TITLE: Point-of-Care HIV Testing: A Review of the Clinical and Cost-Effectiveness and Diagnostic Accuracy

DATE: 08 April 2009

CONTEXT AND POLICY ISSUES:

At the end of 2005, it was estimated that there were approximately 58,000 people in Canada living with HIV (including those living with AIDS), of whom approximately 27% were undiagnosed.\(^1\) Early diagnosis is important in both treatment and the prevention of transmission of HIV infection to other susceptible individuals.\(^2\)

The current standard method for the diagnosis of HIV is a serum or plasma sample tested on an enzyme-linked immunosorbent assay (ELISA), also referred to as enzyme immunoassay (EIA), with confirmation testing using a Western Blot (WB) or other approved confirmatory HIV testing protocol.\(^3\) This process can take several days as the initial EIA test may be delayed and if positive, it can take several more days for confirmation, leading to a large delay in getting the results to the patient.\(^4\)

In an attempt to address the delay in providing HIV test results, rapid HIV tests have been developed which can often provide a preliminary HIV antibody result in less than 20-30 minutes.\(^4,5\) While the rapid tests provide initial results, confirmatory HIV testing at an approved HIV testing laboratory is required for all patients with an HIV reactive rapid HIV test result.\(^3\)

There are currently two rapid HIV tests approved for use in Canada, the MedMira Rapid HIV Screen Test (MedMira Laboratories Inc, Canada) and the INSTI\(^\text{TM}\) HIV-1 Rapid Antibody Test (bioLytical Laboratories Inc. Canada).\(^6\) The INSTI\(^\text{TM}\) HIV-1 test is approved for both laboratory-based rapid HIV testing as well as point-of-care (POC) whole blood testing, while the MedMira Rapid HIV is approved for laboratory use only.\(^5\) POC HIV testing refers to the practice of healthcare professionals providing pre- and post-test HIV counselling and HIV testing using rapid HIV tests in the POC setting.\(^3\) In contrast to standard testing, the healthcare professional in the POC setting assumes responsibility for both specimen collection and testing.\(^3\)
With the increased use of rapid POC HIV testing, there is a need to review the evidence regarding their use. This report will review the evidence for the diagnostic accuracy of Rapid HIV tests, as well as their cost-effectiveness.

RESEARCH QUESTIONS:

1. What is the clinical-effectiveness and diagnostic accuracy of point-of-care testing for HIV?

2. What is the cost-effectiveness of point-of-care testing for HIV?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, The Cochrane Library (Issue 1, 2009), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. Results include articles published between 2004 and March, 2009, and are limited to English language publications only. Filters were applied to limit the retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, observational studies, and economic studies. Due to the high number of observational studies identified, these were limited to those published from 2007 to March 2009.

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, observational studies, and economic evaluations.

SUMMARY OF FINDINGS:

Two health technology assessments, one systematic review, six observational studies, and five economic evaluations on HIV POC testing were identified. No randomized controlled trials were identified.

Health technology assessments

Chou et al. (2005) completed a synthesis of the risks and benefits of screening for HIV infection in pregnant women. The authors examined several aspects of HIV screening in this population including the test characteristics of HIV antibody testing strategies. The authors included studies performed in the US, Australia, Canada, and Western Europe in which epidemiology and management of chronic HIV infection are similar. Systematic reviews, trials, and observational studies were included and assessed for internal validity using predefined criteria from the US Preventative Services Task Force allowing for the grading of “good”, “fair”, or “poor”. Information about setting, patients, interventions, and outcomes were abstracted from included systematic reviews, trials, and observational studies.

Three good-quality and four fair-quality studies evaluating the diagnostic test characteristics of rapid HIV testing during pregnancy that used standard EIA and confirmatory WB as the reference standard were identified. Only one study identified tested a rapid HIV test currently available in the US. This was a good-quality prospective study using the OraQuick® Rapid HIV-1 serum test among 5,744 women presenting in labour in six US cities between 2001 and 2003.
In this observational study, compared to standard testing, rapid HIV testing had a sensitivity of 100% [95% confidence interval (CI), 90%-100%], specificity of 99.9% (95% CI, 99.78%-99.98%), positive predictive value of 90% (95% CI, 75%-97%), and negative predictive value of 100%, with a prevalence of 0.59%. In the other studies of tests which were not currently available in the US [Single Use Diagnostic System (SUDS) HIV-1®; Capillus® HIV-1/HIV-2, Determine® HIV-1/2, Serodia® HIV-1, Multispot® HIV-1/HIV-2, Genie II HIV-1/HIV-2, and HIV-SPOT], sensitivity ranged from 95.8% to 100%, specificity ranged from 98% to 100%, and positive predictive values ranged from 33% to 100%.

Chou et al. (2005) also synthesized the evidence on risks and benefits of screening for HIV infection in the general population. The authors included studies performed in the US or Australia, Canada, and countries of Western Europe, in which the epidemiology and management of HIV are similar. Studies from other countries were included if they addressed a specific key question. The authors evaluated 3 rapid tests which are currently available for use in the US: Uni-Gold™ Recombigen® (Trinity Biotech PLC., Bray, Ireland) and OraQuick Advance® (OraSure Technologies, Bethlehem, Pennsylvania) which are true point-of-care tests, and Reveal® G2 (MedMira Laboratories, Inc., Halifax, Nova Scotia) which must be performed in a laboratory.

Three good quality studies and three fair quality studies were identified that evaluated the performance of the OraQuick® test. In the good quality studies, the sensitivities were 100%, 96%, and 100%, and the specificities were 99.9%, 100%, and 100%. In the fair-quality studies, the sensitivities ranged from 99.6% to 100%, and the specificity was 100% in all the studies. For the Uni-Gold™ Recombigen® and Reveal® tests, seven fair-quality studies reported sensitivities ranging from 94% to 100%, and specificities greater than 99%.

Systematic reviews and meta-analyses

Pai et al. (2007) conducted a systematic review and meta-analysis with the aims to: (i) summarize the overall diagnostic accuracy of rapid HIV tests in pregnancy; (ii) evaluate outcomes such as uptake, patient preference, feasibility, and impact of testing; and (iii) identify practical challenges related to the implementation of voluntary testing and counselling in pregnant women.

To complete the meta-analysis, a search of the literature from January 1991 to July 2005 was conducted to identify studies evaluating rapid HIV testing in pregnant women in antenatal clinics and delivery room settings. Seventeen relevant studies were identified of which 7 reported diagnostic accuracy outcomes and were included in the meta-analysis.

Data was extracted by one reviewer and included study setting, type of laboratory, type of test used, samples tested, participant characteristics, objectives of testing, reference standard, diagnostic accuracy (sensitivity and specificity), agreement between oral and blood-based rapid tests, and other outcomes (HIV prevalence, uptake, patient preference, challenges of counselling). To evaluate the quality of included studies, the researchers used the validated QUADAS (Quality Assessment of Diagnostic Accuracy of Studies) instrument, a checklist which includes study design, selection of participants, reporting of exclusion and inclusion criteria, blinded interpretation of index and reference test, and verification bias.

Overall sensitivity of all rapid tests ranged from 75% to 100% in the meta-analysis. Specificity of the rapid tests ranged from 96.4% to 100%. As the included studies used both oral fluid rapid tests and blood-based tests, the results were further subdivided. Blood-based tests had a
sensitivity of 86.4% to 100% and specificity of 99.5% to 100%. Oral fluid tests had sensitivity of 75% to 100% and specificity of 99.9% to 100%. To further assess this measure, the authors used the Summary Receiver Operating Characteristic (SROC). The area under the SROC presents an overall summary of test performance, and displays the trade-off between sensitivity and specificity and is a global measure of overall test accuracy. An area under the SROC of 100% would indicate a perfect discriminatory ability. In this analysis, the SROC was reported as close to 100% (99.89%). The authors concluded that in settings where pregnant women present for testing for the first time during delivery, a rapid test is the ideal diagnostic test with high diagnostic accuracy.

**Randomized controlled trials**
No RCTs were identified.

**Observational studies**
Lyamuya et al. (2009) evaluated the performance of five rapid HIV tests using 1433 whole blood samples from hospital patients, pregnant women, volunteer counselling and testing attendees, and blood donors in Tanzania. All samples that were reactive on any of the rapid assays and 10% of non-reactive samples were tested on a confirmatory Inno-LiA™ HIV I/II immunoblot assay. Sensitivity, specificity, positive predictive value, and negative predictive values of the tests are reported in Table 1. The authors concluded that the Uni-Gold™ test, the Determine® test, and the SD Bioline tests had the best performance.

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
<th>Positive Predictive Value (95% CI)</th>
<th>Negative Predictive Value (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine® HIV-1/2 (Inverness Medical)</td>
<td>100% (99.1%-100%)</td>
<td>99.6% (99.0%-99.9%)</td>
<td>99% (97.4%-99.7%)</td>
<td>100% (99.6%-100%)</td>
</tr>
<tr>
<td>SD Bioline HIV 1/2 3.0 (Standard Diagnostics Inc.)</td>
<td>100% (99.1%-100%)</td>
<td>99.4% (98.8%-99.7%)</td>
<td>98.5% (96.7%-99.4%)</td>
<td>100% (99.6%-100%)</td>
</tr>
<tr>
<td>First Response® HIV Card 1-2.0 (PMC Medical India Pvt Ltd.)</td>
<td>99.5% (98.2%-99.9%)</td>
<td>99.6% (99.0%-99.9%)</td>
<td>98.5% (96.7%-99.4%)</td>
<td>99.8% (99.3%-99.9%)</td>
</tr>
<tr>
<td>HIV 1/2 Stat-Pak® Dipstick (Chembio Diagnostic System, Inc)</td>
<td>97.7% (95.7%-98.9%)</td>
<td>99.8% (99.3%-99.9%)</td>
<td>97.2% (95.0%-98.6%)</td>
<td>99.1% (98.4%-99.6%)</td>
</tr>
<tr>
<td>Uni-Gold™ HIV-1/2 (Trinity Biotech)</td>
<td>100% (99.1%-100%)</td>
<td>100% (99.6%-100%)</td>
<td>100% (99.1%-100%)</td>
<td>100% (99.6%-100%)</td>
</tr>
</tbody>
</table>

CI = confidence interval

Moodley et al. (2008) evaluated the performance of four rapid HIV tests used by counselors and nurses or skilled laboratory staff compared to ELISA. The tests were performed on 961 antenatal attendees in twelve primary healthcare facilities in KwaZulu-Natal. Sensitivity and specificity of the tests when performed by nurses/counselors in the field are reported in Table 2.
When the tests were performed by skilled laboratory staff, all four rapid tests had sensitivity and specificity of 100%. Since the reliability was dependent on the user, the authors suggested that there is a need for ongoing training, supervision, and quality control for HIV testing programs.

Table 2: Sensitivity and specificity of rapid HIV tests (Moodley et al.11)

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott-Determine® HIV-1/2 (Abbott Diagnostics, Illinois)</td>
<td>97.3% (95.1%-98.6%)</td>
<td>97.6% (95.9%-98.7%)</td>
</tr>
<tr>
<td>First Response® HIV Card Test 1-2.0 (PMC Medical, India Pvt Ltd)</td>
<td>96.9% (94.6%-98.4%)</td>
<td>97.9% (96.3%-98.9%)</td>
</tr>
<tr>
<td>Sensa (Seyama Solutions, SA)</td>
<td>95.8% (93.3%-97.5%)</td>
<td>97.8% (96.1%-98.8%)</td>
</tr>
<tr>
<td>Pareekshak™ HIV Triline (UCB Pharma)</td>
<td>92.5% (89.3%-94.8%)</td>
<td>98.3% (96.5%-99.1%)</td>
</tr>
</tbody>
</table>

CI = confidence interval

Walensky et al. (2008) evaluated the diagnostic test performance of the OraQuick Advance® Rapid HIV-1/2 Antibody Test (OraSure Technologies, Bethlehem, Pennsylvania) within the framework of the Universal Screening for HIV infection in the Emergency Room (USHER) Trial.12 Patients were eligible for participation in the HIV screening study if they were between 18 years and 75 years of age; had an emergency severity index score of 3, 4, or 5 on a scale of 1 (most severe) to 5 (least severe); spoke English or Spanish fluently; not receiving prenatal care; and not knowingly be HIV-infected. The oral rapid test results were collected at the patients’ bedside in the emergency departments, and tests were run and developed at the on-site emergency department laboratory. All patients with reactive results were offered a comprehensive confirmatory test panel including EIA, WB, CD4 count, and plasma HIV-1 RNA testing.

A total of 849 of the 854 patients had valid HIV test results. Thirty-nine patients had a reactive OraQuick® test result and 31 of these 39 patients agreed to the confirmatory testing panel and 8 declined. On confirmatory tests, 5 of the 841 patients with reportable test results were confirmed to be HIV-infected and 26 had conclusive confirmatory testing indicating that they were not HIV-infected. Estimated HIV prevalence was 0.6% (CI, 0.1-1.1). The estimated test specificity was 96.9% (CI, 95.7-98.1). The authors noted that this specificity was much lower than the manufacturer’s reported specificity for the OraQuick® test of 99.8% (CI: 99.6%-99.9%) and that it demonstrated a much higher false-positive rate than anticipated. Test sensitivity could not be assessed as nonreactive rapid tests were not confirmed. The authors conclude that despite the lower specificity than anticipated, rapid HIV screening functions better than many other screening tests used in US clinical practice and that the manner in which providers respond to and support patients with reactive results is critical to ensure the success of HIV screening programs.

Mayhood et al. (2008) evaluated the Capillus® HIV-1/HIV-2 (Trinity Biotech PLC, Bray, County Wicklow, Ireland) and Determine® HIV 1/2 (Abbot Laboratories, Abbott Park, IL) rapid tests with an initial validation study and a subsequent field evaluation.13 A total of 206 blood samples were collected from medical inpatients in northern Tanzania for the validation component of the study. Whole blood was tested using both the Capillus® and Determine® tests. If both rapid tests were negative, the sample was tested with an ELISA. If the ELISA was negative no further testing was done, and if it was positive a WB was completed. If both rapid tests were positive or were discordant, the sample was tested with an ELISA and a WB. Of the 206 subjects, 105 were ultimately shown to be HIV positive and 101 were shown to be HIV negative. There was a 100% concordance between the Capillus®, Determine®, ELISA, and WB results. Sensitivity,
specificity, positive predictive value, and negative predictive value were 100% for Capillus® and Determine®, both when used individually and in combination.

The field evaluation consisted of a total of 12,737 clients who received voluntary counselling and testing (VCT) and had the results of both the Capillus® and Determine® rapid tests. Concordant results were reported and discordant results were subsequently confirmed using an ELISA. For quality control purposes, an ELISA was also performed on every 10th sample regardless of the rapid test results. The sensitivity, specificity, positive predictive value, and negative predictive value of the Capillus® HIV-1/HIV-2 test was 99.7% (95% CI 99.3%-99.9%), 99.8% (95% CI 99.7%-99.8%), 98.7% (95% CI 98.1%-99.2%), and 99.9% (95% CI 99.9%-100%), respectively. The sensitivity, specificity, positive predictive value, and negative predictive value of the Determine® HIV 1/2 test was 99.6% (95% CI 99.2%-99.8%), 99.9% (95% CI 99.8%-100%), 99.5% (95% CI 99.1%-99.8%), and 99.9% (95% CI 99.9%-100%), respectively. The authors concluded that the Capillus® and Determine® rapid HIV antibody tests performed well both in the reference laboratory and under field conditions in Tanzania in a cohort of over 12,000 VCT clients.

Kagulire et al. (2007) evaluated the performance of Aware™ rapid assays for the detection of HIV antibodies in blood (Aware™-BSP) and urine (Aware™-U) compared to EIA and WB as part of an ongoing community surveillance study in Uganda. The evaluation was conducted using specimens from a survey visit in an ongoing community cohort surveillance study in Uganda. A total of 963 blood samples and 942 urine specimens were collected and tested from a survey visit in an ongoing community cohort surveillance study in the Raka District of southwestern Uganda. The sensitivity, specificity, negative predictive value, and positive predictive value of the Aware™-BSP blood test was 98.2% (95% CI 93.6%-99.8%), 99.8% (95% CI 99.2%-99.9%), 99.8%, and 98.2%. The sensitivity, specificity, negative predictive value, and positive predictive value of the Aware™-U urine test was 88.7% (95% CI 81.1%-94%), 99.9% (95% CI 99.3%-100%), 98.6%, and 99.0%. The authors concluded that the performance of the Aware-U test was inadequate.

The Mother-Infant Rapid Intervention at delivery (MIRIAD) study, a large prospective multi-centre project in the US, evaluated the accuracy of using OraQuick® rapid HIV antibody test during labour. Jamieson et al. (2007) reported on the final data from 17 hospitals during the entire 40-month study period as an update to a previously published brief report including initial results from the first 2 years of the study. During the study, voluntary, rapid HIV testing was offered to women with undocumented HIV status late in pregnancy. Once a participant consented to join the study, blood was collected for both rapid and conventional HIV testing. In some hospitals, the rapid testing was performed in the labour and delivery unit by trained staff, whereas in other hospitals it was performed in a laboratory. All specimens were tested in parallel by conventional testing with EIA and confirmatory WB.

Using rapid testing, MIRIAD identified 52 HIV-infected women among the 7753 women tested. There were no false-negative results with OraQuick® or EIA, however, there were 6 false positive OraQuick® results and 18 false positive EIA results. The sensitivity, specificity, positive predictive value, and negative predictive value of the OraQuick® test and EIA is reported in Table 3. The authors concluded that routine rapid HIV testing during labour is feasible, acceptable, and accurate.
Table 3: Diagnostic Test Performance of OraQuick® and EIA (Jamieson et al.\textsuperscript{15})

<table>
<thead>
<tr>
<th>Measure</th>
<th>OraQuick®</th>
<th>EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>100% (93.15%-100%)</td>
<td>100% (93.15%-100%)</td>
</tr>
<tr>
<td>Specificity</td>
<td>99.92% (99.83%-99.97%)</td>
<td>99.77% (99.63%-99.86%)</td>
</tr>
<tr>
<td>PPV (95% CI)</td>
<td>89.66% (78.83%-96.11%)</td>
<td>74.29% (62.44%-83.99%)</td>
</tr>
<tr>
<td>NPV (95% CI)</td>
<td>100% (99.95%-100%)</td>
<td>100% (99.95%-100%)</td>
</tr>
</tbody>
</table>

CI = confidence interval; EIA = enzyme immunoassay; NPV = negative predictive value; PPV = positive predictive value

Economic evaluations

Shresta et al. (2009) assessed the costs of delivery of voluntary counselling and rapid HIV testing (OraQuick®) to jail inmates in four project areas: Florida (Broward County jails, Fort Lauderdale); Louisiana (Orleans Parish Prison, New Orleans); New York (18 upstate county jails); and Wisconsin (Milwaukee House of Correction, Milwaukee, and Rock County Jail, Janesville).\textsuperscript{16} The annual program costs were estimated from a provider perspective, and are expressed in 2005 US dollars. The costs covered program management, training, travel, goods, equipment, counselling and test timing, and test kits. During the 1-year period of this cost analysis, the four projects areas tested a total of 17,433 inmates, of which a total of 152 inmates received a new diagnosis of HIV infection. The cost per newly diagnosed HIV infection was $2,451 in Florida, $3,377 in Louisiana, $7,874 in New York, and $25,288 in Wisconsin. The wide range in cost was due in part to differences in prevalence, with Wisconsin having the lowest prevalence (0.2%) and Florida having the highest (1.3%). The average test cost also varied from $29.46-$44.98 for a HIV negative inmate and $71.37-$137.72 for a HIV positive inmate; this variation was due to differences in staff time spent on counselling and testing, travel costs, and local wages. The authors concluded that their jail-based rapid HIV testing demonstration project resulted in improved access to HIV testing, increased voluntary testing of inmates, and the identification of previously undiagnosed cases of HIV infection.

Farnham et al. (2008) estimated the cost of conventional and rapid HIV testing in the United States in three scenarios: sexually transmitted disease (STD) clinic in which patients are offered an HIV test and receive counselling (STD CT), STD clinic in which all patients are given an HIV test unless they decline (STD screening), and emergency department in which all patients are given an HIV test unless they decline (ED screening).\textsuperscript{17} The costs were in 2006 US dollars, and were estimated from the provider perspective. For the model, conventional testing involves phlebotomy followed by EIA. Positive tests are confirmed using duplicate EIA followed by WB requiring patients to return for the results from conventional testing. Rapid testing is performed using fingerstick blood or oral-fluid swab sample, and results are typically obtained in thirty minutes. Patients with reactive rapid test results receive counselling and must return for a confirmatory test consisting of phlebotomy and WB. Input variables included the costs of materials and test kits, provider time, and the probability of completing various parts of the testing process. Outcome measures included the cost per patient completing the entire conventional or rapid test procedures, and the cost per HIV-infected patient correctly notified of his/her HIV test result. The results indicated that the costs for rapid testing were higher than conventional testing due to the increased cost of the test kits and, if positive, the need for additional specimen selection. However, the cost per HIV-infected patients receiving results was lower for rapid testing ($1,638, $1,868, and $2,925 for ED screening, STD screening, and STD CT, respectively) than for conventional testing ($1,807, $1,995, and $4,334 for ED screening, STD screening, and STD CT, respectively) due to the increased probability of receiving results. The cost per HIV-infected patient correctly notified of his/her HIV test result
Point-of-care HIV Testing

was very sensitive to the cost of the test; an increase of 20% in the price of the rapid test would result in it being more expensive per HIV-infected patient correctly notified than conventional testing. Limitations identified by the authors included the fact that the study did not take into account the long-term effects of counselling and testing or the reduction in value resulting from false positives. The study also did not attempt to address the costs associated with follow-up of HIV-infected people who failed to return for their test results, or of facilitating entry into care following a positive HIV test. The authors concluded that the cost per HIV-infected person receiving test results was lower for the rapid test procedure than for the conventional test in all scenarios and that HIV screening in general health-care settings is economically feasible, particularly with rapid tests. The authors also noted that the cost per-HIV infected patient receiving test results is highly dependent on HIV prevalence and rise drastically when HIV prevalence is extremely low because there are few HIV-infected patients to be identified.

Shrestha et al. (2008) estimated the cost-effectiveness of rapid HIV tests offered through community-based organizations. The settings included either a walk-in clinic in Kansas City or outreach programs in which tests were offered from a mobile van in Kansas City or Detroit. The tests used were the OraQuick® Rapid HIV-1 antibody test or the OraQuick Advanced® Rapid HIV-1/2 antibody test. Pre-test and post-test counselling accompanied the tests. The costs were measured from the perspective of the provider, and are expressed in 2005 US dollars. The main measure was the mean cost per person notified of a new HIV diagnosis following a rapid test. The cost included personnel, facilities, equipment, and materials. The respective costs of the Kansas City clinic, the Kansas City outreach, and the Detroit outreach were $3637, $16,985, and $13,448 per notification of a new diagnosis. Variations in cost per person notified of a new HIV diagnosis was greatly influenced by differences in HIV seropositivity among people tested and in programmatic costs of providing testing in a clinic versus outreach setting.

Paltiel et al. (2006) used simulated models of HIV screening to estimate the cost-effectiveness of same-day rapid HIV testing in adults. The analysis was performed from a societal perspective, with values reported in discounted 2004 US dollars per quality-adjusted life year (QALY) gained. Parameters incorporated into the simulation included antiretroviral therapy efficacy, rapid test protocol, effect on secondary transmission, expected number of secondary infections, and life expectancy. The cost-effectiveness ratio varied based on simulated parameters, including prevalence (0.05%-1%), incidence (0.0084%-0.12%), frequency of screening (one-time versus yearly), and assumptions about the effectiveness of screening on secondary transmission. Assuming moderately favorable outcomes on secondary transmission, prevalence of 1%, and incidence of 0.12%, the cost-effectiveness ratio was $30,800/QALY for one-time screening. The ratio remained below $50,000/QALY with prevalence as low as 0.2% for one-time screening. The authors concluded that rapid HIV testing should be performed routinely for adults in settings where HIV prevalence is at least 0.2%.

Doyle et al. (2005) examined whether OraQuick® (Orasure Technologies, Bethlehem, Pa) rapid testing was cost-effective compared to ELISA for HIV screening in a low-risk Mexican American population in labour. Healthcare costs of two strategies were compared: (1) testing with ELISA with confirmation by WB for positive results and (2) testing with OraQuick® with confirmation by WB of positive results. The two strategies were compared for the desired outcome of avoidance of mother-to-child transmission (MTCT) (ie. dollars per child with HIV-negative results). Actual costs and not charges, as obtained from published literature and from county and private hospitals, were used. Parameters of incidence of HIV in pregnant women (0.05%), incidence of MTCT with no treatment (25%), incidence of MTCT with treatment in labour (10%), sensitivity (98% for ELISA and 99% for OraQuick®), specificity (99.5% for ELISA and 100% for OraQuick®), and positive predictive value (10% for ELISA and 100% for OraQuick®) were
incorporated into the model. Under baseline assumptions, OraQuick® was the preferred testing strategy at $98 spent for each child who was HIV negative compared to $491 for ELISA screening with much of the extra cost coming from unnecessary treatment of women and infants with false-positive test results. Sensitivity analyses were performed over several assumptions including test sensitivity, test specificity, positive predictive value, and costs and it was found that OraQuick® was the dominant strategy if it is priced less than $409.90 under the baseline assumptions. The authors concluded that the universal use of OraQuick® rapid testing is cost-effective due to the prevention of unnecessary treatment for HIV to the new mother and her family and that OraQuick® rapid testing is the preferred screening strategy compared to ELISA in a low prevalence population.

Limitations

There are a limited number of meta-analyses and systematic reviews identified that evaluated the use of rapid HIV tests in the POC setting. Also, despite a large number of observational studies on the use rapid HIV testing, most were conducted in the United States with the OraQuick® rapid test kit. Though it is approved for POC use in the United States, it is not approved for use in Canada. Additionally, little evidence was identified for tests currently available on the Canadian market.

Results are also limited by prevalence of HIV in different regions. Several authors commented on the important of HIV prevalence with HIV testing. Screening in lower prevalence areas may increase the number of false positives as well as increase the cost per newly diagnosed patient with HIV.

Finally, all cost-effectiveness studies identified were based on US dollars and conducted in the US. This may make the results not generalizable to the Canadian healthcare setting.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

Rapid HIV tests appear to have acceptable diagnostic accuracy as both sensitivity and specificity are close to 100% in most studies and appear to be a cost-effective alternative in identifying newly diagnosed patients with HIV. Based on the results of several studies, Rapid HIV tests appear to be an acceptable alternative to current standard HIV testing methods, especially when providing an immediate result is considered important, such as labour and delivery when the mother’s HIV status is unknown, occupational exposure, or when there is concern a patient will not return for their results.

On the other hand, it is important to consider the negative implications of switching to a POC testing strategy. The studies indicated that false negatives and false positives do occur, and it is important that anyone implementing the use of Rapid HIV tests prepare for such events. As the healthcare provider administering the POC test may be responsible for providing the results, policies and procedures must be in place to ensure they are adequately trained and prepared to provide patients with test results, especially initially reactive results.

PREPARED BY:
Marc Richard, BSc. Pharm, MHI
Raymond Banks, AB, MA, MLS, Information Specialist
Health Technology Inquiry Service
Email: htis@cadth.ca
Tel: 1-866-898-8439
REFERENCES:


