

Recommendations for the Rapid Expansion of HIV Self-Testing in Fast-Track Cities

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BACKGROUND

- Globally, an estimated 40% of people living with HIV were unaware of their status in 2015.
- Late HIV diagnosis increases risk of illness, disability, death, and new HIV infections. Cities are heavily impacted by HIV and, by necessity, have served as first responders to the epidemic.
- Recommendations are needed to accelerate access HIV self-testing as part of the Fast-Track Cities initiative that now includes more than 75 high HIV burden priority cities worldwide.

METHODS

- IAPAC and ASLM convened an expert Advisory Panel from Africa, Asia, Europe, South America, and North America.
- The US Centers for Disease Control and Prevention systematically searched for 2000-2016 articles from electronic databases (MEDLINE, EMBASE, CINAHL, and PubMed) using multiple search terms in two areas: (i) HIV descriptors and (ii) self, home or rapid testing (5542 citations).
- Using the scientific literature and policy context, the recommendations were drafted by the co-chairs and technical writing team, and reviewed by the Advisory Panel.

RESULTS

The Advisory Panel developed nine recommendations for Fast-Track Cities and their stakeholders:

1. Support access to HIV self-tests for use at home and/or in assisted HIV self-testing settings
2. Ensure access to quality-assured, affordable HIV self-tests for everyone, with a focus on vulnerable populations
3. Lower the price of HIV self-test kits through price reductions, market diversification, pooled procurement, price transparency, market forecasting and subsidized pricing or for free
4. Accelerate regulatory and supply chain processes by identifying and addressing obstacles
5. Support monitoring and evaluation measures to assess individual barriers to HIV self-testing
6. Develop communication, educational and marketing efforts designed to encourage HIV self-testing
7. Optimize service delivery to facilitate self-referral after HIV self-testing
8. Remove government technical and administrative barriers to improve access to HIV self-testing
9. Monitor expansion of HIV self-testing as part of achieving 90-90-90 targets

CONCLUSIONS

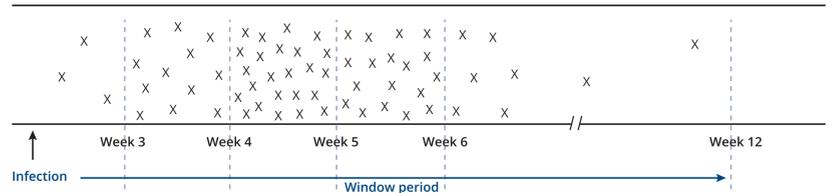
- Without concerted action, changing HIV policy and regulations to reflect new scientific discoveries may take years with serious negative public health consequences.
- Access to HIV self-testing will require strong commitment, smart programming, and ongoing programmatic adaptation.
- The HIV self-testing recommendations will assist cities to realize the potential of HIV self-testing to achieve the 90-90-90 targets and the end of AIDS as a public health threat.

Box 2. Window Period and HIV Self-Testing

The *window period* is a source of some confusion for providers and individuals alike. No HIV test can detect HIV immediately after infection—it takes time for the virus to replicate and for the body to develop antibodies to the virus. The time between a potential exposure to HIV infection and the time when an HIV test will give an accurate result is known as the window period of detection. This is the time taken by the body to produce antibodies in sufficient quantity to be detectable. The window period varies from person to person and also depends on the type of HIV test, as some tests detect antibodies earlier than others. Depending on the tests and the individual, this can be from around 21 days to around three months when most people (99%) will be antibody positive after they are infected.^{1,2} In other words, a negative result may not be accurate until three months after infection. During the window period, a person can be infected with HIV and be very infectious but still test HIV negative as they have not yet produced detectable antibodies to HIV.

While the window period is important for definitively excluding infection, it does not mean that people should wait 3 months to take a test, as the HIV self-tests can detect infection in some people within a matter of weeks. People need to consider their individual risks for HIV exposure and how often they would like to test themselves to catch recent infection earlier and/or confidently exclude HIV infection (i.e., no exposure within three months of an HIV negative test).

UNDERSTANDING THE WINDOW PERIOD



Each "x" represents the time when a different person develops antibodies. Some people develop antibodies rapidly and for others it may take up to three months. Early testing can help pick up HIV infection after a few weeks but the only way to be sure one is not infected is to do a test at three months after exposure.

Adapted from: <http://i-base.info/guides/testing/what-is-the-window-period>

References

- ¹ Delaney KP, Hanson DL, Masciotra S, Ethridge SF, Wesolowski L, Owen SM. Time until emergence of HIV test reactivity following infection with HIV-1: Implications for interpreting test results and retesting after exposure. *Clin Infect Dis*. 2016. doi: 10.1093/cid/ciw666. Advance access published online November 3, 2016.
- ² Online Supplementary materials for Delaney KP, Hanson DL, Masciotra S, Ethridge SF, Wesolowski L, Owen SM. Time until emergence of HIV test reactivity following infection with HIV-1: Implications for interpreting test results and retesting after exposure. *Clin Infect Dis*. 2016. doi: 10.1093/cid/ciw666. Advance access published online November 3, 2016.

Additional Resources

- <https://www.cdc.gov/actagainstaids/basics/testing.html>
<http://www.who.int/mediacentre/factsheets/fs360/en/>
<http://apps.who.int/iris/bitstream/10665/251655/1/19789241549868-eng.pdf>

Table 1. Available HIV Rapid Diagnostic Tests for Self-Testing with Approval from Regulatory Authorities

Assay name (manufacturer)	Type	Sample	Sensitivity (%)	Specificity (%)	Approval status (self-test)	Approximate price per test (US\$)*
Autotest VIH® (AAZ Labs, France)	IgG antibody test	Fingerstick	100.00	99.80	CE marked	\$25–28 to consumers; \$8–15 for NGOs and distributors
BioSURE HIV Self Test (BioSURE, United Kingdom)	IgG antibody test	Fingerstick	99.70	99.90	CE marked	Price to UK retail consumers is US\$36 (includes 20% VAT) Price for supply to public sector is US\$7.50-12.00
INSTI HIV Self Test (biolytical Laboratories, Canada)	IgM and IgG test	Fingerstick	100.00	99.80	CE marked	\$36 to consumers; for NGOs and distributors, cost depends on order size (e.g. \$3/test on offer for bulk sales in Africa)
OraQuick® In-Home HIV Test (OraSure Technologies Inc., USA)	IgG antibody test	Oral fluid	91.70	98.70	FDA	\$36–40 to consumers; no pricing outside USA for NGOs and distributors

CE: Conformité Européene; FDA: U.S. Food and Drug Administration

Source: The above table was adapted from UNITAID's resource document Technology landscape: HIV rapid diagnostic tests for self-testing. December 2016, Semi-annual update (http://unitaid.org/images/marketdynamics/publications/HIV_rapid_diagnostic_tests_for_self-testing_-_semi-annual_update-december_2016.pdf, accessed 30 December 2016). We advise those interested in up-to-date information to contact the manufacturers directly.

For more detailed information on the tests, please see: Autotest: <http://www.autotest-sante.com/en/autotest-VIH-par-AAZ-139.html>; BioSURE: <http://hivselftest.co.uk/>; INSTI self test: <https://www.insti-hivselftest.com/>; Oraquick in-home HIV test: <http://www.oraquick.com/FAQs>

*Pricing varies according to a number of factors including volume and setting; prices in Table are illustrative and may not reflect current rates; contact the manufacturer for more accurate quotes.