Implementation of 4th Generation HIV Testing Algorithm at a Public Health STD Clinic for Real-time Screening and Confirmation

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March 23, 2016
Acknowledgements

- Dr. Sanjib Bhattacharyya
- Jose Navidad
- Manjeet Khubbar
- Kathleen Krchnavek
- Jacob Dougherty
- Willie Genous
- Eze Osuala
- Mark Zemke
- Bill Borzon
- Irmine Reitl
- Dr. Paul Hunter
- Dr. Kwadwo Owusu-Ofori
- Otilio Oyervides
- Julie Becker
- Yvette Rowe
- Commissioner Bevan Baker
Laboratory Testing for the Diagnosis of HIV Infection

Updated Recommendations

Published June 27, 2014
Collaboration……..

- Abbott, Inc.
- MHD Administration
- MHD Laboratory Staff
- MHD Business Office
- DPW Architects
- DPW Building Engineers
- KHC Clinic Management, Staff & Outreach Program
- Clinic Medical Director
- Wisc. Division of Public Health STD/HIV Program and Administrative Staff
- Wisc. State Laboratory of Hygiene
MHDL Implementation & Methods

- HIV Antigen/Antibody (Ag/Ab)
- 4\textsuperscript{th} Gen Enzyme Immuno Assay (EIA)
  - Abbott Architect 1000i system
  - Screen blood samples: p24 Ag & HIV 1/2 Abs
  - Keenan Health Center (KHC) satellite STD Clinic lab
- Multispot assay (Bio-Rad): Confirmation
  - differentiation HIV 1 & 2 Abs from reactive samples
  - Downtown (ZMB) City of Milwaukee PH Lab (MHDL)
- HIV 1-Proviral DNA PCR referral to Wisc. State Lab. of Hygiene (WSLH)
HIV Infection and Laboratory Tests

- **HIV DNA PCR**
- **Architect HIV Ag/Ab**
- **Multispot HIV 1 & 2**
  - Chemiluminescent immunoassay
  - Detects p24 antigen and HIV antibody

*Modified after Busch et al. Am J Med. 1997*
Sequence of Test Positivity Relative to WB

166 specimens, 17 Seroconverters - 50% Positive Cumulative Frequency

Modified from Masciotra et al, J Clin Viral 2011
Keenan Health Center (KHC) & Stat STD Lab

2016: KHC, often referred to as the "STD Clinic," provides STD/HIV related services to uninsured and underinsured residents of Milwaukee and surrounding communities.

STD Services 2nd Floor
- HIV/AIDS & STD screening, testing, counseling & treatment
- TB Control & Refugee Health
- Men’s Health Clinic
- WIC Clinic
- Immunizations
- Healthcare Access assistance
STD Positivity Rates & Ranks
Milwaukee

<table>
<thead>
<tr>
<th>Test</th>
<th># Tests</th>
<th># Pos</th>
<th>% Pos</th>
<th>Rank</th>
<th>Rate/100,000</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gonorrhea - NAAT</td>
<td>8,026</td>
<td>715</td>
<td>9.8</td>
<td>22</td>
<td>259.1</td>
<td>2,477</td>
</tr>
<tr>
<td>Chlamydia – NAAT</td>
<td>6,681</td>
<td>784</td>
<td>11.7</td>
<td>19</td>
<td>971.7</td>
<td>9,290</td>
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<tr>
<td>Trichomonas – NAAT</td>
<td>1,861</td>
<td>239</td>
<td>12.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Syphilis – VDRL/TPPA</td>
<td>4,744</td>
<td>78</td>
<td>1.6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HSV - Culture</td>
<td>272</td>
<td>60</td>
<td>22</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Gonorrhea/Chlamydia/Trichomonas NAAT: GenProbe/Hologic PANTHER @ ZMB Lab
Comparison of STD rates by Metropolitan Statistical Area (MSA):

Figure 5. Ten MSAs with the Highest Incidence of Reported Chlamydia Cases, 2013

Figure 6. Ten MSAs with the Highest Incidence of Reported Gonorrhea Cases, 2013
A Collaborative Process

- Partnerships: City of Milwaukee Health Department & Wisconsin Division of Public Health AIDS/HIV Program
  - 4 years (2011 - 2015) switched state funding
    - Manual “quick test” to automated instrumentation (4th Gen HIV algorithm)
    - Remodeled KHC STD Lab (accommodate Architect instrument)
- Numerous planning & logistics meetings
  - local - state - clinic - lab – public works - administrative staff
Streamlining Clinic Workflow

- Detailed workflow analysis.
- LEAN tools optimize clinic flow
- Assure wait times would not jeopardize **same-day testing & counseling plans** for HIV positive clients.
Making room for the Architect: STD – KHC/STAT Lab

Temp Lab in basement → Renovation → Setup & Training

Remodel blueprint (>60K) delivery

Architect set-up

Training: 2 MLT FTEs
Validation Process

- **326 serum & plasma specimens** analyzed for Architect and Multispot assay validation.
- Staff completed Architect training in January 2015.
Implementation Timeline

2011
- February 2011: MHD begins internal discussions on proposal to work with state on implementation of 4th Gen HIV algorithm
- March-April 2011: MHD begins negotiations with Wisconsin Department of Health Services AIDS/HIV Program and Abbott to pursue new algorithm

2012
- June 2011: CLSI publishes new recommended algorithm
- February-March 2012: MHD begins meeting with Abbott Laboratories & city architects to plan for HIV Architect instrument at Keenan Health Center (KHC) STD Clinic Lab

2013
- Early 2013: MHD lab staff considers several remodeling options from city architects to accommodate the Architect instrument at KHC
- March 2014: STD Lab operations return to newly remodeled 2nd floor space at KHC

2014
- December 2013: STD Lab is relocated to basement of KHC in preparation for remodel
- June 2014: Lab conducts several meetings with KHC clinic & lab staff & state AIDS/HIV Program head to discuss 4th Gen HIV Algorithm implementation logistics; CDC releases 4th Gen HIV testing recommendations

2015
- December 2014: HIV Architect installation & validation at KHC STD Lab
- January 2015: Architect training for KHC & main lab staff completed. Multiplex assay to be implemented at KHC STD Lab

2016
- January-March 2014: KHC STD Lab remodel
- May 2014: State releases 2014 Budget & continued support for KHC HIV rapid testing
- December 2014: HIV Architect installation & validation at KHC STD Lab
- February 2015: Architect & Multiplex use for HIV rapid testing at KHC officially launches
- 2016: Genesius HIV 1&2 confirmatory differentiation assay to be implemented at KHC STD Lab
“GO LIVE”: 4 Years Later
February 9, 2015
Turnaround-Time Improvements

- As a result of workflow LEAN analysis, **15 minutes were saved per patient visit** for most clients.

- In addition, several points of efficiencies were identified by **eliminating wasted steps or time**.

- Between February and December 2015, **3,436 patients** were tested using **4th Gen HIV screening**. The typical wait time for the HIV screening test is **about 1 hour**.
<table>
<thead>
<tr>
<th>HIV Test</th>
<th>Year</th>
<th>Tests</th>
<th>Reactive</th>
<th>% Pos.</th>
<th>Confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual Quick Tests</td>
<td>2012</td>
<td>3,890</td>
<td>18</td>
<td>0.46%</td>
<td>sent out: 1-2 wk</td>
</tr>
<tr>
<td></td>
<td>2013</td>
<td>2,757</td>
<td>11</td>
<td>0.40%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2014</td>
<td>3,799</td>
<td>22</td>
<td>0.58%</td>
<td></td>
</tr>
<tr>
<td>4th Gen Architect</td>
<td>2015</td>
<td>3,436</td>
<td>14</td>
<td>0.41%</td>
<td>in-house: &lt;24 hr</td>
</tr>
</tbody>
</table>
Figure 7. Number of New HIV Diagnoses in the City of Milwaukee and Percentage of Wisconsin Diagnoses, 2005-2014

Figure 8. Percentage of 2014 HIV Diagnoses in Each Risk Category, Milwaukee County

Figure 9. Percentage of 2014 HIV Diagnoses in Each Risk Category, Wisconsin

Changes to HIV Testing

- at Kennan Health Center

- Eliminated manual rapid screening

- Use Architect to screen all patients
  - 40 minutes for negative result
  - 1 hour 20 minutes for reactive result
    \( \textit{(includes repeat)} \)

- Back-up for Architect failure
  - Staff trained on 4\textsuperscript{th} Gen ‘manual’ rapid Ag/Ab
    \( \text{(Determine-Alere) - minimal supplies available} \)
    - Follow up screening on Architect (at WSLH)
    - Continue following up same algorithm
Changes to HIV Testing
at ZMB/Keenan HC

- **Day-1**
  - Ag/Ab + sent to downtown lab (ZMB)
    - Serum tube for Multispot
    - EDTA tube for DNA PCR (if needed)
- **Day-2**
  - ZMB run Multispot to confirm
  - If Multispot + client notified
  - **Ave. TAT 14 HIV+ pts: 23 hrs & 47 min.**
  - **Prior system = 1-2 weeks for written report**
  - **4 business days for verbal report**
- **Day-3**
  - Indeterminates:
  - State Lab for proviral DNA PCR
Real-time Reporting Positives

- All reported to state surveillance program
- If suspect *acute HIV infection*: early indication to state surveillance
  - *(none detected so far)*
  - Send **e-mail** to the state staff with special “A#” (patient identifier)
  - Follow up **pt. referral** to state HIV program and State Lab for PCR confirmation
Patient Counseling

Explanations to patient:

- If infection occurred very recently (~ within last 1 – 2 months)
- Important to get into care immediately to reduce high virus titer in body system
- Highly infectious- use precautions to avoid transmission
- Recent partners should be tested
Conclusions & Lessons Learned

- Eliminated manual rapid screening at STD clinic
- Implemented 4th Gen HIV testing algorithm for real-time, **same-day** screening at KHC STAT clinic, and **next-day** HIV typing and confirmation at ZMB Lab
- Improved TAT *from 1-2 weeks* under previous system, *to <24 hours*, and eliminated time lapse for follow-up counseling & retro-viral therapy for HIV-infected patients
- Enhanced local public health system capacity for early detection & follow-up of HIV cases, improving HIV/AIDS case management with the promise of decreasing morbidity & mortality in Milwaukee and Wisconsin
Future Directions

- **MultiSpot**  
  Downtown Lab  
  **2015**  
  **Downtown Lab**  
  **– 24 hours**

- **Geenius HIV 1&2**  
  **KHC Stat Lab**  
  **2016**  
  **KHC Stat Lab**  
  **– same day**

**Confirmation while-u-wait**

- prior to client departure: 4th Gen HIV screen, type, confirm at KHC STAT lab
- Improved patient follow up, counseling, treatment, surveillance
- HIV 1&2 RT-PCR in-house
- a resource for the community, add other clinics
- Add HCV/HBV to Architect

GOALS
Thank you!

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March 23, 2016