Challenges in implementing point-of-care testing: the case of rapid HIV testing in Australia

Dr Martin Holt
What is HIV?

- Human immunodeficiency virus (HIV) is a retrovirus
- Spread by contact with infected body fluids e.g. through unprotected sex; sharing injecting equipment; contaminated blood products; mother-to-child transmission
- Affects the immune system (particularly CD4 T cells), making the host susceptible to life-threatening opportunistic infections
- If left untreated, can lead to AIDS
- After infection, HIV replicates leading to rapid rise in plasma viral load (no antibodies at this stage)
- Immune response/seroconversion follows (after a few weeks), during which antibodies are generated
What is HIV testing?

- Analysis of a biological specimen for the presence of human immunodeficiency virus (HIV)
- HIV antibody testing available since 1985
- Enzyme-linked immunosorbent assay or ELISA is the most common type of screening test
- Antibodies can be detected within 2-8 weeks of infection
- Western Blot generally used for confirmatory testing
- p24 antigen tests and plasma RNA (viral load) tests can also be used, particularly during the ‘window period’ of early infection
- Combined antibody/antigen (Ab/Ag) enzyme immunoassays (EIAs) were introduced in Australia in 2002 (can detect HIV earlier)
- In Australia, most testing is lab-based and all HIV tests must be approved by the Therapeutic Goods Administration.
What is rapid HIV testing?

- Rapid HIV tests deliver results within 30 minutes
- RHT usually administered at the point-of-care, rather than sending specimens to a lab for testing
- The first rapid HIV test was developed in 1992
- They are self-contained cartridges or strips, to which specimen (e.g. blood, oral fluid) is added, often followed by a chase buffer/fluid
- Most rapid tests detect HIV antibodies; some also detect antigen
- They are in wide use internationally
Examples of rapid HIV tests
Administering a rapid HIV test

1. Obtain specimen (in this case, a finger prick)

2. Add drop to well
Administering a rapid HIV test

3. Add solution/chase buffer (in this case – 4 drops)

4. Read results at set time (in this case – in 10-12 minutes)
HIV testing in Australia

The National HIV Testing Policy 2011 emphasises that:

- Testing is an important tool for minimising transmission of HIV and facilitating access to care
- It should be high quality & readily accessible
- It should be voluntary, confidential & with informed consent
- While testing rates are good among at-risk populations, there is ‘considerable scope for improvement’ e.g. up to 20% of HIV-positive people may be undiagnosed
Rapid HIV testing in Australia

• Australia’s *National HIV Testing Policy 2006* discouraged RHT for *screening* at point-of-care, except in situations where there was no lab access.

• Some rapid tests are approved as *reference* tests:
  – Determine HIV 1/2; Multispot HIV 1/2; Serodia HIV
  – Usually used to assess occupational exposures & to assist clinical decision-making e.g. prior to surgery

• Concerns included:
  – Potential for errors because results are subjectively read
  – Lower sensitivity

• No rapid tests licenced by TGA for screening at PoC
The push for rapid HIV testing

• The Australian Federation of AIDS Organisations began to concertedly investigate RHT in 2008
  – Set up a policy reference group
  – Commissioned a review of research (Holt, 2009)

• The review identified significant benefits of RHT:
  – Greater uptake/frequency of HIV testing
  – More people getting their results
  – High patient satisfaction

• Challenges included:
  – Adapting pre- & post-test discussions to fit RHT
  – Lower sensitivity & specificity
  – How to manage reactive results e.g. ‘preliminary positive’ & confirmatory testing
  – Training and quality assurance mechanisms
The push for rapid HIV testing

• In 2009, AFAO adopted a position advocating for RHT in Australia
• A review of the *National HIV Testing Policy* began in late 2010, commissioned by the Australian Government and led by the Australasian Society for HIV Medicine
• A special group was set up to determine how RHT might be accommodated
• Representatives of clinicians, educators, researchers and policymakers were involved
• Debate was at times fierce
Debate over RHT in Australia: opposition

- Superior lab tests; inferior performance of rapid tests
  - Danger of false negatives among those recently exposed
  - Danger of false positives among low prevalence groups
- High reported rates of testing among at-risk groups, particularly gay men
  - No evidence that people were dissatisfied with current HIV testing
- Challenge of handling reactive, unconfirmed results at point-of-care
- Cost – who would pay for RHT?
- Danger of ‘unqualified’ personnel delivering results
HIV testing in last 12 mths (non-HIV-positive men), Gay Community Periodic Surveys
Debate over RHT in Australia: proponents

- 4th gen EIAs not used in all labs; RHT is as good as 3rd gen tests
- Pre-test discussion should identify people with recent exposure, limiting false negatives
- Rates of HIV testing among at-risk groups may be exaggerated
  - higher frequency of testing needed to identify infections more quickly
- Research indicated consistent barriers to testing:
  - Lack of perceived need; frustration at attending clinic twice; anxiety while waiting for results; dislike of venous blood draw; difficulty in getting appointments/knowing where to go
  - Surveys indicated strong preference for RHT over conventional testing
- Overseas experience identified many successful models of implementing RHT, including non-clinical staff delivering testing
- Reduced no. of clinic visits should offset some costs of RHT
RHT in Australia

- Compromise reached in *National HIV Testing Policy 2011*
- RHT allowed for screening of at-risk populations (and in non-clinical settings) if:
  - Staff are trained and certified
  - RHT providers establish relationship with HIV testing laboratory with NATA credentials
  - All reactive/inconclusive tests confirmed by lab (access to phlebotomist)
  - RHT in non-clinical settings backed up by clinical services as well as a lab
RHT in Australia

• However, no rapid HIV tests have been licenced for screening by TGA
  – One test (Determine Combo Ab/Ag) has been under review for 2 years
  – Information requests to the manufacturer stop/slow the assessment process
  – Assessing public health benefit as well as performance appears to be a challenge

• Current availability of RHT is limited to studies in Melbourne and Sydney
The Sydney rapid HIV testing study

- Initiated by Damian Conway, Kirby Institute
- RHT (Determine Combo) offered in 4 Sydney sexual health clinics
- Eligible participants: gay/bisexual men presenting for HIV testing
- Training supported by NRL
- QA overseen by NSW HIV Reference Lab
- All tests confirmed with conventional serology
The Sydney rapid HIV testing study

- ~1200 men have been tested so far
- Clinician and patient surveys assessing acceptability and implementation issues
- 20 minute test somewhat disruptive to client flow
- Some problems with test performance early on
- Overwhelmingly positive reaction from clients
- Next phase using faster test & no surveys
RHT in 2012 and beyond

• More demonstration projects planned, including community-based testing

• Still waiting for TGA licencing decision
  – 2 more assays have been submitted for assessment

• Pressure on federal and state governments to be increased at *Australasian HIV/AIDS Conference*:
  – Expedite TGA approvals
  – Ask states/territories to provide access programs while Medicare funding for RHT is progressed
  – Research home testing
How likely is it you would you test for HIV if rapid testing were available in the following locations?

- Home: 46% More likely, 23% About the same, 14% Less likely
- Clinic/GP: 47% More likely, 35% About the same, 5% Less likely
- Community organisation: 37% More likely, 32% About the same, 12% Less likely

Data: Sydney GCPS, February 2011, n=2502 non-HIV-positive men
Home-based testing

- The *National HIV Testing Policy 2011* prohibits home-based testing for HIV
- The *Therapeutic Goods Act 1989* also prohibits inclusion of home testing kits in the ARTG
- However, research is encouraged, given that home test kits are available overseas
  - In July 2012, the US FDA approved OraSure’s OraQuick test for over-the-counter sales and home use
Summary

- Changing the delivery of HIV testing in Australia is a slow process.
- Those involved in HIV testing (patients, doctors, clinics, pathology and reference labs, health promoters, policymakers) can have very different perspectives on what is important:
  - Test performance
  - Who does the test/where it is done
  - Who delivers results/where & how they are delivered
  - Who pays for the test/who gets paid for doing it
  - Patient benefit
  - Community benefit
  - Public health benefit
- All these need to be considered in order to achieve the best possible access to, uptake of and delivery of HIV testing.
Acknowledgments

• Invitation to speak:
  – Prof Mark Shephard
  – AIMS Conference

• GCPS CIs: Garrett Prestage, Limin Mao, Iryna Zablotska, John de Wit

• The Sydney Rapid HIV Testing Study investigator team

• Australian Federation of AIDS Organisations

• The National Centre in HIV Social Research is supported by the Australian Government Department of Health and Ageing.