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# HIV Point of Care Testing in Manitoba Report

2016 to 2017



APRIL 2018

**Manitoba** 

# **HIV POINT OF CARE TESTING IN MANITOBA REPORT, 2016 TO 2017**

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## Introduction and Background

In 2013, the Public Health Agency of Canada (PHAC) revised its HIV Screening and Testing Guideline<sup>1</sup>. Instead of basing need for HIV testing on high risk activities (intravenous drug use/IVDU, exchange of sex for money or drugs, multiple partners or men who have sex with men/MSM), HIV testing should now become part of routine medical care. In addition, pre- and post-test counselling has been greatly simplified to encourage increased testing. Manitoba Health recently promoted comprehensive and expanded HIV testing to fulfil its goals as outlined in the Manitoba Sexually Transmitted and Blood-Borne Infections (STBBI) Strategy 2015 to 2019<sup>2</sup>. In 2006, the U.S. CDC revised its guidelines to suggest that routine screening should be performed on all individuals accessing the healthcare system between the ages of 13 to 64 with repeat testing at least annually if the individual was considered high risk<sup>3</sup>. In addition, all patients presenting for STI treatment and those being evaluated for tuberculosis should be screened for HIV. If the prevalence of a given region was less than 0.1 per cent, universal screening was deemed unnecessary. The rationale for this strategy was based on the large proportion of people with HIV infection who are unaware of their status (estimated between 25 to 30 per cent in Canada), and an inability by healthcare workers to determine who would be at risk, paired with the need to link these individuals to appropriate HIV care<sup>1-3</sup>. The CDC HIV testing recommendations were adopted and promoted by the United States Preventative Services Task Force (USPSTF) in 2013<sup>4</sup>. Knowledge of one's status has also been shown to reduce high-risk behaviours to prevent infecting others if positive and minimize risk of acquiring infection if negative<sup>1,5</sup>.

HIV screening in Manitoba is performed almost exclusively at Cadham Provincial Laboratory (CPL) by enzyme immunoassay (EIA). Rapid point-of-care-testing (POCT) for HIV provides a presumptive diagnosis of HIV infection during a single patient encounter. The process of pre-test counselling, testing and delivery of results/post-test counselling can all be delivered in as little as 10 minutes. The INSTI™ HIV-1/HIV-2 Antibody Test (bioLytical™ Laboratories Incorporated, Richmond, B.C., Canada) became licensed by Health Canada in October 2005, and remains the only

licensed product available in Canada. Performance characteristics of INSTI™ POCT are similar to HIV EIA screens with a sensitivity of 99.6 per cent (95 per cent CI 98.9-99.9 per cent) and specificity of 99.3 per cent (95 per cent CI 98.9-99.5 per cent)<sup>6</sup>. Limitations of the POCT<sup>6</sup> include a reduced sensitivity (69.4 per cent) in acute HIV infection (95 per cent CI 54.6-81.8 per cent) and with HIV-2 (sensitivity 98.3 per cent); potential for false positives in a low prevalence setting (positive predictive value range of 12.5 per cent with an HIV prevalence of one in 1000 to 94.0 per cent, if prevalence is 1 in 10); lack of validation for the detection of HIV-1 Group O and N subtypes, potential for false-negative results in those with severe hypogammaglobulinemia and cost of POCT which is approximately \$15/test (Canadian) versus \$1.50/test for standard EIA screening. Confirmatory testing of an individual with HIV infection (HIV-positive) costs approximately \$50, consisting of two EIAs followed by confirmatory HIV Geenius assay.

### **HIV POCT advantages and disadvantages**

Clinical and public health advantages include:

- a) rapid assessment of pregnant women considered at high-risk of HIV for initiation of prevention of mother to child transmission (PMTCT).
- b) immediate linking to HIV care of transient, high-risk individuals should their screening test return reactive.
- c) delivery of HIV screening in remote communities, particularly in the developing world.
- d) occupational or assault exposure to suspected HIV-positive individual.

Potential disadvantages include:

- a) proficiency and quality may not be possible if few tests are performed per site or multiple operators are performing POCT.

- b) demonstrated potential for false positives if used in general population or low prevalence populations.
- c) psychosocial barriers to testing are equally present with POCT as serological screening in northern and rural communities.

### **Sites offering HIV POCT**

Since April 2008, HIV POCT has been introduced and/or trialed at nine sites in Manitoba:

- Nine Circles Community Health Centre (NCCHC)
- Women's Hospital HSC (WH HSC)
- the Adult ED at HSC (HSC AED) pilot study
- Healthy Sexuality and Harm Reduction/Street Connections (HSHR)
- the Main Street Project (MSP)
- Thompson General Hospital (TGH) Emergency Department (pilot study)
- TGH Labour & Delivery (L&D)
- Our Own Health Centre (OOHC)
- St. Boniface General Hospital (SBGH) L&D

In 2016/17, the active sites were NCCHC, HSHR, MSP, OOHC, WH HSC, TGH L&D and SBGH L&D.

### **HIV POCT Site Descriptions**

#### *Nine Circles Community Health Centre*

Introduced in April 2008, NCCHC is the archetype for provision of HIV POCT in Manitoba. Providing medical services to high-risk populations and having extensive experience with STBBI counselling, testing and linkage to care, NCCHC is a high priority site to provide HIV POCT. In addition, NCCHC has provided considerable leadership and training in HIV POCT to other sites.

### *Women's Hospital HSC*

Beginning in January 2009, HIV POCT has been offered to pregnant women in labour who had no or limited prenatal care or continued exposure to high risk factors throughout pregnancy. This site provides care for a majority of high-risk pregnancies (known HIV-infected women) and has approximately 5,000 deliveries per year.

### *Human Sexuality and Harm Reduction/Street Connection*

HSHR started providing HIV POCT services in June 2013. In addition to providing comprehensive STBBI testing, HSHR is closely linked with public health and co-ordinates community outreach STBBI testing and linkage to care.

### *Main Street Project*

MSP provides clinical services to street involved people and began offering HIV POCT in October 2013. MSP has been very aggressive in HIV testing in their high-risk clientele and performs the highest volume of the HIV POCT in the province.

### *Thompson General Hospital L&D*

TGH L&D started HIV POCT in August 2014. Approximately 1,000 infants are delivered per year. Many pregnant women from northern communities receive suboptimal prenatal care, making HIV POCT a useful solution for appropriate initiation of prevention of mother to child transmission of HIV if a woman is found to have a reactive test.

### *Our Own Health Centre*

OOHC provides primary and specialized care to the men who have sex with men (MSM) community and have considerable experience in STBBI counselling, testing and linkage to care. OOHC has been offering HIV POCT since June 2016.

### *St. Boniface General Hospital L&D*

SBGH L&D has approximately 5,000 deliveries per year including high risk deliveries from Winnipeg and northern communities. HIV POCT has been available at this site since April 2017.

### **Selection Criteria and Process for Sites Offering HIV POCT**

The main advantages of HIV POCT are the rapid turnaround time (TAT) and portability. Rapid TAT is important in certain scenarios where the timely institution of preventative measures is paramount. Examples include prevention of perinatal transmission from HIV-infected mothers in labour to their infants, and in occupational and non-occupational exposures where the source HIV status is unknown. Transient populations often benefit from medical outreach programs and are disproportionately affected by sexually transmitted and blood-borne infections (STBBIs) including HIV<sup>7,8</sup>. This population is also less likely to predictably engage the medical system and thus, screening in this high-risk group is sub-optimal. NCCHC, HSHR, MSP and OOHC all fall in the category of providing medical services to high-risk groups and thus they were selected to provide HIV POCT services. Likewise, the three major birthing centres in Manitoba (Women's Hospital HSC, TGH L&D and SBGH L&D) provide care for high-risk pregnant women with limited prenatal care and also provide HIV POCT.

Sites expressing interest in providing HIV POCT are evaluated in the following manner:

1. Familiarity with STBBI screening is determined and the reason for wishing to provide HIV POCT is assessed. Ability to or experience with triaging STBBI positive patients, counselling, linkage to care and management are also considered.
2. If the site is familiar and comfortable with screening clients for STBBIs, the STBBI testing practices are analyzed at CPL for the preceding year. Discrepancies in testing between urine based assays (gonorrhea and chlamydia) and blood-borne pathogens/BBPs (HIV, syphilis, hepatitis B and hepatitis C) are determined. If significant discrepancies are noted (BBP screening rate approximately 50 per

cent of urine testing), then strategies to optimize BBP testing are discussed with the site (concurrent testing, addition of on-site phlebotomy, client and practitioner education). HIV test prevalence for sites is also reviewed. L&D sites utilize STAT HBsAg ordered as a surrogate (HIV STAT prenatal testing is often ordered less, but risk factors are the same) for determining potential HIV POCT needs.

3. If the first two criteria are met, further discussion with the site is undertaken. These operational elements are not always understood by prospective sites, and the administrative burden associated with a test service may not be possible within existing resources. Topics include: personnel training, quality control and quality assurance (QC and QA), role of confirmatory testing at CPL, monthly data sharing with CPL, appropriate laboratory facility, waste management, HIV POCT kit storage and monitoring. Estimation of proposed kit volume is determined by examining testing data, process mapping and review with site practitioners.

### **Centralization of HIV POCT Co-ordination**

HIV POCT kits are provided by CPL to sites determined to meet the above selection criteria. CPL staff provides oversight and technical advice in addition to maintenance of a HIV POCT database. Any site in the province has the ability to independently contract with BioLytical™ to obtain HIV POCT kits if selection criteria are not met and the site wishes to offer HIV POCT. Centralization of HIV POCT supply through CPL has several advantages over multiple sites independently offering HIV POCT:

1. Oversight of POCT kit expiry dates and lot numbers. In the event of abnormal test results, centralization allows timely investigation and rectification of any issues.
2. Central data collection. Number of kits ordered, used and results are kept at CPL. As a result, overall costs and effectiveness of the program can be monitored more efficiently.
3. Centrally procuring kits in bulk optimizes overall procurement, distribution, and quality oversight costs.



- Central HIV POCT kit repository can accommodate for unforeseen increase requirements at other sites.

### HIV POCT Data

In 2016/17, 3778 HIV POCT kits were ordered and distributed by CPL at a cost of \$61,165.82 (\$16.19/kit). Each site received kits as indicated in the following table.

<b>SITE</b>	<b>Number of HIV POCT Kits</b>	<b>Number of Controls</b>	<b>Cost</b>
<b>MSP</b>	1810	4	\$29,303.90
<b>NCCHC</b>	1223	4	\$19,800.37
<b>HSR</b>	300		\$4857.00
<b>OOHC</b>	125	2	\$2023.75
<b>Women's HSC</b>	200		\$3238.00
<b>Thompson L&amp;D</b>	80	1	\$1295.20
<b>SBGH L&amp;D</b>	40	1	\$647.60
<b>TOTAL</b>	<b>3778</b>	<b>12</b>	<b>\$61,165.82</b>

### Manitoba HIV POCT Testing Data for 2016/17

	<b>Tests Performed</b>	<b>Reactive Tests</b>	<b>Percentage reactive</b>	<b>Cost per new HIV case (\$)</b>
<b>MSP</b>	1350	2	0.15%	\$10,928.25
<b>NCCHC</b>	733	10	1.36%	\$1186.72
<b>HSR</b>	172	3	1.74%	\$928.22
<b>OOHC</b>	67	0	0.00%	N/A
<b>Women's HSC</b>	160	0	0.00%	N/A
<b>Thompson L&amp;D</b>	26	0	0.00%	N/A
<b>SBGH L&amp;D</b>	9	0	0.00%	N/A
<b>TOTALS</b>	<b>2462</b>	<b>15</b>	<b>0.61%</b>	<b>\$2,657.32</b>

## HIV POCT Program Value for Money

Utilizing standard HIV testing at CPL with an estimated 80,000 tests per year, 110 new HIV cases/year and a cost of \$1.50/EIA, the cost by this modality is approximately \$1,000 per new case. Please note that this constitutes material cost only and does not include labour or overhead. This makes testing at NCCHC and HSHR cost equivalent. Testing at MSP is significantly more expensive and has a testing incidence comparable to the general Manitoban population. The corresponding cost to screen 2,462 individuals using standard HIV testing at CPL is approximately \$3,700 compared to just under \$40,000 by POCT excluding staff costs.

HIV cost-effectiveness literature has also demonstrated that for each case of HIV transmission from mother to infant prevented, \$250,000 to \$1.4 million is saved<sup>9,10,11</sup>. In addition, adults diagnosed with a CD4 count greater than 350 cells/mm<sup>3</sup> have an annual cost savings of \$6,000<sup>10</sup>. Of the 15 new cases in 2016/17, 10 had CD4 counts >350 cells/mm<sup>3</sup> for a potential cost savings of approximately \$60,000 per year. What is unclear is if these individuals would have sought medical care and received appropriate HIV testing prior to becoming more immunocompromised. According to the Manitoba HIV Program statistics for 2016<sup>12</sup>, 66 per cent of those entering care had a CD4 count <350 cells/mm<sup>3</sup> thus this could represent a true long-term cost savings. An additional \$60,000 in POCT related costs yields a minimum 5 persons with enhanced detection with CD4 >350/mm<sup>3</sup> or \$30,000 x approximately 20 years = \$600,000 in averted costs. There are also interrupted transmissions that carry greater savings. The cost benefit ratio is 0.10, which is highly favourable, and there is a return on Investment (ROI) of longest two years, probably much shorter.

Though no pregnant women were found to be HIV reactive by POCT in 2016/17, historically there has been one case diagnosed in 2011 and an additional two women disclosed their HIV-positive status in 2012 and 2013 when HIV POCT was offered. None of the three HIV-exposed infants were

infected thanks to appropriate early initiation of HIV prevention of mother to child transmission protocols. This would translate to a long-term cost-savings to the healthcare system of between \$750,000 and \$4.2 million.

## HIV POCT Challenges

Several areas of the HIV POCT program present challenges:

1. Underutilization on L&D units: Based on review of STAT samples sent from Women's Hospital HSC and St. Boniface General Hospital L&D on women presenting with limited prenatal care for hepatitis B, we would expect approximately 50 HIV POCT to be performed per site (Thompson L&D with 1/5 of deliveries would be expected to have 10). While both Women's HSC and Thompson L&D (average of 52 and 13 test per year, respectively) approached their expected volumes, SBGH L&D performed nine of an expected 35 to 40 tests. Close monitoring of this site will be necessary as will further collaboration and discussion to optimize testing rates.
2. Quality assurance: QA is an important aspect of any testing, in particular for POCT that falls outside of the scope of a laboratory. Several different avenues exist to ensure QA at the sites offering HIV POCT. Historically, CPL had provided unknown QA samples to be performed by a random operator but with the growth of the program to seven sites, this is no longer feasible. A promising alternative is external QA (EQA) provided by the Institute for Quality Management in Healthcare. This program offers bi-annual unknown sample surveys (April and October) administered to all sites with central review of performance and appears to be cost appropriate.
3. Northern and rural expansion: Service equity is an important component of HIV screening. Manitoba's northern and rural areas have some higher risk populations that could benefit from HIV POCT. The limitation demonstrated by a pilot study at the Thompson General Hospital Emergency Department was the hesitation to access HIV POCT by both patients and practitioners. Their reported

concern was primarily that, due to the smaller population, testing in the setting would be performed without the anonymity provided by testing in larger centres such as Winnipeg. It is unlikely that this perception is limited to Thompson thus limiting expansion to rural/northern Manitoba. In addition, risk for one STBBI should prompt testing for all. Though HIV POCT covers HIV, other prevalent BBI such as syphilis, hepatitis B and hepatitis C would require conventional screening using a phlebotomy specimen. Further strategies and opportunities must be sought.

4. Sustainability: As discussed above, HIV POCT at Nine Circles and HSHR is cost comparable to HIV screening performed at CPL per case of HIV diagnosed with the benefit of providing a key service to higher risk Manitobans. Unfortunately, despite providing services to a high-risk population, MSP is not cost neutral and has equivalent HIV test prevalence to CPL. Options include discontinuing this sites offering of HIV POCT and advocating for exclusive routine phlebotomy. HIV POCT could potentially be maintained at MSP if HIV POCT volumes were to decrease. For comparison, almost 20,000 people could be screened by routine HIV testing for the same cost as the 1,800 screened in 2016/17. Discussion with MSP staff will be essential to determine optimal testing in their client group.

### **Future Directions for HIV POCT in Manitoba**

Overall, the HIV POCT program has been well received by the practitioners at each site and offers a supplementary method to screen high-risk groups for HIV. The program may be overall cost-neutral (estimated at approximately \$60,000 in 2016/17). With the inclusion of cost savings from across the life of the program, there is a clear overall cost-savings to the healthcare system.

In order to optimize the program, the following steps can be undertaken in 2018/19:

1. Reduce in-stock kit numbers to 70 per cent of 2016/17 value (total cost savings \$18,349.02). This does not eliminate any screening capacity and retains the ability for surge capacity if a site's kits become compromised.
2. Discuss reducing testing at MSP by at least 50 per cent by HIV POCT and making up the difference by standard methods of testing provided through CPL (total material cost savings \$10,928.25). This option has the added benefit of screening for other important STBBIs (syphilis, hepatitis B and C) in this high-risk group.
3. Encourage use of HIV POCT in women presenting to SBGH L&D with no or limited prenatal care or continued risk factors throughout the latter part of pregnancy. The expectation would be approximately 50 tests/year (additional cost \$1,619).
4. Initiate HIV POCT EQA at all seven sites to ensure reliability of testing results and to address any issues as they are detected (additional annual cost \$4,013.10).

Overall, these proposed changes would reduce the annual material cost of the HIV POCT program in 2018/19 to \$18,760.33 (-38.7 per cent) while maintaining adequately targeted outreach HIV screening capacity with improved quality. At this time, it is unclear if more cases and any antecedent cost-savings would result from these changes. As well, it is possible that a case may be missed at the MSP with resulting increased long-term healthcare costs until that individual is diagnosed. These factors have not been included in this cost analysis.

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