Unitaid psi NACO National AIDS Control Organisation India's Voice against AIDS Ministry of Health & Family Welfare, Government of India www.naco.gov.in STAR SELF TESTING HIV

Accelerating access and uptake of HIV self-testing (HIVST) in India

STAR HIV Self-testing Initiative

PATH

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Foreword

It is with great pleasure that I introduce this report on HIV self-testing in India. The report provides an overview of the project, including its objectives, methodology, and results. It also highlights the challenges and opportunities that were encountered along the way.

The pandemic has been a curveball in many of the National Program implementations in the country. It has set us back on our steady progress over decades of program implementation. But it also has taught us valuable lessons in newer methodologies, created opportunities for newer solutions, and enabled environments in many instances. I would like to take this opportunity to introduce this study on HIV Self-Testing that was implemented in our country through a diversity of local and international developmental agencies.

The study initiated during the time of the pandemic saw many challenges in implementation as well as challenges due to the differential access to resources across the implementing geographies. This report is a testament to the hard work and dedication of the team that has worked tirelessly to make this project a reality.

HIV self-testing is an important tool in the fight against HIV/AIDS. It empowers individuals to control their health by providing them with a convenient and confidential way to test for HIV. This is particularly important in areas with limited access to traditional testing methods. At a time when there is overall concern about slowing down prevention programs and their reach to key populations, this report is a timely reminder that reaching the last mile through community empowerment and involvement is the key to success.

I would like to commend the team for their efforts in implementing this project. Their dedication and hard work have made it possible to bring this important tool to those who need it most.

A special thanks to leadership of NACO, WHO, CDC, ILO, PISPAG, CAB, SOC and CMB members for the success of this project implementation in India.

I hope this report will serve as a valuable resource for the government to scale up HIV self-testing, and for those interested in implementing similar projects in the future.

Sincerely,

J.V.R. Prasada Rao

Former Health Secretary to the Government of India, and

Former Special Envoy to the Secretary General of the United Nations on HIV/AIDS for the Asia Pacific region

Acknowledgement

For the first time in India, HIV self-testing kits (three types) were introduced through a project supported by Unitaid. This initiative was part of the phased Unitaid-funded STAR HIV Self-Testing Initiative, aimed at generating evidence for decision-making, enabling a supportive environment, and catalyzing the global market for HIV self-testing (HIVST). The project was led by PATH, along with consortium partners, technical advisors, community leaders, and implementation and technical partners. This initiative was a significant milestone for PATH in fostering partnerships, engaging with 22 leading organizations, including government agencies, UN organizations, bilateral and multilateral partners, implementation organizations, and 15 State AIDS Control Societies. Additionally, the project was implemented through more than 250 non-governmental and community-based organizations across 14 states between February 2020 and June 2023.

PATH extends its heartfelt gratitude to the National AIDS Control Organization (NACO), the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), the International Labour Organization (ILO), the Indian Council of Medical Research (ICMR)-National AIDS Research Institute (ICMR-NARI), the ICMR-National Institute of Epidemiology (ICMR-NIE), and the State AIDS Control Societies of Andhra Pradesh, Gujarat, Karnataka, Maharashtra, Madhya Pradesh, Manipur, Mizoram, Mumbai, Nagaland, Punjab, Tamil Nadu, Telangana, West Bengal, and Uttar Pradesh for their invaluable collaboration and guidance. Your unwavering support and expertise have been instrumental in driving impactful initiatives and fostering meaningful progress in our shared mission.

A special acknowledgment goes to NACO leadership, including Ms. V. Hekali Zhimomi, Additional Secretary & Director General; Ms. Nidhi Kesarwani, Director; Dr. Shobini Rajan, Deputy Director General; Dr. Anoop Kumar Puri, Deputy Director General; Dr. U.B. Das, Deputy Director General; Dr. Chinmoyee Das, Assistant Director General; Dr. Bhawani Singh, Deputy Director; Dr. Saiprasad Bhavsar, Deputy Director; Dr. Bhawna Rao, Deputy Director; Ms. Vinita Verma, National Consultant; and other NACO officials who facilitated and guided the entire project implementation with the support of the respective 15 State AIDS Control Societies.

We also take this opportunity to thank Dr. Patrick Nadol, Program Director, Division of Global HIV and TB, CDC-India; Dr. Melissa Nyendak, former Director, Division of Global HIV and TB, CDC-India; Dr. B.B. Rewari, Regional Advisor (HHS), WHO SEARO; Dr. Polin Chan, Team Leader, Communicable Diseases, WHO India; and Mr. Muhammad Syed Afsar from ILO for their valuable contributions and support.

A special thanks to Shri Alok Saxena, former Additional Secretary and Director General, NACO, for his continued guidance in ensuring the successful implementation of this innovative project in India. We extend our gratitude to Shri J.V.R. Prasada Rao for chairing the PATH India HIV Self-Testing Project Advisory Group (PISPAG) and supporting initiatives with the active coordination of Dr. Ashok Kumar, Co-chair of PISPAG. We acknowledge the guidance and inputs provided by Dr. D.C.S. Reddy, Senior Public Health Expert, throughout the scientific writing workshops and data analysis. We also thank Dr. Sanjay Mehendale and Dr. Sundaraman for their continuous guidance and support, which were instrumental in building confidence and guiding the project team. Additionally, we express our appreciation to Smt. Selvi Arumugam and Shri Jaswinder Singh, Chair and Co-chair of the Community Advisory Board (CAB), for ensuring community representation and facilitating community feedback, strengthening the project's implementation.

PATH extends its sincere gratitude and appreciation to our esteemed implementation partners: Humsafar Trust (HST), Solidarity and Action Against the HIV Infection in India (SAATHII), International Training and Education Centre for Health Private Limited (I-TECH), Voluntary Health Services (VHS), Society for Health Allied Research and Education (SHARE India), National Coalition of PLHIV in India (NCPI+), Brihanmumbai Electric Supply & Transport Undertaking (BEST) in Mumbai, Transport Corporation of India Foundation (TCIF), India HIV/AIDS Alliance (IHAA), and Clinton Health Access Initiative (CHAI). Their invaluable contributions were key to the successful implementation and completion of HIV self-testing distribution across the states. We also extend our appreciation to over 250 community-based and non-governmental organizations across the country that played a crucial role as field-level implementing partners. The dedication demonstrated by each partner in planning, executing, and monitoring the distribution process was instrumental in achieving this milestone.

We sincerely thank the Key Population and PLHIV community leaders for their invaluable contributions through the Community Advisory Board (CAB) at the national level, the State Oversight Committee for HIV Self-Testing at the state level, and the Community Monitoring Board (CMB) at the district level. Their active participation and dedicated monitoring visits played a crucial role in the successful implementation and completion of the HIV self-testing distribution in India. We look forward to continued collaboration in future initiatives to further enhance community engagement and strengthen health interventions.

Through your active participation, innovative strategies, and tireless efforts, we have collectively advanced the goal of increasing HIV testing distribution and promoting early detection and treatment. Your partnership has strengthened the healthcare framework and reinforced our shared mission of improving public health outcomes.

As we continue our journey towards achieving our goals, we remain grateful for the continued partnership and shared vision. Together, we can build a healthier, more inclusive future for all.

Neeraj Jain

Country Director – India & Director of Growth Operations – Asia, Middle East & Europe

PATH

Contents

List of abbreviations

ART	antiretroviral therapy
CAB	community advisory board
CBO	community based organizations
CDC	U.S. Centers for Disease Control and Prevention
CDSCO	Central Drugs Standard Control Organization
CMB	community monitoring board
CRO	clinical research organization
DAPCU	district AIDS prevention and control unit
DCGI	Drug Controller General of India
FSW	female sex worker
GFATM	The Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	Human Immunodeficiency Virus
HIVST	HIV self-testing
ICF	informed consent form
ICMR	Indian Council of Medical Research
ICMR- NARI	ICMR- National AIDS Research Institute
ICMR -NIE	ICMR- National Institute of Epidemiology
ICTC	integrated counseling and testing center
IDU	injectable drug user
IEC/BCC	information education communication/behavioral change communication
IFU	instructions for use
ILO	International Labour Organization
IQR	interquartile range
IRB	Institutional Review Board
KP	key population
LRP	learning resource package
MCGM	Municipal Corporation Greater Mumbai
MSM	men who have sex with men
NACO	National AIDS Control Organization
NACP	National AIDS Control Plan

NCPI	National Coalition of PLHIV in India
NMP+	Network of Maharashtra People with HIV
NGO	non-governmental organization
ORA	PATH Office of Research Affairs
OST	opioid substitution therapy
PEPFAR	United States President's Emergency Plan for AIDS Relief
PI	principal investigator
PISPAG	PATH India HIV Self Testing Project Advisory Group
PLHIV	people living with HIV/AIDS
PrEP	pre-exposure prophylaxis
PSI	Population Services International
PWID	people who inject drugs
SACS	state AIDS control society
SIB	scientific integrity board
SOC	state oversight committee
TG	transgender
TI	targeted intervention
UID	unique identification number
USAID	United States Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

Between 2011 and 2021, India has recorded over 1.7 million new cases of HIV in the last ten years.[1] As per the National AIDS Control Organization (NACO), there were approximately 62,967 new HIV infections reported in 2021.[2] Since reaching the peak in 1997, new HIV infections in India have declined by nearly 90%. This significant progress was made possible due to evidence-based and result-oriented strategies and program interventions implemented by NACO and its partners. However, despite the considerable progress made in HIV testing and care, a substantial percentage of people living with HIV (PLHIV) remain unaware of their infection, accounting for approximately 30% of cases worldwide. The knowledge gap associated with undiagnosed HIV status is a significant obstacle in achieving the Joint United Nations Programme on HIV/AIDS (UNAIDS) "95-95-95" goals, which aim for 95% of all PLHIV to know their HIV status by 2030. Undiagnosed HIV status not only leads to late entry into care but also contributes to elevated mortality rates and serves as a substantial driver of the HIV epidemic. Hence, this underscores the World Health Organization's (WHO) recommendation for HIV self-testing (HIVST) as a global priority in addressing this critical gap and enhancing access to testing.

The project "Accelerating access and uptake of HIV self-testing (HIVST) in India" was launched in February 2020 to demonstrate the feasibility and acceptability of HIVST among different key populations (KPs) and other high-risk groups. The overall goal was to increase the demand for and access to HIVST, as well as subsequent treatment and prevention services, thereby contributing to further reduction in the number of new HIV infections and averting deaths due to HIV infection.

This initiative was a part of the phased Unitaid-funded STAR HIV self-testing Initiative aimed at generating evidence for decision-making, enabling the environment, and catalyzing the global market for HIVST. In India, this project was led by Population Services International (PSI) with PATH and its advisors, community leaders, implementation and technical partners, executed the project between February 2020 and June 2023. This effort was built on the lessons learned from the STAR HIV Self-Testing Africa Initiative. **The project aimed to create an enabling environment that would support the introduction of HIVST kits, including policy adoption and product**

STAR India HIV self-testing project obtained 13 different approvals

registration. It also aimed to implement and test service delivery models for increased uptake of HIVST while mapping the linkages to care, treatment, and prevention services. Furthermore, the initiative aimed to disseminate the best practices from the project and help identify and mobilize the resources to support the transition and scale-up of HIVST in the country.

Paving the way for early detection, prevention, and treatment

As there was no precedent for HIVST in India, **PATH initiated a study to collect evidence for its introduction and implemented the project across 50 districts in 14 states.** During the initial landscaping of HIVST kits conducted by PATH for the project, it was discovered that there were no central drugs standard control organization (CDSCO) approved HIVST kits in India. The project used HIVST kits manufactured by three manufacturers and prequalified by WHO, namely the oral fluid-based OraQuick® and the blood-based INSTI® and Mylan® through various delivery models. An import license was obtained from the Drug Controller General of India (DCGI) to import and use these kits in the country for the STAR HIVST project.

Building an enabling environment for introducing HIV self-testing

Prior to this project, HIVST was uncharted territory in India. Although an evidence-based testing strategy exists, implementing HIVST has its own challenges, such as the acceptability of self-tests, individuals' willingness to pay for them, and the ability to reach individuals who are not accessing conventional HIV testing. Additionally, there are issues related to pre-test counseling, post-test counseling, and linkage to care. For the intervention to be successfully piloted in India, close collaboration with NACO and its state counterparts, i.e., the state AIDS control societies (SACS) and

Three types of HIV self-testing kits are used in the project

community-based organizations (CBOs), was essential. **At the time of the study, no certified HIVST test kits were available in the country.** Therefore, it was crucial for regulatory agencies, including CDSCO and the Department of Health Research, to have confidence in the intervention's goals, methods, and purpose. Furthermore, the project required support from HIVST kit manufacturers to make their kits/essential documents available for research by the project.

A series of activities were undertaken to create an enabling environment for introducing HIVST in the country, which included the following:

Formation of guiding groups for creating an enabling environment:

A tailor-made approach was devised by creating several committees with stakeholders with specific capabilities to guide the project. The protocols and implementation plans were presented to these committees with specified terms of reference. They were guiding the study team. See Figure 1.

Advisory and community monitoring

PATH India HIV Self Testing Project Advisory Group (PISPAG)

PATH constituted an advisory group, the PISPAG, which had representation from NACO, SACS, development partners, UN Agencies, ICMR institutions, PEPFAR (CDC & USAID), academic institutions, and technical experts.

The PISPAG played a key role as the project's advisory body providing guidance, insights, and solutions to critical issues during the conceptualization and implementation

Community Advisory Board (CAB) for HIV self-testing

The CAB was a body of representatives from all key population groups and PLHIV and was the voice of the community on the project.

Engaged deeply with the project, the CAB looked at the community processes and practices adopted by the project and ensured that they are community sensitive and community inclusive

State Oversight Committee (SOC) for HIV self-testing

SOC for HIVST was a collaboration between the government, KPs, PLHIV, and community-led organizations from affected communities, as they worked jointly to facilitate more inclusive decision-making on issues that are important to members of KP and PLHIVs.

The project had one SOC for HIVST in each of its 14 intervention states

Community Monitoring Board (CMB) for HIV self-testing

Community Monitoring Board (CMB) was formed at the district level for the STAR HIVST project.

Comprised of leaders and vocal members from the KP and PLHIV communities, the CMB acted as a focal point to address the grievances of the project participants.

Figure 1. Advisory and community monitoring

The HIVST kits procured with the support of Unitaid through PSI

Warranting ethical and regulatory approvals at every step: The intervention also required the confidence of the regulatory bodies, including the Drug Controller General of India (DCGI) and the Indian Council of Medical Research (ICMR), to validate its purpose, objectives, and approach. **The study received approval from the ethics committees of The Humsafar Trust, Mumbai, India (HST-IRB-49-10/2020), and WCG IRB, USA (20212973).** It also received a research determination from the Scientific Integrity Branch of the Division of Global HIV and TB, Centers for Disease Control, Atlanta. Written informed consent was obtained from all participants. All these approvals were obtained during the second phase of COVID-19 pandemic in the country.

Bringing multifaceted capabilities on one platform: To make the project a success, the capabilities of various stakeholders, such as national and state government officials, development partners, implementing partners, community leaders, and HIVST manufacturers, were brought in.

Conducting a formative study to identify the enablers and barriers of HIVST implementation: A formative assessment was conducted to identify the enablers and barriers to HIVST implementation. Using human-centered design thinking, the qualitative study revealed that HIVST has the potential to reduce stigma by minimizing the duration of interactions associated with HIV. Additionally, it addresses the inconvenience and opportunity costs associated with getting an HIV test. To address the concerns identified and find opportunities to enhance the feasibility, acceptability, and demand for HIVST across Kps.

PATH, in consultation with members of PATH India HIV Self Testing Project Advisory Group (PISPAG) and Community Advisory Board (CAB), implemented five different distribution models for HIVST kits: a community-based model, a private practitioners' model, a workplace model, a PLHIV network-led model, and a virtual model. See Figure 2.

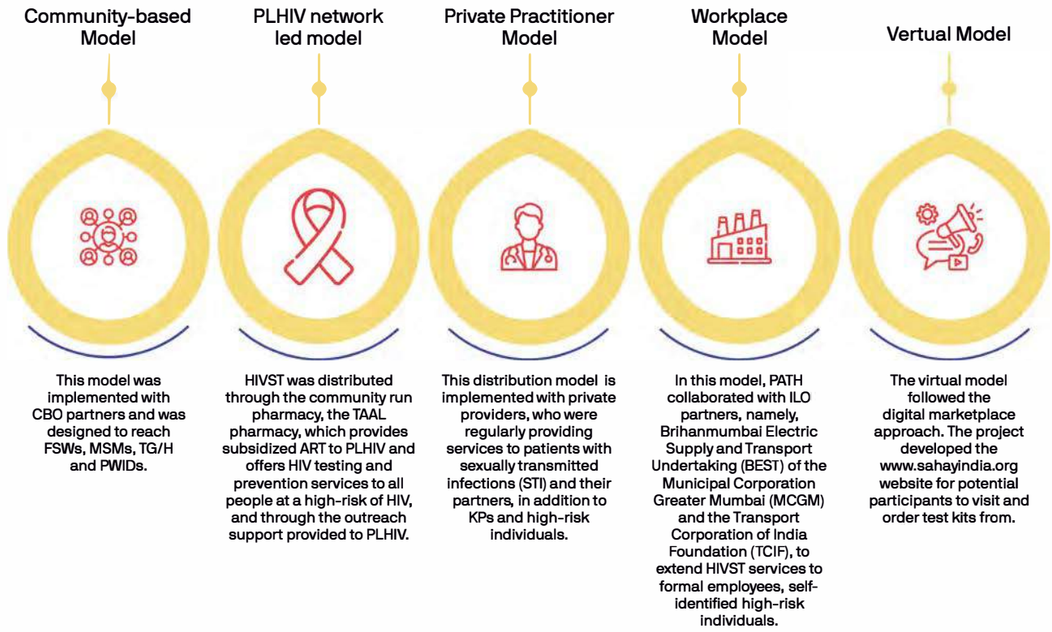


Figure 2. Five models of HIVST distribution

Training and capacity strengthening of project staff. PATH strengthened the capacities of peer educators, counselors, and service providers, state coordinators, district coordinators, site supervisors, data managers, monitoring experts, CAB, SOC and CMB members and facility (ART, ICTC, DSRC, DAPCU and SACS) staff were engaged in this project through numerous training models. It developed a detailed learning resource package (LRP) consisting of training modules, facilitator's guide, implementation protocols, standard operating procedures, IEC/BCC (information education communication/behavioral change communication) materials, instructions for use (IFU), and other learning materials. State managers, along with members of CAB, state oversight committee (SOC), and community monitoring board (CMB), visited the project sites to give supportive supervision for implementation. **Totally more than 1000 staff trained in 14 states through more than 25 batches of training which includes training of trainers (TOT).**

WHO, CDC, ILO and CHAI are the co-funding partners

More than 300 community leaders were engaged

Storage and distribution of test kits: Proper storage and inventory management for the test kits, along with effective microplanning for their distribution under various models, was important. The kits were stored at a designated space within the stipulated temperature range of 2 to 30 degrees Celsius. An inventory register was maintained to keep track of the kit distribution, and cool boxes were utilized to ensure the proper temperature during outreach sessions. Many of the SACS coordinated and supported to store the kits in the warehouse, which significantly aided in smoothening the supply chain and management process.

Initiatives to increase the potential of uptake of HIVST and linkages to confirmatory, care, treatment initiation, and prevention services

After ensuring an enabling environment for implementation of the study through the first phase, the project was implemented, and the following activities were undertaken (see Figure 3):

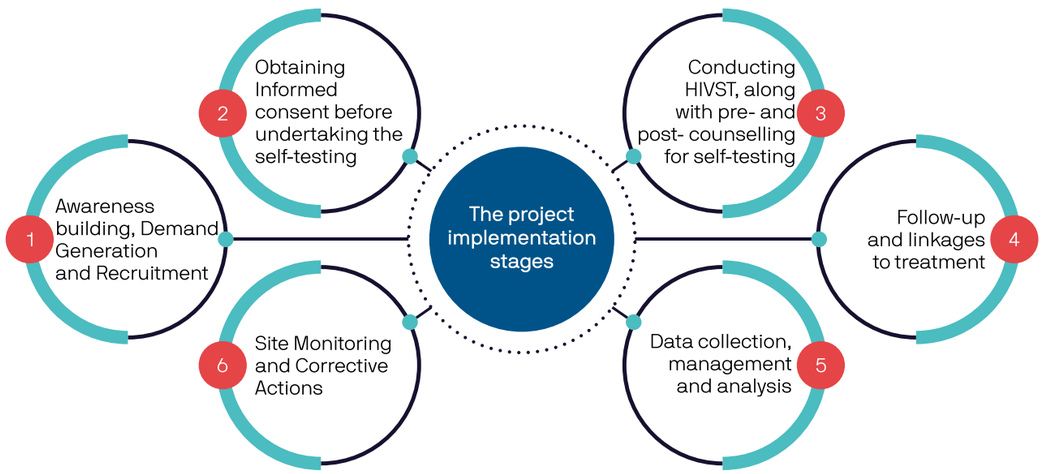


Figure 3. Project implementation stages

More than 250 CBOs/NGOs engaged as field level implementing partners

- A variety of **strategies were devised to increase demand for HIVST** and mobilize the target population for recruitment into the current study, as well as for the delivery of future HIVST services. The demand generation plan was developed after discussions with partners responsible for different models and community input. These demand-generation activities were customized and meticulously designed for all five HIVST distribution models. For example, in the case of the HIVST virtual distribution model, social media marketing was conducted by engaging social media influencers.
- With the support of a **communication agency, communication packages were conceptualized, designed, and field-tested** for KPs, self-identified high-risk individuals, partners of high-risk individuals, and PLHIV, among others. The same tools have been piloted with CAB members. These packages helped the target groups to become knowledgeable about HIVST, accept its use, and implement it effectively. These materials were uploaded and made publicly available for easy access at the following link: **https://www.youtube.com/@starhivselftesting3897.** The package included taglines, IFU in print and videos, counseling videos, and point-of-use promotional products, among other resources. These products were first developed in Hindi, and then further translated into seven regional languages and made available at project sites for use.
- **Recruitment of participants for the study** began with demand generation activities, which included IEC campaigns, interpersonal communication, and events at the study sites, such as group activities. Through these interventions, potential participants were mobilized and provided with information on HIV/AIDS. They were then subjected to eligibility assessment as per the study protocol.

Totally 94,823 HIVST test kits were distributed

- Eligible participants were provided with relevant IEC materials containing all necessary information on the tests, discomforts, potential benefits, protection of confidentiality of the information (data collection, storage, and follow-up), voluntary participation, and the option to withdraw from the study. **Two types of informed consent forms (ICFs) were used for the study participants: i) for in-person recruitment and ii) for virtual recruitment.** Once the consent forms were signed, the participant enrollment form and behavioral questionnaires were filled out to generate a unique identification for the participant. Eligible participants were allowed to choose from the two kinds of kits and were shown demonstration videos to assist in their selection.
- **Self-testing was conducted in two formats:** a) physical or offline testing and b) virtual or online testing. Both formats offered options for assistance (in the presence of the provider, i.e., counselor, outreach, or other trained staff) or through unassisted self-testing (i.e., independently conducting the testing in their preferred location and interpreting the result themselves). Pre-test counseling was provided to all participants, and the procedures for HIVST were explained. The study staff then carried out a video demonstration of the HIVST process and how to interpret the results. Once the results were ready, the staff discussed the results, provided post-test counseling, administered the remaining behavioral questionnaire, and obtained feedback.
- Based on the HIVST result, **referral linkages were established** to either a confirmatory testing site or an HIV prevention program. **If the test result was reactive, a referral was offered to the nearest integrated counseling and testing center (ICTC) for a confirmatory test. If the confirmatory test was also reactive, participants were further linked to the antiretroviral therapy (ART) center for treatment initiation.**
- **Data collection, management, and analysis** were conducted through a structured approach. A clinical research organization (CRO) collected data daily from each site through its online application-based data collection form. The central team routinely assessed all data for quality. All discrepancies were reported to the sites, and the field team requested corrections. Data analysis was performed using SPSS (Version20,2011; IBM Inc., Chicago, IL, USA) and Stata (Version 16, StataCorp LLC, Texas, USA).
- As the project was implemented in multiple sites across the country, each site carried out a specific number of HIV self-tests according to the protocol and guidelines. Trained monitoring experts with experience in HIV programs and basic research knowledge closely **monitored** the entire process **to ensure compliance with the protocols,** standard operating procedures, and guidelines. PATH was responsible for taking **corrective actions** through its site supervisor and study staff within 48 hours of receiving reports.

Initiatives to disseminate the best practices, transition, and scale-up of HIVST

With the conclusion of the study, the study results and findings were shared with both stakeholders and the community. **PATH India organized a national-level dissemination event titled "Dissemination of STAR III Initiative HIV Self-Testing in India: Moving from Evidence to Action" on September 26, 2022, in New Delhi.** During the event, the summary report of the project and seven knowledge products were released. Special invitee speakers and panelists provided expert insights on various HIVST themes, particularly in the Indian context.

48.9% of participants reported never having been tested for HIV

89.4% of participants preferred using an HIVST kit for future testing

Results were encouraging with an increased access and uptake of HIV self-testing (HIVST) in India

The results provided insights into the feasibility, acceptability, and demand for HIVST across specific populations and models. Participants expressed a preference for blood- or oral fluid-based HIVST kits as well as for assisted and unassisted approaches. Additionally, there were discussions about the importance of linking individuals with negative HIVST results to prevention services and ensuring that those with reactive results have access to confirmatory HIV testing and treatment services.

Participants enrolled for HIVST kits based on demography, population groups, gender and models of HIVST distribution

- The enrollment process aimed to include 96,194 individuals, achieving a 99.9% consent rate among eligible individuals provided. As a result, 95,925 participants contributed to the study's success.
- **Nearly 60.9% of those who used an HIVST kit in the study identified themselves as a member of a KP group and their clients/partners.** Additionally, 24.7% of study participants self-identified as high-risk individuals. Among the KP groups, most participants identified themselves as female sex workers (FSWs) or men who have sex with men (MSM).
- Overall, 67.7% of participants identified as male, 26.8% as females, and 5.5% as transgender (TG).
- There were also differences in enrollment models among study participants. The virtual enrollment model reached mainly MSM, while almost all TG participants were enrolled through the community-based model. The PLHIV-network model reached partners and family members of PLHIV.

95.1% of participants reported HIVST kits as easy to use

Distribution of HIVST kits based on age group and distribution model

- As part of the project, HIVST kits were distributed among participants in 14 study states and 50 districts. A total of 94,823 HIVST kits were distributed during the study period.
- In the first phase, the distribution began in September 2021 from a facility in Delhi and gradually expanded until June 2022.
- **All five distribution models were employed to reach participants. The second phase distribution of the kits resumed in December 2022, utilizing both virtual and community-based models. This continued until March 2023.**
- The median age of the study participants was 30 years, with an interquartile range (IQR) of 26-36 years.
- Of the total 94,823 test kits distributed during the study, 80,333 (85%) were provided through the community-based distribution model.

Testing preferences and interpretations of results

- **Overall, 48.9% (46,332 out of 94,661) of participants reported that they had never been tested for HIV. Among the KPs, the percentage of first-time testers was as follows: 43.9% for MSM, 32.4% for TG people, 26.1% for FSWs, and 24.7% for persons who inject drugs (PWIDs).**

95.2% of participants reported the test kit results as easy to interpret

- The proportion of first-time testers varied by testing model: 75.0% in the private practitioner model, 68.6% in the PLHIV network-led model, 67.8% in the workplace model, 61.5% in the virtual model, and 44.9% in the community-based model.
- Overall, 51.3% of participants preferred blood-based test kits, while 48.7% preferred oral-fluid-based test kits.
- Among the enrolled population groups in the study, MSM (55.8%) and TG people (54.2%) showed a higher preference for oral-fluid test kits, whereas 66.1% of people who use drugs preferred the blood-based HIVST kits.
- In terms of future testing preferences, **89.4% (83,397 out of 93,241) of participants stated that they would prefer an HIVST kit over other testing modalities available.**
- Additionally, 95.1% (89,871 out of 94,473) reported HIVST kits as easy to use.
- Overall, 95.2% (89,825 out of 94,398) found the test kit results easy to interpret.
- Finally, **68.2% (55,317 out of 81,170) of participants expressed a willingness to pay for HIVST** kits in the future.
- While a large proportion of participants reported willingness to pay for the kits,
  - 46.6% reported that they were willing to pay less than INR100 (US$1.2) for the kits.
  - among the different population groups, TG people were willing to pay up to INR 250 (US$3) for the kits.
  - among the other three KP groups, the majority of the participants who were willing to pay were willing to pay less than INR 100 (US$1.2) for the kits.

68.2% of participants reported a willingness to pay for HIVST kits in the future

HIVST testing cascade and linkages to care

- Among the 94,823 participants who were given an HIVST kit, 94,734 (99.9%) successfully shared their results, and 9 (<0.1%) participants refused to share their test results.
- The 195 (0.2%) participants who tested indeterminately on their first HIVST test were retested. Among those retested,
  - 170 (87.2%) tested HIV-negative on the subsequent HIVST usage,
  - while 23 (11.8%) tested indeterminate the second time,
  - of the 23 with an indeterminate result, all were referred and 19 retested at an ICTC, and all tested HIV-negative.
- A total of 356 (0.4%) participants reported an HIV- reactive result on HIVST.
- Among the 356 who tested reactive,
  - **86.6% (309) were linked for confirmatory testing at an ICTC.**
  - Among these, 283 shared their confirmatory testing result with the study staff.
  - 23 refused to share their confirmatory testing result, and three refused testing at the ICTC.
  - **Among the 271 who reported HIV-positive, 232 (85.6%) were initiated on ART during the study period.**

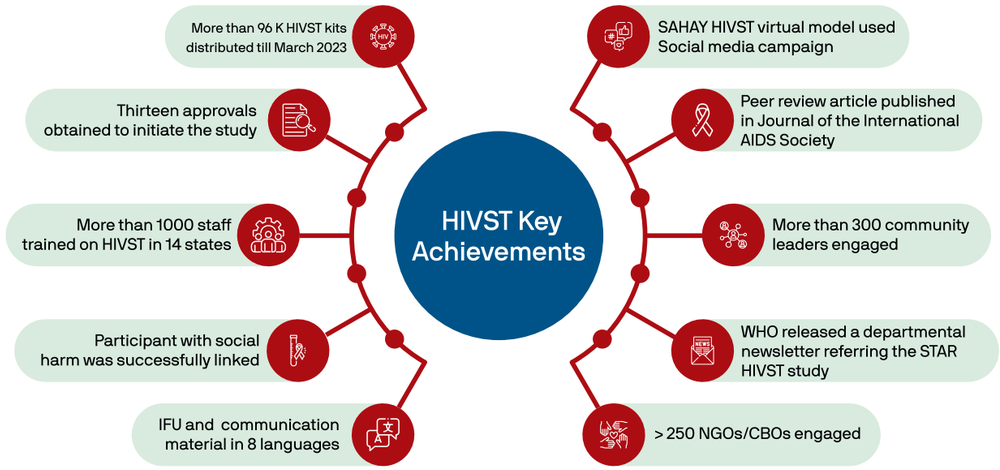


Figure 4. HIVST key achievements

86.6% were linked for confirmatory testing at an ICTC

Greater equity will unlock new opportunities and introducing policies will have the most impact

HIVST has proved that it is an effective testing strategy for reaching individuals who have never tested in the past, including partners of PLHIV, partners of KPs, and those individuals who have not reached the HIV testing facilities so far, irrespective of their risk behavior and risk perception.

Drawing on key lessons learned from the study, the following recommendations are proposed for the government stakeholders, donors, HIVST kit manufacturers, academic and research community, community leaders, and implementation organizations to further access to HIV/AIDS testing opportunities and to widen the response to the AIDS epidemic.

- Build a robust policy framework and integrate HIVST into the basket of services under the National AIDS Control Program.
- Introduce oral fluid-based self-test kits and blood-based self-test kits to ensure wider acceptance and utilization of HIVST approaches.
- Cultivate multistakeholder collaboration for effective scaling-up of HIVST kits.
- Establish a robust ecosystem for an integrated HIVST supply-demand-delivery intervention.
- Utilize communication material developed through the project for information dissemination and capacity building.
- Explore future research, scaling-up, and funding opportunities.

The study presents encouraging indications for integrating HIVST as one of the methods for enhancing coverage of testing opportunities and meeting the first 95% goal of UNAIDS' 95-95-95. Effective HIV solutions require political support, sufficient funding, research and scientific evidence, inclusive and rights-based strategies, and work toward equity. Nations that prioritize people in their policies and initiatives are already at the forefront of the global effort to eradicate HIV/AIDS by 2030.

85.6% were initiated on ART

CHAPTER 1

Background

The HIV landscape in India has experienced transformative changes over the past few decades, showcasing remarkable progress in some areas while still facing persistent challenges in others. Since its peak in 1997, there has been an impressive 90% reduction in new HIV infections. Recent years have also seen substantial improvements, with annual new infections declining by 42% between 2010 and 2022 and AIDS-related deaths decreasing by a staggering 77% during the same period.[3]

According to the Global AIDS Monitoring 2023 report and UNAIDS 2023 HIV estimates, India is currently home to an estimated 2,500,000 individuals living with HIV. Besides, around 66,000 new HIV cases were reported in 2023 alone, signifying an ongoing battle against the epidemic.[4] Further emphasizing the scale of the challenge, the "Sankalak: Status of National AIDS & STD Response (2023)" (SANKALAK) indicated that India ranks second in terms of the magnitude of its HIV epidemic globally, contributing to about 6.3% of all people living with HIV (PLHIV) worldwide. **As of March 2023, out of an estimated 24.67 lakh PLHIV, approximately 79% (76% men and 82% women) were aware of their HIV status.** Among those aware of their status, 86% (84% men and 89% women) received antiretroviral therapy (ART). Notably, 93% of these individuals showed viral load suppression, a critical marker of effective treatment. In comparison to global metrics, India's progress on the 95-95-95 targets—where 95% of PLHIV are aware of their status, 95% of those aware are on treatment, and 95% of those on treatment have suppressed viral loads—stood at an impressive 79-86-93. This gap underscores the challenges associated with ensuring continuous ART adherence and retention, which are pivotal for the lifelong management of HIV. The behavioral nuances associated with this aspect further compound the complexity of achieving these targets.[5]

Given these realities, it is evident that India needs a renewed and innovative approach to HIV testing services. There is an urgent need to diversify testing options, adopt less resource-intensive strategies, and promote innovations like HIV self-testing (HIVST). These steps are crucial to accelerating progress in reducing new infections and AIDS-related deaths.

HIV self-testing is a screening test only

WHAT is HIVST?

HIV self-testing is a screening test for diagnosing HIV in a private setting, whether alone or with the support of someone trusted. This process involves collecting one's specimen (either blood or oral fluid) according to the requirements of the diagnostic test kit, conducting the HIV test, and interpreting the results. A positive result from an HIV self-test cannot definitively confirm HIV infection. To confirm HIV status, a skilled practitioner must conduct further testing on all reactive HIVST results per the national testing protocol.

Why HIVST is Needed

HIVST is needed because of the reasons detailed below:

High prevalence of AIDS in KPs and vulnerable populations

The 2023 NACO study reported that the HIV epidemic in India is primarily concentrated among the key population (KP) groups and vulnerable populations who engage in high-risk behaviors, such as unsafe sex or drug injecting practices. Evidence from the SANKALAK report indicates that the HIV prevalence among transgender (TG) people, men who have sex with men (MSM), and female sex workers (FSWs) is 6 to 13 times higher than the general population.

Additionally, a periodic HIV surveillance conducted by National AIDS Control Organization (NACO) among the KP groups found that the HIV prevalence among injectable drug users (IDUs) was 28 times higher than the overall adult HIV prevalence.[6]

Gaps in implementation of robust diagnostic set-up and interventions

The current diagnostic setup promotes utilizing integrated counseling and testing centers (ICTCs) for HIV screening and confirmation. ICTC is a component of the HIV counseling and testing services and is the first point of contact for beneficiaries seeking HIV counseling, screening, and treatment. However, an evaluation of the ICTCs conducted in Delhi indicated that some centers lacked both male and female counselors as well as the necessary infrastructure to ensure adequate privacy for clients. Furthermore, the study reported a high volume of clients every day, which resulted in delays in reporting the HIV status of the patient.[7]

In India, gaps in the implementation of HIV testing continue to hinder progress towards the 95-95-95 targets. During the COVID-19 pandemic, Maharashtra reported 10,000 undetected HIV cases, highlighting the lack of advanced testing facilities.[8] Another study highlighted missed opportunities for HIV diagnosis, particularly among high-risk groups visiting sexually transmitted disease clinics. Furthermore, research indicates that 55-59% of FSWs, MSM, and IDUs have not been tested for HIV despite targeted interventions in place. To address these challenges, there is an urgent need to introduce cost-effective HIV self-testing (HIVST) kits and other innovative testing methods tailored to the needs of vulnerable populations.[9,10]

Recognition as an effective HIV diagnostic measure and global call for integrating HIVST into the programs

There has been a global call for incorporating HIVST as part of health programs, led by organizations such as the World Health Organization (WHO), United States Agency for International Development (USAID), Centers for Disease Control (CDC), and International Labor Organization (ILO). In 2016, the WHO released recommendations endorsing HIVST as a safe, reliable, and practical method for testing. These guidelines were specifically designed to reach individuals who may not usually access conventional testing methods, such as males, adolescents, and disadvantaged groups. Given the multiple impacting variables, including the high HIV prevalence among KPs, the diagnostic infrastructure in place at the moment, and the difficulties associated with discrimination and stigma encountered by high-risk groups in India, it is crucial to integrate HIVST with current testing services.[11,12,13]

Evidence of effectiveness and safety of HIVST

Ever since the introduction of HIVST kits in the market, numerous pre- and post-launch research have been conducted to evaluate the feasibility, accessibility, and acceptability of these kits. In July 2015, the WHO released the first comprehensive guidelines on HIV testing services, including information on HIVST, following several trials that evaluated the feasibility of the HIVST test kits. These guidelines demonstrated the accuracy and

Humsafar trust is the Principal Investigator for the study

Meaningful community engagement is a success of the project

acceptability of HIVST across a range of delivery models. Furthermore, findings from a systematic review of 32 randomized control trials showed that self-testing increases the uptake of testing and is both feasible and acceptable in different settings.[14,15] These 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.** [16] Furthermore, another study by the Indian Council of Medical Research demonstrated a preference for saliva-based tests over blood-based HIVST testing among truck drivers and young people.[17]

In this context, PATH, in collaboration with its partners, implemented the project in India from 2021 to 2023. This initiative is built on the lessons learned from the STAR HIV Self-Testing Africa Initiative. The goal was to increase demand for and access to HIVST and subsequent treatment linkage and prevention linkage services, which would contribute to a further reduction in the number of new HIV infections and avert deaths due to HIV infection. As there was no precedence for HIVST in India, PATH initiated a study to gather evidence for its introduction of HIVST in the country with the active collaboration and guidance of NACO. The study demonstrated the feasibility and acceptability of HIVST among different key population groups and generated crucial evidence to inform an HIVST policy in India.

STAR HIV self-testing project: Implementation in India

The Unitaid-funded STAR HIVST initiative aims to generate evidence for decision-making, enabling the environment and catalyzing the global market for HIVST. Globally, the project was rolled out in three phases:

oThe first phase of the project in Malawi, Zambia, and Zimbabwe generated vital information on the effective, ethical, and efficient distribution of HIVST products. It also answered questions about the feasibility, acceptability, and impact of this intervention.

- The second phase expanded the evidence generation on HIVST to three additional African countries: South Africa, Lesotho, and Eswatini (formerly Swaziland). This phase built on the lessons learned and evidence gathered from the previous two phases of HIV STAR initiatives in Africa for HIVST.
- The third phase of the project was implemented in India, along with six other countries, to understand and address the barriers to the rollout of HIVST. This phase aimed to provide evidence for developing structures and systems to ensure the long-term sustainability of HIVST in the country. The third phase of the Unitaid-funded STAR HIV Self-Testing project, which began in February 2020, had three desired outputs:
  - Output 1: An enabling environment created to support the introduction of HIVST, including policy adoption and product registration.
  - Output 2: Service delivery models implemented that increase the uptake of HIVST and linkages to care, treatment, and prevention services.
  - Output 3: Dissemination of best practices from HIVST implementation at the country level and identifying and mobilizing resources to support transition and scale-up of HIVST.

The project aimed to demonstrate the feasibility and acceptability of HIVST among different KP groups and other high-risk groups, generating evidence to inform an HIVST policy in India.

- More specifically, the project aimed to do the following:
- Assess the feasibility, acceptability, and demand for HIVST across specific populations and models.
- Assess the preference for blood- or oral fluid-based HIVST kits and approaches (assisted and unassisted).
- Assess linkages to prevention services for those with negative HIVST results, as well as conduct confirmatory HIV testing and treatment services for those with HIV reactive results.
- Identify the challenges related to these linkages and any potential social harm following HIVST.

Partners in the HIV STAR project

This project was implemented by PATH in collaboration with several organizations, including **Humsafar Trust (the principal investigator or PI), Solidarity and Action Against The HIV Infection in India (SAATHII),**

Scale up of HIV self-testing will help to reach UNAIDS's first 95 targets.

HIV self-testing is key to meeting the United Nations Sustainable Development Goals

International Training and Education Centre for Health Private Limited (I-TECH), Voluntary Health Services (VHS), Society for Health Allied Research Education (SHARE India), India HIV/AIDS Alliance (IHAA), National Coalition of PLHIV in India (NCPI+), and ILO, WHO, the Indian Council of Medical Research (ICMR)-National AIDS Research Institute (ICMR-NARI), and the ICMR-National Institute of Epidemiology (ICMR-NIE) and Clinton Health Access Initiative (CHAI) as technical partners. The project received active support from NACO, Ministry of Health, Government of India as well as assistance from over 250 community-based organizations (CBOs) and non-governmental organizations (NGOs) across the country.

Co-funding mechanism of the HIVST study

Unlike many studies, the HIVST study was carried out with a multitude of partners. Although managing a significant number of partners is a tedious process, this study ensured the optimal and ergonomic participation of each partner. PATH performed the role of primary implementor and a fulcrum that ensured two-way communication with the decision makers such as NACO and SACS as well as the partners. PATH was also the designated agency to document and publish the study outcomes with the support of these partners. The process created a vibrant ecosystem of partners during the duration of the study implementation. Some of these partnerships were non-financial, purely to ensure smoother implementation of the study models by utilizing available skillsets and knowledge. These partners signed non-financial agreements with PATH. This showcases the trust between partners and organizations to achieve the common goal of reaching Sustainable Development Goal by combining forces and optimizing efforts. These partnerships and their contributions are mentioned below.

1. Centers for Disease Control: CDC through its existing funding to SHARE India, VHS and I-TECH India, carried out the implementation of the study in Andhra Pradesh, Manipur, Nagaland, and Mizoram. They also carried out the training of all the project staff who were part of the study teams. The training was conducted in 25 batches and trained in total of more than 1000 staff.

The CDC also supported independent site monitoring of the entire study sites through SHARE India. They hired a pool of independent experts including the team from SHARE India, a total of 40 experts. The site monitoring was based on indicators from the protocol and real real-time data monitoring system was developed. CDC also ensured the study received ethical approval from their Scientific Integrity Board (SIB).

2. World Health Organization: WHO assisted the second phase of the social media campaign for the virtual model of HIVST distribution expansion. WHO SEARO as well India Country Office supported the virtual model expansion. This was carried out through both PATH as well as CHRI. Alfluence was hired to carry out the second phase of social media mobilization. WHO also helped with redesigning the Sahay website, hiring the influencers as well as the campaign design for social media mobilization. This helped the project reach the target population intended to use HIVST.

3. International Labor Organization (ILO): ILO supported the Workplace Model of self-testing. They supported this model through two entities, one being Brihanmumbai Electric Supply & Transport Undertaking (BEST) in Mumbai and Transport Corporation of India Foundation (TCIF) in the states of Punjab, Maharashtra, Karnataka, and West Bengal. PATH shared the protocol and HIVST with ILO. ILO ensured the end-to-end implementation within these sites, which included human resources and other expenses required for the implementation.

4. India HIV AIDS Alliance: IHAA approached PATH to pilot the HIVST in their existing project SAMARTH during the second phase of self-testing implementation. Thery have distributed the HIVST kits with protocols and tools shared by PATH. The intervention was carried out in study mode. The Alliance India implemented the distribution of HIVST kits in Punjab, Delhi, and Gujarat. The organization supported the entire implementation including human resources and expenses.

5. USAID: USAID supported the study in the process of protocol development. They provided technical inputs to streamline the study protocol and ensure scientific rigidity. John Hopkins University through USAID supported the training slides preparation which helped the study implementation plan.

5. CHAI: CHAI has supported the scientific writing workshop conducted to analyze the collected data with the support of research experts under the leadership of Dr. DCS Reddy. The scientific writing workshop conducted as two phases based on the requirement of collecting data, cleaning, finalizing the research questions, analysis, interpretation and development of manuscripts.

HIV self-testing can be a gateway to accessing additional sexual health services

Results from an HIV self-test are available within 20-40 minutes

CHAPTER 2

Study design and methodology

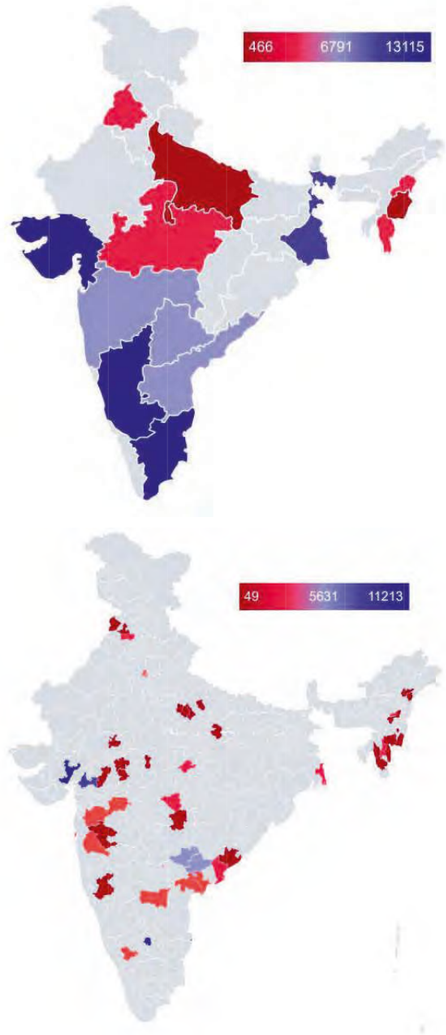
The demonstration study assessed the feasibility and scalability of implementing HIVST kits and their usability among key populations in India.

Selection of study sites: **Fourteen states were identified for the implementation of the project and the conduct of the study.** Given the country's vast geography, these states were chosen based on the National Family Health Survey's regional classification to ensure adequate representation from all five regions of the country: east, northeast, central, north, and west. Preference was given to states with agreements with the United States President's Emergency Plan for AIDS Relief (PEPFAR) (USAID and Center for Disease Control or CDC) and The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) implementing partners in the HIVST project consortium.

Figure 2.1 depicts the details of the project sites, duration, and study population

Six HIVST kits received WHO PQ

Project duration and distribution models



STATE
Andhra Pradesh
Delhi
Gujarat
Karnataka
Madhya Pradesh
Maharashtra
Manipur
Nagaland
Punjab
Tamil Nadu
Telangana
Uttar Pradesh
West Bengal
Mizoram
Grand Total

DURATION

Approvals : 18 months
Kit distribution : 09 months

KEY POPULATION GROUPS

- FSW
- MSM
- H/TG
- PWID

OTHER POPULATION GROUPS

- Employee of industries
- Partner of a PLHIV
- Partner/clients of KPs
- Referred by identified pvt provider
- Self-identified high-risk individuals

Ora-quick, Mylan and Insti self-testing kits were used

- **Types of HIVST testing kits and approaches for testing:** For this study, two HIVST kits were used: OraQuick®'s oral fluid and the INSTI and Mylan blood-based HIVST kits. They were offered in all the service delivery models. These test kits have been pre-qualified by the WHO and were approved for use in several countries, including Vietnam and some African nations. However, neither of these HIVST kits has been approved for commercial use in India, and at the time of the study, no indigenous HIVST kits were available. The **3 types of HIVST kits were procured under the project with the support of Unitaid through PSI.**
- As per NACO's HIV counseling and testing service guidelines, all participants received pre-test and post-test counseling. All participants were offered two options for HIVST: an assisted approach or an unassisted approach.

- In the **assisted approach,** the study team provided participants with pre-test counseling and guided them on the testing process in person. Participants conduct the HIVST process in the presence of a provider (counselor, outreach, or other trained staff).
  - In the **unassisted approach**, the participants conduct the testing independently at a location of their choice and interpret the result independently. The trained study staff offer pre-test counseling and explain the testing process through both online and offline methods, but they do not remain present during the testing process. Participants are expected to voluntarily share their results with the study staff, who will then connect them to appropriate services.

Community Advisory Board (CAB) at national level

Figure 2.2 depicts some of the inclusion and exclusion criteria for the HIVST study participants

Inclusion and exclusion criteria

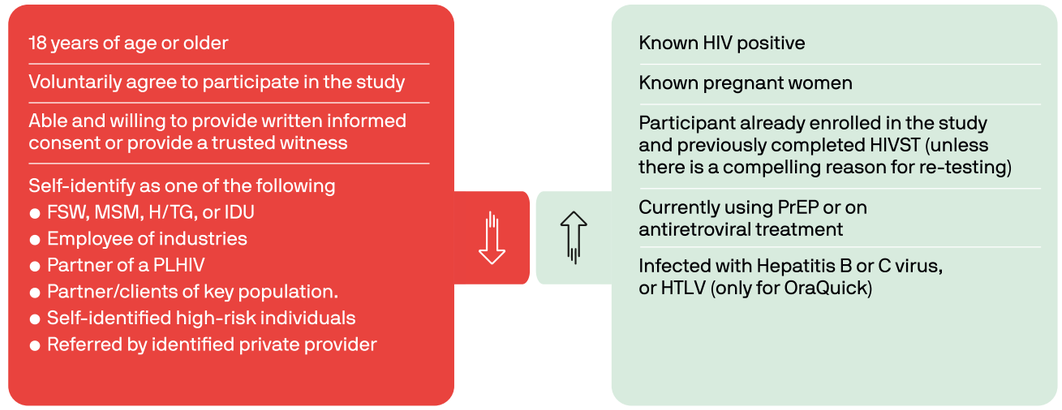


Figure 2.2. Inclusion and exclusion criteria for the HIVST study participants

- **Data collection and management:** The project ensured stringed data privacy and security for data collection, storage, and management. The following are the steps taken for data collection:
  - **Ethical considerations:** The study adhered to strict confidentiality and ethical protocols for data collection, management, and storage. **Each piece of data collected was assigned a unique identification number (UID). Participant names and any other personal identification details were excluded from the enrollment and behavioral data collection forms.** Special care was taken to maintain the confidentiality of

State Oversight Committee (SOC) for HIV self-testing at state level

participants, especially during data collection, storage, and follow-up. Additionally, all staff involved in the project received special training in good clinical practices, emphasizing the importance of safeguarding the confidentiality of participants' identities and HIVST results. All the study staff were responsible for demand generation, recruitment, enrollment, pre-and post-test counseling, referral, and linkages.

- **Format for data collection:** The study developed a data collection tool, finalized after review by implementing partners and feedback from individuals representing potential HIVST end users and community leaders from KP and PLHIV.
  The data collection tool had the following sections:
  - Section A: Study site contact information.
  - Section B: Demographic and risk details.
  - Section C: Risk behavior for high-risk individuals.
  - Section D: Risk behavior for KP members.
  - Section E: HIVST preference.
  - Section F: Experience of HIVST, advantages and disadvantages, and suggestions.
  - Section G: HIVST information and follow-up.
  - Section H: Confirmatory HIV test and ART linkages.
  - Section I: Follow-up call to understand possible social harm among the participants.
- **Hiring a clinical research organization (CRO) for data collection and management:** A CRO was hired for data collection and management.
  - An application-based data collection tool was developed to collect participant's data and their responses to the questionnaire. Each study site was equipped with the facility for application-based data collection and allowed online data collection. The application included built-in data validation provisions, wherever required. Each study site was assigned a separate UID and password for data entry. Online databases were maintained to facilitate data entry, UID generation and validation, ensuring accuracy and minimizing errors.

Community Monitoring Board (CMB) at the district level

  - In instances where the internet connection was poor and direct online data entry was not possible, staff members were trained to utilize paper-based data collection forms. A guideline was prepared for this paper-based data collection, which served as a training tool for the staff, ensuring that data was recorded without any errors. Once the data was collected on paper forms, it was entered into the online database whenever an internet connection became available, carried out by the trained study staff. All paper forms were securely locked at the study sites when not in use. In case the forms needed to be transferred to a different site for data entry, they were transported in sealed envelopes and monitored by the site supervisor. After the data was entered into the system, the UID generated was recorded on the physical data collection form, while the section containing other personal identifiers was destroyed by shredding.
- **Data quality assurance:** The study had put forward some criteria for data quality assurance, which are as follows:
  - Everyday monitoring
  - Regular calls to partners based on performance
  - Handholding states with slower progress
  - Learning from states with good progress
  - Engaging community leaders and discussions with state AIDS control societies (SACS) for smooth functioning
  - Identifying the reactive cases and finding their status of linkage
  - Daily acknowledgment of the study team for their good work
  - Partners understanding their state's performance by district and staff, which helped them navigate and support the team. This helped them address the bottlenecks and enabled them to explore more sites for distributing the HIVST kits.
  - Quarterly review by the Community Advisory Board (CAB), state oversight committee (SOC), and community monitoring board CMB) on the progress

More than 1000 staff trained in 14 states

- Community leaders and CAB members monitoring visits
- Independent site monitoring visits by experts
- Tracking of social media reach
- Tracking of Google analytics for monitoring the performance of online platforms

- **Data storage and protection:** For storage and protection of data, the following guidelines were employed:
  - All study documents, such as the ICF, registration sheets, data collection forms, and site details, were securely stored and managed by the implementing partners until the completion of the study.
  - At the site level, any hard copies of transcripts, data collection forms, notes, informed consent forms, and other materials containing study data were kept in a locked filing cabinet at the sites. Access to these cabinets was limited to the field supervisor.
  - All essential study documents, such as the ICF and hard copy data collection forms, were transferred to the PI's office at Humsafar Trust.
  - Non-essential study documents were destroyed at the sites, but no records were disposed of without written permission from the PI and the study sponsor.
  - Data was not shared with any individual or organization without obtaining formal permission from the PI and the study sponsor. Any shared data did not include personal identifiers.
  - All paper documents will be destroyed five years after the study's completion.

CHAPTER 3

Approach

The project undertook the following three-step approach (see Figure 3.1) to plan and implement the project in the country:

- **Preparatory Phase -** Initiatives to build an enabling environment for introducing HIVST.
- **Implementation Phase:** Initiatives to increase the uptake of HIVST and improve linkages to care, treatment, and prevention services.
- **Final Phase:** Data analysis and dissemination of study findings.

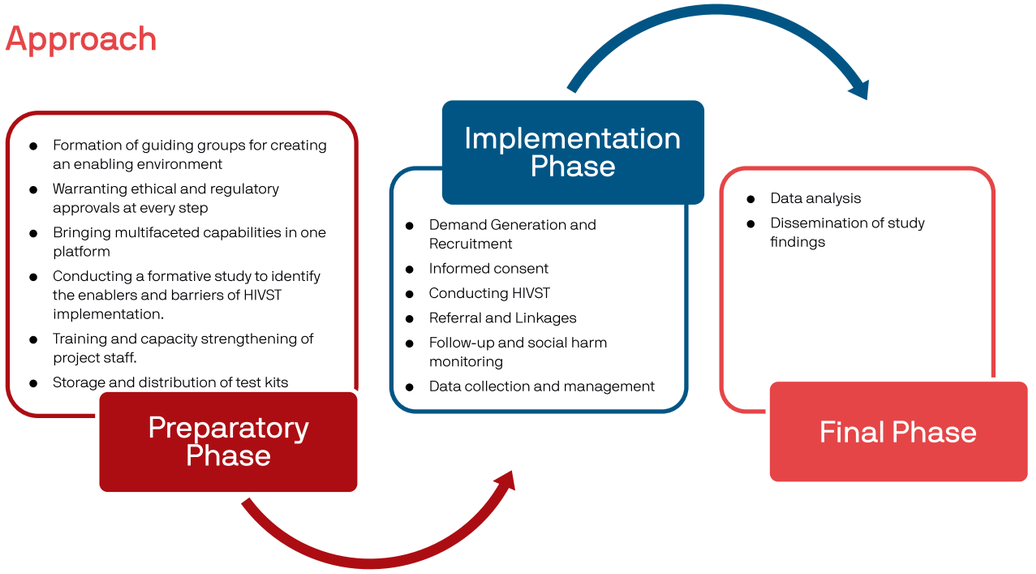


Figure 3.1. Three-step approach to plan and implement the project in the country

The following section provides details of each of the phases mentioned above:

Preparatory Phase - Initiatives to build an enabling environment for introducing HIV self-testing.

Prior to this project, HIVST was an unchartered territory in India. To successfully pilot the intervention in the country, **PATH established an ecosystem where all stakeholdersnational-, state-, and district-level government bodies, organizations representing KPs at national, state and district levels, HIVST kit manufacturers, regulatory bodies, and development partners**-were aligned to explore HIVST as a solution for enhancing HIV testing capacities in the country.

The following activities were undertaken in the preparatory stage of the project:

A. Formation of guiding groups for creating an enabling environment

B. Warranting ethical and regulatory approvals at every step

C. Bringing multifaceted capabilities on one platform

D. Conducting a formative study to identify the enablers and barriers of HIVST implementation

E. Training and capacity strengthening of project staff

F. Storage and distribution of test kits

Formation of guiding groups for creating an enabling environment

A tailor-made approach was devised by creating several committees with stakeholders with specific capabilities to guide the project. Figure 3.2 gives the composition of the guiding groups.

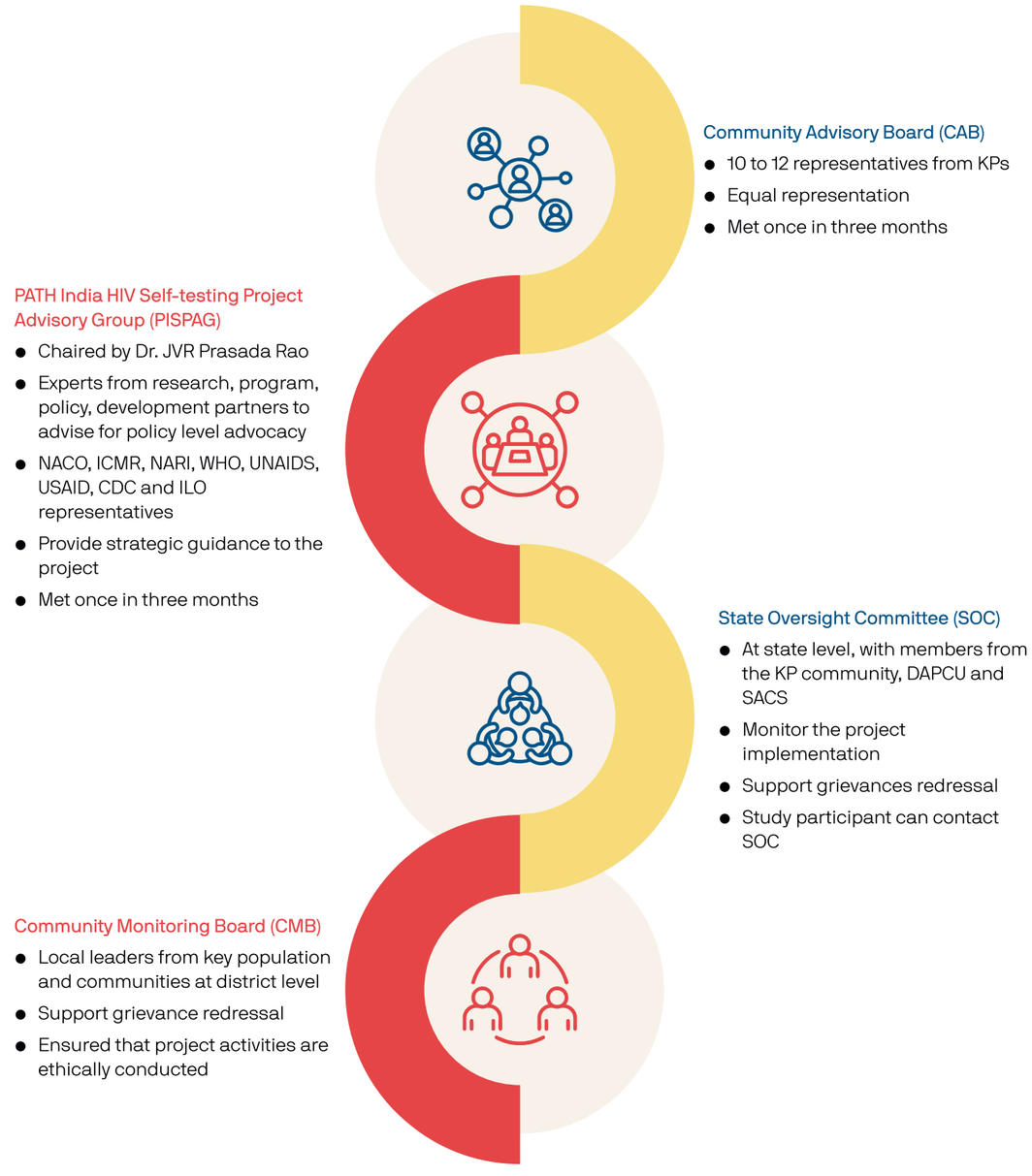
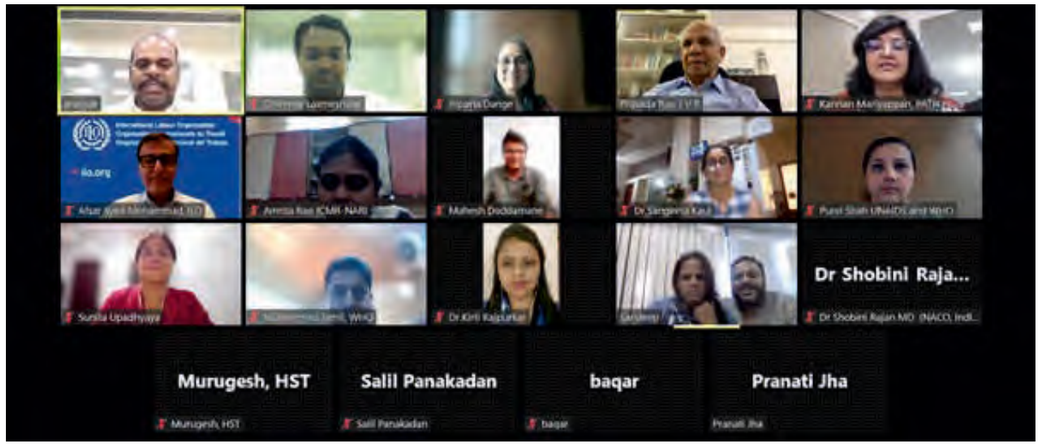


Figure 3.2. Composition of the guiding groups

80,333 (85%) kits were distributed through the community-based model

HIV self-testing allows individuals to test HIV in the privacy of their own home

PATH India HIV Self Testing Project Advisory Group (PISPAG): PATH constituted an advisory group, the PISPAG, which included representation from NACO, SACS, development partners, UN agencies, ICMR institutions, PEPFAR (CDC and USAID), academic institutions, and technical experts. PISPAG played a key role as the project's advisory body, providing guidance, insights, and solutions to critical issues during the conceptualization and implementation phases. **The group was co-chaired by Dr. J.V.R. Prasada Rao, the former Health Secretary to the Government of India, former Special Advisor to UNAIDS, and former Special Envoy to the Secretary General of the United Nations on HIV/AIDS for the Asia Pacific region,** along with Dr. Ashok Kumar, the former Additional Director General, Central Health Services, Ministry of Health and Family Welfare, Government of India. PISPAG also acted as a liaison between the project and policymakers, playing a crucial role in the processes essential for integrating HIVST into the country's HIV testing framework.



Community advisory board (CAB) for HIV self-testing: The CAB comprised a body of representatives from all KP groups and PLHIV. It served as the community's voice for the project. The CAB was actively engaged with the project, reviewing the community processes and practices implemented, ensuring that they were sensitive to and inclusive of community needs. The CAB consisted of 18 members, each invited by name, representing KPs: PWID, FSWs, MSM, and transgender (TG) population, and PLHIV. The chair of CAB was rotational among the community groups.

The PISPAG and the CAB were national-level bodies constituted by PATH that oversaw the project. They met every quarter, though virtually, due to disruptions caused by COVID-19 during the project period. However, they never met jointly. **PATH ensured that the proceedings and decisions of PISPAG were shared with CAB during their meetings and vice versa.**

State oversight committee (SOC) for HIVST: In addition to engaging stakeholders at the national level, the project also involved key stakeholders from the SACS, district AIDS prevention and control units (DAPCUs), and representatives from KP and PLHIV communities at the state level through the SOC for HIVST. The project had one SOC for HIVST in each of its 14 intervention states.

The SOC for HIVST was a collaboration involving the government, KPs, PLHIV, and community-led organizations from affected communities. Together, they worked to facilitate more inclusive decision-making on issues important to KPs and PLHIVs. By adopting a transparent, consistent, and multi-channel communication approach, the project built trust among all participants, including government officials, service providers, community groups, and sponsors. For any issues or further information about the study, one volunteered/nominated community representative's name and contact details were provided in the respective state-level informed consent form for any issue and further information about the study by the participants.

Community monitoring board (CMB) for HIV self-testing: Understanding and acknowledging the importance of strengthening local decision-making,

Self-testing can help increase access to HIV testing in remote or underserved areas

Each data collected was assigned to a unique identification number (UID)

educating communities, and enhancing community capacity and effective community engagement for HIVST, the CMB was formed at the district level for the STAR HIVST project. Comprising leaders and vocal members from the KP and PLHIV communities, the CMB acted as a focal point for addressing the grievances of the project participants. The chair of the CMB was chosen by consensus among all members of the CMB, on a rotational basis. **The kit distribution has been initiated after getting consensus and orientation of CMB members at the district level.**

Warranting ethical and regulatory approvals at every step

The intervention also required the confidence of regulatory bodies, like the Drug Controller General of India (DCGI) and ICMR to validate the purpose, objectives, and approaches.

HIV self-testing can reduce stigma associated with traditional HIV testing

Regulatory and ethical approvals

12 Oct 2020
Ethical Committee approval from Institution registered under DHR, MOHFW
The Humsafar Trust

23 Feb 2021
Import license for-
OraQuick | INSTI | Mylan
DCGI, CDSCO

05 Mar 2021
Approval from Health Ministry's Screening Committee (HMSC)
International Health Division at ICMR

20 Apr 2021
Clinical Trial Registration

29 May 2021
Ethical Committee approval from Institution registered under DCGI, CDSCO, MOHFW
Sai Hospital's Ethical Review Board

02 Jun 2021
Study approval from DCGI

18 Jun 2021
Letter of support from NACO
NACO, GoI

25 Oct 2021
CDC Scientific Integrity Board (SIB)

01 July 2022
Approval for extension of distribution across all models and edit of flow for the virtual model
WCG IRB

15 Dec 2022
Ethical committee approval for extension of distribution across all models and edit of flow for the virtual model
The Humsafar Trust

11 May 2023
Ethical committee approval for workplace model assessment
The Humsafar Trust

07 Jun 2023
Ethical committee approval for workplace model assessment
The Humsafar Trust

Figure 3.3. Ethical and regulatory approvals

A clinical research organization (CRO) handled data collection and management

PATH received approval from different regulatory and ethical bodies before starting the HIVST pilot.

- The Institutional Review Board of Humsafar Trust provided the project ethical approval for the study. Multiple approvals were received based on the study requirements.
- PATH, through Fermish Clinical Technologies Private Limited, received DCGI Subject Expert Committee approval to conduct the field implementation of the project for HIVST kit under the Drugs & Cosmetics Act 1940 and Devices Rules-2017. The approval came with active advisory input from ICMR and NACO.
- **The DCGI provided an import license for the project to use WHO pre-qualified HIV self-test kits INSTI HIV Self-Test, OraQuick® HIV Self-Test and Mylan HIV Self-Test.**
- Registered in Clinical Trials Registry- India, hosted at the ICMR's National Institute of Medical Statistics.
- Approval was given for the proposal by the Health Ministry's Screening Committee (HMSC) for conducting the HIVST study in India.
- The engagement of CDC and the PEPFAR partners in India further required the clinical evaluation protocols for HIVST to be subject to their Office of Scientific Integrity. CDC facilitated their approval.
- In addition to external expert bodies, PATH engaged its research determination committee to determine the nature of the research, The Scientific Merit Review for Human Subjects Research reviewed PATH's research protocols, methodologies, and tools, approving pilot testing in India. Further, the PATH Office of Research Affairs reviewed the research and approved moving forward with the Western Copernicus Group IRB, which also approved implementing the study.
- Received approval and support letter from NACO, further letter of support from respective State AIDS Control Societies.

HIV self-test kits are available over the counter in many countries

Bringing multifaceted capabilities in one platform

The capabilities of various stakeholders were brought in to make the project a success (see Figure 3.4).

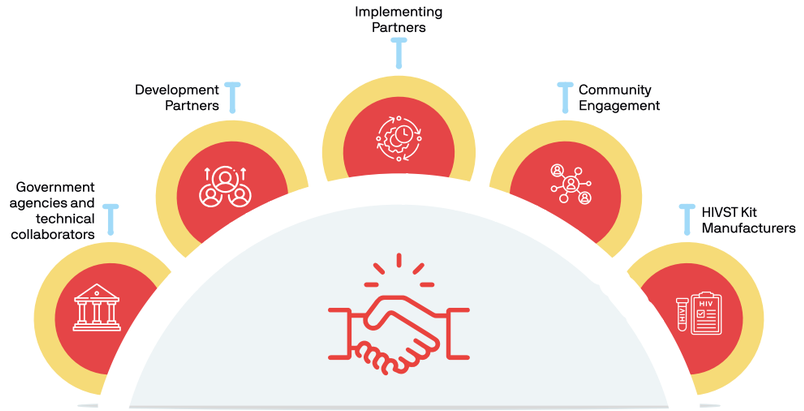


Figure 3.4. Various stakeholders brought into the project

- **Government agencies and technical collaborators:** NACO, under the Ministry of Health, Government of India, served as the overall technical advisor of this project. Additionally, various government agencies contributed as technical partners, such as 15 SACS, the National AIDS Research Institute (NARI) and the National Institute of Epidemiology (NIE), all under the aegis of ICMR. Other organizations such as ILO and WHO provided technical expertise at various steps of the project.
- **Development partners:** The project was implemented in collaboration with several partners, including NACO's targeted intervention (TI) partners, the ILO through its workplace intervention partners, Global Fund partners, and PEPFAR partners via the CDC. The CDC led the HIVST project with support from the Society for Health Allied Research and Education India (SHARE INDIA), which trained the study team and conducted independent site monitoring. The implementation of the study took place in northeastern states—Manipur, Nagaland, and Mizoram—by the International Training and Education Center for Health India Private Limited (I-TECH India), while it was conducted in Andhra Pradesh by Voluntary Health Services (VHS). The engagement of CDC

Communication materials were prepared in Hindi, Bengali, Punjabi, Tamil, Telugu, Kannada, Gujarati, Marathi and English

and PEPFAR partners in India further required the clinical evaluation protocols for HIVST to be subject to their scientific integrity board (SIB). The CDC facilitated this approval process, and the SIB was successfully onboarded for the study.

- **Implementing partners:** This project was implemented by PATH in collaboration with several organizations, including Humsafar Trust (the principal investigator or PI), Solidarity and Action Against The HIV Infection in India (SAATHII), International Training and Education Centre for Health Private Limited (I-TECH), Voluntary Health Services (VHS), Society for Health Allied Research Education (SHARE India), Clinton Health Access Initiative (CHAI), India HIV/AIDS Alliance (IHAA), and National Coalition of PLHIV in India (NCPI+).
- The project involved the constitution of various committees and identifying key stakeholders. It collaborated with several stakeholders to develop training materials, IEC/BCC, instructions for use (IFU) materials, and social media communications. PATH also facilitated ethical and administrative approvals needed from various organizations and committees to implement the project. Apart from this, the Humsafar Trust, one of the project's partner, played a major role in the implementation of the project as a PI of the study. Similarly, Share India, another implementing partner, conducted site monitoring to ensure adherence to study protocols using a standardized checklist. Additionally, other implementation partners brought in their expertise to the project to make it successful.
- **Community engagement:** The project ensured that key communities were engaged at all levels, including planning, protocol development, decision-making, service delivery, monitoring, data analysis, and co-authorship in manuscripts and publications. The KP and PLHIV community representatives were meaningfully engaged through CAB, SOC, and CMB.

HIV self-testing uses a finger prick or oral swab to collect samples

- **HIVST kit manufacturers:** When the project was first conceptualized, HIVST kits were not being manufactured in India. There were three WHO PQ HIVST kits available globally, but only one had a distributor in India. To manufacture HIVST kits, manufacturers required regulatory approval and a test license from DCGI. PATH facilitated consultations between local distributors and HIVST kit manufacturers so they could present their clinical trial protocols to DCGI for regulatory approval. As a result, the two HIVST manufacturers were able to establish local distributorships, which is an essential prerequisite for obtaining a test license from the DCGI for clinical evaluation. At the time of writing this report, seven HIVST kit manufacturers had received test licenses from DCGI, and one had also obtained approval for its clinical evaluation protocol. PATH supported these manufacturers by reviewing their clinical evaluation protocols and providing valuable feedback. The landscape of HIVST manufacturers in India has dramatically changed, going from an initial lack of interest in introducing HIVST to seven HIVST manufacturers actively seeking regulatory approval and test licenses from the DCGI, with more approaching the agency.

Conducting a formative study to identify the enablers and barriers of HIVST implementation

A study was conducted to identify the enablers and barriers of HIVST implementation, and the details of the study are as follows:

- **The formative study:** From August to October 2021, PATH conducted a formative study to identify the enablers and barriers that influence the demand for HIVST among high-risk groups in India and the feasibility and scalability of implementing HIVST. Using human-centered design thinking, the qualitative study found that there is an opportunity for HIVST to reduce stigma by minimizing the length of interactions associated with HIV testing. In addition, it identified that HIVST could reduce the inconvenience and opportunity costs associated with HIV testing. The study also highlighted concerns among participants regarding the potential for errors during self-testing. It raised questions about the credibility of what seemed to be an overly simplistic product

All participants were offered an assisted or an unassisted approach

for HIV testing, especially when compared to confirmatory tests conducted at ICTCs. To conduct the study, in-depth qualitative interviews were carried out with 42 participants. These interviews were recorded, transcribed, and translated into English when necessary. Thematic analysis was conducted to understand the perceptions of stakeholders and potential end-users regarding the feasibility of introducing HIVST into the national program.

- **The findings of formative study:** The findings of the formative assessment are indicated in Figure 3.5.

Summary of factors affecting access, use and linkage

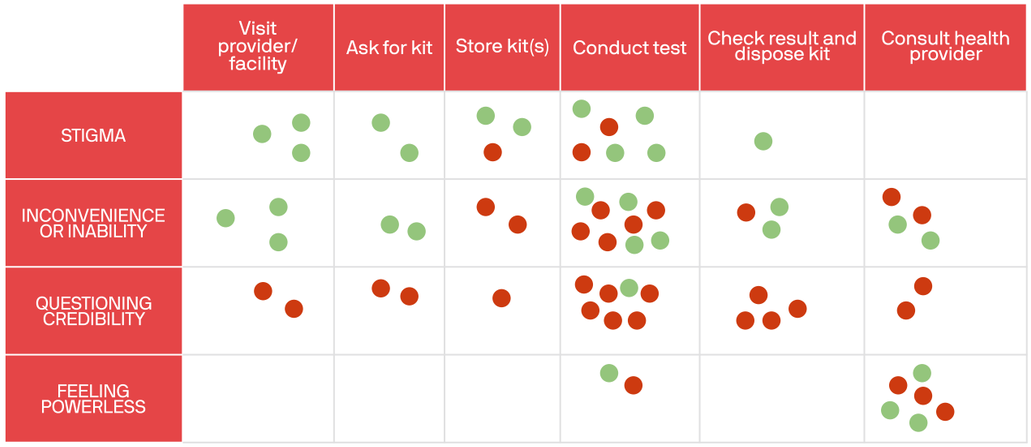


Figure 3.5. Findings of the formative assessment

- The barriers were identified at three levels: personal, interpersonal, and health care system.
  - The personal level barriers included concerns about the cost of HIVST and the credibility of the test kit.
  - The interpersonal barrier was the apprehension about disclosing one's sexual orientation while ordering the kit or using it.
  - The health care system barriers were concerns regarding biosafety and linkage to care.

HIV self-testing empowers people to take control of their sexual health

- The facilitators for the formative study for HIVST were divided into two levels: personal and interpersonal.
  - Personal-level facilitators included convenience, confidentiality, and ease of use.
  - The interpersonal facilitator was peer influence and close partner testing.

To address concerns and identify opportunities to enhance the feasibility, acceptability, and demand for HIVST among KPs, PATH, in consultation with members of PISPAG and CAB, implemented five different HIV self-testing kit distribution models: community-based model, private practitioners' model, workplace model, PLHIV network-led model, and virtual model.

Distribution models

The intent of studying the five models of the distribution for HIVST kits outlined below was not to assess the comparative advantage of one model over another. Instead, the goal was to independently assess the feasibility and acceptability of each of the five models. Furthermore, these models are not directly comparable, as each was designed to target different population groups.

- Model#1community-based model: This model was implemented in collaboration with CBO partners and was designed to reach FSWs, MSMs, TG/H and PWIDs. Additionally, the model also aimed to engage their partners, clients, and other self-identified high-risk groups. In this model, trained peer volunteers from the KP community conducted demand-generation activities. Trained peer counselors performed eligibility assessments and provided pre-test counseling. They also demonstrated HIVST using videos and other job aids to help participants make an informed choice about their preferred HIVST kiteither oral or blood basedand the preferred testing approachassisted or unassisted. HIVST kits were supplied to project staff through the participating CBOs. Based on the results of the HIVST, the CBO followed a specific algorithm for post-test counseling and

The accuracy of HIV self-tests is comparable to laboratory-based testing when used correctly

confirmatory testing (for those who received reactive or indeterminate results with HIVST) and offered prevention, treatment, and care support as per the national testing guidelines. **This model was implemented across 50 districts in 14 states, with Humsafar Trust, SAATHII, ITECH, and VHS serving as the lead implementing partners, along with approximately 250 field implementing CBOs/NGOs.**

- Model#2Private provider model: The second distribution model involved private providers, who regularly provided services to patients with sexually transmitted infections and their partners, as well as to individuals with clinic skin issues, partners of PLHIV receiving private ART, and partners of newly diagnosed PLHIV at private labs. This model also catered to KPs and high-risk individuals accessing private services. In this model, the project recruited private providers who were already mapped and working with NACO-supported programs. Communication materials developed by the project were displayed at the clinics, including videos, to generate demand for HIVST. In addition, demand-generation activities were conducted in areas with KPs located near the selected clinics. Trained private providers conducted eligibility assessments, offered pre-test counseling, and demonstrated HIVST using videos and other job aids. They assisted the participants in choosing an HIVST kit, either oral fluid-based or blood-based, and the mode of assistance (assisted or unassisted). PATH provided the HIVST kits to private providers through the participating project partners. Based on the results of the HIVST, the private provider and the participating project partner followed the algorithm for post-test counseling, confirmatory test (for those who had reactive or indeterminate results with HIVST) and subsequent treatment and care support. **This model was implemented with private providers in five states: Gujarat, Karnataka, Telangana, Tamil Nadu, and West Bengal, with SAATHII serving as the lead implementing partner.**

- Model#3Workplace model: PATH collaborated with ILO partners, namely, Brihanmumbai Electric Supply & Transport Undertaking of the Municipal Corporation Greater Mumbai and the Transport Corporation of India Foundation, to extend HIVST services to various groups. These included formal employees, self-identified high-risk individuals such as truck drivers and informal labor workforce, partners/clients of high-risk individuals, KPs, and partners of PLHIV. In this model, staff from workplace interventions at the two organizations utilized the information education communication/behavioral change communication (IEC/BCC) materials developed by the project. These materials were used to raise community awareness and generate demand for HIVST through community events and interpersonal communication. They also conducted eligibility assessments. The materials were displayed in their office/site premises to promote access to free HIVST services. The service providers received training to conduct pre and post-test counseling, demonstrate how to use the HIVST kits through videos and other job aids, and help participants select an HIVST kit and their preferred mode of assistance. Additionally, they connected HIVST users to facilities offering confirmatory tests, treatment, and care services based on the results of the HIVST. **TCIF and BEST are the implementing partners for the workplace model within their premises.**

- Model#4PLHIV network-led model: **The PLHIV network-led model was implemented by the Network of Maharashtra People with HIV (NMP+), which is a PLHIV network under the National Coalition of People Living with HIV/AIDS (NCPI+).** The Humsafar Trust served as the lead partner. This model distributed HIVST kits through the community-run TAAL pharmacy, which provides subsidized ART to PLHIV and offers HIV testing and prevention services to individuals at high risk of HIV. Outreach support was also provided to PLHIV. This model aimed to reach the partners of PLHIV and other clients who use the network's services. Through this model, HIVST kits were distributed across five districts in Maharashtra.

- Model#5-Virtual model: The virtual model adopted a digital marketplace approach. **The project developed the www.sahayindia.org website, where potential participants could visit to order test kits. The project ran a social media campaign to reach KPs, high-risk individuals, and their partners, as well as partners of PLHIV.** This outreach included search engine optimization and social media promotion through platforms such as Facebook, Instagram, and others. The virtual counsellors appointed with dedicated helpline numbers for counselling and guidance to the study participants.

  Interested participants were directed to the www.sahayindia.org website. On the landing page, an eligibility assessment was

conducted. Participants' statuses were digitally validated using OTP verification, their consent was obtained online, and a UID was generated. Participants could then virtually place orders for the HIVST kit of their choice, with the option to receive the test kit via courier or visit a nearby project site for in-person pickup. For courier orders, the test kit was sent along with IEC materials and IFU after an online pre-test counseling session. In the case of in-person pickups, participants received pre-test counseling on-site and could choose to conduct the HIVST with assistance or in an unassistance mode. Both groups—those receiving the HIVST kits through courier and those picking them up at project sites—were followed up for results and post-test counseling. Participants were encouraged to share their test results with the appropriate health service provider.

Training and capacity strengthening of project team

Study implemented during first and second wave of COVID-19 pandemic

PATH strengthened the capacities of peer educators, counselors, and service providers engaged in this project through a cascading training model.

- PATH developed a detailed learning resource package (LRP) that included training modules, a facilitator's guide, implementation protocols, standard operating procedures, IEC/BCC materials, IFU, and other learning materials. This package was then used during a three-day training of trainers (TOTs) session with all implementation partners. The master trainers then conducted additional training sessions for field-level implementation staff, supported by members of PATH and representatives from CAB and SOCs who provided mentorship and guidance throughout the training rollout. The cascade of training was carried out in all 14 states according to the established training guidelines. Totally more than 1000 staff trained in 14 states through more than 25 batches of training which includes training of trainers (TOT).

- **Trained implementation partners, PEPFAR and GFATM partners, more than 250 CBOs/NGOs who are involved in direct implementation partners across 14 states and most of them are existing targeted interventions partner of NACO/SACS.**

- Based on the findings from the online assessment, PATH and its implementing partners conducted refresher training along with one-on-one mentoring support. All training participants were encouraged to

Self-testing kits are usually accompanied by clear instructions for correct use

respond to a set of questions prepared in a Google form. The responses were analyzed to identify the thematic areas and learning and mentoring requirements.

- Furthermore, state managers and members of CAB, SOC, and CMB visited the project sites to provide hand-holding and supportive supervision for implementation.
- Mentoring visits were conducted by the study team and CAB members.

Storage and distribution of test kits

The preparatory phase involved ensuring proper storage and inventory management for the kits to be deployed and microplanning for their distribution under different distribution models. The kits were stored in a designated space within the stipulated temperature range of 2 to 30 degrees Celsius. An inventory register was maintained to track the distribution of the kits, and cool boxes were used to maintain the appropriate temperature during outreach sessions. **Many of the SACS coordinated to store the kits in the warehouse, which greatly facilitated the supply chain and management.**

The micro plan was developed in collaboration with stakeholders responsible for the particular model. For instance, in the PLHIV network model, the key stakeholders responsible were the community pharmacists, while in the workplace model, managers and supervisors played a crucial role. The micro plan detailed the days and dates for kit distribution and was shared with site-level stakeholders a day in advance to allow for adequate preparation. This advance notice enabled necessary arrangements, such as creating copies of necessary documents and organizing travel logistics, ensuring everything was in place for the study execution.

Implementation phase: Initiatives to increase the potential of uptake of HIVST and linkages to confirmatory, care, treatment initiation, and prevention services

After ensuring an enabling environment for the implementation of the study through the first phase, the project was implemented, and the following activities were undertaken:

A. Awareness building, demand generation, and recruitment

All the IEC and BCC materials reviewed by communities and CAB members

B. Obtaining Informed consent before undertaking the self-testing

C. Conducting HIVST, along with pre- and post-counseling for self-testing

D. Follow-up and linkages

E. Data collection and management

F. Site monitoring and corrective actions

Awareness building, demand generation, and recruitment

As the first step for implementing the project, two activities were undertaken, i.e., demand generation and recruitment, which are described as follows:

- Awareness building and demand generation: A variety of strategies were devised to increase demand for HIVST and mobilization of the target population for recruitment into the current study, as well as for the provision of future HIVST services. The demand generation plan was developed following discussions with the partners responsible for different models and input from the community. These demand-generation activities were customized and meticulously designed for all five HIVST distribution models.
  - In the case of the **HIVST virtual distribution model,** social media marketing was conducted with the help of social media influencers. A marketing campaign among the identified communities was developed using social media platforms for each identified target population group. These included but were not limited to, Facebook

HIV self-testing can increase the first-time testers

and dating apps such as Grindr and Blued. A total of 28 social media influencers who were active on Instagram, Facebook, and YouTube shared key messages about HIVST along with links to the online platform through their personal social media accounts. In addition, influencers posted content on WhatsApp to ensure that semi-offline populations (not active on social media) could view these messages and engage with influencers. People interested in the HIVST were directed to the online platform, i.e., the Sahay India website. Additionally, virtual outreach by trained personnel was conducted, offering services such as one-on-one discussions online or virtual platforms about prevention, testing, treatment, and retention. **WHO has supported this virtual model second phase scale up and strengthening the social media campaign including influencer marketing through Southeast Asia and Country Office.**

- For the other four models of distribution (community model, private model, workplace model, and PLHIV network model), demand generation and community mobilization were implemented through various methods. These included awareness sessions in the community, community information sessions, and the distribution of posters by both study staff and community members. These activities occurred before the implementation at hotspots, community-based offices, and other community-based testing sites. As a result of these interventions, potential participants were mobilized through these interventions.
- **Communication strategy:** Encouraging KPs, self-identified high-risk individuals, partners of high-risk individuals, and PLHIV, among others, to become informed about HIVST and accept its use was a key component for improving demand, feasibility, and acceptability of HIVST. The study team, using the findings from a formative assessment and with the support of a communication agency, conceptualized, designed, field-tested, and developed a communication package. These materials were uploaded and made publicly available for easy access: https://www.youtube.com/@starhivselftesting3897. See Figure 3.6.

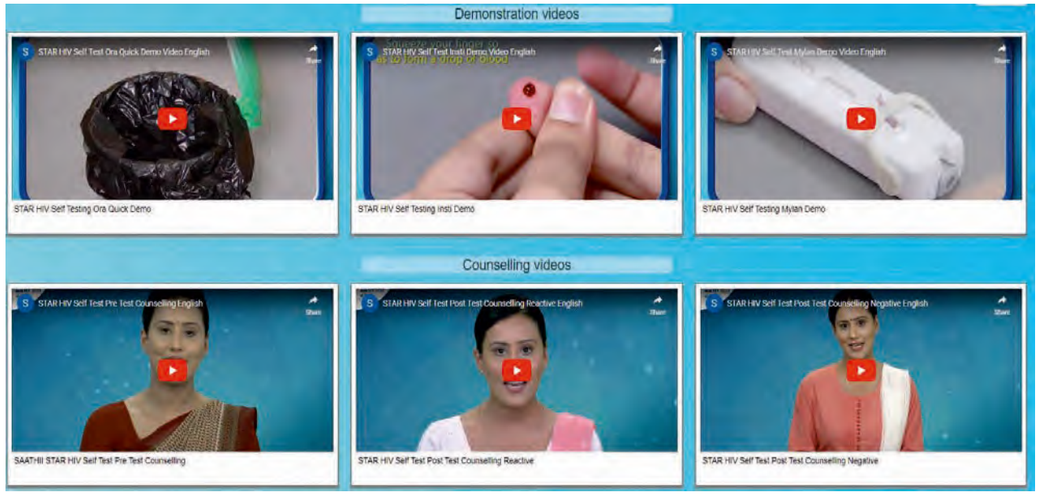


Figure 3.6. Materials uploaded and made publicly available during the project

Figure 3.7. The IEC/BCC products

The package consisted of taglines, IFU in print and videos, counseling videos, and point-of-use promotional products, among others. Initially developed in Hindi, these products were later translated into seven regional languages (Bengali, Hindi, Tamil, Gujarati, Punjabi, Telugu, and Kannada) and made available at project sites for use. In addition to the products, the communication package included guidance for the most effective use in various intervention settings. The IEC/BCC products (see Figure 3.7) were shared with implementing partners and their staff during training sessions, site visits, and virtual mentoring sessions, ensuring they received orientation on using them effectively.

HIV self-testing can increase the reach of partner testing

WHO supported the second phase of the social media campaign for the virtual model

A team member shared an anecdote about the HIVST song, which was written and filmed by the implementation team in Mizoram. This song was later popularized by the study teams and the community (STAR YouTube channel: https://www.youtube.com/watch?v=FJ1CINgGIDU). The study team also provided guidance on how to effectively use these products in different intervention settings, disseminating them to partners through training sessions, site visits, and virtual mentoring.

Recruitment: The recruitment of participants began with demand generation activities that included IEC campaigns, interpersonal communication, and events at the study sites, such as group activities. Through these initiatives, potential participants were mobilized and were provided with information on HIV/AIDS. They were then subjected to eligibility assessment as per the study protocol.

After completing these preliminary steps, participants received detailed orientation on the three HIVST kits, including the IFU leaflets. It was emphasized that these kits are screening tests. Participants then choose between the two kinds of kits and watched demonstration videos to aid their selection.

Obtaining informed consent before undertaking the self-testing

Eligible participants were provided information about the three HIVST kits available under the study.

All participants received relevant IEC materials that outlined all necessary information on the tests, discomforts, potential benefits, protection of confidentiality of the information (data collection, storage, and follow-up), voluntary participation, and the option to withdraw.

Two types of ICFs were used for the study participants: i) for in-person recruitment and ii) for virtual recruitment. While the options and process for conducting HIVST were broadly consistent across the different models, there were differences in obtaining informed consent for those recruited in-person compared to those recruited online/virtual. Additionally, a separate informed consent was used for the formative assessment.

All aspects were explained to the participant. If the participant agreed to participate, their signature was obtained on the consent form, which was also signed by the study staff. If the participant could not read and write, a trusted witness, chosen by the participant and unaffiliated with the study, helped to make the participant understand the procedures and sign the ICF, in addition to the thumb impression of the participant. The investigator retained this. The signed ICF was stored in a locked file cabinet at the implementation partner's office and was later moved to the PI's office (Humsafar Trust) for safekeeping for five years. A copy of the ICF was offered to the participants for their reference.

Participants who chose not to consent were given information about precautions and prevention methods for HIV and AIDS. Once the consent forms were signed, the participant enrollment form and behavioral questionnaires were completed to generate a UID for each participant.

In the virtual model, once the participant was deemed eligible, the website directed them to the ICF section. Once the participant completed the online submission of the ICF, a UID was generated based on the ICF confirmation. Participants were then verified through an OTP sent to their mobile numbers for authentication purposes. This process also allowed further follow-up communications, including providing information, videos, counseling, verifying the kit courier/pickup, and checking for potential social harm. The consent form was virtually verified by the study staff. A copy of the ICF, along with the test kit, was sent to the participant via courier.

Conducting HIVST, along with pre- and post- counseling for self-testing

The self-testing was conducted in two formats: a) physical or offline testing and b) virtual or online testing. Both formats offered two options: assisted testing (in the presence of the provider, i.e., counselor, outreach, or other trained staff) and unassisted self-testing (i.e., independently conducting the testing at their preferred location and interpreting the result independently).

- **Physical or offline testing:** Offline testing refers to the administration of HIVST at study sites established in different states. The study sites were established within 3–5 kilometers of the recruitment sites. Once the participants arrived at the study site, the study team ensured that the participants were informed about the study's purpose and processes. All participants recruited in person received face-to-face pre-test counseling. during which the HIVST procedures were explained. The study staff conducted a video demonstration of the HIVST process and how to interpret the results. Participants were offered a choice of test kits—either blood-based or oral fluid-based.

Further, participants were allowed to take the HIVST kit to their setting and perform the test at their convenience (unassisted approach) or at the study site (in unassisted or assisted approach). For participants who opted for assisted HIVST, the staff offered support in performing the test and reading the results (if requested by the participant). The participants performed the test. Once the results were available, the staff discussed the results, provided post-test counseling, administered the rest of the behavioral questionnaire, and obtained feedback.

Education about how to interpret HIV self-test results is key to their effectiveness

If the participant opted for unassisted testing, they received a test kit (along with the instructions on how to perform the test). They conducted the test independently (privately in another room without guidance) or took the HIVST kit to a location of their convenience and comfort. They were given instructions and a video demonstration on how to conduct the test, which was performed by the staff.

- **Virtual or online testing:** Virtual testing was an unassisted method of conducting tests in which the participants were recruited online. They were shown a video explaining HIVST procedures and how to interpret the test results before completing the ICF. Once the ICF was submitted, participants were enrolled in the study and provided a UID. They were then directed to fill out an online behavioral questionnaire. Participants who were recruited and enrolled online could collect the HIVST kit at the nearest distribution model/study site office or have it delivered to their address.
- Those who chose to collect the kit from nearby sites were given the address and contact details of the distribution site. Participants who

CDC supported independent site monitoring of the entire study sites through SHARE India

opted for delivery needed to share their name and address. The project assured them that this information would be delinked from their personal data immediately after the successful delivery of the HIVST kit and documentation. The HIVST kit was then couriered to the participants, along with the following documents:

- Communication material (pictorial and in local language) with links to essential video messages with detailed descriptions to use, read, and share results of the test.
- HIVST kit with IFU.
- One-pager pictorial document on the HIVST testing process.
- Hard copy of ICF for the participant's reference.
- Details of nearest ICTCs for each city in the state.
- Information on safe disposal of the used HIVST kit and other associated items.
- Study helpline number information.

Follow-up and linkages

Based on the HIVST result, referral linkages were established either to the confirmatory testing site or with the HIV prevention program.

- The participants who opted for an unassisted approach were provided with the option of face-to-face or virtual post-test counseling after the HIV self-testing. All of them were requested to share their results by phone/WhatsApp voluntarily.
- In the unassisted approach, if they did not inform the results within a week of receiving the HIVST kit, they were followed up to check if they intended to do the test or if there was any reluctance or apprehension.
- This was then addressed by the staff, peer educator, or any other designated trained staff. During the follow-up communications, participants who did not share an HIVST result were provided with referral information in the case of both reactive and non-reactive HIVST results, so they are prepared in the event of either outcome.
- If the participants did not share the HIVST result, they were followed up. The participants were followed up for a maximum of three times a week to share the results after the receipt of the HIVST kit.
- No coercive practices were used to report the results.
- For participants who opted for virtual testing, the designated virtual counselor regularly contacted them through email/WhatsApp/phone and ensured that the HIVST kit reached them, was used correctly, and the result was shared. The participant was requested to voluntarily share the test result.
- The staff provided online post-test counseling through video chat/ WhatsApp/phone call, based on the participant's choice.
- At the time the HIVST was reported, all participants were asked a series of questions to provide feedback and suggestions based on their experience using HIVST that can inform future implementation of HIVST in India. These questions were administered via video chat/ WhatsApp/phone call, based on the participant's choice.
- Based on the HIVST result, further referrals were established to the confirmatory testing center or the prevention program.
- If the test result was reactive, a referral was offered to the nearest ICTC for a confirmatory test. The participant was further linked to the ART center for treatment initiation if the confirmatory test was also reactive.
- A review of the socio-economic status of the patient was conducted and linked to social entitlements where needed. The patient was followed up after a week to review their health and well-being.
- If the test results were negative, the participant was informed about repeating the HIV test after six months at the nearest ICTC and linked with NGO/CBOs through whom most of the study participants were reached.

The participant was further linked to a field worker for prevention services with the participant's consent. He/she was followed up after a week to review health status and well-being and linked to crisis management teams if required.

HIV self-testing promotes regular health check-ups and early intervention

Tagline was finalized by communities

Data collection, management, and analysis

As mentioned in the previous section, a format for data collection was used, and UIDs were given to each participant to ensure data confidentiality.

- **Data entry and management:**
  - The CRO collected data daily from each site using an online application-based data collection form. This data was then uploaded to a centrally managed cloud server, which was accessible and managed by the central data management team. The application included built-in data validation provisions, wherever required.
  - In locations with poor internet connectivity where direct online data entry was not feasible, staff members were trained to utilize paper data collection forms. A guidance note was created for paper-based data collection, which was used during the staff training sessions. Once data was collected on paper forms, it was entered into the online database when internet access was available, and this was performed by the trained study staff. Throughout this process, all paper forms were securely locked at the study sites when not in use. In case the forms needed to be transferred to another site for data entry, they were transported in a sealed envelope and kept under the supervision of the site supervisor. After the data was entered into the database, the UID generated was entered into the physical data collection form. The section containing personal identifiers was then destroyed by shredding.
- **Data collection for HIVST kit distribution through virtual model:** The data collection, in this case, was undertaken through the SAHAY India website and was undertaken in two phases:
  - In the first phase, extensive data variables were collected from the beneficiary visiting the SAHAY India website and placing an order for the HIVST kit. However, an interim review of the model's performance revealed how time-consuming the process was and that it often deterred participants from ordering the kits.
  - Hence, in the second phase of the virtual model, minimal variables were collected through the website to ensure expedited utilization of the Sahay website and placement of order of the HIVST kits.
  - The information required from the beneficiary was collected by the virtual counselor assigned to conduct the post-test counseling for the beneficiaries who received their test kits from the order placed on the Sahay website.
- **Data quality assurance:** Apart from internal validation checks available in the application, 10% of the reported data was reviewed and validated for quality issues. Records with an error rate exceeding 10% were excluded from the analysis and final reporting. The central team routinely assessed all data for quality. Any discrepancies found were reported back to the sites for correction. Entries that could not be corrected were not included in the analysis.
- **Data analysis:** The primary outcomes measured in the study were the acceptability of HIVST for current and future testing, the usability of the HIVST products included in the study, and the participants' willingness to pay for these kits. To understand the amount that the participants were willing to pay, after the testing process, participants were asked to specify a price range they would be willing to pay for an HIVST kit. To determine the factors associated with the primary outcomes, unadjusted odds ratios along with 95% confidence intervals were first calculated. Variables with a p-value<0.20 were selected for multiple regression analysis. During this process, it was found that the variable population group and gender were collinear; hence, only the population group was used for further analysis. Using these variables, directed acyclic graphs were constructed to identify potential confounders for each outcome-factor association. Confounders to be adjusted using the multiple logistic regression were identified by comparing the -2 log-likelihood ratios of the models with and without the confounding variables for each exposure variable separately. Data analysis was conducted using SPSS (Version20,2011; IBM Inc., Chicago, IL, USA) and Stata (Version 16, StataCorp LLC, Texas, USA).

Site monitoring and corrective actions

The HIVST was implemented in multiple sites across the country using five different models, which included both assisted and unassisted approaches. Each HIVST site was assigned a defined number of HIV self-tests to conduct in accordance with the established protocol and

While HIV self-testing is a powerful tool, it is not a substitute for regular visits to a healthcare provider

ILO supported the Workplace Model of self-testing

guidelines. The entire implementation process and the data collection were monitored to ensure compliance with the protocol and the standard operational procedures and guidelines.

- **The site monitoring of the HIV self-testing initiative was conducted in 13 of the 14 states involved in the program.** As per the proposed site monitoring plan, approximately 15.2% (104) of the 685 proposed implementation sites across 50 districts nationwide were included in the monitoring activities, which took place from December 2021 to May 2022. The number of sites from each state/district was computed proportionately to the total number of sites under specific models in the state/district.

The HIVST processes were monitored by trained monitoring experts who had experience in HIV programs and foundational knowledge of research methods. A team of around 25 monitoring experts was identified and given an orientation covering the study objectives and processes, site monitoring objectives, methodologies, tools, and processes to be adopted during the site monitoring, data collection, and submission procedures.

A site monitoring checklist was designed to document the observation of the HIVST processes. Each day, a site monitoring expert filled out the checklist after reviewing all cases observed at the site on that day. The monitoring experts observed and verified whether all processes and steps were carried out per the guidelines/standard operation procedures. The monitoring methods included observations, record reviews, and interviews with site supervisors as required. The site monitoring experts used a master sheet to capture the information related to individual HIV self-testing, which subsequently helped them complete the site

People who test negative for HIV can use self-testing to continue practicing prevention, such as using condoms or taking PrEP

monitoring checklist with aggregated/consolidated information for the day.

The daily reporting of the information/data captured through the site monitoring checklist was entered into the online platform every day. This was done after all the observations were completed and aggregated/consolidated information was collated using the master sheet. **The web/mobile-based platform was created by SHARE INDIA with the support of the CDC. The SHARE INDIA team analyzed the daily data submission and prepared reports with recommendations to the central study team.** This was done through the online portal. In addition, the report copy was emailed to key officials on the central study team. The performance of sites was graded as good (above 75%), average (50-75%), and poor (up to 50%) based on the obtained scores.

Following the scoring, the sites graded "Good" were informed about the gap areas that needed to be addressed immediately. The sites graded "Average" were recommended for orientation and training but allowed to continue with the self-testing activities. Additionally, the sites graded "Poor" were recommended to suspend activities until all gaps were addressed through necessary training and other technical support. **Site monitoring reports were submitted to PATH the day after the site monitoring took place and PATH acted within 24-48 hours as per the site monitoring guideline.**

- **Corrective actions:** PATH was responsible for taking corrective actions through its site supervisor and study staff within 48 hours of receiving reports. Each study site received a performance score, and a report

The availability of HIV self-testing allows for quicker diagnosis and helps prevent delays in treatment

detailing comments and recommendations was submitted to PATH by the site monitoring committee. This report was then communicated to the implementing organization at each site. Any sites that scored less than 50% would have halted the self-testing initiative, but none of the sites reached that threshold.

In terms of overall performance score, two sites scored less than 75% (66% and 74%). These sites received intensive onsite training on the HIV self-testing processes, which included pre-test, testing, post-test, and data management processes. In addition, the sites that scored below 75% in specific technical areas underwent reorientation focused on the specific procedures or steps where the gaps were identified. This reorientation was conducted by trained technical personnel (primarily site supervisors) from the implementing agencies, with support from PATH. It was provided either virtually or onsite within 24 hours of the report. Furthermore, site monitoring experts offered technical assistance and mentored the study staff on minor deviations from the study protocol.

Site monitoring was conducted at only 15% of the locations. The learnings gained and the corrective actions implemented at these monitoring sites were communicated as “alerts” to all staff involved in the HIVST program through alerts sent via WhatsApp. In March 2022, all study staff received refresher training on the HIV self-testing process in their respective states, during which the learning from the site monitoring was also communicated.

ACCELERATING ACCESS AND UPTAKE OF HIV SELF-TESTING (HIVST) IN INDIA

Site Monitoring and Support Supervision Checklist

(selftesting.php) July 21, 2022

Name & ID of the site monitoring consultant:					
Name of Consultant:	Dr.Mahalingam Periasamy	Consultant ID:	Mahalingam007		
Date of visit:	Day: 31	Month: Mar	Year: 2022		
Name of Site:	ARM 2				
State:	Tamil Nadu				
District:	Chennai				

Score Board

		Obtained Score	Maximum Score	Percentage
Pre-Test Process	Eligibility Assessment	6	6	100
	Informed Consent	12	12	100
	HIV Preference	18	18	100
Self Testing Process		9	9	100

IHAA distributed HIVST kits through SAMARTH project

Scientific writing workshops

PATH has conducted two phases of scientific writing workshops with research, program, technical and community experts to understand the collected data and analysis process. The scientific writing workshop was supported by CHAI. The scientific writing workshop was headed by Dr. DCS Reddy. The first writing workshop was conducted on 24-25 June 2022 and the second workshop was conducted on 25-28 August 2022 in New Delhi. The workshop had detailed discussions around different thematic papers and divided the writer's group among the partners and community leaders. All the partners were actively involved and supported the process.

HIV self-testing kits should be used in accordance with the instructions for accurate results

Final phase: Dissemination of study findings

At the conclusion of the study, it was crucial to share the study results and findings with the stakeholders and the community. To accomplish this, PATH India conducted a national-level dissemination event titled "Dissemination of STAR III Initiative HIV Self-Testing in India: Moving from Evidence to Action". This event took place on September 26, 2022, in New Delhi. The goal of the dissemination workshop was the following:

- Share the findings from the study.
- Provide support for accurate interpretation and understanding of the findings.
- Capture feedback and insights from the participants.

Daily acknowledgment of the study team for their good work

- Encourage practical applications of study findings in planning, policy-making, and operationalization of services.

The event brought together key stakeholders, including NACO and its state counterparts, PSI, WHO, CDC, UNAIDS, USAID, ILO, and various implementation partners. Shri Alok Saxena, AS&DG, NACO was also in attendance when the summary report of the project and seven knowledge products were released. The special invitee speakers and panelists shared their expert insights on various themes surrounding HIVST, particularly in the context of India.

Prior to this project, HIVST was an unchartered territory in India

CHAPTER 4

Results and achievements

This section provides the results of the study, which are categorized as follows:

1. Participant enrollment for HIVST kits based on demography, population groups, and gender.

2. Distribution of HIVST kits based on age group and distribution model.

3. Testing preferences and interpretations of results.

4. Linkages to care.

The results provided insights into the feasibility, acceptability, and demand for HIVST across specific populations and models. It explored preferences for either blood- or oral fluid-based HIVST kits and approaches (assisted and unassisted). The findings also emphasized the importance of linking individuals with negative HIVST results to prevention services and those with reactive results to confirmatory HIV testing and treatment services. Additionally, the results highlighted the challenges in establishing these linkages and identified potential social harm following HIVST. (Refer to Annex 1a to 1e for data related to the results.)

Participant enrollment for HIVST kits based on demography, population groups, and gender

In the STAR HIVST project, a comprehensive effort was made to enroll participants across various states and districts. See Figure 4.1.

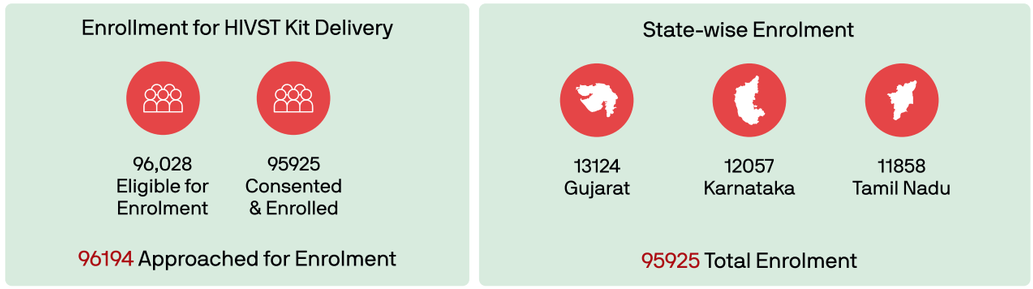


Figure 4.1. Demographic distribution of enrollment

PATH established an ecosystem for HIVST implementation

- The enrollment process targeted 96,194 individuals, with 99.8% eligibility rate, resulting in 96,028 participants deemed suitable for the study. A total of 99.9% of eligible individuals gave their consent and successfully enrolled, culminating in 95,925 participants enrolled to the study's success.
- The distribution of participants among states was notable, with the highest enrollments observed in Gujarat (13,124), Karnataka (12,057), and Tamil Nadu (11,858).
- The district-wise enrollment data reveals a granular understanding of participant distribution within states, exemplifying the project's reach and effectiveness.

Population groups enrolled

- In the study, nearly 60.9% of the population who used an HIVST kit identified themselves as members of the KP group along with their clients/partners. This was followed by 24.7% of study participants who self-identified as high-risk individuals.
- Among the KP groups, most participants identified themselves as FSW or MSM (see Figure 4.2).

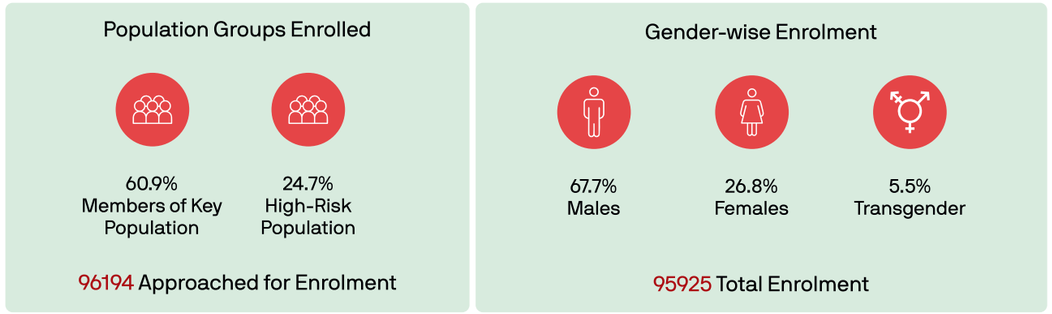


Figure 4.2. Population groups enrolled

The kit distribution initiated after consensus of CMB members at the district level

Gender-wise enrollment

- Overall, 67.7% of participants identified as male, 26.8% as female, and 5.5% as TG.

Model-wise enrollment

There was also a difference in the model-wise enrollment of study participants. These are as follows:

- The virtual model reached mainly MSM. The private practitioners, workplace, and virtual models enrolled mainly males, while the PLHIV network-led model had a relatively higher proportion of females, which also included spouses of PLHIV.
- The CBM reached many KPs, their partners, and clients, along with self-identified high-risk individuals. Almost all TG participants were enrolled through the community-based model.
- The PLHIV-network model reached partners and family members of PLHIV.
- Among the self-identified high-risk individuals, 40.7% were unskilled laborers and 30.1% were truck drivers

Distribution of HIVST kits based on age group and distribution model

As part of the project, HIVST kits were distributed among participants in 14 study states. The details of the distribution are as follows:

Distribution of kits

In the first phase, kit distribution began at a facility in Delhi in September 2021 and gradually expanded until June 2022. All five distribution models were used to reach out to the participants. The distribution of kits resumed in December 2022 in which virtual- and community-based methods of distribution were adopted. This continued until March 2023. **During the study period, 94,823 HIVST test kits were distributed.** See Figure 4.3.

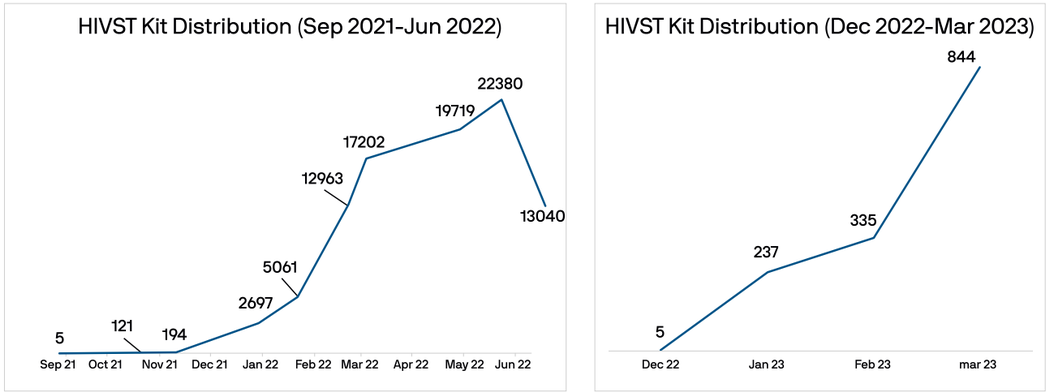


Figure 4.3. HIVST kits distributed

Distribution of kits age-wise

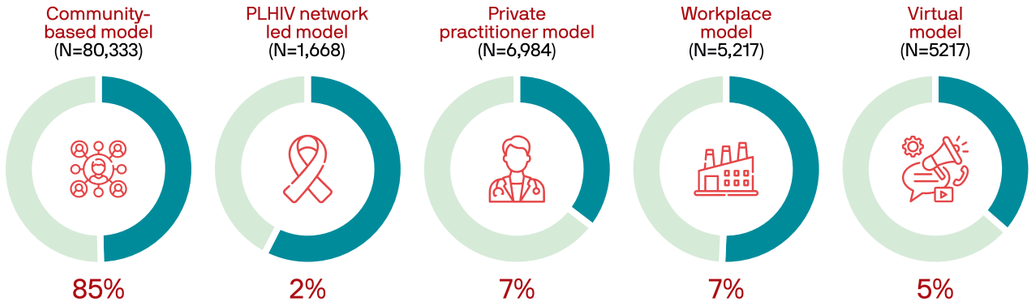
The median age of the study participants was 30 years (interquartile range or IQR: 26-36 years).

- Participants in the virtual model had the lowest median age of 26 years (IQR: 23-31 years),
- The CBM had the second lowest median age of 30 years (IQR: 25-35 years),
- The PLHIV network-led model had the third lowest median age of 32 years (IQR: 24-42 years).
- The workplace model had the highest median age of 40 years (IQR: 33-46 years).
- Among the population groups enrolled, MSM and PWIDs had a lower median age and partners of PLHIV, and employees of organizations had the highest median age.

Independent virtual platform development for online distribution

Social media campaign and influencer marketing was working

Distribution of Kits – model wise



A total of 94,823 HIVST test kits were distributed during the study period.

Figure 4.4. Model-wise distribution of kits

Model-wise kit distribution

Of the total 94,823 test kits distributed during the study, 80,333 (85%) were distributed through the community-based distribution model. See Figure 4.4.

Testing preferences and interpretations of results

First-time testers

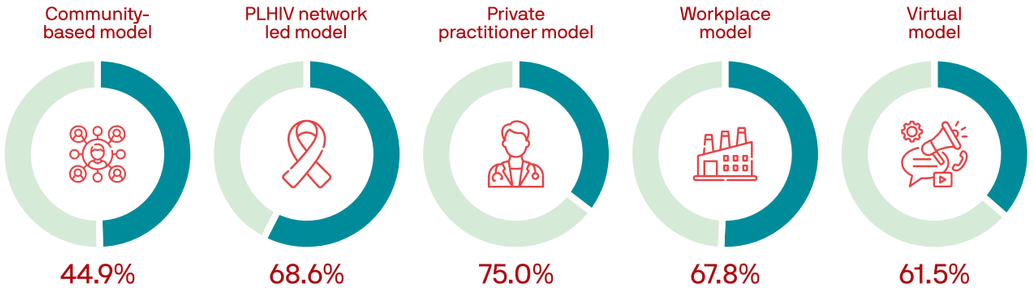
Overall, 48.9% (46,332 out of 94,661) of participants reported never having been tested for HIV. The proportion of first-time testers was 75.0%, 68.6%, 67.8%, 61.5%, and 44.9% in the private practitioner model, PLHIV network-led model, workplace model, virtual model, and community-based model, respectively.

- Among the KPs, 43.9% of MSM, 32.4% of TG, 26.1% of FSWs, and 24.7% of PWIDs were first-time testers.
- Among the non-KP participants, nearly all family members of PLHIV (98.2%), 76.2% of private practitioner referrals, 67.0% of partners/clients of KPs, and 63.4% of self-identified high-risk individuals reported testing for the first time (see Figure 4.5).

WHO included virtual model as a case study in HTS guideline 2024

- Of first-time testers, 38.2% (17,920 out of 46,869) and 34.1% (15,965 out of 46,869) considered themselves as being at medium and low risk, respectively. Additionally, 9.4% (4425 out of 46,869) of them reported having a high self-perceived risk.
- Out of all testers, 46.9% (19,489 out of 41,596) considered themselves at medium risk, 28.6% (25,286 out of 41,596) considered themselves at low risk, and 20.4% (12,916 out of 41,596) perceived a high self-risk.

First Time Testers



48.9% (46,332/94,661) never tested for HIV

Figure 4.5. First-time testers

HIVST kit preference

HIVST kit preference was analyzed for participants enrolled before January 2023 and those who did not report having Hepatitis B virus or Hepatitis C virus infections.

- Overall, 51.3% of participants preferred the blood-based test kit, while 48.7% preferred the oral-fluid-based test kit.
- The slightly lower percentage of preference for the oral-fluid-based test can be attributed to the exclusion criteria prescribed by the IFU, which excluded participants who had consumed any food or beverages 15 minutes before the test, chewed tobacco, or used mouthwash 30 minutes before the test.

The web/mobile-based platform was created by SHARE INDIA for independent site monitoring

- A higher proportion of participants in the PLHIV network (57.3%) preferred oral-fluid-based kits.
- Among the various population groups enrolled in the study, the preference for oral-fluid test kits was particularly pronounced among MSM (55.8%) and TG people (54.2%). Conversely, a significant 66.1% of people who use drugs preferred the blood-based HIVST kits.

Testing preference in future

All participants who used an HIVST kit were asked for their testing preference for the next test (see Figure 4.6).

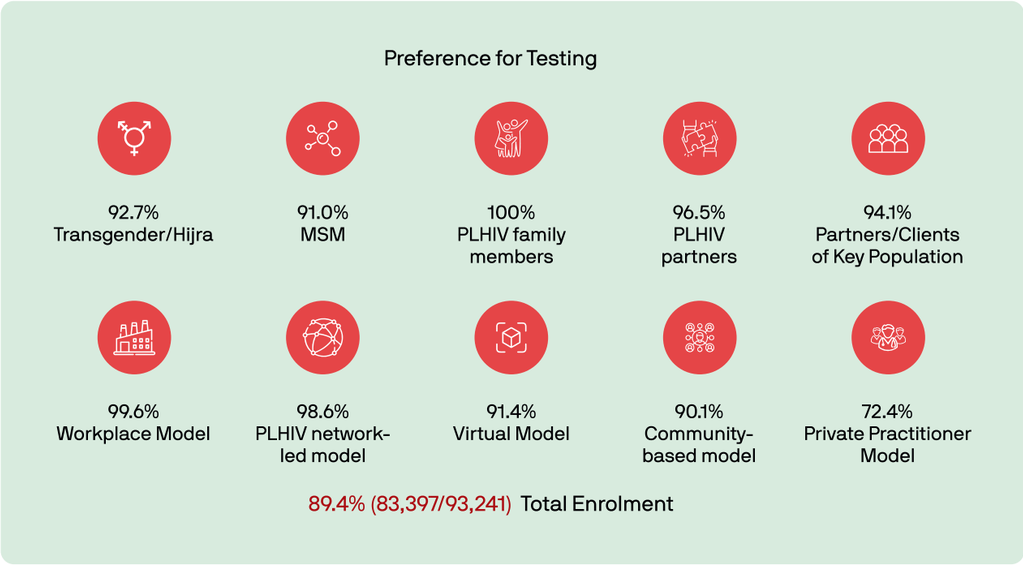


Figure 4.6. Testing preference in future

- Overall, 89.4% (83,397 out of 93,241) of participants preferred using an HIVST kit over other testing modalities available for future testing.
- Among the KP groups, 92.7% of TG people and 91.0% of MSM expressed a preference for HIVST compared to other testing methods. An overwhelming proportion of family members of PLHIV (100%), partners of PLHIV (96.5%), and partners/clients of KPs (94.1%) also preferred HIVST for future testing.
- Among the different models, 99.6%, 98.6%, 91.4%, 90.1%, and 72.4% of participants from the workplace model, PLHIV network-led model, virtual model, community-based model, and the private practitioners model, respectively, reported that they would prefer HIVST for future testing over other testing modalities.
- Among first-time testers, 89% of users preferred HIV self-testing compared to other HIV testing modalities for future needs. Similarly, among individuals who had tested before, the majority of users (86%) preferred HIV self-testing for future testing needs.

HIVST could be able to reach hilly areas, difficult-to-reach areas, unreached population and partners of PLHIV

Ease of using the test kits

Overall, 95.1% (89,871/94,473) reported HIVST kits as easy to use.

- A higher proportion of participants who used the oral-fluid-based kits (96.5%) found them easier to use than those who used blood-based HIVST kits (93.9%).
- Among various population groups, except PWIDs, over 94% of participants reported that the HIVST kits were easy to use.
- Even among PWIDs, 89.9% of participants responded that the kits were easy to use.
- The majority of users, including first-time testers (94.1%) and ever-testers (95.3%), found the HIVST kit either easy or very easy to use.

Ease of interpreting the result

- Overall, the ease of interpreting the result remained high, with 95.2% (89,825 out of 94,398) participants reporting the test kit results as easy to interpret.
- Similar to the ease of using the kits, a lower proportion of participants using blood-based HIVST kits (94.4%) reported that these kits were easier to interpret than those using oral-fluid-based HIVST kits (95.9%).

- Among the population groups enrolled, a high proportion of participants reported the test results as easy to interpret, with the lowest proportion being among PWIDs (89.4%).

Willingness to pay

Participants who reported a preference for HIVST for future testing were asked about their willingness to buy an HIVST kit and the amount they would be willing to pay (see Figure 4.7).

- Overall, 68.2% (55,317 out of 81,170) of participants reported willingness to pay for HIVST kits in the future.
- Among the population groups enrolled, a high proportion of TG people (88.4% or 4,125 out of 4,667) reported willingness to pay for HIVST kits. Among the other KP groups, 72.9% (10,032 out of 13,770) of MSM, 67.1% (3,104 out of 4,623) of PWIDs, and 65.7% (10,525 out of 16,030) of FSWs reported willing to pay for HIVST kits.

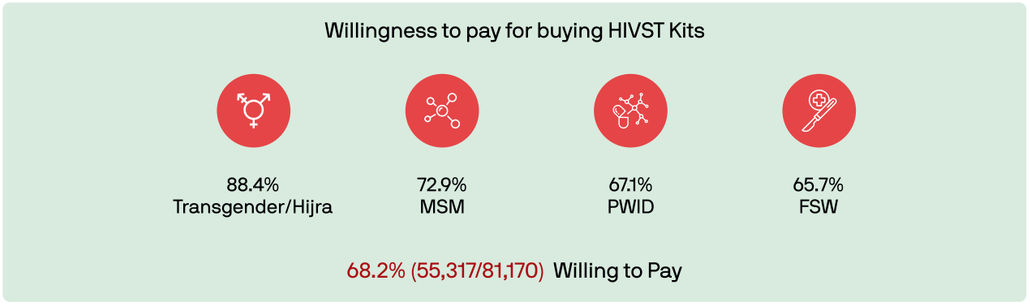


Figure 4.7. Testing preference in future

- The lowest proportion of participants who reported a willingness to pay for the HIVST kit was in the workplace model (45.2%; 2,144 out of 4,743). 52.4% (2,636 out of 5,043) in the private practitioner's model, 70.8% (49,073 out of 69,344) in the community-based model, 73.9% (1,191 out of 1,611) from the PLHIV network-led model, and 74.7% (327 out of 438) from the virtual model reported a willingness to pay for the HIVST kit. The differences in willingness to pay may be attributed to varying levels of risk awareness among the population groups. Participants in the workplace model and private practitioner model tended to view themselves as low risk, as described in Table 6. This perception likely led to a lower need to test themselves and, hence, the willingness to buy the HIVST kits.

- While a large proportion of participants reported willingness to pay for the kits,
  - 46.6% reported that they would pay less than INR100 (US$1.2) for the kits,
  - among the different population groups, TG people were willing to pay up to INR 250 (US$3) for the kits,
  - among the other three KP groups, the majority of the participants willing to pay preferred a price lower than INR 100 (US$1.2) for the kits.

Awareness of advantages and disadvantages of using HIVST

All participants who used an HIVST kit were asked to report the advantages and disadvantages they perceived in using these kits (see Figure 4.8).

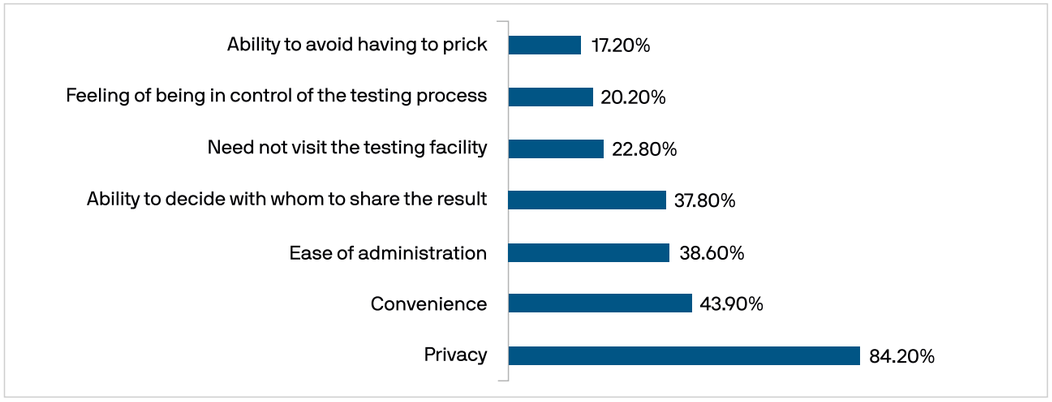


Figure 4.8. Advantages and disadvantages of using HIVST

The advantages reported include the following:

- Privacy [84.2% (79,732/94,644)]
- Convenience [43.9% (41,505/94,644)]
- Ease of administration [38.6% (36,558/94,644)]
- Ability to decide with whom to share the result [37.8% (35,774/64,644)]
- Need not visit the testing facility [22.8% (21,554/94,644)]
- Feeling of being in control of the testing process [20.2% (19,086/94,644)], and
- The ability to avoid having to prick [17.2% (16,320/94,644; 13928 oral-based kits users, 2376 blood-based kit users, 16 blanks].

Participants reported a gender-wise difference in the advantages.

- More men (24.7%) reported not having to visit a health facility as an important advantage compared to 19.5% of women and 15.0% of TG people.
- The ability to choose whom to disclose the results with was an important advantage for more men (40.8%) and TG people (36.4%) as compared to women (30.4%).

Apart from the disadvantage of the need to prick oneself (26.9%) for blood-based testing,

- 10.9% (9,496/87,046) participants reported concerns that the kits might produce false results, and 10.6% (9,198/87,046) participants reported fear of interpreting the results incorrectly.
- Only 2 (0.002%) participants reported concerns about self-harm.

HIVST testing cascade and linkages to care

The following are the details of the HIVST testing cascade:

- Among the 94,823 participants who were given an HIVST kit, 94,734 (99.9%) successfully shared their results, and 9 (<0.1%) participants refused to share their test results.
- A total of 94,167 (99.4%) participants reported a negative HIVST test result.
- The 195 (0.2%) participants who tested indeterminately on their first HIVST test were retested.
  - Among those retested, 170 (87.2%) tested HIV-negative on the subsequent HIVST usage.
  - Among those retested, 23 (11.8%) tested indeterminate the second time.
  - Of the 23 with an indeterminate result, 19 were retested at an ICTC and all tested HIV-negative.
- A total of 356 (0.4%) participants reported an HIV- reactive result on HIVST.

- The highest proportion of those who tested HIVST reactive were partners of PLHIV (2.1%) and PWID (1.3%). See Figure 4.9.

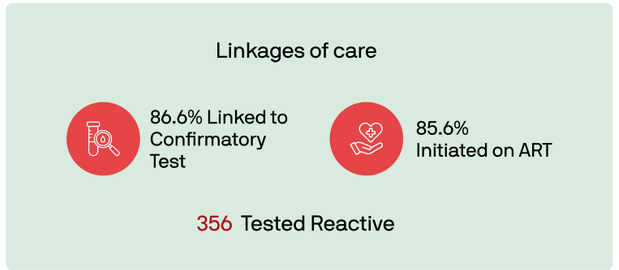


Figure 4.9. HIVST testing cascade and linkages to care

- Among the 356 who tested reactive, the following were the results:
  - Of the individuals tested, 86.6% (309) were linked for confirmatory testing at an ICTC.
  - Among these, 283 shared their confirmatory testing result with the study staff.
  - While 23 refused to share their confirmatory testing result, three refused testing at the ICTC.
  - Among the 271 who reported HIV-positive, 232 (85.6%) were initiated on ART.
- The high follow-up rate is due to the utilization of community members, CBOs, and TI NGOs to implement the study cascade.

These results underscore the effectiveness of the STAR HIVST project in achieving high rates of linkage to confirmatory testing and subsequent initiation of ART among those identified as HIV-positive through self-testing.

ACHIEVEMENTS

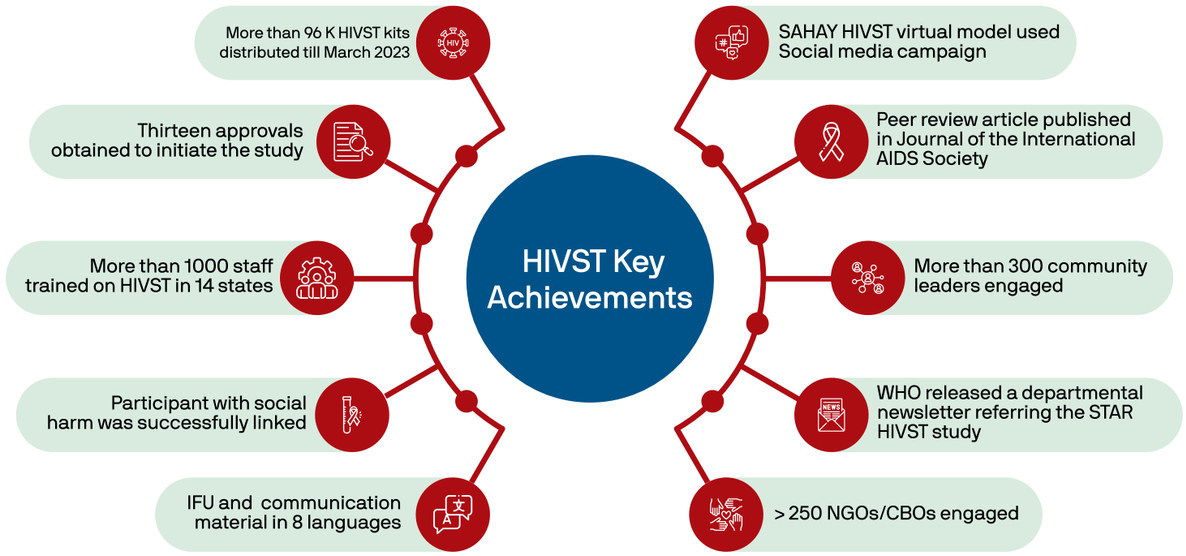


Figure 4.10. HIVST key achievements

COVID-19 impact and virtual interactions

COVID-19 disrupted the initial implementation timeline due to the unavailability of key personnel needed to obtain the necessary permissions. The study team also faced similar challenges. Throughout the study, COVID-19 protocols were followed to ensure the safety of both participants and the implementation teams. Restrictions on transportation and gatherings forced the team to conduct virtual meetings with decision makers. Fortunately, the necessary permissions were obtained without significant delays or complications. This situation highlights how the pandemic has encouraged stakeholders to adopt technologies that improve efficiency. The study implemented during this period also proves the need for additional testing methods for HIV screening, which are easily accessible and administrable. Incorporating newer testing methods, such as HIVST, alongside existing traditional methods is the need of the hour to attain the milestone of the first 95, especially for populations that are less likely to visit traditional screening centers.

Pathway to regulatory, ethical, and administrative approvals

One of the impacts of the study has been the facilitation and guidance of 8-9 HIVST manufacturing companies in applying for the test license and providing clear direction towards the regulatory approval pathway for HIVST in India.

Willingness to pay and beneficiary feedback

Most study participants preferred the use of HIVST for future testing. This is a testament to the ease and comfort of using the HIVST kits. Additionally, these kits boosted the participants' confidence to conduct testing independently, including for their partners, while maintaining confidentiality. Among those who preferred HIVST, more than 70% indicated they would be willing to pay for the kits in the future. In a developing nation where health programs typically provide free services, this willingness to pay demonstrates a strong acceptance of HIVST kits among the intended beneficiaries.

Reaching the unreached

- A prominent impact of this study was the number of first-time testers who participated. This is added to the target of the first 95, and if adopted on a larger scale along with the traditional testing mechanisms, this will help reach a much larger population.
- The study covered the difficult geographies where access to testing was.
- The virtual model, with sufficient mobilization through social media campaigns, has successfully reached certain populations.

Partnership engagement and increased level of interest in HIVST

A larger number of partners were involved in this study, as detailed in the report in the earlier sections. The study also saw partnerships with more than 250 NGOs/CBOs. Essentially, this created an enabling environment to carry out the HIVST study. It also created trained organizations the national program can enroll in executing HIVST models in the country.

Knowing one's HIV status and early initiation of treatment

The study has shown that HIVST empowered the targeted population to access testing immediately after indulging in high-risk behaviors. This means that more KPs, as well as their partners and partners of PLHIV, would access testing without worrying about stigma. This will significantly cut short the average lead time it takes to know one's HIV status as of now. This would ultimately lead to early treatment initiation and linkage to care.

WHO recommendation for HIVST

As a direct impact of the HIVST study, the WHO released a departmental newsletter that referenced the PATH HIVST study and recommended HIVST as an important tool to close the gap in HIV diagnosis among KPs.

Study tools, communication package, and consent form in multiple languages

The project initially envisioned developing consent forms, study tools, communication packages, and other materials in Hindi. Recognizing the importance of having participants, peer educators, and service providers feel comfortable and familiar with the tools provided for the study, PATH translated the entire study toolkit. The final products were made available in eight languages: Hindi, English, Marathi, Gujarati, Kannada, Tamil, Telugu, and Bengali. The tools were customized to meet local requirements and received approval from NACO, PISPAG, and CAB for use in the project. These tools are readily available for similar undertakings within the country and can also be added to the national programs in the future.

Community engagement and ownership

Throughout the project, PATH emphasized the importance of community ownership and engagement. To ensure that the expectations of all stakeholders aligned with the project objectives and that their suggestions were incorporated into the study protocols, several rounds of active engagement and iterations were necessary. This process involved establishing committees of representatives from the communities and engaging them at every stage of project implementation. Furthermore, the project team presented the implementation design to the community system, strengthening the technical working group, which had representation from key communities. They received their concurrence to implement the project through the CBOs and key community representatives. All study productsprotocols, tools, communication and training packageswere reviewed by the CAB, with the SOCs and CMBs playing an active role in overseeing the on-ground implementation. Furthermore, they reviewed and approved the consent form for participants, ensuring that the key concerns of affected communities were addressed.

PUBLICATIONS RELATED TO STAR INDIA HIVST PROJECT

- Communication and HIVST demonstration videos in eight different languages videos: https://www.youtube.com/@starhivselftesting3897
- Testimonial video from STAR HIVST experiences: This is a documentary video from stakeholders and community leaders on STAR HIVST experiences: https://www.youtube.com/watch?v=G6xYiaTusac&t=273s
- STAR HIVST song: https://www.youtube.com/watch?v=FJ1CINgGIDU
- STAR HIVST report publications: https://www.path.org/our-impact/resources/hiv-self-testing-/
  - Interim report of STAR HIVST India
  - Compendium of case studies from STAR HIVST India
- WHO press release: HIV self-testing to take off in India: findings from the STAR Initiative: https://www.who.int/news/item/13-03-2023-hiv-self-testing-to-take-off-in-india--findings-from-the-star-initiative
- PSI press release: HIV SELF-TESTING TO TAKE OFF IN INDIA: FINDINGS FROM THE STAR INITIATIVE: https://www.psi.org/2023/03/hiv-self-testing-to-take-off-in-india-findings-from-the-star-initiative/
- CEPA evaluation report of STAR HIVST which includes experiences and lessons from India (Page no: 46-53):
  - CEPA evaluation presentation: https://unitaid.org/assets/CEPA-evaluation-UNITAID-HIVST_Final-Report-Supplementary-Appendices.pdf
  - CEPA STAR project evaluation: https://unitaid.org/assets/CEPA-evaluation-Unitaid-HIVST-portfolio_Executive-Summary_Final.pdf
- STAR HIVST virtual model as a case study in WHO HTS guideline 2024: HIV self-testing distribution through virtual model has been included in the latest WHO HCTS guidelines 2024, as a case study, attached for your easy reference (pg-27): https://iris.who.int/bitstream/handle/10665/378162/9789240096394-eng.pdf?sequence=1
- Manuscript: HIV self-testing (HIVST) study titled “Acceptability, usability, and willingness to pay for HIV self-test kits distributed through community-based, PLHIV network-led and private practitioners' models in India: Results from the STAR III Initiative” published in JIAS: https://pubmed.ncbi.nlm.nih.gov/39118294/#:~:text=Among%20those%20who%20used%20the,pay%20less%20than%20US%24%201.20.

CHAPTER 5

Challenges and limitations of the study

- The project experienced a few challenges from the very beginning. Some of these challenges arose from the novelty of HIVST testing and the lack of familiarity with the study procedures. Others were related to administrative issues or part of the overall learning process. Each challenge was rigorously analyzed to identify its root cause, and mitigation strategies were developed in consultation with PISPAG and CAB, which were then implemented.

- **Time-consuming approval processes:** HIVST was a new concept in India. There were no previously approved manufacturers, clear policy guidelines, protocols or studies conducted earlier on HIVST implementation in the country. When PATH initiated the project to understand the demand, feasibility, and acceptability of HIVST in India, there were no precedents to guide their efforts. As a result, PATH learned through the implementation that evaluating a new scientific technique or a new technology required several approvals (from national to global ethics committees), regulatory approval, and test licenses, among others. While each approval was essential for the study implementation, the entire process of securing all the necessary approvals took over 18 months of the project's time.

- **Study tools, communication packages, and consent form in multiple languages:** PATH ensured the translation of the entire study toolkit, resulting in final products available in eight languages: Hindi, English, Marathi, Gujarati, Kannada, Tamil, Telugu, and Bengali. This process was time-consuming and required several rounds of review and iteration to ensure the tools were customized to local requirements. The customized tools received approval from NACO, the PISPAG, and CAB for use in the project.

- **Limited resources:** The scope of the study expanded significantly beyond the original approved proposal, with new tasks, such as translations and a wider range of stakeholder engagement. However, the project had limited resources to accommodate these additions. The CDC, through PEPFAR, stepped in to cover the cost of training and support the implementation and site monitoring of HIVST implementation as per the protocol. Additionally, other partners, such as ILO, chipped in with smaller grants and assisted with the rollout of the HIVST pilot in workplace settings.
The study faced some limitations. The sampling frame was not designed to be nationally representative of KPs and their sexual/injecting partners or clients. Additionally, it did not include pregnant women or private sector pharmacies or allow for secondary distribution.

The study required approval from multiple agencies to initiate the process, which led to confusion regarding the pathway, especially since self-testing was being introduced for the first time in the country. In addition, the COVID-19 surge posed potential challenges in processing and getting approval in time.

Due to the administrative requirements, the study had to be conducted in two phases to strengthen the virtual model intervention, with co-funding support.

CHAPTER 6

Recommendations

The HIVST study has proven to be an effective testing strategy for reaching individuals who had never tested in the past, including partners of PLHIV, partners of KPs, and those individuals who have not reached the HIV testing facilities, irrespective of their risk behavior and risk perception. Through the UNITAID-funded STAR HIV Self-Testing Initiative, HIVST is now integral to HIV diagnosis in many countries in Africa and Asia. Self-administered HIV testing has shifted the paradigm for HIV testing globally. It has emerged as a promising strategy to improve testing among hard-to-reach KPs and at-risk populations.

With no precedence for self-testing for HIV in India, a lack of registered commercial test kits, and several implementation barriers, the study demonstrated the feasibility and acceptability of HIVST through multi-centric interventions by exploring various distribution channels, thereby generating evidence, key lessons learnt on HIVST, and the implications for UNAIDS 95-95-95 targets and ending AIDS in the country.

Deriving from the study, the following recommendations are proposed for the government stakeholders, donors, HIVST kit manufacturers, academic and research community, and implementation organizations to further access to HIV/AIDS testing opportunities and widen the response to the AIDS epidemic.

Recommendation 1: Build a robust policy framework and integrate HIVST into the basket of services under the National AIDS Control Program

The HIVST demonstration study has generated a huge amount of interest in adopting and utilizing newer testing modalities through various partners and organizations in the country. The study has also ignited interest in HIVST within communities of PLHIV and key populations. Furthermore, the study's findings provide encouraging evidence for prioritizing self-testing for populations such as discordant partners, new and repeat testers, and self-identified high-risk populations who are reluctant to frequently go to

conventional testing facilities, among others. The study also demonstrated five different approaches for reaching individuals and delivering kits at their convenience, and the national program could adapt. Besides, the study has created a large number of workers who are trained and capacitated to carry out HIVST, including CBOs, SACS, DAPCU, community leaders, and key populations. The readily available tools, created for study purposes, can be replicated or adapted for scaling up the intervention in new settings.

This momentum should be utilized to **create a policy framework by the regulatory bodies and the national program for successfully adopting HIVST in the country and scaling up.** To further expand the coverage of HIVST, the government may consider introducing subsidized HIVST kits through social marketing initiatives. The policy framework should also pave the way to creating clear guidelines for local-level decision-makers and implementors.

The study recommends that HIVST may be explored as an additional testing strategy and for policy design by the national program, considering the in-country evidence. In addition, HIVST should be integrated with other services offered through the NACP, such as the distribution of condoms, pre-exposure prophylaxis, post exposure prophylaxis, opioid substitution therapy (OST), and the needle and syringes program. It is recommended that the availability of HIVST kits should be ensured through the national program as a supplement to the existing testing methods to reach a larger number of first-time testers, a population that does not have access to testing centers, hilly areas, and difficult-to-reach areas as well as the unreached population. This would help to ensure early treatment initiation for many targeted populations.

Recommendation 2: Introduce both oral fluid-based self-test kits and blood-based self-test kits to ensure wider acceptance and utilization of HIVST approaches

The study demonstrated that although preference for the test kit type is determined by many underlying factors, there is a huge demand for both oral fluid-based self-test kits and blood-based self-test kits. Besides, a

large share of study participants showed a willingness to pay for HIVST. The study also found that many intrinsic and extrinsic factors may determine the price of HIVST kits that most of the population is willing to pay. It is recommended that the manufacturers take all these factors into account while pricing the HIVST kits, as there is the possibility that many of the at-risk population may still miss out despite the appropriate pricing of the kits. **It is also recommended that manufacturers consider collaborating with the government to introduce subsidized HIV self-test kits through social marketing initiatives.**

Recommendation 3: Cultivate multistakeholder collaboration for effective scaling-up of HIVST kits

The study recommends that for implementing HIVST at scale, active participation of key stakeholders such as policymakers, regulatory bodies, implementing partners, trained counselors and health care staff, manufacturers, among others, and seamless supply chain and logistics networks is imperative.

For policymakers and stakeholders looking to carry out similar studies or propose policies in the future for any interventions relating to any community, **we recommend the active engagement of the beneficiaries from the start and create an opportunity for them to be part of the planning from conceptualization till implementation including monitoring and feedback.**

Key development partners, such as Unitaid, the Global Fund, PEPFAR, and the ILO, among others, may contribute to catalytic donor investments. WHO and UNAIDS may provide technical support and undertake partnerships with the national and state governments in enabling and informing the scale-up of HIVST in the country. UNAIDS and WHO may also facilitate support in capacity-building of the community and create a demand for HIVST by empowering the community.

Participation from the community is also necessary for reaching KPs. This should include targeted outreach techniques to reach high-risk populations, including FSWs, MSMs, TGs and PWIDs, and the active participation of CBOs and social influencers. Systematic and meaningful engagement of communities, including PLHIV and KPs at all levels of the study implementation from the beginning, has led to the project's success. It improves accountability and ownership and empowers the community to make informed choices.

It is recommended that research be carried out to determine the technical knowledge of strategic partners and that a multistakeholder approach be developed to build the HIVST service delivery model.

Recommendation 4: Establish a robust ecosystem for an integrated HIVST supply-demand-delivery intervention

The study emphasized the need for a robust ecosystem for HIVST supply-demand-delivery and recommended the following:

- **Ensuring Availability of HIVST kits:** The CDSCO/DCGI and ICMR should expedite and simplify the approval process of regulatory approvals and ensure that the HIVST kits are available and accessible in the market like condoms, lubes, needle/syringes and other essential commodities for the prevention, testing and treatment for HIV. This would help in reaching first-time testers as well as the unreached population. This would help ensure early treatment initiation for many targeted populations.
- **Develop unified digital platforms to enable real-time monitoring of changing ecosystem:** It is recommended that a unified HIVST virtual/digital platform should be deployed that has modules for demand and order tracking, provision for uploading test results, online pre- and post-counseling by trained health care professionals or chatbots, procurement management, logistics management and tracking, interactive/self-paced training and learning, and educational videos, among others. This will provide data for decision-making and automate various functions for quick resolutions.
- **Simplify the testing process:** Streamline the self-test kit ordering process to make it user-friendly and accessible to many individuals. Develop a simple, step-by-step guide for ordering kits online, and consider alternative ordering methods for those facing technological barriers. Provide support and assistance to individuals needing help ordering or navigating the process.

- **Address privacy and confidentiality concerns:** Take measures to protect participant confidentiality and minimize stigma associated with HIVST. Ensure discreet packaging without revealing the nature of the contents. Provide information about the size and dimensions of the kit to alleviate concerns about confidentiality. Consider options for secure delivery or alternative pickup locations to further protect privacy.
- **Expand and integrate the HIVST delivery options for effective distribution among target groups:** It is recommended that HIVST be expanded into additional distribution models, such as secondary distribution for partners and pharmacy models. These might be done in research or implementation mode after the HIVST kits are certified for commercialization in India. The secondary distribution plan will ensure that all partners of the primary HIVST subject are tested. The pharmacy model will test the population who walk-in into pharmacies to access HIVST.
- **Integrating HIVST with other national programs:** The study team recommends early planning to integrate HIVST kits into the supply chain of other national initiatives that might aid in the kits' effective distribution. The study provided adequate insight into the challenges of an effective supply chain and logistics for HIVST kits, particularly the last-mile modes of delivery. The national program, with an innate understanding of the country's numerous challenges, may use the research findings to design an effective supply chain and logistics system.

Recommendation 5: Utilize communication material developed through the project for information dissemination and capacity building

The study has created many tools, HIVST messages, counseling content/videos, and relevant communication materials for HIVST. We recommend that these materials be incorporated into the NACO helpline 1097 and into the helpline counselor training module to ensure adequate preparation to handle the scale-up of HIVST in the future.

The standard operating procedures of the study may be leveraged to frame the operational guidelines for HIVST initiatives in the country. Likewise, the communication material, counseling, and demonstration videos that were developed as part of the project, tested and used to encourage the uptake of HIVST among KPs and at-risk populations may be adapted by the national program.

Furthermore, survey participants expressed, the potential HIVST manufacturers should consider the need for IFU and pamphlets in languages other than Hindi and English to increase HIVST penetration. This is a key suggestion from both the research participants and SACS representatives. The test kit package should also contain reading material for counseling on the pretest and post-test action points, as well as interpretation of test results. The test kit should also include the NACO helpline QR code, which will direct the beneficiary to the nearest ART or ICTC clinics. This would empower the recipient to seek care.

Recommendation 6: Explore future research and funding opportunities

The study is unique as it was undertaken in partnership with key communities, besides introducing HIVST to a wide spectrum of populations and through different approaches. It further substantiates HIVST as a potentially useful tool for improving testing rates and access to care for seropositive individuals, especially among vulnerable and hard-to-reach populations. However, HIVST distribution through the secondary distribution model and private pharmacy model requires further study. An assessment of these models as an effective channel for the distribution and uptake of HIV self-test kits is required. Considering the limitations of the current study on implementing HIVST through a virtual platform, a separate study is required to understand the operational feasibility of reaching the population accessing social media platforms. The findings of this study and the emerging recommendations may not be new, and more evidence-based research would be required to understand the feasibility and acceptability of HIVST kits among the communities, which can then be taken forward to introduce as a complementary approach to HIV testing in the country.

Besides, the study engaged PEPFAR and GFATM partners, which respond

to UNITAID's mandate of capacity building for these partners on HIVST. The PEPFAR partners include the CDC and USAID, while the GFATM partners include SAATHI, IHAA, and Humsafar Trust. Hence, **it is recommended that PEPFAR and GFATM include HIVST within their country plans and utilize the existing resources, such as tools, data systems, and trained human resources, to scale up HIV self-testing.**

CHAPTER 7

Conclusion

The high uptake of HIVST kits among testers underlines their acceptability and feasibility. Furthermore, nearly all users reported that the kits were easy to use and interpret, which further supports the acceptance of HIVST as a valuable option desirable for KPs and at-risk bridge populations, as well as their partners, for early detection and timely treatment-seeking behavior. This study also provides encouraging evidence for the integration of HIVST as one of the methods for enhancing coverage of testing opportunities and meeting the first 95% goal of UNAIDS' 95-95-95.

All five models showed promising results, with limited and sometimes not-so-significant differences in user response regarding usability, willingness to pay, and acceptance for future use. Therefore, it will be beneficial to consider all five approaches to expand the coverage of HIVST services. While a significant proportion of participants expressed a willingness to pay, most indicated they were willing to pay less than INR 250 for the test kits. The willingness to pay is likely affected by factors such as user experience, income, and other socio-economic characteristics, along with the perceived self-assessed risk of acquiring HIV. Other influencing factors include education levels, health insurance coverage, and comfort in encouraging sexual partners or clients to use HIVST.

From an access point of view, individuals who incur higher travel costs, among other costs, or loss of pay to get HIV tests done at ICTCs are more likely to pay for HIVST kits. While the study highlights a high level of acceptance and feasibility for HIVST in India, successfully integrating HIVST into the NACP in the country will require several key elements. These include the availability of regulated, high-quality HIV self-test kits, strong, rights-based policies and regulatory frameworks, a clearly defined pathway for referral, support, treatment, and care, and a mechanism for regularly monitoring and reporting the effectiveness of self-testing and redressing any grievances that arise.

CHAPTER 8

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ANNEX

Annex 1 a: Participant enrollment for HIVST kits based on demography, population groups, and gender

Participants enrolled			
State	Target	Achieved	% of Total
Andhra Pradesh	8,000	7,748	8.1
Delhi	5,500	4,665	4.9
Gujarat	9,000	13,124	13.7
karnataka	10,500	12,057	12.6
Madhya Pradesh	4,500	4,702	4.9
Maharashtra	16,000	7,601	7.9
Manipur	6,000	1,781	1.9
Nagaland	6,000	2,654	2.8
Mizoram	6,000	2,728	2.8
Punjab	6,000	5,727	6.0
Tamil Nadu	6,000	11,858	12.4
Telangana	13,500	10,463	10.9
Uttar Pradesh	2,500	492	0.5
West Bengal	15,000	10,325	10.8
Grand Total	114,500	95,925	100

Participants enrolled			
State	Target	Achieved	Achieved vs Target (%)
Andhra Pradesh	8,000	7,748	96.85
Delhi	5,500	4,665	84.82
Gujarat	9,000	13,124	145.82
karnataka	10,500	12,057	114.83
Madhya Pradesh	4,500	4,702	104.49

Table 1. State-wise enrollment of participants

Participants enrolled			
State	Target	Achieved	Achieved vs Target (%)
Maharashtra	16,000	7,601	47.51
Manipur	6,000	1,781	29.68
Mizoram	6,000	2,728	45.46
Nagaland	6,000	2,654	44.23
Punjab	6,000	5,727	95.45
Tamil Nadu	6,000	11,858	197.63
Telangana	13,500	10,463	77.50
Uttar Pradesh	2,500	492	19.68
West Bengal	15,000	10,325	68.83
Grand Total	114,500	95,925	83.78

Table 2. District-wise number of participants enrolled in the study

District	Participants enrolled
Andhra Pradesh	7,748
East Godavari	1,498
Guntur	1,500
Krishna	1,967
Kurnool	1,807
Visakhapatnam	976
Delhi	4,665
Delhi	4,665
Gujarat	13,124
Ahmedabad	8,216
Vadodara	4,908

District	Participants enrolled
Karnataka	**12,057**
Belagavi	843
Bengaluru	8,866
Mysuru	2,348
Madhya Pradesh	**4,702**
Bhopal	587
Indore	1,445
Jabalpur	1,147
Jhabua	617
Neemuch	664
Ujjain	542
Maharashtra	**7,601**
Ahmednagar	386
Chandrapur	921
Jalgaon	808
Mumbai	1,971
Nagpur	1,631
Nashik	853
Pune	1,031
Manipur	**1,781**
Bishnupur	119
Chandel	150

District	Participants enrolled
Churachandpur	555
Imphal East	946
Imphal West	11
Mizoram	**2,728**
Aizawl	1,493
Champhai	608
Lunglei	415
Mamit	212
Nagaland	**2,654**
Dimapur	1,160
kohima	262
Mokokchung	580
Tuensang	652
Punjab	**5,727**
Amritsar	1,278
Jalandhar	1,360
Ludhiana	3,142
Tamil Nadu	**11,858**
Chennai	11,858
Telangana	**10,463**
Hyderabad	1,532
Khammam	4,498

District	Participants enrolled
Warangal	4,433
Uttar Pradesh	**492**
Auraiya	94
Kanpur	99
Lucknow	247
Prayagraj	52
West Bengal	**10,325**
Haldia	916
Kolkata	6,420
North 24 Pargana	2,989
Grand total	**95,925**

Table 3. Population group-wise enrollment in the different HIVST models

Population group		Community -based model	PLHIV network model	Private practitioner model	Virtual model	Workplace model	Total
Key population	Female sex worker	19,508 (24.3)	24 (1.4)	295 (4.2)	38 (6.1)	-	19,865 (21.0)
	Men having sex with men	15,425 (19.2)	26 (1.6)	36 (0.5)	438 (70.6)	-	15,925 (16.8)
	Person who injects drugs	5,530 (6.9)	3 (0.2)	2 (<0.1)	-	6 (0.1)	5,541 (5.8)
	Transgender	5,228 (6.5)	3 (0.2)	2 (<0.1)	16 (2.6)	-	5,249 (5.5)
Partner/client of key population		11,081 (13.8)	24 (1.4)	41 (0.6)	19 (3.1)	7 (0.1)	11,172 (11.8)
Partner of PLHIV		1,865 (2.3)	537 (32.2)	3 (<0.1)	3 (0.5)	2 (<0.1)	2,410 (2.5)
Family member of PLHIV		-	340 (20.4)	-	-	-	340 (0.4)
Partner of PLHIV		1,865 (2.3)	537 (32.2)	3 (<0.1)	3 (0.5)	2 (<0.1)	2,410 (2.5)
Referred by a private physician		353 (0.4)	91 (5.5)	6,111 (87.5)	-	-	6,555 (6.9)
Employee of one of the participating companies		-	-	-	-	4,359 (83.6)	4,359 (4.6)
Self-identified high-risk individual		21,341 (26.6)	620 (37.2)	494 (7.1)	106 (17.1)	843 (16.2)	23,404 (24.7)
Total		80,331	1,668 (100)	6,984 (100)	620 (100)	5,217 (100)	94,820 (100)

Table 4. Population group-wise median age of participants

Population group		Median (in years)	IQR (in years)
Overall		30	26-36
Key population	Female sex worker	31	27-35
	Men having sex with men	27	23-31
	Person who injects drugs	27	23-31
	Transgender	30	25-36
Partner/client of key population		30	26-36
Partner of PLHIV		35	29-41
Family member of PLHIV		27	22-40
Referred by a private physician		32	28-38
Employee of one of the participating companies		40	32-48
Self-identified high-risk individual		32	26-38

Annex 1 b: Distribution of HIVST kits and testing

Table 5. Population group-wise distribution of the last HIV test

Population group		Never tested	0 to 12 months	12+ months	Unknown time since the last testing	Total
Overall		46,331 (48.9)	28,211 (29.8)	13,133 (13.9)	6,985 (7.4)	94,660 (100)
Key population	Female sex worker	5,193 (26.1)	11,258 (56.7)	2,925 (14.7)	487 (2.5)	19.863 (100)
	Men having sex with men	6,926 (43.9)	5,433 (34.4)	2,345 (14.9)	1,086 (6.9)	15,790 (100)
	Person who injects drugs	1,368 (24.7)	3,046 (55.0)	805 (14.5)	320 (5.8)	5,539 (100)
	Transgender	1,696 (32.4)	1,787 (34.2)	1,606 (30.7)	142 (2.7)	5,231 (100)
Partner/client of key population		7,485 (67.0)	1,410 (12.6)	1,321 (11.8)	955 (8.5)	11,171 (100)
Partner of PLHIV		804 (33.4)	772 (32.0)	738 (30.6)	96 (4.0)	2,410 (100)
Family member of PLHIV		334 (98.2)	1 (0.3)	-	5 (1.5)	340 (100)
Referred by a private physician		4,992 (76.2)	527 (8.0)	464 (7.1)	572 (8.7)	6,555 (100)
Employee of one of the participating companies		2,687 (61.6)	398 (9.1)	52 (1.2)	1,222 (28.0)	4,359 (100)
Self-identified high-risk individual		14,846 (63.4)	3,579 (15.3)	2,877 (12.3)	2,100 (9.0)	23,402 (100)

Table 6. Gender-wise distribution of study participants

Gender	Community-based model	PLHIV network led	Private practitioner model	Virtual model	Workplace model	Total
Male	52,050 (64.8)	815 (48.9)	5,633 (80.7)	529 (85.9)	5,192 (99.5)	64,219 (67.7)
Female	23,067 (28.7)	850 (51.0)	1,349 (19.3)	69 (11.2)	25 (0.5)	25,360 (26.8)
Transgender	5,148 (6.4)	3 (0.2)	2 (<0.1)	16 (2.6)	-	5,169 (5.5)
Prefer not to disclose	48 (0.1)	-	-	2 (0.3)	-	50 (0.1)
Total	80,313 (100)	1,668 (100)	6,984 (100)	616 (100)	5,217 (100)	94,798 (100)

Table 7. Population group-wise proportion of those tested HIV-reactive on HIVST

Population group		Reactive	Total tested
Overall		356 (0.4)	94,734
Key population	Female sex worker	45 (0.2)	19,837
	Men having sex with men	103 (0.6)	15,901
	Person who injects drugs	73 (1.3)	5,530
	Transgender	26 (0.5)	5,244
Partner/client of key population		12 (0.1)	11,165
Partner of PLHIV		51 (2.1)	2,403
Family member of PLHIV		0	340
Referred by a private physician		6 (0.1)	6,553
Employee of one of the participating companies		9 (0.2)	4,358
Self-identified high-risk individual		31 (0.1)	23,403

Table 8. Self-perceived risk stated by participants based on testing frequency

Self-perceived risk	High-risk	Medium-risk	Low-risk	No response	Total
First-time testers	4,425 (9.44)	17,920 (38.23)	15,965 (34.06)	8,559 (18.26)	46,869
Ever tested before	8,491 (20.41)	19,498 (46.87)	9,321 (22.41)	4,286 (10.30)	41,596
Total	12,916 (14.6)	37,418 (42.30)	25,286 (28.58)	12,845 (14.52)	88,465

*Note: 7,563 no responses for testing frequency

Annex 1 c: Testing preferences and interpretations of results

Table 9. Population group-wise HIVST kit type preference

Population group		Blood-based	Oral fluid-based	Total
Overall		47,899 (51.3)	45,538 (48.7)	93,437 (100)
Key population	Female sex worker	9,411 (47.4)	10,425 (52.6)	19,836 (100)
	Men having sex with men	6,797 (44.2)	8,584 (55.8)	15,381 (100)
	Person who injects drugs	3,661 (66.1)	1,878 (33.9)	5,539 (100)
	Transgender	2,211 (45.8)	2,612 (54.2)	4,823 (100)
Partner/client of key population		6,359 (57.8)	4,647 (42.2)	11,006 (100)
Partner of PLHIV		1,120 (46.7)	1,276 (53.3)	2,396 (100)
Family member of PLHIV		179 (52.6)	161 (47.4)	340 (100)
Referred by a private physician		4,031 (61.5)	2,524 (38.5)	6,555 (100)
Employee of one of the participating companies		2,169 (49.8)	2,190 (50.2)	4,359 (100)
Self-identified high-risk individual		11,961 (51.6)	11,241 (48.4)	23,202 (100)

Table 10. Testing modality preference for future testing by testing frequency

Testing Frequency	HIV self-testing	Community-based screening under TI	Integrated counseling and testing center (ICTC)	Private and other facilities	No response	Total
First-time testers	41,725 (89.02)	374 (0.79)	914 (1.95)	2,848 (6.07)	1,008 (2.15)	46,869 (100)
Ever testers	35,680 (85.78)	1827 (4.39)	3,030 (7.28)	458 (1.1)	601 (1.44)	41,596 (100)
Total	77,405 (87.5)	2,201 (2.49)	3,944 (4.45)	3,306 (3.74)	1,609 (1.19)	88,465 (100)

Table 11. Testing modality preference for future testing by distribution model

Model	HIV self-testing	Community-based screening under TI	Integrated counseling and testing center (ICTC)	Private and other facilities	Total
Overall	83,397 (89.4)	2,286 (2.5)	4,185 (4.5)	3,373 (3.6)	9,3241 (100)
Community-based model	71,178 (90.1)	2,263 (2.9)	4,119 (5.2)	1,450 (1.8)	79,010 (100)
PLHIV network led	1,627 (98.6)	-	21 (1.3)	2 (0.1)	1,650 (100)
Private practitioner model	5,046 (72.4)	13 (0.2)	23 (0.3)	1,890 (27.1)	6,972 (100)
Virtual model	466 (91.4)	3 (0.6)	16 (3.1)	25 (4.9)	510 (100)
Workplace model	5,080 (99.6)	7 (0.1)	6 (0.1)	6 (0.1)	5,099 (100)

Table 12. Testing modality preference for future testing by population group

Population group		HIV self-testing	Community-based screening under TI	Integrated counseling and testing center (ICTC)	Private and other facilities	Total
Key population	Female sex worker	16,577 (84.7)	1,062 (5.4)	1,594 (8.1)	339 (1.7)	19,572 (100)
	Men having sex with men	14,203 (91.0)	457 (2.9)	799 (5.1)	153 (1.0)	15,612 (100)
	Person who injects drugs	4,821 (89.1)	327 (6.0)	251 (4.6)	12 (0.2)	5,411 (100)
	Transgender	4,704 (92.7)	89 (1.8)	270 (5.3)	11 (0.2)	5,074 (100)
Partner/client of key population		10318 (94.1)	128 (1.2)	407 (3.7)	117 (1.1)	10,970 (100)
Partner of PLHIV		2,311 (96.5)	2 (0.1)	73 (3.0)	8 (0.3)	2,394 (100)
Family member of PLHIV		338 (100)	-	-	-	338 (100)
Referred by a private physician		5,280 (81.0)	6 (0.1)	32 (0.5)	1,202 (18.4)	6,520 (100)
Employee of one of the participating companies		4,232 (99.6)	7 (0.2)	5 (0.1)	4 (0.1)	4,248 (100)
Self-identified high-risk individual		20610 (89.2)	208 (0.9)	754 (3.3)	1,527 (6.6)	23,099 (100)

Annex 1 d: Ease of interpreting test results

Table 13. Ease of using the HIVST kit by testing frequency

Testing frequency	Very easy or easy	Difficult	Very difficult	Neither easy nor difficult	No response	Total
First-time testers	44,099 (94.09)	600 (1.28)	26 (0.05)	1,765 (3.77)	379 (0.8)	46,869 (100)
Ever testers	39,650 (95.32)	179 (0.43)	25 (0.06)	1,581 (3.8)	161 (0.38)	41,596 (100)
Total	83,749 (94.67)	779 (0.88)	52 (0.06)	3,346 (3.78)	540 (0.6)	88,465 (100)

Table 14. Ease of using the HIVST kit by type of test kits

Type of test kit	Easy	Not easy	Total
Blood-based	45,305 (93.9)	2,965 (6.1)	48,270 (100)
Oral fluid-based	44,566 (96.5)	1,637 (3.5)	46,203 (100)
Overall	89,871 (95.1)	4,602 (4.9)	94,473 (100)

Table 15. Ease of using HIVST kits by population groups

Population group		Easy	Not easy	Total
Key population	Female sex worker	19,221 (96.8)	632 (3.2)	19,853 (100)
	Men having sex with men	14,773 (94.1)	928 (5.9)	15,701 (100)
	Person who injects drugs	4,964 (89.9)	559 (10.1)	5,523 (100)
	Transgender	4,988 (95.5)	237 (4.5)	5,225 (100)
Partner/client of key population		1,0571 (94.8)	584 (5.2)	11,155 (100)
Partner of PLHIV		2,334 (97.0)	72 (3.0)	2,406 (100)
Family member of PLHIV		340 (100)	0 (0)	340 (100)
Referred by a private physician		6,376 (97.3)	177 (2.7)	6,553 (100)
Employee of one of the participating companies		4,350 (99.9)	4 (0.1)	4,354 (100)
Self-identified high-risk individual		21,952 (94.0)	1,409 (6.0)	23,361 (100)

Table 16. Ease of interpreting the result by kit type

Ease of interpreting the result	Easy	Not easy	Total
Blood-based	45,539 (94.4)	2,695 (5.6)	48,234 (100)
Oral fluid-based	44,286 (95.9)	1,878 (4.1)	46,164 (100)
Overall	89,825 (95.2)	4,573 (4.8)	94,398 (100)

Table 17. Ease of interpreting the result by population group

Population group		Easy	Not easy	Total
Key population	Female sex worker	19,315 (97.3)	533 (2.7)	19,848 (100)
	Men having sex with men	14,764 (94.1)	919 (5.9)	15,683 (100)
	Person who injects drugs	4,927 (89.4)	587 (10.6)	5,514 (100)
	Transgender	4,904 (94.0)	313 (6.0)	5,217 (100)
Partner/client of key population		10,560 (94.8)	585 (5.2)	1,1145 (100)
Partner of PLHIV		2,356 (97.9)	50 (2.1)	2,406 (100)
Family member of PLHIV		340 (100)	0 (0)	340 (100)
Referred by a private physician		6,378 (97.3)	176 (2.7)	6,554 (100)
Employee of one of the participating companies		4,346 (99.8)	7 (0.2)	4,353 (100)
Self-identified high-risk individual		21,933 (94.0)	1,403 (6.0)	23,336 (100)

Annex 1 e: Willingness to pay for HIVST kits

Table 18. Willingness to pay for HIVST kits by distribution model

Model	Not willing to pay	Less than 100 rupees	Between 101 and 250 rupees	Between 251 and 500 rupees	More than 500 rupees	Total
Overall	25,799 (31.8)	37,790 (46.6)	14,854 (18.3)	2,341 (2.9)	386 (0.5)	81,170 (100)
Community-based model	20,271 (29.2)	33,179 (47.8)	13,509 (19.5)	2,043 (2.9)	342 (0.5)	69,344 (100)
PLHIV network led	420 (26.1)	905 (56.2)	255 (15.8)	27 (1.7)	4 (0.2)	1,611 (100)
Private practitioner model	2,398 (47.6)	1,946 (38.7)	579 (11.5)	102 (2.0)	9 (0.2)	5,034 (100)
Virtual model	111 (25.3)	203 (46.3)	88 (20.1)	22 (5.0)	14 (3.2)	438 (100)
Workplace model	2,599 (54.8)	1,557 (32.8)	423 (8.9)	147 (3.1)	17 (0.4)	4,743 (100)

Table 19. Willingness to pay for HIVST kits by population groups

Population group		Not willing to pay	Less than 100 rupees	Between 101 and 250 rupees	Between 251 and 500 rupees	More than 500 rupees	Total
Key population	Female sex worker	5,505 (34.3)	6,519 (40.7)	3,220 (20.1)	712 (4.4)	74 (0.5)	16,030 (100)
	Men having sex with men	3,738 (27.1)	7,055 (51.2)	2,354 (17.1)	442 (3.2)	181 (1.3)	13,770 (100)
	Person who injects drugs	1,519 (32.9)	2,036 (44.0)	1,011 (21.9)	50 (1.1)	7 (0.2)	4,623 (100)
	Transgender	542 (11.6)	1,935 (41.5)	1,991 (42.7)	168 (3.6)	31 (0.7)	4,667 (100)
Partner/client of key population		3,900 (39.3)	3,900 (39.3)	1,927 (19.4)	180 (1.8)	20 (0.2)	9,927 (100)
Partner of PLHIV		551 (24.0)	1,181 (51.4)	474 (20.6)	84 (3.7)	7 (0.3)	2,297 (100)
Family member of PLHIV		257 (78.1)	72 (21.9)	0 (0)	0 (0)	0 (0)	329 (100)
Referred by a private physician		2,472 (47.0)	2,049 (38.9)	628 (11.9)	106 (2.0)	9 (0.2)	5,264 (100)
Employee of one of the participating companies		1,765 (45.3)	1,551 (39.8)	417 (10.7)	146 (3.7)	17 (0.4)	3,896 (100)
Self-identified high-risk individual		5,550 (27.3)	11,491 (56.4)	2,832 (13.9)	453 (2.2)	38 (0.2)	20,364 (100)

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