Rapid/point of care Diagnostic Tests for HIV and syphilis: where are we at in Alberta?

Ameeta Singh, BMBS (UK), MSc, FRCPC
Clinical Professor, Division of Infectious Diseases, University of Alberta
CIHR Rapid Diagnostics Workshop, Montreal (by teleconference)
Which of the following statements is/are true about the availability of rapid diagnostic tests for HIV/STI in Alberta?

1. Rapid HIV tests are available at the point of care at STI Clinics
2. Rapid HIV tests are available through select hospital laboratories for acute care settings
3. Rapid diagnostic tests for syphilis are coming to Edmonton!
Background to rapid testing for HIV in Canada

- Previous HIV kit in Canada (Biochem) removed from market in 2002 due to “performance” difficulties
- Vancouver: test kit did not detect some early HIV infections

INSTI™ HIV test kit

- INSTI™ HIV Test kit (bioLytical Laboratories, Richmond, British Columbia) approved for use by Health Canada in October 2005
  - Serum, plasma and whole blood
  - Detects both HIV 1 & HIV 2
  - Storage at ambient temperature
  - May be performed outside of laboratory setting (e.g., clinics, ER departments, etc)
The INSTI™ HIV-1/HIV-2 Rapid Antibody Test is a rapid in vitro qualitative test for the detection of antibodies to Human Immunodeficiency Virus Type 1 in human whole blood, serum or plasma. The test is intended for use by trained personnel in medical facilities, clinical laboratories, emergency care situations, and physicians’ offices as a screening assay capable of providing test results in less than 60 seconds. The assay is packaged as a kit containing INSTI™ Membrane Units, Sample Diluent, Color Developer and Clarifying Solution, and is available in point-of-care use packaging, or packaging suitable for laboratory use.

1. Add 50µl of blood, serum or plasma with pipette to the Sample Diluent.
2. Pour the diluted sample into the Membrane Unit.
3. Re-suspend the Color Developer and add it to the Membrane Unit.
4. Add the Clarifying Solution.

Results in 60 seconds or less:
- negative
- positive
- invalid
In 2006/7, provincial discussions about how to use the new kit - needed to weigh the unknown performance of kit in “real life” but make available in clinical settings.

Decision made to introduce pilot to evaluate kit in acute care settings where immediate medical care would change based on test result.
Albert Rapid HIV Testing Policy/Guidelines: Clinical Decision Making

• Negative Rapid HIV test result
  – Parallel testing to be performed
  – Consideration of “window period” for HIV testing

• Preliminary positive Rapid HIV test result:
  – Requires confirmatory testing
  – Urgent medical intervention as required depending on clinical situation
  – HIV epidemiology and public health considerations
Alberta Rapid HIV Pilot
Alberta Rapid HIV Pilot: Sites

- Piloted at 5 hospitals in Alberta
- 2 urban/3 non-urban
- Sites selection based on provincial HIV epidemiology patterns
Alberta Rapid HIV Pilot: Methods

- Used the INSTI Kit (BioLytical)
- Performed in hospital labs (not POC) and using serum (blood draw) not whole blood (fingerprick)
- Run in parallel to routine serology testing (ProvLab)
- Used for 3 clinical criteria only:
  1. Pregnant woman at delivery or close-to-term
     - no previous prenatal HIV test or
     - previous negative HIV tests with ongoing risk for HIV
  2. Source in blood and body fluid exposure (e.g. needlesticks)
  3. Acutely ill patient with risk factors or clinical suspicions for HIV infection
### Alberta Rapid HIV Pilot: Start Dates by Site

<table>
<thead>
<tr>
<th>RHA</th>
<th>Hospital</th>
<th>Start date</th>
<th>1st spec collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital</td>
<td>Royal Alexandra Hospital, Edmonton</td>
<td>30-Apr-07</td>
<td>2-May-07</td>
</tr>
<tr>
<td>Palliser</td>
<td>Brooks Hospital, Brooks</td>
<td>15-May-07</td>
<td>4-Jun-07</td>
</tr>
<tr>
<td>Northern Lights</td>
<td>Northern Lights Health Centre, Fort McMurray</td>
<td>20-Jun-07</td>
<td>13-Jul-07</td>
</tr>
<tr>
<td>Peace Country</td>
<td>Queen Elizabeth II Hospital, Grande Prairie</td>
<td>11-Jun-07</td>
<td>14-Jun-07</td>
</tr>
<tr>
<td>Calgary</td>
<td>Peter Lougheed Hospital, Calgary</td>
<td>1-Dec-07</td>
<td>5-Dec-07</td>
</tr>
</tbody>
</table>
Reason for Rapid HIV Testing by Site (n=1737)

- Brooks Health Centre
- Northern Lights Health Centre
- Peter Lougheed Centre
- Queen Elizabeth II Centre
- Royal Alexandra Hospital

- Pregnant Woman
- Source Patient
- Acutely Ill
- Needlestick recipient
- Not provided

*Data reported up to November 23, 2009
Alberta Rapid HIV Pilot: Results

- 25 Reactive Rapid Tests
  - 24/1737 (1.4%) – Confirmed positives (Western Blot)
  - One false-positive test

<table>
<thead>
<tr>
<th>Clinical Category</th>
<th>New Positive (n=11)</th>
<th>Previous Positive (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acutely Ill Patient</td>
<td>10</td>
<td>4</td>
</tr>
<tr>
<td>Source of BBFE(^1)</td>
<td>1 *</td>
<td>9</td>
</tr>
<tr>
<td>Pregnant Women</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* From Northern site – usual transportation time >24 hrs

\(^1\)Blood and body fluid exposure
Alberta Rapid HIV Pilot: Performance Characteristics of Test

- In Comparison to Standard HIV Testing
  - One False-Positive
  - No False-Negatives

- Sensitivity (24/24) =100%
- Specificity (1702/1703) =99.9%
- Positive Predictive Value (24/25)=96%
- Negative Predictive Value (1702/1702)=100%
Alberta Rapid HIV Pilot: Quality Assurance important

Study coordinator

- rapid test inventory
- lot release
- distribution of kits to pilot sites
- proficiency testing
- follow-up with the manufacturers in case of issues with the assay
- training on the use of the kit was provided to testing sites using a train-the-trainer model
Alberta Rapid HIV Pilot: Results and Recommendations

- Significant Decrease in Median Turn-around-Time
  - Rapid Results reported back in ~ 1 hour
  - Standard specimens received at ProvLab: 5-45 hrs
    - Urban: 5 hrs (<1-41 hrs) - Non-Urban: 44 hrs (3-318 hrs)

- Direct feedback and questionnaires from participating sites
  - Rapid HIV testing enhanced clinical care and provided results in a clinically helpful timeframe.
  - Would like this program to continue past the pilot phase

- Recommended to provincial authorities:
  - Review re continuation of the program at existing sites
  - Expansion to other sites (e.g. other hospitals, STI clinics)
  - Continue to confirm all positives in parallel with routine serology; ? Need to routinely conduct parallel testing for all negatives vs samples for QA only
Rapid/point of care tests for Syphilis and HIV project in Alberta
Rapid/Point of Care Syphilis and HIV Project: Background

- Alberta – ongoing syphilis outbreak
- Syphilis and HIV cases affecting similar populations; many cases co-infected
- Syphilis POC tests widely used internationally – no test approved for use in N. America
- “Test and treat” – infectious syphilis easily treated with one dose of penicillin
Rapid Syphilis/HIV Project: Methods

- Syphilis and HIV POCT will be offered at Edmonton STI clinic and outreach services using fingerprick (whole blood) specimens.

- Parallel standard HIV and Syphilis testing (7-10 days TAT)

- Objectives:
  - Evaluate performance characteristics of POC
  - Examine correlates of positive HIV and Syphilis tests
  - Evaluate use of POC tests and for syphilis, improving syphilis treatment
Alberta ProvLab evaluation of SD Bioline Syphilis 3.0 kit

- 90 serum samples tested: 10 negatives
- **Crude sensitivity**: 92% (declines with low EIA values)
- **Specificity**: 100%
- **Quick test**: 2-5 mins for a positive, and 20 mins for a negative (complete by 10 mins; manufacturer states 20 mins is max cutoff time for reading)

Courtesy: Dr. Kevin Fonseca, Alberta ProvLab, 2009
Rapid Syphilis/HIV Project: Current Status

• Approvals in place:
  – Health Canada Therapeutics Products Directorate to use SD BioLine Syphilis 3.0 kit
  – Ethics – University of Alberta and Health Canada

• Funding from:
  – Public Health Agency of Canada and the Edmonton Inner City Health Research Network (EICHREN)
Rapid Syphilis/HIV Project: Current Status

- Kits ordered from Korea
- Note: Canadian distributor (Affinity Diagnostics) in place but unable to provide kits at previously agreed price
- Tentative start date: February 1, 2011
- Proposed project duration: 2 years
Which of the following statements is/are true about the availability of rapid diagnostic tests for HIV/STI in Alberta?

1. Rapid HIV tests are available at the point of care at STI Clinics
2. Rapid HIV tests are available through select hospital laboratories for acute care settings
3. Rapid diagnostic tests for syphilis are coming to Edmonton!
Conclusions

• Reliable rapid diagnostic tests for HIV are available in Canada and have the potential to provide a preliminary test result at the point of care within \( \frac{1}{2} \) hour

• Rapid diagnostic tests are available on the global market for syphilis and we hope to try them in the not too distant future!
Acknowledgments

Alberta:
- Dr. Bonita Lee
- Dr. Sabrina Plitt
- Dr. Jutta Preiksaitis
- Jayne Fenton (Senior Technologist, ProvLab)

Alberta Health and Wellness

Edmonton Inner City Health Research Network (EICHREN)

Public Health Agency of Canada
- Dr. Tom Wong
- Dr. Gaya Jayaraman
- Dr. Chris Archibald

London School of Hygiene and Tropical Medicine
- Dr. Rosanna Peeling

Colleagues across the province of Alberta who contributed to the development and implementation of the rapid HIV pilot