



# Dissemination of STAR III Initiative

## HIV Self-Testing in India : Moving from Evidence to Action

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# HIV SELF-TESTING IN INDIA: A TOOL TO REACH THE FIRST 95 OF 95-95-95 GOAL

## HIV/AIDS IN INDIA: THE CURRENT SITUATION

Although recent evidence indicates a diminishing HIV\* trend, the AIDS\* epidemic that swept the world in the 1980s continues to be a public health issue. The first AIDS case in India was reported in 1986, among female sex workers (FSWs) in Chennai, India. While early measures to mitigate the spread of HIV infection involved sero-surveillance strategies, a more comprehensive approach began in 1992 with the launch and roll out of the National AIDS Control Program (NACP).[1][2] The years after 1992 were significant for India owing to the exceptional response to HIV prevention and treatment services. The prevalence of HIV among adults in India dropped from 0.36 percent in 2006 to 0.22 percent in 2020, whereas AIDS-related mortality decreased by 66 percent since the epidemic's peak in 2010. [2-5]

Despite these achievements in reducing HIV rates, India has the third highest burden of HIV in the world in terms of absolute numbers, with an estimated 23.19 lakh (18.33 lakh–29.78 lakh) people living with HIV (PLHIV) in 2020.[2] The current HIV burden in India indicates the need for a scale-up of HIV policies and programs to achieve the Sustainable Development Goal (SDG) targets. The SDG 3 target aims to end AIDS by 2030, leaving no one behind. Therefore, the Joint United Nations Program on HIV/AIDS (UNAIDS) extended the 90-90-90 target of 2020 to a 95-95-95 target to meet the SDG 3 goal of eliminating AIDS by 2030. The 95-95-95 target aims to diagnose 95 percent of all HIV-positive individuals, provide antiretroviral therapy (ART) to 95 percent of those diagnosed, and achieve viral suppression for 95 percent of those treated by 2030.[6] Furthermore, the SDG 3 target necessitates the need for HIV-sensitive Universal Health Coverage (UHC) to promote health equity in India while integrating it with other sexual and reproductive health services.[6]\*Acquired immunodeficiency syndrome (AIDS) is a chronic, potentially life-threatening condition caused by the human immunodeficiency virus (HIV). [1]Thus, to successfully achieve the 95-95-95 targets, the first 95 percent, which involves screening for HIV, is indispensable. As a result of scientific breakthroughs, numerous diagnostic tests have been developed, and HIV self-testing (HIVST) has garnered attention globally.

**\*Acquired immunodeficiency syndrome (AIDS) is a chronic, potentially life-threatening condition caused by the human immunodeficiency virus (HIV). [1]**

## WHAT IS HIV SELF-TESTING <sup>[7]</sup>

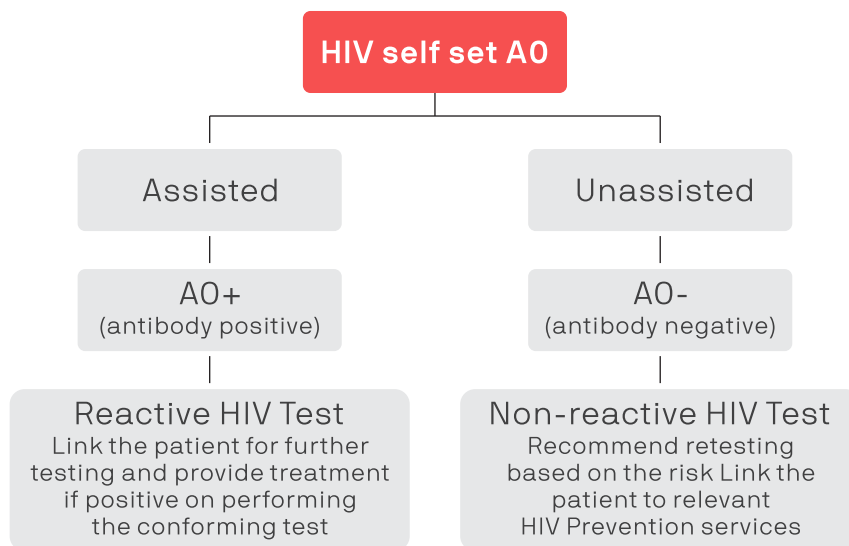
HIV self-testing is a screening test to diagnose HIV in a private setting, alone or with someone a person trusts. It involves collecting an own specimen (blood or oral fluid) depending on the diagnostic test kit requirement, testing for HIV, and interpreting the results.

HIV positivity cannot be determined based solely on a reactive (positive) HIV self-test. To confirm HIV status, a skilled practitioner must conduct further testing on all reactive HIVST results as per the national testing protocol.

Except for those initiating pre-exposure prophylaxis (PrEP), others with non-reactive HIVST need no immediate additional testing. However, HIVST cannot replace the initial testing for patients starting or already taking PrEP.

Those who received invalid HIVST results must try the test again with a different HIVST kit or get tested by a qualified physician. WHO does not recommend HIVST in known HIV-positive individuals as HIV-positive individuals taking ART may lead to false-negative findings.

Only individuals who continue to be at risk, such as members of key population groups and those who have reported possible HIV exposure in the last 12 weeks, should retest in case of a non-reactive result from an HIV self-test.



as one of the solutions to achieve the first 95 of the 95-95-95 targets. [7-11]

## WHY HIVST IS NEEDED

### PREVALENCE OF AIDS IN HIGH-RISK GROUPS AND VULNERABLE POPULATIONS

The 2020 study by the National AIDS Control Organization (NACO) reported that the Indian epidemic is concentrated among the high-risk groups and vulnerable populations who engage in unsafe sexual practices and risky behaviors.[4][12][13] Evidence from the SANKALAK report by NACO,[4] lends credence to the previous statement and indicates that the HIV prevalence among hijra/transgender (H/TG) people, men who have sex with men (MSM) and FSW is 6 to 13 times higher than the adult HIV prevalence.[4]

A periodic HIV surveillance conducted by NACO among the eight high-risk groups found that the HIV prevalence among injectable drug users (IDUs) was 28 times higher than the overall

adult HIV prevalence.[4] Additionally, key population groups such as FSW, MSM, H/TG, persons who inject drugs (PWID) and partners/clients of the key populations and self-identified high-risk individuals account for more than 68 percent of clinical footfalls for sexually transmitted infection (STI) screening.[12]

### **IMPLEMENTATION GAPS IN THE CURRENT DIAGNOSTIC SETUP AND INTERVENTIONS**

The current diagnostic setup promotes utilizing Integrated Counselling and Testing Centers (ICTCs) for HIV screening and confirmation. ICTC is a component of the HIV Counselling and Testing Services (HCTS) and is the first point of contact for the beneficiaries regarding HIV counselling, screening, and treatment. However, an evaluation of the ICTCs in Delhi identified a few ICTCs lacking male and female counsellors and the necessary infrastructure to maintain adequate privacy. Privacy was reported as a prime concern among the beneficiaries, as people did not want to disclose their presence for HIV screening to others in the health facility. Further, the study reported a high daily client load, resulting in delays in reporting the HIV status to the patient.[14] Along with testing at ICTCs, community-based testing (CBS) through the targeted intervention (TI) program is also offered to members of the key population groups. Through CBS, decentralized screening tests are provided to them. However, the acceptance of this program beyond the targeted key groups is unknown.

Likewise, although the current targeted interventions focus on the high-risk groups to control the spread of HIV in India, we are still falling behind in the first 95 percent of the 95-95-95 targets. Moreover, situations like the COVID-19 pandemic affected the provision of testing through facilities. A recent report from Maharashtra indicated 10,000 missed cases of HIV during the pandemic due to the lack of advanced testing services.[15] A similar report proposed that missed opportunities for HIV testing and diagnosis were high among the high-risk population of sexually transmitted disease clinic patients. In addition, another study found that despite targeted interventions, 55–59 percent of MSM and IDUs did not undergo HIV testing. [16,17] For this reason, self-testing kits and other testing methods that are more readily available, acceptable, and economical for the vulnerable population, are urgently needed.

### **GLOBAL CALL FOR INTEGRATING HIVST INTO THE PROGRAMS**

The World Health Organization (WHO), United States Agency for International Development (USAID), Centers for Disease Control and Prevention (CDC), and International Labour Organization (ILO) recommend the use of HIVST as a screening test to diagnose HIV.[7-11] Moreover, WHO released guidelines for HIVST in 2016 as a safe, reliable, and practical method of reaching those who might not otherwise undergo testing, such as members of vulnerable groups, men, and adolescents.[7] In a nutshell, the prevalence and incidence of HIV among the key population groups, the status of the current diagnostic setup, and the stigma and discrimination experienced by the high-risk population demand the integration of HIVST as an addition to the currently provided services in India.[4-12]

### **EVIDENCE ON EFFECTIVENESS AND SAFETY OF HIVST**

Since HIVST kits became available in the market, several studies have been carried out to assess the feasibility, accessibility, and acceptability of the test kits. After multiple trials demonstrated the feasibility and acceptability of HIVST and distribution through various models, WHO published the first consolidated guidelines on HIV testing services, including a brief on HIV self-testing. [8] As per the WHO 2022 report, 98 countries now have a policy on HIV

self-testing, but only 52 countries have implemented it.[8] Furthermore, findings from another study, a systematic review containing evidence from 32 randomized control trials (RCTs), showed that HIVST increases the uptake of HIV testing, and various HIVST models are feasible and acceptable in different settings.[18]

Global studies provided a strong foundation to test the feasibility of HIVST in India. Thus, NACO conducted qualitative research to understand the acceptability and feasibility of HIVST among key populations. The study reported that HIVST is highly acceptable, convenient, confidential, and non-invasive among the population studied.[19] Another study conducted by the Indian Council of Medical Research (ICMR) among truck drivers and young people demonstrated a preference for oral fluid-based tests over blood-based HIVST testing.[20]

To further understand the feasibility of integrating HIVST into the AIDS program in India, PATH conducted a multi-centric demonstration project called the STAR HIV project. The project was carried out in 50 districts of 14 Indian states with funding from UNITAID through Population Services International (PSI).

PATH started by conducting a qualitative study in 2021 and employed human-centered design (HCD) thinking to understand the enablers and barriers to introducing HIVST in the country. The study used the community-based model, private practitioners' model, workplace model, PLHIV network model, and virtual model implemented as part of the STAR HIV project.

This study reported that HIVST can help reduce stigma, inconvenience, and missed opportunities associated with getting an HIV test. While some users were initially apprehensive about HIVST, mainly the oral test kits, the study showed that Information, Education, and Communication/ Behavior Change Communication (IEC/BCC) materials and interpersonal communication were effective in addressing their doubts about the reliability and simplicity of HIVST. Participants also suggested that they were willing to pay for self-testing if the price was not higher than laboratory-based HIV tests.

## **INDIA-SPECIFIC CHALLENGES AND BOTTLENECKS IDENTIFIED BY THE STUDIES**

Although the results of studies conducted by NACO and others in India aligned with the previous positive findings of HIVST worldwide, a few challenges emerged from each study. The research by NACO showed that the low levels of literacy, unawareness about HIVST, high cost, and potential coercion act as some bottlenecks for effective implementation of HIVST.[18] In addition, the report suggested that linking people using HIVST to further services and providing assisted and unassisted HIVST testing options for the beneficiaries will improve its acceptability rather than having only one service delivery model.[18] Meanwhile, the study on truck drivers deduced that the lack of instructions in local languages makes it challenging for users to utilize HIVST services.[19]

Furthermore, the STAR HIV project conducted by PATH demonstrated challenges in accessing registered HIVST kits due to the unavailability of licensed HIVST kits in India. Therefore, it is necessary to consider policies that Various service delivery models used in the STAR HIV project by PATH

address these issues when integrating HIVST into India's national programs. Beyond that, prior research, and the STAR HIV study demonstrates that HIVST is acceptable as an addition to the HIV testing service to reach first time testers.



*Various service delivery models used in the STAR HIV project by PATH*

## RECOMMENDATIONS TO INTEGRATE HIVST INTO THE SYSTEM [21]

Since HIVST aims to supplement and enhance current testing methods, it is important to consider the status of existing testing programs, and the characteristics of key populations and reach the inaccessible populations. HIVST should be planned and implemented at different levels in the population to lower barriers to HIV testing services among priority populations and cut down on opportunity costs. Based on the findings from the STAR HIV project and other studies, the following are a few recommendations that can be taken forward:

**Recommendation 1:** Strengthen the health systems through policies and regulatory mechanisms for HIV self-testing. The following points may be considered for successful integration of HIVST into the programs:

- Developing regulatory pathways that are simple and clear for product registration.



- Involving the community and private partners to ease the transfer to domestic health budgets when donor financing stops.
- Framing simple operational guidelines for HIVST in the private sector may increase the accessibility and availability of HIVST.
- Developing a national HIVST plan to target specific regions and groups with the highest testing coverage gaps.
- Examining market competition and dynamics for making testing kits available at a feasible price for the community.
- Customizing HIVST delivery models for specific communities can address gaps in the current testing coverage for key populations and their partners/social network.
- Adopting a simple testing strategy for confirmation of HIV diagnosis that can help people use HIVST confidently while being aware of further steps in the prevention or treatment process.
- Developing a monitoring and evaluation plan may optimize HIVST implementation and aid in assessing the effectiveness of HIVST and address its misuse if it occurs.

**Recommendation 2:** Bring awareness among communities and engage them in service delivery to take informed decisions.

- Providing communities with the tools and resources to build and modify HIVST delivery and support mechanisms, including information about access to ART and diagnostic tests using IEC/BCC materials can widen access and reduce the stigma associated with HIV.
- Developing messages and communication plans can enhance awareness of assisted and unassisted HIVST. In addition, providing information on how to report and address complaints through the country's post-market surveillance system can reduce information gaps and promote the acceptability of HIVST to a greater extent.

**Recommendation 3:** Support the beneficiaries and service providers for preventive care and treatment.

Setting up a helpline number for the end beneficiary and the service providers on any query related to HIVST and treatments, along with counselling or mental health support, can help people deal with stress, anxiety, or any other form of mental discomfort due to HIV.

## THE WAY AHEAD FOR HIVST, A POTENTIAL PROSPECT FOR BETTER HEALTH

The strategy of 95-95-95 is a plan for accelerating change at the national, provincial, district, and local levels. It entails establishing challenging goals and speeding up the provision of high-impact HIV prevention and treatment programs. HIVST involves utilizing innovation to broaden service offerings, better address people's needs and viewpoints, and concentrate on the regions and populations most affected by HIV. In addition, it enhances gender equality and human rights while addressing social and legal constraints.

Investments in HIVST can have better health and social effects when integrated into the existing system.[8,11] Thus, with the integration of HIVST into the current HIV plan, we can achieve additional benefits like increased population productivity, growth, equity in health, and increased coverage, in addition to decreased morbidity and mortality among people living with HIV/AIDS, reduced HIV transmission and infections, and savings in costs and time.[11]

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# HIV SELF-TESTING: EXPANDING THE SCOPE FOR SELF-CARE IN INDIA

Self-care refers to actions taken by an individual to keep themselves healthy. As per the World Health Organization, self-care consists of three components: self-awareness, self-testing, and self-management.<sup>1</sup> From screening tests for pregnancy, non-communicable diseases, and infectious diseases, self-testing is expanding across different realms of health.

## HIV TESTING IN INDIA

In the context of HIV, there are three major methods of testing: facility-based testing, community-based testing, and self-testing. Facility-based testing centers, also known as Integrated Counselling and Testing Centers (ICTC) in India, have been primarily established for providing screening and confirmatory tests together. Hence, as part of India's National AIDS Control Program (NACP), all key populations (KPs) are expected to visit an ICTC once every six months—as KPs are at a heightened risk of and increased vulnerability to HIV.

Community-based screening offers a screening test, for HIV, to make testing facilities more accessible and increase periodical screening among KPs, without compelling them to visit an ICTC.

HIV self-testing (HIVST) is a step forward in making the screening process more accessible for KPs, their clients/partners and beyond, as there are many among the key and bridge populations who are unwilling to access HIV testing (facility or community-based) for various reasons. Hence, HIVST is expected to bring these individuals to the ICTC if they find themselves reactive. HIVST can also be used by population groups that are at higher risk of HIV infection for continued enrolment in prevention services. In self-testing, an individual obtains a testing kit (oral/blood based) and takes the test by themselves at their convenience. If the results are reactive, they need to visit a health facility for a confirmatory test.

## HIVST: BACKGROUND

The growth of HIVST started in 1996 in the United States (US) with over-the-counter tests, wherein an individual was required to collect a sample of their blood and submit it to a testing facility. After a few years, different versions of the OraQuick test kit that used oral fluid for testing were introduced (2002, 2003, 2004).

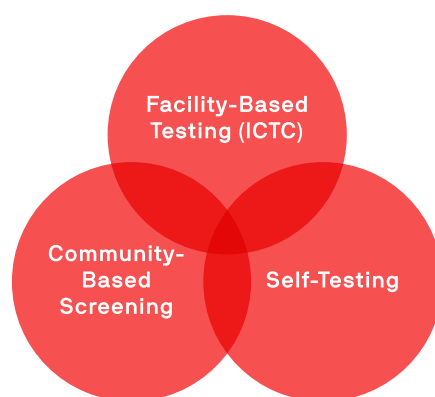


Figure 1. HIV testing approaches

These were designed and encouraged for use in health facilities to test for HIV. In 2012, the US Food and Drug Administration (FDA) approved OraQuick as an in-home testing kit, making it the first kit in the US that could be used for HIVST.<sup>2</sup>

In terms of acceptability and usage of HIVST kits, the results vary by countries and regions. In sub-Saharan Africa, the acceptability of these tests varies between 22.3%-94% with higher acceptability for the tests among males as compared to females.<sup>3</sup> Research among young people in Malawi and Zimbabwe demonstrated high acceptability towards HIVST if it was provided for free or at a very low cost, along with a preference for home-based distribution.<sup>4</sup> A study among transgender people in Larkana, Pakistan found HIVST kits were easy to use and recommendable to their peers.<sup>5</sup>

Recently, several studies on acceptability of HIVST in India have been conducted. One qualitative study in Maharashtra showed that there is acceptance of HIVSTs among youth and truck drivers. It also demonstrated apprehensions around self-testing, such as accuracy of the result, possible usage of the fluid (reagent) that comes in the kit for injections by drug users, disposal of used kits, and mental distress following a positive result, among others.<sup>6</sup> Another study among female sex workers in Pune revealed that they were willing to use HIVST but expressed concerns related to hiding and discarding testing material in brothels and their safety and confidentiality after a positive result.<sup>7</sup>

## IMPORTANCE OF EARLY IDENTIFICATION

Testing is an important aspect in early identification. A major issue that exists in HIV testing is that when an individual decides to go for testing, it is often late with respect to the progression of the disease.<sup>8</sup> Although high-risk populations are encouraged to take HIV test every six months,<sup>9</sup> other individuals, such as partners of KPs and unreached KPs, often face delay in the diagnosis of HIV.<sup>8</sup> Experiences from HIV/AIDS programs globally have shown that individuals usually go for testing when they start observing symptoms.

The study presented here focused on understanding and addressing the barriers in the rollout of HIVST and providing evidence of developing structures and systems for long term sustainability of HIVST in the country.

Findings suggest that 33,462 out of 41,901 (79.86%) participants, including, self-identified high-risk individuals, partners/clients of KPs, or those referred by private practitioners, clients at PLHIV network led model, and formal work force groups did not engage in consistent condom usage for vaginal and/or anal sex. Such risky sexual behavior points to the need for regular testing as a form of self-care.

It also emerged that 339 out of 93,380 cases (0.4%) had reactive results. Of the 109 with CD4 results available, 15.6% (17) had CD4 results that indicated advanced disease (median CD4=345 cells/mm, IQR: 236-455). Had these individuals been tested earlier, the disease may have been identified at an early stage and initiated early treatment, with potential for reaching U=U (undetectable=untransmissible). The concept of U=U is defined as “people with HIV who achieve and maintain an undetectable viral load—the amount of HIV in the blood—by taking antiretroviral therapy (ART) daily as prescribed cannot sexually transmit the virus to others.”<sup>10</sup>

## SELF-TESTING: THE BROADER PICTURE

Our study demonstrated favorable responses to HIVST.

- Overall, 97.8% of the participants reported satisfaction with the process of accessing the self-testing kit.
- Both types of kits were found to be acceptable to the participants - oral-based (48.7%) and blood-based (51.3%).
- 89.4% of participants reported that they would recommend HIVST to a partner or friend needing to know their HIV status.
- Privacy and convenience of the HIVST was reported by many participants (83.7%) as being an important advantage a self-test kit.

The results indicate a positive outlook towards HIVST and validate its potential to contribute to universal health coverage, i.e., easy access to health services whenever and wherever required (Figure 2). The process of self-testing, early identification, and early treatment support the pathway for viral load suppression and reaching U=U to be achieved.

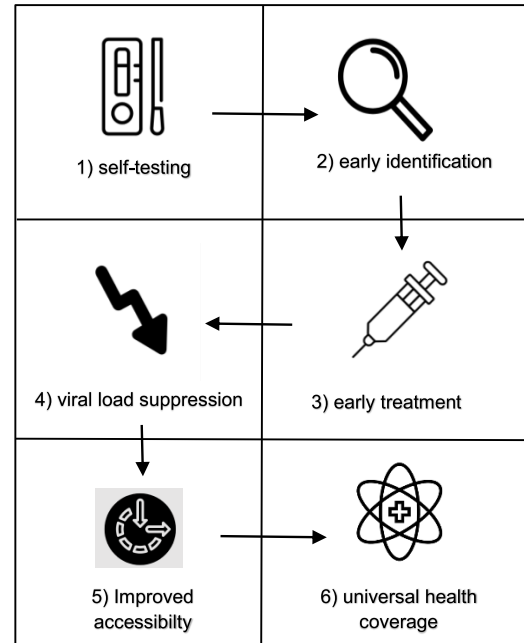


Figure 2. How self-testing contributes towards universal health coverage

## CHALLENGES

Understanding the importance of HIVST is often not enough to battle some of its challenges. There are some limitations that exist. Out of 94269 participants, more than half (53.4%) reported no disadvantages to HIVST, there were some participants who reported pricking themselves (25%), misinterpreting test results (9.7%), and stress of a false positive/negative (10.1%) as some key drawbacks.

There is also the risk of mental health concerns following a reactive result. Within the study, there was one reported case of an individual having suicidal thoughts following a positive confirmatory test result. The participant was linked to appropriate mental health counselling by the support staff. Thus, it is important that participants who use HIVST should have easy access to counselling and related support services

## CONCLUSION

Self-testing is an important aspect of self-care. This study focused on demonstrating the feasibility and acceptability of HIVST kits among KPs in India. Through this study, we attempted to show the utility of HIVST, which is an important component of self-care. The growing evidence shows acceptability among various KPs and other vulnerable populations. Furthermore, including HIVST in the national HIV testing guideline will allow HIVST to become

a complimentary strategy to HIV testing and will help in reflecting its impact on the overall HIV cascade.

While challenges still exist with self-testing, HIVST is proving to be an important aspect in providing the last mile connectivity to individuals who are unable to or unwilling to go for regular facility-based testing or community-based screening. We hope, that as HIVST scales up, testing for HIV can be viewed as a routine process of self-care and contribute towards achieving universal health coverage.

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# STUDY APPROVAL MECHANISMS FOR HIV SELF-TESTING IN INDIA: AN 18 MONTH JOURNEY

PATH implemented a research study titled, “Accelerating access and uptake of HIV self-testing (HIVST) in India” under the UNITAID-funded STAR initiative. The research focused on demonstrating the feasibility and acceptability of HIVST kits among different key population groups and other high-risk groups to generate evidence to inform an HIVST policy in India. As with all research, there are rigorous processes of approvals and permissions in place within India. For the present study, these processes spanned across 18 months. There were numerous challenges, such as delays in reaching the concerned departments, demanding processes, COVID-19, etc. It was a lengthy and tedious journey of seeking multiple approvals before the study could be initiated.

## BACKGROUND

The HIVST study led by PATH was among the largest studies being carried out globally on HIVST. It included multiple partners and was targeted to reach 112,000 participants across 14 states in India. It also involved piloting various models with different study populations using three World Health Organization (WHO) prequalified approved HIVST kits. Prior to our research project, there were no projects that had distributed HIVST kits at scale.



Figure 1. Partners involved in the study

Since there was no existing HIVST policy in India, nor the availability of a commercially approved HIVST kit in the country, the project was implemented as operational research.

PATH ensured involvement of the national-level stakeholder, the National AIDS Control Organization (NACO) from the beginning of the process. The first draft of the concept note was shared with NACO, and their feedback was incorporated into the subsequent versions.

NACO encouraged PATH to obtain all the required approvals that were necessary before they



could provide a support letter. With this, PATH began the process of obtaining multiple approvals in the challenging backdrop of the COVID-19 second wave.

The approvals that had to be sought can be collated into three major types: ethical, in-country, and regulatory. The journey started with the ethical approvals, at the end of 2019.

## ETHICAL APPROVALS

There are different sub-types under this approval head: Indian (local) and international. For the former, one must obtain local Institutional Review Board (IRB) approval to initiate the study. For the latter, as per PATH policies, an international ethical approval from PATH's identified ethics review board was obtained.

## LOCAL IRB APPROVAL

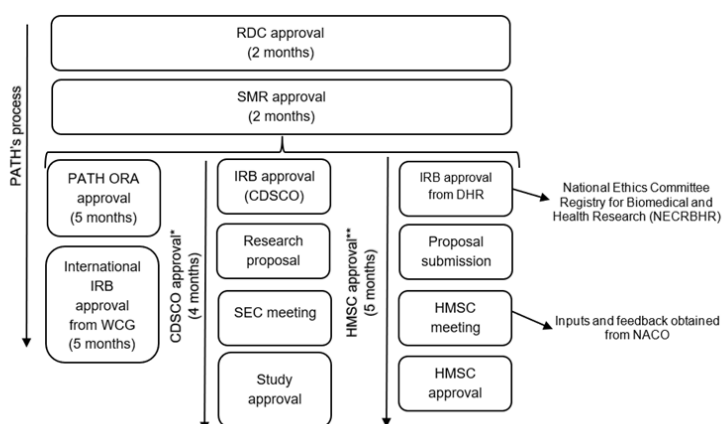
First, as for any research, approval was necessary by a committee that was registered with the Department of Health Research (DHR), Ministry of Health and Family Welfare (MoHFW), Government of India (GoI).

The institutional review board of The Humsafar Trust (HST) as the institute of the principal investigator for the study was selected to review the protocol.

At the time of IRB approval processes, HST had acquired approval from the US National Institutes of Health for their ethics review board and was in the process of seeking registration from the DHR under the MoHFW, GoI. Once HST IRB approval was obtained and submitted to the Health Ministry Screening Committee (HMSC), the HMSC approval came with the caveat that the HST IRB needed to have a DHR registration, and the study approval was subject to this registration. The HST then made all the necessary submissions and successfully registered their IRB. This certification was submitted to the HMSC, and ethical approvals were received.

**The following link can be accessed for a better understanding of the DHR registration process, and for information on the registered ethical committee list:**

[https://naitik.gov.in/DHR/app\\_srv/soam/reports\\_pc\\_issued.jsp](https://naitik.gov.in/DHR/app_srv/soam/reports_pc_issued.jsp)



\*For unregistered medical devices and/or products

\*\*For foreign funded research in India; current HMSC approval process requires registration on the biorrap portal

Figure 2. Flow chart of the approvals seeking process

Given the use of an unregistered medical device, approval from a committee registered under the Central Drugs Standard Control Organization (CDSCO) is mandatory in India. So, the project took a separate approval from an ethical committee registered under CDSCO, MoHFW, Gol.

To obtain an import license from DCGI, PATH reached out to the ethics committee from Sai Hospital, Mumbai and got the local IRB approval from an ethics committee registered under CDSCO, which completed the local IRB approval process. There was also an international IRB approval seeking process that PATH had to complete. This approval seeking process was carried out simultaneously with the national approval seeking process. Its major aspects have been listed below.

**(The following links can be accessed for greater understanding of the CDSCO registration process**

**<https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/>, and for the registered ethical committee list: <https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/Ethics-Committee-Registration/>)**

## INTERNATIONAL IRB APPROVAL FOR PATH

This approval process started from the PATH Research Determination Committee (RDC). The purpose is to determine whether a proposed project should be considered a research study. Once the RDC labeled the project as research, it was passed on to the Scientific Merit Review (SMR) committee of PATH.

Upon their approval, it went on to the PATH's Office of Research Affairs (ORA). Coincidentally, it was during this time that PATH decided that it will give research projects to an external agency for approval, Western Copernicus Group (WCG) IRB. The entire process took 17 months, and by November 2021, PATH received the approval from the WCG IRB.

The HIVST kits were planned to be distributed through the Centers for Disease Control and Prevention's (CDC) implementing partners in the country. For the same, the CDC needed to take approval from its Scientific Integrity Board (SIB). This resulted in an additional two months to receive ethical approvals.

In addition to the primary ethical approvals from HST, Sai Hospital and WCG, there were multiple rounds of IRB approvals as the study needed to undergo numerous revisions and amendments based on the feedback and requirement of the study.

Local	International
<ul style="list-style-type: none"> <li>● IRB registered under DHR</li> <li>● IRB registered under CDSCO</li> </ul>	<ul style="list-style-type: none"> <li>● PATH Research Determination Committee (RDC)</li> <li>● PATH Scientific Merit Review Committee (SMR)</li> <li>● PATH Office of Research Affairs (ORA)</li> <li>● WCG IRB (PATH's external ethical approval agency)</li> <li>● CDC-SIB approval for CDC implementing partners</li> </ul>

Figure 3. Local and international IRB approval sub-processes

## IN-COUNTRY APPROVALS

The second set of approvals were the in-country approvals. Any research in India that is using foreign funding requires approval from the Health Ministry Screening Committee (HMSC). The HMSC issued expedited approval due to the COVID-19 surge and understanding the importance of the role of self-testing in the time of regular HIV testing interruption in the hospital infrastructure and due to non-availability of adequate manpower. This committee is chaired by the Secretary, DHR, MoHFW, GoI and the Vice-Chairperson of the Committee is the Secretary to the Department of Biotechnology (DBT), GoI. NACO is also one of the members of HMSC committee. Based on the revised HST IRB approval submission, HMSC issued the final approval after receiving the feedback from NACO. (The regulatory approval mechanisms have been updated and centralized. For updated regulatory approval mechanisms in the country the following link can be accessed: <https://biorrap.gov.in/>).

The study was also registered under Clinical Trial Registration India (CTRI). The CTRI, hosted at the Indian Council of Medical Research's (ICMR's) National Institute of Medical Statistics (<http://icmr-nims.nic.in>), is a free and online public record system for registration of clinical trials being conducted in India. CTRI requires protocols, supporting documents, other approvals obtained, related to the study and then they issued the registration number. The process of obtaining in-country approvals took around six months, a process which started in October 2020.

## REGULATORY APPROVALS

The third type of approvals to be acquired for the study were regulatory approvals. The project engaged a professional regulatory agency who closely work with CDSCO. The regulatory agency facilitated and received the entire regulatory holding-license, import licenses for the HIVST kits, and DCGI study approval from SEC, whose members include ICMR and NACO. These approvals can be obtained after the local ethical approvals and HMSC approvals are in place.

## IMPORT LICENSES

Overall, 140,000 self-testing kits were imported for this study. Each diagnostic kit (OraQuick, INSTI, and Mylan) required a separate license. These licenses were obtained through our regulatory agency and consulting company, Fermish Clinical Technologies Pvt. Limited. Fermish was selected because they are familiar with the DCGI rules and regulations and are authorized to process regulatory procedures..

These approvals require submission of voluminous application that can easily extend to 200+ pages. These documents include justification, undertaking, performance evaluation, internal reports and approvals, investigator's brochure, WHO pre-qualification details, contract copy with implementing partners, role of each partners engaged in this project, instruction for use, manufacturing, processing, materials, purpose of material, clinical performance evaluation plan, approved protocols, requisite IRB approvals, project and community advisory committee meeting minutes, HIVST study reports, countries that are implementing these HIVST kits as part of their national program, and other details.

Here it is important to note that under DCGI, diagnostic kits have been categorized into four types. Based on the provisions of the Medical Device Rules (MDR) 2017, the DCGI issued a classification of in-vitro diagnostic (IVD) medical devices used in various clinical fields on July 23, 2021. IVD medical devices were classified into four classes: Class 1 (low risk), Class 2 (low moderate risk), Class 3 (moderate high risk), and Class 4 (high risk). This classification is based on the intended use, the risk associated with the device, and various other parameters enlisted in the First Schedule of MDR 2017. The HIV diagnostic kit falls under Class 4, i.e., high risk. PATH had to give an undertaking to the DCGI before obtaining approval from, stating that the results would not be used to acquire commercial licenses for the HIVST kits. This is important as the study results cannot be used for obtaining commercial license for the HIVST kit and can only be used for the stated study objectives.

## STUDY APPROVAL BY DCGI

After submitting all the aforementioned documents, the study proposal was submitted to the subject expert committee in DCGI, for review and approval. This committee includes all the ICMR institutions, experts, NACO, among others.

In the DCGI meeting, the experts agreed that this is an implementation feasibility assessment and not a performance evaluation of the HIVST kits, which would not come under the purview of a clinical trial. NACO provided crucial support during this meeting. During this meeting, NACO unequivocally voiced the necessity of this study and the way they intend to use the evidence generated from this study. The DCGI claimed that the study is social in nature and thus would be considered as a clinical performance evaluation.

Here it is important to note that if a study is declared a clinical trial, the processes are much more tedious. The ethical and administrative requirements for clinical trials are highly stringent as compared to operational research and thus affects multiple aspects, including required resources, for the project.

Import Licenses	DCGI Study Approval
<ul style="list-style-type: none"> <li>● DCGI approval for each of the three kits: Mylan, INSTI, OraQuick</li> </ul>	<ul style="list-style-type: none"> <li>● DCGI SEC approval</li> </ul>

Figure 4. Sub-processes of regulatory approvals

Once all approvals had been obtained, the last step was to acquire a letter of support from NACO to implement the study in India. The letter was received in June 2021. NACO also sent a letter to 14 states requesting their cooperation in implementing the study. Due to the COVID-19 related restrictions that were in place, a request was made for two separate virtual orientations, the first being an orientation to all NACO officials after which the support letter was issued, and the second being an orientation and sensitization to officials from the 14 states that were a part of the study. The study was initiated on 20th September 2021 in New Delhi.

## CONCLUSION

Overall, it was a lengthy and difficult process spanning a year and a half to receive all necessary approvals to initiate the HIVST study. The backdrop of COVID-19 along with strict quarantine guidelines did not make things easier. There were no officials, stakeholders, or communities who could be met in-person to discuss the purpose of the project. Even obtaining a date from the concerned departments was a challenge due to the pandemic situation.

There were a few key learnings:

- Realistic timelines related to the approval process should be communicated early. It should be a part of the proposal process with the funder and partners to ensure there is adequate time and funding accounted for before the research is implemented.
- Once the local IRB approval(s) have been received, the following can be done simultaneously: a) processing and submission of the proposal for HMSC approval, b) CTRI registration, and c) DCGI study approval.
- Approvals are not instant in nature. There will be multiple clarifications, questions, requirements for additional supporting documents and other body's approvals, after which a final approval may be issued.
- While dealing with diagnostic kits, it is pertinent to obtain all relevant details of the products, the approvals already received, dossier, and supporting documents which clearly state that the diagnostic kit is from the manufacturer. It is also important to share the manufacturing agencies' common agreement for production, manufacturing, and marketing (export and import) rights to other agencies, an essential step for the DCGI review and approval of the study.
- Selecting an ethics review board having both DHR and CDSCO registration is crucial to avoid having multiple committees.
- Some approval processes can occur simultaneously to save time (e.g., RDC, SMR, and ORA can be initiated at the beginning).
- The approval process and regular engagement with stakeholders can result in a positive relationship with the latter, resulting in their support throughout the implementation of the project.

An important result of getting all these approvals is that NACO has been supportive and has indicated that the results from our study can be used for policy making without any hindrances. These approvals have also helped increase the credibility of the study processes and its ethical soundness.

# STRENGTHENING CAPACITIES TO FACILITATE HIV SELF-TESTING IN INDIA

## BACKGROUND

HIV self-testing (HIVST) is a WHO-recommended approach to improve people's knowledge of their HIV status and help achieve UNAIDS' 95-95-95 targets by 2030. This method is particularly recommended for hard-to-reach populations that are not often engaged through prevailing medical systems for HIV prevention, care, and treatment. Acceptability of self-testing is a key factor to increasing HIV testing and moving towards elimination.

PATH, under the UNITAID-funded STAR initiative, implemented the study 'Accelerating access and uptake of HIV self-testing in India' which focused on demonstrating the acceptability of HIVST among key populations and at-risk groups/vulnerable populations. Capacity-building was adopted as the important first to ensure that participating community-based organizations (CBOs) and their staff followed the appropriate study protocols. Subsequently, through short orientation sessions they were reoriented with HIVST and the study.

The study engaged multiple organizations as partners which included governmental bodies such as State AIDS Control Society (SACS) as well as non-governmental organizations (NGOs) and CBOs. The SACS were involved in supervision of the study implementation in the respective states. The NGOs and CBOs were involved in demand generation, community mobilization, ensuring eligibility and informed consent, conducting HIVST (oral or blood-based), and referring cases to Integrated Counselling and Testing Centers (ICTCs) for reactive results and to Antiretroviral therapy Treatment Centers (ART) for positive cases for treatment and counseling.

Since the study involved a diverse population, it adopted a 'team training' approach along a cascade model where a set of potential instructors were trained as master trainers to enable them to train other facilitators—known as a training of trainers (TOT). This involved the study team and the staff from targeted intervention (TI) to help in community mobilization and reaching the unreached groups. The staff from ICTC, ART, and District AIDS Prevention and Control Unit (DAPCU) were involved in managing district-level tasks involving peer educators and community leaders.

Capacity-strengthening materials were developed to accommodate diverse modes of communication and varying interpretations. This helped the field teams understand the study objectives, processes, linkages, and follow-up provisions required to complete the study. Additionally, sensitization programs were conducted to capacitate the understanding of national, state, and district-level officials and community leaders involved in the study.

The STAR HIVST study capacity-building activities provided supportive supervision to efficiently implement the study in India. This case study highlights how the study strengthened the capacity of implementation staff on a new and less familiar testing techniques, namely HIVST, for which people have polarizing opinions.

## DEVELOPING A LEARNING RESOURCE PACKAGE

A comprehensive learning resource package (LRP) was developed comprising standard operating procedures (SOPs), facilitator's guides, instruction for use (IFU) pamphlets, demonstration videos, pre- and post-test counselling videos, posters, etc. The study was implemented as per protocols of five HIVST distribution models included in SOPs and training modules.

All instructions and learning material, including the IFUs for medical devices and informed consent forms, were translated into eight languages which covered the linguistically diverse key communities involved. A communication package was developed with the support of an external agency which created taglines, interactive and visual material, promotional products, etc. to enable self-learning of HIVST kits in the users. The counselling videos developed were used to convey instructions and steps in reactive and non-reactive cases.

Finally, the entire resource package went through a round of content approval, where the Hindi and English content was approved by the National AIDS Control Organization (NACO), and regional language content was approved by the respective SACS. The feedback received by the community teams and community advisory boards (CABs) was also incorporated. The LRP was pre-tested with small groups of key communities. Inputs from all stakeholders were incorporated and the LRP was ready to use for capacity-strengthening.

## CASCADE TRAINING

In collaboration with partner organizations, PATH conducted TOTs for 67 master trainers over a period of three days. The participants were oriented and trained on HIVST procedures and study protocols. This was followed by the training of field-level facilitators conducted by the master trainers across 50 districts. This helped in training more than 1000 HIVST champions in 14 implementation states. Among them, 300+ were part of the study team and the rest were from TI, ICTC, ART, DAPCU, and SACS. State-level training was also conducted for members and representations of key populations and people living with HIV of State Oversight Committee (SOC) and Community Monitoring Board (CMB). The training programs were majorly supported by the Centers for Disease Control and Prevention through their implementing partner Society for Health Allied Research and Education India (SHARE INDIA).

Following a hub and spoke model, knowledge was transferred to the implementation staff, who also received guidance and mentorship from SOC members present at the hub and spoke facilities. The training primarily focused on familiarizing the staff with HIVST, its principles and protocols, distribution models, and guidelines for site monitoring and evaluation. The pedagogy included participatory methods, role-play, and practical demonstrations, which were enhanced by incorporating feedback received by the participants at the end of each session. Additionally, a pre- and post-training evaluation was conducted to measure the success of the session.

## SENSITISATION AND ORIENTATION

Based on the request from NACO, more than 30 officials from all divisions were virtually oriented on the study and its implementation process. Further, virtual sensitization sessions were conducted for all the 15 SACS (including Mumbai District AIDS Control Society) and Technical Support Unit officials. Overall, 150 officials from 14 states participated in these sessions. The sensitization sessions included orientation on the purpose and objectives of the study the approvals obtained, engagement of NACO and SACS at all stages of the study, implementation strategy through the existing AIDS prevention and control system, and the role of stakeholders and communities involved.

Virtual and physical orientations were conducted for implementation partners and community networks, which included members of All India National Sex Workers Forum (AINSW), National Coalition of People living with HIV (NCPI+), NACO's Technical Working Group on Community System Strengthening (TWG-CSS), PATH India HIV Self-testing Project Advisory Group (PISPAG), Community Advisory Board (CAB), SOC for HIVST, and CMB. More than 300 community leaders engaged and oriented to the study through CAB, SOC, and CMB. Additionally, study details were presented at AIDSCON, Chandigarh and ASICON, Hyderabad.

For effective and successful interventions, participation of different stakeholders facilitated a holistic approach and initiated cross learning to promote capacity-building of participants at all levels.

## ASSESSMENT, SITE-MONITORING, AND TROUBLESHOOTING

Due to the breadth of the study, it was important to continuously revisit and re-evaluate the implementation of the study through feedback mechanisms. To make sure that protocols were uniformly understood and implemented by facilitators, a google form was circulated which carried a set of questions regarding the study protocols. The answers received were analyzed to assess the depth of understanding among facilitators.

Based on this assessment, an appropriate refresher course was conducted to clarify doubts and fill knowledge gaps regarding the protocols. Additionally, one-to-one mentorship and targeted support were provided in the field as well as over the phone through a helpline, where educators, implementing partners, and experts were available to guide and support the facilitators, and address any troubleshooting queries.

Independent site monitoring was another method adopted to assess the progress of the study, where experts conducted site visits to observe the implementation process and cross-check the activities with the standardized guidelines. The checklist included various sections covering pre-test eligibility, informed consent, HIVST preference of assistance or non-assistance, post-test referral, and linkages to care. The result of this monitoring was reported within 24 hours which allowed prompt corrective action to be taken without disrupting the implementation. These experts also shared feedback and provided targeted support and supervision to the study team during their intensive four-day visits to the study sites.



## LESSONS

Several lessons can be drawn from the capacity-building activities.

- A subject like HIVST requires a comprehensive package of learning and training approaches – from classroom training to mentoring and learning how to operate a helpline, which encourage care-seeking behaviors.
- Focused orientation based on assessments helps in improving knowledge and skills and enables efficient project delivery.
- As there are multiple stakeholders in public health interventions and it is important to encourage capacity-building for all partners involved in the study for effective implementation of the program.

## CONCLUSION

Introducing a new diagnostic kit in the country and to the communities come with a variety of challenges. Capacity-building played a huge role in creating an enabling environment for the introduction of HIVST kits. All stakeholders and members of the study team were made aware of the study requirements, its challenges, and solutions, which made the implementation process transparent and effective.

Capacity strengthening efforts under the STAR HIVST study helped in integrating HIVST in the health ecosystem and contributed towards creating a larger enabling environment for encouraging care-seeking behavior and overcoming the stigma associated with HIV.

# WORKPLACE MODEL FOR ENABLING HIV SELF-TESTING IN INDIA - A CASE STUDY

## INTRODUCTION

Globally, the number of people living with HIV in the workforce has reached about 29.9 million by 2020, up from 20.9 million in 2010. HIV/AIDS poses a major threat in this segment as it affects productivity and loss of skills and experience. This leads to huge costs for enterprises and increased labor costs. India has a working population of over 400 million people, and nearly 90% of the reported HIV infections are from the most productive age group of 15–49 years. Of these, 93% are from the informal economy. [1]

HIV self-testing (HIVST) is an option recommended by the World Health Organization (WHO) that can be used to reach the undiagnosed population. HIVST services at the workplace can be effective in reaching migrant workers, key populations, and other populations that are at risk of HIV. This model can be effective as healthcare facilities can be made accessible within the workplace.

HIV self-testing at workplaces offers an opportunity by which one can reach workers or employees who are at risk of HIV infection with lower access to regular testing services. Certain industries, such as mining, construction, security, military, petroleum, agriculture, fishing, long-distance driving, and many others, may face a particularly high risk of HIV.[1] Though not all migrant workers are at equal risk, the process of migration enhances vulnerability to infections such as HIV, particularly for those who are single, stay away from their families for long durations, and work under difficult conditions. Moreover, the workers and employees in such industries may not have easy access to traditional HIV testing services, and the workplace may be the best place to reach them.[2]

As HIV is associated with social stigma, there are barriers to the uptake of HIV testing in the community. To address this barrier, the workplace model can be seen as an ideal site for HIVST as it not only provides the ideal environment, such as regular knowledge or education programs, safe and secure facilities, and has people onsite [2], but also gives workers or employees more choices, greater confidentiality, and convenience. This not only scales up workplace policy for HIV but also ensures an HIV-free workplace. [3]

This case study captures the insights of HIV self-testing at workplaces in India as an opportunity to reach unidentified workers or employees who are at risk of HIV with lesser access to testing services.

# IMPLEMENTATION HIVST AT THE WORKPLACE

For the workplace model, PATH implemented the study by bringing in its technical partner, the International Labour Organization (ILO), a global partner for seven countries, including India. Initially, three agencies were selected for implementation of the Brihanmumbai Electric Supply, Transport Undertaking (BEST), Coal India, and the Transport Corporation of India Foundation (TCIF) in Maharashtra, West Bengal, Gujarat, Punjab/Chandigarh, and Karnataka states. However, due to ethical and legal considerations, only two companies were included for the study. The Brihanmumbai Electric Supply & Transport Undertaking (BEST) of the Municipal Corporation of Greater Mumbai (MCGM) and the Transport Corporation of India Foundation (TCIF) collaborated to extend HIVST services to employees, truckers, and other formal sector workforce at their workplaces.

Stakeholder consultations with partners were conducted to map the industries and their locations in the states. During these consultations, the management and unions of these industries were informed about the study. Formal memorandums of understanding were signed with both the organizations before implementation.

Appropriate communication materials were prepared, which included videos demonstrating the self-testing process that were adapted to the local context; a pictorial guide explaining the self-testing steps; interpretation of results (translating the instructions in the kit); and linkages to services for individuals (based on HIVST results). All these were then translated into the relevant local languages as per the study location (Hindi, Marathi, Kannada, Bengali, Telugu, Gujarati, and Tamil). All potential participants were provided with relevant promotional materials and process flow charts on HIV self-testing.

A communication strategy was developed for all staff and contractual employees to inform them on the ease of using the self-testing kits and their associated benefits. Medical officers and other health educators from the participating organizations used the information and educational communication/behavioral change communication (IEC/BCC) materials, such as posters, etc., to generate demand for HIVST. These IEC/BCC materials were created by the study team.

As part of the communication to the workers and employees, staff members trained by the study team shared information on various aspects of self-testing, such as an overview of HIVST, study enrolment, the informed consent process, and how to conduct pre-test and post-test counselling. They also talked about the importance of referrals and linking screened reactive participants to the confirmatory test and treatment. The service providers were trained to do eligibility assessments and pre-test counseling, demonstrate HIVST use through videos, and other job aids. The trained staff also helped the participants to choose their preferred HIVST kit, i.e., blood-based or oral-based testing. The study provided options for all participants to choose either the assisted (supported and in the presence of trained staff) or unassisted (on their own, whereby participants independently conduct self-testing in a private space like home, office, etc.). The results are then interpreted, and treatment is made available through the trained staff and clinics. Based on the results, a referral was established to ICTC and the ART center for confirmatory tests and treatment.

Once the tests are completed, a unique identification number (UID) was generated for each participant, and the same UID number was used for all future reference.



Figure 1: (a) TCIF staff training at West Bengal, and (b) BEST staff training at Maharashtra



Figure 2: IEC material displayed at one of the study sites in Punjab



Figure 3: Map depicting study sites

## STUDY SITE AND POPULATION

Four study sites were chosen for the Transport Corporation of India Foundation in the states of Karnataka, West Bengal, Maharashtra, and Punjab; and ten sites were chosen for the BEST in Mumbai.

The study was conducted among the workforce, including both formal and contractual employees working in these industries. Other participants who considered themselves at risk and approached these facilities were also included in the study.

## STUDY LIMITATION

The study has a few limitations associated with it, which includes -

- First, besides ILO, which was already a project partner, no other organizations were included for this study.
- Second, because the study necessitated legal adherences such as signing legal tract contracts or Memorandums of Understanding (MoU), onboarding companies proved challenging.
- Thirdly, in certain cases, although the company agreed to the study in the initial stages, during the implementation phase some states declined permission, citing the need for local approval.

## ROUTINE MONITORING

A monitoring system was instituted to keep track of the number of self-test kits being distributed and utilized at the workplace. This mechanism helped in preventing cases of possible misuse of kits, exploitation, and risks associated with them.

As a part of the monitoring procedure, it was emphasized not to force people to self-test, intentionally or unintentionally.

An independent site monitoring exercise was carried out to ensure that the study protocols were followed, and the team also provided supportive supervision to the field implementation team during their visits. The Society for Health Allied Research and Education India (SHARE INDIA) carried out this independent activity with the support of the Centers for Disease Control and Prevention (CDC).

## KEY LESSONS LEARNED

- **HIVST can be made more effective by involving key stakeholders and forming strategic partnerships within the participating organization.** It is important to engage key stakeholders within the organization, such as senior management and employee unions, to build momentum for HIV self-testing and make it more effective.
- **Strategic planning and flexibility in implementing procedures can make HIVST successful.** The first point of contact for implementing HIVST in these industries is the medical staff. To onboard them for this study, focus should be on communicating the objective and benefits of the study rather than on contracts or Memorandums of Understanding (MoU) .
- **Customizing the IEC/BCC materials as per the participating organizations' requirements is helpful in implementing HIVST:** The participating organizations should endorse the communication materials such as posters and leaflets on the use and benefits of HIVST with their logos. These posters can be displayed at appropriate locations in the workplace and can be made available in local languages.

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- WORKPLACE HIV SELF-TEST TOOLKIT: A Toolkit for Implementation of HIV Self-Testing in the Workplace. 1st September 2022. Link: [Workplace-HIV-Self-Test-Toolkit\\_Aug-2021.pdf \(psi.org\)](#)

# ONLINE DELIVERY OF HIV SELF-TESTING IN INDIA

## BACKGROUND

HIV self-testing (HIVST) is a World Health Organization (WHO)-recommended approach to strengthen testing interventions for HIV case finding. The method, as per global studies and pilots, is considered to be a potential tool in helping India achieve its commitment to end AIDS by 2030. HIVST can address infrastructural and logistical gaps by reaching the population that are currently unable or unwilling to access the current testing facilities. For increase in reporting, treatment of cases and elimination of HIV, acceptability and accessibility of self-testing are essential.

Under the UNITAID-funded STAR initiative, PATH implemented the study 'Accelerating access and uptake of HIV self-testing in India', focusing on demonstrating the acceptability and feasibility of HIV self-testing among key population groups and other high-risk groups. Based on research of the enablers and barriers in the demand for self-testing, PATH identified various models of service delivery to study the feasibility and acceptability of HIVST. In this study, a virtual model was among the five different delivery models that were adopted. This model followed the digital marketplace approach. This model is especially relevant to address the 'missing cases' by conventional testing methods, as it expands coverage by facilitating access of HIVST to key populations and other high risk groups in virtual spaces.

## DIGITAL ORDERING OF HIVST KITS

Following the digital campaign, interested participants were guided to the Sahay India website ([www.sahayindia.org](http://www.sahayindia.org)), where they were required to check their eligibility. The form was designed to generate a series of follow-up questions based on the data entered by the participant. The data requirements included information like age, sexual history, occupation, health record, etc. This information was used to direct the participant to a set of videos relevant to them. After authenticating oneself through a one-time password received on their registered mobile phone number, providing consent and watching kit demonstration videos the participant was guided to the screen for self-verification of the application for an HIVST kit. Following verification, the software generated a unique user ID for the participant, digitally validated. The participant then used this user ID to place an order for the self-testing kit.

The privacy and security of the data submitted were ensured by encrypting the entire database of the users, adhering to the HIV/AIDS act. The data on the number of verified users was also used to coordinate and ensure the delivery of self-testing kits.

## CAMPAIGN AND OUTREACH

The virtual model was initiated by running a digital campaign targeted towards the potential members of four key population groups; persons who inject drugs (PWID); female sex workers (FSW); men who have sex with men (MSM), and transgender/hijra population and other high-risk groups in the virtual spaces. Different social media platforms were utilised for outreach. As per the key populations the platforms ranged from mainstream social media platforms like Facebook, Instagram, and Twitter to niche platforms like Grindr, Planet Romeo, and WhatsApp groups. Search engine optimization was also undertaken. Images related to HIV testing were shared on these platforms with strategized captions and hashtags.

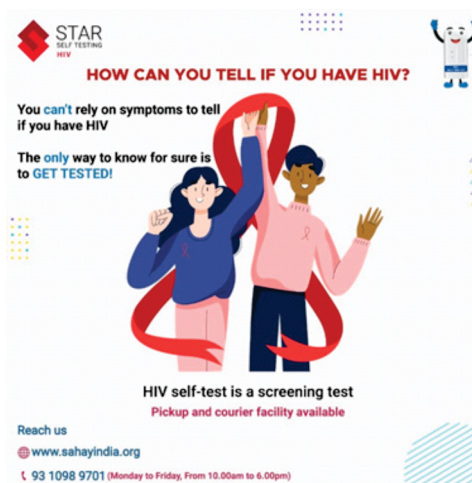


Figure 1. Campaign poster

One-on-one engagement was also done for high-risk individuals to promote self-testing. Through this campaign, people were made aware of the online tools being offered as part of the project to enable self-testing without any physical assistance or external involvement. With an easy and quick way of conducting HIVST at home or in other convenient locations, along with ensuring privacy and confidentiality, HIVST appealed to the participants reached through the digital campaign.

## KIT DELIVERY

Pre-test counselling was conducted for the virtual participants, where they were offered the choice of receiving the kit by courier or at the nearest study site. Those who chose the online mode were couriered the kits along with educational materials and Information For Use (IFU) while the other participants picked up the kit from a designated site in the study district where they received pre-test counselling. Post-test counselling was provided in which the users were guided on the correct course of action based on their results. Those with the status confirmed as reactive were closely assisted, linked to care and encouraged to share their results with the appropriate health service provider, while those with negative status, were informed of preventive measures, including information on processes to access testing easily in the future.

## RESULTS

The virtual model was implemented to strengthen response to HIV testing in India by bringing HIVST kits to the doorstep. A campaign with information on HIVST was designed to reach key populations through different social media platforms and respective outreach strategies.

Subsequently, the interested audience accessed HIVST kits from Sahayindia.org. The results as per the number of hits examined on the website are as follows:

- **HIVST campaigns had a wider reach among the young population:** Technology is an important part of the young generation and is playing a key role in shaping lifestyles of the generations to come. The virtual model can play a crucial role in bridging accessibility

gaps in future. According to the study 28% people accessing through the virtual model were less than 25 years of age and 55% were from the age group of 25-34 years

- **Assisted approach is preferred for HIVST even in a virtual model:** The study concluded that while virtual model gives autonomy to the people reaching out for HIVST, the users preferred assisted approach. With drop of users preferring unassisted self-test from 74% to 43.2% in the next testing, it is indicated that support in a virtual model is required. Support may include a helpline (in different languages) to address any queries, a video call with medical authorities or a physical set up in proximity for any counselling requirements.

## LESSONS

The following lessons can be drawn from the virtual model for delivery of HIVST kits:

- Need for simpler mechanisms to encourage uptake of HIVST: It has been observed that long and complex questionnaires lose interest of potential users. The online mechanisms including lesser tabs and easier access are preferred.
- Need for stronger linkage between HIVST and post HIVST treatment: While HIVST assures, privacy and confidentiality to users, following the confirmation of HIV status among the users, there is a need to strengthen efforts to encourage the users for confirmatory tests, followed by post-test HIV care
- Need for participation of social media influencers and celebrities: Considering the stigma associated with HIV, endorsement of HIVST on digital platforms can facilitate a conducive environment to increase access of HIVST kits.
- Strategic communication to target different audiences on social media platforms: As different social media platforms target different cohorts of population, messaging designed as per the accessibility criteria of different audiences can strongly advance awareness on HIVST.

## CONCLUSION

An accurate and error-free data report was one of this model's key components. Since the participants had to fill many forms and data, the actual hits were over 14,000, out of which, 452 participants enrolled, and the project was able to deliver kits to 187 participants. The online model was extremely useful in participant enrolment in the study. It encouraged care-seeking behavior by making the self-testing kits easily accessible to the user through a user-friendly online interface. Bridging the gap between the participant and the self-testing ecosystem eliminated geographical limits and facilitated adoption at scale.



# A COMPENDIUM OF SUCCESS STORIES OF OVERCOMING BARRIERS TO HIV SELF-TESTING IN INDIA

## INTRODUCTION

Accessing HIV testing services can often pose hurdles for individuals due to reasons such as stigma, lack of confidentiality, discrimination, and access to testing sites.<sup>1, 2</sup> HIV self-testing has the potential to help people overcome these challenges by providing them the option of testing at a time and place they are comfortable with.

This document is a collection of stories that demonstrate the success of HIV self-testing (HIVST) kits in breaking some of the barriers that inhibit the access to HIV testing. These stories bring out the human experience behind the numbers and demonstrate how HIV self-testing can contribute to the better health of an individual, a family, a community, and ultimately the nation and beyond. These stories have emerged from different regions across India, namely Nagaland, Tamil Nadu, and West Bengal. All the names have been changed for privacy reasons.

## NAGALAND: CONQUERING THE ACCESSIBILITY BARRIER

The first case is about a couple in Nagaland—Sumi and Devi. Sumi is a daily wage laborer in his late twenties, with a history of injecting drug use. Being an injecting drug user (IDU), he was concerned about his vulnerability to HIV and wanted to get himself tested. However, the closest Integrated Counseling and Testing Center (ICTC) was a 90-minute walk from his home.

Sumi learned about HIVST kit through other IDUs, some of whom were also outreach workers of the HIV self-testing study in their community. Curious, Sumi reached out to one of the study staff. Through the assisted approach, he took the blood-based self-test and was detected sero-reactive, calling for confirmatory testing at the ICTC.

Since there was no public transportation system in place, and the ICTC was far from his home, one of our outreach workers accompanied Sumi to the ICTC and helped him get his confirmatory testing done. The result was confirmed as HIV positive. Counselling was conducted at the ICTC after which Sumi was linked for treatment initiation process.

Once he returned home, he disclosed his status to his wife, Devi. She too decided to test

herself using the HIVST and was found to be reactive. She then made the arduous journey to the ICTC, where her HIV status was confirmed positive.

As they both decided to go for treatment, they faced another challenge. The nearest ART center was at least two hours trip away by the state transport from their village. Furthermore, Sumi, being a daily wage worker, could not afford the cost of regularly travelling to the ART center for ART therapy initiation. Working with the CBOs associated with the study, the community members came together to link them to care and extend the financial assistance needed by the couple to access ART services.

This case highlights the importance of self-testing in breaking the barrier of access to testing and linkage to treatment. Both Sumi and Devi are currently successfully seeking HIV treatment.

## TAMIL NADU: OBLIVIOUS TO INFORMED

There were two cases in Chennai that highlighted the role of HIVST in overcoming lack of awareness. The cases are about Ramu and Dhira, migrant laborers from different states, working in Chennai. In both cases, they were oblivious to the risks of HIV and AIDS. By holding awareness camps and screening camps, our team was able to generate awareness about HIV and encourage people to test for the same. The cases have been detailed below:

### CASE 1: RAMU

In March 2022, our team held an HIV screening camp in a construction site on the outskirts of Chennai. One individual, Ramu, a man in his early fifties, took the oral fluid-based HIV self-test with assistance of study team. His test results returned reactive, following which he was advised to go for confirmatory testing.

**“Ramu appeared to be in a state of shock and denial initially, refusing to seek confirmatory testing. Claiming that he was healthy and that he hadn't indulged in high-risk activities, he refused to accept that he could be HIV positive.” -State Program Specialist**

The next day, the team went to the construction site again and spoke to Ramu. They spent some time with him and counseled him about the importance of confirmatory testing, after which he finally agreed to be accompanied to the ICTC. The very next day, the team took Ramu to an ICTC at a general hospital, 10 kilometers from the construction site. At the center, he was tested and was found to be HIV-positive, thus, had to be linked to ART. That day, the team took him to an ART center. There, the ART staff counseled him to alleviate his fears.

When Ramu left the ART center, he still carried some doubts and sought guidance from his peer counsellor. However, Ramu was not satisfied with the support and advisories he received from the peer counsellor. The peer counsellor took Ramu to a more seasoned, trained and experienced resource, his site supervisor. The site supervisor held counselling

sessions with Ramu. Understanding that Ramu was worried about losing his work and source of income for his family by going to the designated ART center, he assured Ramu of access to a medical center of his choice and convenience for ART treatment.

The site supervisor coordinated with the project team to link Ramu to an ART center, which could provide him the required medicines for ART. In the meantime, Ramu fell severely ill and returned to his hometown. During this time, the team stayed in regular contact with him, encouraging and motivating him to seek ART. One day, the team received a call that lifted their spirits. Ramu had voluntarily visited the ART center and was successfully seeking treatment! The team's efforts communicating with and educating Ramu had paid off.

This case demonstrates on how counselling/education of HIV and teaching Ramu the importance of receiving confirmatory testing post HIVST and initiating ART treatment led him to the decision to get tested and seek treatment. The HIVST that Ramu took after the meeting, not only made him aware of his HIV status but also helped him get quality counselling and treatment in time. This case also demonstrates how the project team, with most of them Tamil speaking individuals, and Ramu, who was from another state and did not speak or understand Tamil, overcame the barrier language to achieve a larger goal.

## **CASE 2: DHIRA**

The project team organized a screening camp in one of Chennai's wholesale markets for fruit, vegetables and flowers in March 2022. Dhira, a migrant laborer in his late forties who worked in Koyambedu market, took an assisted oral self-test and was detected as reactive.

He became anxious on knowing the result. Following the counselling session with the peer counsellor and a community mobilizer, which assuaged his anxieties, he agreed to go to the Urban Primary Health Center (UPHC) with the project team member for confirmatory testing.

The counsellor at the UPHC was on leave the day when Dhira and project staff reached the health facility. When the project staff spoke with the counsellor over the phone, explained the situation and request her to come to the facility to counsel and support Dhira, she made an exception, cut short her leave and came to the UPHC. Although she counselled Dhira, both the project staff and she observed that Dhira needed further counselling before he goes for confirmatory test. When they jointly counselled Dhira, it had a positive effect on him. With his concerns and anxieties were put to rest, Dhira underwent the confirmatory test.

His status was confirmed as HIV positive and underwent post-test counseling. He was informed that he needs to be put on ART treatment.

The project staff accompanied Dhira on the day he went for the first time to the hospital for ART to help him with the process. Dhira went regularly to the hospital for the next two days and on the second day, ART was initiated. Even now, when he sees the project team in the market, he always waves and smiles at them.

This case highlights the importance of proper counseling in trust building with the participants. Dhira and our team seem to have formed a bond of mutual trust, respect, and gratitude.

These cases highlight the role of HIVST in removing the barrier of unawareness and oblivion. By providing Ramu and Dhira with information and a mode of testing, they were able to know their status easily and move towards treatment smoothly.

**“They were not aware of what HIV is. We held an awareness providing session and told them all about it. We then helped them in screening for HIV by providing self-testing kits.”**

**- State Program Specialist**

## **KOLKATA: UNAWARENESS TO UNDERSTANDING**

This case follows a married couple, Subroto and Debanjana, and their 18-year-old son, Dipankar. Both Subroto and Debanjana were HIV positive for many years and were on ART. On one of the occasions when Debanjana went to ICTC for her routine checkup, she had gotten Dipankar to accompany her.

The staff at the facility asked her if she had ever gotten her son tested for HIV. While she had not, Debanjana, encouraged by the health staff, decided to encourage, and advise Dipankar to take a HIVST.

Dipankar underwent pre-test counselling and took an assisted HIVST. When the results returned reactive, both Debanjana and Dipankar were shocked and not ready to believe the result.

The counsellor counselled Dipankar and the post-test counselling helped them understand that the HIVST results, though reliable, needs to be followed up with a confirmatory test. They agreed to let Dipankar undertake the confirmatory test. The test confirmed Dipankar's HIV positive status. Dipankar underwent post-counseling, and the family underwent several rounds of counselling at the facility and with peer counsellor before they came to accept Dipankar's status. Now, Dipankar accompanies his parents for ART treatment. This case presents the importance of knowing one's HIV status. This case also highlights how self-testing can enable people overcoming the knowledge barrier, make people more cognizant and understanding of their HIV status and seek timely support, treatment, and care services.

## **MADHYA PRADESH: AN EASY SOLUTION FOR A BUSY SCHEDULE**

This case follows Ravi, a 20-year-old member of the men who have sex with men (MSM) community and an extremely busy makeup artist with a hectic schedule. One day, when Ravi complained about irritation and drowsiness with his close friend, who was also the community mobiliser with the project, he urged Ravi to get tested for HIV.

As Ravi never had the time to go to an ICTC for testing, his friend – the community mobiliser – got a peer counsellor to Ravi's house, who introduced him to HIV self-testing kit. After pre-test counseling, Ravi undertook assisted oral fluid-based HIV self-test.

When the result returned reactive, Ravi grew anxious and flustered. Both the community mobiliser and the peer educator counselled him post-test and advised him not to worry and encouraged Ravi to go for confirmatory testing at ICTC. The following day, they accompanied him to the ICTC for confirmatory test. The result confirmed his HIV positive status.

Deeply upset about his HIV positive status, Ravi required several rounds of counseling by the community mobiliser, the peer counsellor as well as the ICTC counselor, he understood that there is more to life and the ART and lifestyle change will help him maintain low viral load and live a longer life.

Ravi later informed his only partner, Pankaj, a 35-year-old married man with children, about his HIV status and encouraged Pankaj to get himself tested. Pankaj, supported and guided by the project team, took an assisted blood-based self-test. His result too returned reactive. Confirmatory test also confirmed Pankaj's HIV positive status. During post-test counselling, Pankaj appeared calm and composed, and interested in knowing the next actions to manage his health.

Although Pankaj had a difficult marriage with his wife, on advice of the counsellor, he agreed to get her also tested for HIV. The next day, he got his wife to the ICTC for HIV testing, which returned positive.

Ravi, Pankaj, and his wife, all three are on ART today.

This case highlights the role of self-testing in being an easy and convenient option for a person. It also emphasizes a domino effect of how one self-testing case led to the testing, early identification, and initiated treatment of two other individuals.

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