The Global Laboratory Initiative and Partnership Laboratory Capacity Building Efforts with WHO

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CCID/CDC
Latest global TB Estimates - 2006

- **Estimated number of cases**
  - All forms of TB: 9.15 million (139 per 100,000)
  - Multidrug-resistant TB (MDR-TB): 489,000
  - Extensively drug-resistant TB (XDR-TB): ~35,000
  - HIV-associated TB: 709,000 (8%)

- **Estimated number of deaths**
  - All forms of TB: 1.65 million (25 per 100,000)
  - Multidrug-resistant TB (MDR-TB): ~130,000
  - Extensively drug-resistant TB (XDR-TB): ~20,000
  - HIV-associated TB: 231,000
Background (1)

• Health systems weaknesses one of the greatest challenges in TB control

• Laboratory services one of the weakest links

• Lack of diagnostic capacity a crucial barrier preventing an effective response to the challenges of HIV-associated TB and drug-resistant TB
Background (2)

Unsatisfactory laboratory performance due to

- Inadequate human resources
- Lack of recognition of laboratory importance in TB control
- Weak communication between NTP and laboratory services
- Insufficient financial resources
- Problems of availability and accessibility
- Delay in technology transfer to resource-limited settings
- No or minimal interaction with private-sector laboratories
- Biosafety concerns
Diagnostic gaps & needs

9.1 million

More laboratories
Better technology
More staff
Quality assurance
Reliable systems

5.1 million

4.1 million

2.5 million

Smear+ TB
All TB

To reach MDG targets, a global capacity need of **120 million smears, 60 million cultures** and **6 million DST investigations** must be met by 2015, requiring at least **1 billion USD** investment in laboratory infrastructure and annual variable cost.

Establish 5,000 new microscopy laboratories;
Establish 2,000 new culture and DST laboratories;
Train 9,000 new technicians in smear microscopy;
Train 23,000 new technicians in culture and DST.

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**MDG Target**

- **2008**
  - Required expansion of **Smear capacity**: from 80 to 200 mln pa
  - USD funding required (mln): 50

- **2010**
  - Required expansion of **Culture capacity**: from 10 to 60 mln pa
  - USD funding required (mln): 100

- **2012**
  - USD funding required (mln): 150

- **2015**
  - USD funding required (mln): 200

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**Urgent**

- **2015**
  - USD funding required (mln): 2500
# HBC laboratory capacity 2006

(Source: WHO Global Report 2008)

<table>
<thead>
<tr>
<th></th>
<th>National Reference Laboratory</th>
<th># culture laboratories per 5 million population</th>
<th># DST laboratories per 10 million population</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>India</td>
<td>Yes</td>
<td>0.03</td>
</tr>
<tr>
<td>2</td>
<td>China</td>
<td>Yes</td>
<td>1.4</td>
</tr>
<tr>
<td>3</td>
<td>Indonesia</td>
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</tr>
<tr>
<td>4</td>
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<td>1.3</td>
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<td>5</td>
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<td>6</td>
<td>Bangladesh</td>
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<td>7</td>
<td>Ethiopia</td>
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<td>8</td>
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</tr>
<tr>
<td>9</td>
<td>Phillipines</td>
<td>Yes</td>
<td>0.2</td>
</tr>
<tr>
<td>10</td>
<td>DR Congo</td>
<td>Yes</td>
<td>0.1</td>
</tr>
<tr>
<td>11</td>
<td>Russian Federation</td>
<td>No</td>
<td>34</td>
</tr>
<tr>
<td>12</td>
<td>Viet Nam</td>
<td>Yes</td>
<td>1.0</td>
</tr>
<tr>
<td>13</td>
<td>Kenya</td>
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<td>0.3</td>
</tr>
<tr>
<td>14</td>
<td>UR Tanzania</td>
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<td>15</td>
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<td>16</td>
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<tr>
<td>17</td>
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<td>Yes</td>
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</tr>
<tr>
<td>18</td>
<td>Thailand</td>
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<tr>
<td>19</td>
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<tr>
<td>20</td>
<td>Zimbabwe</td>
<td>Yes</td>
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<td>21</td>
<td>Cambodia</td>
<td>Yes</td>
<td>1.1</td>
</tr>
<tr>
<td>22</td>
<td>Afghanistan</td>
<td>No</td>
<td>0.2</td>
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</table>
A functional laboratory requires more than commodities:

- Essential instruments, reagents, supplies
- Additional components to ensure quality diagnostic services
- Logistics and supplies
- Human Resources (Guidelines, Technology transfer)
- Infrastructure
- Quality Assurance
- Linked referral systems and reporting
Evolution of GLI

• WHA call for universal access to culture and drug susceptibility testing, May 2007

• Agreement on critical lack of TB laboratory capacity as a global crisis

• Paradigm shift in laboratory policy guidance, coordination, quality management and knowledge creation

• GLI endorsed by STP-CB in October 2007
  – Expansion of WHO laboratory strengthening team
  – Integration of SLCS and SRLN
TB Diagnostic: Direct AFB Smear Microscopy
STP-GLI as an active facilitator of communication and provider of global infrastructure services synchronized to be a coherent network service

Key STP-GLI activities

Guidance
- Laboratory policies
- Laboratory manuals
- Training materials
- Resource mobilization
- National roadmap advice

Assurance activities
- Coordination of EQA
- Equipment specifications
- Global accreditation system
- Monitoring/evaluation

Knowledge Sharing
- Coordinating TA, training
- Communication technologies
- Online knowledge resource network

Interface Connection
- Matchmaking projects between countries and implementing partners
- National “roadmaps”
- Advocacy
- Other disease networks

Capacity building
(expanding SRLN, building diverse and flexible national, regional, international consultants base, systematic and structured training)
Global Laboratory Initiative – Proposed Structure and Function

- WHO Stop TB Department – Stop TB Partnership

- GLI Secretariat
- GLI Core Group
- GLI Partners Committee (Organizations, STP Working Groups, Country NTP+Lab, NGOs, etc)

Core Group approves, governs, evaluates projects and advises GLI Secretariat

Partners Committee: approves and advises strategic agenda of GLI

Technical Working Groups
- Laboratory strengthening country roadmaps
- HR development & training strategy
- Laboratory biosafety
- Laboratory accreditation
- Other
GLI Challenges at Global Level

- Majority of donor resources focused at country level
- There is no forum or structure to coordinate GLI, OGAC Lab WG, WHO HIV Collaborative, Polio, IDSR, etc.
- Address and promote TB technical needs and contribute to integrated systems
- Shortage of full time laboratory scientists in partner organizations to contribute to GLI---dependent on part-time volunteers
- WHO GLI office is 4 staff
**Roadmaps – Developing the process for coordinating activities and strategies**

<table>
<thead>
<tr>
<th>Development Partners (Donors)</th>
<th>Laboratory Implementation Partners</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>GFATM</td>
<td>APHL</td>
<td>22 TB High burden countries</td>
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<tr>
<td>USAID</td>
<td>ASM</td>
<td>High HIV prevalence countries</td>
</tr>
<tr>
<td>PEPFAR</td>
<td>CDC</td>
<td>High MDR countries</td>
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<tr>
<td>BMG</td>
<td>CLSI</td>
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<td>World Bank</td>
<td>FIND</td>
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<tr>
<td>DFID</td>
<td>IOM</td>
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</tr>
<tr>
<td>UNITAID</td>
<td>IUATLD</td>
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<tr>
<td>CIDA</td>
<td>MSH</td>
<td></td>
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<tr>
<td>Fondation Merieux</td>
<td>MSF</td>
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<tr>
<td></td>
<td>PATH</td>
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<td></td>
<td>Universities</td>
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<td>WHO</td>
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</table>
Are These Efforts Coordinated?

- Do the efforts overlap?
- Do they duplicate each other?
- Are they synergistic?
- Are there opportunities to leverage new partners?
- How many such relationships are there?

Ref: Rand Corp, CDC GLB 2008
Global Guidance for Laboratory Strengthening
Selected Recommendations for Integrating Systems

- Quality Systems (QS) planning should be part of a larger National Laboratory System (NLS) strategic plan that is managed by the MoH and coordinates the contributions of donors and programs into the NLS
- Include all disease programs, clinical services and other stakeholders in strategic planning
- NLS strategic planning process is an opportunity to combine program resources for an integrated system
- Global framework of disease programs is needed to support integrated laboratory systems/health systems
INTEGRATED LABORATORY CAPACITY STRENGTHENING FOR DISEASES OF PUBLIC HEALTH IMPORTANCE

TIERED LABORATORY SERVICES

CROSS-CUTTING STREAMS

INTEGRATED SERVICE DELIVERY

Ref: GAP/CDC
New Diagnostics for TB
WHO technical consultations 2007-8

• Interim guidance for first and second line drug susceptibility testing
• Use of liquid culture media
• LED-based fluorescence microscopy (pending WHO approval)
• Line probe assay molecular screening for MDRTB
GLI strategic priorities

- Establishing GLI partnership projects
- Developing a template for country-specific roadmaps for laboratory strengthening
- Developing human resource strategies, including consultant training, training of different laboratory technical cadres, career development and retention
- Developing appropriate and adequate laboratory biosafety norms and standards, strategies and documents
- Developing a TB laboratory accreditation system
- Moving new diagnostics into countries
GLI activities and projects

• Global policy guidance
  – Second-line drug susceptibility testing
  – Use of line probe assays
• Laboratory norms and standards
  – Equipment specifications
  – Equipment procurement
  – Laboratory standard operating procedures
  – Laboratory biosafety
• Expanding access to MDR-TB diagnostics in a partner approach – UNITAID project
Goal

- Improve control of MDR-TB through expanding and accelerating access to new diagnostic technologies, and
- Ensure that these tools are properly integrated within TB control programmes

Objectives

- To secure access at lowest possible price to diagnostic instruments, reagents, and supplies through UNITAID support
- To leverage UNITAID support with additional resources to:
  - Revitalize and modernize national reference laboratories
  - Ensure training in good laboratory practice, biosafety, and new diagnostic methods
  - Provide sustained technical assistance to ensure proper use of diagnostic tools
### Project partners

- **Three partners with complementary capacities**

<table>
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<th>Global Laboratory Initiative</th>
<th>FIND</th>
<th>Global Drug Facility</th>
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<tr>
<td>- Network of international partners dedicated to lab strengthening</td>
<td>- Public-private partnership focused on development, evaluation, and accelerated uptake of new diagnostics</td>
<td>- Ensures access to anti-TB drugs and diagnostics at lowest possible price</td>
</tr>
<tr>
<td>- Components include:</td>
<td>- ISO 13485 certified</td>
<td>- Provides procurement services (29 countries in 2007)</td>
</tr>
<tr>
<td>- Policy guidance</td>
<td>- Extensive experience with clinical trials of new diagnostics in developing countries</td>
<td>- Technical expertise in managing and monitoring of commodities</td>
</tr>
<tr>
<td>- Capacity development and coordination</td>
<td>- Will ensure access to new diagnostics including:</td>
<td>- Has achieved cost-containment for first-line TB drugs under UNITAID</td>
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<td>- Integration with other lab networks</td>
<td>- TB liquid culture</td>
<td>- Current projects with UNITAID also include scale-up of procurement for drugs to treat MDR-TB and paediatric TB</td>
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<tr>
<td>- Standardized quality assurance</td>
<td>- Immunoassay for species identification</td>
<td></td>
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<tr>
<td>- Coordination of technical assistance</td>
<td>- Line probe assay</td>
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<tr>
<td>- Knowledge sharing</td>
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**Global Laboratory Initiative**

- Network of international partners dedicated to lab strengthening
- Components include:
  - Policy guidance
  - Capacity development and coordination
  - Integration with other lab networks
  - Standardized quality assurance
  - Coordination of technical assistance
  - Knowledge sharing

**FIND**

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**Global Drug Facility**

- Ensures access to anti-TB drugs and diagnostics at lowest possible price
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- Technical expertise in managing and monitoring of commodities
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Expected results

74,000 MDR-TB patients diagnosed (and provided with treatment)

- 15% of global MDR-TB burden
- At least 3-fold increase over current situation

Images:
- Diagnostics
- Drugs
- Patients
Integration: Biosafety Initiatives

• GLI identifies biosafety as a critical issue for scaling up laboratory capacity for smear, culture, DST, and molecular testing

• Discussion between CDC (DTBE, GAP, OHS, DLS) and WHO programs (TB, Biosafety, IHR coordination) to propose integrated biosafety activities
  – Technical consultation, Atlanta, Fall 08
  – Technical guidance on BSL2/BSL3 engineering and facility design (funding requested)
  – Recommendations and guidance for simple “fan boxes” for smear microscopy (funding requested)
  – Guidance on integrated safety practices at all levels of laboratory network (funding requested)
Strengthening TB laboratories

‘From unimaginable...to indispensable’
全国传染病监测试验室质量管理体系培训班 2007.7.30
Acknowledgements

• STB/THD Laboratory Strengthening Team
  – Paul Nunn (THD Coordinator)
  – Kalpana Singh
  – Veronique Vincent
  – Karin Weyer

• GLI Core Group
  – Lucia Barrera
  – Francis Drobniewski
  – Chris Gilpin
  – Case Gordon
  – Moses Joloba
  – Kai Man Kam
  – John Ridderhof (Chair)
  – Rick O'Brien
  – Tom Shinnick
  – Armand van Deun

• GLI Partners
  – American Society for Microbiology (ASM)
  – Association of Public Health Laboratories (APHL)
  – Bill & Melinda Gates Foundation
  – Centers for Disease Control and Prevention (CDC)
  – CDC Global AIDS Programme (GAP)
  – Fondation Merieux
  – Foundation for Innovative New Diagnostics (FIND)
  – International Union Against TB and Lung Disease
  – PEPFAR
  – USAID
  – KNCV
  – Merieux Alliance
  – Management Sciences for Health (MSH)
  – Medecins Sans Frontiers
  – National TB Programmes
  – WHO
  – and growing…

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