Linkages across the Continuum of HIV Services for Key Populations Affected by HIV (LINKAGES) Project

REPORT OF
EXPLORING THE UPTAKE AND ACCEPTABILITY OF HIV SELF-TESTING FOR MEN WHO HAVE SEX WITH MEN, MALE SEX WORKERS, AND TRANSGENDER PEOPLE IN NEPAL

Study Reference Numbers:
Nepal Health Research Council (NHRC): 474/2017
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Contents

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Abbreviations and Acronyms

AE	Adverse event
ART	Antiretroviral therapy
ARV	Antiretroviral
CBO	Community-based organization
CBS	Community-based supporter
CMO	Contract manufacturing organization
Co-PI	Co-principal investigator
DDA	Department of Drug Administration
ELISA	Enzyme-linked immunosorbent assay
EMMP	Environmental mitigation and monitoring plan
FGD	Focus group discussion
FSW	Female sex worker
HA	Health assistant
HBV	Hepatitis B Virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HIVST	HIV self-testing
HQ	Headquarters
HTC	HIV testing and counseling
HTLV	Human T-lymphotropic virus
IPA	Implementing partner agency
IRB	Institutional Review Board
KP	Key population
M&E	Monitoring and evaluation
MIS	Management information system

MSM	Men who have sex with men
MSW	Male sex worker
NCASC	National Centre for AIDS and STD Control
NGO	Nongovernmental organization
NHRC	Nepal Health Research Council
NPHL	National Public Health Laboratory
PHSC	Protection of Human Subjects Committee
PI	Principal Investigator
PLHIV	People living with HIV
SACTS	STD/AIDS Counseling and Training Services
SAE	Serious adverse event
SBC	Strategic behavioral communication
SOP	Standard operating procedure
SSI	Semi-structured interview
STI	Sexually transmitted infection
TG	Transgender
TU	Technical unit
UIC	Unique identification code
UNAIDS	The Joint United Nations Program on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization

Study Summary

Summary of HIV self-testing pilot study conducted in Lalitpur

Title: Exploring the uptake and acceptability of HIV self-testing for men who have sex with men, male sex workers, and transgender people in Nepal

Study #: 1089845 (Protection of Human Subjects Committee [PHSC]), 474/2017 (Nepal Health Research Council [NHRC])

Design: This was a cross-sectional, descriptive, mixed-methods study. Quantitative data were collected using recording forms developed for the HIV self-testing (HIVST) pilot study and monitoring and evaluation (M&E) data; secondary data were collected from HIV testing registers from HIV testing facility run by Linkages across the Continuum of HIV Services for Key Populations Affected by HIV (LINKAGES) Nepal implementing partner agency. Qualitative data were collected through semi-structured interviews (SSIs) with key population (KP) study participants, health care providers, management staff, and government officials, and through focus group discussions (FGDs) with community-based supporters (CBSs).

Sample size and populations:

1. A total of 440 individuals including 213 men who have sex with men (MSM), 108 male sex workers (MSWs), and 119 trans women who were 18 years of age or older and reached through LINKAGES Nepal project's peer outreach workers/CBSs in outreach activities.
2. One FGD was conducted with four CBSs; SSIs were conducted with 46 study participants, three health care workers, three management staff involved in HIVST, and four government officials who oversee HIV testing and treatment activities.

Study Duration: June–September 2018

Objectives:

1. To describe self-test use by participating MSM, MSWs, and trans women, including choices made between assisted (supervised) and unassisted (unsupervised) testing
2. To monitor rates of confirmatory testing among those known to have a reactive result to the self-test
3. To understand the acceptability of self-testing and preferences for self-testing implementation among MSM, MSWs, trans women, CBSs, health facility staff, and government officials

Study Sites: Lalitpur district of Nepal where LINKAGES Nepal project works with MSM, MSWs, and trans people for HIV prevention, care, support, and treatment services.

Study Management: The study was implemented by LINKAGES Nepal, STD/AIDS Counseling and Training Center (SACTS) and Parichaya Samaj in collaboration with the National Center for AIDS and STD Control (NCASC) and the National Public Health Laboratory (NPHL), Ministry of Health and Population (MOHP) with funding support from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for Development (USAID).

Results

Quantitative results:

1. During the study, 482 people were offered HIVST, out of which 440 (91.3 percent) provided consent and accepted HIVST. Acceptance was similar for MSM, MSWs, and trans women.
2. Of the total, 277 (63 percent) were 20–24 years old, and the average age of participants was 24 (23.7 among MSM, 23.9 among MSWs, and 25.1 among transwomen).
3. Of the total, 99 percent chose assisted/supervised HIVST, and only five participants (four MSM and one MSW) (1 percent) chose the unassisted/unsupervised approach.
4. Participants and service providers preferred performing HIVST under supervision.
5. Out of 440 who participated in HIVST, 428 (97 percent) were HIVST non-reactive and 12 (3 percent) were HIVST reactive. All 12 individuals with HIVST reactive results had an HIV confirmatory test using the national standard HIV testing algorithm, and all were confirmed HIV positive. Of the 12 positive cases, 11 (92 percent) were identified through the assisted/supervised approach.

Qualitative results:

1. All the MSM, MSWs, and trans women participants reported they decided to have HIVST because it can be done easily, without drawing blood, and the result can be obtained immediately in front of them. The majority of respondents (n=34) said they would use HIVST in the future and would also recommend HIVST to their partners or friends.
2. Almost all MSM, MSWs, and trans women participants (n=42) preferred receiving the HIVST kit from the community people/organization. They felt they could trust the community, and their information would be kept confidential.
3. Almost all MSM, MSWs, and trans women participants agreed they had been given full information regarding HIVST, and they were aware the result would be kept confidential, HIVST is not a confirmatory test, and they would be enrolled in ART if confirmed HIV positive.

4. According to MSM, MSWs, and trans women participants, the information provided by the CBSs was easy to understand and follow, and the pictures on the leaflet were clear and easy to understand. HIVST users did not have any difficulty opening the test kit package, performing the test, and interpreting the results. CBSs and health care staff also reported it was easy to provide information to study participants.
5. The instructions provided in the leaflet were adequate for performing the test. However, CBSs and health care staff suggested enlarging the size of the type font and the pictures in the instruction material, and using an instructional video, if needed.
6. According to CBSs, health care providers, and government officials, there were no difficulties implementing HIVST. They advised that people should have awareness about HIV and HIVST before introducing it to the market. Platforms such as social media, mass media, and community groups should be used to raise awareness about HIV and HIVST among the population. HIVST should also be introduced to other KPs besides MSM, MSWs, and trans women. The test kit should be made available in all parts of the country. MSM, MSWs, and trans women said they would use HIVST if the cost for the HIVST kit were between NRs.100 (about US$1) and NRs.500 (about US$5), or free. According to both groups of participants, stigma related to HIV, sexual orientation, and disclosure of HIV status are challenges for implementation. Other challenges include interpreting the result when a distinct line does not appear in test window of the kit, acceptance of HIV-positive status, anxiety related to HIV-positive status, and taking HIVST reactive clients to the facility for confirmatory tests.

Recommendations

1. HIVST is acceptable among MSM, MSWs, and trans women in Nepal. Coordinate with NCASC and NPHL for rolling out HIVST as an additional method of HIV testing along with facility-based testing and community-based testing for triage across the country.
2. Use the assisted/supervised approach, mobilizing community/outreach workers as a preferred method of implementation of HIVST. Use the unassisted/unsupervised approach as an alternative when individuals prefer it and/or when there are issues related to disclosure of being a member of a KP, HIV status, and stigma.
3. Use HIVST as an additional method of HIV testing, especially when traditional approaches are not adequate to increase case finding.
4. Mobilize the KP community for a community-led approach for performing HIVST during rollout.

5. Use the individual or one-to-one educational approach for providing information. Prepare a standard operating procedure for implementation including the procedures followed during the pilot study.
6. Mobilize CBSs or similar level lay providers for introducing HIVST during roll-out.
7. Develop instruction materials using the information provided in the leaflet used for client instruction during the pilot study. Enlarge picture and type font size in instruction materials and develop audiovisual instructions.
8. Develop information, education, and communication (IEC) materials and social media campaign messages for HIVST. The messages should focus on how HIVST uses saliva, and HIV is not transmitted through saliva.
9. Explore the options for either social marketing of HIVST test kit or providing free of cost.
10. Focus on maintaining confidentiality of the HIVST result, as well as the sexual orientation and personal information of the individuals. Develop message for providing counseling for HIVST reactive results. Develop and implement approaches for accompanying clients with HIVST reactive results to HIV testing facilities for confirmatory tests.

1. Introduction

LINKAGES Nepal project introduces innovative ideas and technologies to improve and expand access to HIV testing services. Among the new technologies, HIV self-testing (HIVST) is a complementary approach to reach those who are not reached by existing traditional HIV testing and counseling (HTC) services.

The World Health Organization (WHO) defines HIVST as "a specific process in which a person collects his or her specimen (oral fluid or finger stick blood) and then performs a test and interprets the result, often in private or with someone they trust" (WHO 2015). WHO also recommends HIVST as an additional approach to other HIV testing services (WHO, 2016).

HIVST may be implemented with different models, which vary in the level of support provided and how and where kits are distributed. "Models include support from health workers, distribution or sale in the community or a health facility, as well as sale in pharmacies, kiosks, vending machines and through the internet. Direct or indirect assistance may also be available through a demonstration on how to perform self-test via an instructional video, telephone hotlines and printed instructions or other package inserts" (Unitaid, 2016).

Self-testing is an approach for screening HIV in the community and only those having a reactive test result need further confirmatory testing. Having a reactive result may lead those individuals to early access to health services to establish an HIV diagnosis and become linked to prevention, treatment, and care. For those with a nonreactive result, HIVST may support increased uptake of prevention interventions and adoption of safer behaviors to remain HIV negative and retesting if there is a history of possible exposure in the last three months. HIVST may also lead to increased frequency of testing, which is particularly relevant for individuals with high and ongoing risk for HIV and who are advised to test every three or six months. Similarly, this may also help save travel time and costs for potential clients and stimulate testing scale-up in settings with low coverage or shortages of health workers (Unitaid, 2016).

HIVST studies report high levels of acceptability (74–96 percent), primarily for oral fluid-based tests, among MSM, young people and adults from the general population, health workers, and couples who already have used HIVST and want to use self-testing. Studies show that HIVST with oral fluid is accurate, with a sensitivity of at least 91.7 percent and specificity of at least 97.9 percent (UNAIDS/WHO, 2014).

1.1. Rationale for the Study

Despite achievements in scaling up HIV testing, substantial gaps remain; 25 percent of all people living with HIV (PLHIV) globally are yet to be diagnosed (UNAIDS, 2017) and 36 percent of the estimated PLHIV in Nepal do not know their HIV-positive status (NCASC, 2017). There is a critical need to increase current efforts to ensure access to the continuum of prevention, care, and treatment, particularly among KPs who are disproportionately affected by HIV and comprise approximately 40 percent of the 1.8 million new HIV infections every year.

In high-risk populations, testing coverage remains low (UNAIDS, 2015). In many settings where there has been a growing number of HIV tests every year, these tests do not necessarily reach PLHIV who are unaware of their status and others who are at high risk for HIV infection (AIDS, 2014). Low uptake of HIV testing services among KPs is not only related to availability but also depends on acceptability and is impacted by unfriendly service providers and fear of stigma and discrimination (Arreola et al., 2012). KPs are further disadvantaged and vulnerable due to the existence of punitive laws that criminalize their behaviors (UNAIDS, 2016). MSM, MSWs, and trans people are often stigmatized and exposed to increased rates of violence, which increases the disparity in access to testing and treatment services for HIV (Arreola et al., 2012; Avert, 2017; UNAIDS, 2013).

It is expected that without improving access to and uptake of HIV testing for KPs, we will not be able to achieve UNAIDS' 90-90-90 targets. Therefore, countries are seeking ways to rapidly increase access to and uptake of HIV testing services, particularly among populations with lowest coverage and highest risk.

1.2. HIV Self-Testing

HIVST has been proposed as a new approach to help countries expand access to HIV testing services and reach those at high risk who may not otherwise get tested, such as stigmatized KP members. By providing an opportunity for people to test themselves discreetly and conveniently, HIVST may provide people who are not currently reached by existing HTC services with information about their HIV status. WHO's latest guidance encourages HIVST through community and facility-based programs that address barriers to access (WHO, 2016). All individuals with a reactive self-test result should receive confirmatory testing with a trained provider using a validated test within the health care system (WHO, 2016).

Several studies in Africa were conducted to understand the feasibility and acceptability of self-testing. In 2011, two pilot studies were conducted by providing HIVST kits to health care workers and their partners in Kenya (Kalibala et al., 2014) and community members in Malawi

(Choko et al., 2011). Both studies focused on reaching individuals and couples who were not accessing current HTC approaches, and on finding more acceptable and cost-effective ways of expanding access to testing. In both studies, among those who received a self-test kit, the rate of testing was high (greater than 75 percent), and more than 90 percent of participants said the test was easy to use (Choko et al., 2011; Kalibala et al., 2014). Furthermore, in Malawi, even though in 10 percent of observed self-tests, the person conducting the test made a minor mistake, the results were highly accurate (99 percent) (Choko et al., 2011). An important finding in the Malawi study was that self-testing was more acceptable if somebody from outside the community was available for post-test counseling (rather than a neighbor) (Choko et al., 2011). These pilot studies provide initial evidence that self-testing is an acceptable, easy, and accurate way to obtain preliminary HIV test results.

There has not, however, been research regarding self-testing's feasibility and acceptability in South Asia, including Nepal.

1.3. HIV Self-Testing in Key Populations

Evidence about the impact of HIVST on KPs in sub-Saharan Africa and Asia is lacking. Because loss to follow-up is high for KPs (Tang et al., 2015), some stakeholders worry that offering self-testing might lead to increased losses to follow-up in the HIV cascade among those whose self-test is reactive but fail to go for confirmatory testing and treatment.

One literature review found that KPs perceive self-testing to be preferable to the typical HIV testing method due to its increased privacy, convenience, painlessness, and ease of use (Figueroa et al., 2015). Results also showed that oral tests were preferable to blood-based ones (Figueroa et al., 2015). Across studies, results were mixed as to whether counseling should be provided at the time of the self-test; but concerns of KPs regarding the self-test included not being counseled and fear of inaccurate results or user error (Figueroa et al., 2015). In a study done in Kenya that measured the intent to seek confirmatory results, 40 percent of MSM and 75 percent of female sex workers (FSWs) reported they would seek counseling and confirmatory results after taking a self-test (Ochako, 2014). A recent study shows that HIVST is acceptable, accessible, and safe for FSWs in Zambia; however, uptake of HIVST was lower with facility-based delivery, and linkage to care was delayed following HIVST (Oldenburg et al., 2017). Another study in Zimbabwe showed that 54 percent of FSWs chose self-testing as an option. During follow-up, 100 percent said the test was easy to use and trusted the result they had been given, and 98 percent were comfortable learning the result without someone else present. A substantial proportion of study participants expressed a willingness to pay for testing

kits. Of those tested HIV positive, 99 percent connected with follow-up services within two weeks of the test (Mavedzenge et al., 2017).

Given the competing importance of maintaining privacy for KP members and ensuring linkage to care for those who test positive, using peer outreach workers as self-test service providers could improve testing and treatment outcomes. HIVST, if implemented carefully and with the involvement of peers, may provide an opportunity to increase HIV case findings while maintaining the five Cs of HTC: consent, confidentiality, counseling, correct results, and linkage to care.

LINKAGES, funded by the PEPFAR and USAID, is the largest global project dedicated to KPs. It is designed to improve their access to HIV prevention, care, and treatment. Peer outreach is one approach used to reach KPs by mobilizing CBSs. Given the stigma that KP members often report experiencing in health care facilities, they may be more accepting of peers sharing information about HIV prevention and treatment with them. Using peer CBSs to implement HIVST provides an opportunity to offer KP members appropriate support for testing and linkage to conventional facilities where those who are confirmed positive can be enrolled in HIV treatment and care services.

The LINKAGES project in Nepal, working in close collaboration with the Government of Nepal, KPs, and PLHIV, seeks to identify and reach KP members who face the greatest risk for HIV infection, conducts HIV testing, ensures linkage to treatment for those who test positive, and supports retention for those on treatment. The project covers FSWs and their clients in 17 districts of Nepal and focuses on MSM, MSWs, and trans people in five districts.

As part of this study, LINKAGES Nepal, in collaboration with the NCASC and the NPHL under the MoHP, provided HIVST kits to MSM, MSWs, and trans women in order to increase access to testing and to treatment if diagnosed HIV positive. One of LINKAGES' guiding principles is to offer options to KP members to better meet their individual needs and encourage empowerment. For that reason, the intervention model included several decision points with options for how they would be tested, who would be with them, when they would be tested, and how they would be linked to care. Understanding their choices and how other stakeholders, including peer outreach workers, health care providers, and government officials, perceived this option-oriented intervention were intended to provide information for government leaders as they consider implementing HIVST programs. Furthermore, knowing if HIV testing rates, enrollment in care, and initiation of treatment increased for MSM, MSWs, and trans women after the intervention was also expected to help decision-makers consider the potential impact of HIVST for KPs in meeting the 90-90-90 targets by 2020.

Access to HIV prevention, care, support, and treatment services has increased significantly over the years in Nepal. However, substantial challenges to the HIV response related to KPs remain despite some notable successes. Many KP members still do not have access to HIV testing or are unwilling to access current services because of stigma and discrimination. A recent report from the NCASC shows that after adjusting for deaths and duplication, only 64 percent of those estimated to be infected have been diagnosed (NCASC, 2017).

These challenges require a new focus and new approaches to reach KPs who do not have access to HIV testing services and remain undiagnosed early in their infection. Innovative approaches to testing, as recommended by the National HIV Strategic Plan (NHSP) 2016–2021, are required to adequately reach these people and contribute to achieving national targets. The new testing strategies could help accelerate uptake and case detection. HIVST has been proposed as one of these approaches and is recommended in the National HIV Testing and Treatment Guidelines 2017.

Therefore, LINKAGES Nepal, in collaboration with NCASC and NPHL, conducted a pilot study of HIVST using OraQuick® Rapid HIV self-test (produced by OraSure Technologies) among MSM, MSWs, and trans women (referred to as study participants in this protocol) in Lalitpur district.

1.4. OraQuick® Rapid HIV Self-Test

OraQuick® Rapid HIV Self-Test, manufactured in Thailand for OraSure Technologies, Inc., was used for this project. OraQuick® was prequalified by WHO in July 2017. In Nepal, the OraQuick® test is not yet registered and publicly available but had been validated and approved for this pilot study by NPHL, Ministry of Health and Population.

According to OraSure Technologies, Inc., the test kit has 100 percent sensitivity and 99.1 percent specificity compared with a fourth-generation laboratory test. The test kits had certain limitations. The test may show a false report if the person is taking antiretroviral (ARV) drugs, infected with hepatitis B virus (HBV) and hepatitis C virus (HCV) or human T- lymphocytic virus I/II (HTLV (I/II). Oral bleeding may result in an invalid result and the test kit may not detect an HIV infection that has occurred within the last three months. Reactive HIVST results should be verified using another test performed by a trained professional to confirm an HIV diagnosis (OraSure Technologies, Inc., 2017).

A research study in India found 100 percent sensitivity and 100 percent specificity of the oral test when compared to the enzyme-linked immunosorbent assay (ELISA) and Western blotting (WB) standard HIV test among 450 adults suspected of being infected with HIV; however, the test was given by a health care provider (Pant Pai et al., 2007). In Cameroon, another study with

health care worker administration of the test demonstrated 93 percent sensitivity and 99 percent specificity (Nkenfou et al., 2013).

OraQuick® one-pouch kit contains a single-use test device, preservative and a developer solution vial, test stand, and instructions. The test kit is recommended to be stored in a cool area with temperature of 2–30 degrees Celsius, and the test to be performed at temperature of 15–37 degrees Celsius.

The OraQuick® is a single-use qualitative immunoassay to detect antibodies to HIV-1 and HIV-2. The kit is intended for lay users to aid in the diagnosis of HIV infection. The device is placed into the mouth with the flat pad between the cheek and outer gums, then the flat pad is swabbed across the outer gum line. The device is then placed into a tube containing a premeasured amount of solution. Fluid from the surface of the gums enters the device through the flat pad, then flows onto a test strip. As it flows across the strip, a colored line appears in the T (test) area of the result window if HIV antibodies are detected. If no line appears, there are no HIV antibodies in the gum secretion. For all tests performed correctly, a line appears in the C area of the result window (See Figure 1). It takes 20 minutes to see the result.

Figure 1. Display of nonreactive and reactive HIV test results for OraQuick

		
A: Reactive test result	B: Non-reactive test result	C: Invalid test result

To prepare, individuals are asked not to eat, drink, or do any mouth cleaning for at least 15 minutes prior to the test. Next, a watch or device is set nearby for measuring time, and the two pouches—one with tube and stand; the other with testing device—are placed on a table. The individual performing the test opens the pouch with the tube and places it on the stand after removing the cap. Then the person opens the other pouch with the test device, takes it out without touching the flat pad, and swabs along the upper and lower gums. The flat pad of device is placed into the tube containing liquid; after 20 minutes the person can look at the results in the test window. No reading should be done after 40 minutes from swabbing the gum.

LINKAGES Nepal implementing partner agency (IPA), which is also a KP-led organization, implemented the field activities for the HIVST pilot study with technical assistance from LINKAGES Nepal Project.

1.5. Study Goal, Objectives, and Outcomes

The goal of this study was to explore the feasibility and acceptability of HIVST among MSM, MSWs, and trans people in Nepal. The objectives were:

1. To describe self-test use by participating MSM, MSWs, and trans women, including choices made between assisted/supervised and unassisted/unsupervised testing
2. To monitor rates of confirmatory testing among those known to have a reactive result to the self-test
3. To understand the acceptability of self-testing and preferences for self-testing implementation among MSM, MSWs, and trans women, CBSs, health facility staff, and government officials

The primary outcomes were:

1. The proportion of self-testers who were tested for HIV for the first time
2. The proportion of self-testers who choose unassisted/unsupervised versus assisted/supervised testing
3. The proportion of self-testers known to have tested reactive and get a confirmatory test at HIV-testing service sites
4. Description of participant's views on the acceptability of self-testing and their preferences for how it is implemented
5. Description of challenges and barriers to HIV self-testing

2. Methodology

2.1. Study Design

This was a cross-sectional, descriptive, mixed-methods study using M&E data and semi-structured interviews (SSIs) with MSM, MSWs, and trans women, health care providers, and

government officials, and a FGD with CBSs. The duration of the study was six months, from June through November 2018.

2.1.1. Quantitative

We offered options for assisted/supervised and unassisted/unsupervised HIVST. MSM, MSWs, and trans women were informed of the availability of self-testing by CBSs during outreach activities in the community. Once the test had been explained, they were given an opportunity to choose either an assisted/supervised or unassisted/unsupervised test.

Assisted/supervised test: For participants choosing assisted/supervised testing, the CBS showed the step-by-step procedure using a pictorial guide and helped the participant do the self-test. The CBS also stayed with the individual as he/she administered the test and the result appeared, providing a second opinion in interpreting the result and appropriate counseling.

Assisted/supervised testing was done at the home/residence of the participant or in a place chosen by the participant, maintaining privacy and confidentiality.

If the participants were HIVST nonreactive, the CBS suggested they return in three months and linked those eligible to prevention services, according to standard service. If the participants were HIVST reactive, they were accompanied to a LINKAGES Nepal static or mobile clinic for a confirmatory test. All participants with HIVST reactive results accepted accompanied referral to a LINKAGES HIV testing facility. All participants with a confirmed HIV-positive result were linked to care and treatment as part of the standard service package.

Unassisted/unsupervised test: In the unassisted/unsupervised option, the CBS provided the necessary information and the kit with pictorial guide and asked the participant to share the result within 48 hours either by phone or in person. The CBS also asked the participants to remember to return used HIVST kits after conducting a test. All participants who chose the unassisted/unsupervised option responded with results within 48 hours and confirmatory tests were done within seven days.

Used test kits collected after both approaches were disposed following safe health care waste management practice in the Environmental Mitigation and Monitoring Plan (EMMP) of LINKAGES Nepal Project.

The quantitative portion of this research involved tracking HIVST rates and test results over the three-month period of the study. Data collected included the proportion of self-testers tested for HIV for the first time, proportion of self-testers who chose unassisted /unsupervised versus assisted/supervised testing, and proportion of self-testers known to have tested reactive during

the study and took a confirmatory test at HIV-testing service sites. To capture this information, we used M&E tools developed for the pilot study. For details, see Table 1. Confirmatory test results of the HIVST reactive participants were recorded in the SACTS Lalitpur, which were later transferred to the client record forms by a health assistant (HA). Staff provided confirmed test result with post-test counseling to clients at SACTS Lalitpur.

Table 1. Quantitative tools, contributions to indicators, and data collectors

Data collection tool	Person responsible	Data collection technique/source	Indicators contributed
HIVST client register	CBS	One-to-one basis during HIV self-testing by asking the clients and recording result of self-test	Do not contribute to any indicators used to record personal information of study participants for follow-up
HIVST client record form	CBS, HA	1. One-to-one basis during HIV self-testing by asking the clients and recording result of self-test 2. HA completed the same tool initially filled by CBS by adding confirmatory HIV test result for clients with HIVST reactive results. Data collected from LINKAGES clinics HIV testing and counseling register	1. The proportion of individuals who accepted HIVST 2. The proportion of self-testers who were tested for HIV for the first time 3. The proportion of self-testers who choose unassisted/ unsupervised versus assisted /supervised testing 4. The proportion of self-testers known to have tested reactive and get a confirmatory test at HIV testing service sites

Data collection tool	Person responsible	Data collection technique/source	Indicators contributed
Study participant tracking sheet for unassisted/unsupervised HIVST	CBS	Entering study participants opting for unassisted/unsupervised test, follow-up made and lost-to-follow-up status.	The proportion of individuals who accepted HIVST

Data collection was completed exactly in three months from the start of testing. All information related to the study participant, choice of approach, result of HIVST were collected by CBSs using the *HIVST client record form*. As soon as a CBS received any reactive result, she/he asked the study participant to take the confirmatory test and accompanied the participant to the health facility. During registration at the clinic, the participant was provided a new standard unique identification code (UIC). The CBS handed over the *HIVST client record form* to the HA doing counseling for the test. The HA transferred the confirmatory HIV test result from the HIV testing register in the same form. Participants with confirmed HIV-positive results, as part of standard care, were linked with treatment.

2.1.2. Qualitative

FGD and SSIs were the qualitative methods used to understand perceptions and concerns about self-testing and various components of the implementation of the self-testing intervention.

FGD was conducted only among CBSs, as they shared similar backgrounds and roles in the study.

SSIs were conducted to obtain information from the smaller number of people, who could not be grouped and had different backgrounds. These included study participants with reactive and nonreactive results; they could not be grouped because of confidentiality- and stigma-related issues. Other participants had different backgrounds and different roles in the study. See Table 2 for details.

Table 2. Qualitative tools, contributions to indicators, data collectors

Data collection tool	Person responsible for administering the tool	Targeted study participants	Data collection technique/source	Indicators contributed
SSI questionnaire	Qualitative study consultant	1. Study participants with HIVST reactive and nonreactive results 2. Health service providers including their program and data managers 3. Government officials (NCASC and NPHL)	One-to-one qualitative in-depth interview	1 Description of participant's views on the acceptability of self-testing and their preferences for how it is implemented 2. Description of challenges and barriers to HIVST
FGD guide	Qualitative study consultant	CBSs	Conducting FGD and notes of the discussion recorded by a note taker	1 Description of participant's views on the acceptability of self-testing and their preferences for how it is implemented 2. Description of challenges and barriers to HIVST

A FGD was conducted among CBSs by a qualitative interviewer in the Parichaya Samaj office, Lalitpur, using a guide. FGD with CBSs were conducted within two weeks of the completion of field implementation of the HIVST pilot and quantitative data collection to ensure they had time to encounter confirmatory test cases.

SSIs were conducted by a qualitative interviewer using semi-structured questionnaires with three populations: (1) MSM, MSWs, and trans women who have used a self-test; (2) health care

workers, project coordinators, and the management information system (MIS) officer at HIV testing sites; and (3) government officials.

SSIs with participants in the first group were conducted about one month after the intervention had begun. Based on our convenience, all participants who tested reactive and 10 percent of participants who tested nonreactive were invited for SSIs.

All measures for assuring confidentiality of the participants were implemented. SSIs were conducted in a private room. Consent was taken prior to all interviews. All the interviews were conducted in a place chosen by participants; most of them chose Parichaya Samaj's office in Lalitpur. Notably, this office is routinely used by those who work with the study population, where participants felt comfortable.

All health care workers, project staff, and government staff involved in the pilot study were interviewed at places of the participants' convenience.

2.2. Settings

The study was conducted in Lalitpur district, which has a high concentration of MSM, MSWs, and trans women. It is one of five districts where LINKAGES Nepal is implementing HIV prevention, care, and treatment for these groups. The district was selected for the study because of the convenience for providing confirmatory testing; transportation; monitoring by the principal investigator (PI) and co-principal investigator (Co-PI), NCASC, NPHL, and USAID; and logistic supply.

The quantitative part of the study was conducted in the community, either at the home of or place chosen by the participant. HIVST procedure and data collection were done on a one-to-one basis, maintaining privacy.

Qualitative interviews of MSM, MSWs, and trans participants were conducted at Parichaya Samaj, Lalitpur, on a one-to-one basis to maintain privacy. All health care workers, project staff, and government staff involved were interviewed individually at the places of their choice. SSIs with facility staff (service providers and program staff) were conducted within two weeks of the completion of field implementation of the HIVST pilot and quantitative data collection to ensure they had time to encounter confirmatory test cases. SSIs with health facility staff were conducted at SACTS Lalitpur office. SSIs with government officials were conducted in their individual offices near the end of the intervention, to include their responses regarding the intervention to be rolled out. A FGD with CBSs was conducted at Parichaya Samaj office, Lalitpur.

2.3. Target Population

Quantitative

The target population was MSM, MSWs, and trans women living in Lalitpur district who met the following eligibility criteria:

- Self-identified as MSM, MSW, or trans woman. In the case of MSWs, they had agreed that they exchanged sex for money and/or goods
- Self-identified as being at risk of getting HIV with at least one of the following risk activities in the last three months:
    - penetrative or receptive anal sex without a condom, and/or
    - vaginal sex without a condom, and/or
    - sharing syringes/needles with another peer to inject drugs
- 18 years of age
- Provided consent to give access to their HIV confirmatory test result

Individuals not eligible for the study were: those known to be HIV positive, those receiving or who had received any ARVs in last two months, individuals with gum bleeding, and individuals with known diagnosis of HBV, HCV, or HTLV (I/II). All the information related to previous diagnoses was collected by asking questions; no verifications were done.

Among trans people, participants were trans women only.

Qualitative

The target population for FGD was CBSs. For SSIs, it included (1) all those tested HIVST reactive and 10 percent of those tested nonreactive, (2) health care workers, project coordinator and MIS officer of LINKAGES IAs, and (3) government officials (NCASC and NPHL).

2.4. Sampling, Sample Size

Sample size was determined by the LINKAGES Nepal project, based on its annual targets and achievements. The number of participants targeted for this pilot was the number of MSM, MSWs, and trans women that LINKAGES Nepal could cover in a three-month period. LINKAGES Nepal had a target to reach 1,153 high-risk MSM, 575 MSWs, and 474 trans women in the community through outreach in the study district during the 15 months of the project period (October 2016–December 2017). The sample was determined by dividing the total targets by the number of months of the study, which yielded 230 MSM, 115 MSWs, and 95 trans people.

All were included in the sample, making the total sample size of 440. However, during the study we reached 482 (245 MSM, 104 MSWs, and 133 trans women) out of which 440 (222 MSM, 95 MSWs, and 123 trans women) accepted testing using HIVST.

The purposive sampling method was used to select participants for SSIs from KPs, health care workers, and project staff and government staff involved in this study. For KP participants, based on our resources, we decided to include all HIVST reactive clients and 10 percent of those with nonreactive results. FGD was conducted among all CBSs involved in the study. All health care providers involved in the study and at least four government officials overseeing HIV testing services and involved in monitoring of the HIVST pilot were invited for SSIs.

2.5. Recruitment

2.5.1. Obtaining Consent for Recruitment

This study was conducted in compliance with all relevant human rights and ethical standards including the Nepalese national guideline on clinical trials, and the WHO and/or prevailing international standards for import, transportation, labeling, and storage. The study protocol was submitted and approved by the Protection of Human Subjects Committee of FHI 360 and Nepal Health Research Council ethical review board.

Documentation of informed consent was obtained individually from each participant. Consent forms were translated into Nepali language before use. The documentation of consent was written; participants were encouraged to use initials or a symbol to sign the form rather than writing their name, in order to reduce the risk of disclosure via the consent forms.

The consent form included a description of the study purpose, the participant's role in the research, benefits, risks, compensation, confidentiality, that participation is voluntary, and contact information for questions. For applicable participants who met the inclusion criteria for testing, the consent form asked permission for: (1) to use the participants' personal program data that LINKAGES already collected on them (as part of routine M&E) for research purposes and (2) to take a self-test. Potential participants consented to the use of their program data for the purposes of this research. The consent form also described the limitations of self-test and noted that the test kit was not available and not approved in the country for general use. Those study participants not providing consent for participation in the pilot were not excluded from other services provided by the LINKAGES project.

For the qualitative interviews, written informed consent was obtained from all participants. For the FGD, this process occurred individually prior to the FGD in a private location. The consent forms for qualitative data collection included a description of the study purpose, the

participant's role in the research, benefits, risks, compensation, confidentiality, that participation was voluntary, and contact information for questions.

2.5.2. Recruitment for HIV Self-Testing

As part of standard practice following "Guidelines for Implementing HIV Prevention, Care, and Support Services among Key Populations" of LINKAGES Nepal project, CBSs identified and reached new and/or previously contacted MSM, MSWs, and trans people either one-on-one or in groups at cruising sites or hot spots in Lalitpur district and provided HIV prevention education and referral for HIV and sexually transmitted infection (STI) services.

During this routine outreach, CBSs also provided HIVST information, invited them to participate in HIVST and, if they consented, enrolled them during the regular education session for HIV prevention. KP members providing consent were considered to be study participants. Their names and contact information were recorded and assigned study identification (ID) numbers in a register, which were linked to the UICs used for programmatic work in case the HIVST was a reactive result only. Then the participants were asked by the CBSs if they would like to take the HIVST kit in a assisted/supervised or unassisted/unsupervised manner. After performing HIVST, those with a reactive result were asked to have an HIV confirmatory test at SACTS Lalitpur, LINKAGES Nepal nongovernmental organization (NGO) clinic and government-approved HIV testing site. Participants were accompanied by the CBS who provided the HIVST to the facility. Participants were registered in the facility, provided a site-specific ID, and given a confirmatory HIV test following standard procedures. Their confirmed HIV test results were recorded in the standard HTC register of the facility. HIVST participants seeking confirmed HIV testing were noted in the "remarks" column of the register for easy identification.

With participants' consent, confirmed HIV test results of the study participants tested reactive by HIVST were collected from the HTC register of LINKAGES Nepal NGO clinic at Lagankhel, Lalitpur. The HA conducting pre- and post-test counseling was responsible for entering the confirmed HIV status in the HIVST client record form. Participants diagnosed HIV positive were accompanied to the treatment center as part of standard care.

2.5.3. Recruitment for Qualitative Data Collection

Among MSM, MSWs, and trans women who participated in HIVST, both those who tested nonreactive and reactive were included in qualitative data collection. The purposive sampling method was used for SSIs with health care workers, project staff, and government staff involved in the study. Based on our convenience and available resources, we interviewed all

who tested reactive and around 10 percent who tested nonreactive to understand the perception and opinion on HIVST procedures from both groups.

See Table 3 for breakdown of the expected samples and actual recruitment for qualitative data collection.

Table 3. Sample for qualitative data collection

Study participants	With non-reactive HIVST results	With reactive HIVST results	Total participants
In-depth semi-structured interview (SSI)			
MSM	21	4	25
MSWs	8	3	11
Trans people	6	4	10
Health care worker and project management staff			6
Government officials			4
Focus group discussion (FGD)			
CBSs			4

2.6. Data Collection

2.6.1. Workshop for National Stakeholders

To support the roll-out and implementation of the HIVST pilot in Nepal, LINKAGES in coordination with the Ministry of Health (NCASC and NPHL), conducted a workshop to sensitize stakeholders and discuss protocol and tools. Participants included representatives from NCASC, NPHL, and treatment centers; international development partners (WHO, UNAIDS, UNICEF); NGO partners involved in the pilot study; and LINKAGES Nepal staff (laboratory specialist, program officer for Lalitpur district, and technical advisor).

2.6.2. Training for the Researchers

LINKAGES Nepal provided a three-day training for CBSs and clinical staff who were involved in the HIVST pilot. Participants included LINKAGES Nepal staff involved in the study (laboratory specialist, program officer for Lalitpur district), and the implementing partners team. The team included the project coordinator, M&E officer, and CBSs working in Lalitpur district.

The following topics were included:

1. Providing pre-test and post-test information to study participants: the procedure for performing the test, meaning of the results, importance of confirmatory testing, HIV treatment options, and HIV prevention options (pre-exposure prophylaxis, repeat testing, condom and lubricant use)
2. Procedure for self-test kit sample collection, testing procedure, interpretation of results, using informational brochure, and practical exercise for conducting HIV self-test
3. Follow-up and referral
4. The importance of privacy of testing and confidentiality of information
5. FHI 360 code of conduct/research ethics
6. Social harm, adverse event reporting, adverse device event and failure reporting
7. Universal precautions and health care waste management including EMMP of LINKAGES Nepal
8. Documentation on M&E forms

LINKAGES Nepal provided orientation for the qualitative data collection consultant on the study, study partners, study populations, and KP-friendly approaches. The consultant completed FHI 360's online research ethics training.

2.6.3. Quantitative and Qualitative Data Collection

Quantitative data were collected by CBSs administering the HIVSTs using the HIVST client register and the HIVST client record form. Confirmatory test results of the HIVST reactive study participants were obtained from the *HTC register* of the Lagankhel clinic by HAs and entered in the HIVST client record form. The tracking sheet of HIVST unassisted/unsupervised test was used by CBSs to track study participants who chose the unassisted/unsupervised option.

Qualitative data were collected by the consultant conducting the FGD and SSIs. SSIs were conducted in Nepali language using SSI questionnaires in a room at Lagankhel SACTS clinic for HIVST reactive participants; in Parichaya Samaj office for HIVST nonreactive participants; and at their respective workplaces for clinical staff, managerial staff, and government officials.

The FGD was conducted in Nepali language in a room at Parichaya Samaj office following FGD guidelines. Discussions were recorded on paper by a note taker.

2.6.4. Tools for Data Collection

Tools used for quantitative and qualitative data collection are shown in Table 4.

Table 4. Data collection tools

S. No.	Tools	Description
Quantitative tools		
1.	HIVST client register	Initial register for collecting name and contact information of the study participants; confidential register maintained by CBS
2.	HIVST client record form	Primary data source used to collect quantitative data mentioned above; contains no name; paper-based form in Nepali language filled with pen, requiring approximately five minutes to fill out
3.	HTC register	Primary data source kept at confirmatory HIV testing center, confirmatory test result of HIVST reactive study participants were extracted from this register. This was an existing tool of LINKAGES Nepal project. HA (HIV counselor) was responsible for maintaining this register at the facility that provides data to the consultant.
4.	Tracking sheet for HIVST unassisted/unsupervised test	Kept by CBS; used to track study participants who chose unassisted/unsupervised HIVST
5.	Tracking sheet for adverse events	Used to track adverse events related to the pilot study by CBS, reported to PI through HA. PI reported to LINKAGES Nepal project director, NHRC, and Protection of Human Subject Committee (PHSC).
Qualitative tools		
1.	SSI questionnaires	Used to guide interviewer and capture study participants' responses. These were pretested and finalized before conducting interviews. SSIs were conducted on a one-to-one basis by the consultant.
2.	FGD guidelines	Used to conduct FGD among CBSs; designated note taker made notes of the discussions

2.7. Data Management

CBSs submitted all filled forms to the HA, who was also a counselor for HIV testing in SACTS Lagankhel every week, who checked for completeness of information. Any incomplete

information was refined in consultation with the CBS. The HA sent filled forms/tools to the senior laboratory specialist at LINKAGES Nepal country office on a weekly basis. The entered data were kept in password-protected computers in the FHI 360 office in a secure location.

2.7.1. Quantitative Data Management

All information related to the study participant, choice of approach, HIVST result were collected in a paper-based format by CBSs using the HIVST client record form. Forms for clients with nonreactive HIVST results were submitted by CBSs every week to the HA at Lagankhel clinic. Forms of clients with HIVST reactive results were handed over to the HA on the same day when reactive result was received. For confirmatory tests, clients were registered in the clinic and provided a new standard UIC of the clinic. After receiving the confirmed HIV result, the HA recorded the result in the same form initially filled out by the CBS. The HA also reviewed the form for missing information, added it with the support of the respective CBS, and sent the form to the LINKAGES office. LINKAGES Nepal senior laboratory specialist was responsible for checking for data completeness and verifying with SACTS for any missed information. Data were double entered in the Excel sheet and compared to reduce data entry error. These data were then transferred to a password-protected SPSS-version 24 database. During data entry personal identifiers were removed and replaced by codes. Data coding and data entry were completed by trained staff at LINKAGES Nepal country office.

All paper consent forms and the HIVST client register were kept in a locked storage cabinet at Parichaya Samaj during the study period and were handed over to FHI 360 Nepal office at the end of the study. All forms will be stored for five years after the end of the study, per FHI 360 policy.

2.7.2. Qualitative Data Management

All qualitative data were transcribed and translated by the qualitative data consultant and FHI 360 staff who have signed an oath of confidentiality agreement. Transcripts were prepared from field notes, translated to English, and entered as electronic files into NVivo 11r software. Each transcript or file was given an identifying archival number for later reference. Password-protected electronic copies of all transcripts were kept by LINKAGES staff and are only accessible by designated study team members. Electronic transcripts were de-identified prior to analysis.

The LINKAGES Nepal office has stored all hard copies of informed consent, interview guides, and notes in a physical location secured with locks. No records will be destroyed without written permission from FHI 360 HQ.

2.8. Data Analysis

Descriptive analysis of the quantitative data was performed using SPSS-24 Version. We analyzed the proportion of self-testers who accepted the HIVST, their respective age groups, and the proportion of self-testers who chose unassisted/unsupervised testing or assisted/supervised testing. These indicators were calculated separately for MSM, MSWs, and trans people. We also calculated the proportion of HIVST users with reactive results and compared the results with the confirmatory HIV test result following a standard national HIV testing algorithm.

Qualitative data analysis was done by the FHI 360/LINKAGES team and consultant, using NVivo 11r software. Analysis included deductive codes generated from the data collection instruments and inductive codes created from emerging data. Approximately 20 percent of transcripts were double-coded to ensure intercoder reliability. Study staff ran code reports and created memos summarizing themes, including supporting quotes.

3. Results

3.1. Quantitative Results

3.1.1. Acceptance of HIVST

A total of 482 people were offered HIVST, out of those 440 (91.3 percent) provided consent and accepted HIVST (see Table 5). Acceptance was similar for MSM, MSWs, and trans women. Around 9 percent declined the offer for HIVST as they did not want to test, felt they were not at risk, or recently had an HIV test. Some committed to test later but not on the day offered.

Table 5. Number of individuals accepting HIVST

Descriptions	MSM		MSWs		Trans women		Total	
	N	%	N	%	N	%	N	%
Total number of individuals offered HIVST	236	100.0	117	100.0	129	100.0	482	100.0
Individuals who accepted HIVST	213	90.3	108	92.3	119	92.2	440	91.3
Individuals who did not accept HIVST	23	9.7	9	7.7	10	7.8	42	8.7

Of the study participants 48 percent (213) were MSM, 25 percent (108) were MSWs, and 27 percent (119) were trans women. All eligible participants responded that they were doing an HIV test for the first time.

3.1.2. Age of Participants

Table 6 presents the age distribution of study participants. A majority 277 (63 percent) were from 20–24 years of age. Individuals below 18 years were not eligible. The mean age was 24 (23.7 for MSM, 23.9 for MSWs, and 25. 1 for trans women).

Table 6. Age distribution of study participants

Age group	MSM		MSWs		Trans women		Total	
	N	%	N	%	N	%	N	%
18-19	13	6.1	13	12.0	6	5.0	32	7.3

Age group	MSM		MSWs		Trans women		Total	
	N	%	N	%	N	%	N	%
20-24	145	68.1	70	64.8	62	52.1	277	63.0
25-29	30	14.1	14	13.0	31	26.1	75	17.0
30-34	13	6.1	3	2.8	12	10.1	28	6.4
35-39	7	3.3	2	1.9	4	3.4	13	3.0
40 or above	5	2.3	6	5.6	4	3.4	15	3.4
Mean age	23.7		23.9		25.1		24.2	
Total	**213**	**100.0**	**108**	**100.0**	**119**	**100.0**	**440**	**100.0**

3.1.3. Approach Choice for HIVST

Of total participants, 99 percent chose the assisted/supervised HIVST and only five (four MSM and one MSW) (1 percent) chose unassisted/unsupervised; no trans woman chose unassisted/unsupervised testing.

Table 7. HIV self-testing approach choices

HIV self-testing approaches	MSM	MSWs	Trans women	Total
Number who chose assisted/supervised self-testing	209	107	119	435
Percentage who chose assisted/supervised self-testing	98.1%	99.1%	100.0%	98.9%
Number who chose unassisted/unsupervised self-testing	4	1	0	5
Percentage who chose unassisted/unsupervised self-testing	1.9%	0.9%	0.0%	1.1%
Total	**213**	**108**	**119**	**440**

3.1.4. Reactive HIV Self-Test vs. Confirmed HIV Test Results

Out of 440 who took the HIVST, 428 (97 percent) had a nonreactive result and 12 (3 percent) a reactive result. Of the 12 positive cases, 11 (92 percent) were identified through the assisted/supervised approach and one (8 percent) through the unassisted/unsupervised approach (see Table 8).

All 12 individuals had an HIV confirmatory test using the national standard HIV testing algorithm, and all were confirmed HIV positive. This group included four (2 percent) MSM, four (4 percent) MSWs, and four (3 percent) trans women. One HIV-positive individual later responded during a SSI that he had done HIV testing prior to self-testing, and the result was positive.

Table 8. Results of HIV self-test vs. confirmed HIV test

Descriptions	MSM	MSWs	Trans women	Total
Total participants	213	108	119	440
Number who had nonreactive HIV self-test result	209	104	115	428
Percentage who had HIV nonreactive result	98%	96%	97%	97%
Number who had reactive HIV self-test result	4	4	4	12
Percentage who had HIV reactive result	2%	4%	3%	3%
Number who had confirmed HIV-positive result	4	4	4	12
Percentage who had confirmed HIV-positive result	2%	4%	3%	3%

3.2. Qualitative Results

3.2.1. HIVST Decision-Making

MSM, MSWs, and trans women

All participants (n=46) mentioned they heard about HIVST from someone they knew who works in a community organization. They reported they decided to participate in using the HIVST because it can be done easily, without drawing blood, and the result can be obtained immediately.

"*I decided to do this test because result can be seen in front of my eyes. First, I didn't know about this test. I know about the blood test, where blood is drawn from syringe to have test. My friend (name) told me about this test. He mentioned about the HIV testing. I was worried about the painful procedure, withdrawing of blood, and all those things, but I got surprised; this testing kit is easy and done from oral saliva."* (NRC-11, MSM)

A few participants (n=9) had misconceptions regarding the HIVST when they heard about it. They found it difficult to trust initially.

"First I didn't know about this test. I know about the blood test, where blood is drawn from syringe to have test. When I heard about this test, which is done by oral saliva, I thought of trying this." (NRC-12, MSM)

A few participants mentioned they thought the HIVST was fake. But when the success of the kit in other countries was explained, they trusted it and found it simple to use.

"First, I didn't trust this test, I thought HIV testing from mouth is fake. But when they explained all those things and success of this kit in other countries as well, I trusted them. When I did my test after, I realized that test was very simple." (NRC-17, MSW)

Almost all participants (n=42) preferred receiving the HIVST kit from people in the community or a community organization. They felt they could trust the community, and their information would be kept confidential. However, a few participants (n=4) reported they preferred a health facility as being expert and providing adequate information.

Most participants (n=43) chose the assisted/supervised approach. They said they felt comfortable performing the test under supervision. A few participants feared getting errors while performing the test by themselves.

"*I was having that test for the first time; there may be some errors. So, I decided not to take any risk. I was even nervous during that time. Now, [moving] onward, I can do it independently, even at home.*" (NRC-3, MSM)

On the other hand, very few participants (n=3) chose the unassisted/unsupervised approach. One participant said: *"First, the place where she talked about the test kit was much crowded; it was difficult to maintain privacy. And second one was, I have multiple sex partners, some were there as well. So, I thought having test at home is far better, because result is limited to me only."* (NRC-32, MSM)

Another participant said he felt uncomfortable in front of other people. *"I was here for first time; I didn't feel comfortable. I observed closely the test done by them, how they opened the*

kit, how they move spatula around oral cavity, how interpretation of result is done. I followed same procedure at home. It was easy." (NRC-33, MSM)

CBSs, health care providers, and government officials

Five SSI participants and FGD members said they preferred providing the assisted/supervised rather than the unassisted/unsupervised test. The most common reasons cited were high chances of losing, damaging, or not returning test kits after use; and also losing the clients. Whereas the assisted/supervised method allowed them to refer clients whose tests were reactive for further diagnostic tests and provide them counseling at the same time. It also helped them track reactive cases for further management, which was a challenge with the unassisted/unsupervised approach.

"With supervised test, it's easy to track the client with reactive result. And we can immediately bring them to the center. We can start ART as soon as possible. Whereas in unsupervised test, we need to wait for his/her call. If they don't call us in 48 hours, then we can only follow them. it's difficult to bring client with reactive result to the clinic for confirming test. Because of that, there is chance of delaying ART." (SP_4)

Two participants mentioned that people may not prefer the unassisted/unsupervised approach because of the stigma associated with HIV. *"In our context, HIV is still associated with stigma; it's hard to assume people will buy the self-test kit from market. It's not impossible, but before that HIV should be taken as normal like other disease. People still hesitate to buy condoms, so it's hard to expect they will buy the self-test kit."* (GOV_3)

3.2.2 Acceptance of HIVST

MSM, MSWs, and trans women

The majority of respondents (n=34) said they would use HIVST in the future. The most common reasons cited were easy to use (n=27), not painful (n=19), and did not require to draw blood (n= 7).

"My friend told me about this test. He had mentioned about HIV testing; I was worried about the painful procedure, withdrawing of blood, and all those things, but this test kit is easy and done from oral saliva." (NRC, 11)

Other participants compared the test kit to a pregnancy test kit. *"People can perform it in home or with community organization by reading its instruction like a pregnancy kit."* (NRC- 27, MSM).

"When I heard about this test, which is done by oral saliva, I thought of trying it. The test is

really easy to do." (NRC-12, MSM)

"For me its 100 percent reliable, because my result was negative, which was in front of my eyes. Sometimes there may be mistaken report, I mean manual error may be there while preparing report from blood test, writing the report; which is not possible in this test. There is no chance of error." (NRC-4, MSW)

Almost all (n=41) participants said they would recommend HIVST to their partner or friends. The most common reasons cited were the test was easy to use, not painful, safe, did not require blood, and done through saliva.

However, three respondents said they would not recommend HIVST as it was not 100 percent reliable and would recommend blood test instead. The majority of participants (n=37) said the HIVST was as trustworthy as having an HIV test in the facilities.

"First it was difficult for me to believe in the test. But when I did my test and result was in front of my eyes, I trusted the result." (NRC-11, MSM)

Eight participants mentioned that since they were not in HIV-related risk behavior and their HIVST test results were negative, they felt they could trust the test kit. Four respondents said since the test was done in front of their eyes, they felt it was reliable; two respondents felt the test was trustworthy because it was tested in other countries as well.

Five participants said they do not trust the HIVST. Two had doubts regarding the use of saliva for testing HIV since HIV is not transmitted via saliva; one felt that HIVST may be trustworthy, however, he needed to confirm and verify by doing a blood test. Another participant said since his result was positive, but he did not have any symptoms yet, he felt he could not trust it completely, while another said he found the kit only 60 to 70 percent trustworthy. Two participants could not comment on whether they trusted HIVST or not since they were waiting for the confirmative test result or had not had a blood test.

CBSs, health care providers, and government officials

Most SSI respondents (n=7) and FGD participants reported that the HIVST is easy to use and is less painful compared to the traditional HIVT test. They said HIVST was less hazardous and there were lower risks of getting HIV compared to the traditional approach.

"*HIVST is harmless; I mean to say we are not at risk of getting infection because sometimes in conducting finger prick for test, we may get exposed to HIV*." (P3, FGD)

One FGD participant and two SSI participants said HIVST provided an option for having a test done privately with high level of confidentiality. Three participants (two service providers and

one government official) also mentioned HIVST helped screen cases at the community-level than the facility-level. *"It saved time for both lab and client. If the client was nonreactive, then there was no need to do a blood test for HIV, which avoided clients making extra visits to the clinic for an HIV test".* (P4, FGD)

One government official said HIVST was beneficial as it helped in finding hidden members of the population who avoided going to hospitals or HIV testing sites for the tests. A second official said it will be helpful among high-risk populations as it can be conducted privately with less chance of disclosing sexual orientation and/or HIV status.

All four government officials along with two service providers said HIVST was highly reliable.

3.2.3. Understanding the Testing Procedures and Performing the Test

MSM, MSWs and trans women participants

It is encouraging that almost all participants agreed they had been given full information regarding the HIVST, and they were aware the result would be kept confidential (n=45), it is not a confirmatory test (n=45), and they would be enrolled in ART (n=45) if confirmed HIV positive.

The majority of participants (n=40) mentioned the information provided by the CBSs was easy to understand. They said the procedure was not so difficult.

"Yes, these people are very friendly, so it wasn't difficult to understand the information they provided. I also looked on the leaflet; the picture provided was clear enough to understand all the procedure." (NRC-11, MSM).

Almost all KP participants said the instructions were easy to follow. Seven said the pictures on the leaflet were clear, which made it easy to understand.

Three participants said even though the instructions were clear and easy to understand, it was difficult to perform the test for the first time just by looking at the pictures. They recommended placing arrows on the pictures to help them understand the various steps in sequence.

Almost all participants (n=41) reported they did not have any difficulty opening the test kit package. Most (n=34) did not have any difficulty performing the test and interpreting the results.

*"There wasn't any difficulty opening the test kit. I just opened the box like ordinary box, took out the spatula, moved around the mouth, and dipped in bottle. There was an arrow showing the tearing point." (*NRC-29, MSW).

"No, there were not any. After the test we needed to wait 20 minutes. I set the alarm on my mobile for 20 minutes and watched TV. After 20 minutes result was in front of my eyes. It was negative, because there was only one line; if the red line was two, the test result is positive." (NRC-1, MSM)

On the other hand, two participants requested the CBS to open the kit and interpret the result for them, as they said they were too nervous to get the result.

CBSs, health service providers, and government officials

All FGD and SSI participants (n=14) reported it was easy for CBSs and other staff to provide instructions to the study participants.

"*Yes, the provided information was sufficient to understand and use HIVST. The CBS was even demonstrating how the client needed to move the spatula around their oral cavity. They answered questions from the clients."* (SP_2)

Government officials reported CBSs had no problem providing instructions as they were written in Nepali language and the leaflet had colorful pictures; the procedure was simple to do. Six participants reported that clients easily understood the instructions provided.

"CBS was providing instruction clearly. She was showing the procedure; how client needed to move the spatula over the oral cavity…CBS was quite confident in giving instruction, because client clearly understood the procedure. I didn't find any problem in understanding the procedure." (GOV_4)

FGD participants reported clients understood the instructions provided as the leaflet was written in Nepali language and had pictures. One government official agreed the instruction in the leaflet was adequate for performing the test but thought more information on HIV would be beneficial. *"I couldn't find any gap in the information…it was sufficient for the test, but it would be better if more information about HIV is also provided."*

No participant mentioned that the information in the leaflet was inadequate. However, they said clients may have difficulties in understanding the first time it is explained.

Government officials said HIVST is suitable for both literate and illiterate people. Those who have completed school level education can easily do the test by reading instructions, and those who are uneducated can understand by looking at the pictures.

On the other hand, two participants reported it was somewhat difficult to understand the instructions provided by CBSs.

"In my personal experience they are unable to understand all the information. Most of them understand partial information. Because sometimes, they asked the same question frequently. It's difficult to make them understand in a single attempt. We need to explain to them many times." (SP_2)

Nine participants gave suggestions for the instruction leaflet. FGD participants and service providers (n=6) suggested enlarging the type font and picture size. One government official suggested including more information about HIV. Other suggestions were to create a video to show the HIVST procedure and to print instructions in other languages including the local language of the community other than Nepali.

"The instructions are in Nepali language, and some people may not understand Nepali. So, we need to use a multilingual approach in the future." (GOV_4)

3.2.4. HIVST Perception on HIVST Roll-Out and Other

MSM, MSWs, and trans women

Fourteen participants said people should have some knowledge and awareness about HIV and HIVST before introducing the kit to the market. Community awareness would be an important element in the rollout or availability of HIVST in the market. Two respondents talked about educating people on the modes of HIV transmission and about HIV in general so that they would have sufficient knowledge.

"*The main problem with this kit is, trust. As I have mentioned earlier, we have knowledge that HIV is not transmitted by kissing, then how can [this kit] give the result of HIV status. People may think this test kit is fake or done only for promotion. So, first, people need to become aware of how this test kit actually works. Otherwise, there may be chance of confusion among public…We are saying that HIV is not transmitted via kissing and at same time we are saying HIV is tested via saliva. Therefore, awareness must be done first before launching program in another place.*" (NRC-32, MSM)

"Most people don't know that HIV test [can be] done from saliva. They may have confusion about how HIV is tested from saliva because HIV is not transmitted via kissing. So, they may not trust this test kit easily." (RC-11, MSM)

Another respondent added that people should know how the test kit works and how to use it.

"But first they should know how the test works. It's simple, just like having a pregnancy test. If someone has positive pregnancy test, then only she consults hospital. Same applied here as well. If test kit shows positive result, we need to go for further test." (NRC-28, MSW)

Six participants mentioned platforms for creating awareness about HIV and HIVST among the general population such as social media (Facebook), mass media (television, radio, newspapers), and community groups (mother's support group).

"You can launch a program for awareness by community people. You can target other audiences such as in school, on campus, or at an army/police barrack. Or you can use Facebook, or any other social media, because most people use FB [facebook] nowadays." (NRC-27, MSM)

Twelve participants shared views on the use and availability of HIVST in the market. They felt people would use HIVST if it was available in the market at such locations as hospitals and medical shops. "*It's easy to use. And people can have their test at home as well if they feel comfortable."* (NRC-30, MSW)

One participant said the test kit was more suitable in remote areas where they lacked HIV testing resources. He added it would be beneficial for other key populations such as migrant workers as it does not require them to go to the health posts and only takes 20 minutes.

"I think this test kit is more suitable and effective in remote places of Nepal. There are many migrants from India and other countries in remote village areas, they and their wives are always at risk of having HIV. Wives of foreign labor migrants can keep test kit with them and use when husband is back to home, it takes just 20 minutes; they don't need to go health post or any other place. More importantly, privacy is highly maintained with this test kit." (NRC-32, MSM)

However, five respondents brought up costs related to the kit. They said people would use HIVST provided the cost was between NRs.100 (approximately US$1) and NRs.500 (approximately US$5), or free.

CBSs, health care providers, and government officials

It is encouraging that almost all service providers and government officials (n=10) said there would be no difficulty in implementation of HIVST. Furthermore, FGD participants said implementation of HIVST would be useful to reach the hidden population throughout the country to achieve 90-90-90 by 2020 goals.

"It will be very good to implement this program in other places of Nepal as well. People are also demanding it, one client even wanted to buy it…There are other hidden populations throughout the country. If this program were implemented in other places of Nepal, they will also benefit." (FGD, CBS)

Government officials also said since the test does not require blood and can be done in a short time, it will be easy to convince people at risk to use it.

"As we know in our context, key populations are hidden. So, this test is more effective for them. It will be easy to track them. As blood is not needed in this test, it is easy to convince them to do the test. In a short time, we can even do interpretation of result. It's time saving as well." (GOV_1)

Almost all participants (n=8) mentioned HIVST will be useful to other key populations as well.

"*If this program has success here, we can easily implement it in other places as well. We can target for general population, but more emphasis can be given to drug users, FSWs, wives of migrants."* (GOV_3)

"*Definitely, we need to expand this program. Once we implement this program, high preference must be given to the unsupervised test. And I just mentioned earlier, awareness is a must for success. And while [scaling] up we need to be conscious about misuse of test kits and false reporting.*" (GOV_4)

"Yes, this test is superior to blood test. We can extend this program, but caution must be taken; I mean to say this test should be taken as a screening test not as a final confirmatory test." (GOV_2).

One participant noted assisted/supervised approach by CBSs is best for further rollout.

"*In the initial stage going through CBSs is best, because key populations trust them, and CBSs can reach out to them. When the program is implemented widely and people are aware of availability of test kits and easily accept it, then, in that case, we can change our modality."* (GOV_4)

A service provider mentioned that HIVST should be initiated after conducting community awareness activities. Participants also focused on the need for supervision for proper use of HIVST and correct reporting of the results.

3.2.5. Challenges

MSM, MSWs, and trans women

Some participants (n=9) reported that HIV stigma exists in the community and home as well.

"In Nepal there is still discrimination for LGBTI. I have heard a few of my friends were kicked out from their house when their parents knew their sexual orientation. Family will discriminate more if individual has HIV/AIDS. Still people are thinking of HIV as a fatal disease, and they always connect the disease with individual personal and sexual character. It's a communicable disease and can be transmitted to anyone. Because of such discrimination and stigma, people whose

report is positive do not share to anyone; they don't start ARV, thinking that their family may know their HIV status if found having ARV." (NRC-32, MSM)

Some participants (n=9) reported the issue of HIV or sexual orientation disclosure as a problem. One participant said it would be a big problem for him if his family members know his sexual orientation.

"Yes, because of confidentiality I had this test here. Though my family knows my sexual orientation, my relatives don't. So, I do not think having test in front of them." (NRC-29, MSW)

"They will kick me out of home if they know. My mom always assures me to have girlfriend of my caste; if she knows that I am MSM, I can't imagine the situation how they will treat me." (NRC-33, MSM)

Another participant said disclosure of sexual orientation in the family will not be a problem for him, although he has not disclosed to his family.

"It won't be a big problem in my case; I can explain to them and convince them. But in many other cases, the family does not accept them and [they are] not allowed to stay in their house." (NRC-32, MSM)

Another participant perceived people in the village looking at him in a negative way and backbiting when he was near them. "*Not at home, but a lot in the village. They see us negatively. When they see me, they start backbiting*." (NRC-34, trans woman)

One participant said finding out the test is positive is a challenge for an individual; accepting an HIV-positive result is not easy.

"If people buy the test kit from the market and do the test, unfortunately, if the result is positive, how could he or she manage the condition? Accepting HIV is not easy." (NRC-27, MSM)

Another participant said it would be difficult to perform the test the first time.

"For the first time it will be difficult to take the test looking at the leaflet. But from second attempt, it will be easy. Though instructions are written in Nepali, it's difficult to do just looking at pictures because we are not used to having such test just looking at pictures." (RC-09, Trans woman)

Five participants mentioned challenges associated with HIVST implementation. Three said having only pictures in the instruction leaflet would not be adequate for uneducated and illiterate people.

"*For educated people it is easy; they can read instructions and follow. But for uneducated it may be challenging; although the pictures are there, they may [find it] difficult [to follow].*" (NRC-35, MSM)

CBSs, health care providers, and government officials

Service providers and government officials (n=5) and FGD members discussed challenges related to the clients. All mentioned it was difficult and challenging to get clients who have HIVST reactive results to go for confirmatory tests.

Three SSI participants and one FGD participant said study participants questioned the effectiveness of HIVST. They found it hard to believe that one could know their HIV status by testing saliva using the kit.

"*We have long been saying that HIV doesn't transfer from kissing and, all of sudden, we go in front of them with this test kit and say that this test gives the status of HIV from saliva.*" (SP_1)

Participants also noted challenges related to the kit itself. An FGD member and a government official said disposal of the used kits would be a challenge in the unassisted/unsupervised approach, while two other government officials felt the kits would be mishandled or damaged if given to clients for unassisted/unsupervised use.

Two participants mentioned the appearance of a "fake line" on the kit if it is kept longer than 20 minutes, which causes unreliable results. Lastly, one respondent raised concerns regarding availability of the kits, and another the chances of kits being mislabeled when the test is performed in large groups.

One government official shared concern about people thinking that HIVST is a diagnostic test: "*The main challenge that I have noticed is sometimes they may consider the report of HIVST as a final or conformity test.*" (GOV_2)

Five SSI participants and the FGD members discussed disposal practices for the HIVST kit. Most (SSI=4 and FGD) said the used kits are collected by the CBSs and autoclaved. The used kits are checked against the serial numbers to make sure they match the ones that were given away. One FGD member said that if the test is reactive, then it is marked with red. There was also concern among the participants (SSI=2 and FGD) regarding the disposal of the used kits if people started using HIVST on their own without any supervision.

"*This (disposal) could be one challenge in the coming future if we go for the unsupervised test. Because, I don't think people [will] return used test kits easily.*" (SP_4)

Some participants (n=2) pointed out that implementation could be challenging because HIV is still associated with stigma, and there is discrimination against people based on their HIV status.

3.2.6. Suggestions

MSM, MSWs, and trans women

Most respondents (n=28) said "everything was fine" and "there was no need to change anything."

Seven respondents suggested the test kits should be available everywhere. Some said the kits should be available at different organizations (n=2), medical facilities and hospitals (n=1), and in rural areas (n=1).

Two participants suggested the kit should be smaller so that it would easily fit in a pocket. Another said, "*It would be better if the cover of the test kit would be transparent so that it can be seen from outside."* (NRC-3, MSM)

CBSs, health care providers, and government officials

Although government officials and service providers were not specifically asked for suggestions, they provided some during interviews. Two service providers suggested the test kits should be made available to other parts of Nepal as well. A government official and a service provider suggested targeting other KPs such as people who inject drugs, wives of migrant workers, and FSWs. Other suggestions made by government officials were to educate the general population about HIVST via mass media and ensure safe disposal of used kits.

4. Conclusions and Recommendations

1. During the study, 482 people were offered HIVST. Of those, 440 (91.3 percent) provided consent and accepted HIVST. Acceptance was similar for MSM, MSWs, and trans women. All participants reported they decided to use the HIVST because it can be done easily, does not require drawing blood, and the result is available immediately. The majority of respondents (n=34) said they would use HIVST in the future and recommend it to their partner or friends.

   Recommendation: HIVST is acceptable among MSM, MSWs, and trans women in Nepal. Coordinate with NCASC and NPHL to roll out HIVST as an additional method of HIV testing in addition to facility-based testing and community-based testing for triage across the country.

2. Of the total, 99 percent of participants chose assisted/supervised HIVST and only 1 percent (four MSM and one MSW) chose unassisted/unsupervised. No trans woman chose unassisted/unsupervised testing. Participants and service providers preferred performing the test under supervision.

   Recommendation: Use the assisted/supervised approach and mobilize community outreach workers as the preferred method of implementation for HIVST. Use the unassisted/unsupervised approach as an alternative when an individual prefers it or there are issues related to disclosure of being a member of a KP or of HIV status.

3. Out of 440 who took the HIVST, 428 (97 percent) were HIVST nonreactive and 12 (3 percent) were HIVST reactive. All 12 individuals had HIV confirmatory tests using the national standard HIV testing algorithm, and all were confirmed HIV positive. Out of the 12 positive cases, 11 (92 percent) were identified through the assisted/supervised approach.

   Recommendation: Use HIVST as an additional method of HIV testing, especially when traditional approaches are not adequate to increase case findings.

4. Almost all participants (n=42) preferred receiving the HIVST kit from community people or a community organization. They felt they could trust the community, and their information will be kept confidential.

Recommendation: Mobilize the KP community as a community-led approach for performing HIVST during rollout.

5. Almost all participants agreed they had been given full information regarding the HIVST, were aware the result would be kept confidential, HIVST is not a confirmatory test, and would be enrolled in ART if confirmed HIV positive.

   Recommendation: Use the individual or one-to-one education approach for providing information. Prepare a standard operating procedure for implementation including the procedures followed during the pilot study.

6. Information provided by the CBSs was easy to understand and follow; the pictures on the leaflet were clear and easy to understand. HIVST users did not have any difficulty opening the test kit package, performing the test, and interpreting the results. CBSs and health staff found it easy to provide information to the study participants.

   Recommendation: Mobilize CBSs or similar level lay providers for introducing HIVST during rollout.

7. The instruction provided in the leaflet was adequate for performing the test. However, suggestions were made to enlarge the type font and picture size and use a video if needed.

   Recommendation: Develop instruction materials using the information provided in the leaflet used for client instruction during the pilot study. Enlarge pictures and type font size in instruction materials and develop audiovisual instructions.

8. No difficulties were reported in implementing HIVST. However, the general population should have awareness about HIV and HIVST before introducing the kit to the market. Use social media, mass media, and community groups to raise awareness. Ensure that messages include how HIVST works using salvia when HIV is not transmitted through saliva. People would use HIVST provided the cost was between NRs.100 (about US$1) and NRs.500 (about US$5) or was free. HIVST should be introduced to other KPs besides MSM, MSWs, and trans women and made available in other parts of the country beyond the pilot district.

   Recommendation: Develop IEC materials and social media campaign messages about HIVST. Messages should focus on how HIVST works using salvia, and HIV is not transmitted through saliva.

9. Stigma related to HIV, sexual orientation, and disclosure of HIV status could be challenges for further implementation. The personal information of individuals and their HIV status should be kept confidential. Other challenges include interpreting the result when no distinct line appears in the test window of the kit, acceptance of HIV positive status, anxiety related to HIV-positive status, and getting HIVST reactive clients to go to a facility for confirmatory tests.

   Recommendation: Focus on maintaining confidentiality of the HIVST result, sexual orientation, and personal information of individuals. Develop messages for providing counseling for HIVST reactive results. Develop and implement approaches for accompanying clients with HIVST reactive results to HIV testing facilities for confirmatory tests.

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