What is needed for Different Levels of TB Laboratory Accreditation

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WHO, Geneva
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The findings and conclusions in this report are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention
## TB laboratories under the supervision of National TB Reference Laboratories in Tier 1 Countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Smear Microscopy</th>
<th>Culture</th>
<th>DST</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>per 100,000 popn</td>
<td>% in EQA</td>
</tr>
<tr>
<td>2008 WHO data</td>
<td></td>
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<tr>
<td><strong>Routine Dx Min Req</strong></td>
<td>1</td>
<td>1</td>
<td></td>
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<tr>
<td>Afghanistan</td>
<td>545</td>
<td>1.9</td>
<td>72</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>753</td>
<td>0.5</td>
<td>100</td>
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<tr>
<td>Brazil</td>
<td>4,044</td>
<td>2.1</td>
<td>45</td>
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<td>Cambodia</td>
<td>205</td>
<td>1.4</td>
<td>93</td>
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<tr>
<td>DR Congo</td>
<td>1,545</td>
<td>2.4</td>
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<tr>
<td>Ethiopia</td>
<td>1,000</td>
<td>1.2</td>
<td>0</td>
</tr>
<tr>
<td>India</td>
<td>13,000</td>
<td>1.1</td>
<td>93</td>
</tr>
<tr>
<td>Indonesia</td>
<td>4,855</td>
<td>2.1</td>
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<td>Kenya</td>
<td>930</td>
<td>2.4</td>
<td>4</td>
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<tr>
<td>Mozambique</td>
<td>252</td>
<td>1.2</td>
<td>100</td>
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<tr>
<td>Nigeria</td>
<td>1,138</td>
<td>0.8</td>
<td>44</td>
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<tr>
<td>Pakistan</td>
<td>1,131</td>
<td>0.7</td>
<td>32</td>
</tr>
</tbody>
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Source: WHO Global Tuberculosis Report 2009
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<td>per 100,000 popn</td>
<td>% in EQA</td>
</tr>
<tr>
<td><strong>Routine Dx Min Req</strong></td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Philippines</td>
<td>2,374</td>
<td>2.6</td>
<td>100</td>
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<tr>
<td>Russia</td>
<td>4,048</td>
<td>2.9</td>
<td>0</td>
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<tr>
<td>South Africa</td>
<td>249</td>
<td>0.5</td>
<td>97</td>
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<td>Tanzania</td>
<td>717</td>
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<td>Uganda</td>
<td>741</td>
<td>2.3</td>
<td>100</td>
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<tr>
<td>Ukraine</td>
<td>-</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>Zambia</td>
<td>158</td>
<td>1.3</td>
<td>13</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>180</td>
<td>1.3</td>
<td>0</td>
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<tr>
<td><strong>USAID Tier 1 Total</strong></td>
<td><strong>37,865</strong></td>
<td>Yes=15 (75%)</td>
<td><strong>66</strong></td>
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</tbody>
</table>

Source: WHO Global Tuberculosis Report 2009
Scaling up diagnostics and laboratories

• Accelerating WHO policy development
  2007: Commercial liquid culture and DST
  2008: Molecular line probe assay
  2009: LED microscopy, MODS, NRA and CRI methods
  2010: IGRAs, commercial serodiagnostics, Xpert MTB/RIF
  2011: Laboratory bio-safety

• Moving new diagnostics into countries
  EXPAND-TB - New technologies in 27 countries with funding from UNITAID and other donors

• Providing laboratory tools and training
  Global Laboratory Initiative: Roadmap and tools set, Laboratory accreditation

• Increasing laboratory support and quality
  Supranational Reference Laboratory Network

Reference: Chris Gilpin, WHO
GLI Accreditation Strategies (1)

• Strengthen National Reference Laboratories to implement new diagnostics and assure accuracy with quality management systems

• GLI Project: Promote ISO 15189 accreditation of National Reference Laboratories with general guidance, TB-specific technical requirements and a phased approach for implementation
  – Lead by KIT, with WHO, CDC
GLI Accreditation Strategies (2)

• Develop guidance and measures to incentivize countries to implement, monitor and maintain country microscopy networks

• GLI Project: Develop a guidance tool that measures country implementation of WHO/GLI recommendations and technical requirements for managing smear microscopy networks including EQA, training, supply chain
  – Lead by Union, with WHO, CDC, MSH
National Laboratory Infrastructure

Ministry of Health

National Reference Laboratory

Province Laboratories

District Laboratories

Health Centers

International Accreditation

Country Accreditation Program
Accreditation of TB Laboratories =

Twelve Quality System Essentials +
TB Laboratory Performance Indicators +
GLI and WHO TB technical resources
Performance Indicators for TB

- *Recovery rate of MTB and NTM*
- Contamination rate (specimen, solid, liquid)
- Percentage of specimens reported as smear positive
- Correlation between positive smears and positive cultures
- Percentage of negative smears resulting in positive cultures
- Turn around time of AFB smear, culture and DST results
- Proficiency testing performance (AFB microscopy, culture, drug susceptibility testing)
GLI guidance, tools, programs
Proposed GLI Phased/Steps toward Accreditation

• Step 1 – Fundamentals of Quality Management System (QMS)
• Step 2 – Extending QMS
• Step 3 – Focus on the management components of quality system
• Step 4 – Proving/documenting QMS system established in Steps 1-3
## 2008 High Burden Country Report

**Laboratory Services**

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of smear microscopy laboratories</th>
<th>Percentage covered by EQA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afghanistan</td>
<td>500</td>
<td>100</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>687</td>
<td>99</td>
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<tr>
<td>Brazil</td>
<td>4044</td>
<td>52</td>
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<tr>
<td>Cambodia</td>
<td>186</td>
<td>100</td>
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<tr>
<td>China</td>
<td>3010</td>
<td>92</td>
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<tr>
<td>Dem. Rep. Congo</td>
<td>1069</td>
<td>100</td>
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</tbody>
</table>
TB Care Project: Develop a Tool for Country Smear Microscopy Network Assessment/Accreditation

• Does the NTP/NRL provide:
  – National Policy/Strategy for Network Management
  – How is microscopy used in the country
  – Clear organizational structure
  – Human resource development
  – Supervision
  – Recording and reporting including documents/records
  – Equipment and supply management
  – EQA
Network Management: Performance Framework

• Percentage coverage of EQA (75%?)
• Process indicators for microscopy network
  • Documenting errors versus no errors
• National level
  • Manuals, SOPs, training curriculum, procurement, 2\textsuperscript{nd} rechecking
• Intermediate level
  • Supplies, stains, EQA implementation, supervision, reports
• Peripheral level
  • Collection, labeling, storage, recording, supplies
Organization of Rechecking Process

Peripheral Laboratory

Intermediate Laboratory
  - Blinded rechecking

Random Sample

Discrepancies resolved
  - National Laboratory

Feedback

Feedback
D.6  Rechecking Report of Multiple Laboratories for District Supervisor & NTP

District:

District Supervisor:

Sampling Period:

Supervising Laboratory:

<table>
<thead>
<tr>
<th>Peripheral Lab</th>
<th>Annual Volume</th>
<th>SPR</th>
<th># Slides Rechecked</th>
<th>HFN</th>
<th>HFP</th>
<th>LFN</th>
<th>LFP</th>
<th>QE</th>
<th>Total Errors</th>
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<tr>
<td>District Averages</td>
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Remaining Work

• Extending accreditation guidance/QMS beyond the NRL?
  • Targeting requirements for culture, molecular methods, DST at intermediate level
    – ISO or country accreditation?

• Biosafety accreditation?
Network Management is Necessary for all Diagnostics

• Training
• EQA
• Supplies
• Reporting
Acknowledgements

Chris Gilpin
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Tom Hearn

Stella Van Beers
Djeerd Datema
Paul Klatser

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E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

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