4th Generation HIV Screening in Massachusetts: A Partnership between Laboratory and Program

2012 HIV Diagnostics Conference
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Tammy Goodhue
Massachusetts Department of Public Health
Bureau of Infectious Disease, Office of HIV/AIDS
Massachusetts Department of Public Health (MDPH):

- Set a goal to transition from 3\textsuperscript{rd} to 4\textsuperscript{th} Generation HIV screening for all serum samples:
  - Collected at all Office of HIV/AIDS (OHA) funded Prevention & Screening sites statewide
  - Tested at the Hinton State Laboratory Institute (HSLI)

- Endeavored to accomplish this goal within six months (January – June 2012)

- Successfully made this transition within the allotted time
OHA-funded HIV testing is offered:

- At 75 program locations
- In 27 cities/towns across MA
- During a variety of hours
- By ~ 275 individuals
- Using rapid & conventional sample collection methods
Laboratory & Program Partners

**MDPH**
- Hinton State Laboratory Institute
- Bureau of Infectious Disease
  - Office of HIV/AIDS
  - Division of STD Prevention

**Capacity Building Vendors**
- Justice Resource Institute
- AdCare Educational Institute

**Prevention & Screening Program Sites (Statewide)**
- Managers
- Front-Line Staff
Transition Components

**Laboratory:**
- Algorithm development
- Collaborative laboratory service negotiation
- Test and algorithm validation
- Results language development
- IT systems configuration
- Specimen handling procedure modifications

**Program:**
- Sample shipping standardization
- Client messaging development
- Acute infection response system development
- Curriculum & supportive materials development
- Training delivery
- Technical assistance delivery
Transition Timeline

2012

Algorithm & Results Dev.
- Jan: Research; select tests & design algorithm
- Feb: Setup, pilot, & validate tests and algorithm; provide feedback for supporting sites
- Mar: Phase out use of previous tests & algorithm over 2 wks; use new tests & algorithm exclusively; provide data for trouble-shooting with shipping carrier & test sites

Shipping
- Jan: Research & select shipping carrier
- Feb: Setup, pilot & trouble-shoot new system
- Mar: Statewide training & roll-out (site by site)
- Apr: Monitor shipping system, trouble-shoot & renegotiate with shipping carrier; provide feedback & technical assistance to testing sites as needed

Training & Support
- Jan: Select & educate training team; develop curriculum & knowledge assessment; logistics
- Feb: Mandatory in-person trainings
- Mar: Web trainings
- Apr: Knowledge assessment analysis & follow-up; ongoing individualized support; group support

Materials & Policy Dev.
- Jan: Modify and create policies & documents
- Feb: Additional modification & creation
- Mar: Refinement of contractual expectations; site preparation and implementation

IT, Other Logistics
- Jan: Research; modify specimen handling procedures & results documentation systems
- Feb: Lab reporting IT systems rebuild & testing
- Mar: Use new procedures and systems exclusively
New HIV Testing Algorithm

4th Gen EIA (antigen/antibody)

Reactive

HIV-1 & HIV-2 Negative

HIV-1 & HIV-2 Non-reactive

Multispot (antibody)

HIV-1 Positive

HIV-2 Positive

NAAT (HIV-1 RNA)

HIV-1 Positive

HIV-1 Non-reactive
# New HIV Testing Algorithm Results

<table>
<thead>
<tr>
<th>Lab Report Language</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Negative.</strong> HIV-1 p24 antigen, HIV-1 and HIV-2 antibodies not detected.</td>
<td>If client did not have risk in the two weeks before the test or since, the client does not have HIV.</td>
</tr>
<tr>
<td><strong>Positive.</strong> HIV-1 antibodies detected.</td>
<td>The client has HIV-1.</td>
</tr>
<tr>
<td><strong>Positive.</strong> HIV-2 antibodies detected.</td>
<td>The client has HIV-2.</td>
</tr>
<tr>
<td><strong>Positive.</strong> A reactive HIV antigen/antibody test and a positive HIV-1 RNA test indicate acute HIV-1 infection.</td>
<td>The client has HIV-1 and the test result indicates that s/he was recently infected (likely 2-8 weeks before taking the test).</td>
</tr>
<tr>
<td><strong>Negative.</strong> HIV antibodies not detected. No detectable HIV-1 RNA. HIV-2 infection cannot be excluded.**</td>
<td>The client does not have HIV-1. The client should be retested in two weeks to rule out possibility of acute HIV-2.</td>
</tr>
</tbody>
</table>
Collection – Results: Timeframe

- The time between sample collection and results delivery was cut in half (from 14 days to 7 days)
  - Shipping
  - Sample processing & testing
  - Backup results system

- Helpful for buy-in
- May increase return rate
Change is Hard
Guidance is Essential
Rapid vs. 4th Gen Conventional Testing: OHA Guidelines

- **Pre-test assessment:**
  - Exposure risk (type of risks, date of last risk)
  - Likelihood to return for results
  - Need for hepatitis C, STI screening

- **Encourage 4th Gen conventional:**
  - Recent (less than 8 weeks) or continuous risk
  - **Likely to return for result**
  - Also drawing blood for hepatitis or STI testing
Post-Test Sessions: Risk Reduction and Linkages

- Continue with established processes for
  - Risk reduction planning
  - Supportive referrals to prevention services, DIS, and medical care as needed

- Solidify and enhance process for linkage to clinicians and DIS re: acute infections
  - Acute infections require a tailored clinical protocol which includes extraordinary effort to ensure client is immediately linked with clinician and DIS
Preparing and Shipping Samples

- HIV samples MUST be centrifuged
- HIV samples MUST NOT be refrigerated
- HIV samples MUST be received by the State Lab 1-2 days after collection
- All samples MUST be shipped on the day that they are collected with few negotiated* exceptions
- If samples are received more than 2 days after collection, they will not be tested
Script for Submission Errors

- Serum samples submitted in error will not be processed – a new blood draw is needed
- Contact clients immediately and directly

**Script:** Due to our error in submitting your sample for processing, we need to re-take your blood sample. Re-taking your sample is not suggestive of your result or quality of testing technology used to process samples by the HSLI.
How Did We Do?
What Did We Learn?
Test Data

Between June 21st and November 30th 2012:

- HSLI tested 5,097 serum specimens using the new algorithm. Of those:

- 100 samples tested reactive on the Biorad antibody/antigen test and continued to supplemental Multispot testing. Of those:
  - 96 samples tested positive for HIV-1.
  - 0 samples tested positive for HIV-2.
  - 4 samples tested non-reactive for both HIV-1 and HIV-2 and continued to supplemental NAAT. Of those:
    - 3 samples tested non-reactive.
    - **1 sample tested positive for HIV-1 indicating acute infection.**
Lessons Learned

- Implementing a new standardized shipping system is time-intensive
  - Understanding new test parameters and requirements
  - Researching, negotiating, and setting up systems
  - Training and monitoring program sites; trouble-shooting

- Program sites need multiple engagements
  - Training and technical assistance for all levels of staff
  - Providing supportive materials with specific, concrete examples
  - Conducting quality assurance monitoring and offering support
  - Disseminating updated information

- Relying on a multi-disciplinary team to plan and implement the transition is critical to success
  - Understanding implications of using new technology
  - Identifying laboratory and program systems needs
  - Providing feedback throughout transition for course-correction
  - Offering various supports during implementation
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All Prevention and Screening Program Staff throughout MA
Contact

Arthur Kazianis, HSLI
Test, Algorithm, Laboratory Systems questions
617-983-6372
Arthur.Kazianis@state.ma.us

Barry Callis, OHA
Prevention & Screening Vendor, Shipping System questions
617-624-5316
Barry.Callis@state.ma.us

Tammy Goodhue, OHA
Project Management, Training, Messaging questions
617-624-5338
Tammy.Goodhue@state.ma.us