

Impact and Use of Point of Care HIV Testing: A Public Health Evidence Paper

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EXECUTIVE SUMMARY

Point of care (POC) HIV tests are screening tests for HIV available for use by health care professionals in clinical settings. This paper is an update of a 2007 review of the evidence regarding the use and impact of POC HIV tests, in order to guide the appropriate use of this technology in BC.

The key characteristics of POC HIV tests are:

- POC HIV tests licensed for use in Canada will have similar sensitivity and specificity compared to standard HIV screening tests ($S_n, S_p > 99\%$). False positive POC HIV tests will occur (particularly in settings with low HIV prevalence).
- With standard HIV testing, the result returned to the patient is final. While a negative POC HIV test is considered final and no confirmatory testing is required, a positive POC HIV test is a preliminary result and confirmatory testing is required.
- The window period may differ slightly between POC HIV test products and standard HIV screening tests, which may lead to infrequent discrepant results. Standard HIV screening tests may perform better than POC HIV tests for detection of early HIV infections.
- Typically health care professionals find POC HIV tests to be easy to use. Unlike automated protocols in place for interpretation of standard HIV testing, interpretation of POC HIV tests is subjective. Inter-reader variability in test interpretation is low, although variability may be greater in early HIV infection.
- With standard HIV testing, a follow-up visit is required for receipt of results. The same applies to POC HIV testing if the result is preliminary positive; however if the test is negative a follow-up visit is not required.
- Unlike standard HIV testing, the health care professional administering the POC HIV test assumes the responsibility for quality assurance activities to ensure that the test is carried out correctly. Sites adopting POC HIV testing are recommended to implement and maintain appropriate quality assurance measures, including staff training and competency assessments, documentation and monitoring of test outcome, and regular use of test control kits.

The potential impacts of POC HIV testing are:

- Use of POC HIV testing may result in increased acceptance and volume of HIV testing.
- Individuals undergoing POC HIV testing are more likely to receive their test result, particularly if HIV negative. Receipt of a final HIV positive result may not differ from standard testing, although individuals may be more likely to present independently for receipt of confirmatory test results.
- The rapid turnaround time associated with POC HIV testing can guide urgent decision-making to prevent HIV infection or to improve patient care.
- POC HIV testing may lead to decreased uptake of testing for other infections (e.g., hepatitis C, syphilis).
- Increased incidence of sexually transmitted infections has been associated with the use of POC HIV testing, possibly due to disinhibition on receipt of a negative test result or compression of counselling into a single visit.

POC HIV tests have been recommended for testing of pregnant women with unknown or undocumented HIV status at the time of labour, and for testing of source or exposed individuals in blood and body fluid exposures (particularly for occupational exposures). The use of POC HIV tests has also been found to be feasible in: hospital-based settings (e.g., emergency rooms, inpatient wards), STI or HIV testing clinics, corrections facilities, a variety of different outreach and community settings, and primary care settings.

The findings of this review demonstrate that POC HIV tests may be of use in BC, however, their potential benefit must be weighed against potential harms. Studies reviewed here were largely based in large, urban centres in the US in settings having high volumes of HIV testing and a high prevalence of HIV infection, which may limit the generalizability of these findings to BC.

The development of new test technologies such as POC HIV testing may facilitate the identification of persons infected with HIV and their engagement in HIV prevention and connection to appropriate care and support. When considering the use of a POC HIV test product, these findings should be weighed against the specific characteristics of the POC test product and standard HIV testing protocols in place.

INTRODUCTION

Point of Care (POC) or rapid HIV antibody tests are screening tests for HIV which are available for use in a clinical setting, typically providing results within minutes. The first POC HIV tests were developed in the late 1990's, and kits have been developed for use with oral fluid, fingerstick or venous blood specimens. One POC HIV test has been licensed for use in Canada, the INSTI™ HIV-1 Antibody Test Kit.¹ In the US these products have been adopted for use in multiple settings, with the development of a national rapid test distribution program in 2003.² In Canada, use of POC HIV testing is becoming more common. In Ontario a provincial POC testing program was established in 2007 through an existing network of anonymous HIV testing sites; pilot projects have also been established in Quebec, Manitoba and Alberta. POC HIV tests have also been increasingly used in BC, and a provincial POC HIV testing program is currently under development.

This document updates a previous literature review conducted in 2007, to provide the current evidence related to the following three questions:

- i) What are the characteristics of POC HIV tests compared to standard HIV testing?
- ii) What is the impact of POC HIV tests compared to standard HIV testing?
- iii) In what settings and for what indications has POC HIV testing been used or recommended?

Please note that this is a general review of POC HIV tests. Specific characteristics or impacts may differ depending on the POC HIV test and specimen type under consideration and the current standard HIV testing protocols in place. These need to be considered in evaluating the potential regional impact of specific POC HIV test products. As new standard HIV test protocols are implemented (such as pooled nucleic acid amplification testing or fourth generation enzyme-linked immunoassays (EIA)) the impact of an adopted POC HIV test product may need to be reconsidered.

METHODS

For this review, we considered POC HIV tests to be HIV tests which provide a result within minutes to hours, with same day provision of test results at the point of care (i.e., at the site of interaction with client being tested such as within a clinic or in an on-site laboratory). We defined standard HIV testing as HIV antibody testing requiring venipuncture and follow-up for receipt of results (i.e., a screening test such as a second or third generation EIA and a confirmatory test as required such as a Western Blot).

We searched MEDLINE using the subject heading Point-of-Care systems, and the key words HIV, test, testing, rapid, point of care. Articles describing the use or impact of POC HIV tests published prior to September 2010 were identified and reviewed, and relevant citations from bibliographies were retrieved. Online abstract

databases for scientific conferences related to HIV were also searched for relevant material (i.e., International AIDS conferences, Conferences on Retroviruses and Opportunistic Infections, Canadian Association for HIV Research).

We included studies from industrialized countries only as these studies are more likely to be generalizable to British Columbia. Tests for all specimen types were included. Studies which were designed primarily to evaluate the diagnostic properties of specific POC HIV test products were not included. For the assessment of the impact of POC HIV testing compared to standard HIV testing, we reviewed studies which included a comparison between POC HIV testing and standard HIV testing, excluding results which could be biased by differences between comparison arms (e.g., using different recruitment approaches).

RESULTS

1. Characteristics of POC HIV tests compared to standard HIV testing

1.1 Test Performance

Any POC HIV test licensed for use in Canada will have similar performance compared to standard HIV screening tests (sensitivity and specificity > 99%).³ POC HIV tests have high negative predictive value and a negative result is considered final; however, the positive predictive value will vary according to HIV prevalence and false positive results will occur. Consequently a positive POC HIV test result is considered a preliminary result which requires confirmation by collection of a venous blood specimen. Some have recommended qualifying a preliminary positive result according to an individual's risk of HIV (i.e., as a positive POC test result in a person from a population with a high prevalence of HIV is more likely to be a true positive).⁴ With standard HIV testing, screening and confirmatory testing if required are performed in sequence, and the result returned to the client is considered final.

In a summary of the US rapid test distribution program in 2003-2005 of over 370,000 OraQuick POC HIV diagnostic tests, 5385 (1.4%) of tests were preliminary positive, of which 4640 (1.2%) were confirmed positive.²

1.2 Window Period

The window period may differ slightly between specific POC HIV test products and the standard HIV screening tests in use, which may indicate differing sensitivities for early infection. Several studies have demonstrated POC HIV tests to be less sensitive than standard EIA screening tests for the detection of early infection.⁵⁻⁸ Studies assessing the performance of POC HIV tests in individuals with advanced HIV disease (i.e., when antibody levels have diminished) have demonstrated high sensitivity (95-100%).^{9,10}

Like standard HIV testing, POC HIV test products are unable to detect acute HIV infection prior to seroconversion.⁸ In San Francisco and Seattle, nucleic acid amplification testing is performed on blood specimens from high risk individuals with negative POC HIV tests in order to identify individuals with acute HIV infection (approximately 1% of individuals undergoing POC HIV testing, increasing case detection by up to 18%).¹¹⁻¹³

1.3 Use of test kits

POC HIV tests are generally found by health care providers to be easy to use.¹⁴ Use typically involves collection of an appropriate specimen then following test kit instructions (e.g., addition of reagents, a series of timed steps) to achieve a result. Test kits usually include an internal control which assists in appropriate interpretation of results by identifying tests which have been performed incorrectly.

POC HIV tests are typically used by health care providers who do not have formal laboratory training and require subjective interpretation of visual results (in contrast to standard HIV testing which is performed in a laboratory and uses automated protocols for interpreting screening tests). Few studies have looked at inter-reader variability in test interpretation. A World Health Organization assessment of a variety of POC HIV tests by three independent readers on defined HIV positive and negative panels demonstrated low inter-reader variability (range 0 to 4.6% per product).¹⁵ A US study examined the interpretation of a POC HIV test kit by untrained health care workers from a variety of disciplines (following manufacturer's instructions only) on patient specimens and evaluation panels using sera with differing strength of antibody signals.¹⁶ Excluding invalid test results (<10% of tests performed, due to incorrect procedure and discounted), of 856 tests 96.6% were interpreted correctly (range 93-100% per discipline). Of the remainder, 1.9% were falsely read as negative and 1.5% were falsely read as positive. Variability in POC test result interpretation may be greater in early HIV infection.¹¹

1.4 Provision of results

One of the attractive features of POC HIV tests is the same-visit availability of a test result, and if the test is negative and exposure did not occur within the window period no additional testing is necessary. This differs from standard testing where there is a delay between specimen collection and result availability (in some jurisdictions up to two weeks after specimen collection). Additionally pre- and post-test counseling are incorporated within the same, initial visit and must be tailored to the use of POC HIV tests.^{17,18}

1.5 Quality control and assurance

Unlike standard laboratory-based HIV testing, the health care professional administering the POC HIV test assumes the responsibility for ensuring that the test is carried out correctly. Sites adopting POC HIV testing are recommended to implement appropriate quality assurance measures, including staff training and competency assessments, documentation and monitoring of test outcome, and regular use of test control kits.^{17,19-21} Recent U.S. surveys of sites delivering POC HIV tests identified that while initial training of staff and competency assessments prior to delivering testing was universal, maintaining periodic competency assessments and on-site quality assurance after testing programs began was a challenge at some sites.^{22,23}

Through these measures, regional POC HIV testing programs have been able to monitor POC HIV test performance and identify and investigate potential problems. For example, in 2004-05 in the US several regions identified increases in false positive results using an oral fluid POC HIV test at specific test sites.²⁴⁻²⁷ While subsequent investigations failed to identify any explanation for these results and the lower specificity at certain sites was determined to be within the acceptable range^{25,26}, site-specific factors related to test use and interpretation could not be ruled out leading some jurisdictions to switch to a different testing protocol.²⁸

In addition to ensuring POC test kits are performing optimally at the site of use, it is important to ensure consistent quality of POC test kits and that their performance is within licensed specifications. In BC an unexpected increase in false negative results using a POC HIV test product in 2002 and reduced test sensitivity was attributed to changes in the manufacturing process, leading to the withdrawal of the product from market

and recommendations for retesting of individuals with negative test results.²⁹ It is recommended that a robust quality assurance process be in place prior to widespread adoption of a specific POC HIV test product.³⁰

2. Impact of Point of Care HIV testing compared to standard testing

We identified 29 studies that compared POC rapid HIV testing to standard HIV testing (Appendix).^{14,31-58} The majority of studies were observational in design (23 studies), including 20 studies evaluating POC HIV testing programs with comparison to a baseline period where standard HIV testing was offered, and three studies using concurrent controls (patients choosing standard HIV testing over rapid HIV testing, or simultaneous standard HIV testing). The remaining non-observational studies included one meta-analysis and five randomized controlled trials.

2.1 Test volume

Eight studies reported an increase in test volume following introduction of POC HIV testing.^{31,33,36,44,51,55,56} In only two studies was the use of POC HIV testing not accompanied by promotion efforts or a different recruitment strategy from that used during the baseline period.^{31,55} In these two studies of programs involving multiple HIV testing sites, HIV test volume increased by 36.9% and 102.9% following introduction of POC HIV testing (with over 90% of clients choosing rapid testing).

2.2 Uptake of testing

There is good evidence to suggest that rapid HIV testing can result in increased HIV test uptake or acceptance in outreach settings. In one RCT among MSM in bathhouses and among needle exchange clients, rapid HIV testing was significantly associated with 1.3 to 1.7 times increased acceptance of testing respectively per site compared to standard HIV testing.⁵² Smaller studies in other settings also report increased test uptake.^{49,53}

The impact of POC HIV testing on engaging individuals who have not previously tested was not assessed by any study reviewed. Where reported the proportion of participants without a history of previous testing ranged from 9-28% in outreach or clinic settings^{47,52,54} up to 55% in one emergency room.⁴¹ In one study, 11% of clients undergoing rapid HIV testing at anonymous test sites reported that they would not have tested if rapid HIV testing were not available.³¹

2.3 Receipt of test results

It is commonly reported that with standard HIV testing a proportion of both HIV negative and positive clients will not return for test results; this proportion is variable by test site and population testing (ranging from 16 to 58% in some studies).⁵⁹⁻⁶³ POC HIV testing allows for same-visit delivery of test results, with follow-up for confirmatory test results only required for those who obtain a preliminary positive result. Improved receipt of test results is commonly cited as an important reason for adoption of POC HIV tests. Receipt of test results is important as knowledge of HIV positive status is associated with a reduction in self-reported risky sexual behaviours⁶⁴ (the impact of receipt of a negative HIV test is less understood). Site-specific HIV prevalence and return rate for result should be considered in assessing this impact of POC HIV testing.⁶⁵

There is strong evidence that use of POC HIV testing improves the receipt of HIV test results. Studies in multiple settings and of varying design have consistently demonstrated that individuals tested by POC HIV tests have a greater receipt of final test results (ranging from 85-100% of participants overall).^{14,31,33,42,44,46-48,52-54,57,58}

In a recent meta-analysis of the efficacy of alternative HIV testing and counseling approaches in improving the receipt of results, the use of rapid HIV testing significantly increased receipt of test results (RR 1.80). The greatest impact was observed in emergency room settings, followed by STI clinics and outreach venues, and the overall increase in receipt of rapid test results was greater for HIV negative (RR 2.00) than HIV positive persons (RR 1.19).³⁸

In this meta-analysis receipt of a preliminary positive result in HIV positive persons was the outcome of interest, and some have thought that the receipt of a preliminary positive POC HIV test result and accompanying counseling alone may be of benefit. A relevant question is the impact of POC HIV testing on receipt of final confirmed results in HIV positive individuals (including individuals with false preliminary positive HIV results). The evidence is scant on this issue, likely due to the overall small number of HIV infections identified per study. Some studies have reported an increased receipt of final test results among HIV positive persons with rapid testing^{33,40,46} while other studies find no significant difference.^{31,41} Individuals who receive a preliminary positive result by rapid testing may be more likely to return of their own volition for receipt of the confirmatory test result, and less likely to require finding by public health staff.^{31,40} In the US national rapid test program in 2003-2005, 21% of individuals who received a preliminary positive POC HIV test result did not return for receipt of confirmatory test results.² It is important to note that individuals with false preliminary positive results may also not return for receipt of confirmatory test results.

2.4 Psychological impact

The psychological impact of POC HIV testing compared to standard HIV testing for patients undergoing testing has not been assessed. Two studies evaluating the testing of source patients during occupational blood exposures identified decreased anxiety among exposed staff when POC HIV testing was used.^{43,45}

2.5 Time to availability of results and impact on medical decision-making

The use of POC HIV tests results in a significantly reduced turnaround time for results (dependent on the POC HIV test kit used).^{32,34,44,45} Where knowledge of HIV status is required to guide urgent medical decision-making (for clinical care or prevention of HIV infection) POC HIV testing may be superior. The introduction of POC HIV testing for source patients in the evaluation of occupational blood exposures for health care workers has been found to result in fewer initiations or shorter courses of antiretroviral post-exposure prophylaxis.^{43,45,49} Similarly, the use of POC HIV testing in labour and delivery units for women with undocumented HIV status has been associated with increased availability of results prior to delivery and greater opportunity for administration of antiretroviral prophylaxis to HIV-positive women.^{34,37}

2.6 Entry into care

Few studies have assessed the impact of POC HIV testing on entry into HIV clinical care for persons with newly identified HIV infection. Two studies assessing this outcome obtained conflicting results. While one study found that the introduction of POC HIV testing led to an increased proportion of HIV-positive individuals presenting for HIV clinical care, no significant difference was found in the second study.^{33,41}

2.7 Impact on other testing

POC HIV testing may have a negative impact on testing for other infections (e.g., Hepatitis C, STI) although this has not been well assessed. In Houston, a decline in the number of syphilis tests performed by community-

based organizations was observed following the implementation of a POC HIV testing program (from 710 to 41 tests per month, a 95.7% decrease), leading to a recommendation to re-emphasize the use of venipuncture as the primary source of testing for HIV.³⁹ Similarly, following the introduction of POC HIV testing in a public health clinic in Japan a decrease in the proportion of clients tested for syphilis (from 77% to 63%) and chlamydia (from 76% to 33%) was observed; however, the overall number of tests for syphilis and chlamydia increased due to the increased client volume attributed to offering POC HIV testing.⁵⁰

2.8 Impact on incident sexually transmitted infections

An early observational study of POC HIV testing in STI and anonymous HIV testing clinics did not demonstrate an increase in STI incidence following introduction of POC HIV testing (based on return of clients with a new STI).⁴⁰ One RCT in a STI clinic setting was designed to assess the relative efficacy of POC HIV testing to standard testing on STI incidence.⁴⁷ In this trial, clients randomized to POC or standard HIV testing were followed over 12 months with repeated specimen collection for STI (including HIV). At each follow-up time point the overall incidence of STI was higher among patients who received POC HIV testing (19.1% vs 17.1% at 12 months); this difference was significant for males (15.5% vs 11.6%, RR 1.34 at 12 months) and individuals without STI detection at baseline (10% vs 7%, RR 1.44 at 6 months). There was also a trend towards an increased STI incidence among MSM clients (21.8% vs 11.8% in heterosexual men).

This study concluded that in the short term and in some sub-groups, rapid HIV test interventions may be less effective at preventing STI, and that the use of POC HIV tests may be most indicated in settings with high prevalence of HIV infection and a low rate of return for HIV test results. Potential explanations for these findings included disinhibition following receipt of a negative test result, and slightly greater time with a counselor (development of risk reduction plan, reinforcement of prevention messages) in the standard testing group over two visits.

2.9 Impact on knowledge and behaviour

Two small-scale studies have examined the impact of POC HIV testing compared to standard HIV testing on knowledge and behavioural outcomes related to HIV. A randomized controlled study in a primary care setting compared POC HIV testing and streamlined counseling to traditional testing/counseling models and found no differences between arms at four weeks post-test on HIV knowledge scores or self-reported risk behaviours.⁵⁸ The second study was an observational study in a bathhouse which compared a convenience sample of clients receiving standard and POC HIV testing. In this study, at three months post-test there was no significant difference in self-reported risk behaviour. Both groups reported an increase in communication to sexual partners about HIV at three months post-test; however, this increase was significantly greater for clients receiving standard HIV testing.

3. **Settings and Indications for use of POC HIV tests**

3.1 Testing in Pregnancy

US and UK guidelines recommend the use of POC HIV testing for pregnant women with unknown or undocumented HIV status at the time of labour.⁶⁶⁻⁶⁸ Nine studies have evaluated the use of POC HIV tests in pregnant women with undocumented HIV status (where eligibility for testing is usually defined as gestational age \geq 34 weeks, or active labour at gestational age $>$ 24 weeks; ranging from 8-50% of women seen).^{32,34,35,37,69-73} Acceptance of POC HIV testing among eligible women was high (range 69-95%).^{32,35,37,69-71} All studies

successfully identified women with HIV, with the majority of women (range 63-76%)^{35,37,71,72} and exposed infants (range 89-100%)^{35,71,72} receiving ART prior to delivery or after birth, respectively. However, in most studies women with false positive POC HIV test results were also identified (range 0.07-1.5% of women)^{32,34,35,37,70,73}, leading in some cases to unnecessary ART.^{32,73} Clinical judgment, knowledge of HIV prevalence and POC HIV test characteristics are required to counsel pregnant women appropriately^{32,70}, and continuous education of health care providers may be needed to ensure POC HIV tests are used as recommended.⁷⁴

The main concern expressed about POC HIV testing in pregnant women at the time of labour is related to the capacity for informed consent.⁷⁵ No studies have assessed the experience or attitudes of women with undocumented HIV status at the time of delivery to POC HIV testing. Three pilot studies have looked at this question with women at low risk for HIV or with a high compliance with prenatal HIV testing; in these studies, the majority of women felt that POC HIV testing was important and should be offered during pregnancy.⁷⁶⁻⁷⁸ In one pilot study, all pregnant women presenting in labour at an inner-city hospital were offered POC HIV testing.⁷⁶ The majority of women in this study demonstrated good understanding of test rationale and felt reassured by the test, with 80% stating it was not difficult to make a decision about HIV testing (14% reported difficulty due to contractions/pain). A minority of women reported feeling insulted or angry (9%), high anxiety (4%) or embarrassed (4%) at POC HIV test offer.

In a study piloting an informed consent form for POC HIV testing for women in labour (39% in active labour, 61% reporting substantial pain), the majority were able to restate the purpose and benefits of testing (to prevent vertical transmission), although understanding of the potential for unnecessary ART treatment if false positive was initially poor.⁷⁷ Similar findings were found in another pilot of an informed consent form in Canadian women who had given birth in the previous five years.⁷⁸

POC HIV testing has also been incorporated into prenatal visits. In a UK study, the majority of low-risk women with a high compliance with HIV testing in prenatal care indicated that POC HIV testing would be acceptable, including approximately a third of women who did not accept standard testing during their pregnancy.⁷⁹ An evaluation of POC HIV testing in women in prenatal care in the US verified this finding, with high test acceptance (72%).⁸⁰

3.2 Blood and body fluid exposures

HIV testing of source and exposed individuals is recommended in the evaluation of blood and body fluid exposures to HIV.⁸¹⁻⁸⁵ In occupational settings, the use of POC HIV testing and timely receipt of test results is acknowledged to facilitate decision-making regarding use of post-exposure prophylaxis (PEP).^{66,81-83}

No studies have evaluated the use of POC HIV testing in sexual exposures, and in this scenario the source may be less available for testing. However, HIV testing of exposed persons is recommended to avoid unnecessary PEP in individuals already infected with HIV.^{81,83} In one case report, unnecessary PEP was avoided during an evaluation of a sexual exposure when the exposed individual was determined to be HIV positive.⁸⁶

3.3 Hospital-based HIV testing (Emergency rooms, inpatients)

There has been considerable attention to the issue of HIV testing in hospital settings given the recognition that marginalized HIV positive individuals unaware of their HIV status may access hospital care prior to diagnosis⁸⁷ and recent recommendations for opt-out screening in this setting.⁶⁷ A number of studies in large urban centres have looked at the use of POC HIV testing in emergency room, inpatient wards or outpatient clinic settings –

usually in the context of evaluating universal screening compared to targeted testing.^{14,33,41,44,53,88-95} Consequently it is difficult to separate the impact of POC HIV testing from the impact of differing recruitment strategies which are not the focus of this paper.

In general, the use of POC HIV tests is feasible in these settings, with programs demonstrating an acceptance of testing ranging from 24-98% among individuals not known to be HIV positive or to have recently tested. The most commonly reported reasons for refusal of testing include having tested recently or not perceiving self at risk for HIV.^{41,53,90,92,94} There is limited information regarding the experiences of individuals undergoing rapid HIV testing in hospital settings. A qualitative assessment of emergency room patients offered rapid or standard HIV testing identified a general preference for rapid testing due primarily to the increased turnaround time for results.⁹⁶ The infrastructure for POC HIV testing in hospital settings must be in place, as provider barriers to conducting testing can include ignorance regarding test protocols, and time required to obtain informed consent and perform testing.⁹⁵

While not evaluated in any of the identified studies, POC HIV testing may be of use in hospital settings in patients where knowledge of HIV status will have an impact on further workup or treatment (e.g., in patients presenting with opportunistic infections). A common problem with standard HIV testing in the hospital setting is the delay to result availability, which may affect therapeutic choices. In addition, using standard HIV testing results may not be available until after discharge and public health case follow-up is difficult. The use of POC HIV testing for diagnosis of HIV in hospital settings may be superior to standard testing as individuals are more likely to receive their results at the same visit, and there may be greater opportunities to facilitate public health follow-up and early connection to clinical care. One retrospective chart review comparing the outcomes of inpatients tested by POC or standard HIV testing identified reduced time to diagnosis and admission to the inpatient HIV ward, and to first outpatient visit for HIV-related care in patients undergoing POC HIV testing.⁹⁷

3.4 STI or HIV testing clinics

When given a choice, 90% or more of clients attending STI or HIV testing clinics for HIV testing will choose rapid HIV testing and same-visit result availability over standard testing.^{31,54,98,99} While up to 30% of clients report that POC HIV testing is stressful, the majority of clients prefer POC HIV testing and same-day delivery of results.^{31,40,47,54,98-100} Clients choosing or preferring standard testing commonly report valuing a confirmed or more accurate result, perceiving less stress related to testing, and more time to prepare for a result (particularly among first-time testers).^{31,47,99,100} Clients presenting to STI or HIV testing clinics should be given a choice of preferred testing options.

Typically clinic or program staff report initial apprehension about using POC HIV tests; however, after appropriate training and after a short period of use the majority of staff report feeling very comfortable with the use of these tests.^{31,40,99,101} Concerns include lack of time to prepare for and discomfort with delivering a positive result, client perceptions of accuracy of result, and reduced time for counseling and reinforcement of prevention messages without a second visit. Perceived advantages include continuity of counseling, ensuring receipt of test results, greater ability to focus on risk issues, and convenience.

3.5 Corrections settings

A common priority area for HIV testing are corrections facilities, which may be an ideal point of engagement in HIV testing for individuals with undiagnosed HIV infection. It has been estimated that a substantial portion (up

to 26% in 1997) of the population with prevalent HIV infection passes through the corrections system each year in the US.¹⁰² The 1994 prevalence of HIV in BC provincial prisons was estimated at 1.1%.¹⁰³

Two studies have reported evaluations of POC HIV testing programs in US Corrections facilities.^{91,104} The largest is a report of a four state rapid HIV testing program in the US.¹⁰⁴ Programs were set up at each facility in collaboration between corrections programs and state health departments, with promotion of HIV testing to male and female inmates; inmates were tested if they requested HIV testing or were referred for testing by medical staff. Over a 2.5 year period, 6% of 550,000 new inmates were tested of which 1.3% of individuals had a preliminary positive result (1.2% confirmed positive). The other reported approach is the routine offer of HIV testing to new admissions, which in a female corrections facility resulted in 46% of 2128 inmates accepting HIV testing.⁹¹ In both studies, preliminary POC HIV test results were received by >99% of inmates tested. A third pilot feasibility study, in a corrections facility with a strong history of inmate HIV testing, also found POC HIV testing to have a high acceptance rate.¹⁰⁵

In these studies, many individuals with new HIV infections did not report risk factors for HIV infection^{91,104} and in one study individuals who reported no HIV risk factors were four times more likely to be HIV positive.¹⁰⁴ Disclosure of risk behaviour in corrections may be challenging, and risk-based testing may be less successful.¹⁰⁶ Other challenges include delivery of confirmatory test results to released individuals^{104,105}, connection to HIV clinical care⁹¹, and difficulty in determining the best time for testing (i.e., balancing potential distress or intoxication at admission with rapid turnover).^{105,106}

3.6 Outreach settings

Incorporating POC HIV testing into outreach programs is attractive due to both the ability to engage untested or persons with a higher risk of infection in HIV testing, and same-day provision of test results in populations which may not return for a follow-up visit. Numerous studies have demonstrated the feasibility of POC HIV testing programs in outreach settings targeting high prevalence populations, including:

- bathhouses⁵²
- gay pride events¹⁰⁷
- needle exchange sites^{52,108}
- sex work venues or programs^{109,110} and with clients of sex workers¹¹¹
- homeless shelters and single room occupancy hotels^{108,112}
- community centres accessed by youth¹¹³
- ethnic minority groups^{114,115}
- mobile clinics^{46,116}
- substance abuse programs or detoxification centres^{108,112,117,118}
- churches^{119,120}
- dental offices¹²¹
- pharmacies^{122,123}
- neighbourhoods (i.e., door-to-door, block-by-block)^{124,125}

These programs have demonstrated variable acceptance of testing by site (ranging from 14-82% of persons approached). Concerns have been identified with some of these approaches (e.g., confidentiality, privacy, clients not prepared for testing, testing leading to disinhibition or unprotected sex).^{75,126,127} These concerns have not been well evaluated.

While the use of POC HIV testing improves overall receipt of HIV test results, individuals in some outreach settings who receive a preliminary positive HIV result may not agree to confirmatory testing, or return for the results of confirmatory testing.¹¹² Some clients may also choose not to receive a preliminary result of a POC HIV test.¹¹⁰

3.7 Primary Care

Recent reports have demonstrated that POC HIV tests can be feasibly integrated within primary care settings such as family practice clinics or community health centres in high prevalence areas, with good acceptance of test offer among patients.^{56,128,129} Challenges to incorporating POC HIV testing within these settings may include: addressing concerns of staff regarding dealing with a positive POC test result and being able to provide support for newly diagnosed persons, fulfilling requirements for regular quality control, time constraints to deliver pre-test counselling, and not always having a private environment for testing (i.e., if patient is accompanied by partner or children).¹²⁸

DISCUSSION

The findings of this review demonstrate that POC HIV tests have individual and population benefits, and their use has been demonstrated to be feasible in a variety of settings. POC HIV testing is highly acceptable to and preferred by patients and staff performing testing in most settings, and introduction of POC HIV test programs may result in increased uptake and volume of HIV testing. Individuals undergoing POC HIV testing are more likely to receive their test result, particularly individuals who are HIV negative, which may be particularly useful in settings where receipt of results is difficult such as some STI clinics and outreach programs. While the benefit on final receipt of confirmed HIV positive results is less clear, studies have reported equivalent or increased receipt compared to standard testing, and individuals receiving a preliminary positive POC HIV test result may be more likely to return for a confirmatory test result, reducing public health follow-up efforts. Improved receipt of test results and timely connection to public health follow-up and clinical care may also be of benefit in settings such as emergency rooms or corrections facilities. Finally, the rapid availability of results can facilitate more timely prevention of vertical transmission and avoidance of unnecessary PEP to prevent occupational transmission of HIV.

As with the introduction of any new health technology, these benefits need to be weighed against disadvantages and potential harms. POC HIV testing by definition is not laboratory-based, and with shift of testing to the point of care and subjective interpretation of results there may be greater potential for user error or other site-specific factors to influence the quality of testing. Recommendations for quality assurance measures, staff training, and documentation and monitoring of test outcomes must be heeded in any site where POC HIV tests are used (and maintained after implementation of testing). The use of POC HIV tests may adversely affect the control of other sexually-transmitted or blood-borne infections, by potentially reducing the number of individuals tested for other infections (e.g., Hepatitis C, syphilis), or leading to increased risk of STI. Finally, with POC HIV testing, individuals will receive preliminary positive or false positive results and may require additional support. These potential harms have not been well evaluated. Other issues of concern such as impact of POC HIV testing on case reporting to public health and HIV surveillance, and monitoring of HIV testing volume and patterns have not been assessed.

There are limitations to this review that may affect the generalizability of these findings to BC. The majority of these studies are from the US, where important differences exist in the populations affected by HIV, in access to free HIV testing, and the regulatory framework surrounding HIV testing. All studies were from urban,



typically inner-city settings, usually in settings where large volumes of HIV testing were performed, and often in areas with a high prevalence of HIV. No studies in rural or remote settings were identified. Finally, these studies spanned over a decade of research, a variety of different POC HIV test products, and a number of different program models.

The development of new test technologies such as POC HIV testing provides new opportunities to identify persons infected with HIV, engage them in HIV prevention and connect them to community resources, clinical care and effective treatment. When considering the use of a POC HIV test product, the findings in this report must be weighed against the specific characteristics of the POC test and standard HIV testing protocols in place. The studies reviewed here have compared POC HIV testing to standard HIV testing protocols which include second or third-generation ELIA HIV screening assays (similar to what is currently in use in BC). The role and impact of POC HIV testing must also be weighed against other new HIV testing technologies which may become available in the near future (e.g., fourth-generation EIA or nucleic acid amplification testing) which have the capacity for increased identification of persons acutely infected with HIV.

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APPENDIX: Description of studies assessing the impact of POC HIV Testing

Study (Period, Location)	Setting	Study design	Intervention (POC test used)	Control	Eligibility	Sample size (Intervention arm)	Outcome	Result (Intervention compared to Control arms)	Ref
Hutchinson 1990-2005	Various	Meta-analysis	Rapid HIV test	Standard HIV test	---	17520 (NS)	Result receipt	Increased return for results (overall RR 1.80 [1.46, 2.22]). Less pronounced in studies based on RCT or concurrent (vs baseline) controls. Greatest impact in ER (RR 2.19) over STD or outreach, and HIV negative (RR 2.0) over HIV positive (RR 1.19).	³⁸
Metcalfe 1999-2000 USA	STI clinic	RCT	Rapid HIV test (SUDS)	Standard HIV test	HIV-vaginal/anal sex in past 3 months 15-39 yrs	3342 (1648)	STI incidence Result receipt	Increased STI incidence in intervention arm (19.1% vs 17.1% at 12 mos, not sig). Significant increase in males (RR 1.34 at 12 mos) and participants without STI at baseline (RR 1.44 at 6 mos). Trend to increased rate in MSM (<10% of sample). Increased receipt of test result (99% vs 69.4%).	⁴⁷
Spielberg 1999-2000 Seattle	NEX, bathhouse	RCT	Rapid HIV test (SUDS)	Standard HIV test. Option of getting results by phone.	Age>14 HIV-last test > 3 mos	3455 (1633)	Test acceptance Result receipt	Increased acceptance: NEX OR 1.7, bathhouse OR 1.3 Increased receipt of test results: NEX OR 2.4, bathhouse OR 1.9	⁵²
Wurcel 2003-2004 Boston	Hospital (in-patient)	RCT	Rapid HIV test (OraQuick)	Standard HIV test	In/outpatient Physician-referred HIV-last test > 1 mos	203 (101)	Test acceptance Result receipt	Trend towards higher acceptance of testing (59.4% vs 41.2%), significant in Caucasian, Hispanic subgroups. Greater proportion received results (p<0.001).	⁵³
King 1998-1999 Switzerland	Occupational exposure	RCT	Rapid HIV test of source (Genie II)	Standard HIV test of source	Source patients from occupational blood exposure	60 (30)	False Negative results PEP uptake Psychological distress	No false negative results identified Lower use of PEP (3% vs 83%; p<0.001) Increased proportion reporting no anxiety or stress (24% vs 7%)	⁴³
Kelen 1994-1995 Baltimore	ER	OBS (baseline control)	Rapid HIV test (SUDS)	Standard HIV test	18-55 years HIV-	1449 (467)	Result receipt Entry to HIV care	No significant difference among HIV+ (73% vs 62%). No significant difference in follow-up for HIV clinic appointment (55% vs 64%) (NB: includes 146 persons who were given a choice between rapid and standard testing)	⁴¹
Kendrick 1999-2000 Chicago	STI clinic	OBS (concurrent control)	Rapid HIV test (SUDS)	Standard HIV test	HIV-Last test > 3 mos Not presenting for results	1581 (1372)	Result receipt Entry to HIV care	Increased receipt (>99% vs 84%) Greater entry into care (97% vs 84%) and retention after 1 month (83% vs 68%). (NB: possible differences in ensuring compliance)	⁴²
Liang 2003-2004 Baltimore	Mobile clinic	OBS (concurrent control)	Rapid HIV test (Oraquick)	Standard HIV test	Recruited on street or presenting for testing	439 (284)	Predictors of test choice Result receipt	Rapid test choice associated with African-American ethnicity (OR 1.91), drug treatment in last three mos (OR 0.58). Not CSW, IDU, STI history. Increased receipt of post-test counseling (HIV- 93% vs 40%,	⁴⁶

Study (Period, Location)	Setting	Study design	Intervention (POC test used)	Control	Eligibility	Sample size (Intervention arm)	Outcome	Result (Intervention compared to Control arms)	Ref
								HIV+ 89% vs 11%)	
Guenter 2001-2002 Toronto	HIV testing clinic	OBS (concurrent control)	Rapid HIV test (Fast Check)	Standard HIV test	NS	1610 (1468)	Predictors of test choice Receipt of test results	Rapid test choice significantly less likely in females (27% vs 39%), more likely in first testers at clinic (43% vs 32%), and persons aware of choice of test prior to arrival at clinic (34% vs 26%). No difference in risk profile. Increased receipt (99.7% vs 93.4%). Of HIV+, final result received by 100% and 82% of rapid and standard testers respectively.	54
Jackson 2005 Houston	CBO	OBS (baseline control)	Rapid HIV test (Unknown)	Standard HIV test	NS	NS (NS)	STI testing	Decrease in syphilis testing by 95.7% after introduction of rapid testing (from 710 to 41 specimens per month)	39
Kassler 1993 Dallas	STI clinic, HIV testing clinic	OBS (baseline control)	Rapid HIV test (SUDS)	Standard HIV test	NS	4555 (2477)	Result receipt STI incidence	Increased receipt (HIV- 96% vs 59%, HIV+ 98% vs 88%). HIV+ more likely to return for confirmatory result without field follow-up (94% vs 45% at STI clinic site). No significant difference in STI incidence at clinic over 1 year (6.0% vs 5.9%)	40
San Antonio-Gaddy 2003 New York	HIV testing clinics	OBS (baseline control)	Rapid HIV test (Unknown)	Standard HIV test	NS	10595 (6122)	Test volume Result receipt	Increased volume: 36.9% increase compared to baseline (p<0.001; of which >99% chose rapid test) Increased receipt (HIV- 99% vs 84%, p<0.0001; HIV+ 75% vs 72%, not sig). Greater return for receipt of confirmatory test result (81% vs 72%).	31
Shima 2003-2004 Japan	HIV testing clinics	OBS (baseline control)	Rapid HIV test (Determine HIV-1/2)	Standard HIV test	NS	NS	Test volume	Increased test volume at each clinic site (350%, 1200%), with promotion of testing.	51
Henn 2005 New York City	STI & TB clinics, Jails	OBS (baseline control)	Rapid HIV test (pamphlet & video pre-test counseling)	Standard HIV test (routine pre-test counseling)	NS	91292 (47771)	Test volume	Increased test volume (by 68%)	36
Kroc 2001 Chicago	ER	OBS (baseline control)	Rapid HIV test, routine offer (SUDS)	Standard HIV test, targeted offer	18-60 years HIV-	NS (1652)	Result turnaround time Test volume Result receipt	Increased turnaround time (average <2 hrs vs 14.5 days) Increased test volume (9.5 times greater). Increased receipt of results (99.3% vs 24%)	44
Greenwald	Hospital	OBS	Rapid HIV test	Non-rapid	Inpatients	NS	Testing offer	More patients offered testing (100% vs 50-66%). Note: also	14

Study (Period, Location)	Setting	Study design	Intervention (POC test used)	Control	Eligibility	Sample size (Intervention arm)	Outcome	Result (Intervention compared to Control arms)	Ref
2001-2003 Boston	(In-patients)	(baseline control)	(OraQuick)	HIV test (OraSure) with results in 7 days			Result receipt	increased number of testing staff Increased receipt of results (100% vs 77%)	
CDC 2000 Atlanta	Urgent care centre	OBS (baseline control)	Rapid HIV test (SUDS) or standard HIV testing, routine offer	Standard HIV test, targeted offer	18-65 years HIV- Last test > 6 mos	3887 (2787)	Test volume Detection of New HIV+ infections Result receipt (for HIV+) Entry to HIV care	Increased test volume (2.5 times, sig). Note: different recruitment strategies – not a valid comparison. More new HIV+ infections detected (1.6 times, sig), likely related to volume Increased receipt of HIV+ test result (2.0 times, sig) Increased entry into care (2 times, sig)	³³
Paneth-Pollak 2004-2005 New York City	STI clinics	OBS (concurrent control)	Rapid HIV test (OraQuick))	Standard HIV test	NS	23586 (21687)	Predictors of test choice Receipt of results	No difference in: HIV prevalence, demographics, concurrent STI diagnosis, most risk behaviours. Clients with rapid test more likely to report previous STI (18.3% vs 16.2%, p<0.02). Increased receipt (97.8% vs 63.3%, p<0.0001)	⁴⁸
Shima 2003 Japan	Public health center	OBS (baseline control)	Rapid HIV test (Unknown)	Standard HIV test	NS	583 (453)	Test volume STI testing	250% increase in test volume, with promotion of testing. Decreased proportion of clients tested for chlamydia (33% vs 76%) and syphilis (63% vs 77%). STI test volume increased due to overall increase in number of clients presenting.	⁵⁰
Landrum 2003 Texas	Occupational exposure	OBS (baseline control)	Rapid HIV test of source (OraQuick)	Standard HIV test	Source patients from occupational blood exposure	150 (79)	Result turnaround time Uptake of PEP Psychological distress	Faster turnaround time (mean 117 min vs 3254 min) Fewer mean doses PEP dispensed (5.5 vs 12.7; not sig), fewer mean doses PEP ingested (1.2 vs 3.8; sig). No large differences in self-reported anxiety, except fewer reported repeated thoughts of the exposure (26% vs 61%, p=0.049)	⁴⁵
Puro 1995-2002 Italy	Occupational exposure	OBS (baseline control)	Rapid HIV test of source (Capillus HIV-1/HIV-2)	Standard HIV test	Source patients from occupational blood exposure	1481 (769)	Source patients tested Uptake of PEP	Increase in proportion of source patients tested (88.6% vs 62.9%) Decrease in proportion of HCW started on PEP (2.3% vs 18.4%)	⁴⁹
Forsyth 2000 USA	Pregnant women	OBS (baseline control)	Rapid HIV test (SUDS)	Standard HIV test	NS	100 (36)	Result turnaround time Result receipt	Increased turnaround time (mean 8 hours vs 35.3 hours, p<0.0001) Greater availability of results available prior to rupture of membranes (36% vs 2%) and delivery (64% vs 8%)	³⁴
Garcia 2004-2005 Illinois	Pregnant women	OBS (baseline control)	Rapid HIV test	Standard HIV test	NS	NS (99888)	Documentation of HIV status	Prior to program implementation, 28% of women arrived in labour and delivery without a documented HIV status. After program implementation this proportion steadily decreased to	³⁵

Study (Period, Location)	Setting	Study design	Intervention (POC test used)	Control	Eligibility	Sample size (Intervention arm)	Outcome	Result (Intervention compared to Control arms)	Ref
								10% by Sept 2005 (sig).	
Hillis 2002, 2004 Russia	Pregnant women	OBS (baseline control)	Rapid HIV test (Determine HIV-1/HIV-2) (universal offer)	Standard HIV test (targeted offer)	HIV- or unknown No HIV test after 34 weeks GA	NS (704)	Receipt of ART	Greater receipt of ART (76% vs 41%).	³⁷
Bulterys 2001-2003 USA	Pregnant women	OBS (concurrent control)	Rapid HIV test (OraQuick)	Standard HIV test (simultaneous)	HIV status undocumented Active labour at ≥ 24 weeks GA Presentation ≥ 34 weeks GA	4849 (4849)	Result turnaround time	Decreased turnaround time for results (median 66 min [IQR 45-120 min] vs median 28 hours; p<0.001).	³²
Fernandez-Lopez Spain 2006-2007	HIV testing clinics	OBS (baseline control)	Rapid HIV test (Determine HIV-1/HIV-2)	Standard HIV test	NS	5601 (3752)	Test volume	103% increase in HIV testing (range 8-330% per testing site).	⁵⁵
Myers 2007-8 South East US	Community Health Centres	OBS (baseline control)	Rapid HIV test (Uni-Gold, routine offer)	Standard HIV test (targeted offer)	NS	13847 (3078)	Test volume	3.5 times greater test volume with rapid test plus routine offer.	⁵⁶
Huebner 2003-04 USA	Bath-house	OBS (baseline control)	Rapid HIV test (OraQuick, routine offer)	Standard HIV test (routine offer)	NS (convenience sample for behaviour substudy)	1020 (528) 294 (161)	Test volume Result receipt HIV risk behaviour	No significant increase in test volume. Of HIV positive, 85% vs 50% received result with rapid test (sig). Of HIV negative, 97% vs 71% received result with rapid test (sig). Both arms more likely to communicate with partners about HIV after testing and reduced likelihood of UAI; however no significant difference between arms at 3 months.	⁵⁷
Anaya California	Primary/urgent care clinics	RCT	i) Standard HIV test & counseling (RN) ii) Rapid test & abbrev. counseling (RN, OraQuick)	Standard HIV test & counseling (MD)	18-65 yrs, unaware HIV status, no HIV test past year, appt for that day, English	251 (i. 64) (ii. 63)	Test uptake Result receipt HIV knowledge HIV risk behaviour	No difference between intervention arms [i) RR 2.1, ii) RR 2.3] but both significantly more likely to be tested compared to control arm. Difficult to distinguish effect of POC test from changes in counseling/referrals. Intervention arm i) most likely to receive results; arm ii) more likely compared to control. No differences between arms at 4 weeks post-test. No differences between arms at 4 weeks post-test.	⁵⁸

Legend: ART (antiretroviral therapy), CBO (community-based organization), ER (Emergency room), GA (gestational age), NS (not specified), NEX (needle exchange), SUDS (Single Use Diagnostic System HIV-1 test), RN (registered nurse), MD (physician)