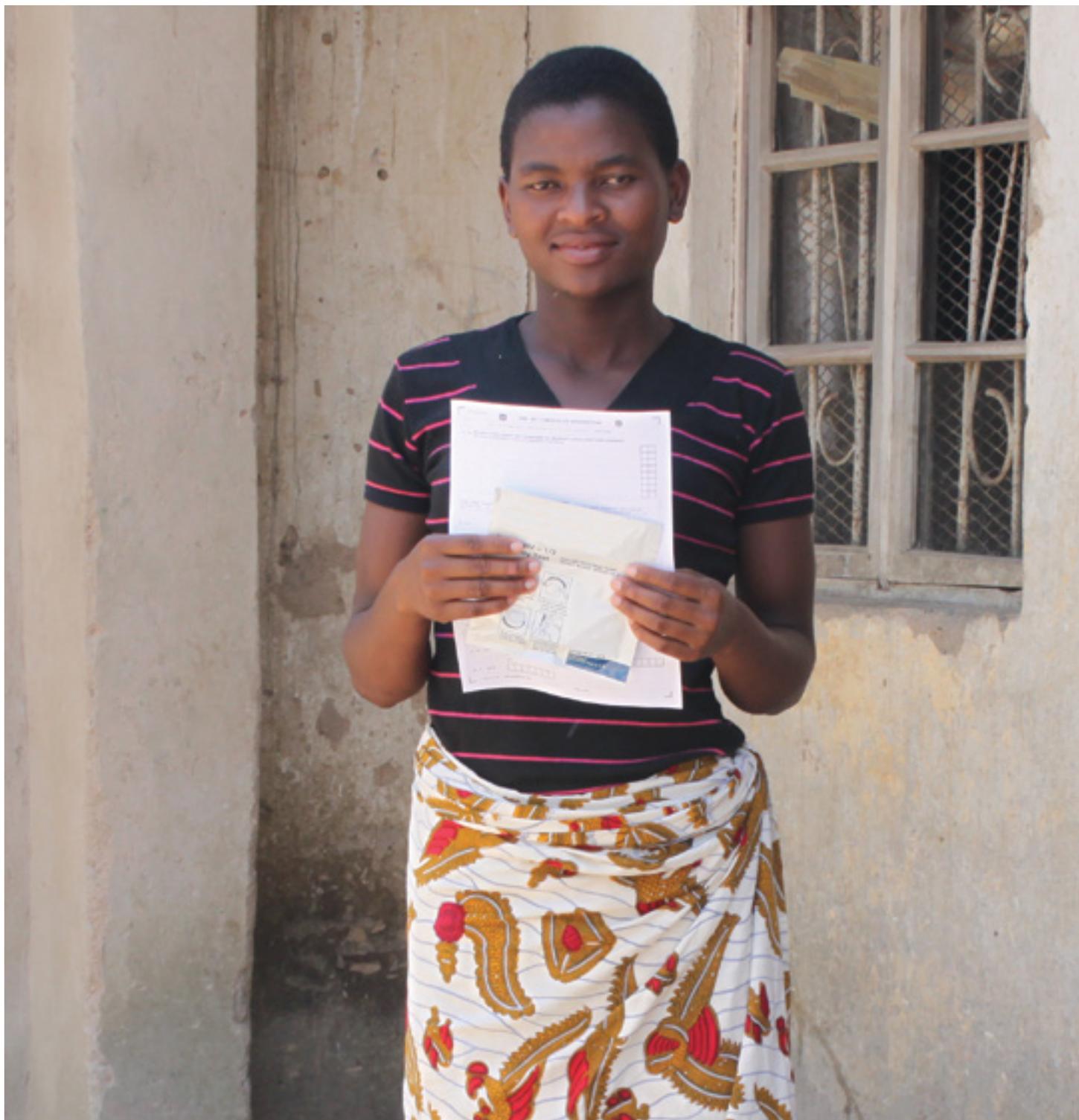


## A short technical update on self-testing for HIV



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## 1. What is HIV self-testing and what could it accomplish?

HIV self-testing is a process whereby a person who wants to know his or her HIV status collects a specimen, performs a test and interprets the test result in private.<sup>1</sup> HIV self-testing does not provide a definitive diagnosis; instead, it is a screening test for the presence of HIV-1/2 antibodies or the HIV-1 p24 antigen. Any positive HIV result must be confirmed by a health worker in accordance with national testing algorithms.<sup>2,3</sup>

HIV self-testing enables individuals to test themselves for HIV in private. By providing an opportunity for people to test themselves discreetly and conveniently, HIV self-testing may provide people who are not currently reached by existing HIV testing and counselling (HTC) services with information about their HIV status.

## 2. Current status and research

There are a number of HIV rapid diagnostic tests (RDTs) available, but at the moment, only one RDT specifically packaged for self-testing has the approval of the United States Food and Drug Administration (FDA).

Most HIV RDTs are blood-based (fingerstick/capillary) or oral fluid-based tests that provide results in less than 30 minutes. They determine HIV infection by detecting the presence of antibodies that have developed as a response to HIV exposure. Since antibodies generally take 6–12 weeks to develop (known as “the window period”), RDTs can only detect HIV infection after this time. The cost of HIV self-test kits varies, with prices ranging from US\$ 0.50 to US\$ 50.

Other products for HIV self-testing also could be developed (e.g. RDTs using other types of specimen collection, painless or integrated lancets, simplified sampling systems, integrated buffer delivery systems, and shorter minimum and maximum reading times).

Policy development regarding HIV self-testing varies across countries.<sup>5</sup> Over-the-counter sale and use of the OraQuick In-Home HIV Test began in the United States of America in 2012. In April 2014, the United Kingdom of Great Britain and Northern Ireland legalized the sale of HIV self-test kits.<sup>6</sup> France has also announced plans to approve over-the-counter sale of HIV

*This technical update was prepared in November 2013 in collaboration with key experts, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS). Its primary objective is to synthesize experiences, research and policies on HIV self-testing to inform stakeholders who are considering or already implementing HIV self-testing.*

self-test kits in 2014. Kenya,<sup>7</sup> has developed national HTC policies that include HIV self-testing. Other countries—including Malawi,<sup>8</sup> South Africa<sup>9</sup> and Zimbabwe<sup>10</sup>—are considering its introduction. In some countries, HIV self-testing is explicitly illegal,<sup>11</sup> but in many others there are no formal regulations or policies. Despite this, HIV RDTs have been informally available and used by individuals for self-testing for some time.

Current evidence on HIV self-testing comes from high-, middle- and low-income countries in Africa, Asia, Europe and North America. Research findings (including those from pilot programmes) have shown promising results in both generalized and concentrated epidemic settings. However, more documentation is needed to inform the development of WHO normative guidance.

HIV self-testing studies generally report high levels of acceptability (74–96%), primarily for oral fluid-based tests, among men who have sex with men adults, young people, health workers and couples who already self-test for HIV (or want to do so). A study in Malawi reported that HIV self-testing—combined with home-based antiretroviral therapy (ART) initiation—improved linkage to services, uptake of (and retention of) ART and care at a population level (when compared to facility-based HTC).<sup>12</sup>

Studies also report that HIV self-testing with oral fluid self-test kits is accurate, with sensitivity of at least 91.7% and specificity of at least 97.9%.<sup>13</sup> Although HIV self-tests are generally accurate, their sensitivity, specificity and positive/negative predictive values can be affected by the prevalence of HIV among the population and by user errors. User-friendly specimen collections allow RDTs to be performed by anyone and do not require medical training.

Error, which can take place with any test, occurs among both trained and untrained users, and it can result in incorrect test results. In studies of untrained self-testers, the rate of operator error ranged from 0.37% to 5.4%.<sup>14</sup> Reported errors include misinterpreting test results, failing to follow instructions and performing the self-test incorrectly.

For instance, a study of false-positive test results found that trained staff in the Democratic Republic of the Congo did not follow standard operating procedures. A study based in the United States of oral fluid-based HIV RDTs used by trained health workers also indicated that user error was the most common cause of lower sensitivity and specificity, attributing it to factors such as poor vision, inadequate lighting and failure to read the results within the specified time period.<sup>15,16</sup>

## 3. Programmatic approaches and models

Researchers have proposed various approaches to delivering HIV self-testing. These approaches differ as to:

1. How support is provided to users before and after testing (e.g. demonstrations of the procedure, presence of peer support, telephone hotlines);
2. How the self-test kits are distributed (e.g. facility, outreach, to the home or over the counter); and
3. How linkages are made from HIV self-testing to further HIV testing for confirmation of test results and for linkages into HIV care.

### PRIVATE OR SUPERVISED HIV SELF-TESTING

Private and supervised approaches to HIV self-testing differ as to (1) the amount of support provided to users and (2) where HIV self-testing kits are administered or distributed.

Private HIV self-testing is when a person self-tests in private. Support may or may not be indirectly provided via telephone hotlines, leaflets, referral information, support groups, legal aid demonstration videos and services for HIV treatment, care and prevention).

Supervised HIV self-testing involves support from a health worker or volunteer who is physically present before or after the individual self-tests for HIV. Such support may include a demonstration of how to use the test, pre- or post-test counselling and referrals to additional services.

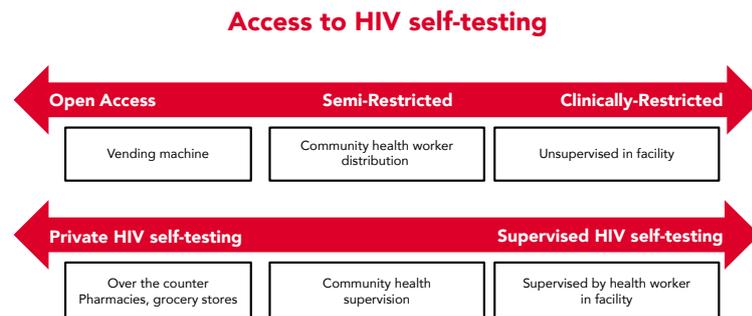
### ACCESS TO SELF-TESTING

Access to HIV self-testing can be clinically restricted, semi-restricted or non-restricted.

Clinically restricted: health professionals only provide specific populations and groups with HIV RDTs for self-testing, as decided by national policy or guidelines.

Semi-restricted: health workers or volunteers provide some pretest instructions and counselling before distributing the HIV self-test kits to individuals (e.g. health workers distributing them through a health-care facility, or trained staff distributing them to patients or the general public at pharmacies and workplaces).

Non-restricted (open access): HIV self-test kits are made available through many types of programmes and locations, including pharmacies, clinics, convenience stores and vending machines.



#### DISTRIBUTION AND INITIATION OF HIV SELF-TESTING

Distribution and initiation of HIV self-testing can take place at a range of places within communities, including health-care facilities and other suitable venues.

Community-based approaches to HIV self-testing involve distributing HIV self-testing kits to community members through volunteers or community health workers. This approach involves some supervision from a community health worker or volunteer before and/or after individuals test themselves for HIV in private. Pre-test support may include a demonstration of how to use the test and interpret the result, as well as information on where and how to seek additional support, further testing and services for HIV prevention, care and treatment. Post-test support may provide an opportunity for community members to disclose their result, and it also may include face-to-face counselling, peer support and referrals for additional services for HIV prevention, treatment and care.

Facility-initiated or facility-based approaches allow clients to self-test at home or in a private setting in a health facility. Health-care providers may encourage individuals to take self-test kits home for themselves and/or to give to their spouses and partners.

Alternative venue-initiated or venue-based approaches involve the public distribution or sale of HIV self-test kits through pharmacies, convenience stores, the Internet and other venues. This open-access approach is currently employed in the United States.<sup>17</sup> A modification of this approach could include restricting access to HIV self-test kits to pharmacies, where they would be distributed by pharmacists or on-site nurses who have been trained to provide additional support and information about where to seek test confirmation and services for HIV prevention, care and support. HIV self-test kits also could be clinically restricted and only made available by prescription to specific individuals.

## 4. Weighing potential benefits and risks

Policy-makers and implementers need to weigh the potential benefits and risks related to the introduction and scale-up of HIV self-testing.

Potential benefits of HIV self-testing include increased access to testing and earlier diagnosis for people living with HIV. People who self-test also experience greater convenience, autonomy and privacy when testing, and this may provide an option for individuals who are not using existing HTC services or those who do not have regular contact with (or access to) health services where HIV testing is offered. Key populations (including men who have sex with men, transgender people, sex workers and people who inject drugs) may benefit from self-testing, as might members of the general population in areas with a high prevalence of HIV (including health workers, couples and partners, serodiscordant partners, adolescents and retesters). Some research also suggests that HIV self-testing may reduce sexual risk behaviour and increase testing frequency among men who have sex with men, and that HIV self-testing may also facilitate voluntary disclosure within couples. These findings also indicate that HIV self-testing may complement existing HTC and public health strategies to reduce risk of exposure to (and transmission of) HIV.

As for risks associated with HIV self-testing, no adverse events or harm has been reported to date (e.g. there have been no human rights violations from the misuse of HIV self-testing, nor have there been accounts of violence or self-harm). Some stakeholders, however, have concerns about operational issues, including the slightly reduced sensitivity and specificity of RDTs in the hands of untrained or non-proficient users, the risk of operator error, the potential for the misinterpretation of results, and the lack of linkages to care. There are also ethical, legal and social concerns, such as potentially increased risks for vulnerable populations (through domestic violence, for instance, or through coercive testing). These considerations apply to all forms of HIV testing, however, and they are not unique to self-testing.

WHO and UNAIDS provide clear guidance on the critical requirements for all forms of testing, including the guidance that all testing must be voluntary. Mandatory or coerced HIV testing of individuals is never warranted.<sup>18</sup>

## 5. Policy and regulatory considerations

HIV self-testing takes place in many countries that do not have policies that regulate the quality, sale, distribution or use of HIV self-test kits. In order to optimize HIV self-testing, a number of policies and regulations will likely need to be adapted or developed.

In particular, policy-makers and implementers must consider:

- Laws and regulations permitting the sale, distribution and use of in vitro medical devices will generally need to be adapted or developed.
- Policies regarding access to HIV testing; for example, the age of consent may need to be adapted or developed to enable populations to self-test for HIV (e.g. adolescents).
- Human rights and protection laws, policies and regulations that address misuse and abuse (such as coercive testing, violence, discrimination and prosecution) may need to be developed or adapted to protect people who self-test. Channels through which misuse or abuse can be reported and monitored also may need to be established (this includes the distribution or sale of HIV self-test kits of poor quality).
- Health-care and managerial policies and regulations, national testing strategies and validated testing algorithms may need to be adapted or developed to incorporate HIV self-testing. This may involve reviewing existing policies to ensure that HIV self-test is recognized as a screening test (as part of a triage assay and not in lieu of a first-line assay) and revisiting policies about who can perform an HIV test and who can interpret an HIV test result. Health-care providers and other staff of facilities and national programmes are likely to need guidance, technical support and training on the integration of HIV self-testing into existing HTC frameworks.
- Regulation of HIV RDTs and test-kit evaluation must be considered, with evaluations of self-test kits being performed with the intended users in the intended setting of use. Minimum standards should be established to ensure that the design and packaging of HIV self-testing kits presents clear pre-/post-test information for users.
- Legal issues concerning disclosure of HIV self-testing results to others (including sexual partners) where the law requires disclosure of known HIV-positive status must be reviewed. Messaging and other information on HIV testing should address local legal implications of HIV self-testing and disclosure, keeping in mind that disclosure should be encouraged when it is safe and beneficial.

- In accordance with existing HIV testing and counselling policies and guidelines, retesting should only be required for non-reactive HIV self-testing results within the window period and for individuals at ongoing higher risk of HIV infection, following national algorithms.
- Quality assurance indicators and procedures for monitoring quality and adverse events may need to be re-interpreted to include HIV self-testing.

## 6. Other policy and programme considerations

HIV self-testing may provide people with an additional pathway to HIV prevention, care and treatment. Providing pretest information and counselling can facilitate access linkages to care, as can post-test referrals and follow-up (through face-to-face counselling, telephone hotlines, videos, web-based video chats, short message service (SMS) services and eHealth applications).<sup>19</sup>

An individual with a reactive (positive) HIV self-test result should be advised to seek further testing to confirm the result in accordance with the national testing guidelines. If the self-test result is non-reactive, the individual should be considered HIV-negative. As noted above, however, if an individual self-tests during the window period, has had a recent exposure or is at ongoing risk, then retesting is recommended.

To reduce the risk of HIV self-testing being used as a first-line assay, policies and regulations may need to adapt national testing strategies and validate testing algorithms so that they include HIV self-testing. Furthermore, health workers and health-care facilities will need information on how to apply the national testing algorithm following the integration of HIV self-testing.

HIV self-testing accuracy is a priority concern for users and other stakeholders. The accuracy of test results depends on the type of HIV RDT, the specimen type (e.g. oral fluid or fingerstick whole blood), the sensitivity and specificity of the test, the way in which the RDT is used for self-testing and how test results are interpreted. HIV prevalence also affects accuracy: in a low HIV self-testing setting, positive predictive values will be lower than in a setting with a high prevalence of HIV, and the negative predictive values will be higher (and vice versa). Thus, population and setting have implications for the messaging around the use of HIV self-test kits, to the person using self-test kits.

*Appropriate and adequate instructions for use of the HIV self-test kit are critical to reducing errors and maximizing its accuracy. Clear and concise printed instructions – written and/or pictorial – are essential to support correct use and interpretation. In particular, users need to understand that a reactive (positive) test result must be confirmed through further testing.*

## 7. Key points to remember about HIV self-testing

- HIV self-testing has the potential to increase access to HIV testing including among people living with HIV without their knowledge, and those who are in need of HIV care, treatment and support.
- Populations that may benefit from HIV self-testing include the general population and health workers in settings with a high prevalence of HIV, key populations at higher risk in all settings, and those who frequently retest due to ongoing risk.
- HIV self-testing shares many characteristics with current HTC approaches, including products, accuracy issues, linkages to prevention and care services, potential benefits and risks, and regulatory policies and frameworks.
- HIV self-testing is already available—both formally and informally—in many places. Given the current demand for HIV self-testing, its use and availability is likely to increase in many settings.
- Research on HIV self-testing is continuing. It is essential to continuously expand the evidence base on HIV self-testing to inform not only the development of national policy and regulations, but also WHO normative guidance.
- Programmatic approaches and implementation models for HIV self-testing vary according to the type of support, the range of access and the site of sale or distribution. Although a number of models of RDTs are currently in use, many others could be developed or adapted to suit the local context.
- Key concerns regarding HIV self-testing also apply to all other types of HIV testing. The potential for harm can be minimized if HIV self-testing is provided within a human rights framework, and if it is done with adequate information, regulated and high-quality self-test kits, and community involvement in decision-making.
- National policies and regulations can be adapted to include HIV self-testing in existing HIV testing, as well as current counselling strategies and policies.

## Endnotes

1. This is different from home specimen collection, where individuals send their specimens to a laboratory to be tested and receive the test results from a trained professional.
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**UNAIDS**  
**Joint United Nations**  
**Programme on HIV/AIDS**

20 Avenue Appia  
1211 Geneva 27  
Switzerland

+41 22 791 3666  
distribution@unaids.org

[unaids.org](http://unaids.org)