EXPAND-TB Program

Country Update

Global consultation of the TB Supranational Reference Laboratory Network

April, 14th-15th, 2010

EXPAND-TB is supported by WHO-GLI, WHO-GDF and FIND under a Grant from UNITAID
TARGETS

- Reduce the Dx Gap
- Service up to 1/3 world population
- 30% MDR-TB estimated prevalence
- 27 countries
- Funding M$87 to WHO-GLI, WHO-GDF, FIND
- Assess and strengthen 101 labs
3 MAIN OBJECTIVES

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

Phase 1: Laboratory Preparedness

- Political commitment -- signing MOU - Prerequisite
- 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
A UNIQUE PARTNERSHIP MODEL

Logistics and supplies

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

Human Resources (Guidelines Technology transfer)

- 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

Infrastructure

- 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

Quality Assurance

Linked referral systems and reporting

Funding for essential instruments, reagents, supplies

Global Laboratory Initiative

Global Drug Facility

UNITAID

TOGETHER TO HEAL

EXPAND-ITB

EXPanding Access to New Diagnostics for Tuberculosis
WHAT IS INCLUDED IN THE PROJECT?

- **Initial and continuous assessment** of TB laboratories and TB labs networks

- **Procurement:**
  - Equipment for liquid culture/speciation and line probe assay
  - Reagents and consumables for project length

- **Training:**
  - Quality assurance and data management
  - Liquid culture and LPA
  - Biosafety and waste management

- **Follow-up** of the laboratories

- **Overall project management**
WHAT IS NOT INCLUDED IN THE PROJECT

- **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>
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<tr>
<td>Ethiopia</td>
<td>MOH, PEPFAR-CDC, GAP/ILB, JHU &amp; ICAP</td>
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<tr>
<td>Lesotho</td>
<td>MOH, PIH, PEPFAR/CDC, WHO, URC, GF, BD, SAMRC</td>
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<td>Côte D’Ivoire</td>
<td>MOH, PNLT, IPCI; CAT Adjame, CeDReS, ASM, PEPFAR, EGPAF</td>
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<td>Uzbekistan</td>
<td>MOH, WHO, KfW (EPOS), GF, USAID, Euros Lab strengthening task force</td>
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<td>Myanmar</td>
<td>MOH, WHO, NTPL, AKK, JAICA, PSI, MSF, UNION</td>
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<tr>
<td>Haïti</td>
<td>MOH, NTP, WHO, NPHL, NRLM, GESKIO, Fondation Mérieux, CDC-PEPFAR, ASM, Cornell University</td>
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11 trainees (India, Myanmar, Vietnam & Thailand)

10 day training with Exptb, CDC/GAP & NTRL Bangkok.

Train young TB personnel to perform and interpret quality assured liquid culture/DST/species ID

Using a standardized training curriculum
Extensive hands-on practice sessions
Several topics concerning quality assured laboratory practices (GLP, QA, QC measures)

Laboratory sessions for technical proficiency.

Basics of biosafety and adequate BSL3 laboratory layout
Sputum processing
PCR and DNA hybridization/management of spills

Pre and Post KAP (knowledge, attitude and practice) evaluation showed a significant increase.

Comment: "This training increased my understanding, basic knowledge and grasp of laboratory practices. The lectures were informative and our hands-on exercises will help us to organize things more efficiently in our home laboratory."
Model for electing suppliers through EXPAND-TB

To enlarge the pool of quality manufacturers to further reduce the diagnostics price through a comprehensive competitive bidding process.

Procedure requirements are:

- 9001 and 13485 ISO certification
- Registration by strict regulatory authorities (e.g. FDA, CE ...)
- Equivalency to the gold standard diagnostics used for approval by WHO

To demonstrate equivalency:
At least two SNRLs will compare the new tests according to the product specifications of the gold standard (STAG-TB endorsed)
The SNRL will finally submit the results through WHO for expert evaluation
Equivalent diagnostics will be selected in the next GDF public tendering
PROGRESS AT A GLANCE

2009

- Kazakhstan
- Azerbaïdjan
- Swaziland
- DR Congo
- Haïti
- Côte d’Ivoire
- Myanmar
- India

2010

- Cameroon
- Moldova
- Georgia
- Belarus
- Uzbekistan, regional
- Lesotho, regional
- Ethiopia, regional
- Tajikistan
- Kyrgyzstan
- Senegal
- Peru
- Zambia
- Uganda
- Tanzania
- Kenya

- Djibouti
- Ethiopia
- Uzbekistan
- Lesotho
**LESOTHO**

**A Model for Scale UP**

1. **Reference lab**: QEI hospital
2. **Regional lab**: Mafeteng government hospital

**1- 2006-2008:** FIND, PIH and WHO renovated the NRL and reinforced microscopy services, streamlined culture and DST and introduced modern TB diagnostic methods.

**2- 2007:** Established BSL3, solid culture and DST and an EQA for smear microscopy within 4 months.

**3- Liquid culture and DST were introduced a month later.**

**4- 2008:** A year later, introduced LPA for the rapid detection of MDR-TB

**6- 2009:** the National TB/HIV Strategic Plan for 2008 – 2012 was finalized

- 2009 FIND conducted retraining for laboratory technicians at the NRL
- Validation of new TB diagnostics algorithm presented
- 1 regional laboratory is currently being renovated, and biosafety facilities are being installed

**7- Have started enrollment under ExpTB**

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**Experience establishing tuberculosis laboratory capacity in a developing country setting**

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**OBJECTIVE:** To describe the experience of strengthening laboratory diagnosis of tuberculosis (TB) in a resource-limited country with high TB-HIV burden in the context of scale-up and operational improvements.

**METHODS:** In the Kingdom of Lesotho, which is classified as a high TB burden country, scale-up was supported by the Foundation for Innovative New Diagnostics (FIND) and the Ministry of Health. The Ministry collaborated to set up a National TB Reference Laboratory (NTRL) that would strengthen diagnostic services, introduce modern culture methodologies, and expand the capacity of laboratory services.

**FINDINGS:** The NTRL was established in 2006 as an independent entity, charged with implementing the findings of a pilot project conducted in 2005. The laboratory was equipped with modern diagnostic equipment, including a GeneXpert® instrument for rapid TB diagnosis. The laboratory also introduced liquid culture and DST testing, which were introduced a month later.

**CONCLUSION:** The experience of Lesotho demonstrates that it is possible to establish and scale-up TB diagnostic capacity in resource-limited settings, and that such capacity can be used to improve patient care and health outcomes. The NTRL has become an important resource for TB diagnosis in Lesotho and has contributed to the national TB control programme.

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Key words: TB laboratory capacity; liquid culture; liquid probe assay; MDR-TB; low-income country
ETHIOPIA

8 sites supported:

2 central labs: EHNRI (NRL), St Peters Hospital
and 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
40 sites to be supported:

4 national reference lab, 27 intermediate reference state laboratory, 9 medical colleges

Joint project involving UNITAID (EXPTB) and GF (CTD-MoH)

In 2008, Collaboration Agreement GoI and FIND to demonstrate introduction Liquid Culture/LIPA/Species ID

In 2010 FIND’s role as a sub-recipient for India’s GFr9:
- 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
2 sites supported:

1 reference lab in Tashkent and 1 regional lab in Samarkand

Have started enrollment under ExpTB

Samarkand regional lab re-equipped by KfW, negative air pressure to be implemented by Exptb

Pilot drug resistance surveillance being finalized

A regional assessment visit is planned May 2010.
COTE D’IVOIRE

3 sites in Abidjan:

1 central lab, IPCI, and 2 regional labs, CeDReS, CAT-Adjame handles 60% of all TB patients

Buildings under construction/renovation, BSL3 to be functional in Q2, 2010

In-country training is being coordinated by ASM/Exptb

- Training packages have been translated to French
- Liquid culture training will take place in Q2, 2010 when negative pressure in BSL3 is fully functional
- LPA training just conducted by Exptb
MYANMAR

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

Exptb consultant coordinating all activities

Government of Myanmar has refurbished the lab areas

5 Lab techs underwent 2-week training in Bangkok
THANK YOU

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