Health services evaluation of an emergency department HIV and syphilis testing program using rapid point-of-care diagnostic tests in Detroit, Michigan: 2015-2016

Cal Ham MD, MPH

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Background

- From 2010-2013 annual number of primary and secondary syphilis cases in Detroit increased 173%
  - 52% HIV co-infected

- Most (56%) syphilis cases were among black men who have sex with men (MSM) aged 34 years and younger

- In October 2013, the Herman Kiefer Health Complex was closed, which included Detroit’s only STD clinic
  - Center of public health activities
  - Major HIV and STD testing site for the city
  - Served approximately 11,000 clients annually
Background

- Since 2013, there has been a gap in HIV and syphilis testing services in Detroit
  - Need for novel HIV and syphilis testing models integrated into the healthcare operations of existing venues
  - Emergency departments (EDs) are healthcare venues that frequently serve at-risk populations

- Henry Ford Hospital (HFH)
  - Large tertiary care center in central Detroit
  - ED serves ~90,000 patients annually
  - Infectious disease (ID) clinic located in same facility
**Syphilis**

**Traditional Algorithm**

Nontreponemal test

- Nontreponemal test +
  - Treponemal test
    - Treponemal test + (syphilis past or present)
    - Treponemal test - (syphilis unlikely)

- Nontreponemal test -

**Reverse Algorithm**

Treponemal test

- Treponemal test +
  - Nontreponemal test
    - Nontreponemal test +
      - 2nd treponemal test
        - Treponemal test + (syphilis past or present)
        - Treponemal test - (syphilis unlikely)
    - Nontreponemal test -
      - 2nd treponemal test
        - Treponemal test + (syphilis past or present)
        - Treponemal test - (syphilis unlikely)
Objectives

- Implement a health services model in an urban ED using recently CLIA-waived rapid point-of-care (POC) tests for HIV and syphilis
- Assess the feasibility of the HIV and syphilis testing program
- Identify and link new HIV cases to care
- Identify and treat new syphilis cases
- Determine the prevalence of undiagnosed HIV and syphilis among young males in an ED to guide public health prevention efforts in Detroit
Methods

- **Study population**
  - Target 1,000 Men aged 18-34 years
  - Monday through Friday, 7:30am to 5pm
  - Enrolled from 6/10/2015 to 1/15/2016 (n=690)

- **Exclusion Criteria**
  - Previously tested for either syphilis or HIV during the study period
  - Known HIV-positive patients
    - Tested for syphilis but not HIV
  - Category I trauma patients

- **Dedicated ID staff conducted counseling and testing**
  - Reduced ED staff burden
  - Allow for immediate linkage to care (HIV) and treatment (syphilis)
Methods

- **Rapid POC tests:**
  - Alere Determine HIV-1/2 Ag/Ab Combo test (Determine)
  - Syphilis Health Check (SHC) treponemal test
  - Both tests received CLIA waiver late 2014

- **Lab-based testing for HIV**
  - HIV: Biorad HIV Combo Ag/Ab assay, Evolis platform
    - If reactive HIV Ag/Ab, confirmed by Multispot
    - If reactive Ag/Ab and non-reactive Multispot → RNA testing

- **Lab-based testing for syphilis**
  - Rapid plasma reagin (RPR) (non-treponemal Ab)
    - PLUS
  - Treponema pallidum particle agglutination assay (TPPA) (treponemal Ab)
Methods

- **Study outcomes**
  - Number of new cases of HIV and syphilis identified
  - Performance of rapid POC tests compared to lab based testing
    - Sensitivity (Sn), Specificity (Sp), Positive Predictive Value (PPV), Negative Predictive Value (NPV), Positive Concordance, and Negative Concordance
  - Linkage to care for HIV cases
  - Treatment in ED for syphilis cases

- **Performance gold standards**
  - HIV: Biorad Ag/Ab assay confirmed by Multispot and RNA testing for discordant results
  - Syphilis: laboratory confirmed syphilis cases-RPR confirmed by TPPA
Results

- From 6/10/2015 to 1/15/2016: 690 men aged 18-34 tested

Demographics

<table>
<thead>
<tr>
<th>Demographic Characteristic</th>
<th>All Participants (N=690)</th>
<th>HIV cases (n=5)</th>
<th>Syphilis Cases (n=4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean, years)</td>
<td>26</td>
<td>22</td>
<td>26</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black (%)</td>
<td>87</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>White (%)</td>
<td>10</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hispanic/Latino (%)</td>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>MSM (%)</td>
<td>5</td>
<td>80</td>
<td>25</td>
</tr>
</tbody>
</table>
### Concordance of Rapid Point of Care HIV Tests with Lab Based Confirmatory Testing

<table>
<thead>
<tr>
<th>HIV Testing</th>
<th>Biorad Ag/Ab assay reactive</th>
<th>Biorad Ag/Ab assay non-reactive</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine Rapid HIV POC reactive</td>
<td>4 (Determine Ab +/Ag-)</td>
<td>1 (Determine Ab -/Ag+)</td>
<td>5</td>
</tr>
<tr>
<td>Determine Rapid HIV POC non-reactive</td>
<td>1 (Determine Ab -/Ag-)</td>
<td>667 (Determine Ab -/Ag-)</td>
<td>668</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>668</td>
<td>673</td>
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## Rapid HIV POC Test Performance

<table>
<thead>
<tr>
<th></th>
<th>HIV Determine rapid POC test compared to lab confirmed Biorad Ag/Ab assay (Gold Standard)</th>
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<tbody>
<tr>
<td>Sensitivity</td>
<td>80%, 95% CI [45%, 100%]</td>
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<tr>
<td>Specificity</td>
<td>99.9%, 95% CI [99%, 100%]</td>
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<tr>
<td>Positive Predictive Value</td>
<td>80%, 95% CI [45%, 100%]</td>
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<td>Negative Predictive Value</td>
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<td>Positive Concordance</td>
<td>4/5 (80%)</td>
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<td>Negative Concordance</td>
<td>667/668 (99.9%)</td>
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## Comparison of Reactive SHC Specimens with Lab Based tests

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<th>RPR</th>
<th>RPR Titer</th>
<th>TPPA</th>
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<tr>
<td>1: SHC reactive</td>
<td>Non-reactive</td>
<td>NA</td>
<td>Non-reactive</td>
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<td>2: SHC reactive</td>
<td>Reactive</td>
<td>1:4</td>
<td>Reactive</td>
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<td>3: SHC reactive</td>
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</tr>
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<td>4: SHC reactive</td>
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<td>1:16</td>
<td>Reactive</td>
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<td>6: SHC reactive</td>
<td>Reactive</td>
<td>1:8</td>
<td>Reactive</td>
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<td>7: SHC reactive</td>
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*All SHC non-reactive specimens (n=689) were RPR non-reactive*
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Results

- Total of 5 new cases of HIV and 4 new active syphilis cases detected

- Confirmed HIV cases (n=4) or syphilis cases (n=4) was identified in 1.2% of participants using rapid POC tests
  - 0% co-infected

- Linkage and Treatment
  - All 5 newly diagnosed HIV patients linked to care at HFH ID clinic (n=4) or nearby ID clinic (n=1)
  - 50% (2/4) of true syphilis cases were treated in the ED
Limitations

- **Staff only available Monday - Friday 7:30am - 5pm**
  - ED operates 24/7

- **Insufficient statistical power to accurately estimate diagnostic test performance**

- **STAT RPRs were not available**
  - Diagnosis of syphilis could not be confirmed in ED
Conclusions

- Rapid POC HIV and syphilis testing program was feasible in a busy ED
  - Used dedicated non-ED staff reduces burden on ED staff
  - Allowed for easy linkage to care and treatment

- Prevalence of HIV and syphilis exceeded expected rates
  - Identified cases that might have otherwise been diagnosed late

- Results highlight potential role for dual HIV and syphilis rapid testing in settings with at risk patients

- Testing for HIV with both rapid POC and lab-based Ag/Ab tests has dual benefits
  - Provides immediate test results
  - Identifies acute infections
Conclusions

- SHC should be used in conjunction with an RPR to identify active syphilis

- Based on preliminary findings, when reactive the SHC was concordant with TPPA in 7/8 cases

- Non-reactive SHC useful for ruling out active syphilis infection
Future Analyses

- Cost analysis
- Staff acceptability survey
- Evaluation of time to linkage to care and time to viral suppression
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