EXPANDx-TB Project

3rd GLI Annual meeting, 4 October, 2010

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WHO Stop TB Department

EXPANDx-TB is managed by WHO-GLI, GDF and FIND under a grant from UNITAID
3 MAIN OBJECTIVES

**EXPanding Access to New Diagnostics for Tuberculosis**

- Improve control of MDR-TB
- Improve market dynamics
- Integrate tools in TB control programmes
3 PROJECT PHASES

Phase 1: Laboratory Preparedness
- Lab assessments
- Infrastructure/biosafety
- Quality Assurance
- SOPs

Phase 2: Introduction of new diagnostics
- Procurement of commodities
- Integration of new diagnostics into screening and treatment guidelines (Training, Validation, Knowledge transfer)

Phase 3: Impact Assessment
- Continued support and oversight of technology transfer
- Impact measured and reported
- Ensuring GLP, IQC and EQA measures
SELECTION OF COUNTRIES

- High-burden MDR-TB Countries
- UNITAID eligible countries
- GLC approved project
- Partner support Infrastructure & Tech Transfer
WORLDWIDE COMMITMENT

2009: 6 countries
2010: 18 countries including India (40 labs)
2011: 3 countries
Project targets*

<table>
<thead>
<tr>
<th>Year</th>
<th>Patients</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>2,036</td>
<td>6</td>
</tr>
<tr>
<td>2010</td>
<td>31,227</td>
<td>25</td>
</tr>
<tr>
<td>2011</td>
<td>94,443</td>
<td>25</td>
</tr>
<tr>
<td>2012</td>
<td>115,929</td>
<td>27</td>
</tr>
<tr>
<td>2013</td>
<td>129,670</td>
<td>27</td>
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Total ~ 129,670

* Targets calculated as a % of the estimated MDR-TB burden, 80% for most countries; 35% for India and 60% for Zambia and Cameroon.
A UNIQUE PARTNERSHIP MODEL

- Policies, norms international standards
- Participate in lab assessments
- Provide long-term, on-site monitoring
- Develop indicators and tools for M&E

- Negotiate with partners to ensure lowest prices
- Ensure customer support in place
- Share know-how from product development process
- Provide long-term, on-site mentoring for technology transfer

- Coordinate and manage procurement and delivery
- With FIND, engage industry to ensure affordability and sustained price decreases
- Collaborate with WHO pre-qualification to include diagnostics

Logistics and supplies

Human Resources
(Guidelines Technology transfer)

Infrastructure

Quality Assurance

Linked referral systems and reporting

Funding for essential instruments, reagents, supplies
• **Initial and continuous assessment** of TB laboratories and TB labs networks

• **Procurement:**
  – Equipment for liquid culture and line probe assay
  – Reagents and consumables for term of the project

• **Training:**
  – Quality assurance and data management
  – Liquid culture and molecular biology
  – Bio-safety and waste management

• **Follow-up** of the laboratories

• **Overall project management**
WHAT IS NOT INCLUDED

• Premises for culture:
  – Need for a negative pressure room
  – Need for a strong biosafety level

• Premises for molecular biology
  – 3 different rooms are required for such analysis

• Equipment:
  – Non-specific equipment is not included in the project, which needs to be covered by other financial sources

➡ Extra partnerships need to be established
## IN-COUNTRY PARTNERS

<table>
<thead>
<tr>
<th>Country</th>
<th>Partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethiopia</td>
<td>MOH, PEPFAR-CDC, GAP/ILB, JHU &amp; ICAP, SRLN, GF</td>
</tr>
<tr>
<td>Lesotho</td>
<td>MOH, PIH, PEPFAR/CDC, WHO, URC, GF, BD, SAMRC</td>
</tr>
<tr>
<td>Côte D’Ivoire</td>
<td>MOH, WHO, PNLT, IPCI; CAT Adjame, CeDReS, ASM, PEPFAR, EGPAF</td>
</tr>
<tr>
<td>Uzbekistan</td>
<td>MOH, WHO, KfW (EPOS), GF, USAID, Euro Lab Task Force</td>
</tr>
<tr>
<td>Myanmar</td>
<td>MOH, WHO, NTPL, AKK. JAICA, PSI, MSF, UNION</td>
</tr>
<tr>
<td>Haiti</td>
<td>MOH, NTP, WHO, NPHL, NRLM, GHESKIO, Fondation Mérieux, CDC-PEPFAR, ASM, Cornell University</td>
</tr>
</tbody>
</table>
ACHIEVEMENTS AT A GLANCE (1)

2009

Kazakhstan
DR Congo
Belarus
Viet Nam
Uganda
Tanzania

Haïti
Côte d’Ivoire
India


Cameroon
Senegal
Peru
Zambia
Kenya
Bangladesh
Indonesia

Djibouti
Georgia
Tajikistan
Azerbaijan
Moldova
Kyrgyzstan
Swaziland

Myanmar
Ethiopia
Uzbekistan
Lesotho
ACHIEVEMENTS AT A GLANCE (2)

- **Uzbekistan**: 1,423
- **Ethiopia**: 271
- **Lesotho**: 116

![Bar chart showing achievements in Uzbekistan, Ethiopia, and Lesotho with years 2007, mid 2010, and project total indicated.]
LESOTHO – a model for rapid knowledge transfer

1 reference lab: QEI hospital
1 regional lab: Mafeteng government hospital

2006-2008: FIND, PIH and WHO renovated the NRL and reinforced microscopy services, streamlined culture and DST and introduced modern TB diagnostic methods

2007: BSL3, solid culture and DST, and EQA for smear microscopy established within 4 months

Liquid culture and DST introduced one month later

2008: LPA introduced for rapid detection of MDR-TB


2009: FIND conducted retraining for laboratory technicians at the NRL

2009: Validation of new TB Dxs algorithm finalised

2010: Regional laboratory currently being renovated

2010: Patient enrolment has started under ExpTB – 116 patients reported Jan-Mar

Experience establishing tuberculosis laboratory capacity in a developing country setting

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†Foundation for Innovative New Diagnostics (FIND), Geneva, Switzerland; ‡Ministry of Health, Maseru; §FIND, Maseru; ¶Partners in Health, Maseru, Lesotho; ¶World TB Organization, Geneva, Switzerland

Objective: To describe the experience of strengthening laboratory diagnosis of tuberculosis (TB) in a resource-limited country with high TB-HIV (human immunodeficiency virus) and multidrug-resistant TB (MDR-TB) prevalence.

Methods: In the Kingdom of Lesotho, which is confronted with high levels of TB, MDR-TB and HIV prevalence, between 2006 and 2009 a coalition of the Foundation for Innovative New Diagnostics, Partners in Health and the World Health Organization renovated the National TB Reference Laboratory and introduced liquid cultures, non-identical conventional culture and drug susceptibility testing (DST) and introduced modern TB diagnostic methods.

Results: It was feasible to establish a biosafety level three facility for solid culture and DST and an external quality assessment programme for smear microscopy within 4 months, all in 2007. Liquid culture and DST were introduced a month later. Preliminary results were comparable to those found in laboratories in industrialised countries. A year later, line-probe assay for the rapid detection of MDR-TB was introduced.

Discussion: Through strong political commitment and collaboration, it is possible to rapidly establish quality assured TB diagnostic capacity, including current methods, in a resource-limited setting. Case detection and management for TB and MDR-TB have been greatly enhanced. From a low baseline, TB case throughput in the laboratory increased ten-fold and has been sustained. This experience has served as a catalyst to translate policy into practice with new diagnostic technologies. It supports global policy setting to enhance and modernise laboratory work in developing countries.

Keywords: TB laboratory capacity; liquid cultures; line-probe assay; MDR-TB; low-income country
ETHIOPIA – a model for integration

**8 sites supported:**

- **2 central labs:** EHNRI (NRL), St Peters Hospital
- **6 regional labs:** Mekelle, Bahir Dar, Jimma, Awasa, Adama (Nazret), Harrar

FIND involved since 2007 with full-time consultant

Integrated HIV viral load testing with Line Probe Assay at central and regional locations

Refresher training in 2 central labs

Technical proficiency validated (sputum processing, SC, LC, LPA)

Negative air pressure and equipment installed at 6 regional labs, training planned

Inauguration March 2009
INDIA – a model for scale-up

40 sites to be supported:

- 4 national reference lab, 27 intermediate reference state laboratories, 9 medical colleges
- Joint project involving UNITAID (EXPTB) and GF (CTD-MoH)
- In 2008, Collaboration Agreement GoI and FIND to demonstrate introduction of liquid culture, LPA and species ID
- 2010 FIND’s role as a sub-recipient for India’s GF R9: support of human resources in data management and lab support -technical assistance and on-site training support for technology uptake.
- Signing of Expand-TB MoU and start of activities April 2010
MYANMAR – a model for political commitment

2 sites

1 central lab, in Yangon and 1 regional lab in Mandalay

Equipment for 2 BSL3s shipped, installation completed

WHO country office acts as recipient of goods

MOH, Government of Myanmar in charge of customs clearance & shipping to sites

EXP-TB consultant coordinating all activities

Government of Myanmar has refurbished the laboratories

5 lab techs underwent 2-week training in Bangkok by FIND, with funding from WHO