HIV Self-Testing and PrEP: Opportunities for scale-up



AVAC

A Guide for Implementers and Ministries of Health

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The purpose of this brief is to address common misconceptions about the use of HIV self-testing (HIVST) for PrEP while highlighting the opportunities that HIVST can provide in order to support further scale-up of this important self-care option.

HIV self-testing (HIVST) is a safe, accurate, and effective alternative to provider-administered testing, and has been recommended by the World Health Organization (WHO) since 2016. In July 2023, WHO issued a new recommendation to offer HIVST for initiation and continuation of tenofovir-based oral pre-exposure prophylaxis (PEP), the dapvirine vaginal ring, and post-exposure prophylaxis (PEP). Provider-administered testing may be a barrier to PrEP uptake in some contexts, so offering HIVST as a more discreet and convenient option may increase access to PrEP. In addition, HIVST can facilitate simplification of PrEP delivery both by enabling use of differentiated models, such as telePrEP and pharmacies, and by reducing the number of facility visits required for follow-up.

Introduction and scale-up of HIVST for PrEP has so far been limited, as many implementers and Ministries of Health (MoH) have questions on how to do this effectively. This guide aims to address those questions.

For complete guidance on HIV testing, including self-testing, see WHO's latest <u>Consolidated guidelines on differentiated HIV testing services</u>. See <u>Annex C</u> and <u>Annex D</u> for additional evidence relating to HIVST and PrEP.

Cost

What you need to know: HIVST for PrEP is cost-effective to implement and can even be cost-saving.

What does this mean for implementers?

Scaling up HIVST for PrEP initiation and continuation can save health systems money, allowing more to be spent on other aspects of PrEP programming. Removing some of the financial barriers for users associated with PrEP- including travel and time- can support increased PrEP uptake.

What does the evidence say?

<u>Modelling has shown</u> that use of HIVST doesn't increase the overall cost of PrEP programmes and can be cost-saving by reducing costs to the health system, such as in provider time, and by reducing the number of facility visits a PrEP user needs to make. HIVST can be cost-saving for users as well by reducing travel costs and the opportunity cost of taking time away from work to visit a facility. HIVST kits are increasingly affordable, with <u>WHO prequalified kits</u> available for as little as \$1 USD each, and <u>a recent systematic</u> review of costs of HIV testing services found HIVST to have the lowest cost per person tested of the modalities reviewed.

Learn more:

Ahmed, Nurilign et al. "Costs of HIV testing services in sub-Saharan Africa: a systematic literature review." BMC infectious diseases vol. 22,Suppl 1 980. 27 Aug. 2024, <u>doi:10.1186/s12879-024-09770-7</u> Cox, Sarah N et al. "Impact of HIV self-testing for oral pre-exposure prophylaxis scale-up on drug resistance and HIV outcomes in western Kenya: a modelling study." The lancet. HIV vol. 11,3 (2024): e167-e175. doi:10.1016/S2352-3018(23)00268-0

Ngure, Kenneth et al. "Efficiency of 6-month PrEP dispensing with HIV self-testing in Kenya: an open-label, randomised, non-inferiority, implementation trial." The lancet. HIV vol. 9,7 (2022): e464-e473. <u>doi:10.1016/</u> S2352-3018(22)00126-6

Ortblad, Katrina F et al. Web Annex C. GRADE table and systematic review: should HIV self-testing be used to support PrEP delivery. In: Consolidated guidelines on differentiated HIV testing services. Geneva: World Health Organization; 2024. <u>doi:10.2471/B09075</u>

Social Harm and STIs

What you need to know: Use of HIVST does not lead to increased social harm or increased incidence of sexually transmitted infections (STIs).

What does this mean for implementers?

HIVST for PrEP can be introduced without concern for increased social harm or STI incidence. New multiplex tests like <u>dual self-tests for HIV and syphilis</u>, as well as other self-collection and self-testing tools for STIs, could encourage increased STI testing in conjunction with HIVST.

What does the evidence say?

A <u>global scoping review of HIVST programmes</u> showed low occurrence of adverse events due to HIVST, including coercive testing, self-harm after positive test results, and interpersonal violence. Randomised controlled trials evaluating HIVST found <u>no increase in STI incidence</u> or <u>reduction in STI testing</u>.

Learn more:

Jamil, Muhammad S et al. "Examining the effects of HIV self-testing compared to standard HIV testing services in the general population: A systematic review and meta-analysis." EClinicalMedicine vol. 38 100991. 7 Jul. 2021, <u>doi:10.1016/j.eclinm.2021.100991</u>

Katz, David A et al. "HIV Self-Testing Increases HIV Testing Frequency in High-Risk Men Who Have Sex With Men: A Randomized Controlled Trial." Journal of acquired immune deficiency syndromes (1999) vol. 78,5 (2018): 505-512. <u>doi:10.1097/QAI.00000000001709</u>

Rivera, Adovich S et al. "Implementation outcomes of HIV self-testing in low- and middle- income countries: A scoping review." PloS one vol. 16,5 e0250434. 3 May. 2021, <u>doi:10.1371/journal.pone.0250434</u>.

Towns, Janet M et al. "The role of syphilis self-testing as an additional syphilis testing approach in key populations: a systematic review and meta-analysis." The Lancet. Public health vol. 8,9 (2023): e726-e734. doi:10.1016/S2468-2667(23)00128-7

Witzel, T Charles et al. "Comparing the effects of HIV self-testing to standard HIV testing for key populations: a systematic review and meta-analysis." BMC medicine vol. 18,1 381. 3 Dec. 2020, <u>doi:10.1186/s12916-020-01835-z</u>

Wray, Tyler B et al. "The effects of regular home delivery of HIV self-testing and follow-up counselling on HIV testing and prevention outcomes in men who have sex with men who test infrequently in the United States: a pragmatic, virtual randomized controlled trial." Journal of the International AIDS Society vol. 27,7 (2024): e26318. doi:10.1002/jia2.26318

Accuracy and Drug Resistance

What you need to know: HIVST kits are highly accurate and have no association with increased drug resistance.

What does this mean for implementers?

HIVST can be offered to users as an additional highly accurate and safe testing option for PrEP initiation and continuation without concern for increased drug resistance.

What does the evidence say?

HIVST kits prequalified by WHO undergo rigorous testing and <u>meet high standards of sensitivity and</u> <u>specificity</u>. Self-testing is <u>accurate and reliable</u> across studies, populations and settings, and there is <u>no significant difference in performance between oral and blood-based tests</u> at a population level. Breakthrough infections on oral PrEP are rare. As <u>HIV incidence declines globally</u>, acute HIV infection is becoming rarer, and healthcare providers are trained to screen for it. Even when scaled up extensively, HIVST for PrEP has <u>not been shown to increase the risk of drug resistance</u>.

Learn more:

Cox, Sarah N et al. "Impact of HIV self-testing for oral pre-exposure prophylaxis scale-up on drug resistance and HIV outcomes in western Kenya: a modelling study." The lancet. HIV vol. 11,3 (2024): e167-e175. doi:10.1016/S2352-3018(23)00268-0

Johnson, Cheryl C et al. "Examining the effects of HIV self-testing compared to standard HIV testing services: a systematic review and meta-analysis." Journal of the International AIDS Society vol. 20,1 (2017): 21594. doi:10.7448/IAS.20.1.21594

<u>WHO Public Reports for In Vitro Diagnostics</u>- features reports for all prequalified HIVST kits, including information on sensitivity and specificity

Reliability

What you need to know: The majority of users interpret HIVST results correctly and report them accurately.

What does this mean for implementers?

PrEP users can be trusted to accurately interpret and report results from HIVST. Data and messaging on accuracy of test results and reliability of reporting, including country and programme case studies, can be used to engage governments who may be hesitant about enacting HIVST policies due to concerns over lack of direct information about testing and test results. This information can also be used to engage providers, who can sometimes be a barrier to HIVST.

What does the evidence say?

The majority of people who use HIVST will <u>accurately interpret</u> and <u>share their results</u> when asked. There is no evidence across self-testing technologies and approaches that suggests the majority of people will misrepresent or misuse their self-test result, especially when provided with accurate messages and support from communities.

Learn more:

Choko, Augustine T et al. "Uptake, Accuracy, Safety, and Linkage into Care over Two Years of Promoting Annual Self-Testing for HIV in Blantyre, Malawi: A Community-Based Prospective Study." PLoS medicine vol. 12,9 e1001873. 8 Sep. 2015, <u>doi:10.1371/journal.pmed.1001873</u>

Figueroa, Carmen et al. "Reliability of HIV rapid diagnostic tests for self-testing compared with testing by health-care workers: a systematic review and meta-analysis." The lancet. HIV vol. 5,6 (2018): e277-e290. doi:10.1016/S2352-3018(18)30044-4

Ngure, Kenneth et al. "Efficiency of 6-month PrEP dispensing with HIV self-testing in Kenya: an open-label, randomised, non-inferiority, implementation trial." The lancet. HIV vol. 9,7 (2022): e464-e473. <u>doi:10.1016/</u> S2352-3018(22)00126-6

Impact

What you need to know: HIVST can improve PrEP service delivery and increase PrEP uptake.

What does this mean for implementers?

Differentiated service delivery strategies can be leveraged to expand HIVST coverage, including delivery via lay providers, vending machines, pharmacies, and telemedicine. These channels can then be linked to PrEP delivery mechanisms to further expand PrEP coverage, though advocacy on task shifting is needed to support PrEP delivery via differentiated channels. Technologies such as artificial intelligence can be leveraged to support HIVST implementation and reporting.

What does the evidence say?

Many populations at heightened risk of HIV transmission, including key populations and adolescent girls and young women, may not feel comfortable accessing HIV prevention services in a health facility. <u>HIVST</u> <u>can facilitate PrEP access for these individuals</u> by offering an additional layer of discretion. In addition to leading to increased PrEP uptake, this increased testing can lead to earlier detection of HIV and associated linkages to timely treatment and reduced onwards transmission.

Learn more:

Joseph Davey, Dvora Leah et al. "Pre-exposure Prophylaxis Recent Adherence With Real-Time Adherence Feedback and Partner Human Immunodeficiency Virus Self-Testing: A Pilot Trial Among Postpartum Women." Open forum infectious diseases vol. 9,2 ofab609. 23 Dec. 2021, <u>doi:10.1093/ofid/ofab609</u>

Mujugira, Andrew et al. "Effect of HIV Self-Testing on PrEP Adherence Among Gender-Diverse Sex Workers in Uganda: A Randomized Trial." Journal of acquired immune deficiency syndromes (1999) vol. 89,4 (2022): 381-389. doi:10.1097/QAI.00000000002895

Ortblad, Katrina F et al. "The effect of six-month PrEP dispensing supported with interim HIV self-testing on PrEP continuation at 12 months in Kenya: a randomized implementation trial." Presentation at: 24th International AIDS Conference; 29 July-2 August 2022; Montreal. <u>https://programme.aids2022.org/Abstract/</u><u>Abstract/?abstractid=2530</u>

Ortblad, Katrina F et al. Web Annex C. GRADE table and systematic review: should HIV self-testing be used to support PrEP delivery. In: Consolidated guidelines on differentiated HIV testing services. Geneva: World Health Organization; 2024. <u>doi:10.2471/B09075</u>

Wagner, Anjuli D et al. "Implementation strategy package improves PrEP implementation for pregnant women in antenatal care clinics in western Kenya." Poster presented at 24th International AIDS Conference; 29 July - 2 August 2022; Montreal. <u>https://programme.aids2022.org/PAGMaterial/PPT/1277_6624/PrEPARE_AIDS2022_poster.pdf</u>

Witzel, T Charles et al. "Comparing the effects of HIV self-testing to standard HIV testing for key populations: a systematic review and meta-analysis." BMC medicine vol. 18,1 381. 3 Dec. 2020, <u>doi:10.1186/s12916-020-01835-z</u>

What about HIVST and PEP?

HIVST offers a significant opportunity to increase testing rates at the start of a course of PEP, which can then prompt users to start PEP quickly without needing further testing or a facility visit. Additionally, HIVST use at the end of a course of PEP removes the need for in-person follow-up for those testing negative, allowing rapid start of PrEP, or enables those with a reactive status to rapidly link to further testing and treatment as needed. For more information on PEP and self-testing, see WHO's latest <u>Guidelines for HIV post-exposure prophylaxis</u>.

In Summary: HIVST and PrEP-Looking toward the Future

HIVST is a cost-effective, safe, accurate, and reliable method of HIV testing that can significantly improve service delivery and increase uptake, particularly by users who highly value discretion and convenience. It has been shown to be feasible and acceptable across populations, and can empower users to make choices for themselves, which can increase their confidence in seeking HIV services. While HIVST is currently only recommended for use with oral PrEP, the dapivirine vaginal ring, and PEP, WHO will continue to review evidence around use with new PrEP options, including injectable cabotegravir and other new formulations and interventions that may be in the pipeline for PrEP, and update recommendations accordingly.



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PrEPWatch

For the latest information and data on PrEP across the globe, visit <u>PrEPWatch.org</u>.