Use of a Three Rapid HIV Test Algorithm at Point-of-care Settings: County of Los Angeles, Department of Public Health Experience

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Acronyms

- **OAPP** – County of Los Angeles Department of Public Health Office of AIDS Programs and Policy
- **RTA** – HIV rapid testing algorithm
- **POC** – point-of-care setting
- **HCT** – HIV counseling and testing
Evolution of Rapid HIV Testing

• 1989 – CDC and APHL two-test algorithm for HIV testing: EIA/WB
  – considered “gold standard”

• 1994 – UNAIDS and WHO
  – 3 types of rapid HIV testing algorithms

• 1994 – present: development of rapid testing technology
  – FDA approved CLIA-waived tests
  – Sensitivity and specificity of tests exceed that of “gold standard”
  – Tests permit use in multi-test algorithms
Los Angeles County

Square Miles: 4,086
Population\(^1\): 10.3 Million

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latino/a</td>
<td>47%</td>
</tr>
<tr>
<td>White</td>
<td>28.9%</td>
</tr>
<tr>
<td>Asian/PI</td>
<td>12.6%</td>
</tr>
<tr>
<td>African-American</td>
<td>9.0%</td>
</tr>
<tr>
<td>Native American</td>
<td>0.3%</td>
</tr>
</tbody>
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Proportion of:
- California Population\(^2\): 29%
- California AIDS Cases\(^3\): 36%
- U.S. AIDS Cases\(^3\): 5%

Living with HIV/AIDS\(^3\):
60,000 (Estimated)

\(^1\)United Way, Los Angeles (2008)
\(^2\)U.S. Department of Commerce (2008)
\(^3\)Los Angeles County HIV Epidemiology Program (2008)
Background: Rapid HIV Testing in Los Angeles

OraQuick HIV Rapid Test (Oral or finger stick)

Negative

Preliminary Positive

Confirmatory Testing EIA/WB

Approx. 1 Week Later: Confirmatory Results

Negative/Inconclusive

Confirmed Positive

Follow-up/ additional Testing

REFER TO CARE

From OAPP 2008 HCT Data:
95.5% Received initial result *

48.7% Received a confirmed result*

HIV Rapid Testing Algorithm (RTA) Study

- Centers for Disease Control and Prevention (CDC) funded study

- Goal: Evaluate the impact and feasibility of using a sequence of up to 3 HIV rapid tests, to provide clients with information about their HIV status within 1 hour and link into care

- Los Angeles Sites: OAPP-funded rapid HCT sites
  - RTA Intervention sites: 4 OAPP-funded rapid HCT sites consisting of mobile testing units, store fronts, community-based clinics
  - Comparison sites: All other OAPP-funded rapid HCT sites (n=12)

- Project period = August 2007 – March 2009
RTA at Intervention Sites

1. **OraQuick** (Oral/Blood)
   - A1-
     - Client Considered HIV Negative
   - A1+
     - A2
       - A2-
         - A3
           - A1+ A2- A3-
             - Client Considered HIV Negative
       - A2+
         - A3+
           - Client considered HIV positive and Referred to Medical Care

2. **Clearview Stat-Pak** (Blood)
   - A1+
     - A2
       - A2-
         - A3
           - A1+ A2- A3-
             - Client Considered HIV Negative
       - A2+
         - A3+
           - Client considered HIV positive and Referred to Medical Care

Results: RTA Intervention vs. Comparison Sites

Study Time Period: August 1, 2007 – March 31, 2009

**Intervention Sites**

- RTA Intervention Sites
  - 10,857 Testers

  263 OraQuick + (2.42%)

  94 RTA + (0.87%)

  163 did not participate in RTA

- 6 RTA – (0.06%)

100% Received their result
100% RTA + referred to care on same day

**Comparison Sites**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td># Tested</td>
<td>32,929</td>
</tr>
<tr>
<td># Screened Reactive</td>
<td>487 (1.48%)</td>
</tr>
<tr>
<td># False Positive</td>
<td>41 (0.12%)</td>
</tr>
<tr>
<td># Received Confirmatory Test Results</td>
<td>206 (42.3%)</td>
</tr>
<tr>
<td>Median # Days Referred to Medical Care (range)</td>
<td>8 days (1 – 55 days)</td>
</tr>
</tbody>
</table>

Data Source: OAPP HIV Counseling and Testing Data, 2009
Results: RTA Intervention Sites Continued

10,857 Testers

263 OraQuick + (2.42%)

163 did not participate in RTA

94 RTA + (0.87%)

6 RTA – (0.06%)

163 did not participate in RTA

100% Received their result
100% RTA + referred to care on same day

163 + OraQuick
RTA non-participants

106 (65.0%)
provided a specimen for confirmatory testing

29 (27.4%)
False Positive

77 (72.6%)
Confirmed True Positive

8 (27.6%)
Received their final result

36 (46.8%)
Received their final result and were linked to medical care

Receipt of final results = Median of 8 days (range = 4 – 54 days)

Site Challenges:

• Client refused confirmatory test

• Phlebotomy capacity not consistently available
Results Summary

• At RTA Intervention Sites:
  – 100% RTA clients received their test results on the same day
  – All RTA reactive clients were referred to medical care on the same day
  – 6 false positive results resolved on the same day
  – Receipt of confirmed results among non-RTA participants was similar to those at comparison sites (~42%)

• Comparison Sites:
  – 42% received confirmatory results
  – Median 8 days till referral to medical care

• Linkage to care? Which worked better? Site specific?
  – analysis currently ongoing
Lessons Learned

• Phlebotomy capacity was not consistently available in order to offer the RTA
  – Solution: Fingerstick law (AB 221) passed in California in September 2009

• Significant time investment at start up
  – Slow roll out of an RTA program is important

• Rarely used the third test in the RTA (n=6)
  – More cost effective to use a two-test algorithm
Los Angeles DPH: Next Steps

• Modified RTA Algorithm – POC Algorithms* 2 and 3 using 2 types of rapid HIV test kits

• RTA will be offered at select POC sites post-study
  – Mobile testing units,
  – commercial sex venues (bath-houses),
  – testing at homeless shelters,
  – jail settings,
  – high testing volume events e.g. test fest, HCT week

• Offer RTA at routine testing clinics
  – Emergency Departments, STD clinics, jail medical centers
  – RTA is currently part of the routine testing training curriculum

Los Angeles DPH: Next Steps
Continued – 2 Test POC Algorithm

- Test must be from a different manufacturer.

± This algorithm may only be used when the same test is available for both oral and blood.

HIV-1 or HIV-1/HIV-2 Rapid Test
(Oral Fluid)±

A1+

A2

A1-

Negative for HIV-1 and HIV-2 antibodies

HIV-1 or HIV-1/HIV-2 Rapid Test*
(Blood)

A1 (oral fluid) +

A2-

A1 (blood) +

Inconclusive rapid test result; requires additional testing

A1 (oral fluid) +

A2-

A1 (blood) -

Negative for HIV-1 and HIV-2 Antibodies

Presumptive positive for HIV-1 or HIV-2 antibodies; requires medical follow-up for further evaluation and testing

HIV-1 or HIV-1/HIV-2 Rapid Test
(Repeated, this time on blood) ±

A1+

A2+

A1+

A2-

A1
Los Angeles DPH: Needs for a Successful RTA Program

Federal

- Clear guidelines/recommendations regarding:
  - Use of an RTA at POC settings
  - Include case reporting with an RTA result at POC without confirmatory testing (EIA/WB or IFA) as an option
Los Angeles DPH: Needs for a Successful RTA Program Continued

State

• Change language in the California Code of Regulations (CCR Title 17 § 1230. HIV Screening Testing by Laboratories.).
  – Currently states “Confirm all reactive or indeterminate HIV test results by following the HIV confirmation protocols recommended by the federal Centers for Disease Control and Prevention as published in the Mortality and Morbidity Weekly Report prior to reporting the result as positive”

• Inclusion of other CLIA-waived HIV rapid HIV tests as part of the testing portfolio at publicly funded testing sites

• Standardized fingerstick training for rapid HIV testing
Los Angeles DPH: Needs for a Successful RTA Program Continued

Local

• Implement RTA training as part of basic counselor training

• Establish criteria for sites offering an RTA
  – Rapid testing and quality assurance history
  – Sustainability for offering an RTA
  – Site testing volume

• Standardize order of tests in an RTA or not?

Thanks!

Kevin Delaney
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