Rapid HIV Testing in Australia

M Clinic and RPHSHC Reports

WA STI & BBV Quarterly Forum
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In the era of effective antiretroviral treatment, HIV testing serves as the gateway to improved health and survival among persons with HIV infection and decreased transmission within communities.

(Branson, B. et. al. JAAIDS 2013)
## Estimated Contributions to New HIV Transmissions

<table>
<thead>
<tr>
<th>Diagnosis &amp; Treatment Status</th>
<th>Proportion of HIV+ Population</th>
<th>Transmission Odds Ratio</th>
<th>Proportion of Annual HIV Transmissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undiagnosed HIV+</td>
<td>25%</td>
<td>1.66</td>
<td>48.4%</td>
</tr>
<tr>
<td>Diagnosed. Unsuppressed Viral Load</td>
<td>43%</td>
<td>1.0</td>
<td>50.1%</td>
</tr>
<tr>
<td>On ART. Suppressed Viral Load</td>
<td>32%</td>
<td>0.04</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

Data source: David Wilson, Kirby Institute
1. Rapid HIV Testing Background
2. WA HIV Testing Data
3. Rapid HIV Test Performance
4. Rapid HIV Testing at RPHSHC and M Clinic
Rapid tests as screening tests

- Rapid tests are used as first-line screening tests in many countries

- If reactive, confirmation by:
  - Lower income countries: 2 or 3 different rapid tests (second/third tests more specific)
  - Higher income countries: Conventional HIV serology

- First line test should be highly sensitive
Rapid HIV Tests at PoCT: Advantages

• Robust and easy to use
  – Most require:
    • 10-20 mins to perform
    • Minimal equipment
    • Minimal technical skill

• Increased access to HIV testing

• Results available quickly; can speed diagnosis, counselling and linkage to care
Background

- HIV diagnoses among gay and bisexual men (GBM) have increased in the past decade.
- HIV testing and treatment is a key prevention focus.
  - ~10% of GBM have never tested (ARTB, CSRH)
  - Only 20% of high risk GBM have re-tested after 6 months (Guy, 2010)
- Barriers to HIV testing include time constraints, not wanting to return for results.
- Rapid testing aims to increase the acceptability and convenience of HIV testing.
Results - Testing preferences

Rapid testing VS Standard-of-care

<table>
<thead>
<tr>
<th>Standard</th>
<th>Rapid</th>
</tr>
</thead>
<tbody>
<tr>
<td>26.7114</td>
<td>73.2886</td>
</tr>
</tbody>
</table>

Kirkby Institute
# Acceptability of rapid testing (after result)

<table>
<thead>
<tr>
<th></th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfied with rapid test result delivery</td>
<td>98.6</td>
</tr>
<tr>
<td>Satisfied with rapid testing overall</td>
<td>98.6</td>
</tr>
<tr>
<td>Would recommend rapid testing to others</td>
<td>88.5</td>
</tr>
<tr>
<td>Would prefer a rapid test next time</td>
<td>78.7</td>
</tr>
</tbody>
</table>

Damian Conway, ASHM 2012. Sydney Rapid HIV Testing Study
Clinic Based Rapid HIV Testing - Opportunities

- The strength of rapid tests is in screening HIV negative people
- ~98-99% of gay men will get a true negative result, with no need to return for results
- Opportunity to increase the convenience of testing and reinvigorate HIV testing
- Opportunity to create new types of testing services through introducing peer testing staff
- New Community-based Rapid HIV Testing services have been established in NSW, Victoria, and Queensland
Rapid HIV Testing at the Point of Care (PoCT)

Limitations

• Longer window periods compared to best lab tests
• Some results will be false-reactive (‘false-positive’)
• Requires more work at the point of care
• Rapid HIV tests are *screening tests*
  • Lab testing is required on reactive rapid HIV tests to confirm an HIV diagnosis
• No Medicare rebates for rapid HIV tests
2 WA HIV Testing Data
HIV testing

Increase in ever tested
Decrease in tested in last 12 months but rising trend.
However, 1 in 7 men in Perth have not been tested for HIV.

Are Self-reported rates optimistic?

• Self-reported testing rates may be optimistic:
  
  – VPCNSS data showed re-testing rates among MSM were well below self-reported testing data (Guy 2010):
    • Less than 40% had retested after 12 months
    • Less than 20% of highly sexually active men had rested after 6 months
## Preliminary estimates

<table>
<thead>
<tr>
<th></th>
<th>COUNT participants</th>
<th>HIV-positive n, %</th>
<th>95% CI</th>
<th>Undiagnosed HIV n, %</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canberra</td>
<td>86</td>
<td>4, 4.7%</td>
<td>1.8–11.4</td>
<td>0, 0.0%</td>
<td>0.0–49.0</td>
</tr>
<tr>
<td>Melbourne</td>
<td>1001</td>
<td>70, 7.0%</td>
<td>5.6–8.7</td>
<td>5, 7.1%</td>
<td>3.1–15.7</td>
</tr>
<tr>
<td>Sydney</td>
<td>948</td>
<td>65, 6.9%</td>
<td>5.4–8.7</td>
<td>7, 10.8%</td>
<td>5.3–20.6</td>
</tr>
<tr>
<td>Perth</td>
<td>310</td>
<td>21, 6.8%</td>
<td>4.5–10.1</td>
<td><strong>4, 19.0%</strong></td>
<td><strong>7.7–40.0</strong></td>
</tr>
<tr>
<td>TOTAL</td>
<td>2345</td>
<td>160, 6.8%</td>
<td>5.9–7.9</td>
<td>16, 10.0%</td>
<td>6.2–15.6</td>
</tr>
</tbody>
</table>

- HIV prevalence lower in COUNT than in GCPS (previously diagnosed men are underrepresented)
- Estimates of undiagnosed HIV at lower end of estimates generated in previous studies/modelling (10-31%)
- Note wide confidence intervals for smaller samples
3  Rapid HIV Test Performance
Test performance evaluation

- June 2013 – 30 September 2014
- 20 study sites across NSW
- **HIV Reference Testing**
  - 4th generation Ab/Ag combo assay
    - p24Antigen (separately)
    - HIV Antibody (separately)
    - Western Blot
- **Analysis**
- Trinity Uni-Gold v’s reference tests
  - Sensitivity: overall, acute and established
  - Specificity: overall
Trinity Uni-Gold HIV 1/2 rapid test

Finger-stick blood

10-minute incubation time

Non-reactive (negative)

Reactive

Invalid
4th Gen Test Reactive

- Negative or Indeterminate Western blot
  + Positive p24 antigen OR HIV-1 RNA

or

- Negative HIV test <3 months

ACUTE

4th Gen Test Reactive

- Positive Western blot

ESTABLISHED
Adapted from McMichael AJ et al. Nature Rev Immuno 2010
Adapted from McMichael AJ et al Nature Rev Immuno 2010
Rapid Tests

Adapted from McMichael AJ et al. Nature Rev Immuno 2010
## Performance overall

<table>
<thead>
<tr>
<th>Trinity Unigold result</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>67 True positive</td>
<td>6 False positive</td>
<td>73</td>
</tr>
<tr>
<td>Negative</td>
<td>14 False negative</td>
<td>9190 True negative</td>
<td>9204</td>
</tr>
<tr>
<td>Total</td>
<td>81</td>
<td>9196</td>
<td>9277</td>
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<td></td>
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</tr>
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**Legend:**
- True positive
- False negative
- True negative
- False positive
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**Total: 9277**
# Performance overall

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<thead>
<tr>
<th></th>
<th>%</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensitivity</strong></td>
<td>82.7</td>
<td>72.7-90.2</td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
<td>99.9</td>
<td>99.9-100</td>
</tr>
<tr>
<td><strong>Positive predictive value</strong></td>
<td>91.8</td>
<td>83.0-96.9</td>
</tr>
<tr>
<td><strong>Negative predictive value</strong></td>
<td>99.9</td>
<td>99.7-99.9</td>
</tr>
</tbody>
</table>
## Sensitivity in acute and established cases

<table>
<thead>
<tr>
<th></th>
<th>%</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td>53.6</td>
<td>33.9-72.5</td>
</tr>
<tr>
<td>Established</td>
<td>98.1</td>
<td>89.9-100</td>
</tr>
<tr>
<td>Overall</td>
<td>82.7</td>
<td>72.7-90.2</td>
</tr>
</tbody>
</table>
Conclusions/discussion

• In this population Trinity failed to detect 46% of acute infections

• 37% of men diagnosed with HIV were acute infections

• Men at risk of acute HIV infection should also have conventional serology performed

• Develop strategies to identify men with recent risk exposures
Conclusions/discussion

• Uni-Gold had sensitivity similar to Determine Ag/Ab HIV 1/2 Combo
  – Uni-Gold overall sensitivity: 82.7% (95%CI: 72.7-90.2)
  – Determine Combo overall sensitivity: 87.2% (95%CI: 72.6-95.7)

• 98.1% sensitivity in established infections

• Excellent specificity

• High PPV

• **998 out of every 1,000 tests were accurate**
Rapid HIV Testing at RPHSHC and M Clinic
Rapid HIV Testing in WA

• 2014 - WA Health support to establish a 12-month trial of rapid HIV testing

• M Clinic (Dr Lewis Marshall) and the Sexual Health Clinic at Royal Perth Hospital (Dr Jenny McKloskey)

• Gay and bisexual men (MSM/GBM)

• Trinity Uni-Gold Rapid HIV Test + Parallel 4th generation laboratory HIV serology

• Support from Pathwest (test storage, expedited results confirmation)

• Kirby Institute: Staff training & support, SOPs, rapid testing supplies, data analysis and reporting.
Rapid HIV Testing at Royal Perth SHC

- Delay in commencement due to nurse recruitment
- Rapid tests offered consistently since mid-December 2014
- 71 tests performed by 19 February 2015
- Average of 7.5 tests per week in January and February 2015
- One HIV diagnosis in a man with a non-reactive rapid test (i.e. a false-negative)
  - High risk exposure reported 3 weeks prior to rapid HIV test
  - Indeterminate Western Blot result
  - Likely seroconverter
Rapid HIV Testing at M Clinic
Rapid HIV Testing at M Clinic: Feasibility

- Rapid HIV testing commenced 1 May 2014
- 844 tests were performed
- 9 reactive rapid HIV test results, all confirmed HIV positive
- No false positive results
- One invalid test, not repeated
Rapid HIV Testing at M Clinic: Feasibility

Percentage of M Clinic HIV Testing Clients who had a rapid HIV test, May-Dec 2014

- 50-60% of HIV test clients had a rapid test
- Rapid testing not offered on Fridays

Source: M Clinic
Rapid HIV Testing at M Clinic: Impact

Percentage of M Clinic HIV Testing Clients who had a rapid HIV test, May-Dec 2014

Av per month = 160

Av per month = 190

Rapid Testing Available

Changes to M Clinic client pathway introduced at the same time as rapid testing increased clinic capacity.

Source: M Clinic
# Characteristics of Men Having Rapid HIV tests

<table>
<thead>
<tr>
<th>Past HIV testing history</th>
<th>M Clinic WA n=735</th>
<th>a[TEST] community based organisation Sydney n=587</th>
<th>a[TEST] time-limited shop-front community site Sydney n=471</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Never tested</td>
<td>74 (10)</td>
<td>139 (24)</td>
<td>81 (17)</td>
</tr>
<tr>
<td>Tested ≥12m ago</td>
<td>165 (22)</td>
<td>206 (35)</td>
<td>165 (35)</td>
</tr>
<tr>
<td>Tested &lt;12m ago</td>
<td>496 (67)</td>
<td>242 (41)</td>
<td>225 (48)</td>
</tr>
</tbody>
</table>

- Lower proportion of M Clinic clients had never tested
- Higher proportion of M Clinic clients had tested in last 12 months

Source: M Clinic, ACON, SSHC, Vickie Knight
Thanks to

Kurt Sales
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Lisa Tomney
Ailsa Allen
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Sue Laing
Meagan Roberts

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• A/Prof Rebecca Guy, Kirby Institute, UNSW
• Dr Damian Conway, Kirby Institute, UNSW
• A/Prof Martin Holt, Centre for Social Research in Health, UNSW
• A/Prof Anna McNulty, Sydney Sexual Health Centre
• Dr Deborah Couldwell, Western Sydney Sexual Health Centre
• Prof Don Smith, Albion Street Centre
• Dr Stephen Davies, North Shore Sexual Health Service
• Philip Cunningham, St Vincent’s Hospital Darlinghurst
• James Gray, ACON
• Phillip Keen, Kirby Institute, UNSW

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• A/Prof Catherine O’Connor, RPA Sexual Health Centre
• Dr Robert Finlayson, Taylor Square Private Clinic
• John McAllister, Immunology & Infectious Diseases Unit, St. Vincent’s Hospital
• Dr Brian Hughes, Hunter New England Health Services
• Dr Chris Carmody, Liverpool Sexual Health Clinic
• Dr Rick Varma, Nepean and Blue Mountains Sexual Health Clinics
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• Justin Manuel
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• Chanelle Stowers
• Nicky Sharp
• Elizabeth Griggs
• Terry Walkinshaw
• James Gray
• Amanda Townsend
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• Pradeep Kumar

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• Sharon Doughty
• Rachel Poga
• Simon Wright
• Maggie Smith
• Anthony Price
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