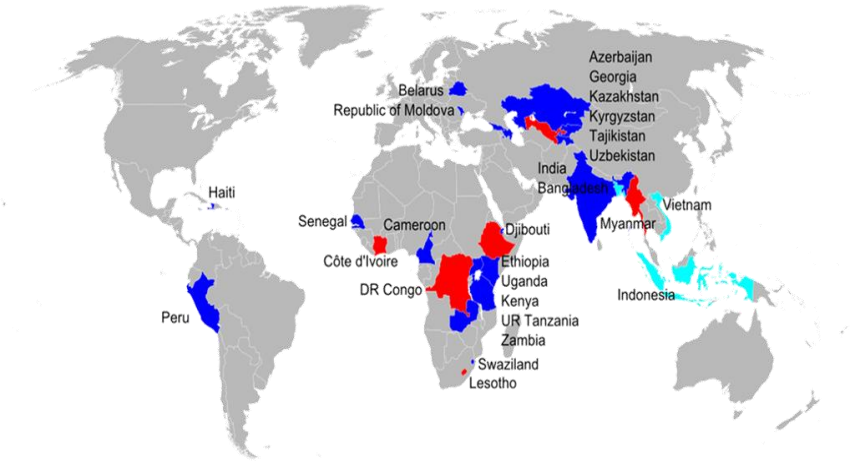


EXPANDx-TB Project

3rd GLI Annual meeting, 4 October, 2010

Fuad Mirzayev
TB Laboratory Strengthening and Diagnostics unit
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

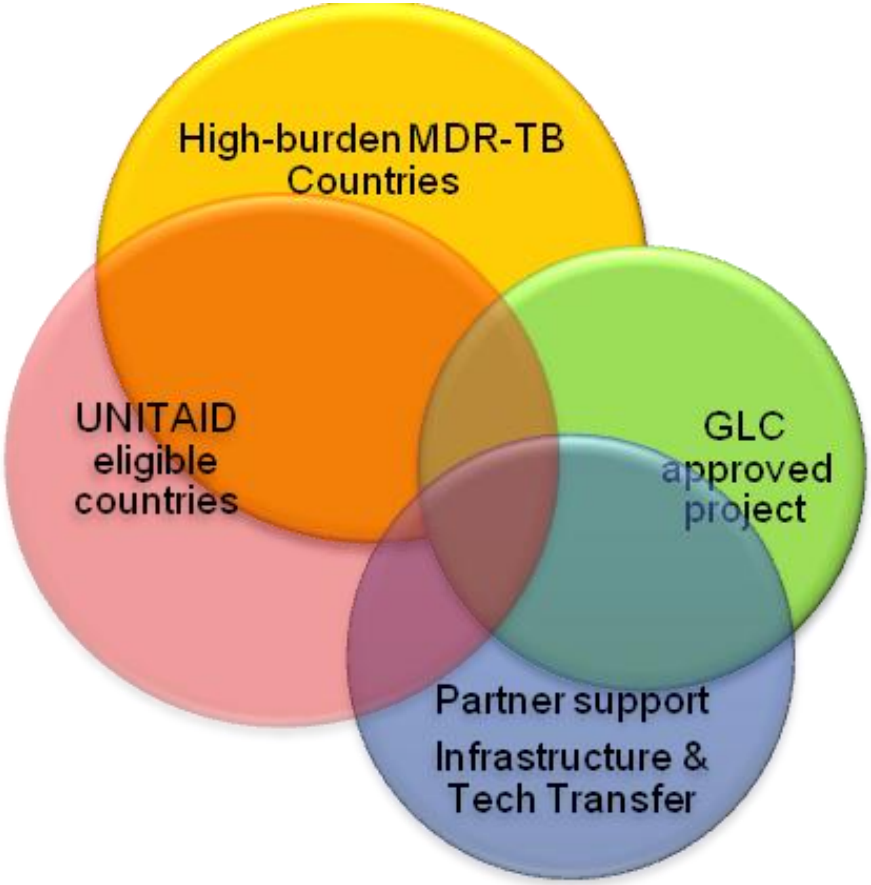
Phase 2: Introduction of new diagnostics

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

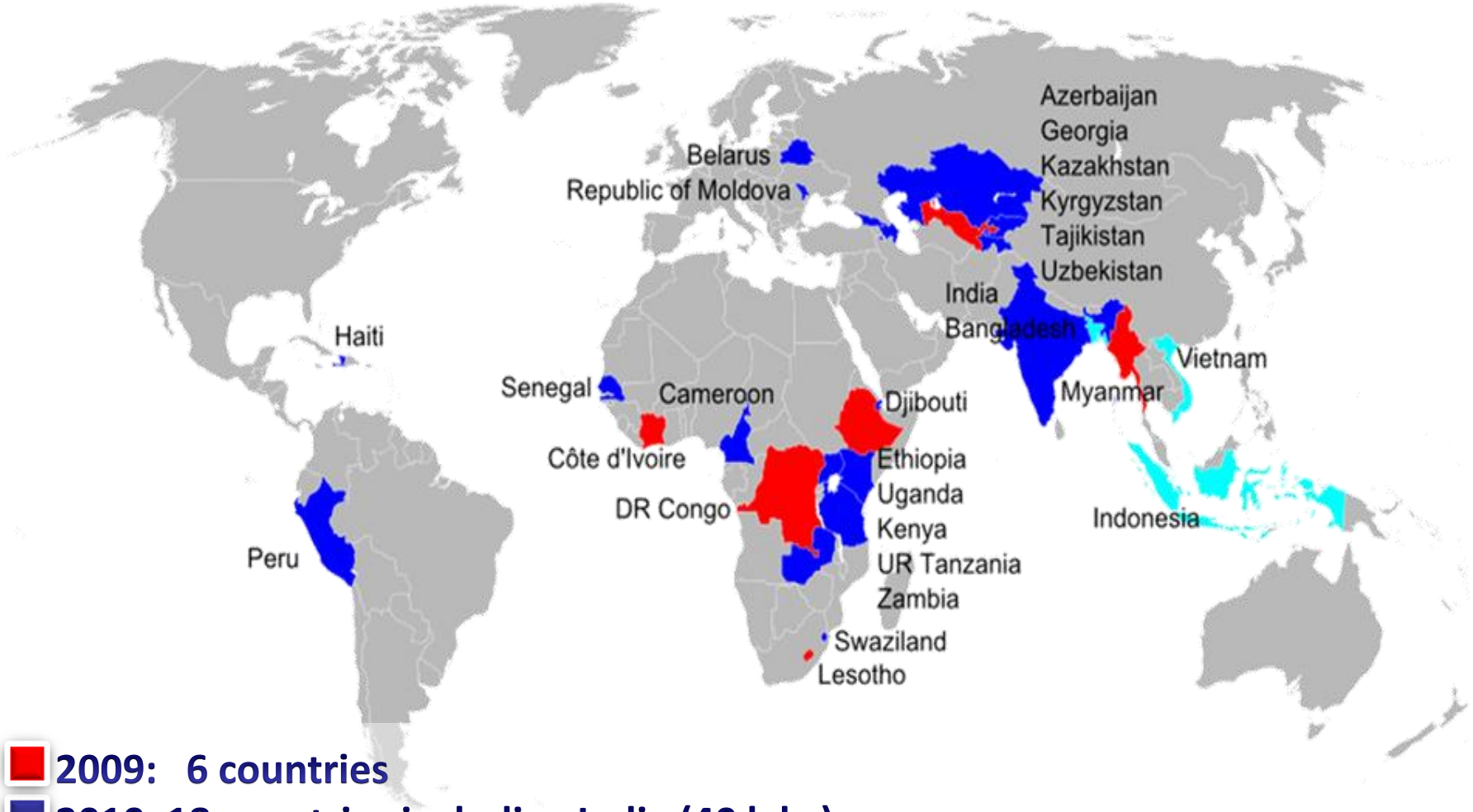
Phase 3: Impact Assessment

- Continued support and oversight of technology transfer
- Impact measured and reported
- Ensuring GLP, IQC and EQA measures

SELECTION OF COUNTRIES

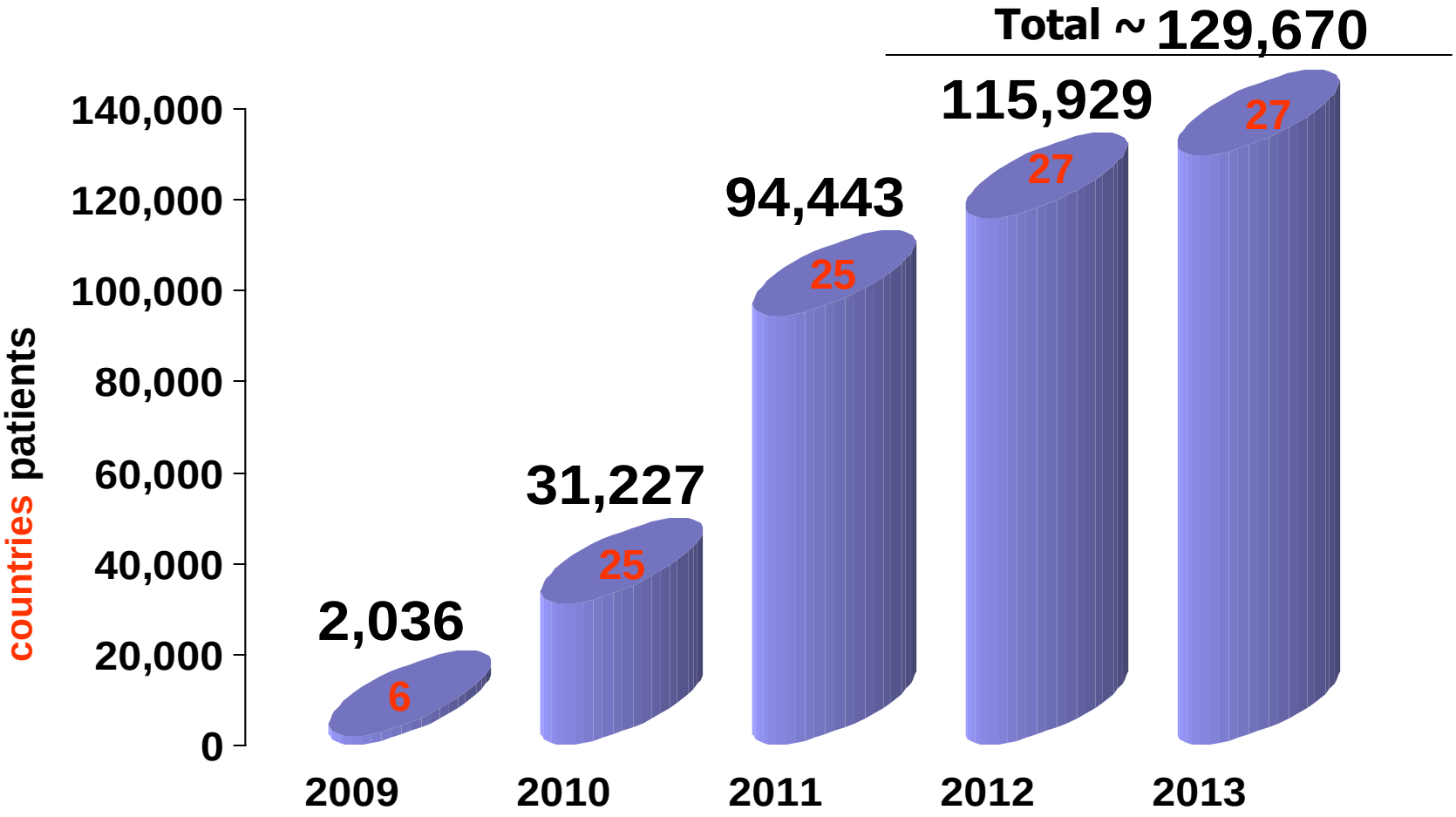


WORLDWIDE COMMITMENT



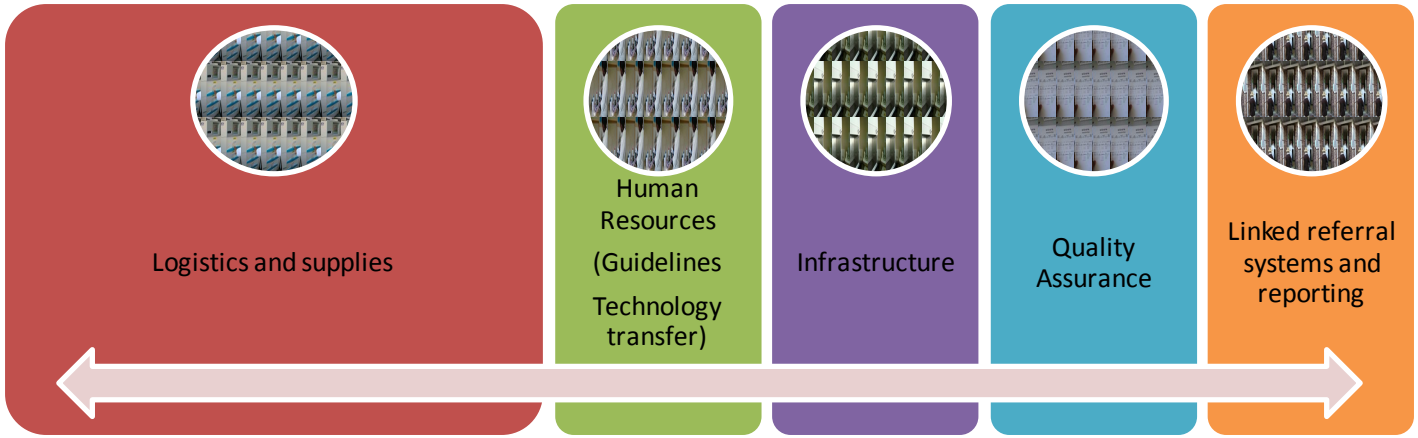
- 2009: 6 countries
- 2010: 18 countries including India (40 labs)
- 2011: 3 countries

Project targets*



* 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



Funding for essential instruments, reagents, supplies

- 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

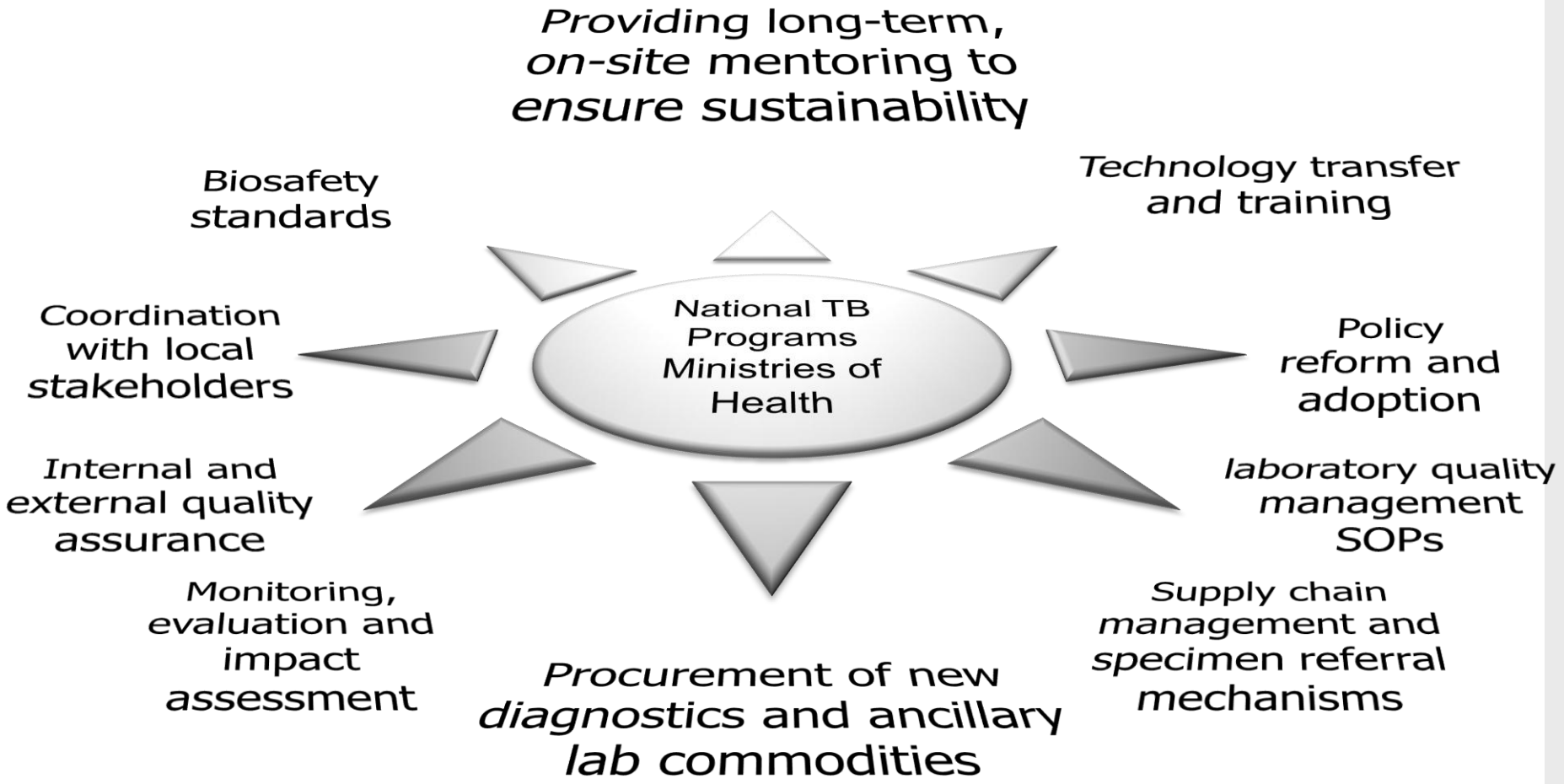
UNITAID
TOGETHER TO HEAL

Global Laboratory Initiative

FIND
foundation for innovative new diagnostics

Stop TB Partnership GLOBAL DRUG FACILITY TB PROGRAMME

PROVIDING DIAGNOSTICS IS NOT ENOUGH: 360° SUPPORT



IN-COUNTRY PARTNERS

Ethiopia	Lesotho	Côte D'Ivoire	Uzbekistan	Myanmar	Haiti
• MOH, PEPFAR-CDC, GAP/ILB, JHU & ICAP, SRLN, GF	• MOH, PIH, PEPFAR/ CDC, WHO, URC, GF, BD, SAMRC	• MOH, WHO, PNLT, IPCI; CAT Adjame, CeDReS, ASM, PEPFAR, EGPAF	• MOH, WHO, KfW (EPOS), GF, USAID, Euro Lab Task Force	• MOH, WHO, NTPL, AKK. JAICA,PSI, MSF,UNION	• MOH, NTP, WHO, NPHL, NRLM, GHESKIO, Fondation Mérieux, CDC-PEPFAR, ASM, Cornell University

ACHIEVEMENTS AT A GLANCE (1)

- Kazakhstan
- DR Congo
- Belarus
- Viet Nam
- Uganda
- Tanzania

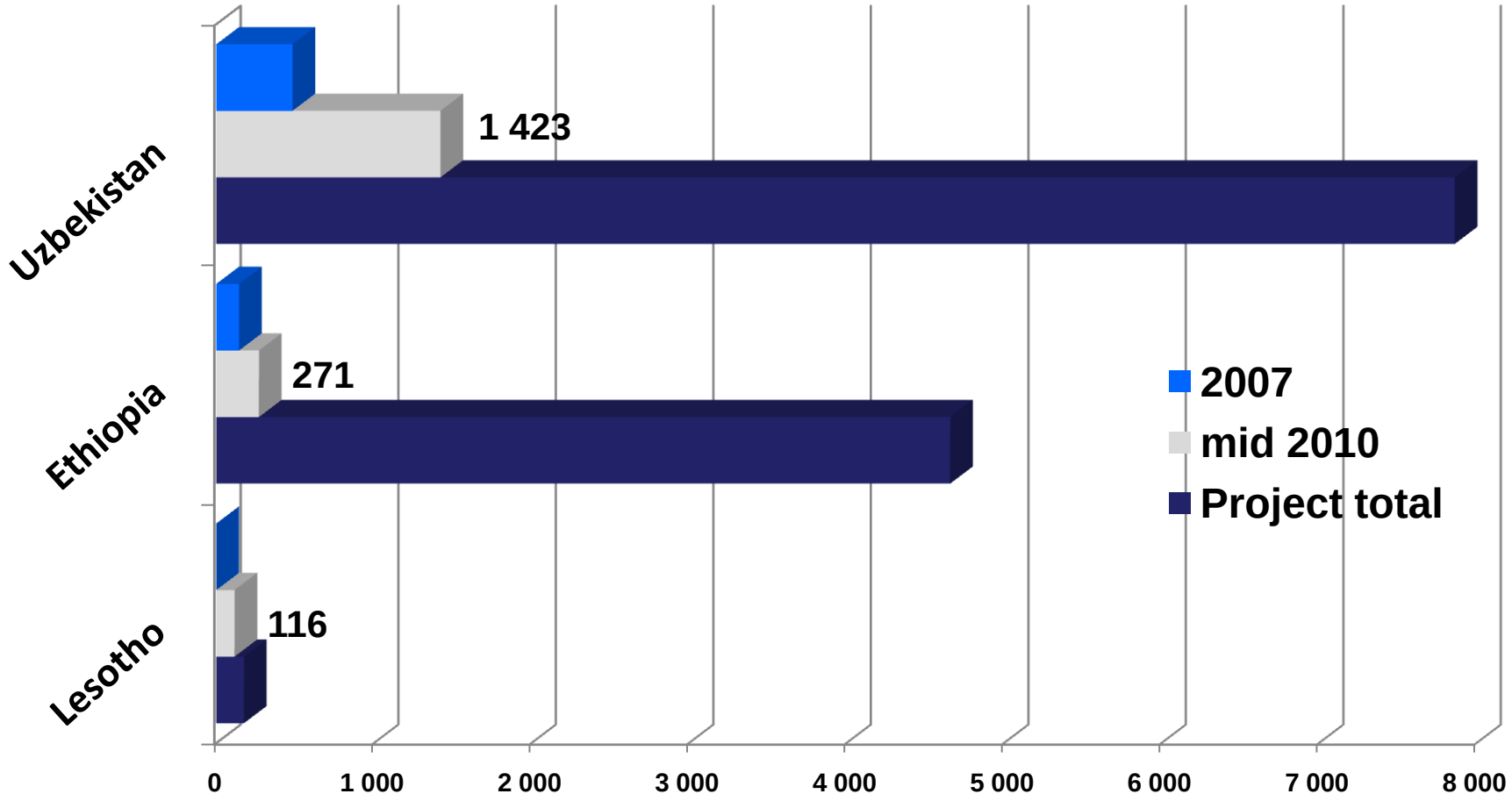
- Haïti
- Côte d'Ivoire
- India

- Cameroon
- Senegal
- Peru
- Zambia
- Kenya
- Bangladesh
- Indonesia

- Djibouti
- Georgia
- Tajikistan
- Azerbaijan
- Moldova
- Kyrgyzstan
- Swaziland

- Myanmar
- Ethiopia
- Uzbekistan
- Lesotho

ACHIEVEMENTS AT A GLANCE (2)



LESOTHO – a model for rapid knowledge transfer

1 reference lab: QEII 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: National TB/HIV Strategic Plan for 2008 – 2012 finalized by MOH

2009: FIND conducted retraining for laboratory technicians at the NRL

2009: Validation of new TB Dxs algorithm finalised

2010: Regional laboratory icurrently being renovated

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

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Experience establishing tuberculosis laboratory capacity in a developing country setting

C. N. Paramasivan,* E. Lee,* K. Kao,† M. Mareka,† G. Kubendiran,‡ T. A. Kumar,‡ S. Keshavjee,§ H. Satti,§ G. Alabi,¶ M. Raviglione,¶ G. Roscigno*

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

SUMMARY

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 2008 a coalition of the Foundation for Innovative New Diagnostics, Partners In Health and the World Health Organization renovated the National TB Reference Laboratory and reinforced microscopy services, streamlined conventional culture and drug susceptibility testing (DST) and introduced modern TB diagnostic methods.

FINDINGS: 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 culture 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.

KEY WORDS: TB laboratory capacity; liquid culture; line-probe assay; MDR-TB; low-income country

ETHIOPIA – a model for integration

8 sites supported:

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

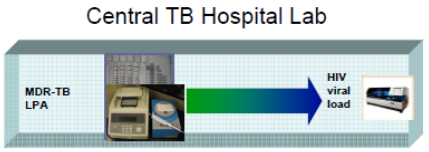
FIND involved since 2007 with full-time consultant

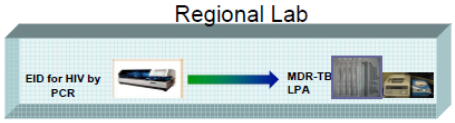
Integrated HIV viral load testing with Line Probe Assay at central and regional locations

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

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

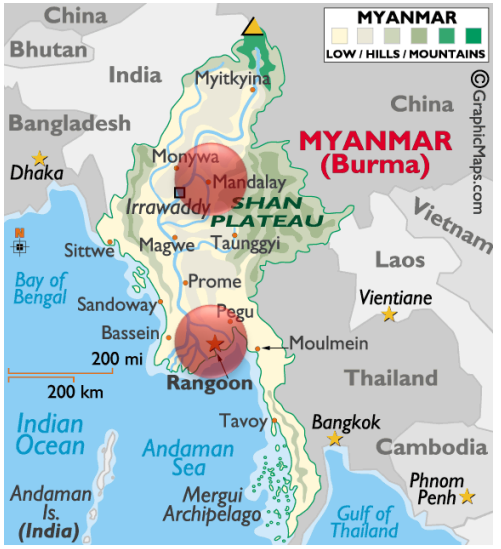
1 central lab, in Yangon and **1 regional lab** in **Mandalay**

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