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Protocols

Rapid HIV tests in acute care settings in an area of low HIV prevalence in Canada

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ABSTRACT

Rapid HIV testing has the potential to improve medical care and reduce the transmission of infection. In this study, rapid HIV testing was performed on serum samples in acute care settings in five hospitals from urban and rural regions using the INSTI™ HIV-1/HIV-2 Rapid Antibody Test (bioLytical Laboratories, Richmond, British Columbia). Parallel standard HIV antibody tests were performed at the provincial reference laboratory. Patient demographics, indication for testing and risk behaviours were collected. From April 30, 2007 and November 23, 2009, 1708 individuals were tested: 875 (50.3%) tests in pregnant women, 730 (42%) in source individuals in blood and body fluid exposures and 119 (5.8%) in acutely ill persons. Twenty-five (1.4%) samples were reactive by rapid HIV testing, of which 13 were reactive previously and 1 was a false reactive. Sensitivity of the rapid HIV test compared to standard HIV testing was 100%, specificity was 99.9%, the positive predictive value was 96% and the negative predictive value was 100%. The median time from specimen collection to availability of the rapid HIV result varied by site and ranged from 54 min to 1 h 42 min. In this study, the INSTI™ HIV-1 Rapid Antibody test identified reactive and non-reactive samples with similar accuracy to the conventional testing algorithm and provided a reliable way to perform rapid HIV testing in acute care settings.

1. Introduction

It is estimated that approximately one quarter of all persons infected with HIV in Canada are unaware of their infection (Boulos et al., 2006). The highest prevalence estimates are seen in men who have sex with men, injection drug users and aboriginal (Canadian First Nations, Metis and Inuit) women. The prevalence of HIV in Canadian provincial and federal offenders is estimated to be between 2 and 8%, more than ten times the reported prevalence of 0.2% in the general Canadian population (Correctional Services Canada, 2000-1). In 2008 in Alberta, it is estimated that there were approximately 4400 individuals infected with HIV, yielding a provincial HIV prevalence estimate of 0.13% (Yang et al., in press; Public Health Agency of Canada, unpublished data).

This high level of undiagnosed infection creates issues for both public health and clinical care. Undiagnosed individuals can unknowingly infect sex partners, unborn children in the case of pregnant women, and health care workers. In addition, rapid diagnosis of HIV in the case of an acutely ill patient can improve greatly the medical management offered to the patient. Therefore, the use of rapid HIV testing, especially among high-risk patients, might improve medical care and reduce transmission of infection. Despite the widespread acceptability of rapid HIV kits worldwide, their utility in acute care settings has not been evaluated widely except in pregnant women.

In Alberta, rapid HIV testing was implemented as a pilot study program in five acute care hospitals in 2007. The hospitals were selected based on provincial HIV epidemiology patterns, and included two large metropolitan hospitals and three hospitals in smaller urban centers. Rapid HIV testing was implemented in selected acute care clinical situations where a rapid test result could change the immediate medical management of the case. The results from this pilot study and performance characteristics of the test kit are described.

2. Materials and methods

The introduction of the Alberta Rapid HIV testing pilot program began on April 30, 2007 and ended with the 5th hospital commencing on December 1, 2007. Testing was offered to individuals over the age of 17 years and in one of the following clinical situations: (1) Pregnant women, near term or in labour with no previous HIV testing or negative for HIV ≥ 4 weeks prior to deliv-

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ery but with ongoing risk factors for HIV; (2) Source individuals in blood and body fluid exposures, most of which were occupational exposures in health care workers; and (3) Acutely ill patients whose differential diagnoses included HIV. Risk factors for HIV were defined as active injection drug use, sexual partner infected with HIV, multiple sexual partners, sex trade work, recent history of sexually transmitted infection (STI), history of incarceration in prison, homeless, aboriginal, from an HIV endemic country, men who have sex with men or having a sexual partner with any of the above risks.

Together with stakeholders, a policy document outlining the use of rapid HIV tests in Alberta was developed. Ethics approval was obtained from the University of Alberta Health Research Ethics Board, University of Calgary Ethics Board and regional boards in the three rural health regions.

The rapid HIV test kit used for this study was the INSTI™ HIV-1/HIV-2 Antibody Test (bioLytical™ Laboratories, Richmond, BC, Canada).

The assay was licensed for HIV-1 in Canada in October, 2005, and licensed for HIV-2 in September, 2008 pending the submission of final documentation by the manufacturer. This rapid HIV test kit is designed for single use on serum, plasma, or whole blood, with the ability to test specimens on whole blood at point of care, i.e. outside of a designated laboratory. This test is a manual, read visually, flow-through immunoassay which uses a combination of recombinant transmembrane proteins imbedded in the test cassette membrane [HIV-1 (gp41) and HIV-2 (gp36)] to capture HIV specific antibodies, if present, in the sample (bioLytical Laboratories™, Richmond, BC, Canada). Reactive results are considered as "preliminary positive" and confirmatory testing using Western blot is required.

In Alberta, all diagnostic anti-HIV testing and prenatal screening for HIV and confirmatory testing is carried out at the Alberta Provincial Public Health Laboratory, which has two sites in the two major urban centers in the province. For this pilot study, serum based rapid HIV testing was performed at the hospital on-site rapid response laboratories, not at the point of care in order to ensure quality assurance. All testing was conducted by trained laboratory technologists. Parallel testing was performed for all samples at the Provincial Public Health Laboratory using a standard HIV antibody test algorithm due to concerns related to previous withdrawal of another rapid HIV kit in Canada in 2002 (Health Canada, 2002). Standard anti-HIV screening was performed at the Provincial Public Health Laboratory using the AxSYM® HIV1/2 gO system (Abbott Laboratories, Chicago, IL, USA). Samples testing as reactive by the first enzyme immunoassay from patients not diagnosed previously were tested with a second enzyme immunoassay (Vitros Immunodiagnostic Anti-HIV 1/2, Ortho-Clinical Diagnostics, Amersham, UK) until December, 2008, then with the HIV-1/HIV-2 PLUS O EIA Genetic Systems™, Bio-Rad, Montreal, QC, Canada) and confirmatory Western blot (Genetic Systems™ HIV-1 Western Blot, Bio-Rad Laboratories, Montreal, QC, Canada).

The Provincial Public Health Laboratory provided an overall quality assurance program for the pilot. A study coordinator at the Provincial Public Health Laboratory was in charge of rapid test inventory, batch release, distribution of kits to pilot study sites, proficiency testing, and follow-up with the manufacturers in case of issues with the assay. In addition, training in the use of the kit was provided to testing sites using a train-the-trainer model.

A specific HIV requisition form was created to be used for this pilot. Data on reason for testing and risk factor information were collected on this form. Rapid HIV testing data were analysed for specimens received between April 20, 2007 and November 23, 2009 and a descriptive analysis was performed using the Stata v.10 (StataCorp, College Station, TX, USA).

3. Results

A total of 1,737 tests were conducted at all five sites in Alberta between April 30, 2007 and November 23, 2009 (Table 1). 1708 individuals were tested, of whom 27 (1.3%) had repeat testing during the pilot period. The largest number of tests, 875 (50.3%) were conducted on pregnant women, followed by those conducted on source individuals in blood and body fluid exposures (730 (42%).

Risk factors or reason for testing was provided for 60.5% (529/874) of the specimens submitted from pregnant women, 60.5% (72/119) from acutely ill patients, and 22.9% (167/730) from sources of blood and body fluid exposures. In pregnant women, the absence of previous prenatal screening for HIV was the most common reason for a rapid HIV test ($n = 451$; 51.6%), followed by Aboriginal ethnicity ($n = 154$; 17.6%). For specimens from acutely ill patients, injection drug use was the most common risk factor ($n = 32$; 26.9%) followed by homeless patients ($n = 20$; 16.8%).

Of the 1737 tests, 25 (1.4%) were reactive by the rapid HIV test. Eleven were newly identified infections confirmed by Western blot, 13 had been diagnosed previously with Western blot confirmation and 1 was determined ultimately to be a false reactive rapid HIV test. Reactive rapid HIV tests were only reported among acutely ill patients (14/119 = 11.8%) and source individuals in blood/body fluid exposures (11/730 = 1.5%) (Table 2). Among the acutely ill patients, 10 of the 14 reactive tests (71.4%) were new diagnoses.

There were 11 non-reactive rapid tests which were reactive by the standard AxSYM screening. Eight of these were negative by Western blot, while three tested as indeterminate by Western blot; these patients were confirmed not to be infected with HIV in follow-up testing. In addition, there were six rapid HIV tests with invalid test results and one instance where the rapid HIV test result was not recorded; all of these specimens were negative on parallel usual testing carried out at the Provincial Public Health Laboratory. The sensitivity of the rapid HIV test compared to standard HIV testing was 100%, specificity was 99.9%, the positive predictive value was 96% and the negative predictive value was 100% (Table 3).

In the six invalid tests, a rapid HIV test result could not be obtained because the human IgG control band was negative on repeat testing. Two tests were performed using kits close to expiry date; one of these patients presented with hypogammaglobulinemia during sepsis and the other patient had received a large volume of fluid for resuscitation. There were no obvious technical or clinical explanations for the other four invalid tests: two of the four patients had recently undergone surgery and one patient died from sudden myocardial infarction, possibly having fluid resuscitation.

The median time between specimen collection and availability of the rapid HIV result was 1 h 10 min. In the 2 urban sites which were staffed 24 h a day, the median time was 1 h 10 min (ranging from 11 min to 5 h 25 min). In the three non-urban sites, which were staffed only during daytime hours, the median time to reporting was similar at 1 h 10 min but ranged from 11 min to 48 h 50 min. Median time from specimen collection to the receipt of the specimen at Provincial Public Health Laboratory varied by site but ranged from 42 min to 318 h 30 min (median: 10 h 48 m). In the 2 urban sites this median time was 5 h 24 min (range: 42 min–41 h 18 min) as compared to the 3 non-urban sites, where the median time was 44 h 6 min h (range: 3 h 6 min–318 h 30 min).

4. Discussion

The results of this rapid HIV pilot study in Alberta report high performance characteristics of the INSTI™ HIV-1/HIV-2 antibody test when used on serum based specimens. This kit is the only

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Table 1
Description of individuals tested by Rapid HIV testing by reason for test, Alberta, 2007–2009.

	Total	Reason for testing					
		Women near term	Acutely Ill	Source of blood/body fluid exposure	Recipient of blood/body fluid exposure[a]	Not provided	*p*-Value
Number	1737	874	119	730	9	5	
Number with reactive POC test	25 (1.4)	0	14 (11.8)	11 (1.5)	0	0	
Number with confirmed positive HIV	24 (1.4)	0	14 (11.8)	10 (1.4)	0	0	
Location							
Large urban	1,220 (70.2)	470 (53.8)	108 (90.8)	633 (86.7)	7 (77.7)	2 (40.0)	0.0000
Small urban	517 (29.8)	404 (46.2)	11 (9.2)	97 (13.3)	2 (22.2)	3 (60.0)	
Median age (years; IQR)	30.5						
(24.0–44.5)	25.9						
(22.0–30.2)	43.3						
(32.4–52.3)	45.5						
(31.3–60.5)	24.5						
(23.7–39.9)	28.8						
(24.5–51.4)							
Female gender	1280 (73.7)	874 (100)	30 (25.2)	369 (50.6)	4 (44.4)	3 (60.0)	0.000
Ethnicity							
Aboriginal	346 (19.6)	225 (25.7)	17 (14.3)	103 (14.1)	0	1 (20.0)	0.000
Black	106 (6.1)	67 (7.7)	10 (8.4)	28 (3.8)	0	1 (20.0)	
Caucasian	935 (53.8)	426 (48.7)	70 (58.8)	431 (59.0)	6 (66.7)	2 (40.0)	
Asian	77 (4.4)	57 (6.5)	9 (7.6)	15 (2.1)	0	0	
Other	81 (4.7)	43 (4.9)	2 (1.7)	32 (4.4)	0	0	
Unknown	192 (11.1)	56 (6.4)	11 (9.2)	121 (16.6)	3 (33.3)	1 (20.0)	
Risk factors[b]							
No prenatal testing	465 (26.8)	451 (51.6)	0	14 (1.9)	0	0	
Recent STI	36 (20.7)	23 (2.6)	1 (0.8)	12 (1.6)	0	0	
Injection drug user	141 (8.1)	46 (5.2)	32 (26.9)	61 (8.4)	0	2 (0.4)	
Homeless/inner city	111 (6.4)	43 (4.9)	20 (16.8)	45 (6.2)	1 (11.1)	2 (0.4)	
Multiple sex partners	81 (4.7)	38 (4.3)	16 (13.4)	26 (3.6)	0	1 (0.2)	
History of incarceration	48 (2.8)	17 (1.9)	6 (5.0)	25 (3.4)	0	0	
MSM	10 (0.6)	0	7 (5.9)	3 (0.4)	0	0	
Sex partner is HIV positive	19 (1.1)	8 (0.9)	4 (3.4)	7 (1.0)	0	0	
Heterosexual endemic	21 (1.2)	7 (0.8)	9 (7.6)	5 (0.7)	0	0	
Heterosexual partner at high-risk for HIV	20 (1.2)	7 (0.8)	6 (5.0)	7	0	0	
Sex trade worker	16 (0.9)	8 (0.9)	4 (3.4)	4	0	0	
Aboriginal	241 (13.9)	154 (17.6)	13 (10.9)	72	1 (11.1)	1 (0.2)	
No risk factors	771 (44.4)	345 (39.5)	47 (39.5)	563	8 (88.9)	3 (0.6)	

[a] Includes one sexual assault.
[b] Risk factors are not mutually exclusive.

licensed rapid/point-of-care HIV kit available in Canada and its performance characteristics are comparable to those licensed by the U.S. Food and Drug Administration (FDA) (CDC, 2008). The sensitivity and specificity of FDA approved rapid/point-of-care tests on serum based specimens are high (99.7–100% and 99.1.6–99.9%, respectively) (CDC, 2008).

Although the rapid test kit used in the present study had excellent performance characteristics compared to standard testing, it has been suggested that like other rapid tests it is less sensitive than standard testing in detecting acutely seroconverting patients who have not yet developed HIV antibodies (Greenwald et al., 2006). Our study did not have sufficient power to detect these events.

Table 2
Q4 Distribution of reactive test results by site and reason for testing.

	Reactive tests	Newly diagnosed	Previously HIV diagnosed	False reactive
Overall	25	11	13	1
By Site:				
Rural	4	3	1	0
Urban	21	8	12	1
By reason for testing				
Acutely ill patient	14	10	4	0
Recipient of blood/body fluid exposure	0	0	0	0
Source in blood/body fluid exposure*	11	1	9	1
Pregnant women	0	0	0	0
Not provided	0	0	0	0

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Table 3
Performance characteristics of rapid HIV testing in comparison to parallel standard serology testing, Alberta, 2007–2009 ($n = 1727$)[a].

	Standard SEROLOGY		Total
Rapid HIV	Positive	Negative	
Reactive	24	1	25
Non-reactive	0	1702	1702
Total	24	1703	1727

Sensitivity: 24/24 = 100%, specificity: 1702/1703 = 99.9%, positive predictive value (PPV): 24/25 = 96%, negative predictive value (NPV): 1702/1702 = 100%.

[a] Excludes 3 specimens with indeterminate Western blot on parallel testing, 6 with invalid tests on rapid test and one whose rapid test result which was not recorded.

However, it is important that clinicians and patients be aware of this limitation of rapid testing and ensure that appropriate follow-up testing is arranged in settings where acute seroconversion is suspected. In addition, it should be noted that the AxSYM® test, a standard screening test, was less specific than the INSTI™ HIV kit with a higher rate of false positives.

The implementation of point-of-care testing is associated with significant challenges from a quality assurance perspective (Greenwald et al., 2006). Although many rapid HIV test devices are easy to use, mistakes can occur at any point in the testing process, including storage and testing temperature, test kit shelf-life, specimen collection, test performance and result interpretation (Greenwald et al., 2006). The clinical settings in which rapid HIV testing was performed in the current study were selected in order to enable the use of rapid response laboratories as testing sites thus facilitating good laboratory practices. The structure of health care services in Alberta has enabled efficiencies through centralized purchase, lot release and inventory control of test kits as well the provision of technical support 24 h daily. Training, ongoing competence assessment and a standardized approach to result documentation, allowing ongoing comprehensive surveillance of HIV testing are also easier to implement in this setting. A challenge experienced during the pilot study was the restricted hours of operation of some rapid response laboratories in rural settings. Comprehensive cost-effective HIV screening programs will likely require a mix of standard testing, testing in rapid response setting and true point-of-care testing.

For this investigation, an *a priori* decision was made to restrict HIV testing in pregnant women to those at highest risk, since the uptake of HIV testing in pregnant women accessing prenatal care in Alberta already exceeds 95%. Testing of women in labour who either continued to be at risk for the acquisition of HIV during pregnancy after an earlier negative screen for HIV or who had had no prenatal screen is consistent with recommendations by the Public Health Agency of Canada (PHAC) (Public Health Agency of Canada, 2007) and the Centers for Disease Control (CDC) in the United States (CDC, 2006a). Previous data have demonstrated a higher prevalence of HIV in women who opt out of HIV testing (Plitt et al., 2007).

The large MIRIAD (Mother Infant Rapid Intervention at Delivery) study in six American cities identified 52 (0.7%) HIV-positive women who had no prior HIV test result available at the time of delivery (Jamieson et al., 2007). Even though participating sites in this pilot study were selected based on epidemiology of HIV in the province, no positive HIV cases were identified among the pregnant women. This may be in part due to the high level of prenatal HIV screening performed in Alberta. It is noteworthy that at one of the non-urban sites, a decision was made to re-screen all women accessing prenatal care in the late third trimester rather than to conduct risk based testing as it was felt that such a strategy would stigmatize women from ethnic minority groups which are prevalent at this centre. That there were no HIV positive women identified, is probably because of the very high rates of prenatal testing, early diagnosis and referral of all HIV positive women to an urban centre for care. Another possible explanation for the lack of positive HIV tests in the pregnant women is under-screening of women who had not been tested or were negative in early pregnancy but had ongoing risk factors for HIV not recognized by clinical staff. Some clinical staff expressed concern about the need to collect information such as ethnicity and sexual history which they perceived to be excessively intrusive, particularly on labour and delivery units where family members are often present. Previous studies have reported that some women may be fearful of disclosing their own HIV status result when they come to hospital for obstetric services (Lindau et al., 2006). The MIRIAD study also reported less testing in women belonging to a racial group other than black or white or admitted during the weekend or evening shift (Jamieson et al., 2007). We are aware of one mother-to-child transmission which occurred during this pilot study at a hospital not participating in it. The transmission to the child occurred from a woman whose partner was known to be HIV positive but who herself had screened negative for HIV earlier in pregnancy. She was not re-screened at the time of delivery because the delivery unit was not aware of her partner's status.

Rapid HIV testing in occupational and non-occupational exposures to blood and body fluids allows the prompt initiation of HIV post-exposure prophylaxis (Panlilio et al., 2005). The availability of the test result from the source individual in blood and body fluid exposure is also likely to reduce the cost and potential side effects of unnecessary HIV post-exposure prophylaxis and may result in less anxiety related to the exposure (Kallenborn et al., 2001; Machado et al., 2001; Landrum et al., 2005). On the other hand, the policy of universal testing of all source individuals in blood and body fluid exposures, even those known to be previously HIV positive, was questioned by some health providers in the present study.

Although acutely ill patients were a small proportion of the rapid HIV testing in this pilot study (6.9%), they represented the highest proportion of reactive HIV tests. Of the 14 positive results among this group, 10 (71%) were new diagnoses which represented 91% of all new diagnoses identified in this pilot study. The selection of acutely ill patients for rapid HIV testing was at the discretion of the ordering physician and as part of this study, detailed clinical information was not collected. Anecdotally, however, some of the patients selected were those with risk factors for HIV presenting with acute pneumonias where the differential diagnosis included *Pneumocystis jirovecii* pneumonia. While the rapid HIV test provides a tool for guiding immediate patient management, this testing strategy would typically identify patients at an advanced stage of HIV and therefore miss the opportunity for early referral and initiation of antiretroviral therapy. Previous studies document missed opportunities for early HIV diagnosis among patients presenting for clinical care (McDonald et al., 2006; White et al., 2009; Liddicoat et al., 2004). In addition, US data show that many patients are still identified late in the course of their infection with 40% developing AIDs <1 year after diagnosis (CDC, 2003).

The use of rapid HIV tests with a result within a median time of 1 h 10 min as seen in this pilot study is clearly beneficial in situations where the result can influence clinical management. As shown in the present study, the median time from collection of the specimen to receipt in the reference laboratory varied considerably with a shorter turn around time in the two urban settings as compared to the three non-urban settings. A single reference laboratory offers all HIV testing in Alberta but the population is spread over a large geographical area so, the turn around time may vary significantly due to delays in transporting the specimens. Although it is possible to offer expedited standard testing, the minimum turn around time is 4 h after receipt of the specimen and for pregnant women in labour, this may be too late to offer interventions which could reduce mother to child transmission of HIV. True point-of-

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care testing would offer a result within 30 min but this advantage would be offset by the need to train multiple clinical personnel and would assume their availability to add this test immediately to their clinical commitments.

Feedback obtained by direct communication and questionnaires from clinical and laboratory personnel at all sites reported consistently satisfaction with the rapid HIV testing and the personnel felt that it enhanced clinical care (data not shown). Research in other settings also shows that the availability of rapid HIV testing is associated with increased acceptance of testing and increased patient satisfaction (Kendrick et al., 2005; Spielberg et al., 2005). Stokes et al. (2007) reported high acceptability for rapid HIV testing by the majority of pregnant women and midwives surveyed in the UK.

One of the limitations of the testing strategy described above is that risk assessment was conducted prior to offering rapid HIV testing. Previous studies have shown, however, that individuals at risk are often not tested, e.g. in one study only 10% of Emergency Departments recommended HIV testing to patients with sexually transmitted infections (Fincher-Mergi et al., 2002). An additional barrier to offering and implementation of rapid HIV testing includes the need as required or recommended by legislation or guidelines, to obtain informed consent and/or to offer pre- and post-test counselling (Jamieson et al., 2007; Liddicoat et al., 2004; Pai et al., 2007). Two recent models have demonstrated that even in low prevalence settings, screening of a defined population, e.g. all Emergency Department attendees is cost effective (Aberg et al., 2009; Paltiel et al., 2005). Recent data from an Emergency Department study including one of the hospitals participating in this pilot study showed a HIV prevalence of 2% (Houston et al., 2010). Screening only patients with acute illness compatible with AIDS would necessarily select for patients with advanced HIV and potentially miss opportunities for earlier diagnosis in asymptomatic patients. Expanded screening is important because testing based on risk assessment fails to test many infected persons (Chen et al., 1998). Lyss et al. (2007) reported that about half of the patients in their study would have been missed by using a risk based screening approach because they did not disclose, were not aware of or did not have risk factors for HIV. In the United States, the CDC recommended voluntary HIV testing in acute care settings almost 10 years ago (CDC, 1993). More recently, these recommendations have been expanded to include screening in acute care and other clinical settings with high HIV prevalence (CDC, 2006b). HIV morbidity and mortality is significantly reduced only when early diagnosis is linked to the opportunity to receive antiretroviral therapy (Holmberg et al., 2004). In addition, some studies have demonstrated that knowledge of HIV status, particularly when positive, decreases behaviour that can result in transmission (Berrios et al., 1993; Coates, 2000; Higgins et al., 1991). Routine HIV testing appears cost effective where the prevalence of HIV is as low as 0.2% (Paltiel et al., 2006). The optimal screening approach and most cost-effective use of rapid HIV testing versus conventional HIV testing required to identify undiagnosed HIV cases in Canada remains uncertain. Approaches that simplify and streamline HIV testing procedures are likely to enhance the uptake of rapid HIV testing in busy clinical settings (Pilcher et al., 2010).

In summary, the evaluation of rapid HIV testing in acute care settings in Alberta shows that the INSTI™ HIV-1/HIV-2 Antibody Test kit performed well and that user satisfaction with the program was high. The study shows that rapid HIV testing can be implemented in a variety of acute care settings where the result can impact immediately on patient care. Implementation was possible at both large urban hospitals and smaller community hospital in rural regions. Among the challenges that remain will be to determine how to make rapid HIV testing available throughout the province, especially in hospitals without onsite laboratories or laboratories with restricted opening hours. An assessment of the feasibility of expanding rapid HIV testing to additional acute care sites and expansion to other settings is underway.

Disclosure

The opinions expressed in this article do not necessarily reflect the views of the authors' affiliated institutions.

Conflicts of interest

None of the authors have any conflicts of interest.

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