

Accelerating access and uptake of HIV self-testing in India

A demonstration project

A summary of interventions, lessons learnt and key takeaways of STAR HIV self-testing project in India





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Abbreviations

ART	Antiretroviral Therapy
CAB	Community Advisory Board
CBO	Community Based Organizations
CDC	Center for Disease Control
CDSCO	Central Drugs Standard Control Organization
CMB	Community Monitoring Board
DCGI	Drug Controller General of India
FSW	Female Sex Workers
HIV	Human Immunodeficiency Virus
HIVST	HIV self-testing
ICMR	Indian Council of Medical Research
ICMR- NARI	ICMR- National AIDS Research Institute
ICMR -NIE	ICMR- National Institute of Epidemiology
ICTC	Integrated Counselling and Testing Centre
IEC/BCC	Information Education Communication/Behavioural Change Communication
IFU	Information 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
PEPFAR	United States President's Emergency Plan for AIDS Relief
PISPAG	PATH India HIV Self Testing Project Advisory Group
PLHIV	People Living with HIV/AIDS
PrEP	Pre-Exposure Prophylaxis
PSI	Population Service International
PWID	Persons Who Inject Drugs
SACS	State AIDS Control Societies
SDG	Sustainable Development Goals

SHARE India	Society for Health Allied Research Education- India
SOC	State Oversight Committee
SOPs	Standard Operating Procedures
SSS	NACP's Sampoorna Suraksha Strategy
TCIF	Transport Corporation of India Foundation
TG/H	Transgender/Hijra population
TOT	Training of Trainers
TWG	Technical Working Group
UNAIDS	United Nations Programme on HIV/AIDS
VHS	The Voluntary Health Services
WCG IRB	WIRB Copernicus Group IRB
WTP	Willing to Pay group

STAR HIV self-testing project in India

As the HIV epidemic enters its fifth decade, India recorded more than 1.7 million new cases of HIV in the last 10 years between 2011 and 2021.¹ As per the National AIDS Control Organization (NACO), the year 2021 witnessed around 62,967 new HIV infections.² The new HIV infections in India has declined by nearly 90 percent since hitting the peak in 1997. This was possible due to evidence-based and result-oriented strategies and program interventions of NACO and partners. However, there is need to further accelerate this response to attain India's commitment to achieve the United Nations Programme on HIV/AIDS (UNAIDS) 95-95-95 targets by 2030 and end the AIDS epidemic as a public health threat by 2030 in line with Sustainable Development Goals. To attain the UNAIDS 95-95-95, i.e., 95% of those living with HIV to know their status, 95% of those who know their status to be on treatment and 95% of those on treatment to be virally suppressed, India needs to strengthen the prevention-testing-treatment-care continuum.³ Prior to introduction of HIV self-testing (HIVST) approach, reaching the "first 95" was primarily through testing strategies, like facility-based testing, community-based testing, index-testing, social network testing and partner testing.

About HIV self-testing

HIVST is a screening test, which is performed often in a private setting, either alone or with someone the person trusts, by using oral fluid or whole blood as specimen. It is an innovative approach, which is recommended by the World Health Organization (WHO) to diversify and amplify existing HIV interventions.⁴ More than 50 countries across the world have adopted HIVST as one of their testing strategies for increasing testing coverage and thus knowledge of one's HIV status.

The global HIVST policies have been informed by several studies. Evidence from various studies has not only shown that HIVST is feasible, acceptable and effective among various populations but has also highlighted that it is safe and easy to administer with minimal support. A few studies conducted in India also observed that HIVST is highly acceptable to key populations (KPs) and recommended it to be introduced for them.^{5,6} Furthermore, there is also evidence that HIVST has rarely been misused or has caused social harms that could be associated with its use.

However, to further strengthen the evidence, and to guide the implementation plan for HIVST in the Indian context, this demonstration project was proposed and implemented.

About STAR HIV self-testing project in India

The Unitaid-funded STAR HIV Self-Testing Initiative is an initiative to generate evidence for decision-making, enabling environment and catalyzing the global market for HIVST. The first phase in Malawi, Zambia and Zimbabwe generated vital information on effective, ethical and efficient distribution of HIVST products and answering 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). Built on the lessons learned and evidence from previous two phases of HIV STAR Initiatives in Africa for HIVST, the third phase of the project was implemented in India, in addition to six other countries, to understand and address the barriers to roll out of HIVST and

provide evidence of developing structures and systems for long term sustainability of HIVST in the country.

The third phase of STAR HIVST project was a multi-centric project implemented by PATH, with the support of UNITAID through Population Service International (PSI), across 50 districts from 14 states of India (Figure 1). Beginning in February 2020, the Unitaid-funded STAR HIV Self-Testing Initiative had three desired outputs –

- **Output 1: Enabling environment** created to support introduction of HIVST, including policy adoption and product registration.
- **Output 2: Service delivery models** implemented that increase the potential of 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 identification and mobilization of 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 to generate evidence to inform an HIVST policy in India. More specifically, the project aimed to –

- Assess the feasibility, acceptability, and demand for HIVST across specific population 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; and to confirmatory HIV testing and treatment services for those with HIV reactive results.
- Identify the challenges to the linkages and any social harm following HIVST.

Figure 1. The states of India where the STAR HIV self-testing project was implemented



HIV self-test kits

When the initial landscaping for HIV self-test kits was done 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 pre-qualified by WHO, namely the oral fluid-based OraQuick® and 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.

Partners in the HIV STAR project

This project was implemented by PATH through Humsafar Trust (Alpana Dange as the Principal Investigator), Solidarity and Action Against The HIV Infection in India (SAATHII), International Training & Education Centre for Health Private Limited (I-TECH), Voluntary Health Services (VHS), Society for Health Allied Research Education (SHARE India), National Coalition of PLHIVin India (NCPI+) and International Labor Organization (ILO), WHO, Indian Council of Medical Research (ICMR)-National AIDS Research Institute (ICMR-NARI), and ICMR-National Institute of Epidemiology (ICMR-NIE) as technical partner with the support of NACO, Ministry of Health, Government of India. Additionally, the project was supported by more than 200 community-based organizations (CBOs) and non-governmental organizations (NGOs) across the country.

Key initiatives to achieve the desired outputs

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

Prior to this project, HIVST was an uncharted territory in India. Although evidence-based testing strategy, implementation of HIVST has its own challenge, such as acceptability of self-tests, individuals' willingness to pay for them, ability to reach individuals not accessing conventional HIV testing, pre-test counselling, post-test counselling, and linkage to care. For the intervention to be successfully piloted in India, close working with NACO and its state counterparts, i.e., the State AIDS Control Societies (SACS) and CBOs, was required.

The project also required to have the confidence of the regulatory bodies, such as the CDSCO, as well as Department of Health Research (DHR) to validate the purpose, objectives, and approaches of the intervention, as there were no approved HIVST test kits in the country at the time of the project. The project further required the support of HIVST kit manufacturers, for them to make their kits/essential documents available for research by the project.

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, academic institutions, and technical experts. The seven core implementing partners of the project, i.e., PATH, Humsafar Trust, SAATHII, ITECH, ILO, SHARE India, and NCPI, also participated in the PISPAG. 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. Jointly chaired by 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, Dr. JVR Prasada Rao, and former Additional Director General, Central Health Services, Ministry of Health and Family Welfare, Government of India, Dr. Ashok Kumar, the PISPAG also functioned as an interlocutor between the project, policymakers, and played a key role in the processes that were essential for integration of HIVST into HIV testing in the country.

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 to 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. The CAB consisted of 18 members, invited by name and representing four KPs – Persons Who Inject Drugs (PWID), Female Sex Workers (FSW), Men who have sex with men (MSM) and Transgender/Hijra population (TG/H) – in addition to PLHIV. The chair of CAB, unlike that of PISPAG, was rotational.

The PISPAG and the CAB were national level bodies constituted by PATH for guiding the project. They met regularly, virtually due to the COVID-19 related disruptions during the project period, but never jointly. PATH ensured that the proceedings and decisions of PISPAG were shared with CAB when they met and vice versa.

State Oversight Committee (SOC) for HIV self-testing: Besides engaging the stakeholders at the national level, the project also engaged key stakeholders from the SACS, District AIDS Prevention and Control Units (DAPCUs) and representatives of 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.

SOC for HIVST was a collaboration between the government, 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. Adopting a transparent, consistent, and multi-channel communication approach, it contributed to building trust among all those involved, including government, service providers, community groups and sponsors.

Community Monitoring Board (CMB) for HIV self-testing: Understanding and acknowledging the importance of strengthening local decision-making, educating communities, and enhancing community capacity and effective community engagement for HIVST, the Community Monitoring Board (CMB) was formed at the district level for the STAR HIVST project. Comprising of leaders and vocal members from the key communities and selected by representatives of the field implementing partners (CBOs/NGOs), the CMB acted as a focal point to address the grievances of the project participants. The chair of the CMB was chosen by consensus of all members of the CMB, on a rotational basis.

Involving HIVST kit manufacturers: When the project was being conceptualized, HIVST kits were not manufactured indigenously in India. There were three WHO PQ HIVST kits available globally but only one of them had a distributor in India. The HIVST kit manufacturers required regulatory approval and test license from DCGI. PATH facilitated the consultations between local distributors and HIVST kit manufacturers, so that they can present their clinical trial protocols to DCGI for regulatory approval. As a result, the two HIVST manufacturers were able to establish local distributorship, an essential pre-condition for receiving test license from DCGI. At the time of writing this report, there were seven HIVST kit manufacturers who had received DCGI test license and one of them had received clinical evaluation protocol approval. PATH supported the manufacturers by reviewing their clinical evaluation protocols and providing them with feedback. From no interest in introducing HIVST in India to seven HIVST manufacturers, and more approaching DCGI for regulatory approval and test license, the landscape of HIVST manufacturers in India witnessed a complete turn-around.

Engaging regulatory bodies: The project obtained approval from multiple regulatory bodies as it took shape of a research project. PATH received approvals from five different regulatory bodies, before starting the HIVST pilot.

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 of ICMR and NACO. The DCGI approved the use of WHO pre-qualified HIV self-test kits – INSTI HIV Self-Test, OraQuick® HIV Self-Test and Mylan HIV Self-Test – for the project, which was archived in the Clinical Trials Registry- India (CTRI), hosted at the ICMR's National Institute of Medical Statistics and functioning under the Health Ministry's Screening Committee (HMSC) for conducting the clinical trials for HIVST. The Institutional Review Board of Humsafar Trust provided the project ethical approval for the study. The engagement of CDC and the United States President's Emergency Plan for AIDS Relief (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.

Development partners: In addition to the partnerships with CBOs and organizations representing key communities, the project also partnered with NACO's Targeted Interventions partners, ILO's workplace intervention partners, Global Fund partners, and PEPFAR partners through CDC.

By the start of field implementation phase of this project, PATH had created an ecosystem where all stakeholders – national, state and district level government bodies; organizations representing KPs at the national, state and district levels; HIVST kit manufacturers; regulatory bodies; and development partners – were aligned for exploring HIVST as a solution to enhance HIV testing capacities in the country.

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

From August to October 2021, PATH conducted a formative study to explore enablers and barriers driving demand of HIVST among high-risk groups, and the feasibility and scalability of implementing HIVST in India. Using human-centered design (HCD) thinking, the qualitative study found that there is an opportunity for HIVST to reduce stigma by minimizing the duration of interactions associated with HIV, in addition to reducing the inconvenience and opportunity cost of getting an HIV test. It also highlighted that there were perceived fears of making an error while conducting a self-test and questions around the credibility of seemingly an over-simplistic product for a deadly disease, besides drawing comparisons with confirmatory tests conducted at ICTCs.

Service delivery models for HIVST

To address these concerns and find the opportunities to enhance the feasibility, acceptability, and demand for HIVST across KPs, PATH, in consultation with members of PISPAG and CAB, identified five different distribution models:

- ▶ Community-based model
- ▶ Private practitioners' model
- ▶ Workplace model
- ▶ PLHIV network-led model
- ▶ Virtual model

The intent of the studying the five models of distribution of HIVST kits shared below was not to assess the comparative advantage of one model over the other, but to independently assess the feasibility and acceptability of each of the five models. Furthermore, these models are also non-comparable as each of them were designed to reach different population groups.

Model#1: Community-based model: This model was implemented with CBO partners and was designed to reach FSWs, MSMs, TG/H and PwIDs. Along with these, this model also aimed to reach the partners and clients of these KP groups and other self-identified high-risk groups. In this model, trained peer volunteers from the KP community conducted demand generation activities. Trained peer counsellors did the eligibility assessment, pre-test counselling, demonstration of HIVST through the use of videos and other job aids to help participants make an informed choice about their preferred HIVST kit – either oral or blood based and the preferred testing approach – assisted or unassisted. HIVST kits were provided to the project staff through the participating CBOs. Based on the result of the HIVST, the CBO followed the algorithm for post-test counselling, confirmatory test (for those who had reactive or indeterminate results with HIVST) and 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 as the lead implementing partners and around 250 field implementing CBOs.

Model#2: Private provider model: The second distribution model implemented with private providers, who were regularly providing services to patients with sexually transmitted infections (STI) and their partners, chronic visitors for skin, partners of PLHIV receiving private anti-retroviral therapy (ART), partners of newly diagnosed PLHIV in private labs, in addition to KPs and high-risk individuals accessing private services. In this model, the project recruited private providers mapped and working with NACO supported programs. Communication materials developed by the project were displayed at the clinics, including videos, for generating demand for HIVST, in addition to the project undertaking demand generation activities in areas with KPs around the selected clinics. The trained private provider conducted eligibility assessment, did pre-test counselling, demonstration HIVST through the use of videos and other job aids, and helped the participants choose an HIVST kit, either oral fluid-based or blood-based, and the mode of assistance (assisted or unassisted). PATH provided the HIVST kits to the private providers through the participating project partner. Based on the result of HIVST, the private provider and the participating project partner followed the algorithm for post-test counselling, confirmatory test (for those who had reactive or indeterminate results with HIVST) and on, treatment and care support. This model was implemented with private providers in five states – Gujarat, Karnataka, Telangana, Tamil Nadu and West Bengal – with SAATHII as the lead implementing partner.

Model#3: Workplace model: PATH collaborated with ILO partners, namely, Brihanmumbai Electric Supply & Transport Undertaking (BEST) of the Municipal Corporation Greater Mumbai (MCGM) and the Transport Corporation of India Foundation (TCIF), to extend HIVST services to formal employees, self-identified high-risk individuals, such as truckers and informal labour workforce, partners/ clients of high-risk individuals and KPs and partners of PLHIV. In this model, staff from workplace interventions with the two organizations used the Information Education Communication/Behavioral Change Communication (IEC/BCC) materials developed by the project for community awareness and demand generation for HIVST through community events and interpersonal communication and conducted the eligibility assessment. The service providers were trained to conduct pre-test counselling, demonstration HIVST through the use of videos, and other job aids, and help the participants choose an HIVST kit and their preferred mode of assistance. They also connected the HIVST users to facilities for confirmatory test, treatment and care services, depending on the result of HIVST.

Model#4: PLHIV network-led model: The PLHIV network-led model was implemented through the Network of Maharashtra People with HIV (NMP+) which is a PLHIV network under the National Coalition of People Living with HIV/AIDS (NCPI+). Through this model, HIVST was distributed through the community run pharmacy, the TAAL pharmacy, which provides subsidized ART to PLHIV and offers HIV testing and prevention services to all people at a high-risk of HIV, and through the outreach support 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 was distributed across five districts in the state of Maharashtra.

Model#5: Virtual model: The virtual model followed the digital marketplace approach. The project developed the www.sahayindia.org website for potential participants to visit and order test kits from. The project ran a digital campaign and reached out to potential members of KPs, high-risk individuals, their partners as well as the partners of PLHIV through search engine optimization and social media promotion through platforms, such as Facebook, Instagram, and others.

Interested participants were guided to the SAHAY India website. On the landing page of the website, eligibility assessment was conducted, participants' status was digitally validated, their consent was taken online, and a unique user identification (UID) was generated. The participants could then virtually place order for the HIVST kit of their choice and had the choice of ordering the test kit through courier or visit a nearby project site for in-person pickup. The test kit was couriered to them along with IEC materials and information for use (IFU), after an online pre-test counselling. For in-person pickups, participants would receive pre-test counselling in person and seek HIVST through assisted or unassisted mode. Both types of participants, those receiving the HIVST kits online, and those undertaking the HIVST from a project site, were followed-up for results, and post-test counselling and were encouraged to share the test results with the appropriate health service provider.

Inclusion and exclusion criteria

Any person more than or equal to 18 years of age, able and willing to give written informed consent, were considered eligible for the study. Illiterate participants could be enrolled in presence of a witness trusted by the participant. Additionally, participants had to identify themselves as a member of a KP group (MSM, FSW, PWID, TG/H), a partner or client of a KP, a partner of PLHIV, as an employee of a participating industry, or a referral by a collaborating private practitioner to be eligible for inclusion in the study. Participants who identified themselves at risk of HIV were also considered eligible for inclusion in the study. Additionally, participants for the virtual model had to provide a verifiable phone number to be included in the study.

Furthermore, anyone who reported as a known case of HIV-positive, on ART at the time of the study, had taken pre-exposure prophylaxis (PrEP), or was pregnant were excluded from the study. Participants who were enrolled once in the study were not eligible for re-enrolment, unless there was a compelling reason for retesting. Additionally, participants who reported that they have undergone test recently for Hepatitis B, Hepatitis C, or Human T-lymphotropic Virus (HTLV) were not eligible to use the oral fluid-based OraQuick® test kit.

Capacity strengthening

PATH strengthened the capacities of peer educators, counsellors, and service providers engaged in this project through a cascading training model. PATH developed a detailed learning resource package (LRP) consisting of training modules, facilitators guide, implementation protocols, standard operating procedures, IEC/BCC materials, IFU, and other learning materials. This was then used during a 3-day training of trainers (TOTs) from all implementation partners. The master trainers further trained the field-level implementation staff through a series of trainings, where members of PATH, and representatives of CAB and SOCs were present to mentor and guide the training roll-out.

PATH and members of the implementing partners, based on the findings and results of the online assessment, conducted refresher training or provided one-on-one mentoring support. All training participants were encouraged to respond to a set of questions on a Google form, which was analyzed to understand the thematic areas, where the learning required further reinforcement through virtual support and mentoring.

Furthermore, state managers, and members of CAB, SOC, and CMB visited the project sites to give supportive supervision for implementation.

Communication strategy

Encouraging members of KPs, self-identified high-risk individuals, partners of high-risk individuals, and PLHIV, among others, to become knowledgeable about HIVST and accept it for use was a key component for improving demand, feasibility, and acceptability of HIVST. PATH, using the findings of the formative assessment and with support of a communication agency, conceptualized, designed, field-tested and developed a [communication package](#). The package consisted of taglines, IFU in print and videos, counselling videos, and point-of-use promotional products, among others. These products were first developed in Hindi, and then further translated into seven regional languages 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 were shared with implementing partners and their staff during trainings, site visits, and virtual mentoring sessions, and they were oriented on its use.

Independent site evaluation

SHARE India, one of the implementing partners, conducted site evaluations of 10% of the project sites to monitor and report on adherence to the protocols for the study. The site monitoring was conducted using a standardized checklist and with prior information to the implementing partners. The checklist monitored adherence to SOPs at the project site and individual staff levels. Any deviations from the protocols were reported using a standardized site monitoring report on a Share India microsite within 24 hours, with PATH mandated to take actions and submit an action taken report within another 24 hours of receiving the report. Corrective actions in the form of training, and virtual and onsite mentoring were taken in case of minor deviations. However, if any site reported a score of less than 75% on the monitoring checklist, then the implementation at that site was immediately stopped. The staff members were then required to undergo intensive training. After the training an assessment was conducted, and only after the staff passed this assessment, they were allowed to restart distribution.

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

The capacity strengthening of various implementing partners – PEPFAR partners, Global Fund partners, ILO partners, NACO's TI partners, besides the other implementing partners of this project has provided the foundation for rapid scaling up of HIVST in India.

PATH has initiated the writing of scientific papers and publishing the findings of the project in peer reviewed scientific journals to contribute to the growing knowledge base on HIVST. Besides this, we are in the process of disseminating the findings, lessons from this project and the conclusions on the national, regional, and global platforms.

However, the biggest impetus to scaling up HIVST in India is the level of interest and attention HIVST is gaining in the national policy discourse. NACO's Technical Working Group (TWG) has published a white paper on HIVST. Moreover, the National AIDS Control Plan, Phase V (NACP 5) has indicated the roll-out of self-testing as one of its deliverables. This intent has been reiterated in the Sampurna Suraksha Strategy (SSS) of NACP-5. Furthermore, the virtual intervention strategy under NACP-5 further underpins the national commitment to enhancing access to HIVST.

Challenges and its mitigation

The project experienced a few challenges, right from its start. Some of the challenges were due to the novelty of HIVST testing and the lack of familiarity with the study procedures, while others were either administrative or part of the learning process. All challenges to the project were rigorously analyzed for their root causes and mitigation strategies were evolved in consultation with PISPAG and CAB and implemented.

Time-consuming approval processes: HIVST was new to India. There were no approved manufacturers, no clear policy guidelines or protocols and no studies conducted earlier on HIVST in the country. When PATH initiated the project to understand the demand, feasibility, and acceptability of HIVST in the country, there was no precedence in the country to learn from. As a result, PATH learnt on the way that a project to evaluate a new scientific technique or a new technology required several different approvals (from national to global ethics committees), regulatory approval, and test licenses, among others. However, each of the approvals was essential for the study to happen. In this case, this entire process of getting all necessary approvals took over 18 months of the project time.

Community engagement and ownership: Besides the technical approvals, PATH laid emphasis on community ownership and their engagement. As various communities were participating in the project, they also had different needs and understanding of the project. Ensuring that all expectations of all stakeholders are aligned with the project objectives and their considerations are incorporated in the study protocols required several rounds of active engagement and iterations. This was done by establishing committees of representatives from the communities and engaging them in all stages of project implementation. Furthermore, the project team presented the project implementation design to the Community System Strengthening Technical Working Group, which has representation of key communities and received their concurrence to implement with CBOs and key communities' representatives. All study products – protocols, tools and communication and training package were reviewed by the CAB, with the SOCs and CMBs playing an active role in overseeing the on-ground implementation. Furthermore, they were involved in reviewing and approving the consent form for participants, ensuring that the key concerns of affected communities.

Study tools, communication package and consent form in multiple languages: The project had initially visualized the consent forms, study tools, communication packages, and all tools in Hindi. Acknowledging that the participants, peer educators and service providers need to be familiar and comfortable with the tools provided to them for the study, PATH got their entire study toolkit translated, and the final products were made available in eight languages, namely, Hindi, English, Marathi, Gujarati, Kannada, Tamil, Telugu, and Bengali. This was a time-consuming process, which required several rounds of review and iterations before the tools were customized to local requirements and approved by NACO, the PISPAG and CAB for use in the project.

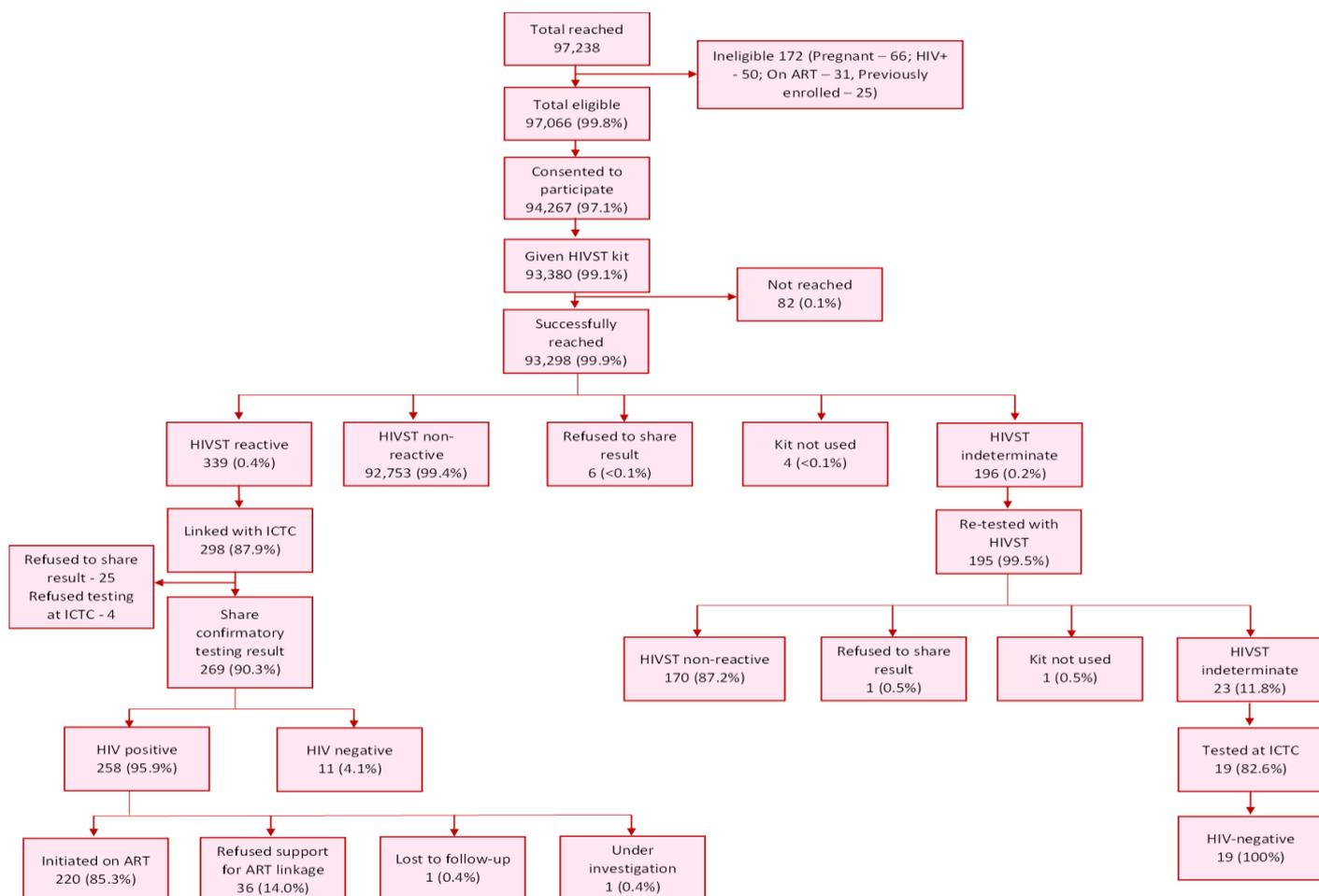
Limited resources: The scope of the study expanded significantly from the original, approved proposal, as newer tasks, such as translations and a wider range of stakeholder engagement got added to the project mandate. The project had limited resources to accommodate these additions. CDC through PEPFAR stepped up and absorbed the cost of training, in addition to supporting the implementation and monitoring of HIVST activities in their cluster districts. Other partners, such as ILO, chipped in with smaller sized grants and helped the rollout of HIVST pilot in workplace settings.

Key results

Enrolment

The study staff conducted eligibility assessment for a total of 97,238 participants. Among these, 172 participants were found ineligible to receive the HIVST kit. Among the ineligible participants, 66 were pregnant, 50 were known HIV-positive cases, 31 reported to be on ART, and 25 returned to be reincluded. Overall, 2,799 participants refused to be enrolled. In total, 94,267 participants were included in the study. The study cascade is detailed in Figure 2.

Figure 2: Study cascade



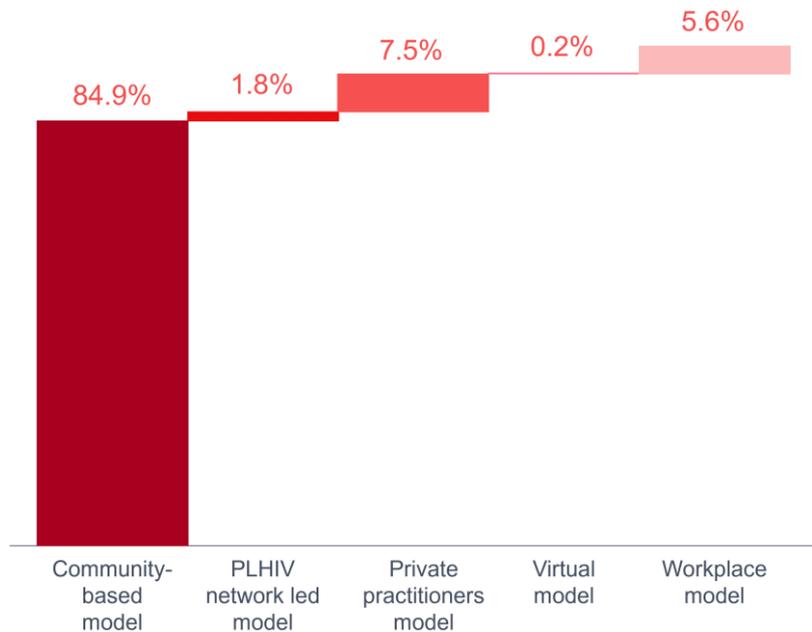
Among the 94,267 participants who were enrolled, 93,380 participants received the HIVST kits. Among the 889 who enrolled but did not get the test kits, 518 were enrolled through the workplace model, 267 through the virtual model, 84 through the community-led model, 17 through the PLHIV network-led model, and three from the private practitioner model.

Overall, 96.2% (93,380/97,066) of eligible participants accepted HIVST kits.

Model-wise enrolment

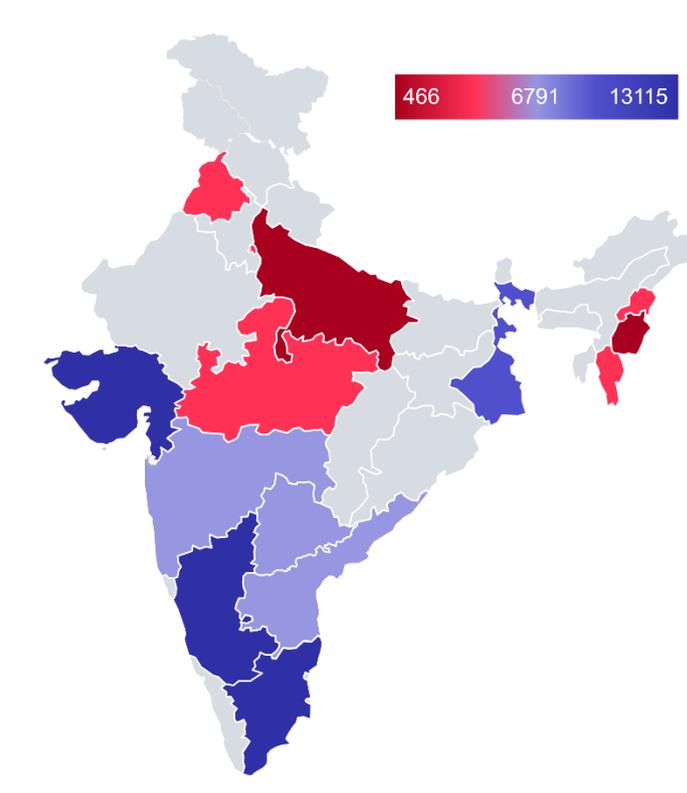
The community-based model enrolled 79,324 participants (Figure 3). The private practitioner model contributed to 7.5% (6,984) of the enrolment, followed by the workplace model (5.6%), PLHIV network-led model (1.8%) and virtual model (0.2%).

Figure 3: Model-wise enrolment (N=93,380)



Among the 14 states where the enrolment was carried out, most participants were enrolled from Gujarat (14.0%), followed by Karnataka (12.9%) and Tamil Nadu (12.0%) (Figure 4). Distribution started in Uttar Pradesh in June 2022 and 466 participants were enrolled.

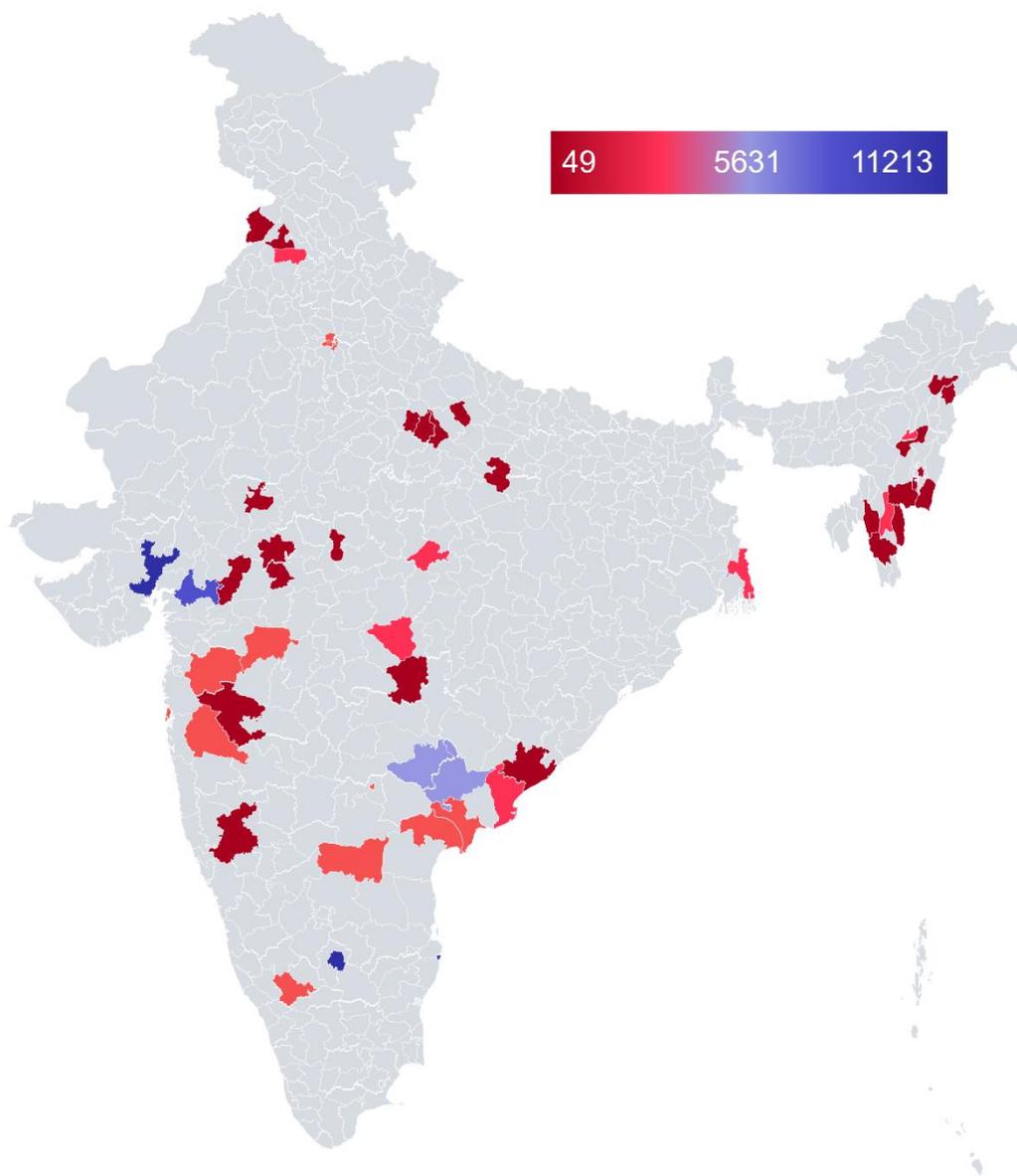
Figure 4: State-wise enrolment



Model-wise enrolment per state: The community-based and the virtual models were implemented in all 14 states. The private practitioner model was implemented in five states, namely, Karnataka, Telangana, Tamil Nadu, Gujarat, and West Bengal. The PLHIV network-led model was implemented only in Maharashtra. The workplace model was implemented in Punjab, Maharashtra, Karnataka, and West Bengal. Highest recruitment for the community-based model happened in Tamil Nadu (13.8%), closely followed by Karnataka (13.3%). In the private practitioner model, most recruitment was from the states of Telangana (42.7%) and Gujarat (40.5%). The PLHIV network-led model was implemented only in Maharashtra. The virtual model saw major contribution from Gujarat (46.5%) and Andhra Pradesh (33.2%). The workplace model saw significant enrolment from Maharashtra (35.3%) and Punjab (31.0%).

District-wise enrolment: The study was implemented in 50 districts across the 14 states. The district-wise distribution is shown in Figure 5.

Figure 5: District-wise test kit distribution



Gender-wise distribution

Overall, 63,341 (67.8%) of participants who were given the test kits identified themselves as males, 25,248 (27.0%) identified as females, and 4,742 (5.1%) identified as transgender (Figure 6). A small proportion of the participants (949, 0.1%) preferred not to disclose their gender. Most transgender people (41.6%) were enrolled from Delhi and Tamil Nadu. Model-wise, there were differences in the gender-wise enrollment (Figure 7). Almost all participants enrolled (99.5%) through the workplace model were men, while, in the PLHIV network-led model that targeted partners of PLHIV, 51% enrolled were women.

Figure 6: Gender distribution (N=93,351)

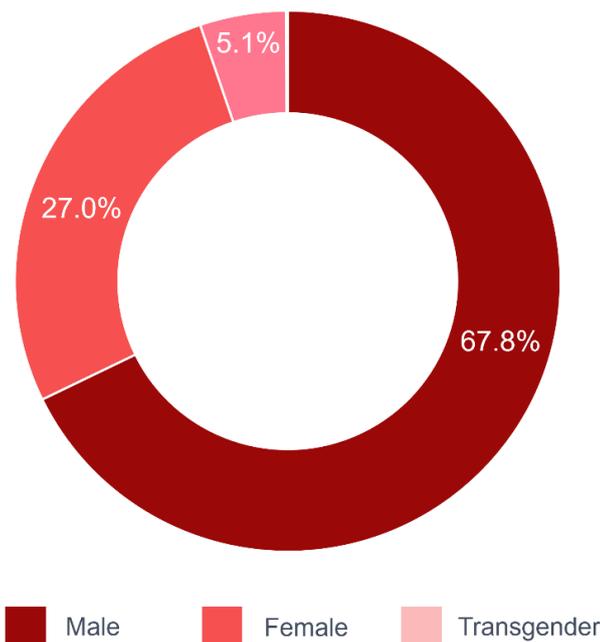
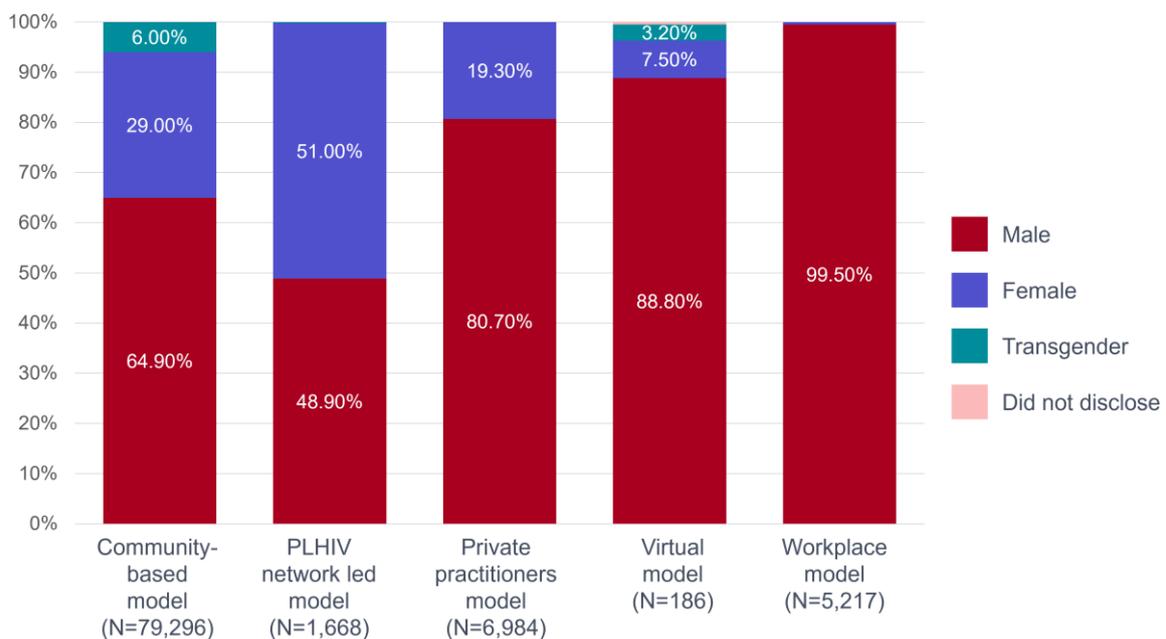


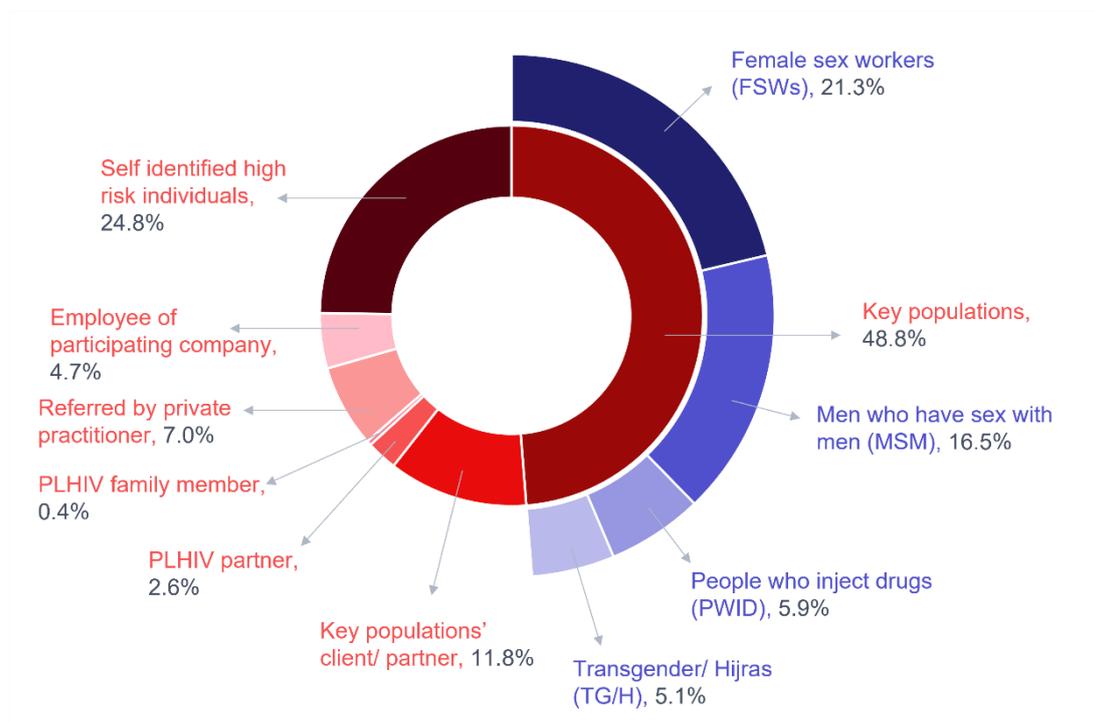
Figure 7: Model-wise gender distribution



Population groups

The highest proportion of participants included in the study identified themselves at a high risk of HIV (24.8%) (Figure 8). Almost half (48.8%) of the participants identified themselves as belonging to one of the KP groups, with FSWs being the highest.

Figure 8: Population group wise enrolment (N=93,351)



The population groups enrolled per model depended on the target population for each of these groups (Table 1). The community-based model reached all the four KP groups, their partners and clients, and self-identified high-risk individuals. More than half (52.2%) the participants in the PLHIV network-led model were partners or family members of PLHIV. The virtual model reached mainly to MSMs (78.5%).

Table 1: Population group wise enrolment (in percentage)

	Female sex worker	Men who have sex with men	People who inject drugs	Trans-gender/ Hijra	KP client/ partner	Partner of PLHIV	Family member of PLHIV	Referred by a private practitioner	Employee of participating industry	Self-identified high risk
Community-based model (N=79,296)	24.6	19.1	7.0	6.0	13.8	2.3	0.0	0.4	0.0	26.7
PLHIV network-led model (N=1,668)	1.4	1.6	0.2	0.2	1.4	32.2	20.4	5.5	0.0	37.2
Private practitioner model (N=6,984)	4.2	0.5	0.0	0.0	0.6	0.0	0.0	87.5	0.0	7.1
Virtual model (N=186)	4.8	78.5	0.0	3.8	0.0	0.5	0.0	0.0	0.0	12.4
Workplace model (N=5,217)	0.0	0.0	0.1	0.0	0.1	0.0	0.0	0.0	83.6	16.2
Total (N=93,351)	21.3	16.5	5.9	5.2	11.8	2.6	0.4	7.0	4.7	24.8

Age

The median age of participants enrolled in the study was 30 years (IQR: 26-36 years). Model-wise, majority of the participants enrolled through the community-based model (72.1%) were less than 35 years old, with a model median age of 30 years (IQR: 25-35 years) (Table 2).

The virtual model reached a younger age group of participants with a median age of 28 years (IQR: 24-33 years). In the private practitioners' model, 83.1% of participants were in the age group of 25-44 years, and the median age was 32 years (IQR: 24-33 years). For the PLHIV network-led model, 78.6% participants were less than 45 years old, and the median age was 32 years (IQR: 24-42 years). The workplace model had participants from with a higher age group, and the median age for participants from this model was 40 years (IQR: 33-46 years).

Table 2: Model-wise age distribution of participants (in percentage)

	18-24 years	25-34 years	35-44 years	45-54 years	>54 years
Community-based model (N=79,296)	20.4	51.8	23.0	4.5	0.4
PLHIV network-led model (N=1,668)	25.5	29.6	23.6	14.8	6.6
Private practitioner model (N=6,984)	10.9	51.6	31.4	6.0	0.0
Virtual model (N=186)	26.9	52.7	18.3	2.2	0.0
Workplace model (N=5,217)	4.5	24.1	41.7	20.7	8.9
Total (N=93,351)	18.9	49.8	24.7	5.7	1.0

First time testers

Overall, 45,729 (49%) of the study participants reported that they had never tested for HIV before. The proportion of first-time testers was highest in the private practitioners' model with 75% participants reporting testing for the first time, followed by the PLHIV network model with 68.6% participants reporting testing for the first time as part of this project. Model-wise proportion of first-time testers is shown in Table 3.

Table 3: Model-wise distribution of first-time testers (in percentage)

	Last HIV test			
	Never tested	0–12 months	12+ months	Unknown
Community-based model (N=79,322)	45.1	33.9	14.7	6.3
PLHIV network-led model (N=1,668)	68.6	10.6	17.4	3.5
Private practitioner model (N=6,984)	75.0	10.1	7.1	7.9
Virtual model (N=173)	41.0	4.6	4.0	50.3
Workplace model (N=5,217)	67.8	7.6	1.0	23.5
Total (N=93,364)	49.0	30.2	13.4	7.4

Among the KP groups, highest proportion of MSM (43.0%) reported to be never tested before. Among all population groups, 98.2% family members of PLHIV reported to be first-time testers (Table 4).

Table 4: Population group-wise distribution of first-time testers (in percentage)

		Never tested	0–12 months	12+ months	Unknown
Key populations	Female sex worker (N=19,840)	26.1	56.7	14.7	2.4
	Men who have sex with men (N=15,375)	43.0	35.1	14.9	6.9
	People who inject drugs (N=5,440)	24.7	55.0	14.5	5.8
	Transgender/Hijra (N=4,770)	34.2	37.2	25.6	3.0
KP client/partner (N=11,008)		67.9	12.8	10.7	8.6
Partner of PLHIV (N=2,398)		33.4	32.1	30.4	4.0
Family member of PLHIV (N=340)		98.2	0.3	0.0	1.5
Referred by a private practitioner (N=6,555)		76.2	8.0	7.1	8.7
Employee of participating industry (N=4,359)		61.6	9.1	1.2	28.0
Self-identified high risk (N=23,151)		63.2	15.4	12.4	9.0
Total (N=93,336)		49.0	30.2	13.4	7.4

Acceptability of HIVST for next test

Overall, 88.2% (82,308/93,371) participants reported that they would prefer HIVST for their future HIV testing needs. This proportion of those preferring HIVST was highest among participants from the PLHIV network-led model (97.5%: 1,627/1,668) and the workplace model (97.4%: 5,080/5,217). The proportion of those preferring HIVST for future testing was 88.7% (70,391/79,317) for the community-based model, 88.6% (164/185) for the virtual model, and 72.3% (5,046/6,984) for the private practitioners' model (Table 5).

Among KP groups, 86.8% participants reported that they would prefer HIVST for their future testing needs over other testing modalities, while among other high-risk groups, 89.4% participants reported that they will prefer HIVST. Among the other high-risk groups, almost all family members of PLHIV (99.4%), 95.9% partners of PLHIV, 97.1% employees, and 92.6% partners of KPs mentioned that they will prefer HIVST over other testing methods.

Table 5: Population group-wise HIVST acceptance for next testing (in percentage)

		HIVST	ICTC	CBS	Private	Others	No response
Key populations	Female sex worker (N=19,839)	83.4	8.0	5.3	1.7	0.0	1.5
	Men who have sex with men (N=15,385)	89.6	5.1	3.0	0.8	0.1	1.4

People who inject drugs (N=5,440)	87.0	4.5	5.9	0.1	0.2	2.3
Transgender/Hijra (N=4,771)	91.8	5.6	1.9	0.2	0.0	0.6
KP client/partner (N=11,004)	92.6	3.7	1.2	1.1	0.0	1.4
Partner of PLHIV (N=2,398)	95.9	3.0	0.1	0.3	0.0	0.7
Family member of PLHIV (N=340)	99.4	0.0	0.0	0.0	0.0	0.6
Referred by a private practitioner (N=6,555)	80.5	0.5	0.1	18.3	0.0	0.5
Employee of participating industry (N=4,359)	97.1	0.1	0.2	0.1	0.0	2.5
Self-identified high risk (N=23,151)	88.1	3.2	0.9	6.6	0.0	1.2
Total (N=93,342)	88.1	4.5	2.4	3.6	0.0	1.4

Ease of using the test kit and ease of conducting the test

Overall, 95.0% (88,695/93,380) participants found the test kits easy to use (Figure 9). This proportion was 99.2% (1,655/1,668) among the PLHIV network model and 99.8% (5,204/5,217) among the workplace model. This proportion was 74,837/79,324 (94.3%) in the community-based model, 6,816/6,984 (97.6%) in the private practitioner model, and 183/187 (97.9%) in the virtual model. While a high proportion of participants found the test kit easy to use, a significantly higher proportion of the participants who used the oral fluid-based test kit (96.3%) found the test kit easy to use compared to those who use the blood-based test kits (93.7%) ($p < 0.001$). The ease of usability was consistently above 93% across population groups with only 89.6% of PWIDs reporting easy of using the test kits (Figure 10).

Figure 9: Users who found HIV test kit easy to use, by kit type and total (in percentages)

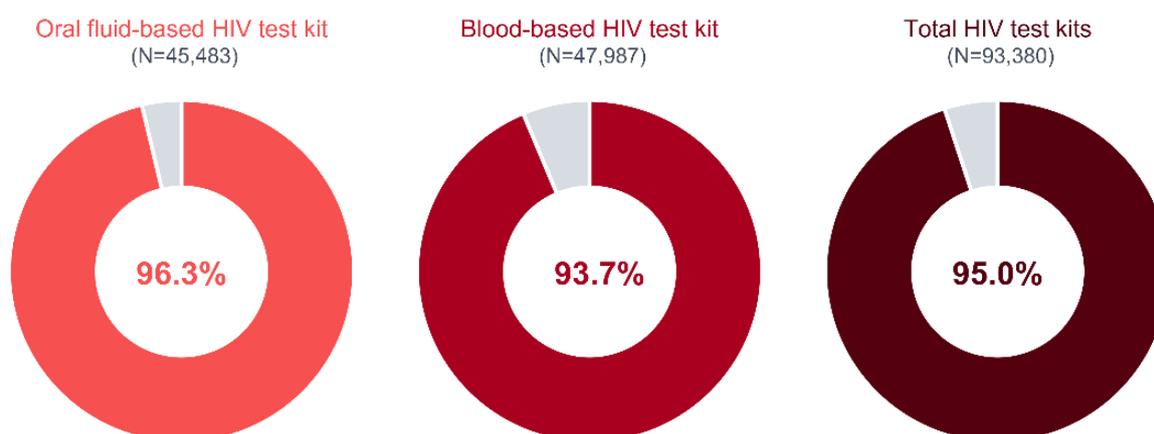
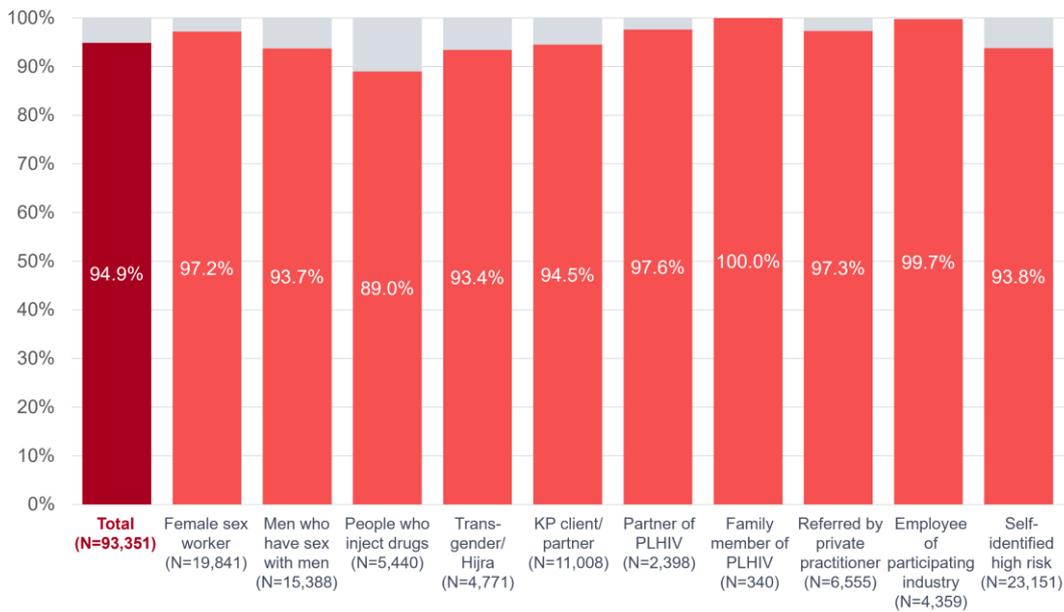


Figure 10: Users who found HIV test kit easy to use, by population groups and total (in percentages)



Ease of interpreting the result

Overall, 94.9% (88,648/93,380) participants reported that they found the test result easy to interpret (Figure 11). This proportion was 94.3% (74,800/79,324) in the community-based model, 98.9% (1,649/1,668) in the PLHIV network-led model, 97.7% (6,824/6,984) in the private practitioner model, 99.7% (5202/5217) in the workplace model, and 92.5% (173/187) in the virtual model. Among participants who used the blood-based HIVST, 94.2% reported the test to be easy to interpret, while the corresponding numbers for those using the oral fluid-based test was 95.7%. Among population groups, except PWIDs – among whom 89.0% reported finding the test result easy to interpret – a high proportion of participants (>93%) from all other population groups reported the results as easy to interpret (Figure 12).

Figure 11: Users who found it easy to interpret the result of HIV self-test kit, by kit type and total (in percentages)

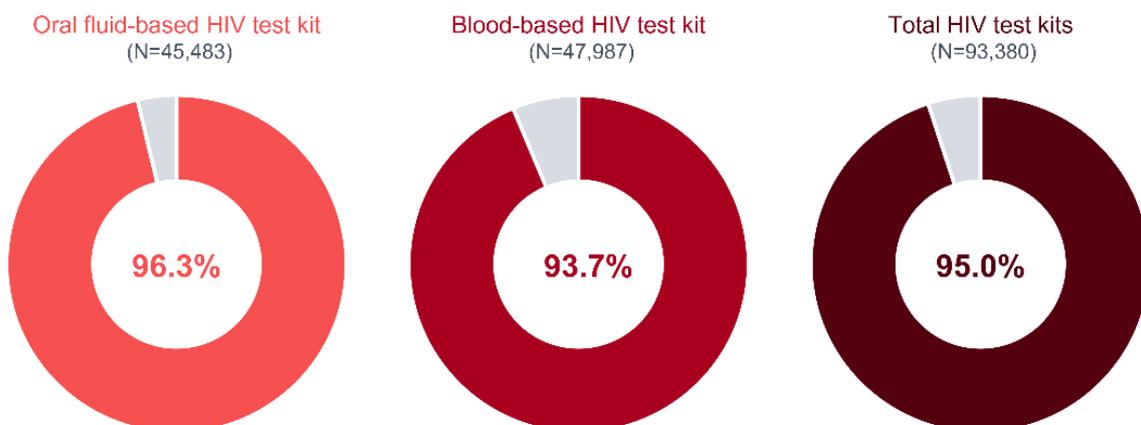
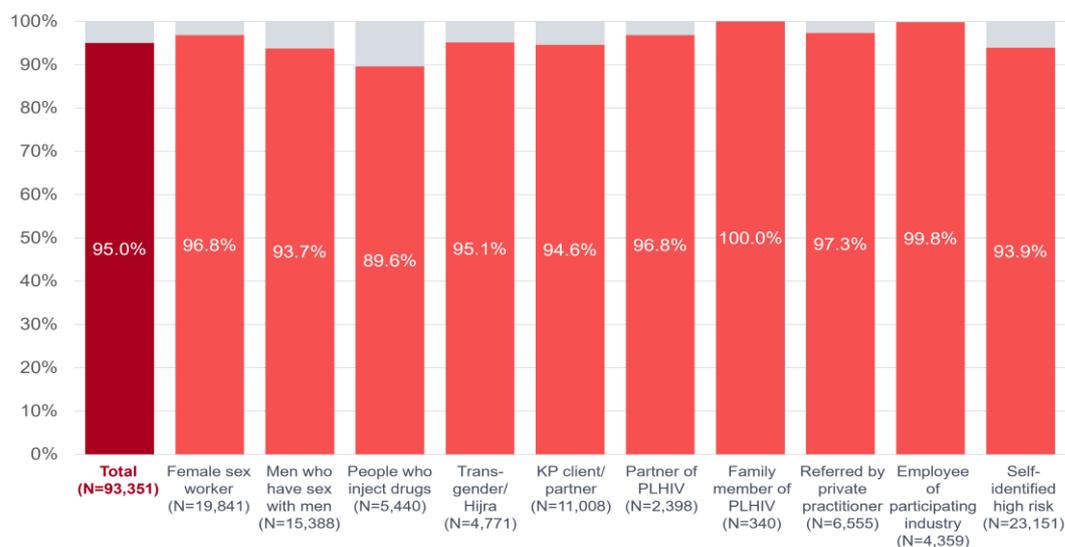


Figure 12: Users who found easy to interpret the HIV self-test results, by population groups and total (in percentages)



Willingness to pay

Among those participants who preferred HIVST for the future, 67.9% (54,407/80,112) participants reported that they were willing to pay to use HIVST in the future. This result significantly differed between models, with 77.9% participants from the virtual model, 73.9% from the PLHIV network-led model, 70.5% from the community-based model, 52.4% from the private practitioners' model, and 45.2% participants from the workplace model reported willingness to pay for the HIVST kits (Figure 13). The willingness to pay also differed for different population groups and ranged from 87.7% among transgenders to 21.9% among family members of PLHIV (Figure 14).

Among those willing to pay, 45.6% (37,506/54,407) reported willingness to pay less than INR 100, while 26.3% (14,307/54,407) were willing to pay between INR 101 and 250.

Higher proportion of participants who reported preferring blood-based HIVST in future reported willingness to pay (70.1%) compared to 65.5% among those preferring oral fluid-based testing.

Figure 13. Willingness to pay, by models (in percentages)

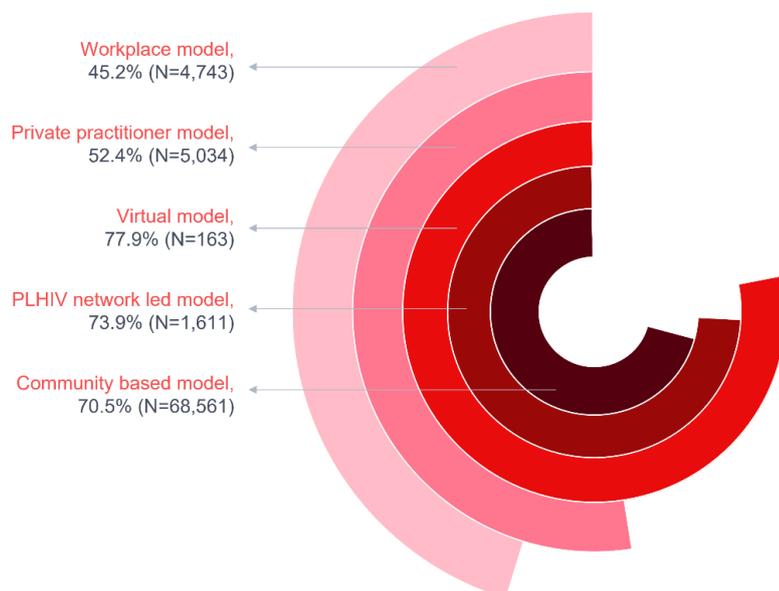
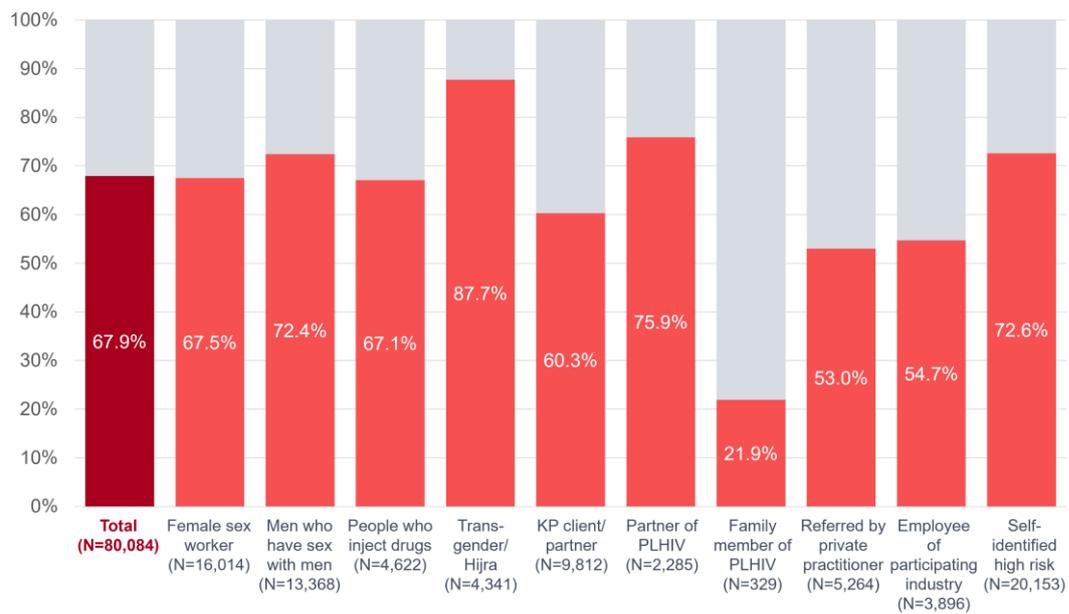


Figure 14: Willingness to pay, by population groups and total (in percentages)



Social harms

A total of 1,266 (1.4% of 93,380) reported feeling anxious about the potential result while conducting the test, and 1,286 (1.4%) reported feeling fear about the possibility of having to disclose their HIV result. Three participants reported feeling concerned that they might lose their job if they test HIV-positive.

One participant reported suicidal tendencies after testing HIV-positive and was linked with appropriate counselling services.

Recommendations

HIVST has proved that it is 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 had not reached the HIV testing facilities so far, irrespective of their risk behavior and risk perception.

Through the Unitaid-funded 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 and 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, 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 for implementation organizations and to further access to HIV/AIDS testing opportunities and for widening the response to the AIDS epidemic.

Recommendations for the national policies and programs

Recommendation 1: HIVST may be explored as an additional testing strategy and for policy design by the national program, considering the in-country evidence. Furthermore, the findings of the study provide encouraging evidence for prioritizing self-testing for populations such as discordant partners, repeat testers, and self-identified high-risk populations who are reluctant to go frequently to conventional testing facilities, among others. The study had also demonstrated five different approaches for reaching individuals and delivering kits at their convenience, which could be adapted by the national program. In order to further expand the coverage of HIVST, the government may consider introducing subsidized HIVST kits through social marketing initiatives.

Recommendation 2: The Standard Operating Procedures (SOPs) of the study may be leveraged for framing the operational guidelines for HIVST initiatives in the country. Likewise, the communication material, counselling and demonstration videos that were developed as part of the project and tested and used to encourage uptake of HIVST among KPs and at-risk populations may be adapted by the national program.

Recommendations for development partners

Recommendation 3: Key development partners, such as the Unitaid, the Global Fund, PEPFAR and the ILO, among others, may contribute catalytic donor investments, and 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 creating a demand for HIVST by empowering the community.

Recommendations for HIV self-testing kit manufacturers

Recommendation 4: There is demand for both oral fluid-based self-test kits as well as for blood-based self-test kits. The preference for the test kit type is determined by many underlying factors.

The manufacturers should consider introducing both types of HIV self-test kits to ensure wider acceptance and utilization of HIVST approaches.

Furthermore, while a large share of study participants showed willingness to pay for HIVST, the study also found that there are many intrinsic and extrinsic factors that would determine the price most of the population is willing to pay. Manufacturers should offer the price at which most people from the at-risk population and KPs are likely to purchase.

In spite of the pricing at which many are able to buy and self-administer the test using HIV self-test kit, a segment of KP and at-risk population may still miss out. Manufacturers may consider collaborating with the government to introduce subsidized HIV self-test kits through social marketing initiatives.

Research recommendations

Recommendation 5: HIVST distribution through secondary distribution model and private pharmacy model requires further study and assessment as an effective channel for distribution and uptake of HIV self-test kits. Considering the limitations of the current study on implementing HIVST through virtual platform, another study is required for understanding the operational feasibility for reaching the population accessing social media platforms.

The findings of this study and the emerging recommendations may not be new, and there have been prior incremental moves to enhance understanding the feasibility and acceptance of HIV self-test kits and to introduce them as a complementary approach to HIV testing in the country. However, 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.

Conclusion

The high uptake of the HIVST kits among testers underlines its acceptability and feasibility. Furthermore, the ease of using the kit and interpreting the result as expressed by nearly all the users further provides ground for acceptance of HIVST as an option desirable among KPs as well as at-risk bridge population and their partners for early detection and enabling timely treatment-seeking behavior. The study also presents encouraging indication 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.

As all the five models showed promising results, with limited and sometimes not-so-significant differences in responses from the users on usability, willingness to pay and acceptance for future use, it will be beneficial to consider all five approaches for expanding the coverage of HIVST services.

While a high proportion of participants reported willingness to pay, most participants reported willing to pay less than INR 250 for the test kits. The willingness to pay is likely to be affected by user experience, their income and other socio-economic characteristics and perceived self-assessed risk of acquiring HIV, among other factors, such as levels of education, health insurance coverage, and comfort in encouraging their sexual partners or clients to use HIVST. From an access point of view, those who will incur higher cost of travel, among other costs, or loss of pay to get HIV test done at ICTCs are more likely to pay for HIVST kits.

While the study has demonstrated the high levels of acceptance and feasibility of HIVST in India, the successful integration of HIVST in the NACP in the country would require availability of regulated high-quality HIV self-test kits, strong, rights-based policy and regulatory frameworks clearly defined pathway for referral, support, treatment and care, and a mechanism to regularly monitoring and report on effectiveness of self-testing and redressal of any grievances.

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Our partners

