The
Global Laboratory Initiative
Roadmap

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On behalf of the GLI Core Group
## Global TB estimates - 2007

(Updated February 2009)

### Estimated number of cases

<table>
<thead>
<tr>
<th>All forms of TB</th>
<th>9.27 million (139 per 100,000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multidrug-resistant TB (MDR-TB)</td>
<td>511,000</td>
</tr>
<tr>
<td>Extensively drug-resistant TB (XDR-TB)</td>
<td>50,000</td>
</tr>
<tr>
<td>HIV-associated TB</td>
<td>1.4 million</td>
</tr>
</tbody>
</table>

### Estimated number of deaths

<table>
<thead>
<tr>
<th>All forms of TB</th>
<th>1.77 million (27 per 100,000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multidrug-resistant TB (MDR-TB)</td>
<td>150,000</td>
</tr>
<tr>
<td>Extensively drug-resistant TB (XDR-TB)</td>
<td>30,000</td>
</tr>
<tr>
<td>HIV-associated TB</td>
<td>456,000</td>
</tr>
</tbody>
</table>
Overall problem: MDR-TB diagnostic and treatment levels far too low

- 511,000 estimated cases annually

- Diagnosed and treated in Green Light Committee programmes

- 3%

No diagnosis and treatment reported. Some treatment probably obtained, quality unknown

Countries report diagnosis and treatment, standard unknown
Laboratory scale-up

Driven by

- Case detection moving towards universal access
- HIV-associated and drug resistant TB

Challenged by

- Weak health systems
- Inadequate human resources
- Insufficient programmatic and managerial capacity
- Inadequate infrastructure (biosafety)
- Problems of availability and access
- Slow technology transfer
- Lack of recognition of laboratory importance in TB control, weak communication between NTPs and laboratory services
Acceleration

Recent developments:

• At least 20 new technologies in various stages of development and evaluation
• Distinct target areas for drug-resistant TB being addressed
• WHO policy formulation
  – Liquid culture, rapid speciation and line probe assays endorsed by WHO 2007-2008;*
  – LED microscopy and selected non-commercial culture and drug susceptibility testing methods 2009
• Expanded access to new diagnostics and laboratory strengthening

*Available at: [http://www.who.int/tb/dots/laboratory/policy/en](http://www.who.int/tb/dots/laboratory/policy/en)
Why a Roadmap?
Process

• May 08: GLI CG meeting
  – GLI strategic objectives defined
• May 08: 1st annual GLI meeting
  – Consultant findings on stakeholder interviews and country fact finding visits
  – Break-out group discussions to identify gaps and next steps
• Oct 08: Dedicated TBCAP funding
• Oct 08 - Jun 09:
  – Conceptual framework defined
  – Country case studies pursued and common themes identified
  – Stakeholder interviews continued
  – WHO policy recommendations incorporated
• Jun 09 – Aug 09
  – Intensive revision by Writing Committee, GLI CG and external laboratory experts
Purpose and scope

- **Structured framework** for TB laboratory strengthening based on WHO-GLI norms and standards, documented best-practices at country level, growing lessons from the field ('learning by doing')
- **Generic document** encompassing managerial, operational and technical aspects of TB laboratory strengthening within the context of national laboratory strategic plans
- **Broad user base** including NTP and NRL managers, technical agencies, donor agencies, implementing partners, programme budgeting and planning officers
- **Living document**, responsive to changes in TB diagnostic landscape and WHO policy frameworks

- Supported by resource list for tools and technical procedures
Core elements

- Laboratory infrastructure and maintenance
- Equipment validation and maintenance
- Specimen referral and transport mechanisms
- Policy framework for implementing new TB diagnostics
- Laboratory commodity and supply chain management
- Laboratory information and data management systems
- Laboratory quality management systems
- Laboratory human resource development
Policy change at country level, based on

- Local epidemiology (TB, HIV, MDR-TB)
- NTP priorities for case detection (risk groups)
- Laboratory networks and capacity
- Laboratory staff resources and skills base
- Treatment policies for drug-resistant TB
- Financial resources
Stepwise approach (2)

Expansion of laboratory services based on

- Tiered system (peripheral, intermediate, central)
- Available technologies
- Ancillary laboratory needs related to specialised treatment (e.g. ART, second-line anti-tuberculosis drugs)
  - General microbiology, biochemistry, haematology, etc.
- Integrated approach
Stepwise approach (3)

• **Phase 1: Laboratory preparedness**
  – Assessment of TB laboratory networks and diagnostic policies
  – Upgrade of laboratory infrastructure and biosafety
  – Development and implementation of GLP, SOPS, QA, etc.
  – Training of core laboratory staff
  – Initiation of NTP policy reform on diagnostics

• **Phase 2: Introduction of new diagnostics**
  – Integration of new diagnostics into NTP policies and procedures
  – Procurement and installation of instruments, reagents, supplies
  – Validation of new tools and laboratory performance
  – Adjustment of NTP policy based on local data

• **Phase 3: Impact assessment**
  – Continued mentoring, technical support and oversight
  – Assessment of impact on NTP outcomes
Analytical process

• Quantify or estimate TB, TB-HIV and MDR-TB burden
• Identify and target patient risk groups, eg.
  – Treatment failures
  – Non-converting patients
  – HIV+ individuals
• Quantify or estimate diagnostic need to identify cases
  – Number of suspects to be screened
  – Number and type of laboratories at each service level
• Estimate budget for comprehensive laboratory services
  – All core components
  – Capacity for diagnosis and monitoring
  – Ancillary laboratory tests
Policy considerations

• Current technologies not mutually exclusive
  – Conventional culture capacity required for SM- specimens
  – Conventional DST capacity required to detect XDR-TB
• Liquid culture and line probe assay as gold standards, to be phased in without loss of existing culture and DST capacity
• LED microscopy as alternative for both fluorescence and conventional light microscopy
• Selected non-commercial culture and DST methods not alternatives for gold standards, but may provide interim solution
Issues for SRL discussion

• Definition of SRL
  – Technical expert in all aspects of laboratory strengthening; or
  – Technical expert in particular aspects of laboratory strengthening

• Role of SRL network
  – In overall laboratory capacity development
  – In drug resistance surveillance
  – ...

• Moving beyond TB
Strengthening TB laboratories

‘From unimaginable...to indispensable’
Acknowledgements

- Consultants: Peer Ederer, Stephan Willms, Georgine Ganzer
- Country Ministries of Health, NTPs and NRLs: Ethiopia, Lesotho, Cote d'Ivoire
- Writing Committee: Chris Gilpin (lead), Jean Iragena, Gavin MacGregor-Skinner, CN Paramasivan, John Ridderhof, Tom Shinnick, Armand van Deun, Karin Weyer
- GLI Core Group: John Ridderhof (chair), Lucia Barrera, Francis Drobniewski, Chris Gilpin, Vijay Gupta, Moses Joloba, Gavin MacGregor-Skinner, Kai Man Kam, Rick O'Brien, Tom Shinnick, Armand van Deun, Karin Weyer
- With additional input from: Catherine Mundy, Giorgio Roscigno, Akos Somoskovi, Veronique Vincent
- GLI partners interviewed: APHL, ASM, CDC, FIND, GTZ, KNCV, PATH, PEPFAR, PIH, TBCAP, Union, WHO

- And with apologies for any unintended oversight…