National Plan for Laboratory Systems: Jurisdictional networks to improve utilization and effectiveness of TB laboratory services

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Value of laboratory services

• 60-70% of clinical decisions are directly influenced by laboratory results (e.g., diagnosis, isolation, and drug therapy)*

• While TB experts consider the diagnosis of TB a clinically based diagnosis, in reality some clinicians delay treatment decisions until laboratory results are available

*Forsman, Clinical Chemistry, 1996, 42:5, 813-816
Recommended TB testing methods

- Fluorescence microscopy
- NAAT for detection directly from clinical specimens
- Broth culture methods
- Rapid ID methods – HPLC & DNA probes
- Broth-based DST for first-line drugs
Recommended Turnaround Times

- Specimen delivery within 24 hours of collection
- Acid fast examination and reporting within 24 hours of specimen receipt
- Confirmation of TB within 48 hours of specimen receipt using NAAT/rapid test (HP2010)
- Identification of Mtb ≤21 days
- DST to primary drugs ≤28 days

Tenover et al (JCM 1993, 31:767-770)
Opportunities for Change

- Specimen Receipt in PHLs

<table>
<thead>
<tr>
<th>% specimens received within 24 h after collection</th>
<th># labs (%) (39 reported)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25%</td>
<td>9 (23%)</td>
</tr>
<tr>
<td>26-50%</td>
<td>14 (36%)</td>
</tr>
<tr>
<td>51-75%</td>
<td>12 (31%)</td>
</tr>
<tr>
<td>&gt;75%</td>
<td>4 (10%)</td>
</tr>
</tbody>
</table>

% of labs receiving specimens within 24 h

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1991</td>
<td>6%</td>
</tr>
<tr>
<td>1994</td>
<td>16%</td>
</tr>
</tbody>
</table>

*Aggregate data from progress report- FY2006*
Rapid Confirmation of Case of TB from Clinical Specimen

<table>
<thead>
<tr>
<th>Methods</th>
<th># of labs (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(54 reported)</td>
</tr>
<tr>
<td>Gen-Probe MTD</td>
<td>32 (59%)</td>
</tr>
<tr>
<td>Roche Amplicor</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Direct HPLC</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Real-time PCR</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Referral</td>
<td>8 (15%)</td>
</tr>
<tr>
<td>No rapid methods</td>
<td>10 (18%)</td>
</tr>
</tbody>
</table>

*Aggregate data from progress report- FY2006*
Opportunities for Change

- New TB Cases Confirmed Within 48 hours of Specimen Receipt in PHLs

<table>
<thead>
<tr>
<th>% of new cases</th>
<th># of labs (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(29 reported)</td>
</tr>
<tr>
<td>0</td>
<td>17 (59%)</td>
</tr>
<tr>
<td>&lt;50</td>
<td>6 (21%)</td>
</tr>
<tr>
<td>50-75</td>
<td>1 (3%)</td>
</tr>
<tr>
<td>&gt;75</td>
<td>5 (17%)</td>
</tr>
</tbody>
</table>

*Aggregate data from progress report- FY2006
To Avoid Delays in Treatment Decisions

• Laboratory test results must be available as soon as possible
• Lab results do not replace clinical judgment
• Clinicians need data to interpret test results
  • performance parameters of the test
  • potential impact of prevalence of TB among TB suspects, degree of clinical suspicion on predictive value, etc.
Potential Impact of Laboratory Delays

- Impedes initiation of appropriate therapy
- Prolonged infectiousness
- Inappropriate therapy
- Missed opportunities to prevent transmission

Laboratory Reporting of Tuberculosis Test Results and Patient Treatment Initiation in California

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California Department of Health Services Tuberculosis Control Branch,1 and School of Public Health, University of California at Berkeley,2 Berkeley, and California Department of Health Services Mycobacterial Diseases Laboratory, Richmond, California; Centers for Disease Control and Prevention IPPO, Atlanta, Georgia; and World Health Organization, Beijing, China*.

Received 25 November 2003/Returned for modification 5 January 2004/Accepted 1 June 2004
Overall Goal of Systems Approach

• Improve TB Control through optimal use of laboratory services
• Ensure timely reporting and effective tracking of information
Aims of Systems Approach

- Use appropriate methods and provide timely, high quality results
- Ensure timely flow of information among submitter, TB laboratory, and TB control program
- Maintain a highly trained workforce
- Ensure the availability of training on basics of TB disease, control, and laboratory testing
Mycobacteriology Services - 1999
National Sample of Mycobacteriology Laboratories

Source: APHL/CDC Mycobacteriology training needs assessment. Billie Bird
Lessons Learned

• Despite new technologies, Mycobacteriology still requires referral and different levels of service.

• There is a need for greater coordination between the public and private sectors for referral services.
Approach

• Guiding principles
• Benchmarks
• Outcome Measures
• Performance indicators
Guiding Principles

- Each jurisdiction must assure access to appropriate levels of quality TB testing and complete, timely reporting.
- Effective TB control requires a network of labs incorporating private and public labs
  - Coordination for referral of specimens & cultures
  - Eliminating delays in lab testing and reporting
- Effective TB control requires timely, complete communication between lab, program, and clinicians.
- PH labs should take leadership in developing the lab network and facilitating communication among labs, clinicians, and TB controllers.
• Interdependent Network
• Ultimate Goal: Improving Public Health
What is the “State-Level Public Health Laboratory System?”

• …More than the state public health laboratory
  – All public, private, and voluntary entities that contribute to public health laboratory practice in the state
  – A network of entities with differing roles, relationships, and interactions

• Depends upon strong PHL systems

APHL, Definition of a State Public Health Laboratory System, June 2007
National Plan for Reliable Tuberculosis Laboratory Services Using a Systems Approach

Recommendations from CDC and the Association of Public Health Laboratories Task Force on Tuberculosis Laboratory Services

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Benchmarks

- Assess available TB lab services and needs of lab service users
- Assess true costs of TB lab services and current level of funding
- Develop strategic plans to implement and maintain a systems approach to TB diagnosis, testing, treatment, and control
1) Understanding the structure, performance, and cost of the current network of service providers and users

2) Developing a referral and information network to ensure reliable testing and the timely flow of specimens and information

3) Using quality improvement principles to evaluate and improve the performance of the laboratory service network
Outcome Measures

• TB Incidence Rate
  - HP 2010 national objective <1 case/ 1,000,000

• Treatment Initiation
  - All newly diagnosed infectious cases of TB started on appropriate treatment within 48 hours of specimen collection

• Average TAT for smear, culture, DST

• Written Procedures for Interaction with TB Control Partners (e.g., specimen submission, optimum testing algorithms, and reporting)

• Mechanisms to assess training needs and evaluate effectiveness of training
Next Steps

- Develop tools
  - Surveys for assessing lab services
  - Cost assessment tools

- Utilize data from co-ag progress reports for performance evaluation and development of benchmarks