HIV Self-Testing

Increasing access by optimizing quality, choice, and convenience

Our capabilities

PATH has been active in HIV prevention and care since 1987, adopting an early focus on HIVST research and development. This focus has evolved over time to include target product profiling, evaluating product performance, fostering an enabling regulatory environment, and product introduction and in-country scale-up. Our expertise includes:

- *Advancing the next generation* of HIV self-tests, through new prototypes or improvements to existing HIVST kits, and generating user insights and personas.
- *Collaborating with manufacturers* to facilitate World Health Organization prequalification of new products and local registration of self-test kits.
- *Shaping markets* for introduction and scale-up of HIVST kits by conducting research on consumer preferences and willingness to pay, identifying optimal distribution channels, and conducting cost-effectiveness and impact modeling to strengthen the investment case.
- *Scaling uptake* of and access to HIV self-tests by leveraging virtual, private-sector (pharmacies), and at-home (peer-delivered, courier, or mail) delivery channels and community/health facility linkages.

HIV self-testing (HIVST) gives people—often first-time or infrequent HIV testers from underserved populations—a tool to know their HIV status. With HIVST, individuals can collect their own specimens (oral fluid or blood), perform an HIV test, and interpret the result, in a setting of their choosing. Especially in areas where the HIV epidemic is concentrated among key populations—such as men who have sex with men (MSM), transgender women, people who inject drugs (PWID), and female sex workers (FSW)—and among young people and men, HIVST helps users overcome perceived and real barriers to provider-based HIV testing, including stigma and discrimination. HIVST provides a quick and confidential testing option and reflects PATH's efforts to promote increased access to health care tools as part of self-care. Introduction and scale-up of innovative HIVST programs like those supported by PATH have accelerated new HIV case detection and linkages to antiretroviral therapy (ART) as well as increased uptake of pre-exposure prophylaxis (PrEP) and voluntary medical male circumcision.

What we do

HIVST research and design

PATH's contributions have increased the global community's understanding of what features improve acceptability and usability of HIVST kits among different populations. In 2014, for example, PATH created HIVST target product profiles through an extensive process including literature reviews, key

Mailing Address
PO Box 900922
Seattle, WA 98109 USA

Street Address
2201 Westlake Avenue
Suite 200
Seattle, WA 98121 USA

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informant interviews, lab-based rapid kit performance tests, and usability assessments with naive users in sub-Saharan Africa. Target product profile results have informed subsequent HIVST design improvements, such as how samples are collected and transferred to test devices, how test kits are packaged, how instructions are presented, and how clients should interpret results. These improvements have led to more acceptable and effective HIVST kits being available for users.

HIVST development and validation

PATH has implemented field evaluations of HIVST products to support World Health Organization (WHO) prequalification processes. Performance and usability data generated under the President's Emergency Plan for AIDS Relief/US Agency for International Development (USAID)–funded, PATH-led Healthy Markets project in Vietnam, for example, has contributed to WHO prequalification of three blood-based HIV self-test products. Healthy Markets also partnered with Wits Reproductive Health and HIV Institute through funding from the Bill & Melinda Gates Foundation and others to assess the performance of four blood-based HIVST kit products that required data for WHO prequalification. These assessments will facilitate market entry for these new products into Vietnam and other lower- and middle-income countries.

Evaluation results helped manufacturers improve their HIVST products. As of December 2020, three blood-based self-tests (Mylan, INSTI®, and SURE CHECK®) and one oral fluid-based self-test (OraQuick®) have achieved WHO prequalification approval.

Assessing HIVST acceptability and willingness to pay

Markets-supported evaluations[a,b,c] generated key early insights on HIVST preferences and usability:

- Between 2015 and 2016, more than 97 percent of evaluation participants stated that they found HIVST to be acceptable and they would recommend it to their peers.
- Participants were offered a choice of blood-based (Alere Determine™ HIV-1/2) or oral fluid assay (OraQuick Rapid HIV-1/2) testing. Nearly 43 percent of the 936 evaluation participants opted for the oral fluid test.
- Among the 936 participants, 54.7 percent were first-time testers. Among those who had tested before, 24.1 percent had not tested in the previous 12 months.
- In a study with 790 self-testers, 64 percent reported difficulty using Alere Determine and 21 percent reported the same regarding use of OraQuick Rapid.
- Despite perceived difficulties, in 98 percent of cases with Determine and 97 percent with OraQuick, self-testers' interpretation of test results aligned with that of a trained observer.
- In terms of willingness to pay for HIVST, in a 2015 Healthy Markets study, 80 percent of 2,557 people in key populations (including MSM, FSW, PWID, and their sex partners) reported being willing to pay for HIVST. PWID were willing to pay up to US$3.90, FSW up to US$4.30, and MSM up to US$5.40. A 2017 follow-up study found that key populations were still willing to pay for HIVST and at a price range equivalent to prices cited in the 2015 study.
- Willingness-to-pay study results and the acceptability data cited above showed that demand for commercially available HIVST kits is clearly present in Vietnam.

HIVST regulatory process and product registration

PATH has worked in India, Indonesia, Uganda, and Kenya to review regulatory processes, identify bottlenecks, and support capacity-building. An assessment in Vietnam identified primary challenges related to the time involved in the registration process, lack of a standard panel to validate oral fluid-based assays, and the fact that Vietnamese law does not recognize WHO prequalification certificates as a basis for registration and import. Following advocacy

[a] USAID/PATH Healthy Markets project. HIV commodity and service consumer preferences, utilization, and willingness to pay. December 2015; Hanoi, Vietnam.
[b] Green K, Vu Ngoc B, Phan Thi TH, Tran Hung M, Vo Hai S, Ngo Van H, *et al*. How acceptable and feasible is HIV self-testing among key populations in Vietnam? Preliminary results from an intervention evaluation study. Presented at: 9th IAS Conference on HIV Science, July 23–26, 2017; Paris.
[c] Green K, Nguyen Thi TH, Vu NB. HIVST is highly acceptable to people who inject drugs and their intimate partners in rural and urban settings in Vietnam. Presented at: 10th Conference on HIV Science, July 23, 2019; Mexico City.

efforts led by Healthy Markets, including dialogues between manufacturers and key departments at the Ministry of Health (MOH), the MOH is now working to minimize barriers that prevent registration of key diagnostic tools, including HIVST, in Vietnam.

At the same time as advocating for easier registration of HIVST kits, Healthy Markets continues to work with several HIVST manufacturers to navigate the current licensure requirements and explore the suitability and pricing of their products in the Vietnamese market. In March 2018, bioLytical® Laboratories Inc., a Canadian company that manufactures blood-based HIVST kits, officially registered their INSTI HIVST kit on the Vietnamese market. The kit was assessed by the National Institute for Control of Vaccines and Biologicals and was the first HIVST kit to receive approval for import and distribution in Vietnam. Healthy Markets worked closely with Vietnamese medical product distributor AMV Group to navigate the necessary requirements for INSTI registration in Vietnam and to develop distribution plans for fiscal year 2020.

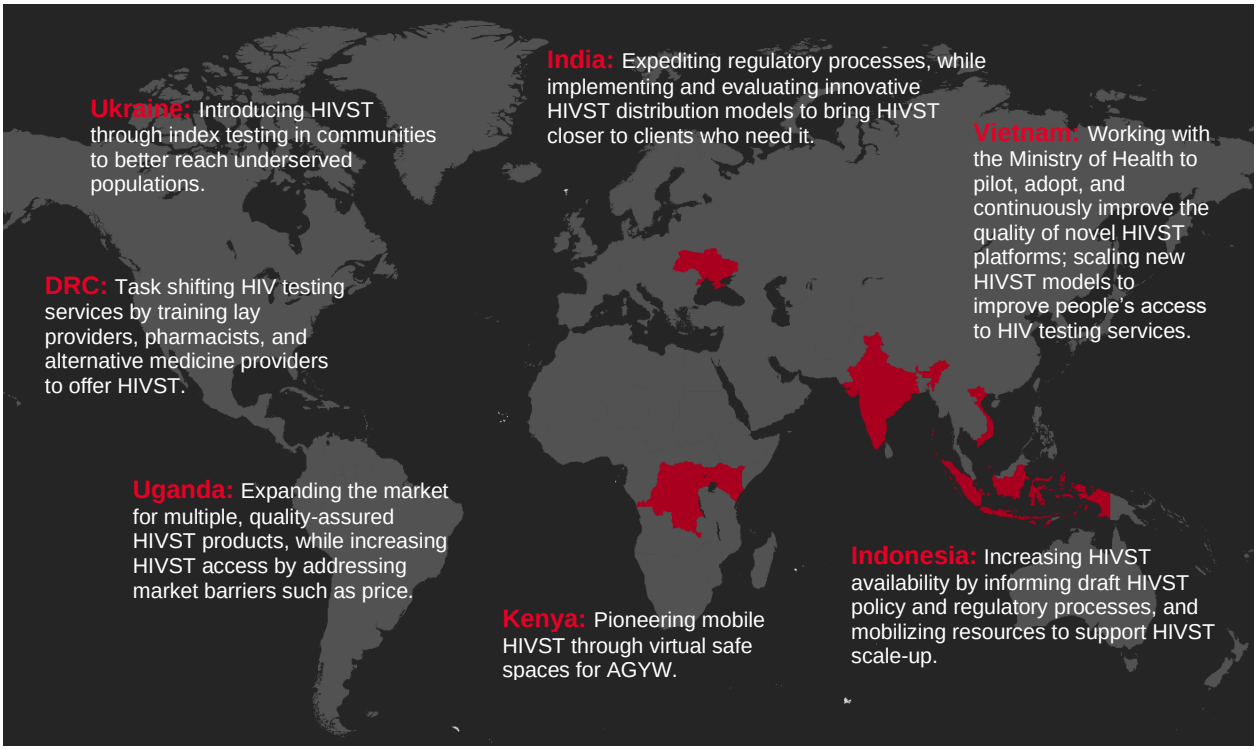
HIVST introduction and program optimization

PATH works hand in hand with national counterparts in the Democratic Republic of the Congo (DRC), India, Indonesia, Kenya, Vietnam, Uganda, and Ukraine (see map below) to introduce and optimize HIVST programs. PATH's support to HIVST program establishment, implementation, and scale-up includes:

- Development of HIVST policies, implementation guidelines, and quality assurance processes.
- Integration of HIVST data into national reporting and information systems.
- Incorporation of HIVST commodities into supply chains.
- Use of human-centered design to shape demand creation campaigns and tools.
- Design, implementation, and evaluation of innovative, differentiated HIVST service delivery models and effective linkage of HIVST users to HIV prevention and care.

Examples of PATH technical assistance include:

- ***Evidence-based policy development in Vietnam:*** Under the Healthy Markets project, PATH worked extensively with the MOH in its effort to include HIVST in its HIV action plan for 2016–2020. With PATH's and other key stakeholders' assistance, in 2018, the MOH released Vietnam's first-ever national community-based HIV testing guidelines, which include self-testing. Vietnam's decision to adopt national HIVST guidelines was based



in part on findings from successful PATH-supported pilot activities and evaluation studies. Similarly, in 2020, PATH worked with the MOH in Indonesia to develop its HIVST service guidelines.

- ***Market shaping in Uganda:*** Under the HIV Self-Testing in Africa and Asia Initiative (STAR-III), PATH will help support the market for multiple quality-assured HIVST products and increase HIVST access by conducting willingness-to-pay studies and costing evaluations of different HIVST delivery and linkages models. Results will help HIVST manufacturers address market barriers such as price and inform further expansion of the more sustainable delivery models.
- ***Developing differentiated service delivery models based on population preference:*** Because preferences for accessing HIVST differ across populations, PATH and its partners have developed a variety of models to get HIVST kits to users. Under the USAID-funded Serving Life project in Ukraine, PATH introduced peer-led, community-based HIVST services to conduct outreach among PWID and MSM, and to partners of HIV-positive people in prisons. Nongovernmental organization (NGO) social workers, including peers who are current or former PWID, MSM, or ex-/recently released prisoners, offer oral HIVST with multiple options for HIVST kit delivery (NGO pick-up; community drop-off; home delivery). For partners with reactive self-test results, an NGO social worker provides an accompanied referral to an AIDS Center for confirmatory diagnosis and treatment initiation.

Helping programs adapt HIVST services during the COVID-19 pandemic

The COVID-19 crisis has resulted in even further differentiation in distribution modes. PATH projects across Africa and Asia are helping counterparts adapt their delivery models to ensure that HIVST services remain available to those who need them. Adaptations include new or increased emphasis on online platforms for requesting HIVST kits, delivery of HIVST kits to be used at home, use of remote means (phone calls or video) for counseling and assisted partner notification services, and offering HIVST services at private-sector outlets.

For example, in DRC, following two-day lockdown orders in Lubumbashi at the start of the COVID-19 outbreak, attendance at health facilities dropped due to transportation restrictions and client fears of contracting the virus in health care settings. To provide clients with testing alternatives, PATH's USAID-funded Integrated HIV/AIDS Project in Haut-Katanga (IHAP-HK) project introduced a public-private model for delivery of assisted HIVST services at 19 pharmacies and two alternative medicine centers (AMCs) in Lubumbashi. Under this model, HIVST is offered to adults coming to pharmacies/AMCs requesting medications for sexually transmitted infections, dermatosis, cough, fever, and/or diarrhea. Clients are given HIVST counseling, a risk assessment, and if eligible and accepted, assisted HIVST services. Clients with reactive self-test results are then escorted (accompanied referral) to a facility as high priority for HIV testing and linkage to care services. PATH also integrated use of HIVST by lay providers conducting household TB screening campaigns as another method to increase targeted HIV testing outreach during COVID-19, offering assisted HIVST to people with presumptive TB and providing accompanied referrals to nearby health facilities for confirmatory diagnosis and linkage to care.

In Kenya, under USAID's Afya Ziwani DREAMS project, adolescent girls and young women (AGYW) in 51 wards have been able to request home-delivered HIVST kits and counseling services over the phone through a "please call

Health care provider using the OraQuick instructional pamphlet to guide a young woman on how to use an HIVST kit at home in western Kenya. Credit: PATH.

me" feature as well as through 111 WhatsApp-based Virtual Safe Spaces, which offer mobile individual or group education sessions on HIVST, PrEP, and COVID-19. Along with HIVST services (and accompanied linkages to PrEP or ART enrollment, based on HIVST result), Afya Ziwani provides AGYW with COVID-19 information on curfews, physical distancing, and handwashing practices. More than 1,170 HIVST kits have been requested by and distributed to AGYW via Virtual Safe Spaces.

In Vietnam, during the COVID-19 outbreak period, Healthy Markets ramped up client-directed online HIVST to maintain provision of HIV testing services for MSM, transgender women, and PWID. The project launched promotional campaigns with integrated HIVST and COVID-19 messaging (#Stayhome #Self-test) on a variety of virtual platforms, including the project's HIVST 3.0 platform, that linked clients to online risk assessment tools. Based on assessment results, clients were able to place an online HIVST order with multiple options provided for delivery method (mail, courier service, or pick up) and self-test type (OraQuick or INSTI). Clients received HIVST packages within two days and were directed to share test results within seven days. (If there was no response from the client, the HIVST distributor followed up to confirm test results and ensured linkage to follow-on testing and treatment or prevention services.) In April–May 2020, more than 2,000 HIVST kits were delivered using this system. The project also delivered more than 1,000 integrated HIV & COVID-19 self-care packages to clients seeking HIV services for the first time through the HIVST 3.0 platform, with kits containing medical masks, HIVST kits, condoms and lubricants, PrEP leaflets, and promotional PrEP materials.

HIVST as a portal to treatment and PrEP

In the DRC, HIVST has been a critical tool for diagnosing those who might not be screened using other HIV testing modalities and linking them to HIV treatment. From May through December 2020, 97% of the 172 people (all first-time HIV testers) offered assisted HIVST at pharmacies and AMCs accepted, among whom 57 received a reactive HIVST result and were all referred to a facility for confirmatory diagnosis. 40 people were confirmed HIV positive (24% testing yield; higher than 6% yield from routine HIV testing modalities), and all were successfully initiated on ART.[d]

In Vietnam, 28,498 individuals opted for assisted HIVST from May 2016 through March 2021, resulting in an additional 703 people living with HIV identified, 95% of whom were successfully enrolled in ART. In Ukraine, between March 2020 and March 2021 (during the COVID-19 outbreak), the Serving Life project provided 5,942 self-test kits to PWID, MSM, and their sexual or injecting partners. Of these, 170 new HIV-positive people were diagnosed, and 139 were initiated on ART.

Dr. Ali Kitoko counsels a client on use of an OraQuick self-test kit at Pharmacie Binamet in Lubumbashi in the Democratic Republic of the Congo. Credit: PATH.

HIVST scale-up and sustained access

If HIVST is to be sustainable long term, HIVST services must be in demand and supply must be consistent and commercially viable. For example, in Vietnam (through the Healthy Markets project) and Uganda (under STAR-III), PATH is assisting the government in various scale-up activities that will help ensure continued availability and quality of HIVST services in the future.

In Uganda, to increase availability and drive demand for HIVST, PATH surveyed past and potential HIVST users, public- and private-sector healthcare providers, and government health personnel to identify audience-segmented delivery preference; develop user- and provider-responsive distribution models; and inform HIVST informational materials. Findings led to the roll-out of a community peer HIVST distribution

[d] Mwamba R, Tendo C, Kapongo, F. Extending reach of HIV testing services (HTS) through private-sector outlets: Feasibility of offering HIV self-testing (HIVST) at pharmacies and alternative medicine centers (AMC) in Democratic Republic of the Congo (DRC). Presented at: 11th Conference on HIV Science, July 18, 2021; Berlin.

model; targeted workplace HIVST distribution; and a virtual HIVST ordering platform. Peer distributors were equipped with *"Ask me about HIVST"* branded materials. More than 46,100 oral and blood-based kits were distributed through these platforms as of April 2021.

In Vietnam, Healthy Markets continues to support an enabling policy environment for HIVST providers, kit manufacturers, and distributors and is engaging with manufacturers, wholesale distributors, and retailers to develop a viable commercial market for HIVST. In 2019, Healthy Markets closely coordinated with AMV Group to advocate for HIVST kits to be traded as "normal goods" (much like condoms), meaning that HIVST kits can be distributed through retail outlets and pharmacies. If approved, the "normal goods" designation will help foster a reliable retail supply chain, which in turn will facilitate a sustainable supply of HIVST kits.

Creating a commercial market for HIVST kits enables access beyond donor procurements. Healthy Markets enabled social enterprises that are led by HIV-affected communities to participate in fee-based HIVST supply chains, contributing to their income generation while enabling community access to HIVST kits. Healthy Markets also launched a partnership with private-sector pharmacy chain Pharmacity to increase the accessibility of HIVST. Pharmacity is the largest pharmacy chain in Vietnam and retails HIVST INSTI in 67 stores across the country. Healthy Markets supported the pharmacy chain to develop and implement an HIVST marketing and communication plan, with the engagement of community influencers.

In Uganda, based on a preference for pharmacy-based distribution among men, key populations, and AGYW, PATH is initiating HIVST distribution at pharmacies, offering an option of oral fluid or blood-based products, with plans to integrate market-based interventions within partner pharmacy chains to enhance HIVST sustainability.

Moving forward

In the future, PATH will continue to work closely with the international public health community; national governments; health providers; HIV self-test kit researchers, manufacturers, and distributors; civil society organizations; and communities around the globe to champion, establish, and support effective HIV self-testing programs. Key priorities will include removing unnecessary regulatory barriers impeding introduction or adoption of proven HIVST diagnostics, brokering more private-sector involvement in global and national HIVST efforts, and using HIVST models as a foundation for co-packaging or integrating other self-care tools, such as hepatitis C self-test kits, COVID-19 self-test kits, and other health commodities. PATH will also continue to innovate, developing and testing new ways to bring HIVST services closer to those who need them most and linking those with positive test results to timely HIV treatment.