POLICY BRIEF

WHO RECOMMENDS HIV SELF-TESTING – EVIDENCE UPDATE AND CONSIDERATIONS FOR SUCCESS

NOVEMBER 2019

World Health Organization

WHO recommends HIV self-testing as an approach to HIV testing services. This policy brief highlights new guidance to optimize HIVST implementation, including effective service delivery models, linkage to care and support tools.

HIV self-testing (HIVST) is a convenient and confidential option for HIV testing. In 2016 WHO recommended HIVST as a safe, accurate and effective way to reach people who may not test otherwise, including people from key populations, men and young people. Lay users can perform HIVST reliably and accurately and achieve performance comparable to that of trained health-care workers. Globally, many countries have developed HIVST policies, and implementation is growing rapidly. This policy brief highlights new guidance to optimize HIVST implementation, including effective service delivery models, linkage to care and support tools.

HIVST is a process in which a person collects their own specimen (oral fluid or blood) using a simple rapid HIV test and then performs the test and interprets their result, when and where they want.

WHO recommendation on HIVST

Update

HIV self-testing should be offered as an approach to HIV testing services *(strong recommendation, moderate-quality evidence)*.

Remarks

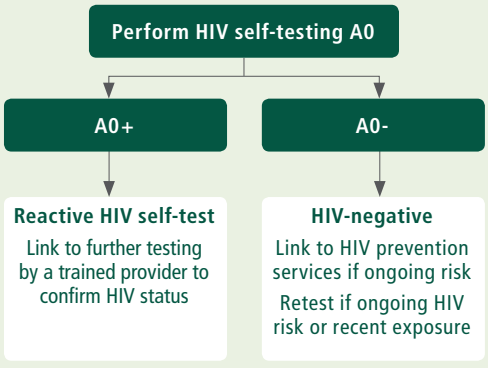
- Providing HIVST service delivery and support options is desirable.
- Communities need to be engaged in developing and adapting HIVST models.
- HIVST does not provide a definitive HIV-positive diagnosis. Individuals with a reactive test result must receive further testing from a trained tester using the national testing algorithm (see Box 1).

Box 1. HIVST is a test for triage and does not provide a definitive HIV-positive diagnosis

A reactive (positive) HIVST result is not equivalent to an HIV-positive diagnosis. All reactive HIVST results need to be followed by further testing by a trained provider to confirm HIV status, starting with the first test in the national testing algorithm.

Nonreactive HIVST results should be considered HIV-negative, with no need for immediate further testing except for those starting pre-exposure prophylaxis (PrEP). **For people starting or already taking PrEP, HIVST cannot replace initial or subsequent quarterly facility visits and testing.**

Those with **invalid HIVST results** need to repeat the test using another HIVST kit or to seek testing from a trained provider. Any person **uncertain about their HIVST result** should be encouraged to seek testing from a trained provider.



A0 = Assay 0 (test for triage)

HIVST is not recommended for people with HIV who are on ART, as false-negative HIVST results can occur. Those who are HIV-positive but not on ART should be encouraged and supported to initiate ART.

Retesting following a negative self-test result is necessary only for those at ongoing risk, such as people from key populations and those reporting potential HIV exposure in the preceding 12 weeks.

Review of evidence

WHO conducted a systematic review to update the guidance on HIVST. Box 2 summarizes key findings.

Box 2. Key findings from HIVST systematic review

Thirty-two randomized controlled trials (RCTs) showed that, compared with standard facility-based HIV testing:

- HIVST increases the uptake of HIV testing.
- Proportions of people diagnosed and linked to care with HIVST are comparable to those with facility-based testing.
- Misuse of HIVST and social harms associated with HIVST are rare. No suicides were reported.
- HIVST does not increase sexual risk behaviour among men who have sex with men.
- A range of HIVST service delivery models and support tools are found to be effective.
- Many people are willing and able to perform HIVST with minimal support.
- HIVST is acceptable and feasible in a range of populations and settings.

HIVST service delivery models

HIVST kits can be distributed through various channels, including those supported by public or donor funding or in the private sector, as well as through public–private partnerships. RCTs found that **a range of service delivery and distribution models are effective** in increasing uptake of HIV testing and reaching people with HIV who are undiagnosed or those at ongoing HIV risk. Other models may be effective and can be considered depending on the local context and community preferences (Fig. 1). Where feasible, **offering choice in HIVST service delivery options and type of test kits** (such as between kits using oral fluid or blood) can help to reach more people.

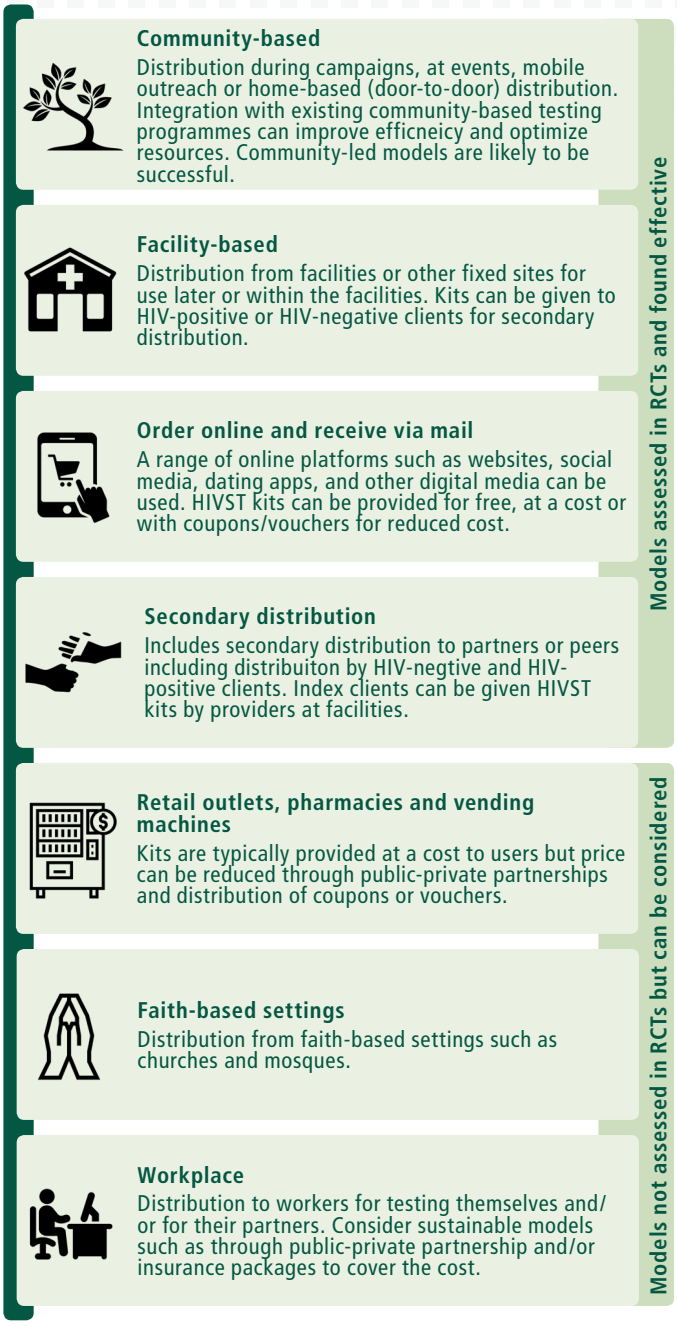


Fig. 1. HIVST service delivery models

Support package and tools

Many people can perform HIVST correctly with minimal or no support. However, some may need and want support, and it should be made available. **Providing support options is important**, where feasible. Support tools and packages should be adapted to address the local context, population needs and community preferences.

Programmes are encouraged to define a **minimum support package** to accompany HIVST implementation. This package can be regularly reviewed and adjusted as programmes expand and scale up. Some options that were assessed in RCTs include:

- no support or basic support only with use of the standard, manufacturer-provided instructions for use (IFUs) and manufacturer-provided telephone hotline or other customer support;
- tailored, translated or pictorial IFUs designed for the populations being served with or without additional support such as local telephone hotline;

- one-on-one in-person HIVST demonstration and/or observation or supervision of self-testers;
- HIVST demonstration in a group setting;
- virtual real-time support or supervision through online platforms (such as messages, social media, videos).

When considering resource-intensive support options, such as training, in-person demonstration and supervision, the added benefit needs to be weighed against use of resources. Such resource-intensive support mechanisms can limit scalability and should be considered for a limited time. The support needs of self-testers are expected to decline as programmes evolve, public awareness increases and people gain experience with HIVST.

New digital, social media and video or messaging platforms can also be considered. These may be readily acceptable, especially to young people, and less costly than in-person support mechanisms.

Linkage to appropriate services after HIVST is critical to achieve its full benefits. Evidence suggests that linkage among those diagnosed with HIVST was similar to that in standard facility-based HTS, whether or not linkage support was offered, such as a financial incentive, home visit/in-person referral, phone reminder/follow-up and virtual real-time linkage support. However, when HIVST only, without linkage support, was compared with HIVST with linkage support, evidence suggests that support in the forms of home-based ART initiation, in-person referral/peer-navigation and provider financial incentives conditional on linkage increased linkage. Where resources are available, these can be considered.

Other important considerations for successful HIVST implementation

National programmes should consider including HIVST in differentiated national HTS plans. The following can support successful HIVST implementation:

- **Develop clear and supportive policies, regulations and standard operating procedures** and disseminate them to distribution sites and providers. These should ensure the registration and availability of **quality-assured HIVST products** and adequate **post-market surveillance** systems for reporting and addressing complaints, adverse events and social harm. The most up to date list of WHO prequalified HIVST kits can be accessed on WHO website: https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/.
- **Implement HIVST within a differentiated national HTS plan in a focused way** that prioritizes areas and populations with the greatest gaps in testing coverage. Consider available resources when selecting service delivery models and support tools.
- It is important to **empower and effectively engage communities** in developing and adapting HIVST delivery and support models. The meaningful participation of community members and people from key populations in designing and delivering services should be ensured. Community engagement should include educating the community and providers to raise awareness about HTS and minimize misuse and harms in relation to HIVST.
- When comparing the costs of HIVST and other HTS approaches, it is important to **consider the full cost of service delivery**, not just the cost of the HIVST kits. Some delivery models in the private sector, such as pharmacy sales, will incur costs to users, and this should be considered in the context of accessible and affordable HTS. Modelling suggests that in high HIV burden settings HIVST can be cost-effective, especially when focused on priority populations, such as men and sex workers. Low-cost, high-impact HIVST models, with a focus on priority populations in strategic geographical areas, are more likely to be cost-effective.
- **Monitor and evaluate programmes regularly** to optimize HIVST implementation. This will require developing a monitoring and evaluation plan, selecting key programme indicators, collecting relevant data, reviewing progress and adjusting service delivery accordingly. Pragmatic approaches and triangulation of available data – for example, use of programme data, ART coverage data and results of special surveys – are needed to effectively monitor HIVST outcomes and impact.

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HIV TESTING SERVICES