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evidence review

Rapid Tests for HIV

What is Rapid Testing?

Rapid testing for HIV provides results in as little as 20 minutes with a finger stick method. Approved rapid tests produce valid results with a high degree of sensitivity and are as sensitive and specific as traditional tests (enzyme immunoassay test [EIA]) (1;2) (Appendix A). All reactive rapid test results require confirmatory testing and are considered only "preliminary" (2;3). Confirmation is commonly performed with a standard Western Blot. In most test protocols, negative rapid tests do not need further confirmation (4). Two of the four approved rapid tests in the U.S. (5;6) can be used in POC by trained staff for finger stick blood or oral fluid (saliva) samples (2). These tests can be performed and interpreted by non-laboratory trained individuals who have taken a two hour learning session. Rapid HIV testing technologies have been approved for point of care (POC) settings in countries around the world.

This evidence review is part of a series on HIV prevention and control produced by the National Collaborating Centre for Infectious Diseases. It is intended to inform public health practitioners and community-based workers and guide their practice.

Is Rapid Testing Available in Canada?

Health Canada approved the first POC rapid test in 2005 and to date only one rapid test has been approved. BioLytical™'s INSTI HIV-1 Rapid Antibody (INSTI) Test is approved for provider-initiated POC testing for finger stick blood sample use (7;8). The test produces results in 60 seconds with the entire process taking 20 minutes including pre- and post-test counselling. Rapid testing sites are expanding throughout Canada. The Health Minister of Ontario, George Smitherman, recently announced that the province will add 24 new HIV testing sites, primarily in northern and rural Ontario, bringing the total number of rapid testing locations to 50 (9).

Highlights

- Approved rapid tests produce valid results with a high degree of sensitivity in as little as 20 minutes.
- Reactive rapid test results require confirmatory testing.
- One rapid test is available for use in Canada. At this time there are no rapid confirmatory tests available in Canada.
- Rapid testing has potential to increase testing in individuals with unknown HIV status, thereby reducing possibility of transmission.
- Concerns with rapid testing include: patients not returning for confirmatory results and testing in emergency situations can cause undue stress.
- Staff who administer rapid testing require training to help patients make informed decisions about testing.

Are Rapid Test and Home Tests the Same?

Rapid testing can be erroneously associated with home testing, and assumed to be available in a format similar to over-the-counter similar to a home pregnancy test. According to Health Canada, no HIV test kits are approved for sale for home use (10). In the U.S., approved Home Access Express HIV-1 Test is available as a "home sample collection kit" whereby a person collects the blood sample and mails it to a laboratory. Results and counseling are provided by phone. In contrast, a "complete home testing kit" would be conducted entirely at home without the intervention of an outside party, and results attained in-house. Complete home tests are not approved in the U.S.

Home testing is appealing to many people because of anonymity and convenience (6). However, the lack of face-to-face counselling, the fact of false positives and negatives, the need for confirmation of positive results, issues of confidentiality (such as the visibility of buying a test in a store, or giving a name and address to mail-in companies), and possible coercion by sexual partners, employers or government are major concerns.

Rapid testing programs have the potential to reach more individuals with unknown HIV status who can benefit from counselling with reduced probability of transmission, and create the possibility of access to care as well as many years of healthy productive life.

What are the Advantages of Rapid Testing?

As of 2003, almost 90% of the estimated 38 million people living with HIV worldwide are unaware of their infection (6). North America has an estimated 25-30% of people infected with HIV who are undiagnosed (11). Rapid testing programs have the potential to reach more individuals with unknown HIV status who can benefit from counselling with reduced probability of transmission, and create the possibility of access to care as well as many years of healthy productive life.

Rapid test technology can also yield higher rates of testing. Higher testing rates using rapid methods compared to traditional testing methods have been reported in: (a) public health testing sites using both voluntary nominal and anonymous screening (2;12-14); (b) mobile units, needle exchange and bathhouses (14;15); (c) acute care settings such as delivery rooms (16), hospitals and emergency departments (17;18), and (d) a Zimbabwean workplace. (19) When used for mobile HIV testing in Zimbabwe, 98.8% of participants chose to receive their test results on the same day (15). Many had not sought HIV testing before because of the location of the test site (20%) and inconvenience of the hours the test site was open (25%).

Another major advantage of rapid testing is the possible reduction of mother-to-child transmission of HIV during labour. This may be a last window of opportunity to offer HIV testing and, when indicated, interventions to decrease perinatal transmission (16;20). Rapid testing of both the victims and the source in occupational exposure and sexual assault emergencies facilitates decisions about initiating post-exposure prophylaxis (2).

Rapid testing can also used for organ donation screening and in geographically remote locations where access to testing facilities is difficult due to isolation. This is advantageous in Canada's north and remote communities.

Some rapid tests kits can be used at sites without refrigeration, electricity, water, or transport to laboratories (6). Thus, they can be used in street outreach settings, mobile clinics, and bathhouses (6;13;21;22). Emergency departments (EDs) are often the only POC for a subset of at risk individuals. Rapid testing in EDs, as in many other settings, can be feasible and cost-effective in reducing risk behaviors and the transmission of HIV (17;23;24).

Several research groups have found that there is a greater likelihood that HIV-negative persons will receive their results with rapid testing than with traditional testing (13;14;24;25). The reasons for increased receipt of results with rapid testing are faster results (20 minutes to three hours), a reduction in the need for a return visit, less stress involved among those who ultimately test negative, and the ease of saliva or finger stick specimen collection compared to phlebotomy (2;14;22;24).

Acceptance rates of the rapid test were moderate to high in a number of studies. The acceptance rate was high among both nominal and anonymous testers, especially pregnant women (83% to 97%) (13;16;20;21;24-26). Further, almost all (~90%) midwives and service providers agreed that there was a place for rapid testing in the delivery ward (13;26). In two studies where participants were offered testing alternatives, 27% selected rapid testing, 20% selected home self-testing, 18-64% selected oral fluid testing, 17% chose urine testing; however, 17% preferred EIA blood testing (14;21). Individual

preference for rapid tests varied according to ethnic and socio-economic background (20;21).

What Are the Concerns with Rapid Testing?

One major limitation of studies investigating rapid testing is that they assume more people will actually receive their results if they test reactive (27). In rapid testing procedures, persons in most developed countries are informed about preliminary reactive results but are required to undergo a second test visit to get confirmation of results with a Western Blot assay. The U.S. Centers for Disease Control found that 31% of patients who tested reactive for HIV with a rapid test did not return to receive results for confirmation (3). Reasons for not returning for results include fear and stigma as well as a chaotic life style (24;28). Strategies to increase the receipt of results for reactive tests include: (a) patients receive counseling and social assistance before leaving the test site (18), (b) offer a financial incentive to return (17)) or (c) receive a telephone call or follow up visit from a public health nurse (28). One study offering a monetary incentive reported an increase (from 8% to 23%) in ED patients who completed HIV counseling and testing offsite (17).

Counseling in a rapid testing environment is slightly different and requires that clients understand: (a) the meaning of the preliminary test result; (b) that the preliminary result will be given in the same session; and (c) that a return for a confirmatory results in the event of a reactive test is necessary (6). Waiting for a long confirmatory test can cause undue psychological distress. Studies have shown that it is essential for individuals testing positive to have substantive opportunity to discuss their results with counselors (13;25).

Consideration is also required when testing people in emergency situations such as in delivery rooms or following occupational exposure or sexual assault. In this setting, persons may be under duress and may have difficulty integrating the information they need to make an informed decision (6). For pregnant women, Pai and colleagues have suggested a short counseling session using visual aids to explain interventions during labour, followed by an extended second post-partum counseling session (20). Increased training of staff is needed in rapid test settings to minimize unintended stress on patients.

In low prevalence sites where the prevalence of HIV infection is less than 0.10%, despite the excellent specificity of current rapid HIV tests, the number of reactive tests will be approximately equal to or may even exceed the number of true HIV-infected persons. This needs to be understood by test users and included in counseling.

Currently, no approved rapid confirmatory HIV test is available in Canada, so standard laboratory delays are unavoidable (3). Pai and colleagues (20), in their meta-analysis of pregnant women being rapidly tested, recommend using two rapid tests during delivery to improve diagnostic accuracy and to reduce false-positive results.

Finally, adequate counseling to enable the client to make an informed decision during delivery and in emergency situations may not always be possible. Home screening methods need sufficient controls to ensure that people testing can receive support, counseling, and subsequent care and treatment.

Emergency departments (EDs) are often the only POC for a subset of at risk individuals. Rapid testing in EDs, as in many other settings, can be feasible and cost-effective in reducing risk behaviors and the transmission of HIV.

What Can We Conclude About Rapid Testing?

The argument that rapid POC screening will significantly increase the number of people who are tested and subsequently receive their confirmatory test results with follow up for care and counseling requires further study in Canada and in other countries with low HIV incidence. Persons found reactive may not return for the results of the confirmatory Western Blot. A second rapid test that would be accepted as confirmatory may increase the proportion of persons who receive their positive results but this may not be possible in societies where the Western Blot has always been considered essential for a conclusive diagnosis. However, most people who test negative usually prefer a rapid test because it is quicker, eliminates the need for a return visit, creates less stress, and is less invasive.

Rapid HIV tests are becoming an important part of the strategy for ensuring that most persons at risk for HIV know their infection status and are informed about care and prevention of further transmission. It makes a major contribution to removing barriers from testing. Further operational studies will delineate its ultimate role in controlling the HIV epidemic.

Reference List

(1) BC Centre for Disease Control. Guidelines for the use of the POC HIV test: Information for health care professionals. BC Centre for Disease Control 2007 April; Available from: URL: http://www.bccdc.org/downloads/pdf/std/reports/2007_poc%20hiv%20test%20guidelines%20april%2012%202007.pdf?PHPSESSID=43f2e2e7cfdea5f940529317fa508ac7

(2) Bogart LM. HIV testing: State of the field and current research. http://www medscape com/viewarticle/553272 2007; Available from: URL: http://www.medscape.com/viewarticle/553272

(3) Greenwald JL. Routine rapid HIV testing in hospitals: another opportunity for hospitalists to improve care. J Hosp Med 2006;1(2):106-12.

(4) BC Centre for Disease Control. Guidelines for the use of the POC HIV test: Information for health care professionals. BC Centre for Disease Control 2007 April; Available from: URL: http://www.bccdc.org/downloads/pdf/std/reports/2007_poc%20hiv%20test%20guidelines%20april%2012%202007.pdf?PHPSESSID=43f2e2e7cfdea5f940529317fa508ac7

(5) bioLyticalTM Laboratories. BC Medical association cites bioLyticalTM Laboratories INSTITM HIV-1 rapid antibody test for point-of-care HIV testing. http://www biolytical com/press_releaseInfo asp?pressID=236 2007 May 10; Available from: URL: http://www.biolytical.com/press_releaseInfo.asp?pressID=236

(6) Schietinger H. Reaching the hidden epidemic with HIV testing and counselling: policies in transition? TheForum for Collaborative HIV Research The Public Health Agency of Canada International Public Health Dialogue on HIV Testing and Counselling and the Hidden Epidemic:Toronto 2006 Available from: URL: http://www.hivforum.org/uploads/EC/2006%20in%20person/Dialogue%20Paper%20AUG%207.doc.

(7) bioLyticalTM Laboratories. BC Medical association cites bioLyticalTM Laboratories INSTITM HIV-1 rapid antibody test for point-of-care HIV testing. http://www biolytical com/press_releaseInfo asp?pressID=236 2007 May 10 [cited 2007 Jun 15]; Available from: URL: http://www.biolytical.com/press_releaseInfo.asp?pressID=236

(8) CNW Telebec. Health Canada approves new MedMira rapid HIV test. http://www cnw ca/fr/releases/archive/October2004/21/c3182 html 2004 October 21 Available from: URL: http://www.cnw.ca/fr/releases/archive/October2004/21/c3182.html

(9) Leslie K. HIV test gives results in just 60 seconds. The Globe and Mail 2007 June 23; Available from: URL: http://www.theglobeandmail.com/servlet/story/LAC.20070623.ONTAIDS23/TPStory/National

(10) Associated Press. Health Canada approves rapid-result HIV test. Associated Press 2005 November 8 Available from: URL: http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/20051108/rapidresult_hivtest_051108?s_name=&no_ads=

(11) Public Health Agency of Canada. HIV testing and counselling: Policies in transition? http://www phac-aspc gc ca/aids-sida/publication/hivtest/index-eng html 2006 Available from: URL: http://www.phac-aspc.gc.ca/aids-sida/publication/hivtest/index-eng.html

(12) San Antonio-Gaddy M, Richardson-Moore A, Burstein GR, Newman DR, Branson BM, Burkhead GS. Rapid HIV antibody testing in the New York State anonymous HIV counselling and testing program: experience from the field. J Acquir Immune Defic Syndr 2006;43(4):446-50.

(13) Guenter D, Greer J, Trow R, Browne G, Robinson G, et al. The effects of a rapid point-of-care HIV testing program: Hassle Free Clinic, Toronto. MacMaster University Working Paper Series 2003 Available from: URL: http://www.fhs.mcmaster.ca/slru/clear/working_papers.htm

(14) Spielberg F, Branson BM, Goldbaum GM, Lockhart D, Kurth A, et al. Choosing HIV counseling and testing strategies for outreach settings: a randomized trial. J Acquir Immune Defic Syndr 2005;38(3):348-55.

(15) Morin SF, Khumalo-Sakutukwa G, Charlebois ED, et al. Removing barriers to knowing HIV status: Same-day mobile HIV testing in Zimbabwe. J Acquir Immune Defic Syndr 2006;41:218-24.

(16) Bulterys M, Jamieson DJ, O'Sullivan MJ, Cohen MH, Maupin R, et al. Rapid HIV-1 testing during labour: a multicenter study. JAMA 2004;292(219):223.

(17) Silva A, Glick NR, Lyss SB, Hutchinson AB, Gift TL, et al. Implementing an HIV and sexually transmitted disease screening program in an emergency department. Ann Emerg Med 2007;49(5):564-72.

(18) Wanyenze R, Kamya M, Liechty C, Ronald A, Guzman D, et al. HIV counseling and testing practices at an urban hospital in Kampala, Uganda. AIDS Behav 2006;10(4):361-7.

(19) Corbett EL, Dauya E, Matambo R, et al. Uptake of workplace HIV counseling and testing: A cluster-randomised trial in Zimbabwe. PLoSMed 2006;3(7):e238.

(20) Pai NP, Tulsky JP, Cohan D, Colford JM, Reingold AL. Rapid point-of-care HIV testing in pregnant women: A systematic review and meta-analysis. Trop Med Int Health 2007;12(2):162-73.

(21) Liang TS, Erbelding E, Jacob CA, Wicker H, Christmyer C, et al. Rapid HIV testing of clients of a mobile STD/HIV clinic. AIDS Patient Care STDS 2005;19(4):253-7.

(22) Spielberg F, Branson BM, Goldbaum GM, Lockhart D, Kurth A, et al. Overcoming barriers to HIV testing: Preferences for new strategies among clients of a needle exchange, a sexually transmitted disease clinic, and sex venues for men who have sex with men. J Acquir Immune Defic Synd 2003;32(3):318-27.

(23) Ekwueme DU, Pinkerton SD, Holtgrave DR, Branson BM. Cost comparison of three HIV counseling and testing technologies. Am J Prev Med 2003;25(2):112-21.

(24) Hutchinson AB, Corbie-Smith G, Thomas SB, Mohanan S, del Rio C. Understanding the patient's perspective on rapid and routine HIV testing in an inner-city urgent care centre. AIDS Educ Prev 2004;16(2):101-14.

(25) Rotheram-Borus MJ, Leibowitz AA, Etzel MA. Routine, rapid HIV testing. AIDS Educ Prev 2006;18(3):273-80.

(26) Stokes SH, McMaster P, Ismail KM. Acceptability of perinatal rapid point-of-care HIV testing in an area of low HIV prevalence in the UK. Arch Dis Child 2007;92(6):505-8.

(27) Australian Federation of AIDS Organizations. Rapid testing for HIV: Preliminary discussion document. 2004.

(28) Hutchinson AB, Branson BM, Kim A, Farnham P. A meta-analysis of the effectiveness of alternative HIV counseling and testing methods to increase knowledge of HIV status. AIDS 2006;20(12):1597-604.

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