A rapid approach to community-based HIV testing

By Len Tooley

It is estimated that 26% of HIV-positive people in Canada do not know their HIV status. With statistics that high it makes sense that improving access to and ease of HIV testing is an important element of HIV treatment and prevention strategies. Across Canada, community-based organizations and health service providers are increasingly looking to rapid point-of-care (POC) HIV testing as a critical tool in the effort to increase HIV testing rates in their communities. POC testing allows service providers to give immediate HIV test results in a variety of community settings. It therefore holds great promise as an important part of the continued expansion of HIV testing to new communities and organizations.

The evolution of HIV antibody testing in Canada: from two weeks to two minutes

Blood tests for HIV antibodies have been available in Canada since 1985. With standard HIV antibody testing, pre-test counselling is conducted and a blood sample is taken. The sample is sent to a laboratory, where a test called an Enzyme Immunoassay (EIA) is done. If the sample is negative for HIV antibodies, the result is sent back to the healthcare provider. If it is positive, the laboratory goes on to do confirmatory testing before sending the result back. The client returns to the clinic after two weeks to get the result and to receive post-test counselling.

In comparison, when the POC test is used, clients are given pre-test counselling, which includes a discussion of the benefits and risks associated with rapid testing, as well as the need for confirmatory blood work if the POC test is reactive (a preliminary positive result). The counsellor then uses a lancet—a spring-loaded device with a small needle—to prick the client’s finger and takes a few drops of blood using a pipette. The test itself is performed out of sight of the client and the result is available in approximately two minutes. If negative, the client is given the result and post-test counselling. The whole process can be completed in one 20-minute visit. If the test indicates a reactive result, the client is informed of the result and, after obtaining informed consent, the counsellor draws a blood sample, which is sent to the laboratory for confirmatory testing. The client is given post-test counselling immediately after receiving a reactive result and again when returning to pick up the confirmatory result one to two weeks later.

The benefits of this POC model of HIV antibody testing are numerous. Rapid testing makes the test much more portable, allowing it to be conducted in an almost unlimited number of community settings. It also allows for continuity of the counselling experience: clients will always be given pre- and initial post-test counselling by the same counsellor, which is much more difficult to ensure with the two-week waiting period that comes with standard HIV testing. Clients who test HIV-positive can receive enhanced follow-up counselling as there is a built-in second visit to receive the confirmatory results.

How do we know if it works?

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The POC test currently in use is the INSTI™ HIV-1 Rapid Test, manufactured by bioLytical Laboratories of Richmond, B.C., which was approved for sale to healthcare professionals by Health Canada in October 2005 after intensive study. Based on an independent study conducted across three provinces, the test was shown to have greater than 99.6% specificity. This means that 99.6% of healthy individuals are correctly identified as being HIV-negative using this test. This sensitivity is comparable to standard laboratory-based EIA HIV antibody testing. The window period for this test is the same (3 months) as for the standard test.

**A community-based beginning**

Hassle Free Clinic, a community-based, collectively run sexual health clinic in downtown Toronto is a good example of how one community-based service provider can greatly influence HIV testing across an entire province. It has been providing medical and counselling services in all areas of sexual health since 1973. Hassle Free immediately began providing HIV education and prevention counselling at the onset of the HIV/AIDS crisis in 1983. When HIV testing became available in 1985, Hassle Free offered anonymous testing illegally to clients for seven years until the Ontario government legalized anonymous testing in 1992 (see box for definitions of the different forms of HIV antibody testing that may be conducted in Canada). The clinic then contributed significantly to drafting the first provincial Anonymous Testing guidelines and training staff in designated sites across Ontario.

In Canada, standard HIV antibody testing may be available in three forms:

1. **Nominal Testing** is the most widely used method of HIV testing. The tester’s name and identifying information are sent to the laboratory with the sample and test providers are legally obligated to report HIV-positive results to public health officials.

2. **Non-Nominal Testing** is similar to nominal testing except the service provider uses a code when sending a sample to be tested. Public health officials are only notified of the tester’s identity if the result is positive.

3. **Anonymous Testing** entails no collection of any personal identifying information about the tester. Only epidemiological data is sent to public health officials regardless of a positive or negative result.

Anonymous testing is not currently available in all provinces and territories despite widely cited research that suggests it leads to an uptake in testing rates among populations at high risk of becoming HIV positive. In most provinces anonymous testing differs from nominal and non-nominal testing in that the service provider is required to provide in-depth pre- and post-test counselling, which includes information about HIV testing, a personalized HIV risk assessment, and support preparing for and upon receiving a positive result.

The clinic initially began offering an earlier, different version of the rapid HIV test (Fast-Check HIV-1/2) in 2001. However, this test had to be taken off the market in 2002 because of concerns regarding its accuracy and Hassle Free had to stop offering this test to clients.

Many good things did come out of this experience, however. The clinic showed that it was able to change its protocols to accommodate the need for pre- and post-test counselling in the same session; and staff created a new data recording system to ensure that epidemiological data were routinely recorded and regularly sent to Public Health for surveillance purposes. A study, *The Effects of a Rapid Point-Of-Care HIV Testing Program*, was conducted in collaboration with the Community-Linked Evaluation AIDS Resource (CLEAR) Unit at McMaster University.
University. This study, which focused on client and provider experiences of rapid testing rather than the technology itself, concluded that:

- Rapid HIV testing can be carried out in a highly efficient and effective manner.
- Rapid testing was the preferred choice for most anonymous testers, being easier and more satisfying for both counsellors and testers than standard testing—irrespective of a positive or negative result.
- Levels of pre-test anxiety were the same whether a client chose to do a standard or rapid HIV test.
- All clients who chose the rapid test received their results.\(^2\)

As this early though short-lived experience had such a positive response in terms of client satisfaction, the clinic was keen to start implementing rapid testing again when the new INSTI™ HIV-1 Rapid Test became available in 2005.

A retrospective look at the results of confirmatory laboratory testing of reactive or indeterminate POC tests, reviewed after a one-year period beginning in May 2006 (comprising 4,180 POC tests), indicated a specificity of 99.7%—slightly higher than that originally reported by bioLytical Laboratories.\(^6\) The results of this study confirmed that the new test was as accurate as standard laboratory testing and thus an appropriate technology to implement in a clinical setting.

A client satisfaction survey was conducted during the first three months of administering the new test. Of the 400 respondents to the survey, 98% reported overall satisfaction with the POC testing experience.

### Overcoming barriers to implementation: successes in Ontario

With a wealth of data that showed the many benefits of rapid testing, Hassle Free was prepared to start advocating for the broader implementation of POC testing at other sites across Ontario. They knew that POC testing was a viable and realistic step toward increasing HIV testing provincially.

But questions had to be asked: Due to the new cost associated with POC testing (each rapid test costs over $10), how could equal access to POC testing be ensured? Further, with the relative ease and speed of the POC test, how could adherence to counselling and procedural guidelines as well as the maintenance of epidemiological data collection be ensured? “We wanted to make sure it was done right,” says Jane Greer, a counsellor and administrator at Hassle Free.

Presented with the opportunity to roll out POC testing across the province, these issues had to be addressed to ensure access to testing and broad confidence in the quality, accuracy, appropriateness and benefits of POC HIV testing versus standard laboratory-based testing.

### Access to POC testing

A collaborative process ensued, involving the Ontario AIDS Bureau, Hassle Free Clinic and other key stakeholders. The proposed solution was to have the Ontario Ministry of Health and Long-Term Care (MOHLTC) centrally purchase and distribute the POC testing kits to appropriate sites, such as anonymous HIV test sites, sexual health clinics and other AIDS service organizations. In this way, access to POC testing could be provided across the province, and central guidelines could be developed to ensure the appropriate implementation of the new technology. These solutions have become the foundation of Ontario’s Provincial Rapid POC HIV Testing Program.

### Quality assurance and control

One of the most critical challenges in rolling out POC testing was that rapid testing took the HIV antibody test out of Public Health labs—which are tightly regulated and have a great deal of expertise in quality assurance and quality control—and put the testing technology into the hands of service providers who may or may not have technical expertise in quality assurance and quality control (QA/QC) measures.

In collaboration with consultants experienced with HIV testing in Ontario, a number of QA/QC measures were put in place and codified in Policies, Procedures and Quality Assurance for Point-of-Care HIV Testing in Ontario.\(^\$\)

Each site that employs POC testing is extensively trained and required to follow a protocol that includes certification of all personnel conducting the POC test, daily temperature monitoring and regular QC testing of kits. POC sites
have found the process to be very manageable; however, some sites with very low testing rates (2 to 3 HIV tests per week) have opted to stick to standard testing as their rates were not high enough to justify conducting regular QA/QC measures.

To ensure continued QA/QC, the Ontario POC testing program is subjected to the same external QC program that all Public Health labs in the province participate in.

**Continued collection of epidemiological data**

One procedural issue of rapid POC testing was that with no blood sample going to the lab for analysis, important HIV testing epidemiological information might not get passed on to Public Health, which could significantly alter the monitoring of HIV prevalence and incidence across the province. The solution was that for each POC test conducted sites would continue sending the same requisition form that had been used for standard HIV testing. A simple sticker system was created that indicates a POC test was conducted and what the result was (see Policies, Procedures and Quality Assurance for Point-of-Care HIV Testing in Ontario pages 3 and 4 for a description of the sticker system). This allows Public Health to continue capturing information such as risk categories, potential exposure, suspected seroconversions, age (by birth year only), gender and first-time testers.

**Changes to pre- and post-test counselling**

Another concern was ensuring that any alterations in pre- or post-test counselling protocols as a result of the switch to POC testing were captured appropriately in the Ministry’s Procedures for Anonymous HIV Counselling and Antibody Testing in Ontario. A working group was established to consider all aspects of the counselling guidelines. The most significant change was that post-test counselling occurs at the same visit as pre-test counselling and testing. Counselling for positive results now happens on two occasions: initially on the day results are given, addressing strategies to cope with stress and anxiety while waiting for the results of the confirmatory blood test; and, secondly, on the follow-up visit to receive the confirmatory test results.

By centrally funding the provision of test kits, QC/QA measures and epidemiological data collection, the AIDS Bureau and MOHLTC are able to require that sites providing anonymous POC testing meet the standards set out for quality assurance, recording of epidemiological data and pre- and post-test counselling standards. This model has proven to be very successful in ensuring consistent, high-quality provision of POC HIV testing across the province.

**The growth of rapid HIV testing in Ontario: from one community to many**

In June 2007, thanks to the efforts of stakeholders such as Hassle Free Clinic, the Minister of Health and Long-Term Care announced the initiation of a province-wide POC HIV testing program. “It just makes sense. If the technology is available, and we know it works, let’s use it,” says Ken English, senior program consultant at the Health System and Accountability Performance Division of the AIDS Bureau, Ontario Ministry of Health and Long-Term Care.

Around the same time, in 2006, the AIDS Bureau had undertaken to expand its provincial anonymous HIV testing program from 24 to 50 sites across Ontario. When the MOHLTC announced the establishment of the provincial POC HIV testing program, the AIDS Bureau took advantage of its pre-existing network of anonymous testing sites, with whom it had already developed strong working relationships, to roll out the POC testing program. There are now about 50 sites in Ontario delivering POC testing. The vast majority of these sites are providing the testing anonymously.

**Some promising results...**

A recent summary of the Ontario HIV POC testing program produced by the AIDS Bureau has shown some very promising results.

- Since the beginning of 2009, almost 14,000 tests have been performed at more than 40 sites in Ontario.
- Almost 1% of tests completed have resulted in a confirmed HIV-positive test result. This is a three- to four-times higher positivity rate than standard testing, which suggests that more people at high risk for HIV are being reached with POC testing.
Of the people testing HIV-positive, 15% were determined to be early and recent seroconverters. This is especially significant because people in these stages of seroconversion are most infectious with respect to HIV. Finally, 32% of the people testing HIV-positive were first-time testers, which tells us that the rapid test is attracting people that otherwise might not have been tested.

Rapid POC HIV testing experiences: what we have learned

Service providers conducting POC HIV testing in urban and rural settings in Ontario have had positive experiences with the uptake and implementation of rapid testing. Three major reported benefits of POC testing over standard laboratory-based testing are discussed below.

Accessibility and portability

Options Clinic in London, Ont., has been providing POC testing since May 2007. It is a good example of how POC testing is increasing access to, and uptake of, HIV testing for high-risk populations.

Lyn Pierre-Pitman, coordinator of Options Clinic, believes that service providers “have to get HIV tests to where people are at, not force them to come to us.” This attitude has led to a strong outreach component to Options Clinic’s HIV testing program; staff make regular visits to a local Youth Action Centre for street-involved youth, a needle exchange for injection drug users, a local bathhouse for gay, bisexual and other men who have sex with men (MSM), and a rural church site.

Prior to the introduction of the POC test, Pierre-Pitman was concerned that as many as 36% of youth at the Youth Action Centre and 16% of the injection drug users at the needle exchange were not picking up their HIV test results. She also remembers numerous clients who declined HIV testing because of the perceived hassle of having to go through pre-test counselling and then wait two weeks for results. Now that POC testing has been made available, clients at outreach locations (considered at high risk of HIV infection) are getting their results the same day they test, drastically reducing the number of testers who aren’t getting their results. Options Clinic has also noted an overall increase in people seeking testing since the advent of the rapid test, as word spreads through the community.

Continuity of counselling

One unforeseen yet very important benefit to POC testing noted by counsellors is the opportunity for continuity of counselling from pre-test counselling to disclosure of results and post-test counselling. With standard testing, pre-test counselling and result disclosure are conducted at separate visits. This can present a number of challenges to a counselling relationship where the client–provider interaction is usually limited to at most two to three visits. When clients return for their standard test result, service providers cannot always guarantee that the tester will be speaking with the same counsellor who provided the pre-test counselling. And even if the client does have the same counsellor, service providers often find that it can be difficult to maintain the therapeutic relationship during the two-week waiting period without any ongoing contact. It can be challenging to (re)initiate a counselling relationship on the premise of disclosing an HIV test result, especially when the result is positive.

Stephanie Vendetti, acting manager of Clinical Services at the Sudbury District Health Unit, also believes that the immediacy of the test provides a greater opportunity to influence any risky behaviours clients might be engaging in. She notes that “for clients who test negative, you can ask the client that—barring any window period concerns—knowing that you are not HIV-positive, what can you do next time to make sure you don’t become HIV-positive? It’s just seizing that teachable moment and making it important to the client.”

Enhanced follow-up for clients testing HIV-positive

Several service providers also appreciate that with POC testing there is more built-in post-test counselling for the client if their initial result is reactive. As only one clinic visit is required for clients who test negative with the POC test, counsellors may have more time to spend with those clients returning to the clinic to pick up confirmatory results.

Often when a client first receives a positive result they retain very little of the information given in the post-test counselling situation. The second post-test counselling session (in which confirmatory results are given) allows counsellors to review information, answer any questions that the client may have, and follow up on any referrals (to
AIDS service organizations, doctors, etc.) that were made initially.

POC HIV testing beyond Ontario

Nine Circles Community Health Centre in Winnipeg, Manitoba, is another service provider that has been successful at bringing POC testing to its site. Nine Circles is a community-based, non-profit centre specializing in STI/HIV prevention and care.

“People were finding out that they were HIV-positive very late in the course of infection, so we wanted to bring in rapid testing to increase uptake of HIV testing,” says Nine Circles Clinical Program Manager Carla Pindera. Nine Circles approached the Minister of Healthy Living in Manitoba and secured funding to provide POC testing nominally and non-nominally at the Nine Circles site and through outreach programs.

In March 2008, Nine Circles started offering POC testing to clients and also set up a system to monitor all POC tests by doing routine confirmatory tests (on both positive and negative results) and conducting patient and provider satisfaction surveys for each POC test performed. To date the results of Nine Circles’s ongoing evaluation are exceedingly positive: 91% of clients were overall satisfied with their experience, 9% neutral and none were dissatisfied. Furthermore, 100% of its confirmatory laboratory tests (for both positive and negative results) have been consistent with the POC test result.

Staff at Nine Circles are working to expand their POC testing program, specifically with pregnant women at the Women’s Hospital in Winnipeg as well as at alternative venues such as the Youth Addiction Stabilization Unit (YASU) where youth with addiction concerns stay from 24 hours to seven days. In order to truly move forward with expanding the POC program on a province-wide basis, however, the Ministry of Healthy Living is waiting for formal evaluation data. Until then, any expansion of POC testing needs to be funded directly by the community organizations wanting to provide the test, which can be a strong deterrent, especially in high-risk communities.

Continued expansion of rapid HIV POC testing: moving forward appropriately

POC testing has the potential to largely and positively affect the landscape of HIV testing and parallel treatment and prevention efforts across Canada, especially in hard-to-reach and high-risk populations.

However, Canada is at a crucial junction: as the availability of POC testing increases, there is a potential for the test to be offered at sites that have no background in HIV pre- and post-test counselling and no experience of collecting epidemiological data or implementing QC/QA measures.

These concerns have been voiced both by community organizations like Hassle Free Clinic and organizations such as the Canadian HIV/AIDS Legal Network. These entities strongly recommend that governments, in consultation with community-based organizations and healthcare providers, should issue regulations and policies restricting access of POC testing kits; only those service providers who are appropriately trained and who can confidently carry out the necessary QA/QC, pre-and post-test counselling and confirmatory testing procedures should have access to POC HIV testing technologies.

Jane Greer of Hassle Free stresses that while POC testing can increase accessibility to testing, especially for at-risk communities, it is essential that service providers are still held to high standards with respect to the “three C’s of HIV testing: high-quality pre- and post-test Counselling, obtaining informed Consent, and ensuring rigorous Confidentiality.” She also points out that for those clients who do have a reactive POC test, service providers must be sufficiently trained to explain the meaning of the result and that follow-up testing must be done.

We are at a moment in time in which there is a solid foundation of groundwork laid to broadly provide POC HIV testing across the country. With continued advocacy from community-based service providers, federal and provincial ministries and public health laboratories have an exciting opportunity to take the lead in increasing access to POC HIV testing and make an important step toward further addressing HIV/AIDS on community, provincial and national levels.

New HIV Testing and Counselling Guidelines for Canada

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**References**


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