Performance of Determine combo and other Point-of-Care HIV Tests Among Seattle MSM

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ABSTRACT

METHODS (continued)

HIV TEST RESULTS

Overall HIV Test Results among 3438 MSM and transgender persons, 2/2010 – 8/2014

<table>
<thead>
<tr>
<th>HIV Test</th>
<th>STD Clinic n=1919</th>
<th>Gay City n=1215</th>
<th>PSC n=224</th>
<th>Total n=3358</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-Negative</td>
<td>2121</td>
<td>1176</td>
<td>1</td>
<td>3298</td>
</tr>
<tr>
<td>Total HIV Positive</td>
<td>68 (3.2%)</td>
<td>39 (3.2%)</td>
<td>18</td>
<td>140</td>
</tr>
<tr>
<td>Concomitant Reactive Tests</td>
<td>51 (75.0%)</td>
<td>31 (79.5%)</td>
<td></td>
<td>18</td>
</tr>
<tr>
<td>Discardant POC Tests</td>
<td>7 (10.3%)</td>
<td>3 (7.6%)</td>
<td>12</td>
<td>23</td>
</tr>
<tr>
<td>All POC Tests Negative/EIA Positive</td>
<td>2 (2.9%)</td>
<td>4 (17.9%)</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Acute (EIA Neg/NAAT Pos)</td>
<td>3 (1.1%)</td>
<td>1 (2.6%)</td>
<td>2</td>
<td>1†</td>
</tr>
</tbody>
</table>

Includes 5 persons tested by Determine Combo
†Includes 1 person with reactive p24 Ag on Determine (#1 below) among 6 persons tested

OBJECTIVE

To compare point-of-care HIV tests and determine their relative abilities to detect early HIV infection in real-time.

METHODS

Study population

MSM and transgender persons recruited when seeking HIV testing at:

- PHSKC STD Clinic
- Gay City Health Project Wellness Center (GC)
- Or when referred to University Washington Primary Infection Clinic (PIC)

HIV tests

Point-of-care tests:

- Determine combo
- OraQuick (oral fluids, OraSure Technologies, Inc)
- Uni-Gold (fingerstick, Trinity Biotech) until 5/2013
- Determine HIV-1/2 Ag/Ab (fingerstick, Alere Inc.)

EIAs:

- PHSKC: 3 gen Genetic Systems HIV-1/HIV-2 Plus O/EIA Bio-Rad
- PIC: 3 gen GS assay until May 2011, then
- 4th gen Abbott ARCHITECT HIV Ag/Ab Combo assay

NAAT:

- PHSKC: 27-specimen master pools (3x3x3 matrix)
- Abbott RealTime HIV-1 RNA assay (lower limit 40 copies/mL)

Data collection and statistical analyses

- Each test performed on separate fingersticks
  - Quarterly participation allowed
  - Longitudinal participation allowed at PIC
  - Viewboard
  - Approved by UW Human Subject Division and all subjects gave verbal informed consent
- Chart reviews conducted for all participants with discordant results
- Sensitivity and specificity calculated for STD patients only
- Field staging characterized for PIC patients only

RESULTS

Between February 2010 and August 2014, 3438 subjects were enrolled (Table). Twenty-four subjects had HIV-infected subjects detected by the different tests.

Sensitivity and specificity of screening HIV tests at the PHSKC STD Clinic

<table>
<thead>
<tr>
<th>Test</th>
<th>Number of tests</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraQuick (oral fluid)</td>
<td>2193</td>
<td>51/288 (75.9%, 63.0-84.7)</td>
<td>2190/2122 (99.86%, 99.59-99.97)</td>
</tr>
<tr>
<td>OraQuick (fingerstick)</td>
<td>2175</td>
<td>53/288 (77.9%, 66.2-87.1)</td>
<td>2170/2127 (99.82%, 99.77-99.99)</td>
</tr>
<tr>
<td>Uni-Gold</td>
<td>1614</td>
<td>45/288 (80.0%, 74.2-93.1)</td>
<td>156/1561 (99.5%, 99.76-99.96)</td>
</tr>
<tr>
<td>INSTI</td>
<td>859</td>
<td>11/15 (73.3%, 64.9-82.9)</td>
<td>534/544 (98.2%, 98.68-99.96)</td>
</tr>
<tr>
<td>Determine Combo</td>
<td>1523</td>
<td>34/40 (85.0%, 70.2-94.3)</td>
<td>1468/1483 (98.9%, 98.39-99.49)</td>
</tr>
<tr>
<td>GS HIV-I/II/IV Plus O/Ab (EIA)</td>
<td>2161</td>
<td>58/66 (87.5%, 77.9-94.6)</td>
<td>2091/2095 (99.81%, 99.51-99.95)</td>
</tr>
</tbody>
</table>

Test results of PIC subjects1 by Fliegb stage

<table>
<thead>
<tr>
<th>Test</th>
<th># (%) with positive test</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraQuick Of/inst</td>
<td></td>
</tr>
<tr>
<td>OraQuick F/S</td>
<td>p=0.002</td>
</tr>
<tr>
<td>Uni-Gold</td>
<td>p=0.002</td>
</tr>
<tr>
<td>Determine Ab/Ag</td>
<td>p=0.001</td>
</tr>
<tr>
<td>INSTI</td>
<td>p=0.002</td>
</tr>
<tr>
<td>Determine Ab/Ag</td>
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</tbody>
</table>

LIMITATIONS

- Findings may not be generalizable to populations with lower HIV prevalence and incidence and less frequent HIV testing.
- Participants were not all tested with the same array of tests.
- Tests are not independently read and may oversimplify sensitivity.

CONCLUSIONS

1) Oral fluid testing, although preferred as a specimen collection method, is less trusted among tested MSM, is significantly less sensitive than fingerstick tests, and should be the test method of choice only in rare circumstances.

2) Determine Combo underperformed compared to laboratory-based testing but did detect one acute infection. If these results are validated, the lower specificity may limit its usefulness in populations with lower incidence.

3) In high HIV incidence populations like ours, currently approved point-of-care tests are not sufficient and must be supplemented with pooled NAAT or 4th generation assays.

4) This testing program for MSM is one example of a setting that could benefit from FDA approval of POCT NAAT.

ACKNOWLEDGEMENTS

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