資料 4.

Epidemiology of HIV and HIV Testing in Nepal- A Report

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Epidemiology of HIV in Nepal

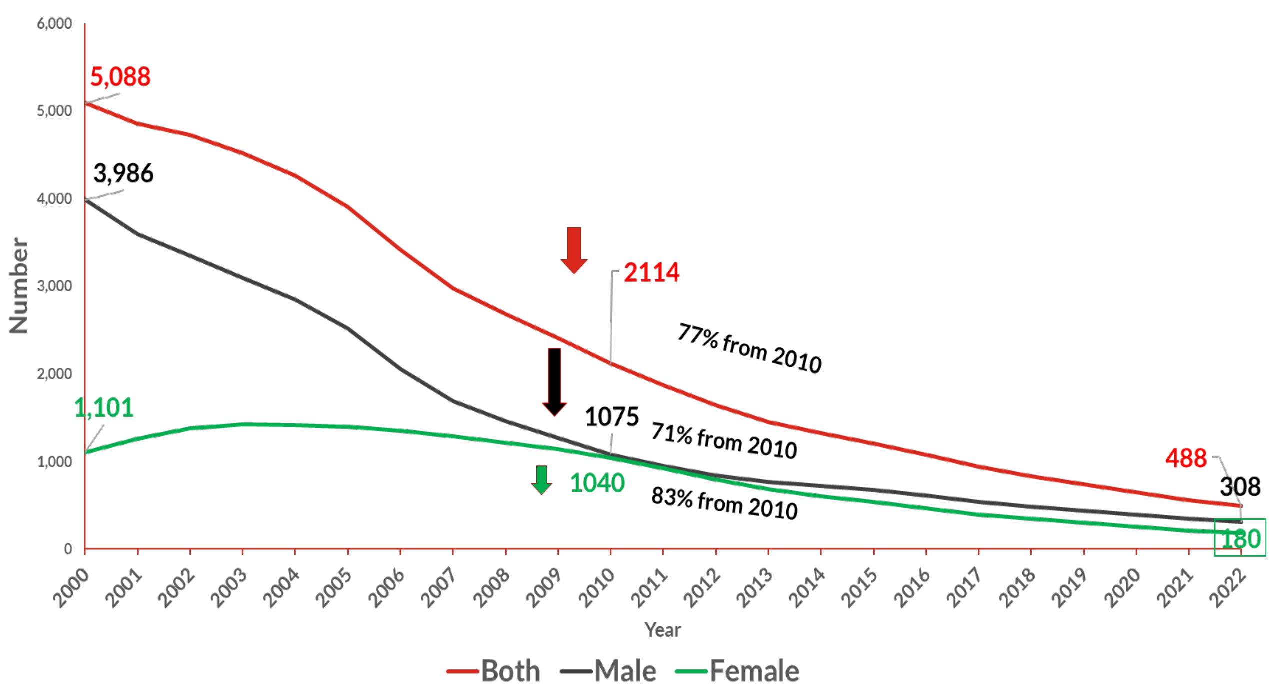
The general HIV prevalence in Nepal is 0.12. However, Nepal has concentrated HIV epidemic among the key populations. The key populations are People Who Inject Drugs (PWID), Migrants and their spouses, Sex Workers and their clients, Men who have sex with men (MSM), Transgender (TG) and Prison inmates. The first HIV case was detected in 1988 in Nepal. Heterosexual transmission is the dominant mode of HIV transmission (72%).

Table 1. National HIV Estimates 2022

HIV and AIDS Estimates in Nepal	Number (min-max)
Adults and children living with HIV	30,000 (27300-32500)
Adults aged 15 and over living with HIV	28800 (26200-31200)
Women aged 15 and over living with HIV	12900 (11800-13900)
Men aged 15 and over living with HIV	15900 (14500-17400)
Children aged 0 to 14 living with HIV	1180 (1020-1320)
Mothers needing elimination of vertical transmission services	230 (190-260)
Adult HIV prevalence	0.13 (0.12-0.14)

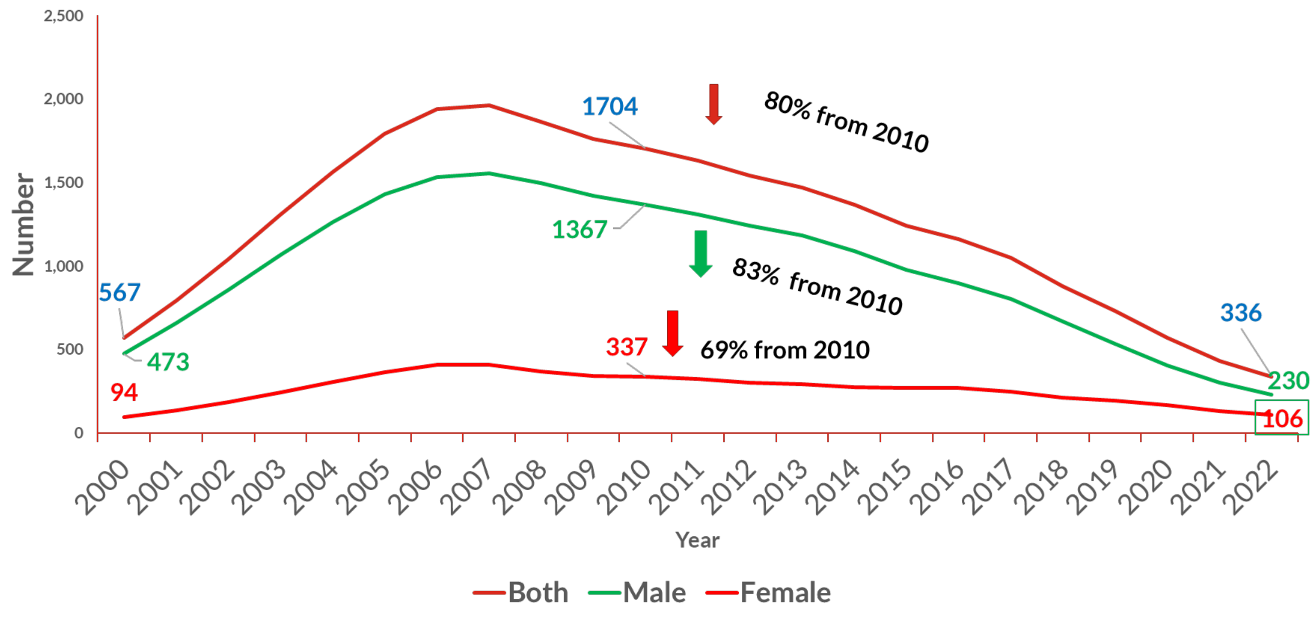
(Source: NCASC 2022)

Figure 1. Trend of Number of New HIV infections



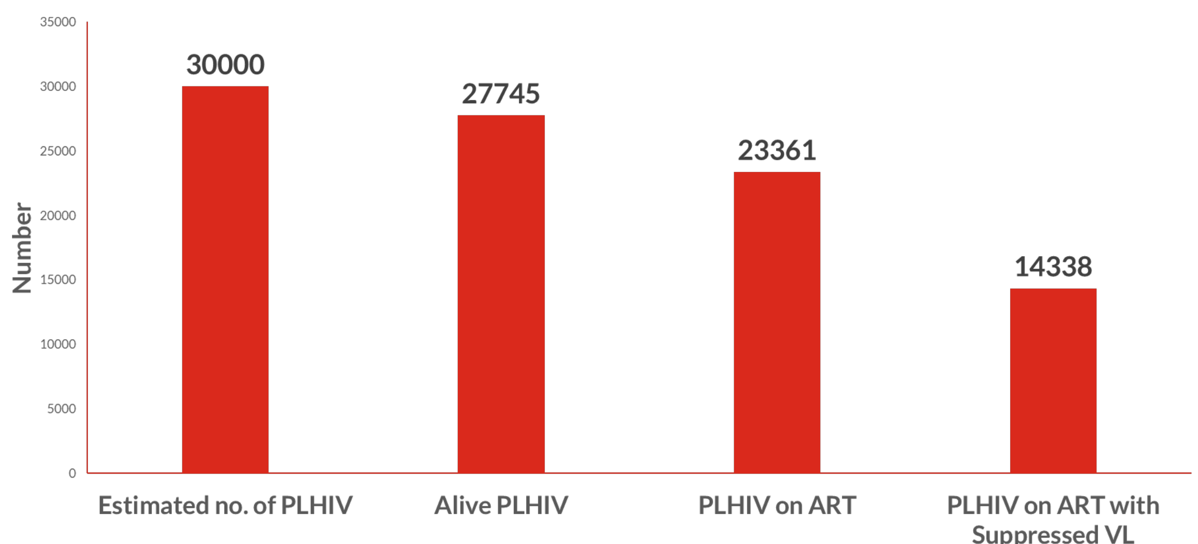
(Source: NCASC 2022)

Figure 2. Trend of AIDS related deaths



(Source: NCASC 2022)

Figure 3 HIV Testing and Treatment Cascade 2022



Note: Total PLHIV on ART tested for Viral Load- 14456 **(Source: NCASC 2022)**

National HIV Program and its components

The HIV program in Nepal follows the National HIV Strategic Plan (NHSP) 2021-2026.The National Centre of AIDS and STD Control (NCASC) is the central governing body under Ministry of Health and Population (MoHP) to lead the entire HIV program related activities in

the country. NCASC's leadership is being supported by National Public Health Laboratory (NPHL), UNAIDs, WHO, External Development Partners (EDPs), NGOs and community networks. The EDPs such as Save the Children (Global Fund grant), Family Health International/FHI (PEPFAR grant) and AIDS Healthcare Foundation (AHF) are major partners supporting the implementation of HIV program. The Anti-retroviral treatment (ART) Centers and Viral Load testing Centers are directly under government portfolio. Save the Children supports the prevention program for key populations; Migrants and their Spouses, PWID and Prison inmates, and Care and Support program for PLHIV. FHI support prevention program for key populations; MSM, TG and sex workers. FHI and AHF both provide supports to government ART centers.

National HIV Testing Algorithm

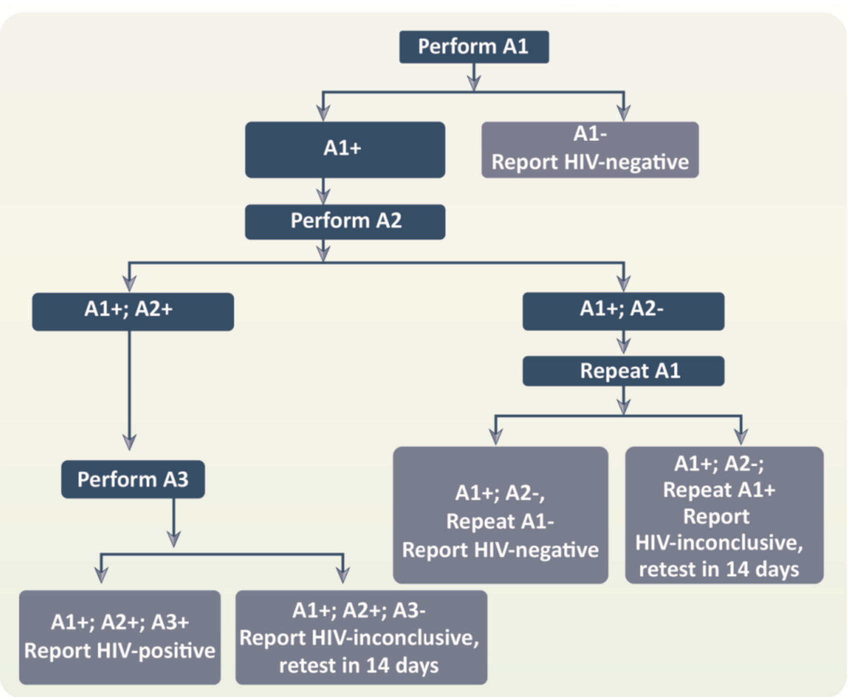
The National HIV Testing and Treatment Guidelines (updated 2022) is the major document that guides the testing protocol for the HIV program. The National HIV testing protocol which is derived from WHO recommendations follows the serial testing algorithm.

Assay 1 by Determine test kit
Assay 2 by Unigold test kit
Assay 3 by Statpak test kit

All these test kits used in the testing algorithm are antibody-based test kits. They have different sensitivity (ability to detect true positives) and specificity (ability to exclude true negative cases) values.

Rapid HIV test Kits	Sensitivity (%)	Specificity (%)
Determine HIV-1/2	100 (95.5-100)	99.4 (96.7-100)
Uni-Gold HIV	100 (95.5-100)	100 (95.5-100)
STAT-PAK HIV-1/2	100 (98.8-100)	99.3 (98.1-99.9)

Figure 4: National HIV Testing Algorithm



Community-Led HIV testing

The Community-Led HIV testing (CLT) started in Nepal in 2018 after the endorsement of National CLT Guidelines in 2017. CLT is a testing approach where the trained lay providers from the key population community itself provide HIV screening test to the clients of the key populations as a part of the outreach work. Those lay providers are called in-reach workers (IRW) and Community-based Supporters (CBS) in prevention programs under Save the Children and FHI respectively. The CLT follows the principal of Test for Triage (A0).The HIV screening test is conducted using Determine test kit or Oraquick test kit (HIV Self-testing). The reactive cases are then done accompanied referral to nearby HIV testing Centers for confirmatory tests. Since the start of CLT in 2018, the HIV testing and case finding have significantly increased.

In 2018, it was implemented in selected districts. In 2019 only, it was fully rolled out throughout the country after completion of all the trainings to the outreach workers. The following table shows the number of HIV screening tests conducted through CLT and the diagnosed positive cases (after confirmatory test).

Period	No. of HIV screening tests (CLT)	HIV positive cases
Mid July 2018-Mid July 2019	1569	72
Mid July 2019-Mid July 2020	85087	1001

Mid July 2020-Mid July 2021	180061	1930
Mid July 2021-Mid July 2022	97455	1359

Note: The Nepali fiscal year starts and ends around mid-July.

During CLT by lay providers, the “5 Cs” are ensured while providing pretest information and post-test counseling.

Consent

People receiving HIV self-testing must give informed consent to be tested and counseled.

Confidentiality

HIV self test must be kept confidential by all the staffs supervising the test.

Counseling

Since extensive counseling may not be possible in the community setting, pretest information must be provided to the people receiving HIV self test.

Correct

Quality assurance (QA) must be built into the HIV testing by lay providers to ensure that people receive good quality pre-test counselling and screening for HIV.

Connection

Long-term HIV prevention. All reactive persons, through screening, need to be linked with and accompanied to an HIV testing site for HIV diagnosis and, if found positive upon confirmatory testing, for further case management.

WHO (2016) recommendations on HIV Self-Testing (HIVST)

Key evidence showed HIVST is:

- Safe and accurate
- Highly acceptable
- Increased access
- Increased uptake and frequency of HIV testing among those at high risk and who may not test otherwise
- Comparable linkage and HIV+

- Empowering
- Can be affordable and cost-effective when focused

Thus, HIV self-testing should be offered as an approach to HIV testing services *(strong recommendation, moderate quality evidence.*

How HIV Self-Testing (HIVST) started in Nepal?

Pilot study of HIVST

In 2018, a pilot study on HIVST using OraQuick® Rapid HIV self-test was conducted in Lalitpur district of Nepal by FHI under PEPFAR grant. The objective of this study was to explore the uptake and acceptability of HIV self-testing for men who have sex with men, male sex workers, and transgender people in Nepal. This was a mixed-method study with quantitative study sample of 440 individuals. 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.

This pilot study provided the following recommendations for the implementation of HIVST in Nepal.

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.

Inclusion of HIVST in National Guidelines

Based on the recommendations of the pilot study, a section on HIVST (below) was included in the National HIV Testing and Treatment Guidelines 2020.

iii. HIV self-testing

HIVST is a process in which a person collects his/her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone he/she trusts. As HIVST reduces the number of visits to a facility and eliminates travel and time to access HIV testing, HIVST may be more convenient for users.

Procedure

HIVST can be delivered through two approaches, i.e. supervised and unsupervised.

- Supervised HIVST means receiving in-person assistance from a trained provider or peer before or during HIVST with instructions on how to perform a self-test and how to interpret the self-test result.
- Unsupervised HIVST means that an individual obtains a kit for HIVST and performs the HIVST himself/herself following the instructions in the package insert.

Oral fluid-based test kits are used for HIVST in Nepal. *Oraquick®* is currently registered in Nepal. Oral fluid-based HIVST is not recommended for people taking antiretroviral (ARV) drugs as this may cause a false non-reactive result. This test should not be performed immediately after using a mouthwash or eating or drinking.

All persons identified as HIV test reactive (A0+) using HIVST or by test for triage should be re-tested using the national testing algorithm to confirm their HIV status.

Implementation of HIVST in Nepal

In the September 2019, FHI organized the first batch of training sessions on HIVST for outreach workers working for MSM, TG, MSW and FSW communities. During these training sessions, some outreach workers working for PWID and Migrant communities (under Global Fund supported programs of Save the Children) were also included. Around 120 outreach workers were physically trained during these first batch of trainings Then, HIVST implementation was formally started in October, 2019 as a part of Community-led testing (CLT) for screening of HIV in the community by mobilizing community based lay workers. In Nepal, OraQuick Rapid HIV Self-Test kit (WHO pre-qualified and NPHL approved) is being used which uses oral fluid as specimen. The sessions on HIVST (both theoretical and practical) have been included in the regular CLT training curriculum for the outreach workers. The CLT training is a comprehensive 3-days training package which includes basic information on HIV virus and transmission, national epidemiology, 95-95-95 targets, testing algorithm, principles of CLT, 5Cs of pretest information and post-test counseling, universal precautions, post-exposure prophylaxis etc. It includes practical sessions for both Determine test kit and HIVST using Oraquick test kit.

Different approach and steps to receiving HIVST in Nepal

There are two ways to conduct HIVST. Either they are **Supervised HIVST—which** refers to service providers giving individuals a demonstration or information before or during HIVST on how to perform the test and interpret the test result, or they are **Unsupervised HIVST—which** refers to when individuals self-test for HIV using an HIVST kit with manufacturer-provided instructions, only, without any support from the service provider. Clients performing unsupervised HIV self-testing are required to inform the outreach worker (IRW or CBS) or the nearest HIV testing center if the test result is “Reactive” for the confirmation of HIV and the information regarding HIV.

HIVST distribution as a part of Community-led HIV Testing (CLT)

Community-led testing (CLT) is a screening test of HIV conducted by people from the community for people of their own community. Trained IRW and CBS in the community can conduct the testing. Testing can only be done by using nationally approved test kits-Determine

for blood-based screening or Oraquick for oral fluid-based screening. All reactive in CLT or screening should have confirmatory HIV testing performed by laboratory staff following full algorithm. These trained lay providers offer testing to key populations (KPs) in the community (especially, high-risk KPs). These lay providers are provided with the kits after orientation of their use, and they take these kits to the community for testing. Upon being reactive, the clients are accompanied to clinic sites and then to ART sites for confirmatory testing and further management. All clients who are KP and at-risk population are eligible to take this service.

Enhanced Peer Outreach Approach (EPOA)

EPOA is an approach that uses a social network of KP members to extend program coverage and to target hidden and highest-risk individuals who may be underserved by hot spot-based outreach approaches. EPOA complements traditional outreach done by CBS or IRW but does not replace it. It focuses on those KPs who are not found at traditional hot spots. EPOA is led by CBS, who identifies the active seed or peer mobilizers (PMs). Peer mobilizers or seeds by utilizing their social and sexual network identify and persuade their peers to be tested for HIV. In the clinic, the peers are further asked if they are interested to become a seed. If agreed, the peer becomes the seed or PM. These seeds or PMs are then orientated are provided with the kits to also offer HIVST to clients within their network.

Online approach and use of media

Currently, there is an online HIV risk assessment and reservation application (www.merosathi.net). MeroSathi, translates to “my friend”. It is an online reservation application (ORA) is ORA that aims to provide the most convenient means to make reservations for HIV testing services, ensuring anonymity and privacy. It has a short questionnaire which accesses individual’s risk of contracting HIV or other sexually transmitted infections (STIs). Next, MeroSathi helps the individual to locate and plan a visit to a testing clinic.

Further, online outreach programs with the use of social media can also reach clients (esp. men who have sex with men (MSM) and transgender) who use this closed networking and can also book for HIVST.

Index client’s partner tracing

In this approach, the index client takes responsibility for encouraging partner(s) to seek HIV testing services(HTS) during the counseling HIV self-test kits can be given to the index client for their sexual and /or people who inject drugs (PWID partner(s) if preferred by the index clients. Once they receive the kit, they are followed up for the results if they wish to share,

Available HIVST kits in Nepal

A. **The OraQuick® HIV self-test kit** is an oral fluid-based HIVST kit. It is a single-use qualitative immunoassay to detect antibodies for HIV-1 and HIV-2 in oral gum fluid. OraQuick® one-pouch kit contains a single-use test device, preservative, a developer solution vial, test Stand, and instructions (materials required but not provided are clock/watch, or timing devices). This in-vitro diagnostic medical device is intended for lay users to aid in the diagnosis of HIV infection.

B. **The CheckNOW HIV self-test kit** is a blood-based HIVST kit. It is a single-use rapid immunoassay that uses a blood sample from a finger puncture for the qualitative detection of antibodies to HIV-1 and HIV-2 in blood. CheckNOWone-pouch kit contains 2 sterile alcohol pads, 1 sterile Plaster, 1 Specimen dropper, 1 Buffer, 1 Sterile Lancet, and instructions (materials required but not provided are clock/watch, or timing devices and tissues). This in -vitro diagnostic medical device is intended for lay users to aid in the diagnosis of HIV infection. *This test kit is under approval process, which is planned to be implemented in 2023.*

COVID lockdown and scaling up HIVST

During COVID pandemic 2020/2021, WHO recommended to continue the essential health services and advised community-based health services to be delivered with proper preventive measures including physical distancing. HIV prevention including HIV testing services was enlisted as one of the essential health services to be continued during COVID pandemic. HIVST may be acceptable alternative to continue HIV testing services in community while adhering to physical distancing guidance. NCASC developed an interim guidance document to continue HIV related service during COVID lockdown in Nepal and recommended to scale up HIVST. Virtual orientations were conducted for Outreach workers (IRW and CBS). The orientations include

both theoretical and practical demonstration sessions through virtual platform. The outreach workers implemented the HIVST in their respective key population communities by taking proper COVID precautions. HIVST helped to reduce the frequency/intensity of exposure between clients and outreach health worker. Even for directly assisted HIVST, the outreach worker can assist the client to perform and interpret HIVST while maintaining physical distancing.

Field level implementation experiences

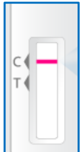
- HIVST was quite useful during COVID times, as it was preferred by both outreach workers and clients over the regular HIV testing by Determine test kit. It reduced the fear of COVID exposure as it was possible to keep physical distancing during testing.
- Currently, the mostly used approach is supervised HIVST. Only around 2% of the tests have been conducted as unsupervised HIVST. The further plan is to promote unsupervised HIVST, as it is more compliant with the clients who face difficulty to access HIV services due to perceived stigma and discrimination.
- During COVID surge, migrant population returning from India had to face the stigma and discrimination as the transmission of COVID cases were found through this bridge population. HIVST was useful in alleviating the COVID related fear among outreach workers working for migrant population, as physical distancing was possible during supervised testing.
- In Nepal, chewing tobacco and related products (gutkha, paan etc.) is very common. To perform HIVST by Oraquick test kit, it is necessary to clean/rinse the mouth and wait for around 15 mins if the client has eaten something. So, clients may not prefer wait for that period to perform HIVST.
- For many PWID clients, one of the effects of the drugs is having dry mouth. So, they may have doubt on adequateness of the oral fluid sample collected during HIVST.
- Many clients believe that the HIV testing done on blood is more reliable than the testing done on oral fluid.
- Since oral fluid/saliva cannot transmit HIV virus, many clients believe that it is impossible to test HIV in oral fluid sample. For them, the outreach workers informed about the role of antibodies in detecting the HIV in oral fluid, in simple language.

- One of the major barriers for less utilization of “Unsupervised” HIVST was the challenges of self-reporting by the client. However, the following instructions were provided to the outreach workers to promote the unsupervised HIVST:
  - Either supervised or unsupervised HIVST could be provided. However, the outreach workers will decide which one to provide, based on the assessment of literacy, understanding and confidence of the clients to perform and interpret the test.
  - For **unsupervised HIVST**, the outreach workers will ensure that the test kit has been used by the particular client (not others) within 48 hours of obtaining the test kit.
  - Frequent follow-ups through distance counselling will be done to ensure that the test-kit has been used and also to help the client to correctly perform and interpret the test.
  - Along with the one-pager document and user manual, video link on HIVST could be also provided to the clients for unsupervised HIVST.
  - Clients will be also asked to send the photo of the test kit results through whatsapp, viber, FB messenger etc.
- HIVST through Oraquick test kit was preferred by the clients who do not want or afraid of needle prick test.
- Some of the clients do not disclose their HIV status or if they are already taking ARVs. So, there are possibilities of false results.
- In Nepal, the outreach activities of HIV prevention program are key populations based. However, if any non-KP voluntarily asks for testing, he/she is also provided HIVST or regular determine kit testing.
- From program perspective, the unit cost of HIVST test kit is higher than the usual determine test kit.
- During Oct 2019- Dec 2022, around 38000 HIVST were performed in Nepal and the reactivity rate is 5%.
- Some instructions given to outreach workers which are useful while conducting HIVST for their clients

REMEMBER while conducting HIVST	• Do not eat or drink for at least 15 minutes before you start the test. • Do not use mouth cleaning products (tooth brushing, mouthwash) at least 30 mins before you start the test. • Read the results after keeping the test device for 20 minutes in the test tube. Do not read result after 40 minutes.

	• For unsupervised HIVST, the outreach workers should do frequent follow ups and ensure that the test kit has been used by the particular client (not others) within 48 hours of obtaining the test kit. You may get **FALSE result**, if • You are on already on HIV treatment (ARVs) • You do not properly follow the instructions mentioned in the user manual (given to you along with the test kit)

- Non-Reactive

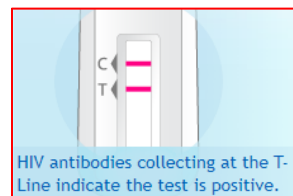


If C-Line turns dark it confirms the test is working properly. If no C-Line appears, the test is not working.

If only C-Line appears, the test is negative.

Non-reactive test result means there is no possibility of HIV infection. However, if it is less than 3 months from the last risk behavior, repeat the test at least 3 months after the possible exposure. If the client engages in risky behavior frequently, testing should be done regularly.

- **Reactive**



Reactive test result means there is possibility of HIV infection. The client needs to visit (accompanied by the outreach worker) the nearby HIV testing center for **confirmatory testing**.

DISPOSAL of used test kits

Used test-kits can be disposed as normal garbage. No need to bring back to Drop in centres/office. However, the test kits should be covered/packed properly during disposal to avoid possible social stigma.

Future perspectives for scaling up HIVST in Nepal

- The National Standard Operating Procedures (SOP) for HIVST is currently under development which is expected to be finalized and endorsed from NCASC by mid 2023.
- This SOP will also recommend the implementation of blood-based HIVST in addition to ongoing oral fluid based HIVST.
- Scaling up the "Unsupervised" HIVST is in the priority. For that, the easy availability of the test kits need to be ensured. Currently the HIVST test kits are being freely provided to the clients through the outreach workers. The plan is to make the test kits also available in pharamacies with nominal cost.
- Secondary distribution of the test kit will be also done. That means the client will be able to take test kits from the outreach workers for his/her sex partners and injecting partners.
- Under the migrant program, HIVST kits will be provided to the migrant group leaders who will distribute them to the migrants under their network in the destination cities of India.

Annexes

Annex 1: Global List of In-vitro diagnostics tests kits pre-qualified by WHO and their performance as per manufacturers that are currently available

Year prequalified by WHO	Kit name	Manufacturer	The type of sample used	Sensitivity *	Specificity*
2017	OraQuick HIV Self-Test[1]	OraSure Technologies, Inc.	Oral fluid	99.4%	99.0 %
2018	INSTI HIV Self-Test	BioLytical Laboratories Inc.	Capillary blood	99.5%	100%
2019	Mylan HIV Self-Test	Atomo Diagnostics Pvt. Ltd	Capillary blood	99.6%	95.2%
2019	SURE CHECK HIV Self-Test	Chembio Diagnostic Systems, Inc	Capillary blood	97.0%	100%
2022	Wondfo HIV Self-Test	Guangzhou Wondfo Biotech Co., Ltd	Capillary blood	95.8%	99.6%
2022	CheckNOW HIV SELF TEST[b]	Abbott Rapid Diagnostics Jena GmbH	Capillary blood	100%	99.9%

**As per the manufacturers kit insert*
Source: Pre-qualified in vitro diagnostics [Internet].WHO- Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control). 2020 [cited 2022 Nov 29]. Available from: https://extranet.who.int/pqweb/key-resources/documents/list-prequalified-vitro-diagnostic-products-excel-version

[1]Available in Nepal
[b]Available in Nepal (currently in the introductory phase)

Annex 2: User manual (in Nepali language) provided in the Oraquick HIV Self test kit.