



THE
STOP TB
DEPARTMENT

New global policy development: diagnosis of TB and strengthening the laboratories

Karin Weyer

Background



- Weaknesses of health systems one of the greatest challenges in TB control
- Laboratory services one of the weakest links
- Patients face economic barriers in accessing TB services in many countries
- Patient pathways to TB diagnosis often prolonged
- Lack of diagnostic capacity a crucial barrier preventing an effective response to the challenges of TB-HIV and drug-resistant TB

New global policies



- **Final**
 - Case finding (sputum smear investigations)
 - Case definition (sputum smear-positive cases)
 - Use of liquid culture
- **In preparation**
 - Second-line drug susceptibility testing



1. Case finding

- Endorsed by WHO Strategic and Technical Advisory Group (STAG), June 2007
 - Supported by key agencies and STP members
- ‘The number of specimens to be examined for screening of TB cases can be **reduced from three to two**, in places where a well-functioning external quality assurance (EQA) system exists, where the workload is very high and human resources are limited’**

2. Case definition



- Endorsed by WHO Strategic and Technical Advisory Group (STAG), June 2007
- Supported by key agencies and STP members

‘The revised definition of a new sputum smear positive pulmonary TB case is based on the presence of **at least one acid-fast bacillus (AFB) in at least one sputum sample in countries with a well functioning external quality assurance (EQA) system’**

Evidence and process



- Expert group meeting, September 2005
- Systematic review of 37 eligible studies
- Incremental diagnostic yield of 3rd specimen

1st specimen 85.8%	2nd specimen 11.9%	3rd specimen 3.1%
--	--	---

- Additional yield of revised case definition 17%

Mase S, Ramsay A, Ng N, Henry M, Hopewell PC, Cunningham J, Urbanczik R, Perkins M, Aziz MA, Pai M. Yield of serial sputum specimen examinations in the diagnosis of pulmonary tuberculosis: a systematic review. *Int J Tuberc Lung Dis* 2007;11(5):485-95.

Bonnet M, Ramsay A, Gagnidze L, Githui W, Guerin PJ, Varaine F. Reducing the number of sputa examined, and thresholds for positivity: An opportunity to optimize smear microscopy. *Int J Tuberc Lung Dis* 2007;

Criteria for implementation



- Well-established microscopy network
- Fully functional EQA programme
- Flexibility to allow country-specific adoption
- **International Standards for Tuberculosis Care**

Impact on service delivery



- Reduction in laboratory workload
 - Reduction in laboratory cost
- ▶ **Which should translate into**
- Improved quality of microscopy
 - Decreased delay in diagnosis and initiation of treatment
 - Decreased number of patients lost from diagnostic pathway

Next steps

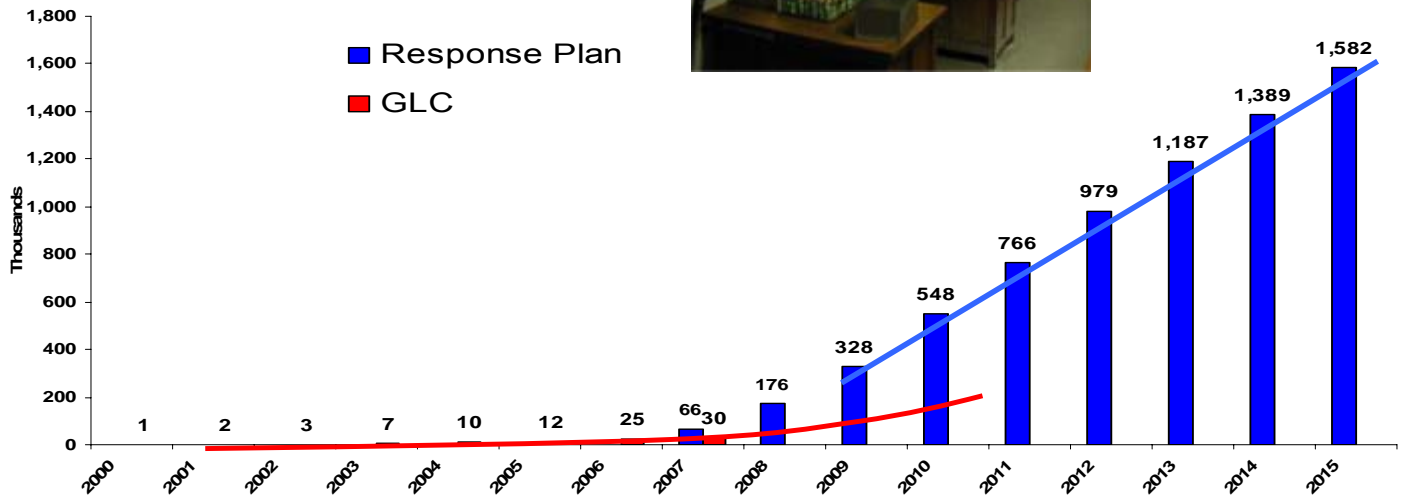
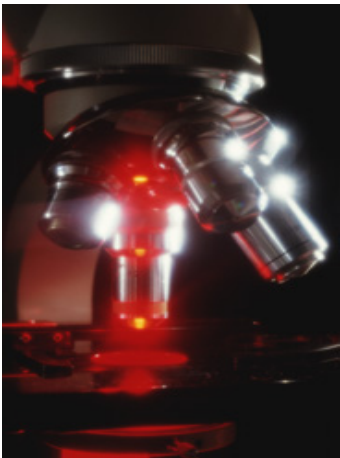


- Guidance and support to countries in modifying relevant normative, training, and recording and reporting tools
- Technical assistance to countries to upgrade and fully expand functional EQA systems for TB microscopy
- Monitoring and evaluation of the impact of the policy changes at country level
- Modeling of the impact of policy changes on laboratory capacity needs and costs

Strengthening laboratories



'From unimaginable...to indispensable'



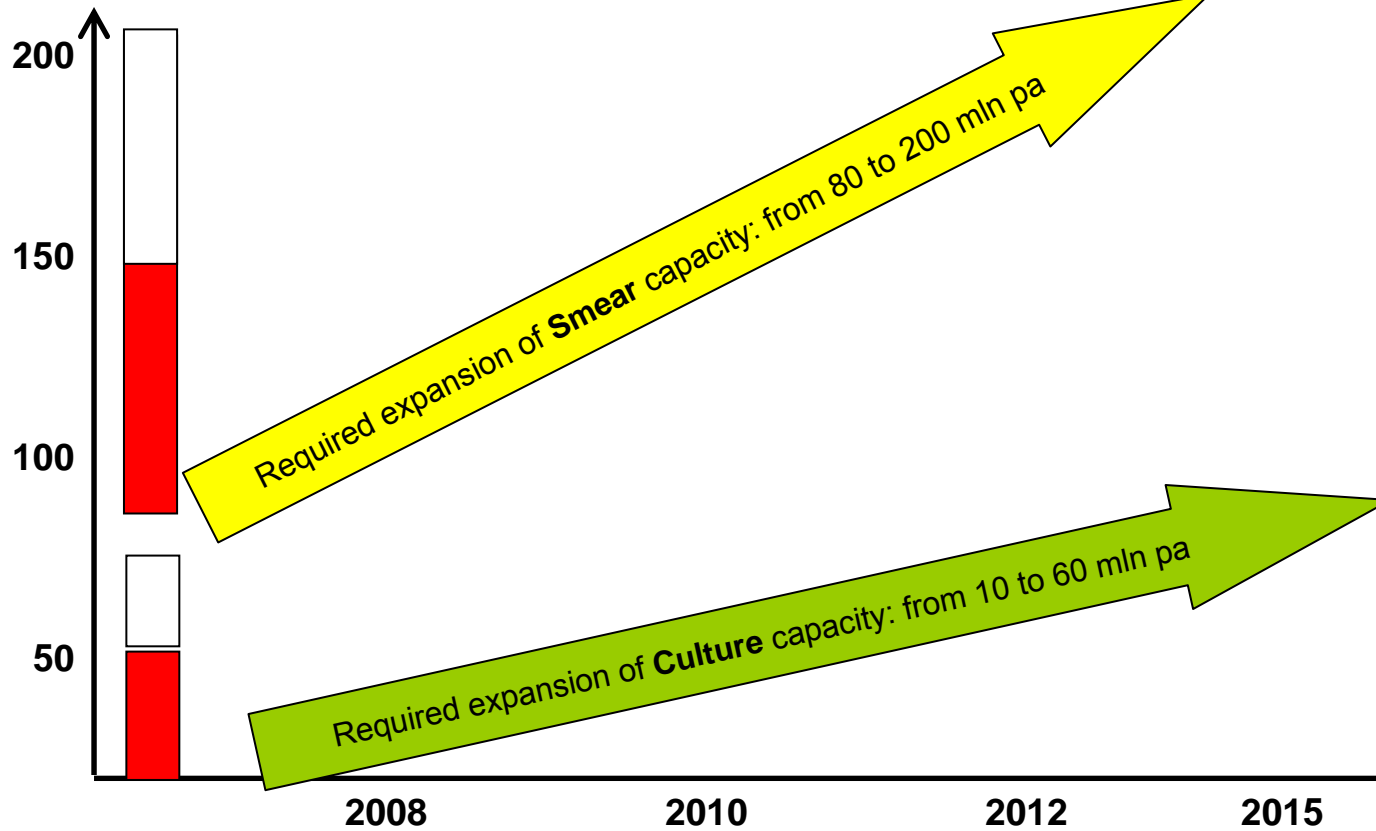
Global Laboratory Initiative



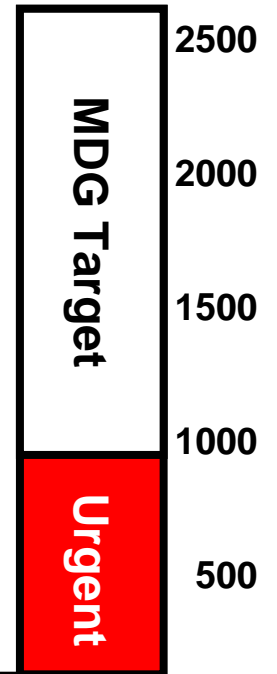
- WHA call for universal access to culture and drug susceptibility testing, May 2007
- Critical lack of TB laboratory capacity a global crisis
- Paradigm shift required in laboratory policy guidance, quality management and knowledge creation
- Global and integrated laboratory network
- *Endorsed by Stop TB Coordinating Board*

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

of tests
required (mln)



USD funding
required (mln)



GLI components



- Global policy guidance
- Laboratory advocacy and resource mobilization
- Laboratory capacity development and coordination
- Interface design
- Standardized laboratory quality assurance
- Coordination of technical assistance
- Effective knowledge sharing

GLI as an active facilitator of communication and provider of various global infrastructure services including guidance, assurance and interface connection activities – all synchronized to be a coherent network service

Key GLI activities

Guidance

- Laboratory manuals
- SLD-DST
- Training materials
- Resource mobilization
- National roadmap advice

Assurance activities

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

~100.000 smear lab centers
200.000-300.000 personnel

~8.000 advanced diagnostic centers
40.000 – 50.000 personnel

150 National Reference Labs

70 SLCS Members

WHO GLI Office

Knowledge Sharing

- Coordinating TA and training
- Organizing meetings
- Advanced communication technologies
- Knowledge resource network online

Interface Connection

- Matchmaking projects between countries and implementing partners
- National “roadmaps”
- Advocacy for lab funding
- Other disease networks

Capacity building

(expanding SRLN, building diverse and flexible national, regional, international consultants base, systematic and structured trainings)

Achievements



- SRLN has evolved to general capacity building
- Technical guidance transitioned from volunteer efforts to structured consensus process
- Increase in technical working groups
- Business plan development
- SLD-DST policy and technical guidelines
- Initial workplan of the secretariat developed
- Re-organization of secretariat and other key teams

Core group

WHO Secretariat, Union, FIND, CDC, Patient Community, National TB Programmes, Supranational & National Reference Laboratories, Observers, Liaisons with other working groups

Next Steps/Priorities



- Clear estimates for numbers of laboratories needed under different epidemiological and resource scenarios, with costs
- Modeling of anticipated impact of new technologies
- Finalization of business plan, supported by appropriate resource mobilization plan
- Prioritization and costing of key activities
 - Standard-setting
 - Building laboratory management capacity at global level
 - Creating conditions for accelerated laboratory strengthening, including private-sector involvement in countries
- Resource mapping and resource mobilization through global stakeholder/funder consultation in April 2008