couple (38). For this reason, a study conducted in Mali as part of the *Gundo-So* program emphasized the need to strengthen programs supporting PLHIV and empower PLHIV so that they can make free and informed decisions regarding the disclosure of their HIV status (22).

HIVST: A Limited Opportunity for Status Sharing and Partner Testing

HIVST could be seen as an opportunity for PLHIV to disclose their status to their partners. Surveys of same-sex couples in China and South Africa found an increase in the disclosure of HIV status with the partner before having sex with each other as a result of access to HIV testing (17, 39). However, this finding may be specific to the marital context and the nature and duration of those relationships. We did not find any specific study that documented the link between access to HIVST and disclosure of HIV status among PLHIV.

The ATLAS project promotes HIVST for the partners of PLHIV regardless of disclosure status, considering that HIVST could represent an opportunity to facilitate the disclosure

process (and thus reduce barriers to access to testing, such as coming to the health center). However, the project recognizes the importance of assisted notification to promote partner testing and has therefore integrated these elements into the definition of dispensing strategies, training programs and tools available to dispensing agents. e.g., one of the key message of the training course was: "Assisted partner notification improves uptake of testing and is a simple and effective way to reach partner of PLHIV." (https://atlas.solthis.org/wp-content/uploads/2019/11/03_Manuel_Formateur_ProSante_M3_ML.pdf) (see **Supplementary Table 5**).

However, in this study, while the ATLAS project did not define the notification of one's own HIV status to one's partner as a condition of the proposal of partner HIVST to PLHIV, disclosure was often considered a prerequisite by the health professionals and by some PLHIV. The hesitance of health care professionals and patients regarding the proposal of HIVST could be interpreted as a desire to anticipate possible adverse effects in couples that are not always justified (40).

Furthermore, the attitude of the patient who requested two HIVST kits to be able to carry out couple testing without having to disclose her HIV+ status and the acceptance of the request by the physician who informed her the result would be "insignificant" (a false negative) raise an ethical issue which could be analyze.

It is essential to strengthen strategies to support HIV+ status disclosure, the HIV testing of PLHIV partners, and the development of anti-stigma programs to improve HIV+ status disclosure and the uptake of HIV testing in general. Experiences with couple testing strategies, especially in the context of the prevention of mother-to-child transmission, could be mobilized to reach more untested partners. Indeed, the effectiveness of couple-based testing approaches and support for women has been demonstrated in numerous studies (41–43).

In Mali, comprehensive testing of HIV-positive partners cannot be effective without improving support for the disclosure of HIV+ status by strengthening "couples" counseling that takes into account the gendered dimensions of disclosure. However, despite the existence of a program to support the disclosure of HIV status like *Gundoso*, the impact of this type of intervention on the sharing of status within the couple has hardly been documented, as in other sub-Saharan countries as noted by systematic reviews (3–5). Also, improving support would involve the consideration of programs to support women's empowerment (22, 44).

Delegation of Tasks: An Opportunity to Improve the Distribution of HIVST

In addition to the non-disclosure of serological status, there were difficulties with HIVST distribution since most of the information and distribution of HIV self-tests to PLHIV for index testing was carried out by medical staff who were already overwhelmed by "normal consultations," which could hinder the distribution of HIV self-tests (45). Increasingly, however, task shifting seems to be a preferred option in the monitoring and support of PLHIV because it has proven its worth in the response to HIV (23). In the context of the introduction of HIVST, particularly through index testing, the involvement of non-medical staff such as social workers, peer educators or other community actors could promote better distribution because these non-medical staff have much more time for exchange with patients and/or proximity with patients, which would reduce the cost of dispensing HIVST (45).

Limitations of the Study

The study was conducted on one site. The results of this study rely on data collected only 3 months after the start of HIVST dispensing activities in Mali. Additional interviews and observations in the same facility are planned before the end of the project in 2021 to document any changes related to the provision of HIV self-tests.

CONCLUSION

The difficulties of offering HIVST to partners of PLHIV raise fundamental questions related to HIV disclosure to sexual partners and the associated stigmatization. Our results highlight the potential role of interventions to support HIVST for index testing that does not rely on disclosure and that is adapted to local contexts to increase diagnostic coverage of partners of PLHIV who are not reached by traditional testing strategies.

It is necessary to develop a specific approach for the provision of HIV self-tests for the partners of PLHIV by rethinking the involvement of stakeholders (caregivers, social workers, peer educators, etc.). This approach would involve reviewing the roles assigned to these stakeholders, providing them with training tailored to the issues related to the disclosure or non-disclosure of HIV status and gender inequalities, and improving counseling for PLHIV regardless of their situations.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

JL, AD, DP, and NR designed and implemented the ATLAS STUDY. SBoy, DP, and JL conceived and designed the analysis. SBou and SBoy collected the data. SBoy wrote the first draft of the manuscript. All authors contributed to the interpretation and presentation of the findings and approved the final version of the manuscript for submission.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2021.653543/full#supplementary-material

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Costs and Scale-Up Costs of Integrating HIV Self-Testing Into Civil Society Organisation-Led Programmes for Key Populations in Côte d'Ivoire, Senegal, and Mali

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Despite significant progress on the proportion of individuals who know their HIV status in 2020, Côte d'Ivoire (76%), Senegal (78%), and Mali (48%) remain far below, and key populations (KP) including female sex workers (FSW), men who have sex with men (MSM), and people who use drugs (PWUD) are the most vulnerable groups with a HIV prevalence at 5–30%. HIV self-testing (HIVST), a process where a person collects his/her own specimen, performs a test, and interprets the result, was introduced in 2019 as a new testing modality through the ATLAS project coordinated by the international partner organisation Solthis (IPO). We estimate the costs of implementing HIVST through 23 civil society organisations (CSO)-led models for KP in Côte d'Ivoire ($N = 7$), Senegal ($N = 11$), and Mali ($N = 5$). We modelled costs for programme transition (2021) and early scale-up (2022–2023). Between July 2019 and September 2020, a total of 51,028, 14,472, and 34,353 HIVST kits were distributed in Côte d'Ivoire, Senegal, and Mali, respectively. Across countries, 64–80% of HIVST kits were distributed to FSW, 20–31% to MSM, and 5–8% to PWUD. Average costs per HIVST kit distributed were \$15 for FSW (Côte d'Ivoire: \$13, Senegal: \$17, Mali: \$16), \$23 for MSM (Côte d'Ivoire: \$15, Senegal: \$27, Mali: \$28), and \$80 for PWUD (Côte d'Ivoire: \$16, Senegal: \$144), driven by personnel costs (47–78% of total costs), and HIVST kits costs (2–20%). Average costs at scale-up were \$11 for FSW (Côte d'Ivoire: \$9, Senegal: \$13, Mali: \$10), \$16 for MSM (Côte d'Ivoire: \$9, Senegal: \$23, Mali: \$17), and \$32 for PWUD (Côte d'Ivoire: \$14, Senegal: \$50). Cost reductions were mainly explained by the spreading of IPO costs over higher HIVST distribution volumes and progressive IPO withdrawal at scale-up. In all countries, CSO-led HIVST kit provision to KP showed relatively high costs during the

study period related to the progressive integration of the programme to CSO activities and contextual challenges (COVID-19 pandemic, country safety concerns). In transition to scale-up and integration of the HIVST programme into CSO activities, this model shows large potential for substantial economies of scale. Further research will assess the overall cost-effectiveness of this model.

Keywords: costs and cost analysis, scale-up, HIV self-testing, key populations, knowledge of HIV status, diagnosis, screening, West Africa

INTRODUCTION

In Western and Central Africa, 5 million people are living with HIV, representing a prevalence of 1.4% in 2019 (1). As in most countries of the region, the epidemic is mixed in Côte d'Ivoire, Senegal, and Mali, with national prevalence in 2018 ranging between 0.4 and 2.6% and much higher prevalence at 5–30% in hard-to-reach key populations (KP) including female sex workers (FSW), men who have sex with men (MSM), and people who use drugs (PWUD) (1). In 2019 in Western and Central Africa, HIV prevalence was 10% for FSW, 14% for MSM, and 5% for PWUD (1). Because of the HIV prevention gap among these groups, KP contribute mostly to HIV transmission (2–4).

UNAIDS has set targets for 95% of people living with HIV to know their status, 95% of known HIV-positive individuals to be on antiretroviral therapy (ART), and 95% of those on ART to have their viral load suppressed by 2030 (5). Despite significant progress on the proportion of individuals who know their HIV status (increase from 4% in 2000 to 67% in 2020), Western Africa remains far below the first 90 UNAIDS target, with disparities observed between Côte d'Ivoire (76%), Senegal (78%), and Mali (48%) in 2020 (6).

Conventional facility-based HIV testing services (HTS) does not adequately reach those KP due to stigma, discrimination, and health services not responding to needs specific to each group. Local civil society organisations (CSO) providing mostly community-based HIV testing services using peer educators have proven successful in reaching the core members of these populations, linking, and retaining them into care (7, 8).

HIV self-testing (HIVST) is defined as a process where a person collects his/her own specimen (oral fluid or blood), performs an HIV test and interprets the result, often in private (9). Following promising demonstration projects in Eastern and Southern Africa (10–15), HIVST was introduced in 2019 as a new testing modality in West Africa with the ATLAS project (*Auto Test VIH, Libre d'Accéder à la connaissance de son Statut*) (16). The project is led by the French non-governmental organisation Solthis—namely international partner organisation (IPO) in this study—in consortium with the Institut de Recherche pour le Développement, Ministries of Health, and local implementing CSO in Côte d'Ivoire, Senegal, and Mali. HIVST has the potential to overcome some of the existing structural barriers to testing and to increase diagnosis coverage among KP (primary distribution) and their peers, sexual partners and clients (secondary distribution) not reached by conventional HTS (17, 18).

OraQuick® HIV self-tests have been subsidised by the Bill and Melinda Gates Foundation, then proposed by Orasure Inc. at US$2 per kit in 50 low- and middle-income countries for public sector distribution (19). However, HIVST is still around twice the price of standard HIV rapid diagnostic tests currently used for HIV testing in Africa. In southern Africa, HIVST increased diagnosis coverage and showed potential value for money for key populations as a complement to current testing approaches (9, 10, 20).

In this study, we estimate the costs of implementing HIVST through CSO for KP in Côte d'Ivoire, Senegal, and Mali. We also assess the costs of scaling up this model to guide project national scale-up, propose costed operational plans, and inform on the sustainability of this distribution model.

MATERIALS AND METHODS

Intervention Setting

HIVST kits were distributed through 23 CSO across Côte d'Ivoire ($N = 7$), Senegal ($N = 11$), and Mali ($N = 5$) from July 2019 to September 2020. Implementing partners' key characteristics are presented in **Table 1**. The deployment strategy identified three sequential intervention phases: (1) *development phase (June 2018–March 2019)*: all activities that identify sustainable distribution models for each country, to fully integrate HIVST into existing programmes; (2) *start-up phase [April 2019–July 2019 (Senegal/Mali), - October 2019 (Côte d'Ivoire)]*: adaptation of self-testing information materials to the local context, development of training manuals, training of HIVST providers, sensitisation of key actors and building partnerships with local partners (regardless of when the costs were incurred), and other start-up costs; and 3) *early implementation phase (up to September 2020)*: demand creation, HIVST kits distribution, and project supervision (**Figure 1**). In each country, all CSO did not start HIVST kits distribution at the same time, and this was accounted for in the cost analysis by adjusting the length of the implementation period by distribution channel. We costed community-based activities used by CSO for reaching KP and excluded facility-based costs corresponding to HIVST kits provision through index testing and sexual health consultations, accounting for a small proportion of CSO activities and outside the scope of this analysis. CSO1 (Senegal) is not technically a CSO but a public facility included in the analysis because they provide community-based services to PWUD.

TABLE 1 | Overview of 1the ATLAS project's implementing partners in Côte d'Ivoire, Senegal, and Mali.

Country	Administrative region	Number of districts covered	Civil society organisation	Distribution channel	Number of trained HIVST providers	HIVST kits HIVST providers
Côte d'Ivoire	Gbôklé, Nawa, San-Pédro	2	CSO1	FSW	13	9,605
				MSM	4	4,172
	Abidjan 1	2	CSO2	FSW	29	9,175
	Abidjan 2	2	CSO3	FSW	20	15,944
				MSM	6	6,812
				PWUD	9	4,230
	Mé, Abidjan 1	2	CSO4	MSM	7	2,177
	Sud Comoé	1	CSO5	FSW	6	2,261
				MSM	5	1,370
	Mé, Sud Comoé	2	CSO6	FSW	13	5,181
				MSM	8	2,511
	Gbôklé, Nawa, San-Pédro	2	CSO7	FSW	8	7,044
				MSM	3	4,406
Sub-total					**131**	**74,888**
Senegal	Dakar, Thiès	11	CSO1	PWUD	22	1,862
	Dakar, Thiès, Ziguinchor	18	CSO-Associations	FSW	25	1,540
				MSM	33	2,933
	Dakar, Thiès	9	CSO-mobile clinics	FSW	4	810
	Dakar, Thiès, Ziguinchor	17	CSO-independent distributors	FSW	16	4,320
				MSM	12	2,400
				PWUD	4	160
Sub-total					**116**	**14,025**
Mali	Bamako, Sikasso, Koulikoro, Kayes, Segou	7	CSO1	FSW	15	11,250
				MSM	14	4,813
	Bamako, Segou, Sikasso, Kayes, Koulikoro	11	CSO2	FSW	78	22,400
				MSM	20	3,360
	Bamako, Segou, Sikasso	5	CSO3	FSW	31	20,910
	Kayes, Koulikoro	12	CSO4	MSM	19	12,321
	Sikasso	2	CSO5	FSW	7	4,623
				MSM	7	2,139
Sub-total					**191**	**81,816**
TOTAL					438	170,729

HIVST, HIV Self-Testing kit; FSW, Female Sex workers; MSM, Men who have Sex with Men; PWUD, People who use drugs.

Cost Data Collection and Analysis

The costing teams followed the Global Health Cost Consortium guidelines and collaboratively analysed data, ensuring consistency of methods across countries (21–23). We used the provider's perspective. We conducted an incremental cost analysis, where only additional resources needed to introduce HIVST to existing service provision were considered. These incremental costs were collated from the IPO and implementing partners' financial expenditures and each line item was categorised by input type and distribution model (top-down costing approach) (24). Inputs were categorised into start-up, capital, and recurrent costs. Inputs were allocated to distribution sites following predefined allocation factors, based on project monitoring and evaluation data, including the percentage of HIVST distributors in each site, estimated cohort size of HIV-positive patients followed by the CSO, percentage of kits distributed, and percentage of direct expenditures, which is a weighted average of the preceding allocation factors. Further details on the methods and allocation factors can be found in **Appendix Table 1**, and elsewhere (25–27). To estimate economic costs, the expenditure analysis was complemented by a valuation, with market prices or financial data provided by the implementers, of all other resources used in the delivery model (donated services such as personnel time at the CSO headquarters and in the field, not paid by the ATLAS project). Finally, a time-motion study was conducted to observe staff providing HIVST alongside other services and allocate personnel costs based on the time spent on each activity (28, 29). The

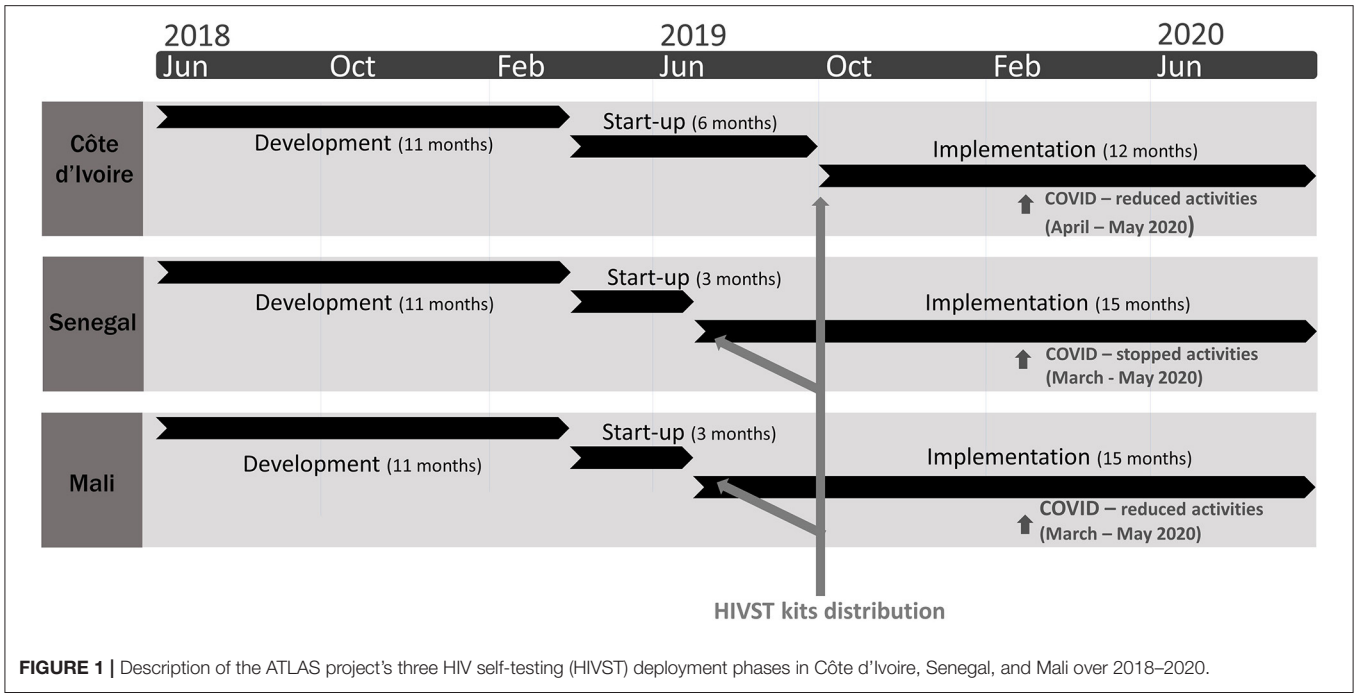

FIGURE 1 | Description of the ATLAS project's three HIV self-testing (HIVST) deployment phases in Côte d'Ivoire, Senegal, and Mali over 2018–2020.

HIVST kit cost was US$2.68 for Côte d'Ivoire and US$3.08 for Senegal and Mali. Start-up, training, and all other capital costs were annualised using a discount rate of 3%. All costs were estimated in 2020 USD dollars using annual exchange rates. Total costs and average cost per kit distributed were estimated at the country level, at the CSO level and per channel.

Sensitivity Analysis of Costs

We conducted a series of one-way sensitivity analyses, using tornado diagrams, to assess the impact of key cost assumptions on the average cost per HIVST kit distributed. We varied the discount rate used to annualised costs to 0 and 16% (base case is 3%) to capture the impact of not discounting or using a higher local central bank discount rate such as in Mali (30). We evaluated the impact of applying alternative allocation factors that is swapping percentage trained distributors to percentage cohort size for IPO expenditures. We varied annualisation (economic life years) time frames: training & sensitisation were varied between 1 and 3 years (base: 2 years), project development life between 5 and 15 years (base: 10 years), and start-up life (training, sensitisation and other costs incurred during this phase) between 2.5 and 7.5 years (base: 5 years) to assess the impact of the assumed project life years on costs. For Senegal only due to data availability, we swapped the allocation of field-based personnel costs from using percentage HIVST time observed during the time-motion study to using percentage HIVST time reported by study participants. Finally, episodes of violence against MSM occurred during the study period, and CSO had to suspend their activities in Senegal and Mali. The COVID-19 pandemic also led to reduced/suspended activities (**Figure 1**), therefore we also estimated the average cost per target HIVST distribution volumes.

Scale-Up Cost Model and Scenario Analysis

We also modelled costs at scale-up when HIVST kit distribution volumes would increase following each country's National Strategic Plan for HIV testing to predict the variation of average cost between the implementation and scale-up phases. The production function, developed by Cobb and Douglas, describes the relationship between outputs and factors of productions (inputs) (31). Accounting cost functions follow step-by-step the intervention production process as close as possible to reality (22, 32). They identify fixed and variable costs, typically assumed to vary linearly with the scale such as that used in input-output analysis as originally developed by Leontief (33, 34). It should be noted that with the exception of training costs (variable cost) and sensitisation costs (fixed cost) considered in the scale-up model, all other costs incurred during the development and start-up phases are considered one-off costs incurred at the start of the programme and therefore, are excluded from the costs of scaling-up. The model algebra is presented here, the detailed model structure listing fixed and variable costs is presented in **Table 2**.

$$\mathbf{C} = \sum_{\mathbf{j}} (\mathbf{FC_j} + \mathbf{VC_j})$$

$$\text{with } \mathbf{VC_j} = \mathbf{UC_j} \cdot \mathbf{S_j}$$

Where:

C: Total cost

j: inputs differentiating intervention levels—international, national, district, and community

$\mathbf{FC_j}$: Fixed cost (independent of S_j) for fixed input *j* (e.g., building, personnel at central level)

TABLE 2 | Model structure—Accounting cost function.

Intervention level	Type of costs	Cost inputs	Scale variable*
International	Fixed costs	S2. Sensitisation—Coordination R1. Personnel and Per diems—Headquarters IPO coordination	
	Variable costs	None	
National	Fixed costs	C1. Buildings and storage C2. Equipment C3. Vehicles C4. Other capital costs S2. Sensitisation—IPO country R2. Personnel and Per diems—Headquarters IPO country	
	Variable costs	S1. Trainings (start-up phase only)	Number of *new* providers to train
		R6. Vehicle operation and maintenance/transportation	Total number of HIVST providers
		R7. Building operation and maintenance	Total number of HIVST providers
		R8. Other recurrent costs	Total number of HIVST providers
Sub-national—Implementing partners	Fixed costs	None	
	Variable costs	R3. Personnel and Per diems—Headquarters Implementing partner	Total number of HIVST providers
Local—HIVST distribution areas	Fixed costs	None	
	Variable costs	R4. Personnel and Per diems—Field (HIVST distributors)	Total number of HIVST providers
		R5. HIV self-testing kits (implementation phase only)	Number of HIVST kits to distribute

**The selection of scale variables was done in a way to account for the fact that the project is in early implementation phase (HIVST kits distribution targets not always reached by CSO in early phase) and the COVID-19 pandemic impact (reduced field activities), meaning CSO were not working at full capacity during the observed costing period. Therefore, the model uses predominantly the number of providers as scale up variable rather than the number of HIVST kits distributed during our observed period to limit the risks of bias. The number of kits to distribute is used to estimate projected costs based on HIVST volume distribution targets for each year 2021–2023.*
IPO, International Partner Organisation.

VC_j: Variable cost for input *j* (e.g., field personnel, HIVST kits)

UC_j: Unit cost per variable inputs *j* for one output (the type of unit depends of each category): new staff to train, HIVST kits to distribute, etc.

S_j: Scale variable for input *j* to reach desired number of outputs: number of new providers required for scale-up, total number of providers at scale-up, number of HIVST kits to distribute.

In anticipation of planned project scale-up by respective country ministries of health and post-ATLAS transition, we conducted a series of scenario analyses varying some of the key model parameters by country and by scale-up year, considering 2021 as a transition year, 2022 partial scale-up, and 2023 as full scale-up. Four potential scenarios are presented in **Table 3**. Logistical and contextual challenges with CSO-led delivery channels to criminalised KP, and current donors' commitments for funding, were noted to cause challenges leading to uncertainty related to the timely attainment of targets. We therefore anticipate that those programmatic objectives might not be reached. Accounting for this would provide more nuanced scale economies, and we applied different percentages for reaching targets—higher percentages in Mali, where more funding is already secured (*scenario 1*). IPO's goal to progressively disengage to promote local project ownership overtime was considered. Note that we still account for 15% of international costs in 2023 because we assume another coordination component will still exist (and incur costs) within the local health system at central level. Year 2023 would then represent what it costs for the country to support HIVST post-ATLAS (*scenario 2*). We also assessed the impact of optimising delivery channels by simplifying the model of partners/sub-partners and decreased CSO headquarter costs by 20%, which is reasonable to assume when evaluating interventions transitioning from pilot (ATLAS) to routine implementation phase (*scenario 3*) (35). Finally, we conducted country-specific simulations to account for varying HIVST kit cost for each year considering factors such as bulk buying, maritime provision instead of airways (except Mali), and integrating HIVST delivery chain with other health supplies (*scenario 4*). Finally, we combined all scenarios above to assess the global impact on average costs at scale per KP and scale-up year.

This study was approved by the London School of Hygiene and Tropical Medicine (n° 17141/RR/13198, 31st March 2019) WHO Ethic Research Committee (n°ERC0003181, 7th August 2019), and by three national ethic committees: Comité National d'Ethique des Sciences de la vie et de la Santé de Côte d'Ivoire (n°049-19/MSHP/CNESVS-kp, 28th May 2019), Comité National d'Ethique pour la Recherche en santé du Sénégal (n°SEN19/32, 26th July 2019), and Comité d'Ethique de la Faculté de Médecine de Pharmacie et d'Odonto-Stomatologie de l'Université des Sciences et des Techniques de Bamako au Mali (n°2019/88/CE/FMPOS, 14th August 2019).

TABLE 3 | Selected parameters for the scenario analysis of costs at scale-up in Côte d'Ivoire, Senegal, and Mali (baseline: all parameters at 100%).

	Scenario 1			Scenario 2			Scenario 3			Scenario 4		
	Reaching HIVST distribution volume targets (% of target achieved)			Progressive disengagement of IPO (% reduction of IPO costs)			Implementing partners headquarter costs (% reduction of IP costs)			HIVST kit cost based on volumes (% reduction of original kit cost)		
	2021	2022	2023	2021	2022	2023	2021	2022	2023	2021	2022	2023
Côte d'Ivoire	−25%	−25%	−30%	As in baseline	−50%	−85%	−20%	−20%	−20%	−9%	−9%	−9%
Senegal	−25%	−25%	−30%	As in baseline	−50%	−85%	−20%	−20%	−20%	−17%	−17%	−17%
Mali	−20%	−20%	−25%	As in baseline	−50%	−85%	−20%	−20%	−20%	−13%	−13%	−13%

IPO, International Partner Organisation; IP, Implementing Partner.

RESULTS

Programme Outcomes in Côte d'Ivoire, Senegal, and Mali

During the costing period, 51,028, 14,472, and 34,353 HIVST kits were distributed in Côte d'Ivoire, Senegal, and Mali through a total of 161, 48, and 191 peer educators, respectively. These volumes corresponded to 68% (Côte d'Ivoire), 103% (Senegal), and 42% (Mali) of planned targets. The average number of HIVST kits distributed was 7,290 (range: 1,295–16,513) across 7 CSO in Côte d'Ivoire, 3,618 (range: 422–7,193) across the main four models composed of 11 CSO in Senegal (CSO-Associations, CSO-Mobile clinics, CSO-independent distributors, and the public partner working with PWUD only), and 6,871 (range: 2,688–17,891) across 5 CSO in Mali. In Côte d'Ivoire, 66% of kits ($N = 33,647$) were distributed to FSW, 26% ($N = 13,250$) to MSM, and 8% ($N = 4,131$) to PWUD. In Senegal, 64% of kits ($N = 9,338$) were distributed to FSW, 31% ($N = 4,472$) to MSM, and 5% ($N = 662$) to PWUD. In Mali, 80% of kits ($N = 27,528$) were distributed to FSW, and 20% ($N = 6,825$) to MSM.

Project Total Costs and Average Costs per Kit Distributed, Distribution Target

In Côte d'Ivoire, the total distribution costs were calculated as $440,648, $201,910, and $65,691 for FSW, MSM, and PWUD, respectively (**Table 4**). Start-up phase accounted for 25, 23, and 26% of total costs for FSW, MSM, and PWUD, respectively, while the development phase only accounted for 2% across key groups. Personnel costs at various intervention levels accounted for a substantial portion of total costs, at 47% for FSW, and 50% for MSM and PWUD, followed by HIVST kits costs at 20, 18, and 17% (**Figure 2**). Average cost per HIVST kit distributed were $13, $15, and $16 for FSW, MSM, and PWUD.

For Senegal, total intervention costs were $159,393, $120,374, and $95,091 for FSW, MSM, and PWUD (**Table 4**). Start-up phase costs were 17% for FSW and MSM, and 5% for PWUD, and at a mean of 5% for development phase costs across groups. Personnel costs were 51%, 57%, and 78% of total costs while HIVST kits costs were 18%, 11%, and 2% for FSW, MSM, and PWUD, respectively (**Figure 2**). Average costs per kit were $17, $27, and $144 for FSW, MSM, and PWUD.

Finally, in Mali, total costs were $438,553 and $188,159 for FSW, and MSM (**Table 4**). Start-up phase and development phase costs accounted on average for 13% and 3% of total costs across groups. Personnel costs were 53%, and 61% of total costs, while HIVST kits costs were at 19% and 11% for FSW and MSM, respectively (**Figure 2**). Average cost per kit were $16 and $28 for FSW and MSM.

While the share of start-up costs as percentage of total costs was comparable between target groups in Côte d'Ivoire and in Mali, it differed in Senegal because the CSO delivering to PWUD were small organisations, hence being allocated a low share of start-up costs. Because the start-up period was longer in Côte d'Ivoire (6 months) compared to the one in Senegal and Mali (3 months), start-up costs as percentage of total costs were higher in Côte d'Ivoire.

Wide variations of average costs per HIVST kit distributed were found between CSO (**Appendix Tables 2a–c**). In Côte d'Ivoire, average cost per kit distributed ranged $9–$27 for FSW, $10–$29 for MSM, and only one CSO worked with PWUD. In Senegal, average costs were $13–$32 for FSW, $25–$28 for MSM, and $121–$156 for PWUD. In Mali, average cost per kit distributed ranged $15–$27 for FSW, and $17–$59 for MSM. In Senegal, CSO-Associations had lower average costs than CSO-Independent distributors (mean: $19 vs. $23), but overall distributed less HIVST kits (5,834 vs. 6,953 kits) to FSW and MSM.

The major driver of these cost differences both between and within key groups for all countries was the number of kits distributed per dispensing agent, except in Côte d'Ivoire where the average number of kits distributed per dispensing agent was comparable between groups. Another important driver of cost variation between and within groups for all countries was the total number of HIVST kits distributed by a CSO. An increase of any of these two drivers would lead to a reduction in average costs.

Sensitivity Analysis of Costs Results

Appendix Figure 1 presents results from the univariate sensitivity analyses by key groups for Côte d'Ivoire (**1a**), Senegal (**1b**), and Mali (**1c**). Our unit costs per HIVST kit distributed remained robust when key cost parameters were varied. In Côte d'Ivoire, varying life of start-up sensitisation and training between 1 and 3 years had the strongest effect on costs ranging between $12–$17, $14–$19, and $14–$20 for FSW, MSM and PWUD, respectively. The life year of development and start-up

TABLE 4 | Observed total and average intervention costs by intervention phase and key group—Côte d'Ivoire, Senegal, and Mali.

	Côte d'Ivoire—Global estimates					
	FSW		MSM		PWUD	
	$	%	$	%	$	%
Intervention phases						
Development	7,612	*2%*	3,518	*2%*	1,118	*2%*
Start–up (start–up and other costs)	120,874	*27%*	52,238	*26%*	18,687	*28%*
Implementation	312,162	*71%*	146,153	*72%*	45,887	*70%*
Total annual costs	**440,648**		**201,910**		**65,691**	
HIVST kits distributed	33,647		13,250		4,131	
Average cost per HIVST kit distributed	**13**		**15**		**16**	
	Senegal—Global estimates					
	FSW		**MSM**		**PWUD**	
	$	**%**	**$**	**%**	**$**	**%**
Intervention phases						
Development	8,262	*5%*	5,684	*5%*	4,754	*5%*
Start-up (start-up and other costs)	35,628	*22%*	25,579	*21%*	9,648	*10%*
Implementation	115,502	*72%*	89,111	*74%*	80,689	*85%*
Total annual costs	**159,393**		**120,374**		**95,091**	
HIVST kits distributed	9,338		4,472		662	
Average cost per HIVST kit distributed	**17**		**27**		**144**	
	Mali—Global estimates					
	FSW		**MSM**			
	$	**%**	**$**	**%**		
Intervention phases						
Development	11,544	*3%*	5,434	*3%*		
Start-up (start-up and other costs)	74,345	*17%*	29,633	*16%*		
Implementation	352,664	*80%*	153,093	*81%*		
Total annual costs	**438,553**		**188,159**			
HIVST kits distributed	27,528		6,825			
Average cost per HIVST kit distributed	**16**		**28**			

HIVST, HIV Self-Testing kit; FSW, Female Sex workers; MSM, Men who have Sex with Men; PWUD, People who use drugs.

phases, allocation factor swapping (for FSW and MSM) had a moderate effect with less than a dollar variation. The variation of discount rate almost had no effect on costs. In Senegal, the discount rate applied had the strongest effect with average costs varying between $17–$19, $26–$30, and $141–$163 for FSW, MSM, and PWUD, respectively due to higher proportion of capital costs compared to Côte d'Ivoire. Allocation factor swapping from trained distributors had an effect on average costs for PWUD (reduction to $127), while swapping from time-motion study results had no effect. In Mali, swapping of allocation factors has the strongest effect, but overall, average costs only varied by <2 dollars suggesting our average costs were quite robust.

Reaching HIVST distribution targets greatly reduced costs (not presented in **Appendix Figure 1**). Average cost per HIVST kit distributed were $9, $9, and $16 for FSW, MSM, and PWUD, assuming distribution targets were reached in Côte d'Ivoire. In Senegal, average costs per kit were $24, $23, and $47 for FSW, MSM, and PWUD assuming distribution targets were reached. Finally, in Mali, average cost per kit would be much lower if targets were reached, at $7 and $8 for FSW and MSM, respectively.

Cost at Scale-Up Following National Strategic Plans

Costs at scale-up for each year of the National Strategic Plans are presented by country, year, and key groups in **Figure 3**, with details in **Appendix Tables 3a–c**.

Over the period 2021–2023, costs per kit distributed are on average at $9 (FSW and MSM), and $14 (PWUD) in

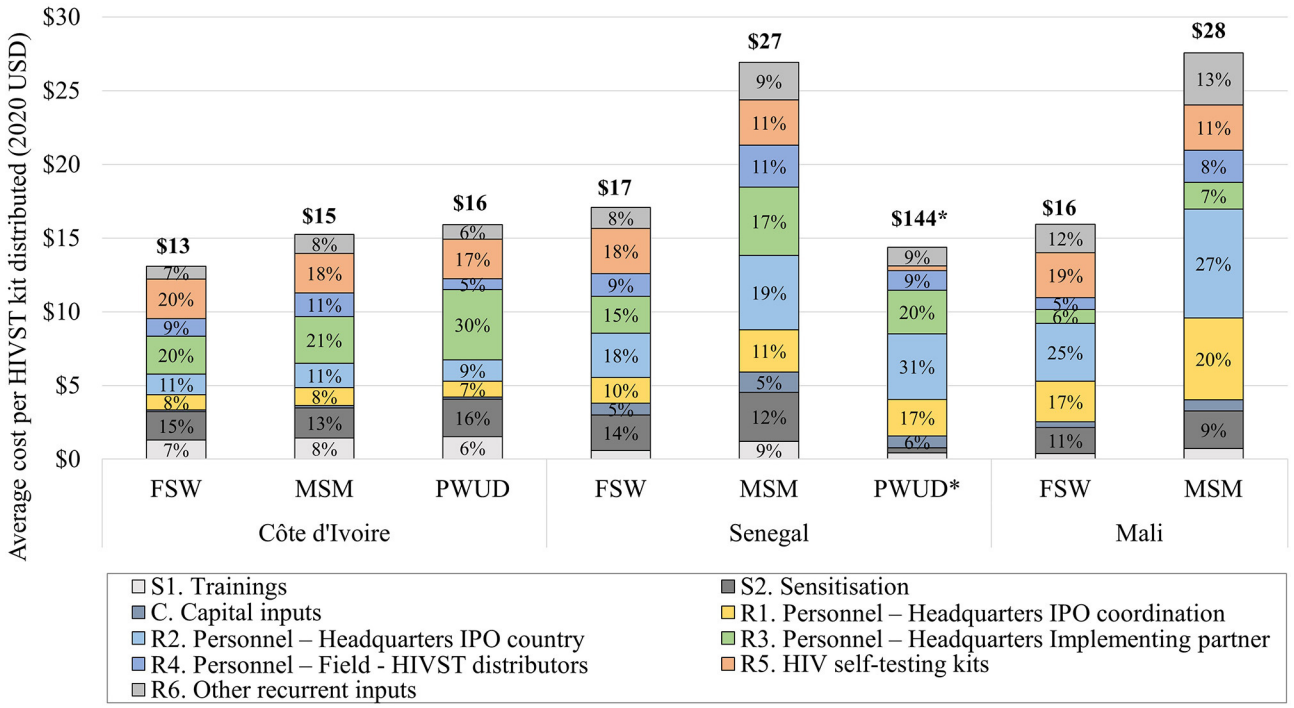

FIGURE 2 | Average intervention costs by inputs for each key group—Côte d'Ivoire, Senegal, and Mali. *For PWUD in Senegal, costs are presented on this figure divided by 10 for scale purpose.

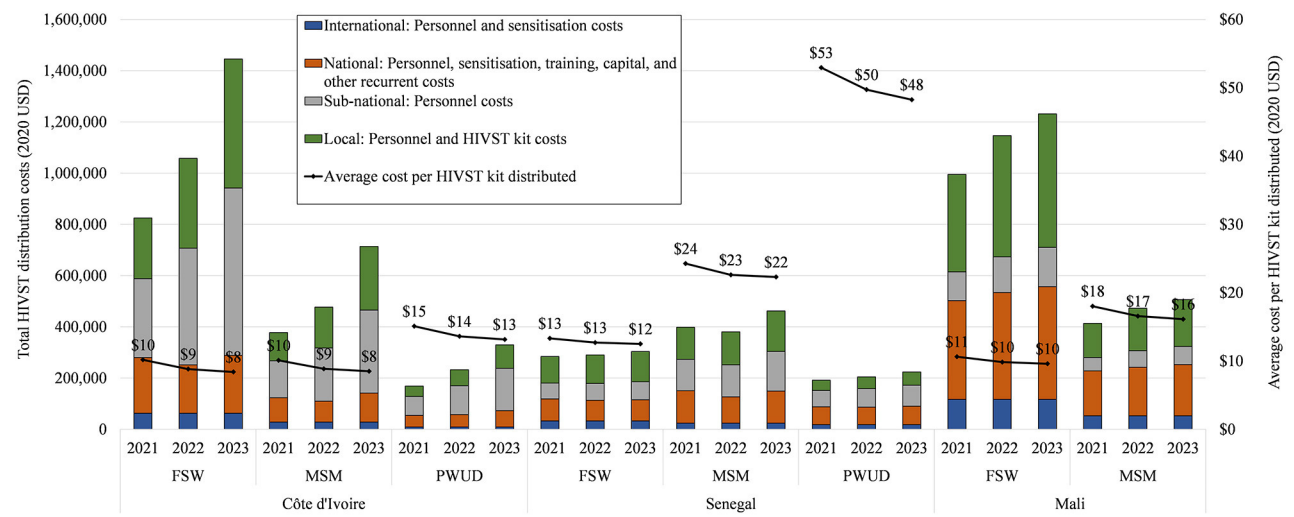

FIGURE 3 | Total and average intervention costs in transition (2021) and at scale-up (2022–2023) by country and key population.

Côte d'Ivoire; $13 (FSW), $23 (MSM) and $50 (PWUD) in Senegal; and $10 (FSW), and $17 (MSM) in Mali. We note the significant reduction of average costs at scale-up vs. observed average costs for FSW and MSM in Côte d'Ivoire, PWUD in Senegal, and all groups in Mali. Across countries, years, and key groups, the trend is an overall increase in total costs as expected. Although we estimate variation between countries and key groups, in transition and scale-up, overall cost drivers are fixed costs such as sensitisation activities, and headquarter-based personnel costs at national and sub-national level, and variable costs such as training and HIVST kits costs (varying with HIVST distribution targets). In Senegal, we estimate higher personnel costs at CSO level (headquarter- and field-based).

Scenario Analysis of Scale-Up Costs

As the scale-up model does not account for other contextual factors related to the transition post-ATLAS, analyses of plausible scale-up scenario are presented in **Appendix Figures 2a–c**.

For all countries and key groups, we find that HIVST volumes are the major determinants of costs per HIVST kit distributed (economies of scale), followed by IPO withdrawal starting in 2022, reduction of implementers' central costs, and the estimated reduction of HIVST kit price. Accounting for all these factors together would increase estimated scale-up average costs between \$9 (FSW—2023) and \$18 (PWUD—2021) in Côte d'Ivoire, from \$12 (FSW—2023) to \$65 (PWUD—2021) in Senegal, and from \$9 (FSW—2023) to \$21 (MSM—2021) in Mali.

DISCUSSION

In this study, we estimated the cost of implementing HIVST for KP and their partners in three West African countries. Across countries, we found that costs ranged between \$13-\$17 for FSW, \$15-\$28 for MSM and \$16-\$144 for PWUD. Note that PWUD channels distribute small quantities of HIVST kits, and average costs are therefore highly sensitive to scale of operation between CSO. Major cost contributors were personnel costs at central and regional intervention levels. Start-up costs across countries, corresponding to sensitisation of CSO and other partners, and training costs contributed to 10–28% of total costs. This is due to the complexity and lengthy process of building partnerships with numerous local CSO and involving key stakeholders in an intervention fully integrated with existing health care delivery services for KP. Costs per kit distributed were lowest in Côte d'Ivoire and highest in Senegal. Across countries, average costs per HIVST were lowest for FSW, followed by MSM, then PWUD. These differences could be explained by HIVST volumes by channels with a total of 70,513 kits distributed to FSW, 24,547 kits to MSM, and 4,793 kits to PWUD during our costing period. However, it is likely that other factors played a role. For instance, in Senegal and Mali, several episodes of violence against MSM were reported at different time points (unrelated to the programme), and CSO had to suspend their field activities for security reasons, contributing to an unstable, and therefore costly, delivery system of kits for this group. In Mali, there were safety concerns due to the country's *Coup d'Etat* in August 2020, and ongoing armed conflict with intermittent suspension of fieldwork activities. Indeed, estimated average costs per kit would be as low as \$7 (FSW) and \$8 (MSM) assuming targets were reached in Mali. Finally, the COVID-19 pandemic also led to reduced (Côte d'Ivoire and Mali) or suspended (Senegal) activities during 2–3 months, leading to high observed costs, although self-testing was shown to be a timely alternative to provider-delivered HIV testing during periods of lockdown and reduced social interactions (36).

Important average costs variations between CSO were observed. High number of kits distributed per dispensing agent led to a reduction in average costs and depended on the type of HIVST distribution activity with high distribution in bars and brothels, and low distribution in small gatherings at KP's house. CSO-specific policy with monthly maximum targets of kits distribution per agent could potentially lead to higher average costs. Small number of HIVST kits distributed per CSO was also driving average costs high and was explained by the type of population reached (e.g., CSO working with PWUD only deliver small HIVST volumes), and the CSO size. To a lesser extent in Mali, numerous HIVST delivery models per CSO (some not presented here such as Index and STI services) could lead to higher spreading of central costs across models, and therefore, a reduction of average costs.

Our costs were comparable to other community-based HIVST costing studies, many of them arising from the STAR (*HIV Self-Testing AfRica*) project (37, 38)[1]. Across six southern Africa countries (Malawi, Zambia, Zimbabwe, South Africa, Lesotho, eSwatini), costs per kit distributed ranged from \$8 for door-to-door distribution in Malawi to \$18 for mobile integration (more similar to the ATLAS programme) in South Africa (25, 26, 39, 40). Although HIVST volumes were generally higher as targeting the general population and benefiting from economies of scale, many of these models were highly vertical incurring significant above service level costs. However, cost per kit distributed to South African FSW and MSM were lower than our observed costs at \$4 and \$6, respectively, for 19,901 and 12,218 kits distributed. This is partly explained by the high number of HIVST delivery models in South Africa and sharing of central costs across models (39). Additionally, our costs were comparable to one study in Côte d'Ivoire reporting HTS unit costs from the Ivorian *Programme National de Lutte contre le Sida (PNLS)* for FSW and MSM at \$16 and \$21, respectively (41). However, one should consider the reduced costs to the kit user (in terms of transportation cost or opportunity cost for example), and therefore to society, when comparing community-based HIVST distribution and facility-based provider-delivered HTS costs (42, 43).

The scale-up model suggests that these early-stage CSO-led community-based HIVST distribution programmes can exhibit economies of scale. When comparing year 2023 with observed costs, we estimated variable scale economies between groups and countries, with about 56% (FSW), 63% (MSM), and 10% (PWUD) of average cost reduction in Côte d'Ivoire, 19% (FSW), 12% (MSM), and 66% (PWUD) in Senegal, and 35% (FSW), 41% (MSM) in Mali. Beyond scale economies, other contextual factors were considered, such as accounting for progressive integration of the ATLAS project to existing CSO and withdrawal of the IPO. The scenario analysis suggests that, overall, even if target were not reached, costs at scale would decrease in Côte d'Ivoire (except PWUD) and Mali. However, results are more nuanced for Senegal with constant (FSW) or increasing average costs (MSM, PWUD) due to high fixed costs at sub-national level.

Our study has several limitations. First, our outcome metric "per HIVST kit distributed" does not fully capture the HIVST cascade. For example, there remain uncertainties related to the true percentage of kits use, the actual final users of the kit (e.g., HIVST distribution through a FSW model could also be used

[1] Ahmed N, Terris-Prestholt F, Ong JJ, d'Elbée M, Rotolo S, Johnson C, et al. A systematic literature review of costs and cost-effectiveness analyses of HIV testing services in sub-Saharan Africa.

by their clients), and among those with a reactive HIVST the linkage rate to confirmatory testing. However, there is now large evidence on high acceptability of HIVST kits in the general population and among KP (11, 13, 14, 17, 18, 44–47). Moreover, the ATLAS programme is currently trying to evaluate the impact of HIVST on HIV case finding and ART initiation, these data will then feed in a modelling analysis to estimate cost-effectiveness. Second, total and average costs are estimated across a diverse range of CSO for each country leading to inevitable cost variation by distribution channel. Third, the COVID-19 pandemic led to reduced/suspended activities during a trimester for some CSO, but also encouraged the use of HIVST by other actors as a timely alternative to HTS in response to lockdown and social distancing, therefore, its impact on costs and project outcomes is difficult to assess (36). Fourth, scale-up costs and scenario analysis were conducted in collaboration with the implementer to ensure model assumptions were close to reality, but these remain arbitrary and should be interpreted with caution.

In three countries of West Africa, HIVST kit provision to KP through CSO had higher initial costs during the study period, related to the progressive integration of HIVST to CSO activities, and a challenging implementing environment (criminalised KP, pandemic COVID-19, security concerns). The analysis of costs at scale suggests that, in transition to scale-up and further integration of the ATLAS project, this model shows large potential for substantial economies of scale as programmes scale-up and mature.

Recent modelling studies in Cameroon, Senegal, Côte d'Ivoire, and South Africa show that key populations and their sexual partners, particularly FSW and their clients, can play an important role in HIV transmission in both low and high HIV prevalence settings due to prevention gaps (3, 4, 48). HIV prevention and treatment strategies targeting these groups are essential for controlling the HIV epidemic and are likely to provide good value for money. The CSO-led HIVST delivery model is particularly relevant as it remains today the most promising strategy for reaching KP, their sexual partners and clients of FSW not accessing HIV testing, so-called "hidden populations." Further research will assess the overall cost-effectiveness of the CSO-led HIVST delivery programme.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the London School of Hygiene and Tropical Medicine Research Committee (n° 17141/RR/13198, 31st March 2019) WHO Ethic Research Committee (n°ERC0003181, 7th August 2019), and by three national ethic committees: Comité National d'Ethique des Sciences de la vie et de la Santé de Côte d'Ivoire (n°049-19/MSHP/CNESVS-kp, 28th May 2019), Comité National d'Ethique pour la Recherche en santé du Sénégal (n°SEN19/32, 26th July 2019), and Comité d'Ethique de la Faculté de Médecine de Pharmacie et d'Odonto-Stomatologie de l'Université des Sciences et des Techniques de Bamako au Mali (n°2019/88/CE/FMPOS, 14th August 2019). The patients/participants provided their written informed consent to participate in this study.

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AUTHOR CONTRIBUTIONS

Md'E and FT-P designed the study. Md'E coordinated, conducted data analysis, and wrote the paper. MT and KB conducted data collection/analysis. AV, AF, OK, NR, PG-F, MM-G, M-CB, GM, and JL provided logistical support and intellectual inputs. All authors revised the manuscript and agreed for publication.

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PERSPECTIVE
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Community-Based Interventions as Opportunities to Increase HIV Self-Testing and Linkage to Care Among Men Who Have Sex With Men – Lessons From Ghana, West Africa

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MSM in Ghana encounter challenges in accessing HIV services and may experience barriers to HIV self-testing due to multiple forms of stigma present in health care settings. We worked with community-based organization partners to implement three interventions that successfully engaged and retained MSM which provides an opportunity for linkage to self-testing and medical care. These interventions were (1) Many Men Many Voices (3MV) a locally-led culturally grounded group-level HIV prevention program, (2) Auntie's Corner: a mobile-app based connecting MSM to health monitoring by a registered nurse and (3) HIV Education, Empathy, & Empowerment (HIVE3): a mobile-app based peer support intervention for MSM living with HIV. The 3MV intervention may be effective in improving HIV self-testing due to its effectiveness in engaging MSM, increasing HIV testing, and improving MSM understanding of the need for HIV testing. The utilization of apps like Auntie's Corner could positively impact HIV self-testing among MSM because it increases contact with nurses and reporting of symptoms. In HIVE3, participants expressed appreciation of the security and privacy that protects their identities as MSM and the peer mentors' abilities to make referrals to the nurses in Auntie's Corners. The confidentiality component has proven key among MSM and connecting MSM to self-testing through apps to report their process and receive care could increase utilization. Together, we show the efficacy of using the community-engaged process in reaching and engaging highly stigmatized populations like Ghana and sub-Saharan Africa, and its potential in increasing HIV self-testing and linkage to HIV care.

Keywords: MSM, Ghana, community-based intervention, HIV self testing, mobile health, HIV peer support

INTRODUCTION

Globally, men who have sex with men (MSM) have an ∼26 times greater risk of contracting HIV than the general population (1). Sub-Saharan Africa (SSA) remains disproportionately affected by the global HIV epidemic– accounting for two-thirds of the global disease burden and 73% of HIV-related deaths (2). MSM in SSA countries such as Ghana carry a disproportionate burden of HIV compared to the general population (3, 4). Yet, HIV testing among MSM in SSA remains low; a large proportion (two-thirds) of MSM living with HIV in South Africa, Kenya, Malawi, and Mozambique remain unaware of their serostatus (5). Although, some SSA countries like Ghana have increased efforts to improve HIV testing by increasing testing sites, MSM still face significant accessibility barriers (6). Stigma (against MSM identity, gender expression, and HIV status) and misconceptions (e.g., low-risk perception) dissuade MSM from testing regularly (7–9). Many MSM express concerns of confidentiality, discrimination, and judgmental interactions with healthcare workers (6, 7, 10) and never tested for HIV or do not test regularly (11, 12).

HIV self-testing (HIVST) technology can increase HIV testing among MSM as it allows for testing in the privacy of their homes (13). Until recently, HIVST was mainly available in high-income countries (14, 15). The 5-year Self-Testing AfRica (STAR) Initiative facilitated a widespread scale up by generating evidence and developing strategic partnerships with manufacturers and regulators that informed the World Health Organization's decision to strongly recommend HIVST in 2016 (13, 16, 17). Currently, up to 38 countries actively implement HIVST policies, and SSA countries receive subsidies from the Gates Foundation (14–16). HIVST can dramatically increase HIV status awareness among MSM because of its acceptability, privacy, non-stigmatization, convenience, and appeal to first-time testers (18, 19). HIVST doubles HIV testing rates, causes no greater social harm than clinic-based testing, and remains associated with reduced risky sexual behavior among MSM (17, 20). While previous HIVST studies largely focused on high-income countries (18–20) recent evidence shows improved testing coverage within low-to-middle income countries, including in SSA (20–27). WHO guidelines highlight the importance of engaging community members in creating and delivering HIVST initiatives (17). However, we have not identified a community based HIVST project has been conducted among MSM in West Africa.

We have conducted three community-based HIV interventions with MSM in Ghana (**Table 1**) that can positively inform the implementation of HIVST programs in West Africa. These three studies include a modified version of the Many Men Many Voices – 3MV (Nyansapo) intervention, Auntie's Corner, and HIV Education, Empathy, & Empowerment (HIVE3). This paper demonstrates how HIVST implementation can be improved with community-based interventions such as the 3MV, HIVE3, and Auntie's Corner.

Nyansapo (Wisdom-knot) Overview

The modified 3MV – Nyansapo was designed in collaboration with an MSM community-based organization (CBO), Priorities on Rights and Sexual Health (PORSH) to address factors that impact HIV prevention efforts among MSM in the country. We used the ADAPT-ITT framework to modify the original 3MV intervention to create a new Nyansapo manual which was used for the implementation. The ADAPT-ITT provides a guide for needs assessment and selecting interventions and modifying the intervention to suit a new population. Nyansapo was a retreat-style intervention where participants received education on HIV and STI risks, HIV testing, and HIV preventive measures in a 3-day housed group workshop. PORSH recruited for the intervention in two stages; first by contacting clients with who they engaged in the past, secondly, using the snowball technique where participants referred others to join the program. The recruitment yielded 57 interested persons, of which 56 participated in the program held in four sessions over 60 days. The person dropped out because of ill-health at the time of the intervention. Details of 3MV and Nyansapo intervention stages and results have been published earlier (12). In brief, condom use increased by 15% for anal sex (rel. f. = 0.80–0.95), and HIV testing by 13%, (4–17%) amongst participants (12). Also, irregular testers decreased by 10% (47–37%) and 100% reported understanding the need for HIV testing (12). The intervention facilitated the preparation of a prevention menu that MSM used to identify and plan on ways to reduce HIV risk behaviors and engaging with HIV testing. The retreat environment was friendly, protected MSM privacy, and provided a sense of safety. As a result, they freely expressed themselves, participated in all activities, and created social support networks among themselves.

HIVE3 and Aunties Corner Overview

Aunties Corner and HIVE3 were components of a secure bi-directional mobile app messaging system between MSM and a team of registered nurses and MSM peers designed to improve care coordination among MSM with structural or psychosocial barriers to accessing clinic services in Ghana. Aunties Corner linked HIV + MSM with nurses to receive services virtually and documented frequency of MSM contacts with nurses and HIV symptoms reports. HIVE3 was developed based on the Dennis Peer Support Model to connect HIV + MSM with trained peer mentors for emotional, and informational support (28). Two CBOs, PORSH, and Center for Popular Education & Human Rights Ghana (CEPEHRG), led the implementation of both interventions over 60 days with a convenience sample of 61 MSM recruited through community outreach. No dropout was recorded. In the study, each participant was issued a smartphone with a pre-installed C5 app, participants received a notification every 14 days on their C5 app reminding them of answering 20 questions about HIV symptoms and their experiences over the past 14 days. Also, participants received a notification every 30 days reminding them of answering 34 questions about the quality of their daily activities and functions over the past month. The intervention was successful in linking MSM living with HIV with care; 52 participants (85%) contacted a nurse, and 59 participants (97%) reported their HIV symptoms in the Aunties Corner. For clarity, contacting a nurse include reaching out for direct support, and reporting symptoms include just filling a survey about conditions on the app. The intervention

TABLE 1 | Field lessons for self-testing studies.

Description	Applications or lesson for self-testing studies
The efficacy of modified many men, many voices 3MV (Nyansapo) for HIV prevention among men who have sex with men in Ghana	
Nyansapo aimed at engaging MSM through the lead of an MSM local organization to address HIV knowledge, risk, and increase positive sexual health behaviors and HIV testing. We used the ADAPT- ITT framework to modify the 3MV into a culturally acceptable Ghanaian intervention named Nyansapo. The intervention comprised seven sessions designed to reduce HIV and STI risk among MSM in Ghana. PORSH recruited 57 MSM, 56 of which participated in the four-session retreat over 60 days. They invited a nurse with expertise in STIs to contribute to the discussion. We used an explanatory mixed-method design to test the efficacy of the program. Where we collected a survey at baseline, immediately after the intervention, and one-week post-intervention. We also held focus group discussion a week post-intervention to gauge participant experiences and suggestions. We found an increase in condom use by 15% for anal sex (rel. f. = 0.80–0.95), an increase in regular HIV testing by 13%, (4–17%). Overall, each participant 1-week post-intervention reported understanding the need for HIV testing. Participants found the intervention helpful as it helped them to prepare a prevention menu that they use to self-reflect and to take conscious efforts to reduce HIV risk behaviors and engaging with HIV testing. Participants also found the retreat environment as very friendly, protected their privacy, and provided a sense of safety. As a result, they freely expressed themselves, participated in all activities, and facilitated a process of creating and maintaining social networks among MSM in the country. Details of the results are reported elsewhere [Abubakari et al. (12)].	• Nyansapo showed that MSM community-based organizations can serve as pathways for successful recruitment and retention of MSM in highly stigmatized environments for HIV self-testing. • Local MSM lead in the implementation of intervention can potentially increase utilization of self-testing as it can eliminate trust concerns and increase acceptability. • Using culturally relevant manuals can help in setting standards and processes for HIV self-testing interventions. • Nyansapo's retreat participatory format when adopted for self-testing interventions, will create a conducive and private environment for learning and demonstration of self-testing among MSM. • Considering the need for results reporting and linkage to care, self-testing interventions could consider virtual ways of communication. Participants can be part of a social network and communicate with each other and even healthcare workers *via* social media or virtual platforms to communicate challenges and also get access to services.
Dual-intervention: nurse-led mobile app-based symptom monitoring for HIV positive MSM in Ghana (Auntie's corner) and HIV education, empathy, & empowerment (HIVE3)	
As a component of our dual intervention, Aunties Corner aimed to test the feasibility and acceptability of a smartphone-based mobile application (app) for use by HIV-positive MSM to report HIV symptoms and quality of life to registered nurses. As the second component of C5, HIVE3 aimed to connect MSM living with HIV with trained peer mentors. The goals of HIVE3 were to increase peer social support, decrease social isolation, minimize the effects of HIV and same-gender stigmas on HIV self-care and healthcare-seeking behaviors. Two local MSM organizations, PORSH), and CEPEHRG led the recruitment and implementation of Aunties Corner and HIVE3 to 61 MSM over a 60 days period. Participants received a smartphone with a pre-installed app, with notifications periodically to answer questions about HIV symptoms and the quality of their daily activities. Participants also completed a Peer Support Evaluation to rate the peer support received. For Aunties, 85 initiated contact with a registered nurse, and 97% reported their HIV symptoms. HIVE3 was also found to be feasible and acceptable among our sample of MSM living with HIV in Ghana. Most participants accessed the HIVE3 app at least one time, and about half accessed the app at least 10 times. Full results of the acceptability and feasibility study will be published elsewhere.	• Like Nyansapo, Aunties Corner, and HIVE3 showed that Partnering with organizations serving MSM stands critical to successful HIV-related programming such as HIV self-testing. • HIV self-testing studies could connect MSM with providers virtually for support and collection of self-reported data to monitor MSM's real-time HIV testing results and behaviors as MSM are comfortable in using mobile apps for sharing personal, and sensitive, health information is feasible, and acceptable. • Community-based strategies can support linkage to care after self-testing for MSM who receive a positive HIVST result. • HIVE3 showed that virtual peers can serve as a liaison between clients and nursing staff by helping to promote and provide access to testing tools and giving peer to peer guidelines. • The success of the use of peers in self-testing will be enhanced if the peers receive training to provide increase credibility. • HIVE3 showed that the success of an app-based HIV-self testing program will rely on ensuring anonymity between peers and clients.

was deemed feasible and acceptable among HIV + MSM for all indicators (supportive interactions, relationship qualities, perceived benefits, and satisfaction). Over three-quarters of the participants initiated at least one conversation with a peer. Nearly half regularly communicated with peers using the peer support app. The full results of Aunties Corner and HIVE3 studies (which were approved by Institutional Review Boards of University of Rochester in the United States, and Kwame Nkrumah University of Science and Technology in Ghana) will be published elsewhere.

DISCUSSION

Self-testing researchers can consider the following in ensuring reach, engagement, retention, and success in self-testing interventions among MSM in stigmatized environments.

CBOs as Pathways for Successful Recruitment, Retention, and Implementation of HIVST

Partnering with MSM focused CBOs was critical to the success of Aunties Corner, HIVE3, and Nyansapo. The CBOs helped in recruiting MSM due to established connections with MSM and a history of providing a safe space for MSM to receive services and peer support. They also received training to lead the implementation. As such, the CBOs can distribute HIVST kits and reach MSM who avoid in-person testing sites for convenience and safety reasons (26, 29). Local CBOscan increase trust, understanding, and acceptability of the self-testing process. Hence, HIVST will be more successful if a similar approach to implementation is taken. Indeed, recruitment and HIVST distribution by peers in CBOs resulted in increased HIVST in Uganda (27) and Nigeria (26).

Culturally Relevant Manuals Can Set Standards and Processes for HIVST Interventions

An established manual, created, reviewed, and accepted in collaboration with the CBOs can provide a standard procedure for engaging HIVST. The use of manuals helped in establishing a successful process during our implementation due to the structure it provided. It remains pertinent that the manual reflects the cultural setting and unique circumstances of the particular MSM population. As seen in the modification of the 3MV to Nyansapo, the culturally relevant contents will facilitate acceptability, relatability, and discourse that address self-testing issues relevant to the cultural setting (12).

A Conducive and Private Environment Will Facilitate Learning and HIVST Practice

MSM face high stigma at various levels (family, friends, community) (30). Therefore, researchers engaging MSM must protect their privacy, confidentiality, and security. This practice contributed to the success of our studies and remains significant for the success of HIVST studies among MSM. In the Nyansapo, by creating a secure and private retreat environment MSM engaged freely without the threat of danger. They candidly recounted their experiences and needs (12). In the HIVE 3 and Auntie's Corners, the relative anonymity provided by the C5 app contributed to its high usage and retention rates. This appeal to anonymity was echoed in a study in Thailand where MSM who reported privacy and confidentiality concerns chose online HIVST intervention over in-person counseling and test administration supervision (31). A meta-analysis established privacy as an essential benefit of HIVST among MSM (18, 26).

Community-Based Strategies Can Support Linkage to Care After Self-Testing for MSM Who Receive a Positive HIVST Result

We recommend that HIVST interventions should not only test but follow-up to connect HIV positive participants to care. Although, Nyansapo was successful, it failed to follow-up to continue to engage participants with testing and linkage to care. On the other hand, Our Aunties Corner, and HIVE3 virtual community-based platforms were successful at linking MSM to HIV care providers. By providing access to community support networks, the application generated trust and provided a sense of privacy and security to users, which made them feel comfortable contacting nurses on the platform. Researchers in Nigeria and China highlighted the pivotal role collaborating with CBOs played in achieving high linkage to care in HIVST studies among MSM in their countries, attaining rates of 100 and 87% respectively (26, 32). A community-based HIVST study among men in South Africa achieved a linkage rate of 68% (33). A meta-analysis on studies in SSA showed that facilitated linkage to care strategies (such as peers, community health workers, or lay counselors following-up after a positive result) increase ART initiation rates by 76% (34). As such, using innovative community-based approaches after HIVST will enhance linkage to care and reduction in viral loads among MSM living with HIV.

Virtual Platforms Can Connect MSM With Providers and Peers for Support and Collection of Self-Reported Data to Monitor Real-Time Testing Results and Behaviors

Given the stigma associated with seeking in-person care as an MSM in Ghana or other sub-Saharan African countries (7), our findings suggest that mobile platforms and digital technology could be useful in ensuring a safe and private healthcare-seeking experience (7, 12). These findings align with prior research suggesting the benefit of digital technology in connecting MSM to health resources and care (7). Using the C4 app, Aunties Corner connected MSM with nurses trained in culturally competent care for MSM; this approach was found to be feasible and effective. Studies have also found that the use of technology for access to social networks has helped with peer support, referrals, and access to services (35). These findings are similar to those in the HIVE3 component of the C4 app. In HIVE3 we found that providing access to peers *via* an online app was a feasible and acceptable method of peer support and could be used to refer clients to medically qualified nursing staff. Although, Nyansapo did not have a virtual component, participants suggested an ongoing virtual component as a way to maintain and extend peer support after completing the Nyansapo intervention (12). A 2014 study based in Ghana found that such online social networks could even extend organization research to include MSM not already reached by the organization (35).

CONCLUSION

As HIVST continues to spread across the globe and contribute immensely to increasing HIV testing acceptability among key populations, MSM within SSA countries who face extreme stigmas at various levels such as family, friends, and even from health care workers will immensely benefit from this new intervention. However, we argue HIVST interventions need to take into consideration the social circumstances facing MSM and incorporate innovative ways to reach and encourage participation among MSM in the sub-continent. Using experiences from our previous studies where we engaged MSM in Ghana (**Table 1**), we provide key lessons or suggestions to ensure increased acceptability and usage of HIVST among MSM in SSA. We recommend a grassroots level work that engages MSM *via* established MSM CBOs in order to increase reach, recruitment, and retention of MSM, and using MSM peer leadership in educating and providing support for MSM. Considering recent technology, we suggest the use of the internet and mobile-app technologies to engage MSM in HIVST management and support. When taken into consideration, our research lessons will help reduce physical engagement with stigmatizing environment, ensure privacy, confidentiality, and security of MSM, thereby bolstering confidence and usage of HIVST among MSM in SSA.

DATA AVAILABILITY STATEMENT

The author selected the following statement: The data analyzed in this study is subject to the following licenses/restrictions: We did not conduct a full analysis for the paper, however, we included abstracted information to provide context for yet publish results of HIVE3 and Aunties Corner. Requests to access these datasets should be directed to mohammed-rabiu.abubakari@yale.edu. And I did not detect any particular expressions.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Kwame Nkrumah University of Science and Technology - Ghana, and University of Rochester - United States. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

LN and GA conceptualized the paper. GA, DT, and ZN led the preparation of lessons for the 3 interventions under consideration with support from LN and DC. All other authors supported with the preparation, writing, and editing of the manuscript with GA overseeing the process and compilation of the various contributions.

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BRIEF RESEARCH REPORT
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Reaching Absent and Refusing Individuals During Home-Based HIV Testing Through Self-Testing—at What Cost?

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Introduction: In the HOSENG trial (NCT03598686), the secondary distribution of oral self-tests for persons absent or refusing to test during a home-based HIV testing campaign in rural Lesotho resulted in an increase in testing coverage of 21% compared to a testing campaign without secondary distribution. This study aims to determine the per patient costs of both HOSENG trial arms.

Method: We conducted a micro-costing study to estimate the cost of home-based HIV testing with (HOSENG intervention arm) and without (HOSENG control arm) secondary self-test distribution from a provider's perspective. A mixture of top-down and bottom-up costing was used. We estimated both the financial and economic per patient costs of each possible testing cascade scenario. The costs were adjusted to 2018 US$.

Results: The overall provider cost for delivering the home-based HIV testing with secondary distribution was US$36,481 among the 4,174 persons enumerated and 3,094 eligible for testing in the intervention villages compared to US$28,620 for 3,642 persons enumerated and 2,727 eligible for testing in the control. The cost per person eligible for testing was US$11.79 in the intervention vs. US$10.50 in the control. This difference was mainly driven by the cost of distributed oral self-tests. The cost per person tested was, however, lower in intervention villages (US$15.70 vs. US$22.15) due to the higher testing coverage achieved through self-test distribution. The cost per person confirmed new HIV+ was US$889.79 in the intervention and US$753.17 in the control.

Conclusion: During home-based HIV testing in Lesotho, the secondary distribution of self-tests for persons absent or refusing to test during the visit reduced the costs per person tested and thus presents a promising add-on for such campaigns.

Trial Registration: https://ClinicalTrials.gov/, identifier: NCT03598686

Keywords: human immunodeficiency virus, self-testing, secondary distribution, Lesotho, Southern Africa, cluster-randomized trial, cost analysis

INTRODUCTION

In 2019, 87% of all people living with HIV in eastern and southern Africa were aware of their status. However, 530,000 people still remained undiagnosed and may be hard to reach through traditional HIV testing services (1). Door-to-door HIV testing campaigns in southern Africa have the potential to increase early diagnosis, reach people that rarely use traditional health services, and yield testing uptake of more than 90% (2–5). However, such testing campaigns are costly and testing coverage—the proportion of a surveyed population tested—often remains low because of absent household members during the campaign day (2, 6, 7). The World Health Organization (WHO) recommends HIV self-testing as a complement to current testing approaches, and thus HIV self-tests are also increasingly offered during door-to-door testing campaigns (8). The HOSENG (HOme-based SElf-testiNG) cluster-randomized trial in rural Lesotho assessed the effect of the one-time secondary distribution of oral-fluid self-tests to absent and household members who refuse standard blood-based HIV testing during a home-based testing campaign on testing coverage. It resulted in 21% higher testing coverage compared to no secondary distribution, however without investigating the cost implications (9).

One common approach to assess the per-patient costs of HIV services is to compare the unit costs such as cost per person tested or cost per diagnosis using either a top-down (total expenditure assigned per arm according to an allocation factor based on patient volume) or bottom-up (sum of each resource use individually calculated according to actual usage) approach (10, 11). A systematic literature review commissioned by the WHO summarized that home-based HIV testing in sub-Sahara Africa incurred a median cost of US$11 per person tested (10), from as low as US$7 in Kenya (12) to US$14 in Lesotho (5) and US$19 in Uganda (13). There are only a few home-based testing studies from the region that assess the testing coverage of the entire surveyed area, and those among them who investigated costs reported costs per person tested ranging from US$3.02 to US$20.50 (7, 14–16). None of these studies include HIV self-testing. Published costing data that evaluated the costs per HIV self-test distributed during home-based testing, including program expenditure, range from US$8.15 in Malawi (17) to US$43.30 in Lesotho (18). Costing data on secondary HIV self-test distribution during home-based testing, however, are scarce, with only one cluster-randomized trial from Zambia reporting such data. Self-tests were offered during a door-to-door campaign and distributed among absent partners of present household members. The researchers calculated that the intervention costed US$30 per person tested (19).

Based on data of the HOSENG trial in Lesotho, we report in this study the cost of home-based HIV testing with and without secondary self-test distribution assessed as the cost per person enumerated, eligible for testing, tested, and confirmed new HIV-positive. This study aims to provide scarce costing data about the secondary distribution of HIV self-tests during door-to-door testing campaigns in sub-Sahara Africa.

METHOD

The Hoseng Testing Campaign

In 2018, the HOSENG two-arm cluster-randomized trial offered home-based HIV testing in 106 village clusters in the catchment area of 20 health facilities in two rural districts in Lesotho (Butha-Buthe and Mokhotlong). The 20 health facilities serve a rural population of about 200,000 inhabitants living in a rather mountainous area with poor infrastructure. The village clusters from urban areas (e.g., Butha-Buthe town and Mokhotlong town) were excluded. A cluster was defined as a village with a consenting village chief and served by a registered and active village health worker (VHW). VHWs are the existing Lesotho Ministry of Health (MoH) lay community health worker network and are supervised by the corresponding health facility where they attend regular monthly meetings. The comprehensive details of the trial design and intervention are published elsewhere (9, 20). Briefly, a trained team of 15 campaign counselors and three drivers conducted the 5-month door-to-door testing campaign and spent 1 to 2 days per village. In both arms, the campaign team enumerated all household members living in the surveyed area and offered blood-based point-of-care HIV testing (Determine HIV-1/2 and UniGold HIV-1/2) to all household members who were present with an unknown HIV status and thus eligible for testing. Household members with a HIV-negative test within the previous 4 weeks or known to be HIV-positive were not eligible for testing.

Control Arm

In the 49 villages assigned to the control arm, the campaign team referred absent household members and those refusing to test to the nearby health facility. The campaign team and the provided services as outlined above were the same in both arms.

Intervention Arm

In the 57 intervention villages, for every household member aged 12 years or older who was absent or refused blood-based HIV testing, the team asked for consent to leave an oral-fluid HIV self-test kit (OraQuick ADVANCE HIV I/II) in the household, and one present household member was trained to correctly use the self-test. The responsible VHW, who lives and works in the same village, followed up the distributed self-tests. The VHWs from all 106 villages received a 1-day refresher training on HIV prevention, testing, counseling as well as result documentation. The VHWs from the intervention arm received additional training about oral-fluid HIV self-testing and a list of all household members for whom a self-test was dispensed. The VHWs revisited all households 2–4 weeks after the reported date of the absent family member's return to collect the self-test if it had not been returned before. The village health workers reread the result of the oral-fluid HIV self-test strip and documented the outcome on the study-specific form. The household members with a reactive self-test were referred to the clinic for blood-based testing in order to confirm an HIV-positive outcome.

Endpoint

After 120 days of follow-up per village, the HIV testing coverage among the enumerated population aged 12 years and

older was assessed through the testing registers at all health facilities (control and intervention arm) as well as the VHWs' documentation tool (intervention arm only).

HIV Testing and Cost Data Sources

This study included HIV testing data from all enumerated household members aged 12 years and above from HOSENG trial in both arms, including the 120-day follow-up period. The cost data were obtained through the trial expenditure records, a Lesotho Public Service Circular and Lesotho Public Health Sector Expenditure Review 2017 (21), and supplemented by interviews with the administrative staff and the study team.

Costing Methodology

We conducted a micro-costing study to estimate the cost of home-based HIV testing with and without secondary self-test distribution from a provider's perspective. A mixture of top-down approach and bottom-up costing was used, following international guidelines (22, 23). We included both financial and economic costs, whereby financial costs reflected resources or goods that were paid for, while economic costs encompassed the valuation of donated goods and services such as the VHW and clinic counselor time provided by the MoH. Expenses only covering research activities, such as the electronic tablet-based data collection tool, were excluded.

Unit Cost Calculation

Supplementary Table 1 provides the details of all cost inputs. The unit cost of the self-test kits was assumed to be US$2.10, which accounted for purchase and shipment. We classified the costs into independent categories: trainings, logistics, clinic overhead, campaign equipment, consumables at both facility and community level (HIV blood-based tests, oral-fluid self-tests, gloves, *etc.*), headquarter-based staff (campaign organizers), and field-/clinic-based staff (campaign counselors, MoH clinic HIV testing counselors, and MoH VHWs).

In a model constructed in Microsoft Excel®, the testing data was outlined along the possible testing scenarios that occurred in the intervention and the control arms (**Supplementary Figures 1A**,**2B**). In the same model, the field- and clinic-based staff time for each activity was determined by using a bottom-up approach, whereby the total time spent by each staff member was divided by the number of clients attended to in each scenario. For the campaign staff, this included the time spent on traveling, waiting, enumeration, and mobilization of the community. Similarly, consumable costs were determined bottom-up based on the actual number of clients per scenario. Notably, HIV self-testing costs and VHW-associated costs occurred only in the intervention scenarios. The remaining cost categories were allocated in a top-down approach and distributed equally by arm and scenario.

The costs incurred for each scenario were then summed up by arm and divided by the respective unit number achieved by arm, i.e., number of persons enumerated, number of person eligible for testing, number of persons tested, and number of persons confirmed to be HIV-positive. We also calculated the incremental cost of distributing self-tests during home-based HIV testing by subtracting the total costs of the control arm from the total costs of the intervention arm. Part of the logistics (one car provided by the research organization) and the training costs were annualized over the assumed years of useful life of each item using a 3% discount rate (23). The costs were inflated to 2018 Lesotho Loti (LSL). These were then converted to US$ using the average Central Bank of Lesotho exchange rate for 2018 (LSL 13.2517 to 1 US$).

Sensitivity Analyses

A univariate simple sensitivity analysis was used to characterize the uncertainty in the key assumptions in the study. The impact of the discount rate was assessed by varying the rate to 0 and 5% as per Drummond et al. (22). Similarly, the years of useful life of the research organization vehicle were varied. Headquarter-based staff salaries were varied by ±10% to assess the impact of the campaign being coordinated entirely by the MoH or a higher cadre, i.e., a project nurse, as it is often the case with such campaigns. We varied the oral self-test kit price to reflect a hypothetical lower market prize to be assumed in the years to come (US$1).

Ethics Statement

The study did not involve patient-level data collection. However, as part of the overarching HOSENG trial, we obtained permission from the Ethics Committees in Lesotho and Switzerland to extract the costing data. The HOSENG trial was approved by the National Health Research and Ethics Committee of the Ministry of Health of Lesotho (ID06-2018) and the Ethics Committee in Switzerland (Ethikkomission Nordwest- und Zentralschweiz; 2018-00283). The trial is registered under the Clinical Trials Network (ClinicalTrials.gov) under registration number NCT03598686.

RESULTS

There were 4,174 and 3,642 persons enumerated aged 12 years and older in the intervention and control arms, respectively. Among those, 3,094 in the intervention and 2,727 in the control were eligible for testing, as they had an unknown HIV status. In the intervention arm, 58% of the distributed self-tests were used and returned within 120 days. Overall, the intervention resulted in a significantly greater testing coverage among persons aged 12 years and above (81%) compared to the control villages (60%) in which no self-tests were dispensed. It was particularly successful among men, adolescents, and migrant workers (20).

The overall program cost of the home-based HIV testing campaign in the control arm, where no self-tests were used nor distributed, was US$28,620. The overall program cost in the intervention arm (with secondary self-test distribution and follow-up by VHWs) was US$36,481 (**Table 1**). Logistics formed the largest cost item of the total costs in both arms, followed by staff costs, with the remaining costs accounting for <15% (**Figure 1**).

In the intervention arm, the cost per person enumerated was US$8.74, and the cost per person eligible for testing was US$11.79, whereas in the control arm, both the cost per person

TABLE 1 | Cost units by arm.

	Intervention	Control
Cost input data (US$)		
Logistics	12,092	12,092
Campaign equipment	3,969	3,969
Headquarter-based staff: campaign organizers	4,119	4,119
Clinic overhead	53	53
Trainings	2,622	477
Consumables	5,536	1,816
HIV blood-based tests, gloves, fingerpricks	1,287	1,816
HIV self-tests	4,248	0
Field- and clinic-based staff: campaign counselors, clinic HIV testing counselors and village health workers	8,091	6,094
Total cost	36,481	28,620
HIV testing data (*N*)		
Total number of persons enumerated ≥12years	4,174	3,642
Number of persons enumerated ≥12years, eligible for testing, with unknown HIV status	3,094	2,727
Number of persons tested	2,913	1,292
Number of persons confirmed new HIV+	41	38
Incremental number of individuals tested	1,621	
Incremental number of individuals confirmed new HIV+	3	
Costing output (US$)		
Cost per person enumerated	8.74	7.86
Cost per person eligible for testing	11.79	10.50
Cost per person tested	15.70	22.15
Cost per person confirmed new HIV+	889.79	753.17
Incremental costs	7,861	
Incremental cost per person tested	4.85	
Incremental cost per person confirmed new HIV+	2,620.33	

enumerated (US$7.86) and the cost per person eligible for testing (US$10.50) were lower (**Table 1**). Three cost items contributed to the higher costs in intervention (**Figure 1**): the oral self-tests, the additional training for the VHWs, and the field-based staff costs related to the follow-up of the distributed self-tests.

The cost per person tested, however, was lower in the intervention (US$15.70) than in the control (US$22.15), with 2,913 out of 3,094 eligible persons tested in the intervention and 1,292 out of 2,727 eligible persons tested in the control. In both arms, about 40 persons were confirmed new HIV+, resulting in unit costs per confirmed new HIV-positive person of US$889.79 in the intervention and US$753.17 in the control (**Table 1**).

The incremental costs of distributing and following up self-tests for absent and refusing household members alongside a home-based HIV testing campaign were estimated at US$7,861. This resulted in an incremental cost per additional person tested of US$3.38 and that of an additional person confirmed new HIV-positive of US$191.73 (**Table 1**).

The cost per person tested remained largely robust when key cost items were varied in the sensitivity analyses (**Figure 2**). The largest impact was observed with a lower oral self-test price, resulting in US$14.76 per person tested. Logistics accounted for the highest proportion of the total costs of the home-based testing campaign; therefore, the variation of the useful life years of the vehicle had a reasonable impact on the results (ranges from US$15.32 to US$16.21). A 10% change in headquarter-based staff salaries as well as the variation of the discount rate only had a minor effect.

DISCUSSION

In this costing analysis, we assessed unit costs comparing home-based HIV testing with and without secondary distribution of oral self-tests for persons absent or refusing to test during a home-based HIV testing campaign in Lesotho. The secondary distribution of oral self-tests increased the overall cost of the campaign due to the direct cost of oral self-tests and additional training cost, but due to the higher testing coverage achieved with self-tests (81%) than without (60%) and the relatively cheap follow-up of the self-tests by an existing MoH lay cadre, the secondary self-test distribution resulted in lower cost per person tested.

A previous home-based HIV testing study from Lesotho reached 72% testing coverage through catch-up visits for absent members on weekends, at a cost of US$20 per person tested (7). Using self-tests instead of catch-up visits, our intervention achieved a higher testing coverage at a lower cost per person tested (US$15.70). In Uganda and Kenya, using multi-disease community health fairs followed by home-based testing for non-attendees of the fair, 89% of all enumerated adults were reached at a cost of US$20.50 per person tested (16). Similar costs were reported in a study from Malawi, whereby a team of counselors conducted two door-to-door campaigns on Likoma, a small island in Lake Malawi, reaching a testing coverage of 89%, at US$13.50 per person tested (14). Only a study in Uganda, engaging 62 community health workers to provide regular HIV testing for 6 months, reported significantly lower costs at US$3.02 per person tested but reaching only 69% of the adult residents (15). Low travel costs as well as the involvement of community health workers (with a stipend of US$30 per month) instead of counselors probably contributed to the low costs incurred in this study.

The WHO recommends HIV self-testing to complement current testing approaches, although the cost of the most widely used self-test (OraQuick ADVANCE HIV I/II), at approximately US$2 per kit, is still around twice the price of the standard blood-based HIV rapid test in Africa (24). Thus, cost-efficient self-testing interventions to complement standard testing are needed. The Self-Testing AfRica project has delivered over 4.8 million self-tests in 38 countries through various distribution models (25). Its economic cost analysis of door-to-door community-based distribution models in Malawi, Zambia, and Zimbabwe reported average costs per self-test distributed at US$8.15, US$16.42, and US$13.84, respectively (17). A recent costing study from Lesotho calculated costs up to US$43.30 per self-test distributed when used as part of mobile outreach testing or index village testing (18). However, none

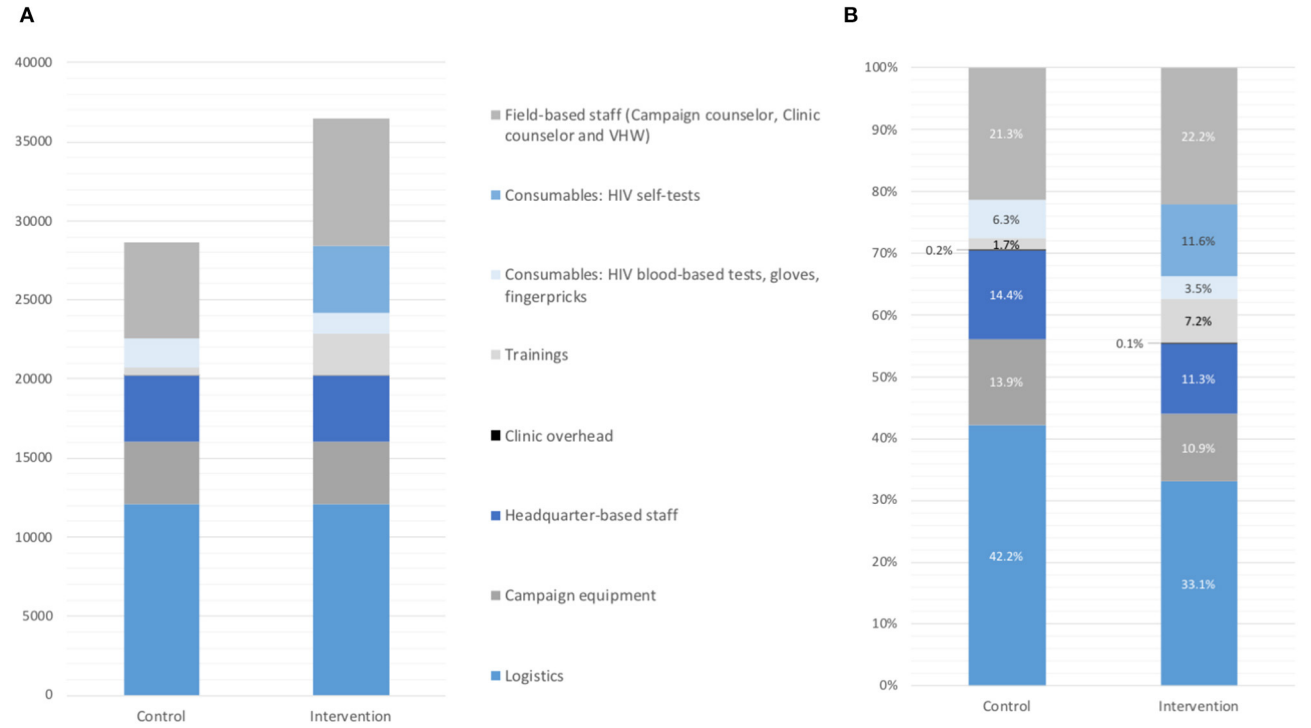

FIGURE 1 | Cost item by arm in absolute US$ **(A)** and proportion of total costs **(B)**.

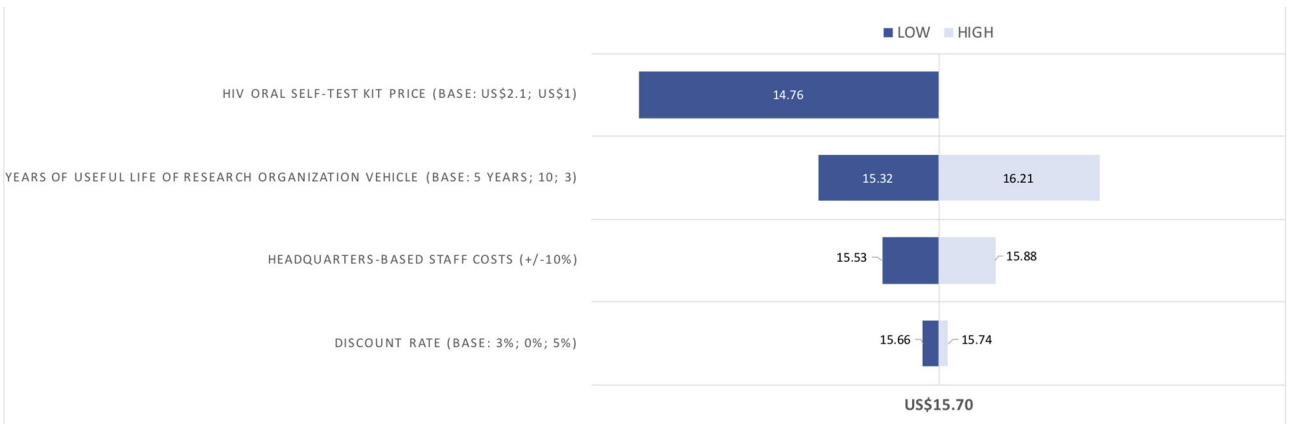

FIGURE 2 | Sensitivity analyses on the costs per person tested (in 2018 US$).

of the above-mentioned community-based self-testing studies assessed testing coverage or the costs of secondary distribution.

A cluster-randomized nested trial within the HIV Prevention Trials Network 071 study in Zambia distributed self-tests among absent partners of present household members and assessed its cost implications (19). Similarly, it showed a high uptake and modestly increased the coverage from 65 to 68%. Community HIV care providers, hired by the study, performed the follow-up. In the self-testing intervention arm, the cost per person enumerated was US$18.37, and the cost per person tested was US$30, 1.37 times higher than in the control arm where no self-tests were used nor distributed. These costs were higher compared to our results, probably because of the very modest difference in testing coverage between the arms and the fact that the campaign and the follow-up were conducted by hired study staff, yielding larger personnel costs.

In a context where 81% of people living with HIV already know their status (26), the positivity yield in our study was low, with 3% during the campaign and 1% during the follow-up (20), and with only a minimal difference between the arms. A

possible explanation may have been the unassisted self-testing of the secondary distributed tests and thus an underreporting of outcomes. Consequently, our cost per person confirmed new HIV+ was higher in the self-test arm (US$889.79) than in the control (US$753.17). Despite the low yield, the cost of identifying one HIV-positive person through our intervention was in the range of what previous community-based testing campaigns reported across sub-Sahara Africa (US$60.20 to US$1725.30) (7, 12, 14–16, 27–29) and lower than in the Zambian secondary self-test distribution trial (US$1,028.46) (19). The variability in cost estimates across the studies depends on the coverage achieved, the HIV prevalence, the intervention offered, and most importantly, the positivity rate.

Our study has several limitations. First, our micro-costing model did not capture all individual- and population-level costs and benefits of the intervention, and no quality-adjusted life years gained or disability-adjusted life years averted were included. Thus, these results should not be interpreted as a cost-effectiveness analysis. Second, the analysis is limited to a provider perspective which excluded key direct and indirect costs incurred by the clients when accessing testing services. However, the intervention offered self-testing at home and self-test return at the nearby village health worker, resulting in minimal time needed and low transport costs for the clients. Third, the study did not include a time and motion component, which would have given a more accurate reflection of the staff time involved for each activity.

CONCLUSION

A self-testing strategy yielding high coverage and the optimal integration of the self-test follow-up in the existing health system resulted in a low incremental cost of secondary self-test distribution during home-based HIV testing in Lesotho. This secondary self-test distribution approach resulted in lower costs per person tested than standard home-based testing alone. These results may inform the current large-scale roll-out of HIV self-tests in Africa—also driven by the COVID-19 pandemic—and should be taken into account in home-based testing policies in similar settings.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

LM built the micro-costing model with inputs from AA, NL and TG. AA drafted the first version of the manuscript. TG provided the HIV testing data from HOSENG trial. TL and MK provided costing source data. All authors read, critically revised, and approved the final manuscript. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fmed.2021.653677/full#supplementary-material

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Introducing and Implementing HIV Self-Testing in Côte d'Ivoire, Mali, and Senegal: What Can We Learn From ATLAS Project Activity Reports in the Context of the COVID-19 Crisis?

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Background: The ATLAS program promotes and implements HIVST in Côte d'Ivoire, Mali, and Senegal. Priority groups include members of key populations—female sex workers (FSW), men having sex with men (MSM), and people who use drugs (PWUD)—and their partners and relatives. HIVST distribution activities, which began in mid-2019, were impacted in early 2020 by the COVID-19 pandemic.

Methods: This article, focusing only on outreach activities among key populations, analyzes quantitative, and qualitative program data collected during implementation to examine temporal trends in HIVST distribution and their evolution in the context of the COVID-19 health crisis. Specifically, we investigated the impact on, the adaptation of and the disruption of field activities.

Results: In all three countries, the pre-COVID-19 period was marked by a gradual increase in HIVST distribution. The period corresponding to the initial emergency response (March-May 2020) witnessed an important disruption of activities: a total suspension in Senegal, a significant decline in Côte d'Ivoire, and a less pronounced decrease in Mali. Secondary distribution was also negatively impacted. Peer educators showed resilience and adapted by relocating from public to private areas, reducing group sizes, moving night activities to the daytime, increasing the use of social networks, integrating hygiene measures, and promoting assisted HIVST as an alternative to conventional rapid testing. From June 2020 onward, with the routine management of the COVID-19 pandemic, a catch-up phenomenon was observed with the resumption of activities in Senegal, the opening of new distribution sites, a rebound in the number of distributed HIVST kits, a resurgence in larger group activities, and a rebound in the average number of distributed HIVST kits per primary contact.

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Conclusions: Although imperfect, the program data provide useful information to describe changes in the implementation of HIVST outreach activities over time. The impact of the COVID-19 pandemic on HIVST distribution among key populations was visible in the monthly activity reports. Focus groups and individual interviews allowed us to document the adaptations made by peer educators, with variations across countries and populations. These adaptations demonstrate the resilience and learning capacities of peer educators and key populations.

Keywords: HIV self-testing, COVID-19, West Africa, Côte d'Ivoire, Mali, Senegal, key populations

INTRODUCTION

HIV testing is an essential part of the epidemic response. It allows undiagnosed people living with HIV (PLHIV) to be linked to care and antiretroviral treatment and those testing negative to be linked to appropriate HIV prevention services (1).

HIV self-testing (HIVST) is a process in which users collect a sample (oral fluid or blood) themselves, perform the HIV test, and then interpret the result alone, often in a private setting (2). It is an innovative tool that empowers individuals and ensures the confidentiality of the test (3). Since 2016, the World Health Organization (WHO) has recommended HIVST as an additional approach to HIV testing (4).

In Southern and Eastern Africa, HIVST has begun to be massively deployed, notably through the Unitaid-funded STAR–HIV Self-testing Africa Initiative, initiated in 2015 (5). Previous studies have suggested that, for many users, HIVST promotes discretion and autonomy, and greatly increases the use of testing (6–8). HIVST is highly acceptable, particularly among key populations and those who do not regularly test for HIV. Initial feedback shows the acceptability, feasibility, and excellent clinical performance of HIVST (9–14). HIVST does not reinforce risk behaviors; on the contrary, it can increase condom use, e.g., among female sex workers (14), and positively impacts health behaviors (15, 16). Finally, some studies have shown that HIVST does not increase negative social consequences or undesirable events or behaviors (17).

Until 2019, access to HIVST remained low in West and Central Africa and was mainly limited to pilot programs (18). Uptake of HIV testing in this region is generally low: in 2019, only 68% (compared to 87% in Eastern and Southern Africa) of PLHIV were aware of their HIV status. According to UNAIDS, in 2019, only 81% of PLHIV knew their HIV status (19).

West Africa is characterized by mixed HIV epidemics: national HIV prevalence rates in the adult population are lower than in southern Africa (between 0.4 and 3%), but HIV remains widespread, and high prevalence rates (>10%) are observed in key populations (female sex workers—FSW, men who have sex with men—MSM, and people who use drugs—PWUD).

Funded by Unitaid and coordinated by Solthis, the ATLAS program *(AutoTest VIH, Libre d'Accéder à la connaissance de son Statut)* aims to promote and implement HIVST in Côte d'Ivoire, Mali and Senegal. This involves distributing nearly half a million HIVST kits as part of the three countries' national AIDS strategies and the integration of HIVST with the testing policies already in place. The different delivery channels and priority populations for each country were developed with country stakeholders (national AIDS programs/councils, international institutions including the WHO, international and national non-governmental organizations—NGOs—involved in local HIV programs, and civil society and community leaders).

ATLAS HIVST distribution is organized through eight different operational delivery channels (**Supplementary Figure 1**): five are facility-based (delivery of HIVST kits through public or community-based health facilities), and three use a community-based approach involving outreach activities engaging FSW, MSM, and PWUD (20). Peer educators conduct these outreach activities through group activities (e.g., talks, discussion groups, night visits, social events, parties) and face-to-face activities (e.g., home visits). Outreach activities represent the majority (more than two-thirds) of ATLAS's delivery objectives. HIVST distribution targets were fixed with implementing partners based on their past experiences and capacities. Therefore, the volume of HIVST kits distributed per channel is not exactly proportional to the weight of each population within the local HIV epidemics.

ATLAS activities rely both on primary distribution—HIVST kits are distributed by peer educators and healthcare professionals to primary contacts for their personal use—and secondary distribution—primary contacts are invited to redistribute some HIVST kits to their peers, partners, and relatives. These secondary contacts are often members of key populations that are more difficult to engage in HIV prevention, along with other peripheral vulnerable populations. This specificity of HIVST implies that HIVST beneficiaries (end users) are not limited to primary contacts. To preserve the anonymity and confidentiality of HIVST and not impede the use of HIVST, ATLAS decided not to track systematically distributed HIVST kits, which could be counterproductive. However, HIVST users can, if they wish, obtain additional support by calling a peer educator or the national HIV hotline.

HIVST distribution started in mid-2019 but was soon impacted by the COVID-19 pandemic (21). In response to the health emergency, the governments of Côte d'Ivoire, Mali, and Senegal, like those of other countries, adopted various public health measures (physical distancing in public spaces, protective masks, hygiene measures) (22). Other more restrictive measures, such as restrictions on international and domestic

travel, curfews, and the closure of party venues and shops, were also adopted, making it difficult to carry out the ATLAS activities as initially planned.

Aware of these issues, Solthis and its implementing partners have had to adapt their field activities to each local context and each delivery channel; the operational challenges are significantly different between channels using facility-based and those using community-based strategies.

This article will focus solely on community-based outreach strategies, considering the set of unique challenges faced by peer educators. We will refer to them as FSW-based, MSM-based, and PWUD-based channels, considering the type of key populations targeted as primary contacts, and keeping in mind that secondary contacts are not systematically from the same key population.

From the program data (both quantitative and qualitative) collected by the ATLAS program, we examine temporal trends in the community-based distribution of HIVST and describe their evolution in the context of the COVID-19 health crisis. Specifically, we investigate the impact on, the adaptation of, and the disruption of field activities. What adaptations have been made by HIVST distributors? How did they integrate COVID-19 hygiene measures? What remained after the easing of governmental measures?

MATERIALS AND METHODS

Sources of Data

We conducted a secondary analysis of the program data collected in the context of the monitoring and evaluation component of ATLAS: (i) quantitative monitoring data corresponding to the monthly activity reports of the various implementing partners; (ii) focus groups routinely conducted with HIVST distributor agents organized annually as part of monitoring and evaluation to collect qualitative feedback; and (iii) *ad hoc* individual interviews conducted by Solthis with peer educators during the Covid-19 pandemic specifically to document activities' adaptations in this specific context.

Monthly Activity Reports

All ATLAS implementing partners (public sector and civil society organizations—CSOs) provide monthly activity reports collected through a web platform specific to the ATLAS program and based on DHIS2 software (https://www.dhis2.org/). For the three community-based delivery channels, the monthly reports include, per channel (i.e., FSW-based, MSM-based, PWUD-based) and per intervention site: the number of interventions (or activities) conducted during the month, the number of primary contacts seen during interventions and who received one or more HIVST, and the number of distributed HIVST.

Primary contacts can be disaggregated by sex and age group (24 or under, 25–49, and 50 and over). Activities are also disaggregated by type (e.g., focus groups, home visits…). In addition, the distribution objectives, set upstream by Solthis with its implementing partners, have also been entered on the monitoring-evaluation platform by month, channel, and country.

Focus Group Discussions

ATLAS's monitoring and evaluation routinely include gathering qualitative feedback from the field through focus groups conducted regularly with distributor agents from each country and each delivery channel. These focus groups are led by different facilitators trained in conducting qualitative interviews.

Two waves of focus groups have been conducted: the first from October to November 2019 and the second in October 2020. Focus group participants were invited by ATLAS country operational teams in collaboration with their structures/organizations. Indications were given to ATLAS country operation teams to diversify the origin of participants (region, organizations…). It was not the same participants in 2019 and 2020.

All the focus groups were conducted face to face, with appropriate hygiene measures and physical distancing for those held in October 2020. While in 2019 the discussion topics mainly addressed the initiation of activities, operational challenges, and primary contacts' perceptions of HIVST, the focus groups conducted in 2020 included COVID-19-related issues and the resulting adaptations. For this article, only the group interviews conducted in 2020 with HIVST distributors involved in community-based outreach strategies were taken into account, i.e., 3 focus groups for Côte d'Ivoire, 2 for Mali, and 3 for Senegal (in Mali, no activities are targeting PWUD). The focus groups were audio-recorded with the agreement of the participants. At the beginning of the group interviews, participants were reminded of the confidentiality rules. Each participant was given a number to refer to each other without using their names. The focus groups were transcribed by the facilitator who conducted the focus group and then coded (with any personal identifiers removed).

Individual Interviews

Furthermore, because of the particular health context linked to the COVID-19 pandemic, Solthis wanted to set up a specific monitoring system to understand the adaptations implemented by field workers and guide program recommendations. Additional semi-structured individual interviews were carried out by telephone between September 8 and October 19, 2020, with peer educators distributing HIVST kits to key populations. Fourteen individual interviews were conducted by the second author (6 women and 8 men; 4 interviews in Côte d'Ivoire, 4 in Mali, and 6 in Senegal). The individual interviews were audio-recorded with the agreement of the participants, transcribed by the second author, and then coded (with any personal identifiers removed).

Data Analyses

Quantitative Analyses

The temporal trends of the different quantitative indicators are presented here by month and stratified by country and delivery channel, taking into account monthly reports between August 2019 (initiation of activities) and December 2020.

Activities are reported by type in the monthly reports. However, the terminology used for activity type varies by country, channel, and implementing partner, making comparisons

difficult. Instead, as the number of primary contacts and the number of activities are reported for each type (per month, site, delivery channel, and implementing partner), we calculated for each line of the monthly reports an average number of primary contacts per activity and thus categorized the activities into five groups according to this average number of contacts per activity (cpa): activities conducted face-to-face (cpa $\leq$ 1. 5), in small groups of 2–4 people (1.5 $<$ cpa $\leq$ 4.5), in medium groups of 5–7 people (4.5 $<$ cpa $\leq$ 7.5), in large groups of 8–10 people (7.5 $<$ cpa $\leq$ 10.5) and in very large groups of 11 or more people (cpa $>$ 10.5).

For metrics corresponding to ratios (e.g., the average number of distributed HIVST kits per primary contact or the average number of primary contacts per activity), 95% confidence intervals were calculated assuming a Poisson distribution.

Qualitative Analyses

The individual interviews conducted by the second author and the focus groups conducted by trained facilitators were initially not designed for scientific qualitative analysis but rather as part of the operational evaluation of the activities.

The second author performed the coding of the individual interviews based on an initial content analysis to identify emerging themes and produce an operational guide of good practices regarding HIVST activities in the context of Covid-19 (available on https://atlas.solthis.org/wp-content/uploads/2021/02/Adaptation-ATLAS_COVID.pdf).

For this paper, the transcriptions of individual interviews and focus groups were reanalyzed together by the second author to describe how HIVST activities targeting key populations were adapted in response to the COVID-19 crisis and identifying convergences and divergences between countries and delivery channels. The themes and subthemes were updated based on discussions between the two first and the two last authors. Verbatims were selected to illustrate the different subthemes retained for the paper.

Ethical Authorizations

Secondary analysis of ATLAS program data is included in the associated research protocol available at https://atlas.solthis.org/en/research/. This protocol (version 2.1, August 5, 2019) has been approved by the WHO Ethical Research Committee (August 7, 2019, reference: ERC 0003181), the National Ethics Committee for Life Sciences and Health of Côte d'Ivoire (May 28, 2019, reference: 049-19/MSHP/CNESVS-kp), the Ethics Committee of the Faculty of Medicine and Pharmacy of the University of Bamako, Mali (August 14, 2019, reference: 2019/88/CE/FMPOS), and the National Ethics Committee for Health Research of Senegal (July 26, 2019, protocol SEN19/32).

Context: Governmental Health Measures in Response to COVID-19

Following the first wave of the COVID-19 pandemic in early 2020, the governments of Côte d'Ivoire, Mali, and Senegal implemented health measures in mid-March 2020 (**Table 1**). Group gatherings were banned from March 15 in Senegal, March 16 in Côte d'Ivoire, and March 19 in Mali. In all three countries, a state of health emergency was declared (on March 20 in Mali and on March 23 in Côte d'Ivoire and Senegal), followed by curfews (on March 23 in Senegal, March 24 in Côte d'Ivoire, and March 26 in Mali) and other measures restricting movement (for example, restrictions on movement between regions or between the capital and other regions). While Europe and North America were particularly affected during this first wave, the number of cases recorded in West Africa has remained limited (23).

The easing of health measures was gradual from May 2020 onwards and began earlier in Côte d'Ivoire and Mali than in Senegal. The curfew was finally lifted on May 9, 2020, in Mali, and on May 15, 2020, in Côte d'Ivoire. Nevertheless, it was not lifted entirely in Senegal until June 30, even though curfew adjustments were introduced on May 11, and intercity travel was again authorized from June 7 onward.

Considering the different measures taken by the governments in response to COVID-19, we identified three periods: (i) *pre-COVID-19* from August 2019 to February 2020, before the implementation of health measures; (ii) *initial emergency response* (March-May 2020), when health measures were most intense (notably with the introduction of a curfew and the restriction of intercity travel); and (iii) the *epidemic management stage* (since June 2020), characterized by the easing of the various measures.

ATLAS Contingency Plans and COVID-19 Guidance

ATLAS coordination developed contingency plans and COVID-19 guidance as soon as the COVID 19 crisis started. Guidance was shared in March 2020 with all implementing partners focusing on how to protect lay providers and clients; and how HIVST could be an opportunity to maintain access to HIV testing in this context. Personal protective equipment support has also been provided to partners to ensure the protection of peer educators while distributing kits. The guidance was not trying to standardize HIVST distribution during the COVID-19 period and let all implementing partners and peer educators contextualize and adapt their strategies already implemented. Therefore, most activities adaptations described in this article came from the initiative of implementing partners within the frame of ATLAS guidance.

RESULTS

HIVST Distribution

Between August 2019 and December 2020, 151,066 HIVST kits were distributed by the ATLAS project among key populations only: 105,788 (70%) through the FSW channel; 40,141 (27%) through the MSM channel; and 5,137 (3%) through the PWUD channel. According to the program data, Côte d'Ivoire accounts for approximately half of all HIVST kits distributed (75,533, 50%), Mali accounts for one-third (54,946, 36%), and Senegal accounts for one-sixth (20,587, 14%).

In all three countries, the pre-COVID period saw a gradual increase in activities (**Figure 1**). For some channels, the month of January was marked by a slight decrease caused by a

TABLE 1 | Main health measures implemented during the COVID-19 crisis in 2020 in Côte d'Ivoire, Mali, and Senegal.

Month	Day	Côte d'Ivoire	Mali	Senegal
March	15			Ban on public gatherings Closure of restaurants, bars, nightclubs, and entertainment venues
	16	Ban on public gatherings		
	18	Closure of restaurants, bars, nightclubs, and entertainment venues		
	19		Ban on public gatherings Closure of bars and nightclubs	
	20		Public Health Emergency Declaration	
	23	Public Health Emergency Declaration		Public Health Emergency Declaration Curfew Limited travel between regions
	24	Curfew		
	26	Limited travel between Abidjan and other regions	Curfew	
April	4	Face mask compulsory in public places		
	19			Face mask compulsory in public places
May	7	Reopening of restaurants, bars, nightclubs, and entertainment venues, only outside Abidjan		
	8	Curfew lifted and public gatherings (200 persons maximum) reauthorized, only outside of Abidjan	Face mask compulsory in public places	
	9		Curfew lifted End of state of emergency	
	11			Curfew adjustments (9 p.m. to 5 a.m.)
	15	Curfew lifted and reopening of restaurants in Abidjan		
June	4			Reopening of restaurants
	7			Curfew adjustments (11 p.m. to 5 a.m.) Intercity travel reauthorized
	30	Reopening of bars, nightclubs, and entertainment venues in Abidjan		Curfew lifted End of state of emergency
July	13	Travel between Abidjan and other regions reauthorized		
August	05			Public gatherings reauthorized Reopening of restaurants, bars, nightclubs, and entertainment venues

brief delay in the resumption of activities at the beginning of the new year.

During the initial emergency response to COVID-19 (March-May 2020), the distribution evolution differed by country. Senegal witnessed a total cessation of activities during these 3 months, irrespective of the distribution channel. Côte d'Ivoire saw a significant drop in the number of distributed HIVST kits, particularly in April 2020. Mali saw the stabilization of the number distributed (i.e., cessation of the growth observed pre-COVID).

From June 2020 onward, with the routine management of the COVID-19 pandemic, a catch-up phenomenon was observed: activities resumed in Senegal, and the number of distributed HIVST kits rebounded in Côte d'Ivoire and Mali.

Size of Outreach Activities

Independent of COVID-19, ATLAS outreach activities were heterogeneous across the countries and the key populations, as several intervention models are used (**Figure 2** and **Supplementary Figures 2, 3**).

In Côte d'Ivoire, outreach activities targeting FSW and MSM were usually based on small group talks (2–4 contacts) in public spaces. In addition, social events and parties (11 contacts and more) were organized to reach MSM. In April and May 2020, such social events were suspended. In June 2020 and later, to catch up on distribution, activities for medium-sized groups (5–7 contacts) were organized.

Activities to reach PWUD in Côte d'Ivoire followed a different model: to limit their presence in smoking rooms (sites of drug use) for safety reasons, peer educators intervened during daylight and tried to maximize the number of contacts they made per visit (usually between 8 and 10). During March-May 2020, they maintained the activities but reduced the size of the groups (5–7 contacts per visit).

In Mali, due to the diversity of the implementing partners, several types of activities were conducted to reach FSW and MSM, including home visits, small group activities, and large group activities. As in Côte d'Ivoire, during the emergency phase,

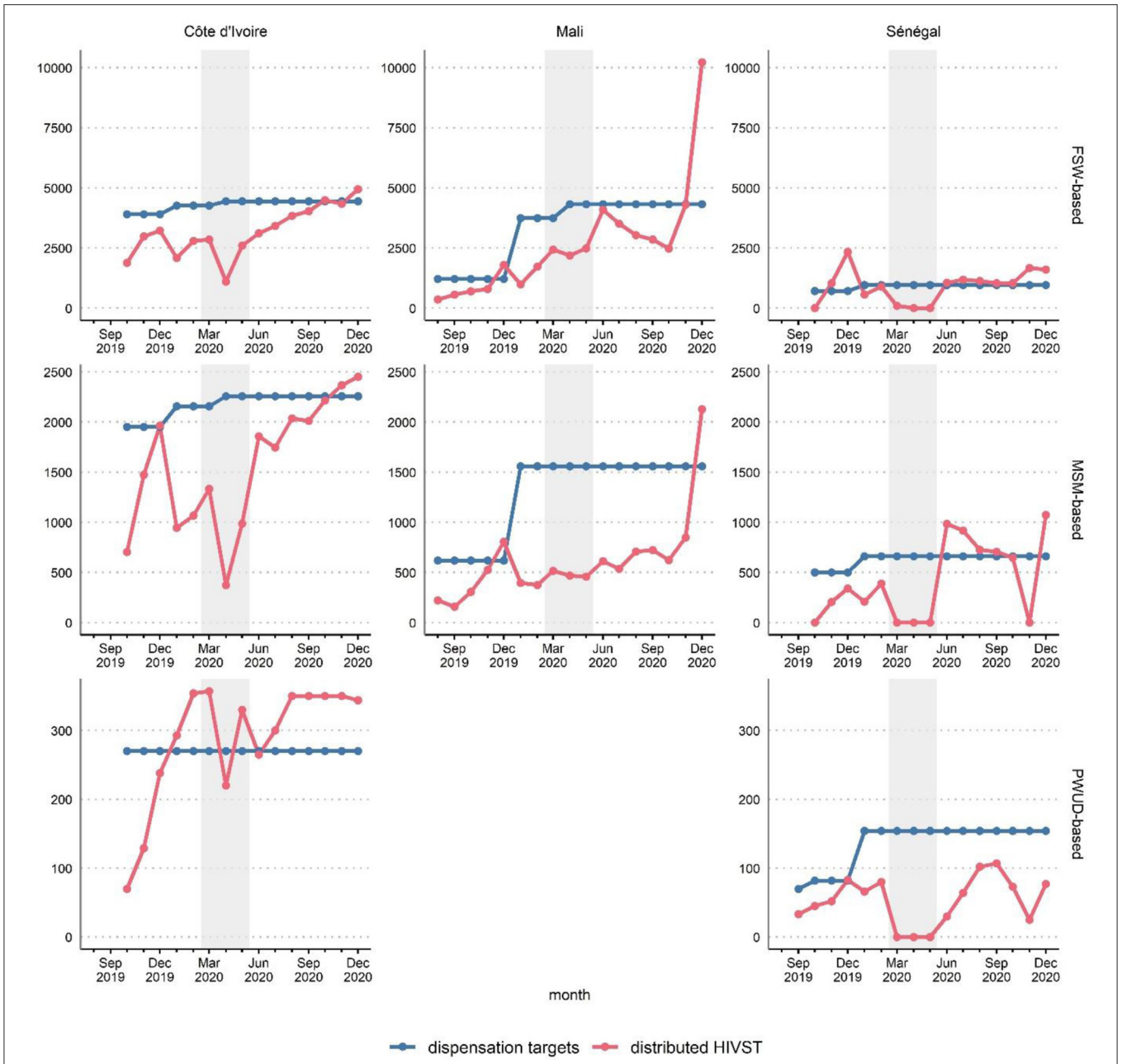

FIGURE 1 | Distribution targets and HIVST distributed during outreach by month, country and delivery channel (FSW-based, MSM-based, or PWUD-based), ATLAS program (August 2019-December 2020). The shaded area corresponds to the emergency COVID-19 response phase (March-May 2020). FSW, female sex workers; MSM, men having sex with men; PWUD, people who use drugs.

large group activities were reduced, and face-to-face activities were prioritized, particularly for the MSM-based channel. This was less the case for the FSW-based channel, as brothels were not closed in all Malian regions.

In Senegal, HIVST implementation used two coexisting distribution models: a model of independent community-based distributors carrying out "one-on-one" activities to reach hidden populations directly and more traditional activities with peer educators working in small groups (e.g., talks, discussion groups, social events). All activities were suspended between March and May 2020. Upon resumption in June 2020, some activities were conducted in larger groups to catch up.

Age Profile of Primary Contacts

The age profile of primary contacts was relatively stable over the three reference periods: pre-COVID-19, the emergency phase, and the routine management phase (**Figure 3**).

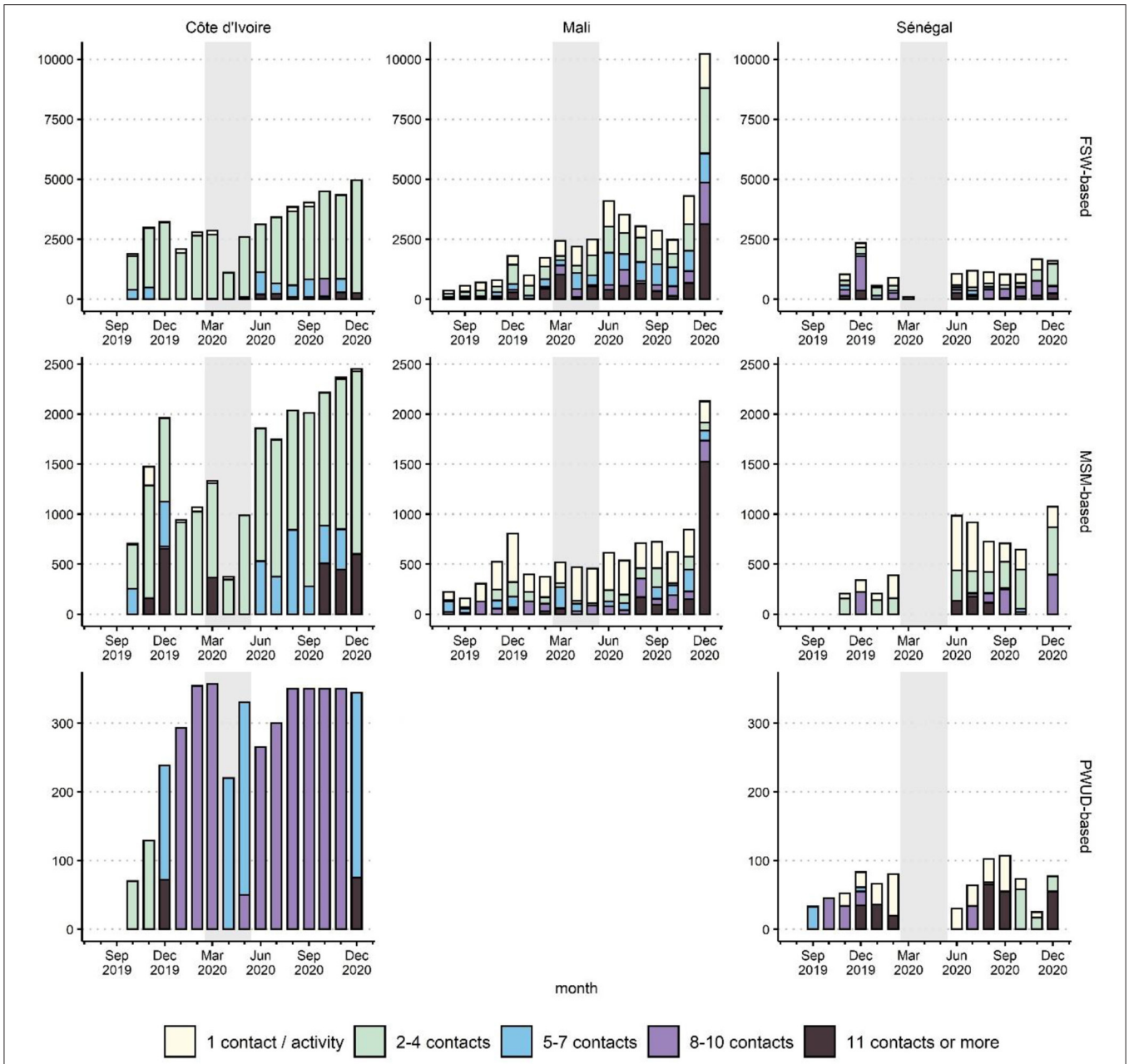

FIGURE 2 | Number of HIVST kits distributed during outreach per average number of primary contacts by activity, per month, country, and delivery channel (FSW-based, MSM-based, or PWUD-based), ATLAS program (August 2019–December 2020). The shaded area corresponds to the emergency COVID-19 response phase (March-May 2020). FSW, female sex workers; MSM, men having sex with men; PWUD, people who use drugs.

Average Number of HIVST Kits Distributed per Primary Contact

The average number of HIVST kits distributed per primary contact (**Figure 4**) is an indirect indicator of secondary distribution.

In Côte d'Ivoire, the closure of bars and restaurants ("maquis") and the curfew led to a drop in social contacts (in particular for MSM) and a decrease in the number of clients (for FSW), resulting in a decline in the average number of HISVT kits distributed per primary contact. When the curfew was lifted (May 2020), a return to the pre-COVID level in the MSM-based delivery channel was observed, whereas a much slower recovery was observed for the FSW-based channel, with numbers not yet back to the pre-COVID level.

In Mali, this indicator was lower than in the two other countries initially but showed continuous progression over time. The curfew at the end of March 2020, which was extended until early May, led to a drop (slower progress observed).

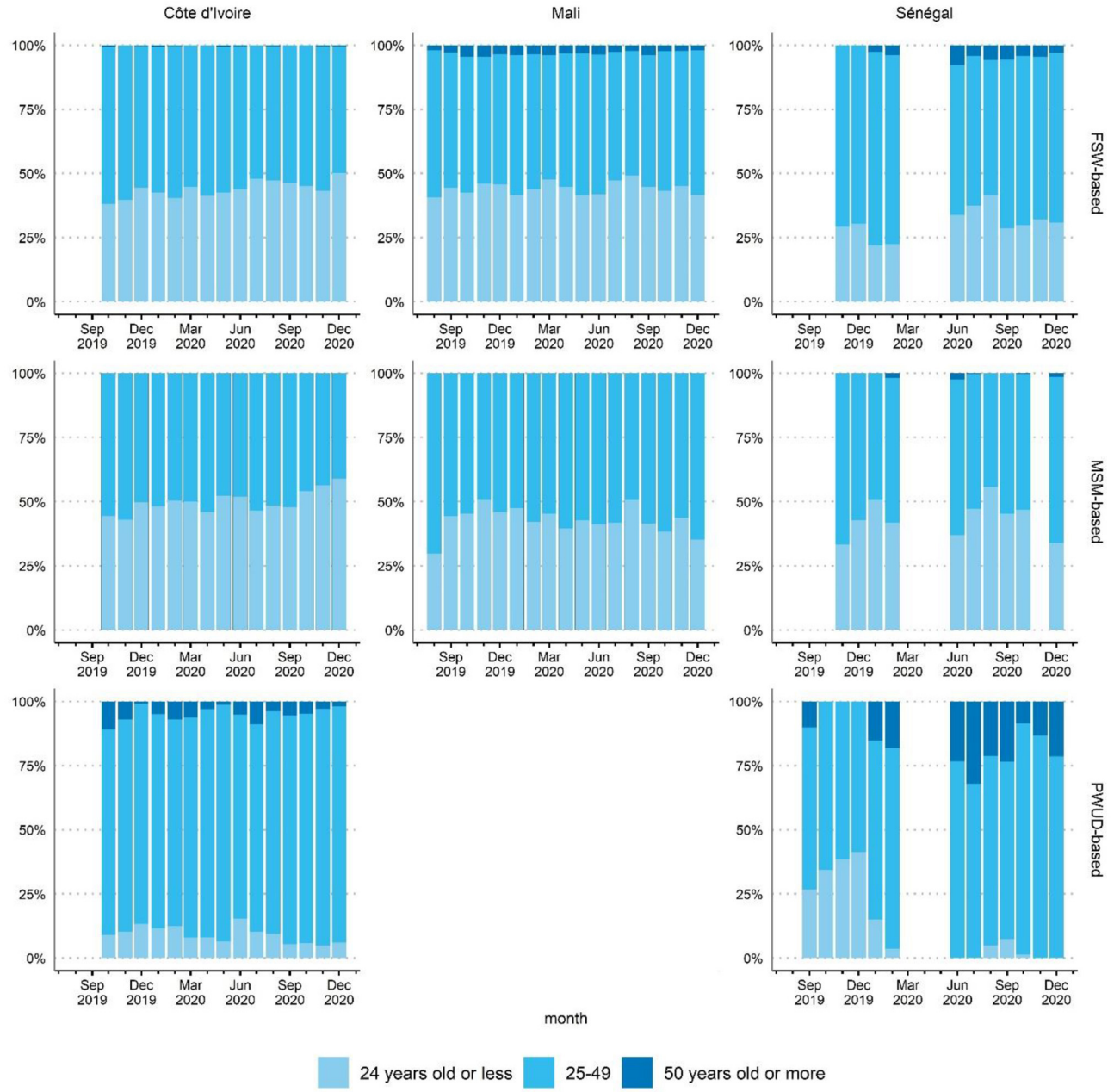

FIGURE 3 | Age profile of primary contacts by month, country and delivery channel (FSW-based, MSM-based or PWUD-based), ATLAS program (August 2019-December 2020). FSW, female sex workers; MSM, men having sex with men; PWUD, people who use drugs.

However, there was a recovery and an increase from May onwards in the MSM-based channel and a plateau in the FSW-based channel.

In Senegal, activities restarted in June, with a significant setback compared to the pre-COVID period. Despite a gradual recovery, the average number of HIVST kits distributed per primary contact had not yet reached its pre-crisis level by the end of 2020.

Adjustments of HIVST Activities to Comply With Governmental Health Measures

The measures taken by governments (**Table 1**) and the application of hygiene measures led to major changes in HIVST outreach activities between March and May 2020. Qualitative feedback from peer educators (through individual interviews and focus groups) is summarized in **Table 2**.

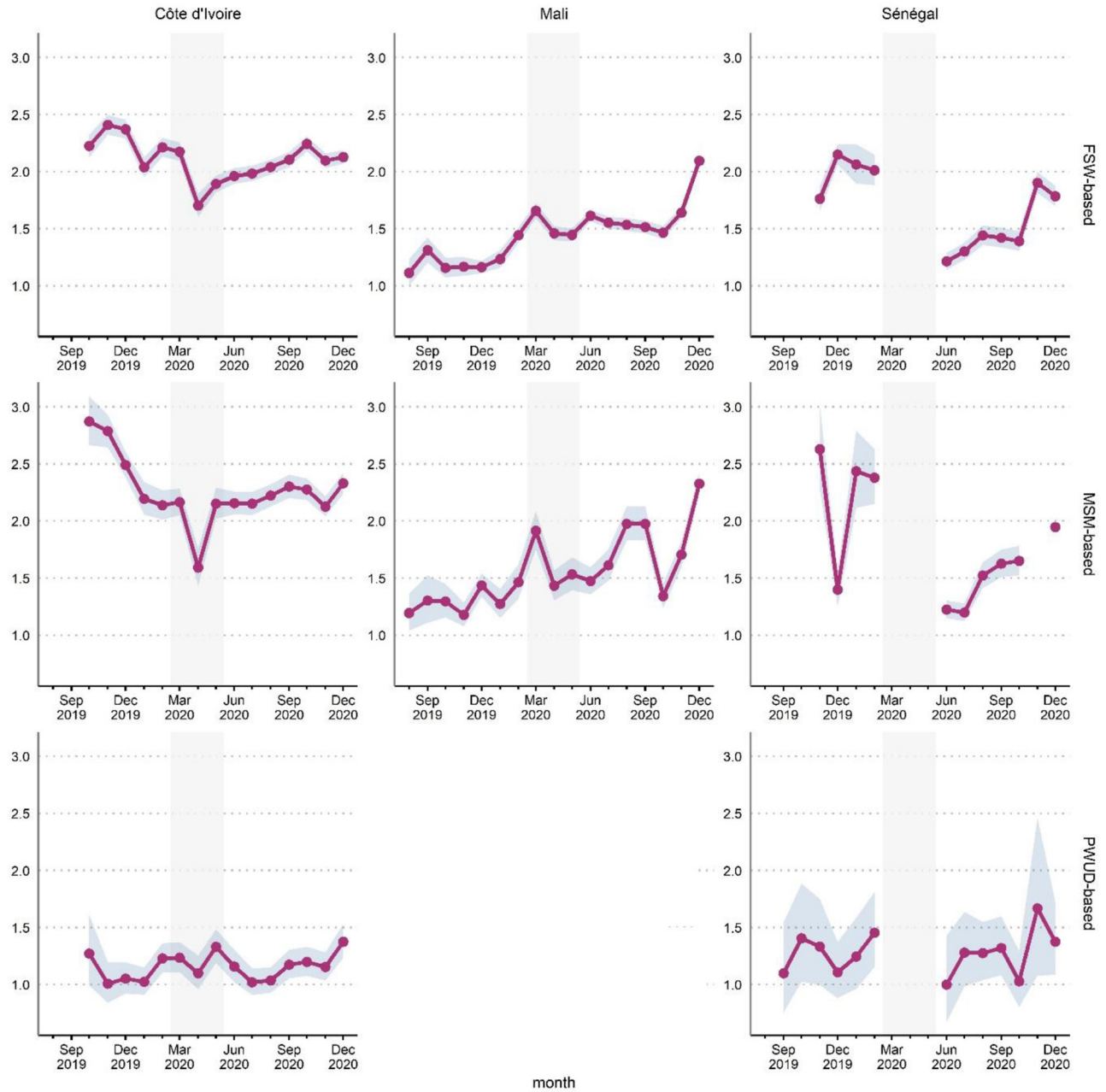

FIGURE 4 | Average number of HIVST kits distributed by primary contacts per month, country and delivery channel (FSW-based, MSM-based or PWUD-based), ATLAS program (August 2019-December 2020). Gray ribbon indicates 95% confidence intervals (Poisson test). The shaded area corresponds to the emergency COVID-19 response phase (March-May 2020). FSW, female sex workers; MSM, men having sex with men; PWUD, people who use drugs.

In Côte d'Ivoire, peer educators made several adjustments for activities targeting FSW and MSM: relocation from public (bars, venues, brothels, etc.) to private areas (home, discreet places, etc.); group size reduction with prioritization of face-to-face talks when possible. Peer educators reported similar adjustments in Mali, with variations by region depending on how closely local populations have followed governmental health measures.

FSW peer educator, focus group, Mali: "*There have been many changes in our work. Before, people used to come to the maquis* [local restaurants], *but after the maquis were closed down and the FSW were obliged to go and take rented flats, we used to go to these homes to give talks, and we were obliged to do so for as long as they could give us. We don't go out into the field at night to go to work anymore.*"

TABLE 2 | Adaptation of HIVST distribution outreach activities according to peer educators' feedback, 2020, ATLAS program.

Delivery Channel	Côte d'Ivoire	Mali	Senegal
FSW-based	• **Adaptation of activities (March-May 2020)** • From public to private spaces • Group size reduction • Night activities moved to daytime • Rapid tests converted into assisted HIVST • Appointment by phone/WhatsApp • **Hygiene measures***	**Adaptation of some activities (March-May 2020, region dependent)** • From public to private spaces • Group size reduction • Night activities moved to daytime • Rapid tests converted • Into assisted HIVST • Appointment by phone/WhatsApp • **Hygiene measures***	• **Suspension of outreach activities (March–May 2020)** • **Resumption of activities (June 2020)** • Prioritization of face-to-face activities • Less HIVST distributed per contact • Appointment by phone/WhatsApp • **Hygiene measures***
MSM-based	• **Adaptation of activities (March-May 2020)** • From public to private spaces • Group size reduction • Night activities moved to daytime • Rapid tests converted into assisted HIVST • Increased use of social networks • **Hygiene measures***	• **Adaptation of some activities (March-May 2020, region dependent)** • From public to private spaces • Group size reduction • Night activities moved to daytime • Rapid tests converted into assisted HIVST • Increased use of social networks • **Hygiene measures***	• **Suspension of outreach activities (March-May 2020)** • **Resumption of activities (June 2020)** • Prioritization of face-to-face activities • Less HIVST distributed per contact • Appointment by phone/WhatsApp • Increased use of social networks • **Hygiene measures***
PWUD-based	• **Adaptation of activities (March-May 2020)** • Unchanged intervention sites (smoking sites) • Group size reduction • Unchanged timing (daytime) • Rapid tests converted into assisted HIVST • No use of social networks • **Hygiene measures***		• **Suspension of outreach activities (March-May 2020)** • Referral to a dedicated clinic (Dakar) • **Resumption of activities (June 2020)** • Prioritization of face-to-face activities • Less HIVST distributed per contact • No use of social networks • **Hygiene measures***

**Hygiene measures: awareness of COVID-19, wearing a mask (distributor), hydroalcoholic gel (distributors + primary contacts), physical distancing (sometimes difficult).*
FSW, female sex workers; MSM, men having sex with men; PWUD, people who use drugs.

All outreach activities conducted at night were stopped by the different curfews and were rescheduled for the daytime.

Social networks (Facebook, Messenger, WhatsApp), commonly used by MSM, were increasingly used by MSM peer educators during March-May 2020 to maintain contact with their peers, promote HIV prevention and testing and organize face-to-face or small group meetings.

> MSM peer educator, focus group, Côte d'Ivoire: "*In the COVID-19 period, since we couldn't really meet I did everything online, that's it; I was raising awareness online. When it comes to dispensing self-tests now, I move around, we meet up and then I give."*

> MSM peer educator, focus group, Côte d'Ivoire: "*I created a Facebook group "les branchés de* [small town in Côte d'Ivoire]*". I created a second group "les branchés de* [other small town]*", and I publish photos, videos, images in a trendy way; we know each other and others have asked to join. And it's like I've broadened my thing a bit and now I'm going out there to go door to door."* ['branchés' is a term used by MSM to refer to themselves.]

FSW peer educators used social networks mainly to make appointments or keep in touch with their peers. Unlike MSM, social networks were not used to expand the peer network.

> FSW peer educator, focus group, Mali: "*If we didn't know their homes, we called them and looked for their homes."*

In Côte d'Ivoire, activities with PWUD have been maintained within the smoking rooms. However, the number of visits and the number of contacts per visit have been reduced.

> PWUD peer educator, focus group, Côte d'Ivoire: "*At the beginning, we had seven visits* [per week], *but when COVID arrived, we went down to five visits.*"

> PWUD peer educator, focus group, Côte d'Ivoire: "*We had to avoid being too in contact with the DU* [drug users] *because they are glued, they like contact! That is to say that if he is not with you, he is not at ease.*"
> PWUD peer educator, focus group, Côte d'Ivoire: "We divided up, we took them in small groups."

In Senegal, activities were suspended from March to May 2020.

> MSM peer educator, focus group, Senegal: "*The context of COVID has impacted the work because we have gone for months without distributing HIVST, and this impacts the achievement of our distribution objectives."*

Rapid Application of Hygiene Measures by Peer Educators

In all three countries, the application of hygiene measures was welcomed by peer educators as offering protection from COVID-19.

MSM peer educator, individual interview, Côte d'Ivoire: "*We are not afraid anymore because we have the means to protect ourselves; there are the gels, there is everything and then we always continue to respect the barrier measures; even if it is not 100%, we respect them all the same.*"

Maintaining Physical Distancing Was the Most Difficult Measure to Implement

FSW peer educator, individual interview Côte d'Ivoire: *"If I am one meter away from the peers and I speak I am obliged to get closer, especially in a bar/maquis, to remain discreet, but I always wear the face mask."*

Some peer educators mentioned the difficulty of not having face masks to distribute to users. For example, some peer educators decided to give them a face mask from their personal dotation when some users did not have a face mask. This meant that the peer educator could not change their face mask as often as recommended.

FSW peer educator, focus group, Mali: *"I think there can be a problem if you are protected and not me, because if you are protected and the rest of us are not, we can be exposed when you come to do the demonstration. So if we are all protected, there is no problem."*

PWUD peer educator, focus group, Côte d'Ivoire: "*So when you arrive on the sites, it's when DU* [drug users] *asks you "Can I have a face mask too?" That's when you give them a face mask, your face mask that is on you that you give them to wear* [i.e. the peer educator gave a mask from his personal dotation, not the mask he was currently wearing at the time]. *Otherwise, we don't have face masks to share."*

Within a few weeks, hygiene measures were routinely integrated.

PWUD peer educator, focus group, Côte d'Ivoire: "*Everyone is now used to wearing masks.*"

Assisted HIVST: A Safe Replacement for Rapid HIV Testing When Physical Distancing Is Needed

Before the COVID-19 crisis, peer educators proposed both conventional rapid HIV testing and HIVST. In March-April, the lack of personal protective equipment, in particular face masks and hydroalcoholic gels, made the application of hygiene measures difficult. Physical distancing was favored during activities. Due to the challenge of safely performing rapid testing in such a context, some peer educators proposed assisted HIVST as a replacement for rapid testing for those who agreed to be tested onsite.

MSM peer educator, individual interview, Côte d'Ivoire: "*Since March when we were talking about distancing, it was a bit difficult even to do the classic tests. We took a lot of advantage of the self-tests because at least you can offer them."*

MSM peer educator, focus group, Mali: *"Our work doesn't allow us to respect safety measures; it's a bit difficult. So I myself from the beginning of the coronavirus until recently, most of my screening is done through self-testing. I give it to you, and I explain it to you, so you do your test, even if it's assisted, you do it, and when you're done doing it, we'll do what needs to be done."*

PWUD peer educator, focus group, Côte d'Ivoire: *"HIVST helped to maintain the link during the crisis."*

HIVST Activities: An Opportunity for COVID-19 Awareness-Raising

Initially, peer educators reported that some key population members perceived hygiene measures as a form of discrimination. Peer educators were gradually able to provide information about COVID-19 and thus promote the importance of these measures. This awareness-raising complemented the governmental messages about COVID-19.

PWUD peer educator, focus group, Côte d'Ivoire: "*We tried to get them to understand that they should try to separate a little, try to loosen up a little. It was difficult; we had to rehearse.*"

PWUD peer educator, focus group, Côte d'Ivoire: *"They finally understood that it wasn't because of their status but because of COVID."*

Gradual Return to Normal With the Maintenance of Hygiene Measures

When activities resumed in June 2020, they were re-adapted: face-to-face activities were prioritized when possible, and activities were moved to private areas and the daytime. It was also reported that instructions were given to distribute only one HIVST kit per contact.

FSW peer educator, focus group, Senegal: "*Before COVID, we used to go out at night to distribute to bars and restaurants. But with the pandemic and the restrictive measures taken on that occasion, we were obliged to change our strategy and give priority to home visits.*"

MSM peer educator, focus group, Senegal: "*In November and December, we were told that up to 3 HIVST kits could be distributed per MSM. But after the resumption of activities in the post-COVID period, between July and August, they came back and told us as an independent distributor to distribute 1 HIVST kit per person from now on.*"

With the easing of public health measures and the routinization of COVID management, activities have gradually returned to as they were before the crisis: held in public places, with larger groups, and sometimes in the evening.

FSW peer educator, focus group, Mali: "*Activities have resumed almost as before. Places have reopened, and people are no longer picked up from their homes but rather from their usual places.*"

Some peer educators suggested maintaining such preventive measures even after the COVID-19 pandemic to prevent other communicable diseases, such as tuberculosis.

> FSW peer educator, individual interview, Mali: "*For me, there are changes that we have to maintain because even after COVID-19 there are other communicable diseases; these are the means of protection that we have put in place.*"

DISCUSSION

The pre-COVID-19 period allowed for a gradual distribution of HIVST in the three countries, with many activities carried out in large groups (5 or more contacts), varying according to the country and the type of targeted key population. During the initial emergency response period (March-May 2020), activities were severely disrupted with a total suspension in Senegal, a significant drop in Côte d'Ivoire, and a less pronounced drop in Mali. Priority was given to activities conducted in small groups (4 contacts or less). Secondary distribution (measured indirectly by the average number of HIVST distributed per primary contact) was also negatively affected. To ensure continuity of activities, peer educators in charge of HIVST distribution showed resilience and adapted by moving from public to private areas, reducing group size, shifting night-time activities to daytime, increasing the use of social networks, integrating hygiene measures, and promoting assisted HIVST as an alternative to traditional rapid testing.

With routine management of the pandemic from June 2020 onwards, a catch-up phenomenon was observed: activities resumed in Senegal, new distribution sites were established, the number of HIVST distributed rebounded, the activities of larger groups resumed, and the average number of HIVST distributed per primary contact rebounded.

Using quantitative and qualitative data from activity reports, individual interviews, and focus groups, our main findings highlight the significant but heterogeneous impacts of COVID-19 disruptions on ATLAS project activities and how peer educators and implementing partners have been able to adapt in such context and showed resilience. The flexibility of HIV self-testing strategies allowed the maintenance of access to HIV testing services for key populations while ensuring hygiene measures.

Our results need to be interpreted in light of some limitations. Unlike survey data, which are usually collected at an individual level, monthly reports are aggregated by site and delivery channel. In addition, though the number of distributed HIVST kits (main indicator) is reported fairly precisely, less attention is given to the number of primary contacts, the number of activities, or the type of activities. Only outreach activities have been considered in this analysis, and it would be relevant to explore the impact on facility-based activities as well. During the crisis, individual interviews were conducted by phone with the primary objective of documenting the challenges faced by program implementers, limiting the depth of these interviews. Finally, the data being collected on behalf of Solthis, the body to which CSOs report their activities, may be subject to response and desirability bias.

However, developing a dedicated survey would have required several months (development, funding, authorizations) before being implemented, and it would not have been possible to observe changes and adaptations of activities during the initial emergency response phase. In that sense, using routinely collected monitoring data for secondary analysis provides valuable information.

Worldwide, the COVID-19 pandemic has impacted all health sectors, including global HIV strategies (24). Emergency public health measures have limited populations' freedom of movement, resulting in lower access to essential HIV prevention, testing, and treatment services (25–27). West Africa has been no exception; the governmental health measures in Côte d'Ivoire, Mali, and Senegal have impacted the daily lives of key populations. For ATLAS, HIVST distribution was disrupted, and secondary distribution was limited. Similarly, there were program-level effects, such as the delayed opening of certain distribution sites (**Supplementary Figure 4**).

However, there is no evidence if risky behaviors may have increased or decreased among key populations during the period where governmental restrictions were in place. For example, the closure of bars/restaurants and curfews may have reduced the number of clients of FSW (reducing exposure to HIV), but condom negotiation may have been more difficult (increasing exposure to HIV). If our results show that HIVST offer has been reduced due to the adaptation of activities, we have no feedback from peer educators that HIVST demand decreased, except probably for secondary distribution (as it was more challenging to redistribute HIVST kits in such a context).

ATLAS's implementing partners had to adapt their operational procedures to ensure service continuity in an emergency context where COVID-19 was not well-known and the discourse on hygiene measures varied from country to country.

In Senegal, where governmental measures were scrupulously followed, local partners decided to suspend activities for two main reasons. First, Senegalese community-based organizations are extremely cautious in a country where stigma toward key populations is high and media scandals frequent. Second, there were financial issues during this period. ATLAS's HIVST outreach distribution is integrated within traditional testing activities funded by other donors. The principal ATLAS community-based partner in Senegal for FSW and MSM was withdrawn from a Global Fund grant in January 2020, resulting in a suspension of certain activities. Nevertheless, HIVST distribution continued through the independent community distributors, and CSO-based activities resumed in June 2020.

In Côte d'Ivoire, where governmental measures were globally respected, HIVST distribution was maintained with considerable adaptation by peer educators.

In Mali, where governmental measures were weaker, and adherence varied according to region, HIVST distribution was less impacted.

From June onward, the easing of public health measures allowed a relative return to normal. During this process of routinization, hygiene measures and COVID-19 awareness-raising were maintained in the field by HIVST distributors,

ensuring the continuity of testing activities to optimize key populations' monitoring and management (28).

From our main results, different lessons can be drawn from the ATLAS project activity reports on the provision of HIVST in the context of the COVID-19 health crisis. Peer educators and key populations have been adaptive and resilient in deploying strategies to ensure continuity of distribution activities while integrating health constraints (22, 29). These adaptations made it possible to maintain access to HIV testing while respecting the barrier measures. HIVST has also helped to maintain access to testing, and its delivery is flexible enough to adapt to different contexts (30, 31).

CONCLUSION

Although imperfect, program data provide valuable information to describe changes in the implementation of HIVST outreach activities over time. The impact of the COVID-19 pandemic on HIVST distribution among key populations was visible in the monthly activity reports. Activities and secondary distribution were disrupted. Focus groups and individual interviews allowed documentation of the adaptations made by peer educators, with variations across countries and populations: relocating activities from public to private areas, reducing group sizes, moving night activities to the daytime, increasing the use of social networks, integrating hygiene measures, and promoting assisted HIVST as an alternative to conventional rapid testing… These adaptations demonstrate the resilience and learning capacities of peer educators and key populations. However, the uncertain evolution of the COVID-19 epidemic in 2021, with the possibility of new waves, could lead to additional impacts on activities.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

AUTHOR CONTRIBUTIONS

GC collected qualitative data. PD, KH, BDia, and BDie managed quantitative data collection. AK, GC, PD, AV, and JL conceived and designed the analysis. GC did the qualitative analysis. AK did the statistical analysis. AK, GC, and JL wrote the first draft of the manuscript. All authors contributed to the interpretation and presentation of the findings and approved the final version of the manuscript for submission.

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The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2021.653565/full#supplementary-material

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Uptake of HIV/AIDS Services Following a Positive Self-Test Is Lower in Men Than Women in the Democratic Republic of the Congo

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As far as HIV self-testing (HIVST) is concerned, proving the link to HIV care for users with a positive result contributes to understanding the implementation of HIVST. We sought to examine whether there were differences by sex in the uptake of HIV services following a positive self-test in the Democratic Republic of the Congo (DRC). This was a mixed-methods study exploring linkage to care for HIVST through a secondary analysis of collected data from three pilot surveys recently conducted in three cities (Kinshasa, Kisangani, and Kindu) during 2018 and 2020 in the DRC. Linkage to HIV care was defined as delayed when observed beyond 1 week. A total of 1,652 individuals were self-tested for HIV. Overall, the proportion of linkage to HIV care was high ($n = 258$; 82.2%) among individuals having a positive result with HIV self-test ($n = 314$), but it was significantly lower in men (65.2%) than women (89.2%). Furthermore, linkage to HIV care of men was significantly delayed as compared with that of women (40.0 vs. 20.7%). These findings show a lower uptake of care following a positive self-test in men than women. This trend already previously observed in sub-Saharan Africa shed light on the need to increase linkages to care among men newly diagnosed through HIV self-testing.

Keywords: HIV, self-testing, linkage to care, men, Democratic Republic of the Congo

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INTRODUCTION

Diagnosing 95% of all people living with HIV (PLWHIV) is the first of three global 95–95–95 targets set by the UNAIDS to end the HIV epidemic by 2030 (1). Indeed, HIV testing is the principal gateway to HIV care and prevention services (2). In the Democratic Republic of the Congo (DRC), UNAIDS estimates that <60% of HIV-infected people know their seropositivity (3). Despite important progress in the scaling up of HIV testing in the DRC in the last 10 years, HIV testing remains remarkably deficient among men (4).

HIV self-testing (HIVST) is a new approach with the potential to increase uptake of HIV testing, especially among men, and other specific groups such as adolescents and key populations. The World Health Organization (WHO) defines the HIVST as a process in which an individual performs an HIV test and interprets the result, often in a private setting (5). Previous pilot studies have shown that the HIVST is practicable, acceptable, and accurate among the Congolese

population (6–9). However, although the HIVST has the potential to reach men, the evidence on the linkage to care for users with a positive result remains to be established (10, 11). Furthermore, linkage to care after performing an HIV self-test is an additional concern because the HIVST can be performed through unassisted approaches in communities without proven monitoring and evaluation methods (10). The reasons explaining a low proportion of linkage to care among men in Africa may include the notorious ignorance of the benefits of antiretroviral therapy, the risk of losing one's job due to frequent clinic visits, the cost of transportation or fear of visibility as an HIV clinic client among asymptomatic patients, and death among those with AIDS (10–13).

With the current "test and treat" approach dictated by WHO since 2016 (14), barriers to assessing eligibility before initiation of antiretroviral therapy have been circumvented (15). Linkage to HIV care for HIVST is currently considered as accessing a healthcare provider through a clinic at four complementary different stages: the possibility to obtain accurate confirmation of HIV positivity, the enrolment into care after diagnosis, the onset of antiretroviral treatment, and the high adherence to antiretroviral treatment (2). However, evidence concerning the opportunity for HIV-positive individuals to receive post-test counseling and immediately enroll on HIV care for community-based unassisted HIVST remains unclear (10). Several studies have reported low proportion of linkage to care among men and have therefore explored other strategies such as home follow-up to improve linkage to care among men (11, 16, 17).

As far as HIVST is concerned, proving the link to care for users with a positive result contributes to understanding the implementation of HIVST in the DRC. In the present study, we sought to examine the linkage to care among Congolese previously self-tested in the three pilot surveys recently conducted in three main cities (Kinshasa, Kisangani, and Kindu) in the DRC.

MATERIALS AND METHODS

Study Design

This was a mixed-methods study exploring linkage to care for HIVST through a secondary analysis of collected data from three pilot studies aimed at evaluating different distribution models of the HIVST during July 2018 and April 2020 in the DRC, followed by in-depth interviews. The STROBE (18) and COREQ (11) guidelines were followed for reporting quantitative and qualitative data, respectively.

Study Setting

This multi-centric survey was carried out in the city of Kinshasa, the capital of the DRC; Kisangani, the capital city of the province of Tshopo; and Kindu, the capital city of the province of Maniema. These cities have different sociocultural and geographical contexts. A total of 18 study sites, integrating HIV testing and care settings, were selected for the study, including eight sites in Kinshasa (Marechal, Bomoi, Elonga, Kimia, Matonge, and Saint Joseph Health Centers; and Kalembelembe and Kimbondo Pediatric Hospitals), six sites in Kindu (Lumbulumbu, Kasuku-2, Sokolo, and Mikonde Health Centers; and Kindu and Alunguli General Referral Hospitals), and four sites in Kisangani (University hospital of Kisangani, Kabondo General Referral Hospital, and Neema and Saint-Joseph Health Centers).

Study Population and Participant Recruitment

All participants were volunteers who were recruited from adolescents at home through a door-to-door approach (pilot study 1) and the general public at high risk for HIV infection (pilot studies 2 and 3), using different delivery HIVST approaches previously reported including home-based directly assisted HIVST by peer educators (pilot study 1) (7), facility-based directly assisted and community unassisted HIVST (pilot study 2) (9), and facility-based unassisted HIVST (pilot study 3) (8) (**Figure 1**). Eligible participants were between 15 and 49 years of age, were unaware of their HIV status, and were able to give written informed consent. Individuals on antiretroviral treatment or pre-exposure prophylaxis, transgenders, or persons who did not meet the study criteria were excluded.

Sampling and Sample Size

Because this is secondary data analysis for the quantitative study, it was only possible to analyze the *post-hoc* power of the study. For the qualitative study, convenience sampling was used among the self-tested men with positive results who arrived in health facilities for linkage to care after 1 week.

Data Collection and Study Procedure

The HIVST was performed using the blood-based self-test kit Exacto Test HIV (Biosynex, Strasbourg, France), as previously reported (6–9, 19).

The participants completed a self-administered baseline questionnaire to collect data on their demographic characteristics, sexual behavior, and HIV testing history, after which they received pretest HIV counseling. Pretest counseling consisted of a 30-min conversation: (i) to review the reasons why participants wanted to be tested for HIV; (ii) to learn about their knowledge of HIV prevention methods; (iii) to help them understand the consequences of HIV risk behaviors; (iv) to assess their level of risk; (v) to provide them with psychological support if their test result came back positive; and (vi) to advise them to be retested 3 months later if they had taken a risk. After HIVST in community or facility, participants who were identified as HIV positive were verbally advised to be link to HIV care at one of the 18 selected health facilities according to their preference. Linkage to care consisted of confirmation of positivity, post-test counseling, and initiation of antiretroviral treatment. Note that only delayed patients were traced, and the time frame for tracing HIV self-test users who tested positive but were not voluntarily linked to care was 2 weeks after HIVST. Men who linked to care after 1 week either voluntarily or by tracing were asked voluntarily to participate in in-depth interviews to understand the reasons for the low proportion and delay for linkage to care.

With a semi-structured guide containing open-ended questions, the in-depth interviews were conducted according

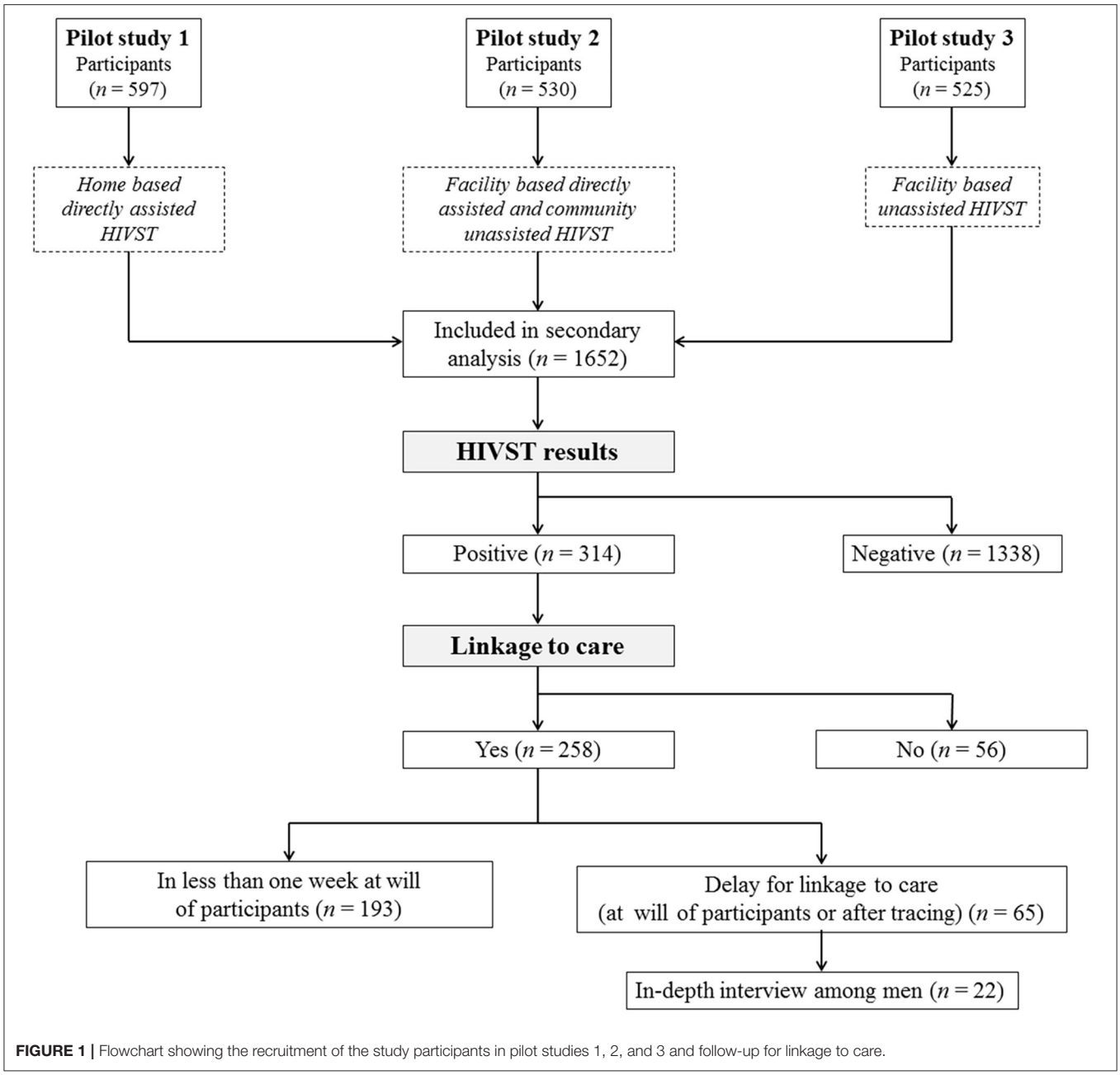

FIGURE 1 | Flowchart showing the recruitment of the study participants in pilot studies 1, 2, and 3 and follow-up for linkage to care.

to the phenomenological approach adapted to qualitative research, as described by Hsieh and Shannon (20). Note that phenomenology approach focuses on the commonality of a lived experience within a particular group (20). Thus, in this study, the lived experience was the linkage to care for HIVST, and the particular group was men. The questions were pretested with three men who had already used the HIVST kits for revising the study tool before actual data collection. Interviews were scheduled at the participant's convenience. Participants were contacted by telephone to arrange an appropriate time for the interview. Interviews were conducted in French, Lingala, or Swahili at the convenience of the participant. The average duration of these interviews was 45 min (minimum 35 min and maximum 60 min).

Outcomes

The principal study outcomes were the linkage to care and the delay for linkage to care. Linkage to care was operationally defined as the reaching for HIV-positive confirmation, the receiving of post-test counseling, and the initiation of the antiretroviral treatment. The total follow-up time to evaluate linkage to care in this study was 30 days. Linkage to care was optimal when it was observed in less than a week, whereas it was considered delayed when observed beyond 1 week.

As previously reported, high risk for HIV infection was defined as a history of unprotected sex with one or more partners in the past 6 weeks as well as exposure to any of the following high-risk factors in the previous 6 months: multiple (i.e., >2) partners; homosexual intercourse (asked of men); receipt of gifts, cash, or other compensation in exchange for sex (asked of women); or infection with another sexually transmitted disease. Participants self-reported the information regarding the risk for HIV. Individuals exposed to any of these factors were classified as "high risk"; the remaining participants were classified as "low risk" if they did not report any sexual activity in the past 6 weeks and as "moderate risk" if otherwise (9, 21, 22). Educational level was categorized according to the educational system of the DRC, as follows: (i) low: unschooled or attending primary school; (ii) middle: attending college (training of 6 years) or technical school (training of 4 years); and (iii) high: attending bachelor's degree, graduate degree (training of 2 years after Bachelor's degree), or postgraduate degree, as previously reported (6).

Ethical Considerations

Ethical approval for this survey was obtained from the Ethics Committee of the School of Public Health of the University of Kinshasa. Written informed consent was obtained from all participants. All participants with HIV-positive result for HIVST who were linked to care were provided with antiretroviral therapy and follow-up according to the DRC's national first-line therapeutic protocol including tenofovir, lamivudine, and dolutegravir, as recommended by the WHO (23).

Data Management and Analysis

Overall linkage to care, delay for linkage to care, and strategy for improving linkage to care were evaluated quantitatively and/or qualitatively.

After identification and consolidation of the data for secondary data analysis from the three raw databases from the three pilot studies, continuous variables were expressed as means (±standard deviations) or median and interquartile range, as appropriate. Frequencies and proportions were used to describe categorical variables and were compared using Pearson's chi-squared test or Fisher's exact test, as appropriate. Unadjusted odds ratios of linkage to care and delay for linkage to care were estimated using the bivariate models. Multivariable-adjusted odds ratios of linkage to care and delay for linkage to care were estimated using the logistic regression analysis. Note that all factors (sociodemographics, sex behavior, and past story regarding HIV testing) studied were included in the bivariate models. However, only factors with $p < 0.2$ in the bivariate analysis were entered into the multivariate analysis. All quantitative analyses were performed using IBM SPSS Version 20 (Chicago, IL, USA) and XLSTAT (Addinsoft, Paris, France).

All qualitative data were first translated into French and then into English. Transcripts were analyzed through an inductive approach; thus, themes were identified during the course of analysis (24). In order to limit interviewers' biases due to preconceived ideas or theoretical perspectives when analyzing qualitative data, two different authors had independently analyzed the responses and coded them manually. Coding concepts were grouped into diverse categories and then linked and compared within inductive analysis (25). After the first list of thematic codes was generated, the answers were refined and grouped according to similarities (25).

RESULTS

Study Participants

A total of 1,652 individuals who had performed the HIV self-test were eligible for secondary data analysis, including 597 adolescents from pilot study 1, 530 high-risk people from pilot study 2, and 525 high-risk people from pilot study 3 (**Figure 1**). After HIVST, 314 participants had reported a positive result and were followed up for linkage to care evaluation. The baseline characteristics of the total study participants and the participants with a positive self-test result are depicted in **Table 1**. In brief, among the participants included in the linkage to care assessment, 70.7% were female participants; 66.2% were aged between 15 and 24 years; 85.4% were single; 46.8% were students; and 40.8% were attending college or technical school. The majority of participants had never been tested for HIV (71.3%) and had no knowledge of the existence of HIVST (68.8%). The interview was conducted among 22 men who had been recruited among men who tested positive for HIV and who arrived after 1 week at the health facilities either voluntarily or by tracing for confirmation, post-test counseling, and treatment. Among them, the majority were <24 years old. Approximately three-quarters were single. One-third were students, one-third were employed or self-employed, and one-third were unemployed. Low educational level was observed in 22.7% of participants; a middle level was observed in 45.5%, and a high level was observed in 31.8% of participants.

Overall Linkage to Care

Among 314 participants having a positive result with HIV self-test, 258 had completed the linkage to care assessment, yielding an overall proportion of linkage to care for HIVST at 82.2%. The linkage to care was in <1 week at the will of participants in 74.8% of cases (**Figure 1**). Overall, the mean time for linkage to care was 9.7 ± 2.4 days. However, it was 5.4 ± 1.2 days among participants linked to care in less than a week and 21.1 ± 5.7 days among latecomers. The variables "sex," "age group," and "educational level" were significantly associated with linkage to care in bivariate models. Indeed, the linkage to care for HIVST was significantly low among men than women (65.2 vs. 89.2%; crude OR: 0.2 [95% CI: 0.1–0.4]) and participants with high educational level compared with those with low educational level (72.6 vs. 87.3%; crude OR: 0.4 [95% CI: 0.2–0.8]). However, the linkage to care for HIVST was significantly high among participants aged between 15 and 24 years (84.6 vs. 69.7%; crude OR: 2.4 [95% CI: 1.3–4.6]) and those aged between 35 and 44 years (97.1 vs. 69.7%; crude OR: 14.8 [95% CI: 1.9–115.6]) compared with those aged between 25 and 34 years. Other variables such as "risk of HIV infection" and "past HIV testing" had a $p < 0.2$ in the bivariate analysis.

As shown in **Table 2**, multivariate analysis showed that male gender (adjusted OR: 0.7, 95% CI: 0.5–0.9) was significantly

TABLE 1 | Characteristics of 1,652 participants using the HIV self-test and 314 participants with positive results.

Characteristics	Total participants (n = 1,652) n (%)	Positive participants with self-test included in linkage to care analysis (n = 314) n (%)
Sex		
Male	664 (40.2)	92 (29.3)
Female	988 (59.8)	222 (70.7)
Age group		
15–24 years	1,080 (65.4)	208 (66.2)
25–34 years	362 (21.9)	66 (21.0)
35–44 years	139 (8.4)	35 (11.1)
>44 years	71 (4.3)	5 (1.6)
Partnership and civil status		
Single	1,237 (74.9)	268 (85.4)
Married/partnered	415 (25.1)	46 (14.6)
Occupation		
Student	928 (56.2)	147 (46.8)
Employed	303 (18.3)	79 (25.2)
Unemployed	421 (25.5)	88 (28.0)
Educational level[#]		
Low	259 (15.7)	102 (32.5)
Moderate	904 (54.7)	128 (40.8)
High	489 (29.6)	84 (26.8)
Risk of HIV infection[£]		
Low risk	800 (28.4)	40 (12.7)
Moderate risk	359 (21.7)	69 (22.0)
High risk	493 (29.8)	205 (64.3)
Previously tested for HIV		
Never tested	1,007 (61.0)	224 (71.3)
Ever tested	645 (39.0)	90 (28.7)
Previous knowledge about existence of HIV self-testing		
Yes	467 (28.3)	98 (31.2)
No	1,185 (71.7)	216 (68.8)
Previously self-tested for HIV		
Never self-tested	1,578 (95.5)	312 (99.4)
Ever self-tested	74 (4.5)	2 (0.6)

[#] *Educational level was categorized according to the educational system of the Democratic Republic of the Congo, as follows: (i) low: unschooled or attending primary school; (ii) middle: attending college (training of 6 years) or technical school (training of four years); and (iii) high: attending bachelor's degree, graduate degree (training of 2 years after Bachelor's degree), or postgraduate degree, as previously reported (6).*

[£] *High risk for HIV infection was defined as a history of unprotected sex with one or more partners in the past 6 weeks as well as exposure to any of the following high-risk factors in the previous 6 months: multiple (i.e., >2) partners; homosexual intercourse (asked of men); receipt of gifts, cash, or other compensation in exchange for sex (asked of women); or infection with another sexually transmitted disease. Individuals exposed to any of these factors were classified as "high risk"; the remaining participants were classified as "low risk" if they did not report any sexual activity in the past 6 weeks and as "moderate risk" if otherwise (9, 21, 22).*

associated with the decrease of the linkage to care, whereas the proportion of linkage to care was increased among young participants (adjusted OR: 2.0, 95% CI: 1.0–4.0) and participants aged 35–44 years (adjusted OR: 2.8, 95% CI: 1.2–4.7) compared with those aged 25–34 years.

Qualitative observations provided additional insights into the factors that influenced linkage to care. When participants were asked to provide reasons for lack of linkage to care, their responses emphasized fear of the unknown, fear of stigma, and doubt about the result of self-testing:

> "I was afraid to confirm my positive result because if I do, I will be a candidate for death while I am still young and have family responsibilities. I preferred to remain in ignorance of my HIV status." (Interview, 23-year-old man, Kindu).
>
> "I knew the risk I had taken in the past, so I found it unnecessary to confirm my HIV status because I knew I was infected." (Interview, 34-year-old man, Kinshasa).
>
> "I was afraid of stigma because at the hospital sometimes people's HIV status is known to everyone…" (Interview, 45-year-old man, Kisangani).
>
> "I doubted the result of the self-test because I was not sick and I had no signs of HIV infection…" (Interview, 38-year-old man, Kinshasa).

Delay for Linkage to Care

The delay for linkage to care was observed among 65 (25.2%) participants (**Figure 1**). The variables "sex" and "risk of HIV infection" were significantly associated with delay for linkage to care in bivariate models. No other variables had a $p < 0.2$ in the bivariate analysis. In the multivariate model, the delays for linkage to care were significantly high among men (40.0 vs. 20.7%; adjusted OR: 1.8 [95% CI: 1.1–2.7]) and users with a high risk of HIV infection (31.8 vs. 9.4%; adjusted OR: 2.1 [95% CI: 1.2–3.8]) compared with women and users with low risk of HIV infection, respectively (**Table 2**).

Of note, no differences were observed when comparing linkage to care and delay for linkage to care in the unassisted vs. the directly assisted HIVST.

DISCUSSION

We herein report on linkage to care among individuals previously self-tested in the three pilot surveys recently conducted in three cities (Kinshasa, Kisangani, and Kindu) in the DRC. Overall, the proportion of linkage to care was high (82.2%) among individuals having a positive result with HIV self-test, and but it was significantly lower in men (65.2%) than women (89.2%). Furthermore, linkage to care of men was significantly delayed as compared with that of women (40.0 vs. 20.7% of cases). Taken together, these findings suggest in the DRC the trend already previously observed in sub-Saharan Africa of a lower uptake of care following a positive HIV self-test in men.

HIVST is a promising approach to reach populations far beyond traditional HIV testing, such as men (5). Furthermore, one of the many hypotheses of transmission in the DRC is based on the belief that mature men, often over the age of 40, who have been infected for several years, are the main vectors of transmission via their numerous sexual partners, often adolescent girls (4). Interventions aiming to increase HIV testing

TABLE 2 | Factors associated with linkage to care among 314 participants interpreting their self-test results as positive and to delay for linkage to care among 258 participants linked to care.

	Linkage to care ($n = 314$)			Delay for linkage to care ($n = 258$)		
	Yes $n = 258$ n (%)	No $n = 56$ n (%)	aOR (95% CI)	Yes $n = 65$ n (%)	No $n = 193$ n (%)	aOR (95% CI)
Sex						
Male	60 (65.2)	32 (34.8)	0.7 (0.5–0.9)	24 (40.0)	36 (60.0)	1.8 (1.1–2.7)
Female	198 (89.2)	24 (10.8)	1	41 (20.7)	157 (79.3)	1
Age group						
15–24 years	176 (84.6)	32 (15.4)	2.0 (1.0–4.0)	41 (23.3)	135 (76.7)	NA
25–34 years	46 (69.7)	20 (30.3)	1	12 (26.1)	34 (73.9)	NA
35–44 years	34 (97.1)	1 (2.9)	2.8 (1.2–4.7)	10 (29.4)	24 (70.6)	NA
>44 years	2 (40.0)	3 (60.0)	0.7 (0.3–22.1)	2 (100)	0 (0)	NA
Educational level[#]						
Low	89 (87.3)	13 (12.7)	1	23 (25.8)	66 (74.2)	NA
Moderate	108 (84.4)	20 (15.6)	0.9 (0.4–4.6)	31 (28.7)	77 (71.3)	NA
High	61 (72.6)	23 (27.4)	0.7 (0.5–1.1)	11 (18.0)	50 (82.0)	NA
Risk of HIV infection[£]						
Low risk	32 (80.0)	8 (20.0)	1	3 (9.4)	29 (90.6)	1
Moderate risk	56 (81.2)	13 (18.8)	1.2 (0.7–4.9)	8 (14.3)	48 (85.7)	1.5 (0.7–4.1)
High risk	170 (82.9)	35 (17.1)	1.4 (0.6–6.6)	54 (31.8)	116 (68.2)	2.1 (1.2–3.8)
Previously tested for HIV						
Never tested	188 (83.9)	36 (16.1)	1.1 (0.8–7.6)	45 (23.9)	143 (76.1)	NA
Ever tested	70 (77.8)	20 (22.2)	1	20 (28.6)	50 (71.4)	NA

aOR, adjusted odds ratio; CI, confidence interval; n, number; NA, not applicable; NS, not significant.

**p-value calculated using regression analysis.*

[#]Educational level was categorized according to the educational system of the Democratic Republic of the Congo, as follows: (i) low: unschooled or attending primary school; (ii) middle: attending college (training of 6 years) or technical school (training of four years); and (iii) high: attending bachelor's degree, graduate degree (training of 2 years after bachelor's degree), or postgraduate degree, as previously reported (6).

[£]High risk for HIV infection was defined as a history of unprotected sex with one or more partners in the past 6 weeks as well as exposure to any of the following high-risk factors in the previous 6 months: multiple (i.e., >2) partners; homosexual intercourse (asked of men); receipt of gifts, cash, or other compensation in exchange for sex (asked of women); or infection with another sexually transmitted disease. Individuals exposed to any of these factors were classified as "high risk"; the remaining participants were classified as "low risk" if they did not report any sexual activity in the past 6 weeks and as "moderate risk" if otherwise (9, 21, 22).

among men and linking them to care are very important in the HIV response in DRC and sub-Saharan Africa.

Linkage to care is a critical step following HIVST to ensure that those who test positive confirm their HIV status and receive counseling and initiation of antiretroviral therapy when their status is confirmed (16, 26). However, several authors have debated the definition of what should be considered delayed uptake of care. For the Centers for Disease Control and Prevention (CDC) experts, linkage to care within 1 week can be considered optimal behavior (27). However, for Njau and colleagues, even a 3-month follow-up delay would not be sufficient to assess linkage to care (28). Because it is possible that people who test positive, but are not immediately cared for, may take some time to change their behavior. This debate about the delay to consider when assessing linkage to care would directly impact our results because it would overestimate the proportion of linkage to care and underestimate the proportion of delayed linkage to care. It is within this framework that the qualitative approach has allowed us to understand the gaps in linkage to care among men. In our study, one participant gave this reason for delaying linkage to care as follows: "I needed some time to adopt a new behavior because I need to put my life in order."

The majority of study participants (82.2%) with a positive HIV self-test result were linked to care with an optimal linkage to care proportion of 74.8% (<1 week). These proportions of linkage to care are lower than those previously reported by Chipungu and colleagues in a representative cross-sectional survey at Lusaka, Zambia, in which intention to link to care after a positive result with HIVST was 90% (10).

Comparing linkage to care among men who tested in the hospital vs. HIV self-tested men, Korte and colleagues reported in Uganda that men who tested positive through self-testing may not be as likely to link to care as men who tested positive at a clinic (17). This question of linkage to care deserves to be studied in more depth for a better understanding in the long term. Currently, large-scale studies funded by PEPFAR and the Global Fund to Fight HIV, Tuberculosis, and Malaria are underway in the DRC to

assess the issue of linkage to care for HIVST in the Congolese context.

Innovative strategies are important to promote linkage to care among men. The HIV assisted partner services have been recommended as a strategy to increase HIV case finding. However, a pilot study carried out in Kenya reported a low rate of linkage to care (only two-thirds) among index clients and sex partners (16). Offering home follow-up for initiation of antiretroviral therapy is an option to bridge the linkage to care gap at the clinic (11). This option merits exploration through operational research, as one of study participants responded that: "I prefer that the confirmatory test be performed at home and that the treatment also be delivered at home or privately if possible."

STRENGTH AND LIMITATIONS

One strength of the study is the inclusion of participants living in the DRC, not previously studied, the largest French-speaking country in sub-Saharan Africa, which gives a certain impact to our results particularly in the cultural context of Central Africa. This study has some limitations. First, linkage to care is expressed as an intention and is not measured as an actual behavior. This is because the study was a feasibility study conducted prior to the introduction of the HIV self-test in the DRC. Intention to link to care may not translate into actual linkage to care behavior. Thus, there is a need to evaluate linkage to care when the self-test will be effectively rolled out in the DRC. Furthermore, the study population was from three cities of the DRC only and is not representative of the entire country. With the follow-up time to evaluate linkage to care of only 30 days, this study may underestimate the overall linkage to care proportion. The sample size was furthermore limited. Lastly, we did not conduct in-depth interviews with those not willing to link to care within a week.

In conclusion, this study shows an overall high proportion of linkage to care among individuals having a positive result with HIV self-test. However, men were less linked to care and linked to care late comparatively than women. These findings highlight the need to implement innovative strategies for increasing the linkage to care, especially in men living in the DRC.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Commité d'éthique de l'Ecole de Santé Publique de l'Université de Kinshasa. Written informed consent to participate in this study was provided by the participants' legal guardian/next of kin.

AUTHOR CONTRIBUTIONS

ST-W and LB conceived and designed the research. ST-W and AT were involved in volunteer recruitment and follow-up. ST-W, SB-A, and LB performed statistical analyses. ST-W, CK, and LB analyzed the results and drafted the manuscript. All authors contributed to the article and approved the submitted version.

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Implementation of HIV Self-Testing to Reach Men in Rural uMkhanyakude, KwaZulu-Natal, South Africa. a DO-ART Trial Sub Study

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Background: KwaZulu–Natal, South Africa has one of the highest HIV prevalence rates globally. Persons <35 years and men have lower rates of HIV testing. HIV self-testing (HIVST) may overcome many barriers of facility-based HIV testing in order to identify HIV positive young persons and men and link them to care. We investigated whether HIVST distribution was a feasible approach to reach men and assessed the proportion of participants who reported their HIVST results, tested positive and linked to care.

Methods: Teams comprised of a nurse, clinic research assistant, and recruiters distributed HIVST kits in rural uMkhanyakude, KwaZulu-Natal from August—November 2018 with a focus on testing men. Workplaces (farms), social venues, taxi ranks, and homesteads were used as HIVST kit distribution points following community sensitisation through community advisory boards and community leaders. HIVST kits, demonstration of use, and small incentives to report testing outcomes were provided. The Department of Health provided confirmatory testing and HIV care at clinics.

Results: Over 11 weeks in late 2018, we distributed 2,634 HIVST kits of which 2,113 (80%) were distributed to persons aged <35 years, 2,591 (98%) to men and 356 (14%) to first time testers. Of the HIVST distributed, 2,107 (80%) reported their results to the study team, and 157 (7%) tested positive. Of persons who tested positive, 107/130 (82%) reported having a confirmatory test of which 102/107 (95%) were positive and initiated on ART. No emergencies or social harms were reported.

Conclusion: Large scale distribution of HIVST kits targeting men in rural KwaZulu-Natal is feasible and highly effective in reaching men, including those who had not previously tested for HIV. While two-thirds of persons who tested HIV positive initiated ART, additional linkage strategies are needed for those who do not link after HIVST. HIVST should be used as a tool to reach men in order to achieve 95% coverage in the UNAIDS testing and care cascade in KwaZulu-Natal.

Keywords: self testing, HIV infection, men, South Africa, mass screening

INTRODUCTION

HIV-associated mortality continues to be high among persons who have barriers to accessing routine health services, particularly African men (1–6). The risk of death to HIV positive persons not engaged in care is 10 times higher than that of HIV negative persons (5). In many settings in sub-Saharan Africa, men are less likely to test for HIV, HIV-positive men are less likely to link to HIV clinical services and start ART at lower rates than women, are more likely to be lost to care, and more likely to die at every stage (1–6). HIV treatment coverage is higher among South African women than men, with 65% of adult women living with HIV on treatment, compared to 56% of adult men (7). Even where an equal proportion of men and women are found to make use of HIV testing services (HTS), men are more likely to get tested for HIV after progressing to advanced disease (8). Data from the South African Demographic and Health Survey suggest that men in general access health services less readily than women (9). Barriers for South African men to access health services arise from multiple factors, including stigma, preference for traditional medicine, cultural ideals of masculinity, and practical issues including an inconvenience with the clinic operating times and problems with transportation (10, 11). KwaZulu-Natal Province has the highest HIV prevalence [27.4% (95% CI: 25.9–28.9%) in 2018] and incidence [1.17% (95% CI: 0.99–1.35%) in 2018] for those aged 15–49 years in South Africa (12, 13) and in this province, individuals aged <35 years and men account for most of the people untested for HIV (14).

Since men are less likely to attend standard facility-based services for testing, more convenient and different testing strategies such as HIV self-testing (HIVST) are needed in order to achieve the "first 95" (95% of persons with HIV knowing their status) in the UNAIDS 95-95-95 testing and care cascade in rural KwaZulu Natal, South Africa. HIVST, using a simple oral-fluid or blood-based self-test at a time and place convenient to the person testing, could overcome some barriers that deter people from testing (15). Furthermore, HIVST may be more convenient for users as it displays the potential to reduce the number of facility visits for frequent testers and eliminate the need for individuals to travel long distances or wait in long lines to access HIV testing (16). The World Health Organization (WHO) has proposed HIVST as an approach to reach people who are not accessing existing HTS such as men and young people (17).

The Delivery Optimization of Antiretroviral Therapy (DO ART) study was developed in part to address disparities in access to HIV care for men (18). In order to further provide access to men, we implemented the HIVST programme. We conducted the programme in uMkhanyakude district in northern KwaZulu-Natal, South Africa with the objectives of providing HIVST as an alternative testing strategy to clinic-based testing, investigating whether HIVST distribution was acceptable in the community, and determining its feasibility to reach men to improve access for testing. In addition to assessing HIV self testing uptake among men, we evaluated the proportion of participants who reported their HIVST results, tested positive and linked to care in both short and long term intervals.

METHODS

The HIVST programme was developed as a sub-study of the DO ART study, which compared community-based ART delivery to standard clinic-based ART services for people with HIV newly initiating on ART (18). One of DO ART's objectives was to determine whether community-based services improved HIV testing and outcomes in men; and initially, clinic-based recruitment identified few male participants since clinic attendance by men is low. Community-based recruitment yielded a greater amount of men than clinic–based recruitment but HIVST would simplify testing, include the opportunity to test privately, and potentially increase the coverage of testing among men. We introduced HIVST as a strategy to increase HIV testing among men and to identify men who would benefit from ART initiation. In August 2018, when the HIVST sub- study was implemented, 47% (n = 99) of DO ART enrolees in the uMkhanyakude district site were men.

Procedures

Identifying Men for HIVST

During the distribution period (August–November 2018), three teams of a nurse and clinical research assistant and four recruiters canvassed the district to introduce and distribute HIVST kits to men as an alternative way to test for HIV. Each team of a nurse and clinic research assistant typically spent afternoons on HIVST kit distribution, while the 4 recruiters spent the day on identifying eligible men for kit distribution.

The Africa Health Research Institute (AHRI) has a long-standing demographic surveillance platform in much of the Hlabisa sub-district (**Figure 1**) of uMkhanyakude, which allowed the study team to enter and distribute kits within these sites based on our existing relationship with the communities. We extended recruitment and kit distribution beyond these areas by approaching the local chiefs and obtaining permission to conduct study activities in their regions.

The recruitment teams identified locations in the district where men were found to congregate, like workplaces (commercial farms), social venues such as sports grounds, taxi ranks, and the streets. Kit distribution was operationalised in phases. Workplace distribution entailed liaising with farm managers for permission to distribute kits on-site. The farm managers gave us permission as long as kit distribution did not interfere with the farm workers' daily duties. We scheduled kit distribution accordingly and found that Sundays and late afternoons were the best times to distribute in the farms. The second phase of kit distribution established community settings where the recruitment teams identified areas where men who are unemployed congregate. This was the more successful phase as we were able to find men in larger numbers in these areas as unemployment is at 42% in uMkhanyakude district (19). The area was divided amongst the team with each team or recruiter being assigned to a specific section of the area. The team focused on recruitment in their assigned area until all sections of the area had been covered.

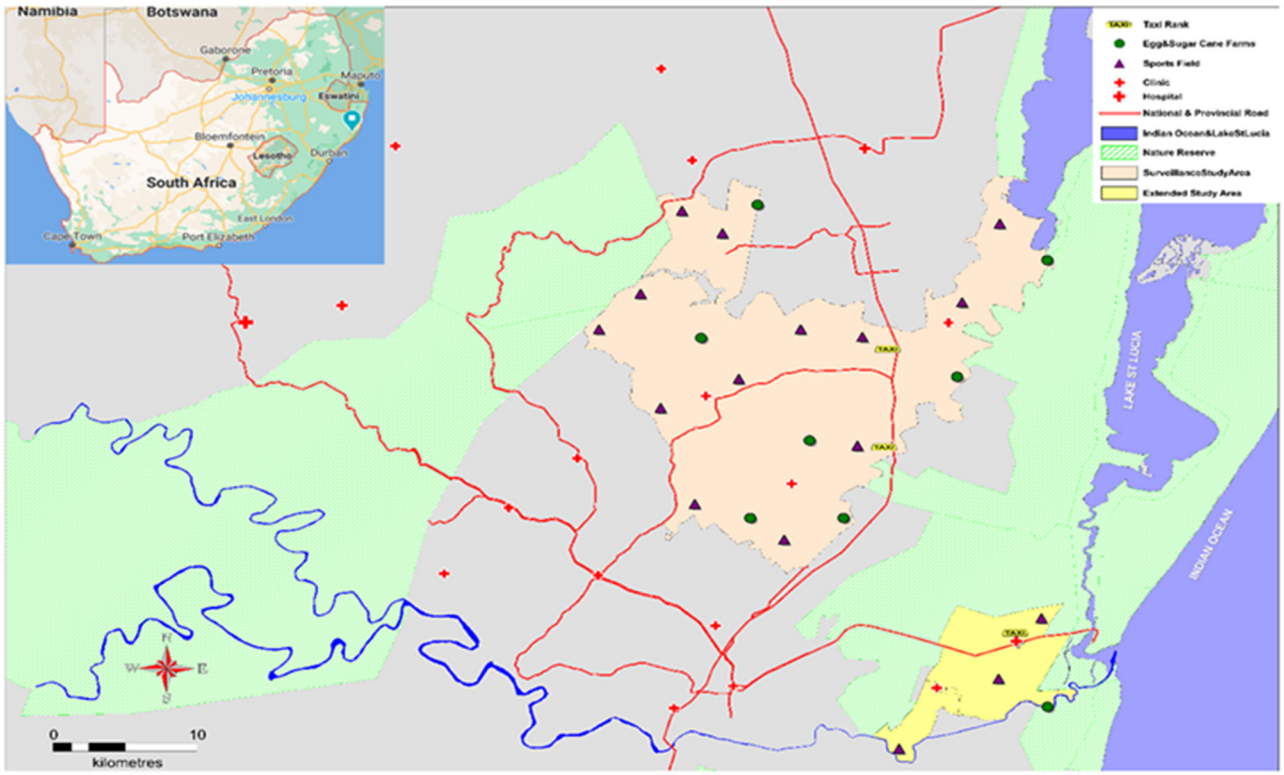

FIGURE 1 | Study area with HIVST kit distribution points.

HIVST kit Distribution Procedures

Procedures for each HIVST kit distribution event have been previously described (20). Briefly, at each recruitment point, participants 18 years and older were given an option to choose between an oral fluid-based HIVST or a finger prick blood-based HIVST. Study team members conducted a live demonstration of how to use and interpret both test kits, and provided cell-phone videos demonstrating kit use, available for watching on site or at home. Study team members also provided counseling that HIVST kits should not be used for testing if persons already knew they had HIV and that HIVST kits may be inaccurate if used in persons taking ART. Written informed consent was obtained prior to kit distribution.

Participants had the option of doing on-site testing using the kit in a private booth, with or without the assistance of a staff member, or choose the option of taking the kit away from the testing site and testing later. Before being issued a test kit, participants completed a questionnaire which included questions on demographics, HIV testing history, sexual behaviors, alcohol use, test kit preferences and cell phone number. Data was collected using Mobenzi software (Cape Town, South Africa) administered on a Samsung smartphone. All who took HIVST kits received a test kit labeled with a unique study identification number. After completing the test, participants were asked to report their results to the study team. All participants received a call back card with their HIVST kit to report the results of their self-test to the study team, as well as a cell phone airtime voucher (valued at USD2) to be redeemed at the time of reporting results. Persons taking kits off site reported results by calling or sending an SMS/text message to the number on the call back card for a free call back by the study staff who issued the self- test kit. Staff then contacted the participant and asked for the HIVST result. Staff provided post-HIVST counseling (in person if on-site or over the phone if off-site) including referral for confirmatory testing and ART initiation if the HIVST was confirmed to be reactive, or HIV prevention information and referral for voluntary male medical circumcision if the HIVST was non-reactive. Participants received a non-identifying reminder text message after 2 weeks if they had not yet reported their result. ("Act now test for HIV! Did the test? Call or send a Please Call Me to XXX"). The reminder was repeated at 1 and 2 months after distribution. If no result was reported by 2 months, staff made an outreach call to assess test use and results. After participants reported their results and received counseling and referrals, staff distributed the airtime incentive and administered a brief questionnaire to assess experience, usability, acceptability and preferences about HIVST.

Linkage to Care and ART for HIV Positive Men

HIVST distribution was done in partnership with the Department of Health (DOH). The DOH agreed to provide confirmatory HIV testing and linkage to ART initiation at

their clinic facilities. In order to address concerns that persons testing positive on their own using HIVST, may experience social harms or personal stress in the absence of having face-to-face post-test counseling available, the HIVST programme provided all participants who took an HIVST kit with a 24-h mobile number which they could use if they felt the need to speak to a health care professional, and created procedures for post-test counseling to be provided telephonically when the participants were reporting their test results to the study teams.

Linkage to care was also offered through the DO ART study (18). Participants who reported a positive HIVST could elect to be visited by study staff members who offered to do confirmatory testing using rapid tests. Those who were confirmed to be positive were offered a chance to be screened for DO ART.

Some participants who reported positive HIVST results were not able to be contacted by study staff to assess linkage to care due to cell phone numbers no longer working or participants emigrating out of the area for employment opportunities. We reviewed individual records for each of these participants using national databases to identify any evidence of linkage to care through DOH clinics.

Long Term Analysis of Linkage to Care (15 Months After the end of the Follow up Period)

In September 2020, we conducted a long-term follow-up analysis using the South African National Health Laboratory Services (NHLS) database to identify if participants who tested positive but had not linked to care by the end of the follow-up period had subsequently linked to care. Documented HIV viral load and CD4 results in the database were used as evidence of linkage.

Statistical Analysis

Percentages were used for descriptive analysis. We fit univariate and multivariate regression models in R (version 4.0) to identify predictors for those who reported back their HIVST results, those who tested positive and those who successfully linked to care during study follow-up. Odds ratios with $p < 0.05$ were considered statistically significant.

Ethical Considerations

Ethical approval was obtained from the University of Washington, Human Sciences Research Council and the University of KwaZulu-Natal Ethics Committees.

RESULTS

In a 11 week interval between August and November 2018, a team consisting of 10 staff members distributed 2,634 HIVST kits to South African adults in rural uMkhanyakude district KwaZulu-Natal. Men were the recipients of [2,591(98%)] kits. Among the men who participated in HIVST, 44% were unemployed while almost a third (31%) reported they were laborers/semi-skilled. Three hundred and fifty-six (14%) of men were first-time HIV testers. From the kits that were distributed, [2,113(80%)] kits were distributed to participants aged <35 years.

The majority of those who received kits [2,294(87%)] preferred to take the kits off-site instead of using the HIVST kit on-site (**Table 1**). Most of the men [2,558(97%)] were unmarried with one or more current sexual partner and the median age was 27 years (IQR 22 to 33). Almost half [1,266(49%)] of the men were circumcised and [1,511(68%)] reported alcohol use. A total of [1,624(62%)] participants preferred to use the blood-based kits, while [1,010(38%)] selected to use the oral fluid kits. From those who took kits off site, [933(35%)] preferred to use oral fluid kits and [1,361(52%)] preferred blood-based kits. A total of [2,258(86%)] reported that their last HIV test was negative. From

TABLE 1 | Characteristics of HIVST kit recipients.

		N	(%)
Distribution setting	Mobile van	2,344	(89%)
	Venue-based	154	(6%)
	Work place	86	(3%)
	Other	5 0	(2%)
Kit type	OraQuick (Oral based)	1,004	(38%)
	Atomo (I-test)	1,630	(62%)
On site testing	OraQuick	71	(3%)
	Atomo (I-test)	269	(10%)
Off site testing	OraQuick	933	(35%)
	Atomo (I-test)	1,361	(52%)
Age, median (IQR)	27 (22-33)		
Gender	Male	2,591	(98%)
	Female	43	(2%)
Education	Primary	387/2,618	(15%)
	Secondary and above	2,231/2,618	(85%)
Marital Status	Married	76	(3%)
	Not married	2,558	(97%)
Employment status	Laborer/semi-skilled	812	(31%)
	Unemployed	1,157	(44%)
	Student	367	(14%)
	Other	297	(11%)
Number of current sex partners	1	1,368/2,623	(52%)
	0	90/2,623	(3%)
	2+	1,165/2,623	(44%)
Circumcised		1,266/2,584	(49%)
Alcohol use (drinks in past week)	0	1,100/2,611	(42%)
	1–6	1,208/2,611	(46%)
	7+	303/2,611	(12%)
Ever tested for HIV	Yes	2,270	(86.4%)
	No	1,208/2,611	(13.5%)
	N/A	8	(0.3%)
Last HIV test	More than a year ago	1,002	(38%)
	Within 12 months	1,203	(45.7%)
	N/A	429	(16.3%)
Latest test result	Negative	2,258	(85.7%)
	Positive	7	(0.3%)
	Didn't receive the results	1	(0.0%)
	N/A	368	(14%)

IQR, inter-quartile range, Other includes professional, farming, housewife and trade/sales categories.

the 356 first time testers, [35(10%)] were found to have tested positive through HIVST.

A total of [2,107(80%)] participants used the HIVST kits and reported their results to the study team. Among persons who reported their results, [157(7%)] tested positive and [102(65%)] were confirmed to have linked to care (**Figure 2**). There were 5 participants who reported a positive HIVST result but subsequently had HIV-negative confirmatory testing, indicating a false-positive HIVST for a total of 152 true positives. Twenty-three men who reported a positive HIVST result had not sought confirmatory tests and did not link to care for ART initiation by the end of June 2019, which was the end of the follow-up period. An additional 27 men had unknown linkage history after they initially reported testing positive through HIVST. No emergencies were reported on the 24-h cell phone number.

We evaluated predictors of whether a participant reported results of HIVST (**Table 2**), predictors of positive HIVST results among those who reported their results (**Table 3**), and predictors of linking to HIV care among persons who had positive HIVST results (**Table 4**). Persons who received a test kit at a place other than the workplace, mobile van and venue based were more likely to report their HIVST results [AOR 3.58 95%CI (1.30–14.84), $p = 0.033$]. Those with a secondary level of education or above [AOR 1.34 95%CI (1.00–1.78), $p = 0.046$] and those who had moderate alcohol use (1–6 drinks in the past week) [AOR 1.59 95%CI (1.28–1.99), $p = <0.001$] were also more likely to report their results.

Factors associated with an increased likelihood of a positive result were testing at venue based recruitment points [AOR 1.94 95%CI (1.02–3.50), $p = 0.034$], being between the ages of 25 to 34 years [AOR 3.59 95%CI (2.28–5.82), $p = <0.001$],being 35 years or older [AOR 3.09 95%CI (1.79–5.40), $p = <0.001$] and heavy alcohol use (more than seven drinks in the past week) [AOR 2.00 95%CI (1.22–3.24), $p = 0.005$]. Factors which were associated with a reduced risk of a positive result included previously testing for HIV [AOR 0.58 95%CI (0.38–0.91), $p = 0.015$) and being circumcised [AOR 0.49 95%CI (0.33–0.72), $p = <0.001$].

Those who reported a positive HIVST result and had previously tested for HIV were less likely to link to care [AOR 0.19 95%CI (0.05–0.60), $p = 0.009$].

From those who reported their test results and completed post-test questionnaires, ($n = 2,107$), [1,875(89%)] said the reason for testing using HIVST was wanting to know their HIV status. One thousand nine hundred and seventeen (91%) said

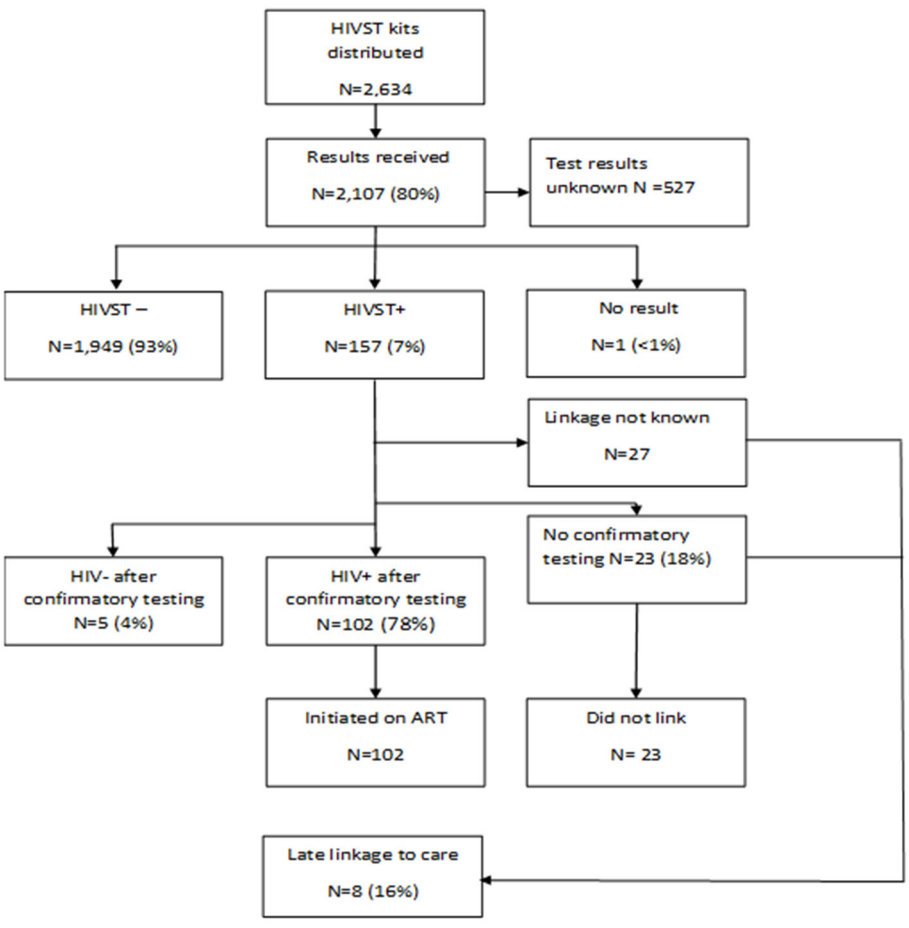

FIGURE 2 | HIVST testing, results and linkage to care flow chart. Percentages are relative to the pervious linked box(es).

TABLE 2 | Characteristics of participants receiving an HIVST kit who reported HIVST results.

	Univariate					Multivariate		
Predictors	***N***	**(%)**	**OR**	**(95% CI)**	***p* value**	**aOR**	**(95% CI)**	***p* value**
Recruitment strategy								
Mobile Van	1,881/2,344	(80%)	-ref-					
Venue- based	118/154	(77%)	0.81	(0.55–1.20)	0.277	1.04	(0.69–1.58)	0.863
Workplace	61/86	(71%)	0.60	(0.38–0.98)	0.036*	0.68	(0.42–1.15)	0.137
Other	47/50	(94%)	3.86	(1.41–15.93)	0.024	3.58	(1.30–14.84)	0.033
Kit type								
OraQuick	821/1,004	(82%)	-ref-			-ref-		
Atomo	1,286/1,630	(79%)	0.83	(0.68–1.02)	0.073	0.84	(0.68–1.03)	0.103
Age								
> 25	910/1,133	(80%)	-ref-			-ref-		
25–34	778/980	(79%)	0.94	(0.76–1.17)	0.595	1.03	(0.82–1.29)	0.793
≥35	419/521	(80%)	1.01	(0.78–1.31)	0.960	1.32	(0.97–1.80)	0.078
Gender								
Male	2,072/2,591	(80%)	-ref-			-ref-		
Female	35/43	(81%)	1.10	(0.53–2.55)	0.817	1.40	(0.66–3.32)	0.407
Education								
Primary	287/387	(74%)	-ref-			-ref-		
≥Secondary	1,810/2,231	(81%)	1.50	(1.16–1.92)	0.002*	1.34	(1.00–1.78)	0.046
Marital status								
Married	57/76	(75%)	-ref-			-ref-		
Not married	2,050/2,558	(80%)	1.35	(0.77–2.24)	0.271	1.30	(0.71–2.28)	0.376
Number of current sex partners								
1	1,087/1,368	(79%)	-ref-			-ref-		
0	66/90	(73%)	0.71	(0.44–1.18)	0.168	0.90	(0.55–1.53)	0.695
≥2	946/1,165	(81%)	1.12	(0.92–1.36)	0.272	1.03	(0.84–1.27)	0.757
Ever tested for HIV								
Yes	268/356	(75%)	-ref-			-ref-		
No	1,832/227	(81%)	1.37	(1.05–1.78)	0.018*	1.22	(0.92–1.61)	0.170
Circumcised								
No	1,034/1,318	(78%)	-ref-			-ref-		
Yes	1,034/1,266	(82%)	1.22	(1.01–1.49)	0.041*	1.17	(0.95–1.44)	0.147
Alcohol use (drinks in past week)								
0	847/1,100	(77%)	-ref-			-ref-		
1	1,024/120	(85%)	1.66	(1.35–2.05)	<0.001*	1.59	(1.28–1.99)	<0.001
≥7	220/303	(73%)	0.79	(0.59–1.06)	0.113	0.75	(0.56–1.02)	0.066

**Odds ratios with $p < 0.05$.*
Each AOR is adjusted for all potential predictors.

using the test kits was either easy or very easy, while [2,044(97%)] said that they would recommend HIVST to someone else. One thousand three hundred and twenty-seven (63%) said that they would pay for a kit if it was available in their communities.

There were seven participants who reported a positive last HIV test before taking an HIVST kit. From these, four reported a positive HIVST result, one reported a negative HIVST result, one did not use the kit, and one did not report their result.

In our second review of linkage to care 15 months after the end of the follow up period, of the 50 participants who reported a positive HIVST result but had no evidence of linkage to care at the end of the follow up period, [8(16%)] persons were identified in the NHLS database with evidence of engaging in HIV care. Thus, by 15 months after use of the HIVST, 110/157 (70%) persons with positive HIVST results had linked to care.

In a 4 month period, 56 HIV positive men were enrolled into DO ART through HIVST thereby increasing the proportion of DO ART enrolees who were men at the uMkhanyakude district site to [206(53%)] by the end of the study.

TABLE 3 | Predictors of a positive result among persons reporting results.

	Univariate					Multivariate		
Predictors	***N***	**(%)**	**OR**	**(95% CI)**	***p* value**	**aOR**	**(95% CI)**	***p* value**
Recruitment strategy								
Mobile van	133/1,881	(7%)	-ref-			-ref-		
Venue- based	19/118	(16%)	2.52	(1.46–4.16)	<0.001*	1.94	(1.02–3.50)	0.034
Workplace	4/60	(7%)	0.94	(0.28–2.33)	0.904	0.75	(0.22–1.96)	0.602
Other	1/47	(2%)	0.29	(0.02–1.32)	0.217	0.24	(0.01–1.19)	0.172
Kit type								
OraQuick	63/821	(8%)	-ref-			-ref-		
Atomo	94/1,285	(7%)	0.95	(0.68–1.33)	0.760	0.88	(0.62–1.26)	0.494
Age								
<25	27/910	(3%)	-ref-			-ref-		
25–34	85/777	(11%)	4.02	(2.61–6.37)	<0.001*	3.59	(2.28–5.82)	<0.001
≥35	45/419	(11%)	3.93	(2.42–6.51)	<0.001*	3.09	(1.79–5.40)	<0.001
Gender								
Male	2,072/2,591	(80%)	-ref-			-ref-		
Female	4/35	(11%)	1.62	(0.48–4.15)	0.371	1.37	(0.39–3.77)	0.582
Education								
Primary	34/287	(12%)	-ref-			-ref-		
≥Secondary	120/1,809	(7%)	0.53	(0.36–0.80)	0.002*	0.91	(0.57–1.46)	0.676
Marital status								
Married	4/57	(7%)	-ref-			-ref-		
Not married	153/2,049	(7%)	1.07	(0.43–3.57)	0.899	1.79	(0.66–6.33)	0.300
Number of current sex partners								
1	79/1,086	(7%)	-ref-			-ref-		
0	4/66	(6%)	0.82	(0.25–2.06)	0.712	1.06	(0.30–2.81)	0.919
≥2	72/946	(8%)	1.05	(0.75–1.46)	0.773	1.29	(0.91–1.84)	0.158
Ever tested for HIV								
No	35/268	(13%)	-ref-			-ref-		
Yes	122/1,831	(7%)	0.48	(0.32–0.72)	<0.001*	0.58	(0.38–0.91)	0.015
Circumcised								
No	112/1,033	(11%)	-ref-			-ref-		
Yes	41/1,034	(4%)	0.34	(0.32–0.72)	<0.001*	0.49	(0.33–0.72)	<0.001
Alcohol use (drinks in 1 past week)								
0	62/846	(7%)	-ref-			-ref-		
1	58/1,024	(6%)	0.76	(0.52–1.10)	0.145	0.73	(0.49–1.10)	0.128
≥7	34/220	(15%)	2.31	(1.46–3.60)	<0.001*	2.00	(1.22–3.24)	0.005

**Odds ratios with $p < 0.05$.*
Each AOR is adjusted for all potential predictors.

DISCUSSION

Large scale distribution of HIVST kits targeting men in rural northern KwaZulu-Natal was found to be feasible, acceptable, and effective at reaching men who have not tested and those below the age of 35. Fourteen percent of those who took HIVST kits reported to have never tested for HIV, 98% were men, and of those, 80% were below the age of 35. These results support findings by Johnson et al., where it was found that willingness to self-test by Zimbabwean men was high at around 85% (21). These results are also consistent with other multiple reports that have suggested that HIVST can increase uptake of testing among high risk groups that are under-represented in HIV testing programs (22–27). Our data provides further demonstration that HIVST is a promising strategy to increase testing uptake among hard-to-reach groups such as men in South Africa and could help to achieve the "first 95%" in the UNAIDS testing and care cascade by 2,030 (28).

HIVST successfully increased the proportion of men enrolled in the DO ART study from 47 to 53% in the uMkhanyakude district site thus highlighting the far-reaching effects that HIVST has in increasing HIV testing amongst men.

The HIVST blood-based test kit was found to be the preferred test over the oral HIVST kit; 62% of participants selected to use the blood-based HIVST kit. These results contrast with

TABLE 4 | Predicators of linkage to care among persons with a positive HIVST result.

			Univariate			Multivariate		
Predictors	***N***	**(%)**	**OR**	**(95% CI)**	***p* value**	**aOR**	**(95% CI)**	***p* value**
Recruitment strategy								
Mobile van	86/128	(67%)	-ref-			-ref-		
Venue- based	12/19	(63%)	0.84	(0.31–2.39)	0.728	1.39	(0.33–6.67)	0.664
Workplace	4/4	(100%)	-	-	-	-	-	-
Other	0/1	(0%)	-	-	-	-	-	-
Kit type								
OraQuick	42/62	(68%)	-ref-			-ref-		
Atomo	60/90	(67%)	0.95	(0.47–1.89)	0.890	1.36	(0.59–3.14)	0.467
Age								
<25	14/25	(56%)	-ref-			-ref-		
25–34	56/82	(68%)	1.69	(0.67–4.24)	0.261	2.02	(0.67–6.13)	0.208
≥35	32/45	(71%)	1.93	0.70–5.42	0.205	2.73	(0.79–9.98)	0.118
Gender								
Male	99/148	(67%)	-ref-			-ref-		
Female	3/4	(75%)	1.48	(0.18–30.44)	0.735	0.58	(0.04–15.42)	0.700
Education								
Primary	21/33	(64%)	-ref-			-ref-		
≥Secondary	79/116	(68%)	1.22	(0.53–2.71)	0.630	2.08	(0.66–6.71)	0.210
Marital status								
Married	4/4	(100%)	-	-	-	-	-	-
Not married	98/148	(66%)	-	-	-	-	-	-
Number of current sex partners								
1	50/78	(64%)	-ref-			-ref-		
0	1/4	(25%)	0.19	(0.01–1.54)	0.154	0.09	(0.00–0.95)	0.068
≥2	50/68	(74%)	1.56	(0.77–3.20)	0.223	1.56	(0.72–3.49)	0.266
Ever tested for HIV								
No	27/34	(79%)	-ref-			-ref-		
Yes	75/118	(64%)	0.45	(0.17–1.08)	0.088	0.19	(0.05–0.60)	0.009
Circumcised								
No	75/110	(68%)	-ref-			-ref-		
Yes	24/38	(63%)	0.80	(0.37–1.76)	0.571	0.72	(0.29–1.80)	0.475
Alcohol use (drinks in past week)								
0	41/59	(69%)	-ref-			-ref-		
1	38/57	(67%)	0.88	(0.40–1.92)	0.744	0.89	(0.35–2.25)	0.810
≥7	22/33	(67%)	0.88	(0.35–2.22)	0.780	0.89	(0.31–2.54)	0.820

**Odds ratios with $p < 0.05$.*
Each AOR is adjusted for all potential predictors.

findings by Ritchwood et al. (29) which found that participants overwhelmingly preferred the oral based HIVST kits. That study was conducted among both male and female participants from a South African rural study setting. Findings by Tonen-Wolyec et al. also found that preference for oral based tests was greater than that of blood-based tests from both male and female participants in Kinshasa and Kindu in the Democratic Republic of Congo (30). Findings by Lippaman et al. found a similar preference for blood-based HIVST among South African men who have sex with men (31). Different preferences for oral and blood-based HIVST in diverse settings in Africa indicate that it is important to provide a choice between oral and blood-based tests when offering HIVST kits.

A total of 157 participants tested positive, of whom 102/130 (78%) linked to care within 7.4 months of testing. This linkage percentage is higher than that reported by other HIVST studies (22, 26) even though by the end of the study, 42/152 (28%) of those who tested positive had not linked to care. Additional work needs to be done to understand reasons for not linking to care, as the UNAIDS testing and care cascade goal of 95% of HIV positive people started on ART and 95% of those on ART achieving viral suppression will be not be achieved without additional

interventions to support linkage among persons who learn that they are HIV positive through HIVST. We found evidence of linkage 15 months after the end of the follow up period in only [8(16%)] of 50 participants who had not linked to care at the end of the study follow-up, which highlights the ongoing barriers men face in accessing facility-based care such as inconvenient clinic hours and transportation problems, as previously reported (11). Community-based ART initiation has the potential to overcome these barriers as highlighted by Barnabas et al. (18) where it was found that community-based ART increased viral suppression rates amongst men. Community-based ART has the potential to increase viral suppression amongst men through immediate ART initiation within the community vs. delayed linkage through facility-based ART initiation which has shown to present a lesser percentage of those who eventually link to care over an extended period.

Factors associated with a reduced risk of a positive HIVST result included having previously tested for HIV and being circumcised. These results show that a greater amount of awareness and health education must be done on men who remain uncircumcised. It also highlights the importance of finding first time testers as these were found to be more likely to test positive. HIV self-testing has been proven to have the potential of reaching first time HIV testers in those hard-to-reach target groups such as men.

No emergencies were reported through the emergency number, supporting that an HIV positive result is no longer seen as a catastrophic psychological blow in this community. These results are consistent with the findings of Choko et al. (22), who found that there were no suicides or partner violence reported from those who tested positive through HIVST in a study conducted in 14 urban neighborhoods in Malawi with 6,124 male and 7,868 female participants, providing further evidence that expansion of HIVST does not lead to an increase in social harms in the community.

Out of seven individuals who indicated that they were aware of a previous positive test but were not on ART, one HIVST result came back negative highlighting the possibility of a false negative HIVST result. Although self-testing is associated with a high specificity, the tests can produce a small number of false negatives (32) but the possibility of the individual being on ART at the time of testing cannot be ruled out.

For scale-up of similar programs in different settings, we recommend that future implementers use strategies that we used in the areas which fell beyond the AHRI study area. In these areas, we first approached community leaders to gain permission to distribute kits. Thereafter, we approached the local clinics to make them aware of the work we were doing and to help them prepare for a possible increase in patients coming into the clinic for confirmatory testing and linkage to care. Thirdly, with assistance of the community leaders, we attended community meetings and gatherings where we made the community aware of the HIVST programme and encouraged them to join. Building a relationship with the community leaders was done in a timely manner without requiring massive additional resources, suggesting that these relationships could be recreated in other settings where they do not yet exist.

Our study had limitations, including that the proportion of first-time testers could be overestimated since some participants may have participated without disclosing that they already knew their HIV status to be positive. Health education on the inaccuracies of testing while on ART was given at every kit distribution event. Respondent social desirability bias could have influenced self-report of HIV testing history, HIVST results and linkage to care. Moreover, by the end of the second linkage review, more than a quarter of those who tested positive had not linked to care. This highlights two additional limitations. First, we did not have a confirmatory test result for people who did not link to care, thus we could be overestimating the number of people with HIV. Second, this is a limitation of the approach of engaging men into care because we cannot confirm the test results and progress on the cascade of those who did not link. A way to overcome this limitation is having community ART services readily available within the community to assist those who have tested positive to link to care. If these services are not easily accessible to men within the community, then the barriers to facility-based care which men experience (11) could prevent them from linking at a clinic.

Strengths of this study include showing that large scale distribution with over 900 HIVST kits per month with a focus on reaching men is both feasible and acceptable in this rural KwaZulu-Natal setting. The HIVST project was conducted with a maximum of 10 staff members with most distribution accomplished by the 4 recruiters. This is important because it shows that a high volume of kits can be distributed with a limited number of staff. This staff complement is similar to personnel available in many district settings highlighting that similar distributing strategies can be applied in such settings. Community health workers could also be trained to perform equivalent tasks in other settings. Another strength of the study was the success of the collaborative partnership between the community, community leaders and the local clinics. The study demonstrated valuable contributions of these stakeholders to the success of the HIVST programme.

CONCLUSION

HIVST was effective in reaching younger men and those who were first time HIV testers in uMkhanyakude. As persons aged younger than 35 and men account for the highest percentage of persons who have never tested for HIV in KwaZulu- Natal (14), HIVST should be used as a component of strategies to reach this target population for testing in KwaZulu-Natal and South Africa at large. Additional interventions beyond HIVST are needed to support persons who test HIV positive with linkage to HIV care and ART.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Ethical approval was obtained from the University of Washington, Human Sciences Research Council and the University of KwaZulu-Natal Ethics Committees. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

AS, CC, and RB designed the study. NS, OK, and MK conducted the project and collected the data. NS, AS, and TS analyzed the data. NS and AS drafted the manuscript. All authors contributed to the revisions and content of the final manuscript.

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Perspectives of Policymakers on the Introduction and Scale-Up of HIV Self-Testing and Implication for National HIV Programming in Ghana

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Background: HIV self-testing (HIVST) has the potential to greatly increase HIV testing uptake, particularly among key populations (KPs) at higher risk for HIV. Studies have shown high acceptability and feasibility of HIVST among various target populations globally. However, less is known about the perspectives of policymakers, who are critical to the success of HIVST implementation. Their views on barriers to the introduction and scale-up of self-testing are critical to understand in order for HIVST to become part of the national HIV guidelines. We sought to understand policymakers' perspectives of challenges and facilitators to the introduction of HIVST at the client and structural levels.

Method: Key informant interviews (KIIs) were conducted with national and regional level policymakers involved in the HIV response. Twenty policymakers were purposively selected from Greater Accra (capital) and Brong-Ahafo (outlying) regions. Qualitative content analysis was used to arrive at the results after the verbatim transcripts were coded.

Results: Client-level challenges included lack of pre-test counseling, the need for confirmatory testing if reactive, potential for poor linkage to care and treatment, and client-level facilitator from policy makers' perspectives included increase testing modality that would increase testing uptake. Structural-level challenges mentioned by policymakers were lack of a national policy and implementation guidelines on HIVST, cost of HIVST kits, supply chain management of HIVST commodities, data monitoring and reporting of positive cases. The structural-level appeal of HIVST to policymakers were the reduced burden on health system and HIVST's contribution to achieving testing targets. Despite the challenges mentioned, policymakers unanimously favored and called for the introduction of HIVST in Ghana.

Conclusions: Findings indicate that a non-conventional HIV testing strategy such as HIVST is highly acceptable to policymakers. However, successful introduction of HIVST hinges on having national guidelines in place and stakeholder consultations to address various individual and structural -level implementation issues.

Keywords: policymakers, men who have sex with men, female sex workers, Ghana, HIV self-testing

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BACKGROUND

Closing the HIV testing gap and reaching the first 95 of the WHO's 95-95-95 targets is critical to the success of the global and national HIV response (1). The HIV epidemic in Ghana is characterized as a mix of a low-level generalized epidemic with a prevalence of 1.6% in the general population (2) but a high prevalence among female sex workers (FSWs) (4.6%) and men who have sex with men (MSM) (18.1%) (3–5). HIV testing remains low with only an estimated 55% of people living HIV who know their status (6). Testing is less than optimal among persons at high risk of HIV infection across the country. In a national survey among FSWs in 2019, only 56.5% tested for HIV in the last 12 months preceding the survey (5). The situation is far worse among MSM as only 26.6% of MSM tested and received the results in the last 12 months preceding the 2017 Ghana Men Study II (4). The low uptake of HIV testing services (HTS) in the country, particularly among those at high risk for HIV results in high numbers of undiagnosed HIV infection. This situation presents a major challenge toward achieving epidemic control in the country.

Conventional facility-based and provider-assisted HTS have inherent barriers to universal access to testing and treatment. These barriers include stigma, negative provider attitudes and discrimination, limited confidentiality, and limited convenience (7–9). The potential of HIV self-testing (HIVST) to increase HIV testing uptake as an entry point to the HIV/AIDS care continuum, especially among the highly stigmatized and hard-to-reach populations, are well-documented (7, 10–17). Convenience, confidentiality, and privacy are highly influential in the acceptability and utilization of HIVST (13, 18–20). These advantages of HISVT would help accelerate the progress toward reaching the WHO/UNAIDS's 90-90-90 targets and effectively link people to HIV prevention and treatment services including antiretroviral therapy (ART), condoms and other prevention services, prevention of mother-to-child transmission (PMTCT), and pre-exposure prophylaxis (PrEP).

The level of acceptability and utilization of HIVST is high as identified in implementation research and randomized controlled trials globally (12, 14–16, 21–26). Studies in African countries have also reported high levels of willingness to use HIVST as well as actual HIVST use when made available to the population. A qualitative exploratory study in two regions in Ghana among FSWs and MSM recruited by outreach workers and peer educators of community-based organizations, the majority of participants expressed willingness to use HIVST kit (27). The evidence in the literature demonstrates high acceptability and uptake of HIVST across different populations. However, national policies for HIVST are still missing for many countries, including Ghana. For example, as of June 2020, there were still 16 countries in Africa with no policies explicitly allowing HIVST, although many of these countries are in the phase of developing such policies (28). National policies around HIVST are not only important for increasing access to HTS, but it is also critical for ensuring quality of products and safe and ethical usage.

Policymakers or policy influencers who drive national policy agenda about HIVST are central for the adoption of HIVST as national HIV testing strategy. The National Strategic Plan 2016-2020 for HIV in Ghana proposes the introduction of HIVST as an important component in the approach of getting KPs to test for HIV and be linked to care (29). The Strategic Plan mentions that HIVST is not yet approved in Ghana and that there is need to pilot HIVST before a policy directive can be made. Understanding the perspectives of policymakers on the potential barriers and facilitators is critical to obtain government approval for the strategy and develop country-specific HIVST guidelines. This article interrogates how policymakers in Ghana perceive the introduction of HIVST in Ghana, specifically with respect to challenges and facilitators at the client and structural levels. This understanding will help drive policy strategy and HIVST implementation as the country introduces HIVST as a testing strategy to increase HIV testing access and uptake.

METHODS

Key informant interviews were conducted in September-October 2017 with 20 national and regional policymakers in the area of HIV and AIDS policy and program implementation in Greater Accra (GA) and Brong Ahafo (BA) regions, which represents two of the then ten regions of Ghana. Greater Accra and Brong Ahafo regions were selected to represent the southern and northern zones, respectively, with Greater Accra being the most urbanized and cosmopolitan region in the country. The Brong Ahafo region lies in the middle belt of the country and is considered a transitional zone attracting populations from both northern and southern sections of the country. After the completion of the study, Brong Ahafo region was divided into three separate regions—Bono, Bono East, and Ahafo. Most study participants came from what is now considered the Bono region. Participants were purposefully selected from Ghana Health Service, National AIDS/STI Control Program (NACP), Ghana AIDS Commission (GAC), and Regional/District HIV Coordinators from Greater Accra and Brong-Ahafo regions. These are institutions whose activities directly determine and influence policy related to HIV testing. Participants had to be a national or regional director or manager working with any of these nationally established HIV and AIDS bodies.

Interview guides were developed by the authors and were field-tested to ensure that questions were appropriate for the intended respondents. Interviews explored potential facilitators and barriers to developing an official HIVST guidelines for Ghana, attitudes and perceptions regarding who should have access to HIVST kits and how it should be provided, impact of HIVST introduction on health systems, policy considerations surrounding HIVST introduction, cost and financing of HIVST, and service provision considerations, and commodity security and supply issues. Interviews were conducted by trained qualitative researchers in English over a period of 8 weeks starting November 2017, digitally recorded with permission from participant, and transcribed verbatim.

Data Analysis

Five out of 20 transcripts were sampled across the different stratum (2 national and 3 regional) and given to the team of researchers (HT, EA, and WT) to read and develop codes. The codes generated were discussed in relation to the study objectives and the research questions that underpinned the study and consensus was reached among the team. The categories and sub-categories emerging from the transcripts were finalized into codebook with clear definitions. The codebook and database with transcripts were entered into a computer-assisted qualitative analysis software package (QSR NVivo 11). Two trained qualitative research assistants coded the transcript in the QSR NVivo 11. The research team (HT, EA, and WT) processed the coded data by running different queries along the main categories (individual and structural challenges and facilitators) using a qualitative content analysis approach (30, 31).

Ethical Consideration

The Population Council Institutional Review Broad in New York and the Ghana Health Service Ethical Review Committee, Accra approved the study. All participants gave written informed consent before the interview. For confidentiality, we do not report institutional affiliations, but assigned a unique code to each policymaker to reflect national or regional level.

RESULTS

The 20 sampled policymakers consisted of 6 national and 14 (seven from each of the two selected regions) regional level policymakers. The designation of the national level policymakers were Director, Deputy Director of Clinical Care, and Director and Deputy Director of Administration. At the regional level, the Regional HIV Coordinator, Monitoring and Evaluation Officer, Regional and Data Manager were interviewed. The results section is divided into the two broad categories of client-level and structural-level challenges and facilitators to the introduction of HIVST in Ghana. The client level barriers were issues such as challenges related to pre-test counseling, confirmatory testing, linkage to care and treatment, and cost of HIVST kits, and client level facilitator was the increased option for testing, especially one that provides greater privacy, confidentiality, convenience with reduced stigma. The structural level challenges were the lack of national policy framework and implementation guidelines, and cost that would have implications for the large-scale implementation of HIVST. Structural level facilitators included reduced burden on the health system and potential to attain testing targets.

Client-Level Challenges and Facilitators

Challenge 1: Lack of Pre-test Counseling

A concern expressed by many of the policymakers was that HIVST would not allow for sufficient pre-test counseling as required by the national HIV testing guidelines and as standardly practiced during provider-assisted testing. They were concerned that without pre-test counseling, clients would not understand the implications of their test results and not know how to seek further services. A few even mentioned that it may lead to negative outcomes such as suicidal ideations. They expressed this concern particularly for those who test for HIV for the first time.

> *"…somebody who does not understand HIV issue and the testing issue well will eventually do the test, if you are not counseled, the results may scare you and you may not know what to do"* (National policymaker #04)
>
> *"…it is going to cause a lot of if not suicidal tendencies, there is going to be a lot of suicides reports especially among the adolescence."* (National policymaker #02)

Challenge 2: Need for Confirmatory Testing

Although a minority, a few policymakers expressed concern that individuals who use HIVST and obtain a reactive test result with the HIVST kit would not access confirmatory testing at an HIV testing site by healthcare providers, as required by the national HIV testing algorithm. They felt that KPs, in particular, would not want to present themselves at a public testing facility for confirmation of test result due to fears of stigma.

> "*One key thing that I am also worried about is the fact that this is a primary test and there's the need to confirm it. One of the factors for self-test is the fact that the person doesn't want to be seen or done by somebody else. …It is because I don't want people to know I am a female sex worker; I do my test at home quietly and go. So, what is the assurance that people would move in for the confirmation test?"* (Regional policymaker BA #02)
>
> *"[A person] may not going for a confirmation, she sits with it and dies with it and probably will not even go for medications."* (National policymaker #01)

Challenge 3: Potential for Poor Linkage to Care and Treatment

Many policymakers expressed concerns about HIVST users not being linked to care and treatment. They pointed out that the absence of counseling with HIVST may be a hindrance for onward linkage to care and treatment.

> *"If you are even positive, it may also delay linking you asking for care… you can seek care early, but you may also seek care late because you didn't receive adequate counseling, you did it on your own, you feeling ok the results is telling you are positive but because you didn't have enough counseling, you will not seek early care."* (National policymaker #04)

This was especially a concern in the context of the *Treat All* national policy with the focus on linking all HIV positive cases to care and treatment upon an HIV diagnosis. Some national policymakers specifically perceived HIVST to be a hindrance to the implementation of the national policy agenda of *Treat All.*

> *"The 'treat all policy' will be affected, in that we want to put all infected persons on treatment, and in this case, people who test positive and not availing themselves will not be on treatment, so to some extent it's affecting that policy"* (National policymaker #01)

One national level policymaker mentioned the importance of supporting KP-friendly drop-in centers to facilitate KPs to seek

services as KPs are more likely to attend KP-friendly drop-in centers as opposed to mainstream health facilities.

> *"I wish to recommend that because the drop-in centers are … working for key population and vulnerable population, they feel very comfortable to access services there so why not strengthen the system and if it becomes I should say the Ghana Health Service should rather support the DICs [drop-in centers] and the implementation of the DICs and take over from partners and ensure that it is well resourced and bring in the necessary doctors to provide services for the KPs."*

Facilitator 1: Increased Testing Modality That Would Increase Testing Uptake

The most common individual-level facilitator for the introduction of HIVST in the country mentioned by policymakers was that HIVST would be an additional strategy to complement all other existing testing strategies and would increase overall HIV testing rates. The current standard protocol for HIV testing in Ghana includes facility-based testing and community-based testing (e.g., outreach, door-to-door), both of which are performed by the provider. Many believed that the introduction of HIVST would strengthen the HIV testing program by making more testing options available to the beneficiary population and consequently increase HIV testing rates. Some policymakers confirmed that HIVST will offer testing options and not replace the existing testing strategies:

> *"It* [HIVST] *will aid in increasing the number of people who will be willing to test to know their HIV status, … Yes, and the number of people who will be willing to test and also know their status will increase."* (National policymaker #01)
> *"I think it will just complement what is there already. It is not going to take away anything from the testing we already have."* (Regional policymaker GA #7)

Many policymakers pointed to multiple reasons why they believed more people would test for HIV with the availability of HIVST, including increased privacy and confidentiality, reduced stigma, convenience, and less invasive.

> *"The second benefit is associated with the stigma being associated with HIV. If the self-testing is being introduced, it will help people to do their own testing that would prevent them from going through the fear of stigma."* (National policymaker #02)
> *"One challenge is confidentiality issues and one is going to go through orientation and do it on her own or, something like that. On her own or on his own, he knows that confidentiality is ok, nobody knows the results."* (National policymaker #01)

A few also mentioned that a great benefit of self-testing was the right of the individual to test and know his/her HIV status.

> *"…to me it gives the person the right to decide … he or she can decide for his or her self when, how, under which conditions he or she should test his or her self for HIV."* (Regional policymaker GA #07)

Structural-Level Challenges and Facilitators

Challenge 1: Lack of a National Policy and Implementation Guidelines on HIVST

Among the structural level barriers raised by many policymakers was the absence of national guidelines on HIVST implementation in Ghana. The only available national level reference at the time of this study was the National Strategic Plan (NSP) 2016-2020 for HIV, which only recommended piloting HIVST among MSM, with no clear policy guidelines or framework on HIVST implementation in the country. The lack of national guidelines on HIVST in the country was identified as an obstacle to any successful introduction on HIVST in the country by some policymakers. Policymakers indicated that such policies would serve as a call to action and provide an operational framework for the rollout of HIVST.

> *"Just because we don't have the policy in place is a barrier in itself. So maybe because we haven't made a point to bring it in the system, all those things rather become barriers."* (Regional policymaker GA #07)
> *"If we are going to roll it in the general population, something that we need to look out for … we have to integrate in a strategic plan, integrate it in our working document and also put it across for stakeholders to know the importance."* (National policymaker #03)

One regional level policymaker mentioned that the current national guidelines and protocol for HIV testing in the country required that all HIV test must be supervised. The participant indicated that this may hinder effective implementation of HIVST without policy change.

> *"Our current strategy is for you to freely go in and ask for the supervised testing that is all the policy now, meaning somebody has to administer it to you."* (Regional policymaker GA #07)

Challenge 2: Cost of HIVST Kits

Many policymakers discussed the cost of HIVT kits and its implication for the national program as well as for the end users. At the national level, policymakers' concerns centered around the cost of procurement of the kits. Resources to finance HIVST programming was a concern to some policymaker as they are already strapped for financial resources to support antiretroviral drugs and services.

> "*Short term, please we cannot (finance HIVST). We are struggling with ARVs for children even EID [early infant diagnosis] blood spots, we cannot cover them … so what we are talking about will re-channel the funds to self-testing — they will not do it."* (National policymaker #03)
> *"Policy barriers usually is the cost of the test kit because if it is going to be expensive then policy is not necessary"* (National policymaker #04)

However, others expressed that it should be a priority in the government programming and budgeting, particularly if it is part of the existing national HIV response and part of the national strategic plan. Some mentioned that it would be helpful if donors

and other entities could help finance HIVST programming until it becomes part of the national program. *"Short term, if it's in the government policy, then it can be pre-financed. But if we can advocate to other individuals [donors], NGOs to help pre-finance until it comes to stay, then maybe the government can accept it."* (Regional policymaker GA #07)

For the end users, if it should be made available through retail distribution outlets (e.g., private pharmacies, supermarkets), it may not be affordable to the consumers. Some policymakers expressed that with facility and provider HIV testing being free, the cost of self-test kit to beneficiary population will become a hindrance to uptake of testing.

> *"And then other thing we know is this test is quite expensive. So, how affordable will it be for people to use it for self-test? Are they going to buy at the pharmacy? What is the cost going to be? So, maybe for those who really need to do the test, the cost may be far above what they can afford. But in the health facility it is free but if it is self-testing, it means you have to go and buy it.… So, the richer, they will be able to buy it and afford it and use. But most of the people who are infected I will say still are the people who are poor. So, if you want to reduce the HIV transmission you should think about the cost of the test kit"* (National policymaker #04)

One of the regional policymakers indicated that while there would be high acceptability among beneficiary population, the cost of the test kit will be a potential barrier, and there should be a modality of cost removal at the beginning and cost-share or total cost transfer to end users later.

> *"The acceptability, how they will accept it, it is very important that they know and of course the cost involved.… Depending upon how they embrace it, then later on, they can even bring in the idea of either cost sharing* [subsidies] *or either to buy* [full cost recovery]*."* (Regional policymaker BA #03)

Challenge 3: Supply Chain Management of HIVST Commodities

Many policymakers felt that the management of the supply chain would be critical to ensuring commodity security. Almost all national and a few regional policymakers indicated that without effective supply chain and logistics management systems in place, it would be a challenge to ensure commodity security and HIVST stock availability.

> *"Shortage, wrong distribution and sometimes poor management of stock.I understand in some cases we have expired commodities in some of the facilities, all because of poor management and they are all gaps. Meanwhile at a particular stage, some partners are ready to receive from a particular channel and yet they don't get."* (National policymaker #01)

Some policymakers indicated that the current challenges confronting commodity security (e.g., stocks, storage, and handling) could also affect the quality and integrity of the HIVST kits.

> *"It also another thing even the storage of the test kits. Ordinary test kits we are facing challenges with storage and how much more bringing in self-test kits and how we even channel it to sell instead of giving it out free."* (National policymaker #03)
>
> *"Safety in handling the commodities could also be affected because … it's a form of chemical. If it is not kept at the right temperature or handling well, its safety can be affected." (Regional policymaker BA #04)*

To ensure accountability, some policymakers called for the establishment of appropriate monitoring systems. They expressed the need for policy guidelines, structures, and systems to support effective monitoring of test kits to track not only the distribution, but also the usage of the kits. *"… I am talking logistical management system and policies on how to track and monitor, policy on the usage on the test kits, policy on reporting. We need to get how the structures should be. We need to also know there is a plan for system and ability of a program."* (National policymaker #3).

Challenge 4: Data Monitoring and Reporting of Positive Cases

Some policymakers mentioned the negative impact that HIVST implementation would have on the national HIV programming and planning, particularly regarding data monitoring and reporting. Accurate data is pivotal for planning and monitoring any program, and many wondered how data would be assembled and fed into the national database. Several policymakers highlighted the need for having a system in place to report positive cases resulting from HIVST. It was particularly worrisome for them that under HIVST, positive cases may be missed in the reporting system if the HIVST user does not return to the health facility for confirmatory testing, where the person would be captured into the health information system.

> *"I think, first implication is data management because at the moment, I don't see how those who will be tested through this system would be captured in our data. In the first place, it is because of stigma and other things that the person went and tested. So how are we able to tell that, let's say, we have 20 people who have tested … we should also know out of the number tested, how many positive and others are, but that limitation is going to be there."* (Regional policymaker BA #02)
>
> *"It is only those who will go to the health centers for confirmation that probably they can record there. So, where we don't have them coming to record or to show themselves, then data is going to be wrong."* (National policymaker #01)

Facilitator 1: Reduced Burden on Health System

One of the greatest benefits many policymakers saw with the introduction of HIVST was that HIVST would reduce the burden on the health system as a result of reduced client load at the health facilities. With HIVST, only reactive cases would seek confirmation at the facilities, thus reducing the burden on the overly stretched and under-staffed health facilities. The resultant will be an improvement and efficient service delivery, and staff would be task-shifted to provide other essential health services.

"I think when it comes to the area of testing, staffing, at that area will come down…Because a lot of people might not need to come [to the health facility]. *If already the person is negative, that person will not come to the facility."* (Regional policymaker BA #04)

Facilitator 2: Contribute to Achieving Testing Targets

Another structural level facilitator for the introduction of HIVST that was mentioned by a few policymakers was its potential to help meet HIV testing targets and help reach the global 90-90-90 targets for HIV epidemic control.

"If we have the available test kits for self-testing and we have the funding for its implementation among KPs, I will be part of number one people to support the initiative. … because we are trying to achieve 90-90 objective by 2020. … if Ghana wants to be part of those who have been able to take up the sustainable development goal, then we need to start now and ensure that by 2020, we have been able to identify all those living with HIV within the community who do not know their status…and can be put on treatment so that we avert death." (National policymaker #04)

Policymakers Support for HIVST

Despite the many challenges expressed, the majority of policymakers were highly in favor of the introduction of HIVST in Ghana, particularly for KPs.

"If we have the available test kits for self-testing and we have the funding [for] its implementation among KPs, I will be part of number one people to support the initiative." (National policymaker #03)

However, there were divergent positions regarding the timing of the initiative. The support for immediate introduction centered around two main issues previously mentioned: increased testing uptake allowing more people to know their status and the potential to meet testing targets. A few policymakers, however, were more cautious in recommending immediate roll-out of HIVST. They felt that public sensitization, capacity building around HIVST of both implementors and end users, and development of an appropriate monitoring system were needed prior to the introduction of HIVST widely.

"I would not support it until capacities have been built. So, I would look at later stage because I am of the view that until all these things we have mentioned are in place [monitoring system, sensitization], we wouldn't be able to have a very effective system. So not now as in today but at least we need some preparations." (Regional policymaker BA #02)

"I will say later [introduction of HIVST] because if a lot of education doesn't go into it, it could be introduced and people might not patronize." (Regional policymaker BA #04)

DISCUSSION

The focus of this study was to gain in-depth understanding of policymakers' perspectives on the barriers and facilitators to the introduction of HIVST as a national HIV strategy. While many studies have reported on high acceptability and usage of HIVST, only a few have reported on the perspectives of policymakers (32, 33), which is critical to the successful large-scale implementation of HIVST. This study revealed that while policymakers were supportive of HIVST implementation in Ghana and that there was no doubt that HIVST would help increase HIV testing uptake, there were a number of client level as well as structural level issues that needed to be addressed before large-scale implementation.

One of the greatest individual-level concerns of policymakers was the absence of counseling and the consequences of lack of psychosocial support, and the counseling around the need for confirmatory testing and linkage to care and treatment for HIVST users who obtain a reactive test result. This is a well-documented concern about HIVST among key stakeholders including healthcare providers, policymakers, academics, activists, donors, among other, in other African countries (34). This concern is certainly warranted; in fact, a recent meta-analysis found that while HIVST significantly increased uptake, linkage to care and treatment was lower compared to standard HIV testing (35). When HIVST occurs in a supervised manner (i.e., aided by a healthcare provider), psychosocial support, counseling, and linkage to care, prevention, and treatment services can be facilitated by leveraging existing HTC services (10). However, for unsupervised HIVST, strategies are needed to provide counseling and facilitate linkage to care. At a minimum, test kits should contain key counseling messages including information on the need for confirmatory testing following an initial reactive self-test using both written (local language) and pictorial instructions. However, to conduct more active follow-up, obtaining contact information and unique personal identifiers (including biometrics) of clients is key to facilitate counseling text-messaging (along with specific locations of HIV clinics) and phone-based follow-up (10). In Ghana, a few strategies using community-based platforms have been piloted with success among the MSM population (36). These pilot interventions showed that virtual community-based platforms through mobile and digital technology could be used to link MSM to HIV care providers. One intervention provided access to peers *via* an online app for peer support and referral to the providers (36). Toll-free telephone hotlines, online counseling, and automated text messaging may also be considered for counseling and facilitating linkage to care (8, 10, 19, 37–40). A study among Nigerian MSM to whom HIVST kits were distributed found that while a hotline was available to study participants, it was rarely used; rather, participants preferred to contact the peer educators from whom they received the HIVST kits as they preferred to go to a known trusted source rather than an anonymous hotline (19). A survey among a representative sample of potential HIVST users were asked about their intention in linkage to care and their preferences for strategies (41). Eighty-five percent indicated they would link to care within the first week of a positive test result and home visits (53%) were preferred over a phone call (30%) or SMS (17%) to be reminded to be linked to care. Currently, there is limited evidence on what strategies are effective in linking self-testers to care and treatment. Selection of the mode of follow-up for counseling and linkage to care and treatment is very context and population -specific;

therefore, implementers will need assess what will work in their context given the available resources. While policymakers in this study mentioned their concerns only around linkage to care and treatment for those who test positive with HIVST, linkage to prevention services, including PrEP, is also important for those who test negative (42). HIVST may be a promising approach to increase linkage of high-risk populations to PrEP and subsequently increase PrEP usage.

Policymakers in this study pointed out the paramount nature of the need for the inclusion of HIVST as a programmatic approach in the NSP and country-specific HIVST implementation guidelines and policy framework/directive in order to be able to implement HIVST in the country. This is consistent with other studies (7, 24, 32, 33, 43–46) that attest that HIVST will require the institutionalization of national implementation guidelines pivoted on outcomes of implementation science research in order to have nationwide large-scale roll-out. At the time of the study, the NSP 2016-2020 had only mentioned the need to pilot HIVST in Ghana before a policy directive could be made. After the completion of this study, national and regional level stakeholder technical discussions were held and Ghana Health Service/National AIDS Control Program led the development of the HIVST guidelines. Additionally, HIVST has been added to the draft of the 2021-2025 National Strategic Plan as a strategy, especially to improve testing for KPs and adolescent girls and young women. While this will make large scale roll-out of HIVST easier, barriers mentioned by the policymakers in this study are still relevant given challenges in nascent stages of real-world introduction of new strategies (as opposed to a study or pilot setting).

The newly-drafted Ghana HIVST implementation guidelines addresses the need for the integration of HIVST kits into the country's supply chain management system to ensure appropriate quantification, distribution and inventory management, product quality assurance, and data reporting. It is envisioned that as the country transitions from a manual data reporting system to an electronic system (Ghana Integrated Logistics Management Information System), there will be more efficient tracking of stock availability and usage of kits from service delivery points, thereby ensuring a more effective supply chain management system.

Direct cost of HIVST kits to the individual constitutes a significant barrier to wider adoption, access and utilization (47–50). If HIVST should be made available through pharmacies and other retail outlets, the price of the kits must be affordable to ensure equitable access. Willingness-to-pay studies in Cote d'Ivoire, Tanzania, and Kenya have shown that people are willing to pay USD 0.87 (Tanzania) to USD 1.77 (Cote d'Ivoire) (51, 52). Partial or full subsidization may need to be considered for low-income populations to increase access and coverage (51, 52). Lastly, public–private partnerships should be considered as an option to facilitate transition to domestic country budgets as donor funding for HIVST programs decrease (53). The cost-effectiveness of HIVST hinges on the benefits of early diagnosis leading to improved treatment outcomes; however, this is dependent on high prevalence of undiagnosed HIV (54). Therefore, a targeted approach to HIVST distribution will be key to ensuring a more cost-effective approach. As mentioned in the new NSP 2021-2025 and the HIVST implementation guidelines, the main target populations for HIVST must be KPs as it will have the greatest impact.

Issues on data capturing and monitoring for programming and assessing the level of coverage were also mentioned as technical areas that needed to be addressed before the large-scale implementation of HIVST. Potential strategies to address this challenge include the use of internet and interactive text message surveys to follow-up with HIVST clients regarding their usage and result of the test (10, 42, 55). This will not only capture HIVST usage and results but could allow for automated referral to post-test services. An important issue to address with these solutions is the need to ensure confidentiality of clients when reporting their self-test results. Routine surveillance surveys such as bio-behavioral surveillance surveys and AIDS Indicator Surveys should also include questions about HIVST usage to determine population coverage of self-testing as well as successful linkage to prevention and treatment (10, 42, 55).

One of the greatest structural level appeals of HIVST as mentioned by many providers was the potential reduced burden on the health system. Only those who self-test positive will need to come in for confirmatory testing to be conducted by a provider; those who test negative can be referred for preventive services such as PrEP. This helps to reduce the burden and time of HIV testing on healthcare providers, thereby improving the efficiency and effectiveness of the health system (42), which will be even more critical as HIVST expands.

A limitation of this study was that regional level policymakers were selected from only two region (out of 16 regions) and thus their views may not be reflective of views held by policymakers from other regions of Ghana. However, national level policymakers are tuned into regional level issues around HIV programming, policies, and implementation issues, and hence, their perspectives likely also convey those of regional policymakers.

CONCLUSION

Overall, this study revealed that while many stakeholders see the added value of HIVST for epidemic control, the roll-out of HIVST must be preceded with policy framework and implementation guidelines, education and sensitization of the population and systems in place to address the various client and structural level challenges. The concerns raised related to counseling, linkage to HIV prevention, care, and treatment, supply chain challenges, monitoring and reporting, and the costs of HIVST kits should be critically considered and addressed. National guidelines on HIVST will support existing HIV policies and strategies and position HIVST as an important complement to existing HTS strategies in Ghana.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Population Council Institutional Review Board, New York (USA) and Ghana Health Service Ethical Review Committee, Accra. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

HN: research design, data interpretation, paper writing, and revision. EA and HT: research design, protocol development, data collection training and supervision, analysis, paper writing, and revision. WT: research design, protocol development, data collection training, analysis, paper writing, and revision. AA: paper review and revision. YR and MK: research design, paper review. SA, KA, and EE: research design, protocol development data interpretation. All authors contributed to the article and approved the submitted version.

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The Impact on HIV Testing Over 6 Months When Free Oral HIV Self-Test Kits Were Available to Truck Drivers in Kenya: A Randomized Controlled Trial

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Background: Studies suggest that offering HIV self-testing (HIVST) increases short-term HIV testing rates, but few have looked at long-term outcomes.

Methods: We conducted a randomized controlled trial (RIDIE 55847d64a454f) on the impact of offering free oral HIVST to 305 truck drivers recruited from two clinics in Kenya. We previously reported that those offered HIVST were more likely to accept testing. Here we report on the 6-month follow-up during which intervention participants could pick-up HIVST kits from eight clinics.

Results: There was no difference in HIV testing during 6-month follow-up between participants in the intervention and the standard of care (SOC) arms (OR = 1.0, $p = 0.877$). The most common reasons given for not testing were lack of time (69.6%), low risk (27.2%), fear of knowing HIV status (20.8%), and had tested recently (8.0%). The null association was not modified by having tested at baseline (interaction $p = 0.613$), baseline risk behaviors (number of partners in past 6 months, interaction $p = 0.881$, had transactional sex in past 6 months, interaction $p = 0.599$), nor having spent at least half of the past 30 nights away from home for work (interaction $p = 0.304$). Most participants indicated a preference for the characteristics associated with the SOC [preference for blood-based tests (69.4%), provider-administered testing (74.6%) testing in a clinic (70.1%)]. However, those in the intervention arm were more likely to prefer an oral swab test than those in the SOC (36.6 vs. 24.6%, $p = 0.029$).

Conclusions: Offering HIVST kits to truck drivers through a clinic network had little impact on testing rates over the 6-month follow-up when participants had to return to the clinic to access HIVST. Clinic-based distribution of HIVST kits may not address some major barriers to testing, such as lack of time to go to a clinic, fear of knowing one's status and low risk perception. Preferred HIV testing attributes were consistent with the SOC for

most participants, but oral swab preference was higher among those in the intervention arm, who had seen the oral HIVST and had the opportunity to try it. This suggests that preferences may change with exposure to different testing modalities.

Keywords: HIV, HIV testing, randomized controlled trial, implementation science, HIV self-testing, Kenya, truck drivers

INTRODUCTION

HIV self-testing (HIVST) is a new biomedical tool that may facilitate reaching individuals not testing regularly under traditional HIV testing programs. HIVST may address the stigma associated with being seen in a testing clinic as well as privacy and confidentiality (1), especially for groups at high risk for HIV infection and that experience discrimination (2). A 2016 systematic review and meta-analysis found that self-administering and interpreting a rapid HIV test was as accurate as provider-administered testing (2), and in 2016 the World Health Organization (WHO) recommended that HIVST be offered as an additional approach to HIV testing services, rating their recommendation as strong and based on moderate quality evidence (2). A number of randomized controlled trials (RCTs) have found that offering free oral HIVST as an option increases HIV test uptake over the standard of care (SOC) of offering only provider-administered testing (3–15). However, most HIVST studies examined HIV testing rates over a short period of time and there is little evidence that the higher HIV testing rate associated with the initial introduction and availability of HIVST will continue over time. Offering a new product for free may motivate people to try it, but when the initial novelty has worn off, testing rates may revert to baseline. In fact, in one of the trials among Kenyan truck drivers, 89.3% of those who chose to self-test at baseline in the clinic with supervision said that they did so because they were curious to try a new test (16). The follow-up period in most RCTs described to date has been short, no longer than 4 months (4–11). Although three trials among men who have sex with men in the United States, Hong Kong and Australia were somewhat longer, ranging from 6 to 15 months (12–14), they did not look at changes in the intervention impact over time. Thus, decisions about rolling-out HIVST are being based on data from relatively short periods of follow-up, with little evidence that the impact will be sustained over the long-term.

In 2015 we conducted an RCT among 305 Kenyan truck drivers recruited from the waiting rooms of two North Star Alliance roadside wellness clinics. Study participants were all men working as truck drivers with a mean age of 37 years. About 36% had graduated high school and 83% were married. The majority (72%) earned 24,000–55,000 KES per month (about $240–550 US) and had worked as truckers for 8.7 years on average. Ninety-eight percent of participants reported having been sexually active in the past 6 months and 56% had paid for sex during that time period. Participants were randomized to one of two arms in which they were offered (1) a choice between (a) the SOC HIV test (rapid provider-administered finger-prick test in the clinic) or (b) supervised self-administered rapid oral HIVST in the clinic before leaving the clinic (baseline); those who refused both in-clinic options were then offered (c) the HIVST kit to take for use outside of the clinic (i.e., home use) (intervention arm) or (2) the SOC HIV test only (SOC arm). In that study we found significantly higher baseline HIV testing rates among those in the intervention arm than the SOC arm (3).

In this same study, we also informed those in the intervention group that they could access HIVST kits from any of the eight North Star Alliance roadside wellness clinics in Kenya over the following 6-month period. At 6 months post-study enrollment, we interviewed all study participants about HIV testing they had undergone since baseline, as well as preferences regarding future HIV testing, and we report those results here.

METHODS

This RCT was registered prior to initiation in the Registry for International Development Impact Evaluations (RIDIE), ID# 55847d64a454f. The methods have been reported elsewhere (3) but here we provide a brief description. In October–December 2015, we invited all truck drivers who visited two North Star Alliance roadside wellness clinics in Kenya to screen for eligibility for participation in a study on HIV testing. Those who were (1) $\geq$18 years old, (2) male, (3) worked as a truck driver or trucking assistant, (4) resided in Kenya, (5) spoke English or Kiswahili, (6) self-reported they were HIV-negative or unknown HIV status, (7) were able to sign the consent form, and (8) were willing to receive payment of participation fees via MPesa (a cell-phone-based money transfer system) were eligible to participate. In order to prevent bias, participants were blinded to the study research question and to the fact that they would be randomized to arms offering different HIV testing options. The study was approved by the City University of New York Institutional Review Board, the Kenya Medical Research Institute Ethics Committee, and the University of KwaZulu-Natal Biomedical Research Ethics Committee.

We administered a baseline questionnaire about demographic background, HIV testing history and sexual risk behavior, after which the fieldworker opened a sealed envelope with the randomization assignment. Participants were randomized on a 1:1 basis to either the SOC arm or the intervention arm, stratified by clinic. For those randomized to the SOC arm, the fieldworker offered the standard HIV test, which was a provider-administered rapid finger-prick test conducted in the clinic with pre- and post-test counseling. For those randomized to the intervention arm, the HIVST kit was demonstrated and then they were given a choice between (1) the SOC test or (2) rapid oral HIVST for use in the clinic with provider supervision, and those who refused both in-clinic options were then offered (3) a self-administered oral rapid HIV test kit to take for use outside of the clinic (home

use). Those who accepted HIV testing in the clinic underwent standard pre- and post-test counseling procedures while those who took a test kit for home use were given pre-test counseling while in the clinic and post-test counseling by phone after testing. Another questionnaire was administered following testing or test refusal and, before leaving the clinic, those in the intervention arm were informed that they could pick-up HIVST kits from any of the eight North Star Alliance roadside wellness clinics in Kenya over the following 6 months for home use or use in the clinic with supervision, depending on their preference. We contacted all study participants 6 months following study enrollment to ask about HIV testing since baseline, reasons for their testing decisions and preferred HIV testing program attributes for future testing. Participants received the equivalent of approximately $6 US for completing the baseline interview and an additional $4 for completing the 6-month follow-up interview as compensation for their time.

Statistical Analysis

We previously described the sample overall and compared characteristics by randomization arm. There were no significant differences by randomization arm (3). We calculated Mantel Haenszel odds ratios for HIV testing during the 6-month follow-up period by randomization arm adjusted for clinic (strata used in the randomization scheme). For those in the intervention arm who tested during follow-up, we described what HIV test they used (SOC, HIVST for home use or supervised use in the clinic). For those in both arms who did not test during follow-up, we described the reasons given for not testing and further explored if those reasons might be modifiers of the association found between HIV testing during follow-up and randomization arm using logistic regression with the pertinent 2-way interaction terms and adjusted for clinic. The factors assessed in the interaction analysis were determined *post-hoc*, driven by the factors participants stated as reasons for not testing, and included proxy measures for recent HIV testing (having tested at baseline), HIV risk (number of sex partners and transactional sex in the past 6 months reported at baseline), as well as a proxy for limited free time (report of having spent more than half of the past 30 nights away from home due to work at baseline). Finally, we described the HIV testing program attributes participants reported they would prefer for future HIV testing. All descriptive statistics were examined for the sample overall and then stratified on randomization arm, with a chi square test (or Fisher's exact when expected cell counts were <5) to assess statistical significance. All statistical tests were two-sided at alpha $= 0.05$ and conducted using SPSS version 25 (Chicago, IL).

RESULTS

Study Flow Over 6-Month Follow-Up

The study flow chart is presented in **Figure 1**. A total of 305 truck drivers were enrolled in the study and completed baseline procedures. Note, one participant in the intervention arm was not offered HIVST as a choice and therefore we analyzed the outcome data both based on intent-to-treat and per protocol. At 6-month follow-up, 21 participants were lost to follow-up (8 in the intervention arm and 13 in the SOC arm), yielding a sample of 284 participants for the 6-month analysis.

HIV Testing Outcomes Over 6-Month Follow-Up

There was no significant association between randomization arm and HIV testing during the 6-month follow-up in both the intent-to-treat analysis (OR $= 1.0$, $p = 0.877$) and the per protocol analysis (OR $= 0.9$, $p = 0.779$) (**Table 1**). Participants who had not tested for HIV at baseline were more likely to test during the follow-up period (63.4 vs. 54.2%), but the difference was not statistically significant ($p = 0.236$) (Data not shown). The most common reasons given for not testing during follow-up were lack of time (69.6%), perceived low HIV risk (27.2%), fear of test results (20.8%) and having tested recently (8.0%). None of these reasons differed by randomization arm (**Table 2**). In an attempt to assess whether some of these barriers might be addressed by HIVST, we explored whether the intervention effect was modified by having tested at baseline, a proxy for having tested recently (interaction $p = 0.613$), number of partners in past 6 months reported at baseline (interaction $p = 0.881$) and report at baseline of having had transactional sex in the past 6 months (interaction $p = 0.599$), both proxies for HIV risk perception, and having spent $\geq$15 of the last 30 nights away from home for work, a proxy for lack of time (interaction $p = 0.304$). None of the interaction terms were statistically significant (Data not shown).

HIV Test Used During 6-Month Follow-Up Among Those in the Intervention Arm

Of the 80 participants in the intervention arm who could access HIVST kits and tested during follow-up, 18 (22.5%) used an HIVST while the other 62 (77.5%) accessed the SOC. Of the participants who self-tested, 3 (16.7%) used the HIVST at the clinic under supervision while the remaining 15 (83.3%) took the kit for home use. Among the 80 participants in the intervention arm who tested during follow-up, those who had self-tested at baseline were more likely to pick up a self-test kit during follow-up (26.1% of those who self-tested in the clinic and 33.3% of those who took a self-test kit for home use at baseline) compared to those who had not self-tested at baseline (20.0% of those who took the SOC test and 7.7% of those who did not test at baseline) but the difference was not statistically significant (Fisher's exact $p = 0.487$) (Data not shown).

HIV Testing Program Attributes Preferred for Future Testing

When asked about preferences for future HIV testing, the majority of participants selected attributes of the SOC test: blood test (69.4%), provider-administered (74.6%) in the clinic (66.8%). However, 25–30% selected attributes of the HIVST that we made available (30.6% oral swab, 25.4% self-administered and 26.9% at home). Preferences regarding testing alone vs. with a partner were evenly split (47.9% preferred to test alone and 52.1% preferred to test with a partner). The only attribute preference

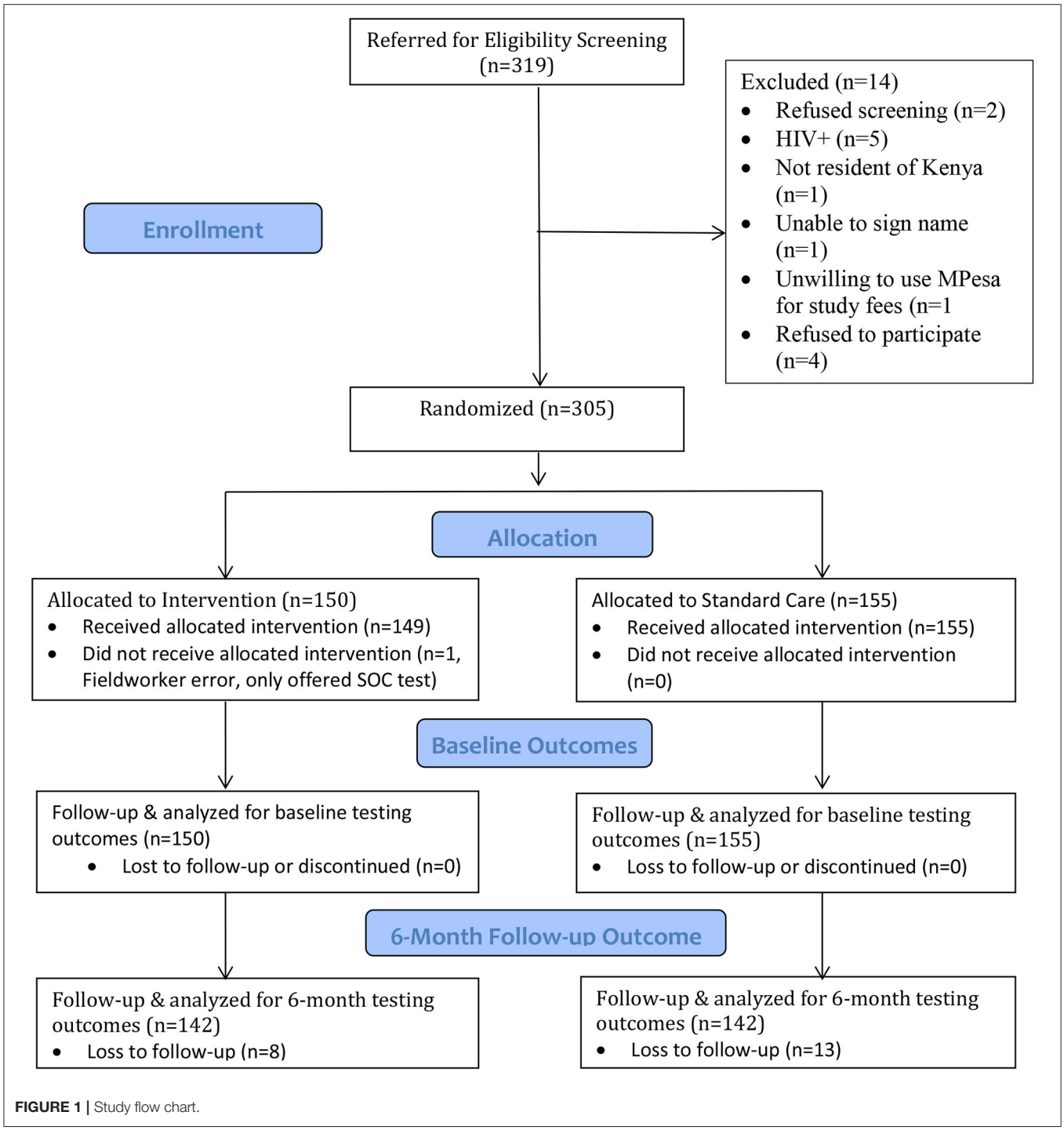

FIGURE 1 | Study flow chart.

that varied by randomization arm was biological specimen, with a higher proportion preferring the oral swab test among those in the intervention arm (i.e., the group that saw a demonstration of an oral swab HIVST test and had the opportunity to use it) compared to the SOC arm (36.6 vs. 24.6%, $p = 0.029$) (**Table 3**).

DISCUSSION

When free oral HIVST kits were made available to truck drivers through a clinic network, HIV testing was higher than among those offered only the SOC at baseline when the participants were already in the clinic (3), but it had little impact on testing

TABLE 1 | HIV test uptake overall and by arm under intent-to-treat and per protocol status.

	Total, *n* (%)	Intervention arm, *n* (%)	SOC arm, *n* (%)	Mantel Haenszel OR (95% CI) adjusting for strata	Mantel Haenszel *p*-value
Tested at 6 month follow-up (intent-to-treat analysis)					
Yes	159 (56.0%)	80 (56.3%)	79 (55.6%)	1.0 (0.6–1.5)	0.877
No	125 (44.0%)	62 (43.7%)	63 (44.4%)	NA	NA
Tested at 6 month follow-up (per protocol analysis)*					
Yes	159 (56.0%)	80 (56.7%)	79 (55.2%)	0.9 (0.6–1.5)	0.779
No	125 (44.0%)	61 (43.3%)	64 (44.8%)	NA	NA

**One participant in the intervention arm was only offered the SOC HIV test at baseline, so that individual is analyzed in the SOC arm in the per protocol analysis.*

TABLE 2 | Reason for not testing during 6-month follow-up among those who did not test.

	Total *n* (%)	Intervention, *n* (%)	SOC, *n* (%)	*p*-value
Total	125 (100%)	62	63	
Tested recently	10 (8.0%)	3 (4.8%)	7 (11.1%)	0.323*
Afraid or don't want to know status	26 (20.8%)	13 (21.0%)	13 (20.6%)	0.963
Not at risk	34 (27.2%)	17 (27.4%)	17 (27.0%)	0.956
Worried about losing job	2 (1.6%)	0 (0.0%)	2 (3.2%)	0.496*
Do not trust test results	3 (2.4%)	1 (1.6%)	2 (3.2%)	1.000*
Do not trust provider or worried about lack of confidentiality	4 (3.2%)	1 (1.6%)	3 (4.8%)	0.619*
No time	87 (69.6%)	42 (67.7%)	45 (71.4%)	0.654
Lack access to HIV care	0 (0%)	0	0	NA

**Fisher's exact test used.*

rates over the 6-month follow-up, when participants had to return to the clinic to access the HIVST. This discrepancy could be attributed to participants having overcome the barrier of presenting at a clinic for HIV testing at baseline, since the participants had been recruited from clinic waiting rooms, whereas over follow-up, that barrier was experienced equally among those in the intervention and SOC arms. A study among female sex workers in Uganda found that offering HIVST kits directly through peers was associated with both a higher initial testing rate and a higher probability of repeat testing over 4-month follow-up compared to making HIVST kits available through healthcare facilities (8). Thus, clinic-based distribution of HIVST kits may not address some major barriers to testing that many face. However, in two subsequent RCTs we conducted in which we sent text messages to truck drivers and female sex workers either reminding them of the availability of general HIV testing at North Star Alliance Clinics (SOC) or announcing the availability of HIVST kits at these clinics, we found higher testing rates among those who received the text messages about the availability of HIVST kits (9, 10). In those studies, participants had to come to the clinic to access both SOC and HIVST testing. It could be that the novelty of making a new product available, in this case HIVST, may be sufficient to overcome the barriers to accessing testing through a clinic, but once the initial novelty has worn off, as may have been the case with the truck drivers in this study who had already been introduced to the HIVST kit and had the opportunity to use it at baseline, the HIVST was no longer sufficiently intriguing to overcome the barriers associated with clinic access. Thus, the impact of new biomedical technology is likely dynamic and uptake may follow a bell-shaped curve rather than the S-shape associated with traditional diffusion theory (17). To put this in the context of health behavior theory, the availability of new biomedical technology might serve as the cue to action in the Health Belief Model, but once that technology is no longer perceived as new, it no longer serves as a cue (18). Of course, this is all conjecture and more research is needed to examine the long-term impact of offering HIVST in general and through different distribution methods outside of the clinic setting.

The reasons given by participants for not testing during follow-up were similar in the intervention and SOC arms. Thus, the primary barriers to self-testing when test kits are distributed for free through clinics and SOC testing appear to be similar and included lack of time, low perception of HIV risk, and fear of the test results. These barriers are likely to directly impact access to HIV testing, be it self-testing or SOC testing, through clinics. Lack of time makes it difficult to fit a clinic visit either for testing or for HIVST kit pick-up into the already busy schedule; lack of risk perception makes adding an inconvenient clinic visit for either testing modality less of a priority; and fear would also make a clinic visit for either testing modality a challenge. Lack of time and low risk perception might be mitigated somewhat

TABLE 3 | Preferred attributes of HIV testing programs for future testing.

	Total, *n* (%)	Intervention, *n* (%)	SOC, *n* (%)	*p*-value
Biological specimen				
Blood	197 (69.4%)	90 (63.4%)	107 (75.4%)	0.029
Oral swab	87 (30.6%)	52 (36.6%)	35 (24.6%)	
Administration				
Provider	211 (74.6%)	100 (70.9%)	111 (78.2%)	0.162
Self	72 (25.4%)	41 (29.1%)	31 (21.8%)	
Testing alone vs. with partner				
Alone	136 (47.9%)	64 (45.1%)	72 (50.7%)	0.342
With partner	148 (52.1%)	78 (54.9%)	70 (49.3%)	
Location				
Home	76 (26.9%)	35 (24.6%)	41 (29.1%)	0.520*
Clinic	201(71.0%)	103 (72.5%)	98 (69.5%)	
Other	6 (2.1%)	4 (2.8%)	6 (2.1%)	

**Fisher's exact test calculated in SAS. When excluding the "Other" category, the difference was still not significant (chi-square p = 0.441).*

through other distribution mechanisms, but fear of an HIV test result requires counseling, a service that is usually accessed once in a clinic. Low risk perception is also something usually addressed through counseling to help people accurately assess their risk and prioritize HIV testing if appropriate. Thus, in addition to considering alternate distribution methods, HIVST programs need to identify mechanisms to address fear of an HIV-positive result and risk perception to increase HIVST uptake. Qualitative interviews with study participants also identified lack of time as an important barrier and an emphasis on the need for counseling (19).

Having tested recently for HIV was the fourth most common reason for not testing during follow-up. The majority of participants in both study arms tested at baseline (72.9% in the SOC and 87.3% in the intervention arm) but high-risk groups in Kenya like truck drivers are counseled to test every 3 months. We attempted to assess if some of the reasons given for not testing over the follow-up period might be mitigated by making HIVST available. We examined these reasons for not testing as possible modifiers of the intervention effect by adding interaction terms to the regression model for having tested at baseline, as a proxy for recent testing, reporting at baseline that $\geq$15 of the last 30 nights were spent away from home due to work, as a proxy for lack of time, and report at baseline of the number of sex partners and having had transactional sex in the past 6 months, as a proxy for risk, However, none of the interaction terms were statistically significant, suggesting that HIVST distributed through clinics does not address these barriers better than SOC testing.

When participants were asked about their preferences regarding future HIV testing, the majority indicated preference for characteristics of SOC testing (blood-based, provider-administered and in the clinic), but about 25–30% preferred characteristics associated with the HIVST (oral-swab test, self-administered and at home). This suggests that multiple HIV testing options are needed to allow people to access testing modalities that suit their preferences and meet their needs. Interestingly, the proportion of participants who preferred an oral test was higher among those in the intervention group than the SOC group. Since participants were randomized to study arm and therefore confounding is unlikely, although not impossible, this may indicate that having seen a demonstration of the oral swab test and had the opportunity to try it made it more acceptable and even preferred by more people. Thus, HIV testing preferences may change over time, especially with greater knowledge and experience with HIVST.

This study had a number of limitations that should be considered when interpreting the results. First, we had some loss to follow-up (7%), which could have biased our results and reduced statistical power. Furthermore, our assessment of effect modification was a *post-hoc* analysis to try to understand the null results for the impact of our intervention on HIV testing over follow-up. *Post-hoc* analyses looking at effect modification can result in small numbers within certain strata and tend to be underpowered. This may have been the case in our *post-hoc* assessment of possible effect modifiers, and the null results should be viewed with caution. In addition, social desirability bias may have affected how some participants responded to our questions, especially regarding the HIV testing outcome, which may have been over-reported by participants in both arms. The HIV testing rate among study participants in both study arms at baseline was much higher than the 60% testing rate at North Star Alliance clinics during the same time period (3). This may also indicate that our sample was not representative of North Star Alliance roadside wellness clinic clients in general and certainly our results cannot be generalized to all truck drivers in Kenya, let alone other countries.

Despite these limitations, this is one of the first studies that looks at both the short- and long-term impact of the availability of HIVST on HIV testing rates. While making HIVST available to various population groups and using different distribution methods has been found to increase HIV testing rates (3–15), the short study duration makes it hard to determine what the

long-term impact might be when HIVST is rolled-out on a wider scale. In this study, our short-term HIV testing outcome was consistent with other studies in finding higher testing rates when HIVST was offered, but the lack of a difference over the 6-month follow-up period leads to concerns that the short-term intervention effect found in most studies may wane over time. This needs to be better evaluated before HIVST programs can be designed to maximize their impact on the HIV epidemic.

DATA AVAILABILITY STATEMENT

The datasets for this study can be found in the Harvard Dataverse repository (https://dataverse.harvard.edu/dataset.xhtml?persistentId=doi:10.7910/DVN/8GVXJY).

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by City University of New York Institutional Review Board, the Kenya Medical Research Institute Ethics Committee, and the University of KwaZulu-Natal Biomedical Research Ethics Committee. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

EAK led the conception and design of the study and conducted the data analysis and drafted this manuscript. GG, JEM, EM, and KG were all major contributors to the study design and coordination and participated in data interpretation and manuscript revision. MLR was responsible for data management and study monitoring and participated in data interpretation and manuscript revision. ENN and JOO were responsible for day-to-day study management and oversight and participated in data interpretation and manuscript revisions. All authors read and approved the final manuscript.

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Enthusiasm for Introducing and Integrating HIV Self-Testing but Doubts About Users: A Baseline Qualitative Analysis of Key Stakeholders' Attitudes and Perceptions in Côte d'Ivoire, Mali and Senegal

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Since 2019, the ATLAS project, coordinated by Solthis in collaboration with national AIDS programs, has introduced, promoted and delivered HIV self-testing (HIVST) in Côte d'Ivoire, Mali and Senegal. Several delivery channels have been defined, including key populations: men who have sex with men, female sex workers and people who use injectable drugs. At project initiation, a qualitative study analyzing the perceptions and attitudes of key stakeholders regarding the introduction of HIVST in their countries and its integration with other testing strategies for key populations was conducted. The study was conducted from September to November 2019 within 3 months of the initiation of HIVST distribution. Individual interviews were conducted with 60 key informants involved in the project or in providing support and care to key populations: members of health ministries, national AIDS councils, international organizations, national and international non-governmental organizations, and peer educators. Semi structured interviews were recorded, translated when necessary, and transcribed. Data were coded using Dedoose© software for thematic analyses. We found that stakeholders' perceptions and attitudes are favorable to the introduction and integration of HIVST for several reasons. Some of these reasons are held in common, and some are specific to each key population and country. Overall, HIVST is considered able to reduce stigma; preserve anonymity and confidentiality; reach key populations that do not access testing *via* the usual strategies; remove spatial barriers; save time for

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users and providers; and empower users with autonomy and responsibility. It is non-invasive and easy to use. However, participants also fear, question and doubt users' autonomy regarding their ability to use HIVST kits correctly; to ensure quality secondary distribution; to accept a reactive test result; and to use confirmation testing and care services. For stakeholders, HIVST is considered an attractive strategy to improve access to HIV testing for key populations. Their doubts about users' capacities could be a matter for reflective communication with stakeholders and local adaptation before the implementation of HIVST in new countries. Those perceptions may reflect the West African HIV situation through the emphasis they place on the roles of HIV stigma and disclosure in HIVST efficiency.

Keywords: HIV self-testing, key population, perceptions, stakeholders, West Africa, ATLAS

INTRODUCTION

To eliminate the HIV epidemic by 2030, the Joint United Nations Programme for HIV/AIDS (UNAIDS) has set targets of 95% diagnosis coverage by 2030 (along with 95% treatment among diagnosed people living with HIV–PLHIV- and 95% viral suppression among those on treatment) (1). Estimates at the end of 2019 showed rates of 81-82-88, and disparities were observed between regions and countries. The corresponding rates were only 68-58-45 in West and Central Africa (2). The last published data confirmed that the rates of knowledge of HIV status by PLHIV are much lower in the countries of West and Central Africa, than those from Eastern and Southern Africa (3).

The underachievement of the first rate can be explained by social factors that negatively influence HIV testing services (HTS) uptake in sub-Saharan Africa. They include fear of HIV, which is a barrier to testing uptake (4), low perceptions of exposure to HIV risk, which can positively (5), or negatively (6–8) influence adherence to testing; and HIV-related stigma and discrimination, which are the main barriers to HTS utilization (7–11). Stigma is reported to be more pronounced in West Africa than in Eastern and Southern Africa (12). The main barrier to couple testing remains the fear of negative consequences, which negatively influences the disclosure of HIV results between sexual partners (13–15).

HIV epidemics in West Africa disproportionately affect members of key populations and their partners: female sex workers (FSW), men who have sex with men (MSM), people who use injectable drugs (PWuIDs), transgender people and prisoners (2). These populations have important unmet HIV prevention needs in this region, where they are subject to intense social or structural stigmatization. Such stigma reduces their ability to seek, access, and use health services, including HTS (16–18).

These social barriers need to be removed to improve HTS access and uptake while protecting the privacy and confidentiality of HIV test results. Overall, confidentiality has been identified as a critical factor for HTS uptake (7, 8, 16). HIV self-testing (HIVST) is offering such a guarantee. This modality is defined by the World Health Organization (WHO) as a "*process in which an individual collects a specimen (saliva or blood) using a simple, rapid HIV test, performs a test, and then interprets the result when and where he/she wants it*" (19). HIVST on its own does not necessarily provide a definitive diagnosis, however. People with a reactive (positive) result must confirm the result through facility-based testing or with a trained professional. Those with a non-reactive (negative) result do not need a confirmatory test unless they have been recently exposed to the virus or are in the initiation phase of pre-exposure prophylaxis. However, a negative test result is an opportunity to connect with other prevention services. WHO does not recommend HIVST for PLHIV on antiretroviral treatment, as they risk obtaining false negatives results. Since November 2019, the WHO has recommended that HIVST be offered by health facilities as part of HTS (19).

This innovative strategy has been implemented in several regions since 2010, and the results of studies in sub-Saharan Africa, mainly conducted in Southern and Eastern Africa, have shown variable but generally high acceptability rates (20). Among the general population, acceptability rates are above 94% in Kenya and Malawi (10, 21). Studies in Eastern and Southern Africa have also found that HIVST is acceptable among key populations and is effective in identifying PLHIV who are unaware of their status, both among MSM and FSW (21–23). However, HIVST is poorly documented in francophone West African countries, where the national HIV prevalence is much lower than in Eastern and Southern Africa.

Coordinated by Solthis, an international non-governmental organization (NGO), and the Institut de Recherche pour le Développement (IRD), the ATLAS program (*AutoTest VIH, Libre d'Accéder à la connaissance de son Statut*) aims to promote and distribute HIVST in three West African countries (Côte d'Ivoire, Mali, and Senegal) from 2019 to 2021, in close collaboration with national AIDS councils, civil society organizations and key population communities. Considering West African countries' HIV epidemiology, the main focus of ATLAS is key populations (FSW, MSM, and PWuIDs) and their sexual partners, peers and clients; sexually transmitted infection patients and their partners; and the partners of PLHIV. An oral HIVST OraQuick HIV Self-Test® (OraSure Technologies, LLC Bethlehem) will be used as it is pre-qualified by WHO and has been validated by the three countries of intervention. To facilitate HIVST uptake and promote the link to confirmation testing and care services, locally adapted brochures describing HIVST steps in addition to the

manufacturer's instructions for use and videos in French and other national languages have been developed. Existing free HIV hotlines in each country were reinforced and their managers trained in HIVST.

In parallel with the implementation, ATLAS includes a research component and has run several qualitative and quantitative studies; in particular, a qualitative study conducted at program implementation has documented and analyzed HTS stakeholders' and key actors' perceptions and attitudes regarding the introduction of HIVST in Côte d'Ivoire, Mali and Senegal and its integration as a strategy for key populations.

MATERIALS AND METHODS

This qualitative study was conducted in Côte d'Ivoire, Mali and Senegal from September to November 2019, within 3 months of the beginning of HIVST delivery activities. In each country, one urban and one rural cities were selected by the teams of ATLAS program who have a good knowledge of the stakeholders at the national level: Abidjan and Mafere in Côte d'Ivoire, Bamako and Kati in Mali, Dakar and Thies in Senegal. These sites were also the implementations ones. Since it is not a representative study, the study results could be useful.

Participants

Mapping of HTS stakeholders was carried out with the local ATLAS implementation teams to identify study participants, who received an invitation letter from ATLAS program, inviting them to take part to a study on HIVST perceptions. They were selected because of their good knowledge of key populations and their relationship to HIV and health. All chosen participants were fully involved in the coordination or delivery of HTS to key populations. On this background, they have been identified on a personal title or by their respective structures. Thus, the research team managed a meeting with them for the interview.

Data Collection

Individual face-to-face interviews were conducted by two trained interviewers: the field research coordinator (MPH, PhD), and a local research assistant in each country (PhD candidates (Sociology) in Côte d'Ivoire and Senegal, Master (sociology) in Mali. A semi structured interview guide was used. Interviews took place in participants' offices, community life spaces (public services, NGOs/associations) or homes. Four participants were not available for face-to-face meetings and were interviewed by telephone (one NGO responsible in Côte d'Ivoire, one health provider and one from the national AIDS program in Senegal, one health provider in Mali). Three participants from the urban area were not interviewed because they were traveling for work (one from the Ministry of health in Mali, one NGO responsible in Côte d'Ivoire) or was on vacation (one in Côte d'Ivoire). They were not replaced because data saturation is observed in each country by the field research coordinator. The interviews, which lasted from 45 to 60 min, covered participants' attitudes and perceptions on (I) opportunities, difficulties and obstacles to the introduction of HIVST and HIVST support tools in the three countries' health system and community-based organizations; (II) difficulties and obstacles linked to secondary distribution; (III) specific difficulties and obstacles for each key population; (IV) support tools for users and links to confirmation testing (advice, hotline, and support tools); and (V) adjustments and recommendations for key populations. The identification of the topics was based on the literature contents at this time, the authors' knowledge on the study context and the needs of the ATLAS project. For this paper, the analyses focuses on data related to topics I to III and V.

Data Treatment and Analysis

Interviews were audio-recorded, translated where necessary, transcribed by each country research assistant, and anonymized to ensure confidentiality. Transcripts were proofread and corrected by the field research coordinator. She designed the coding framework on the basis of the respondents' discourses. Then the transcripts were coded by two researchers involved in data collection (the field research coordinator and one research assistant), who were familiarized with the research subject. First, three transcripts were coded by the two researchers. This process allowed comparison, discussion, correction and agreement on the framework between them. They coded the transcripts, using Dedoose© software (Dedoose.com). A coding report was exported to Word, and a thematic analysis was then carried out code by code by the two researchers, followed by a cross-analysis. Three topics were selected for this analysis: driving factors, Concerns & doubts and the respondents' suggestions. Sub-themes that flow from each of these topics were identified from the respondents' discourses for analysis.

Ethical Considerations

Both the research protocol and the data collection tools have been approved by the WHO and the countries' ethics committees: WHO Ethical Research Committee (2019, August 7th, reference: ERC 0003181); National Ethics Committee for Life Sciences and Health of Côte d'Ivoire (2019, May 28th, reference: 049-19/MSHP/CNESVS-kp); Ethics Committee of the Faculty of Medicine and Pharmacy of the University of Bamako, Mali (2019, August 14th, reference: 2019/88/CE/FMPOS); and the National Ethics Committee for Health Research of Senegal (2019, July 26th, protocol SEN19/32).

The research information sheet was read to respondents before each interview. For face-to-face interviews, all individuals signed a written consent form covering their participation and the audio recording. A copy of the information sheets and signed consents were given to the respondents. Oral consent was obtained from respondents who were interviewed by telephone. Interviews took place in private places, chosen by the respondents, between researchers and respondents only. No name was taken. Interviews were transcribed by the research assistant who participated to the interview, and data were anonymized before codification and analysis.

RESULTS

A total of 60 individuals were interviewed (19 in Côte d'Ivoire, 20 in Mali and 21 in Senegal) through 57 interviews (3

TABLE 1 | Participants' characteristics.

Description	Country			Total (*N* = 60)
	Côte d'Ivoire (*N* = 19)	Mali (*N* = 20)	Senegal (*N* = 21)	
Gender				
Female	9	3	8	20
Male	10	17	13	40
Location				
Urban	16	17	14	47
Other localities	3	3	7	13
Structure				
NGO/association	13	17	9	39
Governmental offices	3	1	11	15
International organizations	3	2	1	6
Role in HTS				
Peer educator/mediator	5	3	3	11
Other responsibilities	14	17	18	49

interviews were conducted with two participants simultaneously; see **Table 1**). One-third were female (20/60), and most of them lived in the main cities (47/60). Among all the participants, 15 were from public services (national AIDS programs, ministries of health), 6 were from international organizations (United Nations system, research institute), and 39 were from national or international NGOs. Of these, 11 were MSM, FSW or PWuID peer educators involved in HIV prevention and testing services for key populations.

Three mains topics emerge of the data analysis: factors driving the introduction of HIVST in these countries; the stakeholders' concerns, fears and doubts; and their suggestions for the implementation of the project in their contexts. Each of these themes is outlined by sub-themes.

Factors Driving the Introduction of HIVST in These Countries

From respondents' discourses, there are many motivations for HIVST introduction in their countries, which could be classified in categories: less stigma, testing hard to reach key population, removing spatial barriers of testing, an alternative tool for usual strategies testing refusers, empowerment of key population and strengthening health and Community system.

In Côte d'Ivoire, Mali and Senegal, HIVST raised hopes among the stakeholders interviewed, as it was expected to improve knowledge of HIV status among key populations. All participants had a favorable attitude toward its integration into national systems as a strategy for key populations. In their view, its advantage was that it removed the obstacles to testing by diversifying offerings and encouraging innovative strategies to achieve high diagnosis coverage. These favorable attitudes were based on interviewees' positive perceptions of HIVST at several levels.

HIVST May Minimize Stigma and Protect Anonymity and Confidentiality

The most crucial advantage of HIVST perceived by most respondents in all three countries was its protection of anonymity and confidentiality. In all the countries, but especially in Senegal, respondents stated that key populations, especially MSM and PWuID, fear the stigma they may face in community organizations or in health facilities because their behavior or identity is outside of accepted social norms. Stigma impedes their uptake of HTS. An HIVST could help mitigate these barriers because it is anonymous. Members of key populations would not have to fear being identified by providers or other users of these services, as their identity cannot be recorded when using HIVST.

> (Usually), upon going to the facilities, people are registered, as they have come to be tested. Anonymity is, therefore, immediately lost (Medical doctor, key populations care provider, NGO, Mali).
>
> We know many (PWuID) on the ground, but we have difficulty getting them to come to (name of the structure)… The more stigmatized they are, the more they stigmatize themselves (Medical doctor, PWuID care, governmental office, Senegal).

Also, through HIVST, it may be possible to better protect the sexual networks of members of key populations, as they themselves interact with their partners for secondary distribution without the intervention of providers.

> *In the case of the usual rapid test, the peer educator must be present, and assistance is needed. In contrast, in the case of HIVST, people are free to reach their hidden partners. There is much more confidentiality and discretion (Program officer, NGO, Senegal).*

Finally, usual outreach strategies can help people avoid having to visit facilities, according to respondents in all three countries, some key populations, especially MSM and PWuID, are concerned that HTS providers, especially peers, may know or discover their HIV test results. The HIVST could respond to their need for a higher level of confidentiality. The testing process can be conducted in private, without the involvement of a third party, since the testing, results, care and treatment sites are known only to the user. This tool may encourage people to learn their HIV status and thus improve testing uptake.

> When we take the key populations… When the peer comes, they refuse because maybe there is this lack of confidentiality: will the peer not disclose my result and everything. If they are offered a self-test, they will quietly go home and do the test (National stakeholder, governmental office, Côte d'Ivoire).
>
> So when we take the specific case of key populations, they are much more afraid of their peers than of the community… because it's a closed environment, everyone knows each other, so there is a real fear that the status will be known in the environment and the risk is that they will no longer have sexual partners (Medical doctor, key population care facility stakeholder, Mali).

HIVST May Help Reach Key Populations That Usual Strategies Cannot Reach

The main advantage of HIVST, as expressed by participants from all three countries, is the opportunities it affords for secondary distribution. According to them, it may allow the detection of undiagnosed PLHIV, particularly FSW and MSM, who cannot be reached through the usual strategies for various reasons: (1) they do not identify themselves as belonging to any key populations; (2) they refuse to visit governmental facilities or community-based organizations because of stigma or self-stigmatization; (3) they do not present themselves as belonging to key populations or are hiding; and (4) they are reluctant to get tested through the usual strategies. Specifically, concerning FSW, such people may include their partners and clients and "clandestine FSW," who often refuse usual HIV testing for fear that their results will be made known to providers or to their peers.

> A FSW who comes, if she agrees to do the test you will find that she has her sexual partner… But he refuses to be tested. We explain it to her, we give her the kit, and then she can go and give (it to) the partner (NGO responsible, Mali).

Hard-to-reach MSM mentioned by the respondents included those with high social status, who are older, who are married (to women) or who have certain social or professional responsibilities.

> There are many tops (insertive sexual role), but they don't think of themselves as MSM. They are men, they have their girlfriend and they always come to us, they date (have sex) with us. They really love us; they are always with us. And if there's anything else, they do it with their girlfriends. In any case, they don't consider themselves MSM (MSM peer educator, Senegal).

Finally, according to some respondents, providing HIVST could be an opportunity to facilitate index testing among key populations.

HIVST May Remove Spatial Barriers to HTS and Save Time

Participants in all countries found that HIVST prevents key populations from needing to go to health facilities or community-based organizations, i.e., it saves time and reduces travel costs.

> When they want to do HIV testing in a health facility, they must go there. They spend money to go, they spend money to come back and they use their time too; but with HIVST, they can do it with their FSW friend (field coordinator, NGO, Mali).

In addition to saving transport time, HIVST eliminates time spent in health facilities or community-based organizations waiting to be tested or to receive results. From the perspective of the participants from Côte d'Ivoire and Senegal, this advantage seemed to be more beneficial to PWuID.

> As for testing activities I participated in, almost an hour was needed to find out one's status. Time is precious for a population like PWuID because they are constantly looking for money to solve their problem. If you keep such a person for more than 2 h, it may bring trouble (Peer educator, PWuID, Senegal).

For FSW, according to some respondents, HIV testing through outreach strategies has limitations. Its inconvenience for FSW is their lack of availability at sex work sites. HIVST introduction could help to mitigate this problem, as long as FSW could take the kits home and test themselves later.

> Specifically, for FSW, when you arrive at the venues, you know they are looking for clients, they do not necessarily have the time to test. Providing them with self-testing kits will save them time and also prevent them from losing clients who are waiting for them (International NGO Responsible, Senegal).

HIVST May Be an Alternative Tool for HIV Testing Strategies

According to HIVST providers from community-based organizations, especially in Mali and Côte d'Ivoire, HIV testing refusals are not uncommon during outreach activities. Having an alternative solution, such as HIVST, for key populations who may decline conventional testing could boost the morale of peer educators because they will be less helpless in such situations.

> We'd come back and it was not too quiet because we'd come back and there were other people who refused the classic test. It's rare to go out (in the field) and you really don't have anyone who has never had somebody refuse the classic test. So when you have an alternative for that… (Medical doctor, field coordinator, Mali).

Beyond providing an alternative when faced with refusals, HIVST could be used to compensate for the lack of HTS provision to key populations when certain social situations do not allow in-person meetings, as reported by a participant from Senegal. He referred to the national context at the time of data collection, where media and public opinion were overtly hostile to MSM, preventing them from accessing health facilities.

HIVST May Empower Users by Giving Them Autonomy and Responsibility

The interviews with participants also revealed their perception that HIVST empowers key populations by making them responsible for their own health because they are free to choose where and when to carry out HIVST, without any pressure from HTS providers.

> There is autonomy, i.e., I'm not the one who's going to say OK, we'll do it now; you're autonomous, you have your test, if it's in the evening, it's daytime, tomorrow, the day after tomorrow, so you're independent (Medical doctor, field coordinator, Mali).

In addition to choosing the place and time of testing, key populations are fully empowered because they perform the test themselves, interpret the results, and then choose a care facility for confirmation, independent of any community or health provider. In Senegal and Côte d'Ivoire, this empowerment would give members of key populations a role as HTS actors in the sense that, in the context of secondary distribution, they could raise

awareness among other members of their entourage and offer HIVST kits.

> It allows them to participate as well, since they have to send the HIVST to their partners and others who are not there. So, they can be at the heart of the project, participate in the project as well (Program manager, NGO, Côte d'Ivoire).

Stakeholders stated that HIVST is a solution for key populations, particularly certain FSW whose partners do not allow them to visit HIV testing facilities. It allows them to learn their status independently of these partners.

HIVST May Help Strengthen the Community and Health System

In all three countries, according to some participants, the introduction of HIVST is a way to strengthen community-based organizations, a tool that will enable them to extend testing strategies and reach the "first 90." They state that it will also provide an alternative in the eventuality that key populations decline testing, notably for reasons of confidentiality. In Mali and Senegal, the economic advantages of this strategy were pointed out, as HIVST does not require mobilization of a full testing team for outreach activities. Finally, HIVST is safer, as outreach personnel avoid contact with body fluids to which they may be exposed in the context of their HIV testing activities.

In Côte d'Ivoire and Senegal, participants noted that HIVST does not require qualified personnel, and its introduction could help relieve the pressure on health facilities if the cases they receive are only reactive cases requiring confirmation. This strategy could help to address the lack of skilled human resources in health facilities and allow health providers to delegate HIV testing to others and thereby have more time for care.

> If I have to do 20 tests a day, I can't get away with it when I have other things to do. Therefore, it frees up time to deal with other diseases, other patients (Medical doctor, PLHIV care, Côte d'Ivoire).

Oral HIVST May Be Appreciated for Being Non-invasive and Easy to Use

Informants, especially those from Mali and Senegal, mentioned the test's oral nature, which may facilitate the uptake of HIVST by key populations, especially MSM and PWuID. Some people may decline traditional testing because of the collection of blood, which can be painful and exposes users to the sight of blood (Notably, in West Africa, most PWuID smoke the drug; few inject it).

> As far as PWuID are concerned, they are a bit resistant to taking blood too… Some refused to have their blood taken for testing. So having another strategy that doesn't use blood, for me, it's something that will really solve an important gap in this system (HIVST provider, public office, Senegal).

The availability of an oral test may allow HTS to be offered to key populations who would refuse the test because of the anticipation of pain during blood collection or because of fear of seeing blood.

Concerns and Doubts About HIVST Use by Key Populations

Though most participants are enthusiastic, have positive perceptions of HIVST and present a favorable attitude toward its introduction, interviewees in all three countries have questions, doubts or concerns, most of them related to the abilities of members of key populations (**Figure 1**). These stakeholders' concerns are summarized in five questions: HIVST kit retention, key populations' capacities to distribute HIVST kit, to perform it correctly, to manage themselves in case of reactive result. Finally, they wondering how to measure usual HIV testing indicators.

With the HIVST Kit in Hand and Without Supervision, Will Key Populations Use It?

Within the ATLAS framework, in primary distribution, the HIVST kit is given to users for their own use, with or without a provider's assistance. They also benefit from counseling and audio-visual or written support to them help with the test and with connecting with care. Some respondents have doubts that the HIVST kit will actually be used without provider assistance. These doubts were most often expressed by participants in Côte d'Ivoire and Senegal. According to these stakeholders, the fear of discovering a reactive HIVST result can hinder HIVST use. Use might also be low in *situations* where the user has not fully understood the procedures for performing the test or where the user is not confident and has doubts about his or her ability to perform it correctly.

> Even when the distribution is done well, they say to themselves that they can't hold that because they will be alone at home; open it, put the tube, put the other tube, take something, take the saliva from the mouth, put it in the diluent and then read the result. It's too long compared to putting a finger on the Determine© (traditional rapid HIV tests) or the Stat-Pak© and then they read the result (Field coordinator, Côte d'Ivoire).

These doubts are more substantial regarding PWuID, as respondents feared that when performing HIVST, users might not have the full mental capacity to comply with HIVST instructions.

Once They Have HIVST Kits, Will Key Populations, Without Supervision, Ensure Secondary Distribution?

For secondary distribution, one or more HIVST kits are given to identified key population members to be redistributed to their partners, peers or clients. Some stakeholders expressed doubts, especially in Côte d'Ivoire, regarding the ability of key population members to redistribute HIVST kits. From their perspective, to redistribute HIVST, it is necessary to have good knowledge of HIV and basic HIV counseling information. They worried that some primary contacts might not be able to assimilate all the information delivered during primary distribution (particularly regarding how to perform the test and the importance of confirmatory testing) and share it correctly with their secondary contacts.

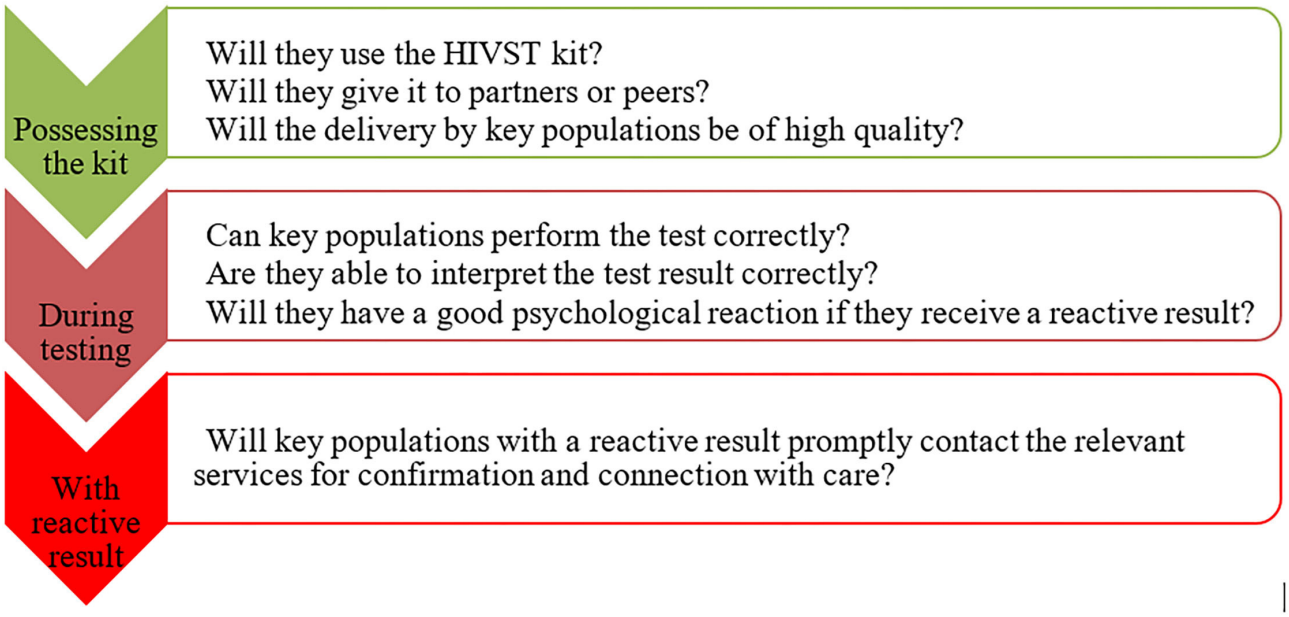

FIGURE 1 | Participants' main question concerning the use of HIVST by key populations.

> My main concern is about secondary targets. It won't be all the FSW or all the MSM who will receive HIVST kits who will be able to really pass all the information back to secondary users (Hotline manager, Côte d'Ivoire).
>
> For HIVST, if an FSW gives the kit to her partner, she will briefly explain to him the procedure and all that, but I mean she doesn't have all the information to manage the result announcement and then the partner will have to face his result alone (National NGO stakeholder, Côte d'Ivoire).

Members of key populations that are not confident may avoid raising the subject with partners or peers to whom HIVST kits should be provided. Doubts about the technical capacity to ensure correct delivery of HIVST to partners were more pronounced for FSW and PWuID than MSM.

In a context of prevalent HIV/AIDS stigma, where having or offering an HIVST kit can be associated with being a PLHIV, some participants feared that FSW's or MSM's willingness to redistribute an HIVST kit to their regular partner might be limited.

> She (FSW) refuses to give it to her boyfriend she is dating, for fear that he might suspect her. I'm going out to help my family, I'm not doing it for anything else; I don't want to have another problem there. What I'm doing here is also a concern, so I don't want to create more problems (FSW social support provider, Senegal).

Some respondents expressed concerns regarding the ability to redistribute HIVST kits of individuals who face social and economic vulnerabilities. This would potentially be the case among FSW who fear their partners' reactions because they do not know that they engage in sex work or know that they engage in sex work but otherwise manage the FSW's money and have influence and authority over them by protecting them at sex work sites. Regarding clients, fear of losing them by openly discussing HIV may limit the willingness of FSW to redistribute HIVST kits to their clients.

> The main difficulty I see is the boyfriend, the regular client and not the occasional client, because among these clients there is one who is not a client (...) who is the partner, who is the concubine, who is the husband, has power that you can't even imagine. When you agree to have sex with a man without a condom, because you are so weak that you must negotiate the use of a condom, I ask myself the question: will that person have the audacity or the ability to get his partner to take the test (Program manager, International NGO, Senegal)?
>
> Because it can put them in a dangerous situation (FSW) in terms of their own status and if they give out a self-test to their clients; they will think that they are positive and that will create a problem in their business and it can expose them as well (Researcher, Côte d'Ivoire).

The fear of partner misreactions could also limit the willingness of MSM to offer HIVST to their partners.

The situation could be more complicated for members of key populations living with HIV. Some respondents expressed doubts that HIVST kit redistribution would be optimal in such a situation, given the low level of HIV status disclosure among couples in these countries.

> The problem is disclosure of HIV status. How do I bring a self-test home, which I can give to my partner, who is not informed of my status? What question is he going to ask me, how do I answer this question: 'Where are you coming from? What did you do in this facility to get a self-test? What could you say about me there?'

> I think that's what might be blocking the thing (Medical doctor, PLHIV care, Côte d'Ivoire).
>
> PLHIV often do not share their status with their partner; first difficulty. If you don't share the status with your partner, how can you come and tell him or her to do the self-test? It's quite a job; people are reluctant to share their status. In this respect alone, others will not adhere because they are not aware of the information (HIV focal point, public office, Senegal).

According to these respondents, the consequences of such situations would be the retention of the kits by key populations, the dissimulation of the nature of the test to the partner, a poor quality of distribution that could lead to non-use because the user would not understand the message or feel unable to perform the test, or a test that is performed without correctly following the instructions for use.

Will Users Be Able to Perform HIVST Correctly?

Although there are support tools for HIVST, including videos, a few respondents expressed doubts about the ability to perform the test and correctly interpret the results of members of key populations who are unable to read instructions.

> If a person is illiterate, even though it has been translated into the national language with the video inside, it can be a barrier in any case. Maybe they're not going to do it well, maybe they're not going to interpret the results properly, maybe they don't know if they have the results, what about these results? Is it reactive? What must he/she do, and so on (Medical doctor, key population care, Senegal).

These doubts mainly relate to secondary distribution. According to the participants, these concerns are less important for MSM than for PWuID. Misuses of the test or reading errors could produce false results. This could have negative consequences, including the discrediting of HIVST, which could negatively influence key populations' adherence to this innovative strategy.

> This means that people should not make mistakes in using the test. At this level, if the test is not well-performed, it can generate errors and doubt about its effectiveness, although the requirements have not been met (Medical doctor, key population care, Senegal).

Concerns that PWuID would not be able to perform HIVST properly were minimized by a peer educator and a key informant who has many years of experience providing various services to PWuID. They claimed that PWuID have the intellectual capacity to perform the test and would not be continuously under the effect of drugs.

Will Users Be Able to Self-Manage in the Case of a Reactive Result?

Referring to the usual strategies, where HIV test results are reported by a trained provider who has the appropriate tools and skills to do so, some participants expressed concerns about the reactions that members of key populations might have when confronted with a reactive HIVST result in a context in which they are alone.

> Some people might find out their HIV status, be confused, be disoriented, be unable to make the right decision (Medical doctor, key populations care, Mali).

For these participants, counseling is one of the decision support tools that HIVST lacks, particularly when HIVST is administered at the secondary level by key populations rather than providers. They claim that without quality counseling, denial of results may be much greater than when using usual strategies.

> We, we offer the classic test, and there are some positives even that are in denial. He knows his status and you know it. In spite of that, he denies it (Peer educator, MSM, Côte d'Ivoire).

On the basis of their experience with usual strategies, peer educators expressed some additional concerns about "losing" some positive people between HIV testing and care services. In Côte d'Ivoire and Mali in particular, interviewees questioned the strategy of systematic confirmation of reactive tests when key populations would not benefit from their support.

> When the test is reactive, do they have the strength, the courage to go for a confirmatory test (Hotline manager, Côte d'Ivoire)?
>
> Because it is precisely the person concerned who interprets the result! It is he himself who can go get confirmation. If he decides not to get confirmation, what we want to achieve, it's going to be really difficult to reach it (Stakeholder, public office, Mali).

However, some participants thought that, whether in the short-term or long-term, key populations with a reactive test would ultimately obtain confirmation of their results at some point.

How Will Their Work Be Acknowledged Without the Usual HIV Testing Indicators?

HIVST's unique feature is that it allows users to determine their HIV status privately, without the provider if they so desire. While respondents mentioned this as one of the strengths of this new strategy, they seemed to be somewhat disappointed with the lack of information about the HIV test results, both at the individual provider and program levels.

At the individual level, from the providers' perspective, without awareness of members of key populations' HIVST results, they cannot fully play their usual role in monitoring and supporting them.

> Usually, providers want to have people's test results… The important thing is that in the end, either the person enters a process where he/she will be aware of his or her HIV-negative status and adopt safer behaviors, or the person is HIV-positive and the provider will fight to get him or her into care and have his or her viral load suppressed (Medical doctor, NGO responsible, Côte d'Ivoire).

On the other hand, across the 3 countries, there were lay providers who were rewarded by some NGOs based on their performance results. Such recognition is essentially related to the number of PLHIV that they have identified. Without any feedback on HIVST results from members of key populations,

peer educators mentioned that the assessment of their individual performance could take into account the number of PLHIV identified through this new strategy.

Finally, at the program level, in all three countries, participants regretted that statistical data on their individual and programmatic efforts in providing HTS through HIVST would not be available, neither the numbers of key population members reached and tested, nor the number of HIV positives detected and linked to care services. This issue was important mainly for respondents from AIDS councils and other NGO stakeholders.

> How to capture the impact, I will say the national result? It's true that we can rely on the fact that, if we see that at the national level the numbers of positives are increasing, we will certainly say that it is HIVST that has brought something. But I mean, the difficulty is to know the real impact, to be able to measure the impact on the result (stakeholder, government office, Côte d'Ivoire).

Among the five matters of concern expressed by stakeholders, four are related to the ability of users to perform HIVST, while one is related to data management in the health system.

The Participants' Suggestions in Relation to the Perceived Abilities of the Members of the Key Populations to Use and Distribute HIVST

In response to their fears and doubts about HIVST use by key populations, some participants considered that the monitoring of HIVST kits should be more active. They proposed diverse solutions and complementary interventions: a physical support to key population who need it, follow up of HIVST distributed, reference of key populations with reactive results to lay providers for test confirmation, and more communication on HIVST at the national level.

To respondents, providing direct support through counseling to people who have been given an HIVST kit until the testing process, may be useful, especially for PWuID. According to them, this would help to ensure high test quality and psychological support for users with a reactive test result.

Additionally, with the aims of helping members of key populations perform the test, providing them with moral or psychological support in the case of a reactive test result, and supporting them in accessing confirmatory testing and care services, some participants suggested that HIVST providers should perform post distribution follow-up with users and secondary providers.

> It's up to the community-based providers to exert more effort, to really get involved in the task. It's not to track people who have a reactive result but to do more listening to look for possibilities of feedback (on test results). For example, a provider who gives HIVST kits to an MSM group, to go (after) and ask "Do you have any problem?" to try to get some feedback so these reactive cases do not escape care services (Medical doctor, NGO stakeholder, Mali).

This is already done by some MSM and FSW peer educators who took part in the survey.

> Anyway, I call them with my other phone number because I have a professional number. So I always call people on that, and if I deliver them (HIVST kits), there are people who call me and there are people I call back. So this number is always available (Peer educator, MSM, Mali).

To minimize the fear of stigma related to visiting health facilities, some participants suggest that key populations wanting to do so should be given the opportunity to present to lay providers who are already performing usual testing for confirmation of reactive results.

> But I think there is some complicity between key populations and lay providers; and the level of confidence between them is higher than between key populations and health workers. So if possible (we should) emphasize much more that confirmation of the status of the person (should be done) through the lay provider who is already able to do HIV testing to confirm the status of the person (Medical doctor, NGO stakeholder, Mali).
>
> He received the HIVST, for example, he takes the test and then despite having taken the test, he still doesn't want to go to a center for confirmation. A peer can go to him/her if he/she gives us the opportunity to touch him/her so that we can do the confirmation test (Hotline manager, Côte d'Ivoire).

Finally, according to stakeholders, more communication on HIVST at the national level is needed. This would (1) inform people more widely about HIVST and empower those in need to seek HIVST kits, (2) facilitate the task of the providers, as potential users would be more informed and trained in the use of HIVST beforehand, and, (3) in the context of secondary distribution, catalyze communication on HIV and testing within couples. Social networks have been proposed for promoting HIVST among key populations.

> Everybody without exception, whether it's MSM, whether it's FSW, today everybody is connected to social networks. Everyone has a phone. Everyone wants to keep up with the new technology. So it's a way to really reach a lot of people among key populations and also to make self-testing widely known (Stakeholder, public office, Mali).

DISCUSSION

In Côte d'Ivoire, Mali and Senegal, stakeholders who took part in the study did not have any experience with HIVST before ATLAS program implementation. Their perceptions and attitudes were a mixture of enthusiasm and reservations and are based on their specific knowledge and experience of their countries' contexts and key populations.

The Stakeholders' Attitudes and Concerns vs. Those of Stakeholders in Other Contexts

Various studies on HIVST perceptions and attitudes have been conducted among stakeholders in many countries like Tanzania and South Africa and have also found favorable attitudes toward HIVST (24–28). Our findings show that even in a context with lower HIV prevalence, such as the study context, there is enthusiasm about the introduction of HIVST for most at-risk populations. The motivations for integrating HIVST are both operational (ease of use, time savings, reduced transport costs, complementarity to usual strategies, relieving congestion in health facilities) and social or health-related (stigma reduction, anonymity and confidentiality, user empowerment, ability to reach hidden populations). However, as an innovative strategy that has never been implemented on a wide scale in these countries, HIVST raises questions, doubts and fears, which were also described in other perception analyses. In Southern Africa and elsewhere, authors have described informants' reluctance to integrate HIVST, which is mainly motivated by the lack of counseling (24–26, 29) doubts about the reliability of the results due to users' inability to perform the test themselves (24, 25), and fear that the link to care may be weak without HTS provider involvement (24, 26). This favorable attitude is a key factor for the introduction of HIVST in these countries, while ensuring that the concerns of the stakeholders are addressed.

Maintaining Confidentiality and Doubts About Access to Care and Support Services

Perceptions and attitudes in favor of HIVST in our study were mainly related to confidentiality and anonymity. These are the primary motivations for HIVST acceptance found in other perception studies like Ethiopia and South Africa (25, 30, 31). HIVST makes it possible to bypass health facilities or community-based organizations, reducing the risk of stigmatization (24, 30). It improves the provision of HTS for people who are afraid of attending health facilities or who may fear unwanted disclosure of their HIV status (25). This is relevant in the West African context, where PLHIV and key populations are even more stigmatized than in countries with a higher HIV prevalence (2, 18, 31). A pilot study in Senegal found that HIVST is an effective strategy for reaching key populations who have never been tested or who are reluctant to be tested (32). However, the observed perceptions that some subcategories of key populations, such as clandestine FSWs or hidden MSM, would be more concerned than others about HIVST seem to be little discussed in the published literature.

In the context of high stigmatization of key populations, doubts about their willingness to connect with care were found in this study. Connecting with confirmatory and care services following a reactive HIVST result is perceived as a challenge in almost all studies (24, 27, 33, 34). However, according to the WHO, people who used HIVST have the same link-to-care practices as those tested with providers' support (18). A previous pilot study in Senegal found that 57% of key population members with a reactive result used confirmatory services (32). This rate is higher than that for home testing followed by referral by a provider (35, 36). These findings should be used to promote HIVST in the countries.

Perceived Empowerment but Little Trust in the User

The potential autonomy and empowerment afforded by HIVST, as foreseen by stakeholders in our study, has been described as a favorable factor for HIVST integration into HIV testing strategies (34). In South Africa, these were perceived as the main benefits of HIVST by women, whereas men preferred HIVST due to its convenience and efficiency (37). As part of index testing, HIVST contributes to empowering women who are HIV-positive to manage their health (38). Stakeholders' perception of the user as both a beneficiary and an actor when engaged in secondary distribution contributes to key population empowerment by HIVST, an aspect that has not been highlighted in previous studies outside of the study context. Reasons for users' low capacity to perform HIVST themselves have been analyzed in other contexts. A study consisting of video surveillance of unsupervised HIVST in Kenya, Malawi and South Africa showed that the main difficulties were related to the collection of biological samples and the interpretation of the results, as $\leq$25% of the participants correctly followed all the steps indicated (39). Misinterpretation of the results and difficulty understanding instructions were also noted by Wolyec et al. in the Democratic Republic of Congo (40). However, Asiimwe et al. have showed that unsupervised HIVST is feasible in a rural African context, with comparable results to supervised testing (41).

Illiteracy was described as a potential barrier to HIVST uptake in Africa (24, 34). Considering the analyses that highlighted the inadequacy of the manufacturer's instructions to support correct performance of HIVST, especially by illiterate people, support tools were developed through cognitive and reiterative tests within the ATLAS program to adapt them to the implementation countries. An assessment found that, without the manufacturer's instructions, these adapted tools were sufficient to allow users to perform HIVST correctly (42). Stakeholders' inadequate knowledge about these preparatory procedures may have influenced their perceptions of this aspect, which can be more deeply analyzed after effective HIVST distribution in the implemented countries.

HIVST reticence was more pronounced regarding secondary distribution due to the absence of provider support throughout the process. However, stakeholders perceived HIVST secondary distribution as the best strategy for the hardest-to-reach key populations, thus accelerating the achievement of the first 90. Uncertainties about the ability of primary contacts to assure good counseling to end users have also been described elsewhere (43). However, secondary distribution to partners has been carried out successfully in the context of couple testing, health workers (43, 44) and among MSM (45, 46). Gender norms and power imbalances could negatively impact the ability of a woman to propose HIVST to her male partner, as mentioned in our study regarding FSW and as observed in other studies among pregnant

women (33). Providing tips to primary contacts so that they have the necessary capacity to inform, negotiate and offer the HIVST kit remains essential for secondary distribution. This requires individual discussion between the providers and the primary contacts, not only to assess their HIVST knowledge and skills but also to discuss the relationship between the primary contact and the end user and provide adapted instructions for effective delivery without major adverse events.

Among the three key populations, stakeholders expressed the greatest concern for PWuID, for whom the ability to use HIVST is almost absent in the literature, to our knowledge. Further analysis is needed to understand if this concern is expressed by stakeholders who usually work with this key population and whose opinion is based on experience or if it relies on social representations focused on subcategories of PWuID, such as people permanently on heroin. This practice is uncommon in our context.

In response to their own concerns about the capacity of key populations to use HIVST, study participants made suggestions. These include (a) providing overall communication about HIVST to the general population, (b) ensuring direct assistance to HIVST users or follow-up after kit delivery, and (c) ensuring that there are close links between key populations and providers to whom they can come for confirmation and care if they so desire. Strengthening communication as a strategy for raising awareness, promoting HIVST and creating demand was also recommended by stakeholders in Haiti and Rwanda (33, 47). Such communication could facilitate both primary and secondary HIVST distribution. However, while support for testing and care by lay providers is useful, the requirement for direct assistance or systematic monitoring of kit distribution could be counterproductive. It could reduce the privacy offered by HIVST and users' autonomy, recognized by most study participants as a major advantage of this strategy. In this regard, the definition of support interventions that do not infringe on users' autonomy may depend on previous contexts for HTS and relationships between key population communities and health teams or peers educators and should be adapted at the national or site level.

Overall Trends

Little difference was observed across the three countries, but all countries showed slight differences compared to the study results obtained from Eastern and Southern Africa. The importance of HIV stigma was highlighted by stakeholders, who pointed to the risk that HIVST users with a reactive result could be stigmatized within communities already stigmatized for "deviant behavior" as key populations: HIV stigma is considered by stakeholders as a barrier to HIVST uptake. Additionally, the importance of HIV stigma may explain why disclosure of HIV status by users to their partners is considered a main barrier to secondary distribution. Finally, the study results show that according to stakeholders, this determinant, which is unspecific to HIVST, may be a main barrier to HIVST efficiency. Stigma may also explain differences in issues identified by stakeholders in those countries compared to Eastern and Southern Africa.

Finally, although the study was focused on difficulties of HIVST integration for users, a crucial aspect was mentioned by stakeholders in all three countries. If HIVST protects users' anonymity, its use or the result of the test is not always known by providers. Therefore, and contrary to traditional HTS approaches, it is not possible to directly measure utilization or the positivity rate. It seems that providers feel they are losing power. In a context where international donors usually evaluate the efficiency of their programs using such quantitative indicators and where stakeholders are strongly encouraged to collect them, peer educators and program heads expressed trepidation regarding the assessment and recognition of their effort. To a certain degree, HIVST is a paradigm shift that requires the revision of evaluation tools and reflective exchanges among HTS stakeholders, program managers and funding institutions to overcome this potential obstacle to the promotion of HIVST based on user empowerment.

As found in other studies, these results suggest strongly the feasibility of HIVST in the study's context, where HIV prevalence is globally low, and key populations are highly stigmatized. Indeed, stakeholders are favorable for HIVST introduction in these countries, even if some reluctance has been expressed. These reserves should be minimized by providing data on the ability of "non-professional" and illiterate people of these countries, to self-test with ATLAS adapted tools, also in rural areas. HIVST must be part a strategy for key populations testing in these countries.

Study Limitations

This qualitative study may be one of the first to provide information on the perceptions and attitudes of key HTS stakeholders in French-speaking West African countries. Participant selection in each country took into account interviewees' field experience and knowledge of HTS derived from various roles at several levels, in urban and rural areas. However, the study was conducted at the initiation of HIVST, and the collected perceptions were based on anticipation and may be influenced by social representations: they did not describe actual issues in the field. Stakeholders' perceptions may change during HIVST implementation. The results cannot be generalized to all HTS stakeholders in the three countries. Though these considerations do not correspond to the definition of a study limitation, we consider that it may be useful to emphasize that stakeholders' perceptions, which do not strictly reflect reality, must be considered for strategic introduction and integration of HIVST within the health system.

CONCLUSION

In the three countries, HIVST is a strategy generating interest in improving key populations' access to HTS. Stakeholders' perceptions and attitudes are favorable to the introduction and integration of HIVST for several reasons. HIVST is considered to reduce stigma; preserve anonymity and confidentiality; reach key populations that do not access testing *via* the usual strategies; remove spatial barriers; save time for users and providers; and

empower users with autonomy and responsibility. It is non-invasive and easy to use. Also HTS stakeholders have expressed concerns about users' ability to perform the test correctly; to ensure quality secondary distribution; to accept a reactive test result; and to use confirmation testing and care services. These results suggest strongly the feasibility of HIVST in the study's context. Providing to stakeholders, data on the ability of "non-professional" and illiterate people of their countries, to self-test could be useful.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author/s.

ETHICS STATEMENT

This study involving human participants was reviewed and approved by the WHO and the countries' Ethics Committees: WHO Ethical Research Committee (2019, August 7th, reference: ERC 0003181), National Ethics Committee for Life Sciences and Health of Côte d'Ivoire (2019, May 28th, reference: 049-19/MSHP/CNESVS-kp), Ethics Committee of the Faculty of Medicine and Pharmacy of the University of Bamako, Mali (2019, August 14th, reference: 2019/88/CE/FMPOS), and the National Ethics Committee for Health Research of Senegal (2019, July 26th, protocol SEN19/32). The research information sheet was read to respondents before each interview. For face-to-face interviews, all individuals signed a written consent form covering their participation and the audio recording. Oral consent was obtained from respondents who were interviewed by telephone.

AUTHOR CONTRIBUTIONS

OK-Z, AD, NR, and JL: conception or design of the work, interpretation of data for the work, drafting the work, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. DP, SB, AV, and MM-G: contributions to the conception and design of the work, drafting of the work and revision for important intellectual content, and approval of the version to be published. AK, SS, SC, and SY: contribution to the data collection, drafting of the work, and revision for important intellectual content. All authors have read and approved the final version of the submitted manuscript.

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Linkage to care and treatment among men with reactive HIV self-tests after workplace-based testing in Uganda: A qualitative study

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Introduction: HIV self-testing at workplaces has the potential to reach men at risk of HIV infection with lower access to HIV testing services. While several studies have reported high uptake of HIV self-testing, linkage to HIV care following a positive result remains a challenge. This study, therefore, explored the motivators for and barriers to linkage to HIV care and treatment among men who returned positive results following workplace-based HIV self-testing.

Methods: A qualitative descriptive study, among men in private security services in Kampala district, Uganda. The men were eligible to participate if they were aged 18 to 60 years and had worked at the company for more than 6 months. Following HIV self-testing, participants with reactive (positive) self-test results were purposively sampled and engaged in key informant interviews. Inductive content analysis was employed to identify the motivators and barriers to the men's linkage to HIV treatment and care.

Results: Overall, 12 men participated in the study, of whom 9 (75%) were security guards, and the rest held management positions. The motivators for linkage to care coalesced under five categories. (i) Communication (open communication, phone reminders, consistent communication) (ii) Navigating health facility systems and processes (enabling health facility environment, easy access to health care, employing ART clinic counselors as part of the study team, health workers) (iii) Linkage support (linkage companions, referral forms, linkage facilitation, individualized linkage plan, pre-arranged clinic appointments) (iv) Psychosocial support (counseling sessions, family support, online and social media support, peer support) (v) workplace environment (employer's support, work schedules and policies). The barriers to linkage to HIV care included (i) Inflexible work schedules, (ii) Far distances to travel to access ART (iii) mandatory work transfers, (iv) disruptive effects of the COVID-19 pandemic, (v) Denial of HIV-positive results and (vi) fear of stigma and discrimination at health facilities.

Conclusion: The findings suggest the need for innovative interventions to facilitate regular follow-up and open communication with workplace-based HIV self-testers, to improve linkage to HIV care and treatment. Furthermore, initiating linkage plans during pre-test counseling and working in collaboration with health facilities and clinics may improve linkage to care.

KEYWORDS

HIV self-testing, men, Sub-Saharan Africa, linkage to care, workplace

Introduction

An estimated 38 million individuals are living with HIV globally (1). Women have historically been more likely than men to take an HIV test or link to care (2). In 2019, the Joint United Nations Programme on HIV/AIDS (UNAIDS) reported that 79% of women living with HIV in Uganda were on HIV treatment, compared to 63% of men (3). Several reasons have been suggested for why men may not engage in HIV testing. Evidence suggests that HIV self-testing (HIVST) may overcome the hindrances that have been reported to the uptake of HIV testing services, including stigma and lack of privacy and confidentiality (4). HIV self-testing at workplaces can further reach men with limited access to HIV testing services and yet are at risk of HIV infection (5). Some of the enablers for the uptake of HIVST include; the ease of accessibility of the self-test kits (6), and the perceived convenience because one can take the test anywhere and at any time (7). Additionally, HIVST overcomes stigma and discrimination, and challenges faced at health facilities since the test is taken privately and independently (8). Furthermore, HIVST assures greater confidentiality of test results than at the health facility (9). Several studies have reported challenges with the uptake of HIVST including concern about the unreliability of tests and low literacy levels about HIVST (10), the anxiety of the repercussions of a reactive test result and the unaffordable cost of the self-test kits (7). Additional concerns raised regarding HIVST include the potential for coercion into taking a test (6). Several studies report recurring challenges in ascertaining and confirming HIVST results (11), and linking individuals to HIV treatment and care following a reactive self-test result (12). While studies have reported high uptake of HIVST in other populations (13–17), linkage to care and measurement of linkage following HIV self-testing remains a challenge (18). We implemented a qualitative study embedded in a clinical trial, to inform the design of future workplace HIV self-testing linkage initiatives, (ClinicalTrials.gov Identifier: NCT04164433) (19). This study explored the motivators for and barriers to linkage to HIV care and treatment among men who received positive self-test results following HIVST in workplace settings.

Methods

Study setting

The descriptive qualitative study was conducted as part of the **W**orkplace-based H**I**V **Se**lf-testing among **Men** (WISe-Men), Cluster randomized trial (Clinical trials.gov ID NCT04164433) (20). In the WISe-Men trial, men working in private security services in two Ugandan districts were offered HIV self-testing or standard HIV testing services at their workplaces. This qualitative descriptive study employing in-depth interviews took place between April and June 2020, at private security companies employing at least 50 men each. We conducted the qualitative study in Kampala district only because this was the trial arm that received HIV self-testing.

Research team and reflexivity

PAM and LEN have expertise in qualitative health research, and all the research team members are health researchers at varying levels of research experience. This qualitative study is nested in the WISe-Men clinical trial; therefore, the research team had an existing relationship with the participants. The participants knew about the overall study and were familiar with the overall and specific objectives of the study.

Study participants and selection

Two months after receiving the HIVST intervention, 20 participants with reactive (positive) HIV self-test results were purposively selected and approached and their consent was sought for participation in this sub-study. Two (2) declined, while one (1) potential participant had a very unstable telephone network which made data collection difficult. Therefore, 17 were eligible for participation in the study, however, enrollment stopped at 12 participants when no new information was obtained from the interviews (data saturation).

Men were eligible to participate if they were aged 18–60 years and had worked at the company for more than 6 months. The

men were engaged in in-depth interviews until a point of data saturation was attained, where no new information emerged from the interactions.

Ethical considerations

Ethical approval was granted by both Makerere University School of Health Sciences Research Ethics Committee (SHS-REC) (Ref. 2018-054), and the Uganda National Council of Science and Technology (UNCST) (Ref. HS 2672). Furthermore, administrative clearance was obtained from the responsible personnel officer at the private security company. Each participant gave individual written consent before enrolment in the WISe-Men trial. Since we conducted phone interviews, the men sent a text message as written consent and gave verbal consent at the start of the interview. Involvement in the study was voluntary and there were no repercussions for non-participation.

In-depth interviews

One-time phone interviews were conducted with the participants during the Coronavirus disease (COVID-19) lockdown period in Uganda (21). Two trained research assistants and PAM made all the phone calls from a private room, on speakerphone and participants consented to an audio recording of the interview. Each interview lasted 45 min to 1 h and employed a semi-structured and open-ended interview guide. The guide was piloted by three men from one security company and their data is not included as part of this study. The questions in the guide sought information regarding what motivated, delayed, or prohibited their linkage to treatment and care, the challenges faced in accessing posttest services, and the men's perceptions on how linkage to treatment and care may be optimized. Field notes were made during each interview. Data collection stopped when no new information (saturation) emerged from the interviews.

Data analysis

The data were transcribed verbatim by PAM and the two research assistants who were involved in data collection. The transcripts of the audio recordings were analyzed in NVivo 12 pro (QSR International) using qualitative content analysis following the procedure by Elo and Kyngas (22). Initially, two team members (PAM and TDN) reviewed the transcripts while continually listening to the audio recordings to ensure that all the information was captured accurately. The transcripts were then read in their entirety to gain immersion into the data and obtain a sense of the whole. The pair undertook the open coding process separately to identify meaningful phrases and codes, and then convened to attain a consensus. Any disagreements that arose were settled by a third member of the study team. The coding team iteratively placed the codes into groups according to the similarity of patterns to form subcategories and then categories.

To ensure trustworthiness and the quality of the data, a sample of the study participants reviewed the categories and subcategories. Interview notes were recorded in the principal researcher's reflective journal for confirmability. Additionally, the degree of congruence attained between the two individuals during analysis provided data accuracy and meaning. Furthermore, prolonged participant engagement during the interviews allowed each participant enough time to express his views. For transferability, this paper provides a rich description of the participants' narratives (23, 24). This paper is guided by the Consolidated criteria for Reporting Qualitative research (25).

Results

Participants' characteristics

Therefore, 12 men participated in the study, of whom 9 (75%) were security guards with the rest in management positions, 4 (33.3%) were aged 26–35 years, 8 (66.7%) were married and 7 (58.3%) had completed secondary education Supplementary Table 1.

Motivators for linkage to care and treatment

The motivators for linkage to care and treatment coalesced around five primary topics: communication, navigating the health facility systems and processes, linkage support, psychosocial support, and workplace environment. The Participant quotations are presented to illustrate the categories and sub-categories. Supplementary Table 2 provides a summary of the coding tree for the motivators for linkage to care.

Communication

Communication emerged as a common thread in all the participant's interviews. Many felt that the open channels of communication and availability of the health workers to respond to their queries motivated their linkage to care. Some also suggested that it was the consistent communication that facilitated this process. The fact that their health providers did not give up on them was critical.

Phone reminders. Many reported that the phone reminders, text messages and the information discussed during the call

played a critical role in the decision to link to HIV treatment and care.

> *I told her* [the nurse] *that I was available to talk only on Saturday evenings. She called me every Saturday to check on me and sometimes it was another person, but the message was the same. When I asked her many questions, she would send me information via WhatsApp after the discussion so that I could do further reading. I finally went after 6 weeks.* (P3, 33 years)

Consistent and regular communication. Initially, some participants found it hard to accept their results, however, the consistent calls and counseling from the research team helped them to come to terms with the result and seek further testing and care.

> *Before the test, the health workers asked us for our phone numbers and permission to call us after we had taken the HIV kit. Two days later, she called me to find out if I had taken the test. I had but was not yet ready to talk. After about a week, she called me again and I was feeling better, so I shared my results. She counseled me and requested permission to make a weekly call. She called me consistently and after 2 months, I was ready to go to the hospital.* (P9, 46 years)

Open channels of communication. The men reported that the health workers kept the channels of communication open which allowed them to seek answers to all their worries and questions. They did not feel pressured to go for further care and felt that they were always in control of their decision.

> *I always felt in control. The nurses did not pressure me at all to go to the hospital. They gave me a special number that I could contact at any time if I had any questions. At the start, I called them every day, but they were very understanding. I liked that openness from them even though they did not know me.* (P10, 51 years)

Navigating the health facility systems and processes

Several studies have previously reported the challenges of navigating health facility processes including long lines and stigma as major reasons why men do not link to care and treatment. In this case, the men reported that the effort that the health workers put in to ensure a smooth transition at the health facility was largely responsible for their linkage to care.

Inclusion of health facility staff on the research team. Several participants found it easy to navigate the health facility, because some of the staff at the hospital were familiar, as they had participated in the workplace testing. This helped with establishing trust and strengthening linkage and retention in care.

> *Some of the staff working at the hospital, were also part of the group that did the testing for us at the office. So, it was easy when I went for treatment because I had already created rapport with the health workers and felt that they were trustworthy.* (P11, 52 years)

Enabling health facility environment. For some participants, the non-stigmatizing environment at the hospital facilitated their linkage to care and treatment.

> *No one was looking at me badly, it seemed like none of the other patients cared why I was there. People were receiving treatment and I felt that this was just another illness with its clinic. It is not what I expected at all. I even told my colleague who was hesitating to go and when he went, it was a similar experience*. (P01, 20 years)

Easy access to care. Limited time to access HIV services was a big concern for many of the participants. Therefore, the short time spent at the facility was a motivator for linkage to care.

> *The referral chit* [form] *was helpful because it had all the information that was required at the hospital. This made the process so much faster for us. All of us who had those pink forms were seen immediately*. I got another test, did some other blood tests, and was started on my HIV medication very quickly. I did not even have to take a sick day because I went home and rested enough to work the night shift. (P12, 36 years)

Trustworthiness of health workers. One of the fears expressed by the men before the test was the potential for breach of confidentiality by the health workers, particularly to their employers. Therefore, when their employers did not mention that they had positive results or treat them any differently, then they felt that they could trust the health workers and seek further care.

> *I was concerned that the nurses were going to tell my boss that I am HIV positive, and I would have denied it. But I went to work for 3 more weeks, and my boss did not say anything. Therefore, it meant that even if I were to visit the hospital, my information would still be safe. So, I went to the hospital about three and a half weeks after the test because I felt that I could trust them.* (P04, 35 years)

Linkage support

The participants appreciated the support that they received in linking to the health facilities. This was in the form of a pre-planned linkage plan, transport facilitation to the hospital, referral forms and the pre-arranged clinic appointments. For

many participants, this was the key motivator for linking to further management.

Individualized linkage plan. Several participants appreciated the creation of a linkage plan during the pre-test counseling session. This plan gave them a clear course of action when they received reactive self-test results.

> *Before receiving the test kit, I met with the counselor and the nurse. We agreed on three possible hospitals I would go to in the event of positive results. Whether I wanted peer support, someone to go with me to the health facility, who I would share my results with and if I was comfortable with the phone to follow up. When I got my results, I was not so confused because we had talked about all this before, and the plan of action was clear.* (P03, 33 years)

Linkage facilitation. The participants verbalized that the facilitation they received enabled them to link to care. The facilitation was in the form of organizing travel for the men to access the health facilities as well as travel vouchers.

> *During this time, I had moved upcountry because of the COVID-19 lockdown. My counselor called me and when I told her that I couldn't access the health facility, she organized with the people at the hospital close to my home and they sent a car to come for me. Because of this, I was still able to reach the facility and start the treatment. When I came back to my workstation, the counselor took me personally and I was able to transfer my care.* (P11, 52 years)

Referral forms. We designed referral forms with input from health workers responsible for registration at health facilities. The participants reported that these forms made it possible for them to receive care much faster since the health workers already knew about to expect these slips.

> *When I went to the health center, the lady where we go for registration welcomed me and when I showed her my referral slip, she quickly directed me to where I needed to go and did not ask me so many questions because some information was already on the slip.* (P07, 36 years)

Study team members act as linkage companions. Some participants who had initial difficulty with linking to care received active linkage support from the study team members. This support was a strong enabler of linkage to care.

> *The lady* [study nurse] *called me to find out how I was doing, and I told her that I was worried about going to the hospital. I told her all my fears and she proposed that I should meet her at the hospital. We went together to the ART clinic; she went with me throughout the entire hospital journey. I appreciate the help she gave me during my first hospital visit.* (P02, 25 years)

Pre-arranged clinic appointments. Participants expressed that the ability to make appointments at the clinic was one of the motivating factors for linking to care.

> *One of my biggest worries was about the line at the health facility because the time I spend at work it is extremely hard for me to go to the hospital and take a day off. Our counselor told us to meet her on Tuesday at the hospital and everything went extremely fast. Can you believe I got everything done during my lunch break? It was a pleasant surprise.* (P06, 35 years)

Psychosocial support

Several participants suggested that they would not have been linked to care if they did not receive counseling and online support from the health workers. Additionally, some men felt emboldened to seek further care because they had the support of their family, and peers.

Counseling sessions. Some participants did not expect to receive reactive HIVST results and could not cope with the diagnosis. A few suggested that they owed their linkage to further care, to the support and the sessions that they received from their counselors.

> *When I got the result, I was devastated. I went home and could not face my wife. I was not sure where this disease came from. I was so bitter and was going to do something very harmful either to myself or to her. The counselor called me the next day because I had told her that I was available on Fridays and from our talk she got concerned. She asked me to make time and go to the health facility. We met and discussed the diagnosis and after about seven in-person sessions, I was able to accept this and go to the hospital. This was about 8 weeks later.* (P08, 40 years)

Online and social media support. During the pre-test counseling session, some participants requested online follow-up support, including the utilization of different social media sites and applications. The regular communication with the counselor helped them to decide to seek HIV care.

> *I have a smartphone so she* [the study counselor] *asked me how I preferred to be contacted after the test. I opted for WhatsApp messages because of privacy. She always started the chat with a code question and when I responded with the answer, then she knew it was me. This chat was helpful for me, and that constant open communication is what helped me to go to the hospital after I received the bad news* [reactive self-test]. (P05, 35 years)

Family linkage support. Several participants preferred to go for further testing and antiretroviral (ART) initiation closer

to home, with their spouses and other family members. This support to link as a family encouraged the men to seek HIV care.

> *The support from my wife and family encouraged me to go to the health facility when I tested positive. I work in Kampala, but my family lives in another district, so I traveled there and got treatment because I could get support from home.* (P10, 51 years)
>
> *They provided my transport, and it was good for me because I wanted to go for further testing and treatment with my wife. This gave me peace of mind.* (P10, 51 years)

Peer-support. Some participants expressed that peer support was a strong influence on their actions following the reactive self-test result.

> *The counselor asked me if I was willing to support other people who were struggling with their diagnosis. I agreed and she sent me to two other people who tested positive. We formed a small accountability group, and we follow up with each other. This has helped us to continue with our treatment and to have people to talk to.* (P07, 36 years)

Workplace environment

The HIV testing intervention was conducted at the men's workplace. Therefore, the workplace environment was a key factor in their decision to seek care and treatment. The environment included the presence or absence of the employer's support and the work schedules and policies.

Employers' support. Support from employers was given in different forms including time off and mitigating potential stigma and discrimination at the workplace. One participant expressed his gratitude to their employer as follows:

> *Since we tested with our supervisors, they gave me the support I needed. They also did not disclose my status to my other colleagues, because I have not seen any change in how my workmates interact with me.* (P12, 36 years)

Workplace schedules and policies. Some participants expressed that they were able to discuss with the employers or responsible managers and were given time off to go to the health facility. They suggested that this had only been possible because the testing had taken place at the workplace. It may have been different if the testing was in a health facility or elsewhere. They also had some workplace policies that offer punitive measures for people who discriminate against others for whatever reason. Therefore, they felt comfortable going for further care because they had support at the workplace.

> *Testing at the workplace made it easier for me to get time off to go for further treatment. If I had taken the test elsewhere, it would have been complicated. So, this means that testing at the workplace is helpful* (P08, 40 years)
>
> *We have a policy here where people are not supposed to discriminate against others for whatever reason maybe disability etc. Someone can even lose their job. Therefore, I was confident that nothing would happen to me, and I was able to access care after 2 weeks.* (P07, 36 years)

Barriers to linkage to care and treatment

These are presented under four categories: workplace-related barriers, socio-economic barriers, health facility-related barriers and personal/individual factors. Supplementary Table 3 provides a summary of the coding tree for the barriers to linkage to care and treatment.

Workplace related barriers

Inflexible work schedules. Some of the participants decried the strict nature of their work schedules, which did not allow them any time to go and access health care. This participant shared:

> *I failed to go to the hospital because honestly there is no time. You are working the dayshift here, and nightshift somewhere else, because the more shifts you work, the more money you get. I asked my manager if I could go for 2 h, and he said that I should find another guard to cover my shift. I have still failed.* (P08, 40 years)

Mandatory work transfers. Men employed in private security services are frequently transferred or deployed to different locations in the country. This was a challenge for some of the participants when it came to linkage to care at new facilities. This is highlighted below:

> *I was working in Kampala for 6 months when I got HIV-positive results. Now I have been transferred to….* [another district] *and when I went to the hospital, it was overly complicated, and I had to start everything afresh.* (P06, 35 years)

Socio-economic barriers

Far distance to health facilities from workplaces. Some of the participants opted to link to care at health facilities close to their permanent homes. Unfortunately, these homes were far from the workplaces where they undertook HIVST, this, therefore, made it inconvenient for them to access treatment and care. One participant stated:

> *Some of the health facilities are far from our workplaces, so we often must pay a lot of money to go there. This is inconvenient.* (P05, 35 years)

Disruptive effects of the COVID-19 pandemic. Several men did not link to treatment due to some of the unforeseen impacts of the COVID-19 pandemic:

> *COVID-19 also was the main reason why I could not get treatment at that time because travel was restricted, so there was no way I could go for the treatment. However, by the time the lockdown restrictions were lifted, I was beginning to have doubts and up to now, I have not yet gone.* (P04, 35 years)

Health facility-related barriers

Fear of stigma at the health facility. Fear of experiencing stigmatizing behavior was another major barrier for some of the participants:

> *There is stigma at the health facility. We go to a clinic where the company pays for our treatment. When you go there, everybody knows you and you just feel like everyone is looking at you.* (P01, 20 years)

Lack of a centralized HIV care information management system. Some participants expressed dissatisfaction with the way they are handled at health facilities when they desire to transfer their care. One participant stated:

> *Every time I go to a new hospital, I must give all my information afresh and sometimes the health workers at the hospital do not understand but just send me away immediately. They tell you to go back to where you registered for treatment* [ART]. *They should organize a system whereby every time someone goes to any hospital their information is accessible.* (P09, 46 years)

Personal/individual factors

Denial of HIV-positive results. Some men were in denial of their HIV-reactive results, which hindered them from seeking healthcare because they did not believe the test results. A participant narrated:

> *I cannot believe that those are my results. I have been living very well, how can these be my results? I will take another test after maybe 6 months with the blood test and then I can confirm. Why should I start treatment for a condition which I do not have?* (P04, 35 years)

Discussion

This study explored the motivators for and barriers to linkage to HIV care and treatment among men who received reactive (positive) self-test results following workplace-based HIVST. Three categories emerged for the motivators, these were: consistent follow-up, enabling health facility environment and psychosocial support. The commonly reported specific motivators were mobile phone support, use of a linkage plan, referral forms, employing staff from the ART clinics and support from the employers. The recurring barriers to linking to care and treatment included worry about stigma at health facilities, inflexible work schedules, far distances to travel to access care and ART, and the negative effects of the COVID-19 pandemic.

Many men in the study reported that the mobile phone support they received after testing, greatly influenced their decision to link to treatment and care, which agrees with findings from other studies on HIVST (26–28). The support was in the form of phone calls, and SMS (Short Message Service) reminders, while for others it entailed social media support using smartphone applications such as WhatsApp. The increased access to mobile technologies presents an unprecedented opportunity to develop different mobile health (mHealth) interventions that may facilitate individuals' linkage to care following community-based HIV testing and HIVST interventions (29). The use of mobile technologies may be viable in settings like Uganda where there are over 24 million cellular phone subscribers (30). Existing evidence indicates that mHealth programs have taken advantage of the wide phone network coverage to enhance the gamut of HIV care ranging from HIV testing and identifying people who test HIV positive, to retention in care and adherence to HIV treatment (31–34). Unfortunately, the shortage of staff in some contexts may make it difficult for each tester to be followed-up for linkage to care. Additionally, it may be difficult to implement new programs that increase the workload of already overwhelmed staff in health facilities. Posadzki et al., suggest that automated systems can transmit messages, retrieve any required health data from patients, and maybe be a good substitute for face-to-face contact (35). Therefore, the limited resources can then be directed to persons living with HIV (PLWH) who request a callback, are unreachable or do not link to care. This calls for creative and affordable solutions that will not place added strain on the current staff.

Several men appreciated the creation of a linkage plan during the pre-test counseling session. The individualized linkage plan included five major aspects: (i) a choice of three facilities where the men could go immediately following an HIVST, (ii) a disclosure list (a list of people to whom the tester would wish to disclose his results), (iii) the option of participating in a peer support group, (iv) family support to link to care and (v) the choice of the mode of follow-up namely, phone calls, text messaging, or smartphone applications like

WhatsApp or Facebook. While the initial planning was time-consuming, the men who did not anticipate a positive test result, found the plan particularly helpful as it gave them a semblance of control and direction. There is evidence that denial of one's HIV-positive diagnosis is a barrier to linkage to care (36, 37). Previous studies also suggest that having a prior plan facilitated disclosure of HIV-positive status (38, 39). Therefore, creating a linkage plan before taking the test may be useful in providing direction, and enhancing emotional readiness to accept a positive HIV diagnosis and seek further care.

Referral forms, slips, cards, or vouchers have been reported several times in the literature as a strong enabler of linkage to HIV care (37, 40, 41). In this study, we designed the study referral forms to collect the exact information that is recorded during standard HIV testing services. The participants were asked to present these forms to the health workers at the health facility if required. This was in addition to the linkage by the study team that worked at the health facility. This had the added benefit of helping the participants to quickly link to the health facilities in the study catchment area and made the transition seamless. As most of the participants were concerned about spending a lot of time at the health facility, the referral form greatly reduced their waiting time. To prevent data leaks, we used participant identity numbers and did not include the names, phone numbers or addresses on the referral forms. This had been agreed upon in a prior arrangement with the health facilities.

In South Africa, a study reported that several clients did not link to care because of previous unpleasant experiences at health facilities such as the long waiting time, poor treatment, and unprofessional conduct from health workers (36). Osingada et al., in their study about engaging men in Uganda, reported that they preferred to receive HIV services from distant health facilities because they did not trust the health workers whom they knew from their communities and were concerned about potential breaches of confidentiality (42). On the contrary, in this study, some of the men found it easier to link to care when they found familiar health workers at the health facilities, however, it is not clear whether this would still be the case if the health workers resided in the same communities as the participants. In this study, health workers from nearby health facilities were included as part of the study research team. This was one of the strategies to make a linkage to the health facility much easier for the participants. Initially, some of the men were concerned about the stigma at the health facilities, but the presence of a health worker they trusted helped them to navigate the health facility environment and lessened their concerns.

Previous studies have reported that top management support is a crucial element, for the success of any program related to HIV in the workplace (43–45). In this study, participants at some private security companies did not link to care because of their inflexible work schedules, and their inability to get time off to go for treatment and care. On the contrary, participants at other companies reported that they were able to get some time off to attend HIV clinics because the employers participated in the HIV testing program. In other places, the employers provided funding support for clinic visits. Furthermore, the support of the employer helped to mitigate stigma in the workplace. Therefore, employers are strongly encouraged to participate in HIV workplace initiatives, to improve linkage to treatment and care.

The current mitigation measures against COVID-19 transmission have increased the barriers to access to HIV services in Uganda. For example, a study among clinic-enrolled HIV-infected adults in Uganda found that 76% of them had their clinic attendance impacted by COVID-19. They highlighted challenges such as lack of transportation, police violence while enforcing the lockdown, and insufficient money for transportation (46). These findings resonate with ours, where some participants were unable to access HIV treatment due to the mandatory lockdowns and difficulty in accessing health facilities. This was coupled with the speed at which the pandemic escalated, which did not give enough time for the health system to adopt alternative measures to ensure access to essential medicines like ART, or treatment for TB. Amimo and colleagues (47) suggest that these restrictions could force the use of substandard drugs and/or doses, and lead to poor HIV and AIDS treatment outcomes, resulting in increased resistance to treatment. This strongly underscores the need for preparation and planning for future unexpected circumstances. Furthermore, programs should design contingency plans to ensure uninterrupted HIV care and treatment for PLWH. This agrees with the assertion (48) calling for the development of medium- and long-term policy-level and operational strategies for HIV care in the face of a potentially protracted COVID-19 pandemic, but also to prevent future shocks.

Several participants did not link to care or were not retained in care because of the challenges they faced while trying to transfer their care from one health facility to another. They were frustrated and recommended the introduction of a centralized HIV care information management system, which allows PLWH to access their care anywhere in the country. In South Africa, one of the proposed ways to resolve this is the use of a National identification, with each person in the country bearing a unique identifier (31). In that case, one may access HIV care and services anywhere in the country. While this seems feasible, it also raises concerns about potentially breaching patient confidentiality. In Uganda, Chamie et al. (49) used fingerprint biometric measurements for identification and confidentiality, during community-based HIV testing. However, further studies are needed to explore the potential users' acceptability of these proposed options.

Study strengths and limitations

This is the first qualitative study to report the perspectives and user preferences of men who returned reactive HIV self-test results regarding linkage to care and treatment following workplace-based HIVST. One limitation was the use of phone interviews for data collection, which made it impossible to observe non-verbal cues from participants during the interview. Additionally, the COVID-19 restrictions and lockdowns at the time did not allow us to understand some of the naturally occurring wider structural challenges in the men's lives, because it was an extraordinary situation (50). Additionally, the study did not include a cost-effective analysis of the strategies that facilitated linkage to care to help policymakers in decision making, this should be the next step.

Conclusion

The findings suggest the need for continual follow-up and open communication with individuals that test positive following workplace-based HIVST. This open communication and support may facilitate linkage to HIV care and treatment. Unfortunately, the limited health workforce in low-resource settings would hinder the use of strategies like constant provider-initiated follow-ups. There is an unprecedented opportunity to design mHealth interventions with automated or interactive voice responses that can provide reminders and follow-up individuals with positive self-test results. We also suggest continuing with tried and tested methods such as referral forms. Additionally, initiating individualized linkage plans during pre-test counseling and working in collaboration with HIV clinics may improve linkage to care about community-based HIVST. Furthermore, there is a need to put in place contingency plans for the continuity of HIV services in the event of future disasters or pandemics. Finally, the development of a national HIV care information management system is recommended. Thus, further research is needed to determine more innovative ways of implementing some of these methods without increasing the workload of current staff.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by Makerere University School of Health Sciences Research Ethics Committee (SHS-REC) (Ref. 2018-054) and the Uganda National Council for Science and Technology (UNCST) (Ref. HS 2672). The patients/participants provided their written informed consent to participate in this study.

Author contributions

PM, NS, NK, and LN made substantial contributions to the conception of the project. TN, PM, and CO drafted the paper. NS, NK, TN, LN, and CO critically revised the manuscript for important intellectual content. All authors gave final approval for the work to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2022.650719/full#supplementary-material

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