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TB SLMTA Update

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Need for a strong TB diagnostic network

- The WHO End TB Strategy calls for:
  - Objective 1: Increase access to rapid and accurate detection of TB
  - Objective 2: Reach universal access to DST
  - **Objective 3: Strengthen the quality of laboratory services**
- A prerequisite for any national TB programme to reach these objectives is a quality-assured laboratory network equipped with rapid diagnostics
- NTRLs are the cornerstone of a strong TB diagnostic network and provide specialized testing, supervision of entire TB lab network, and perform testing for drug resistance and TB prevalence surveys.

Implementing quality management systems

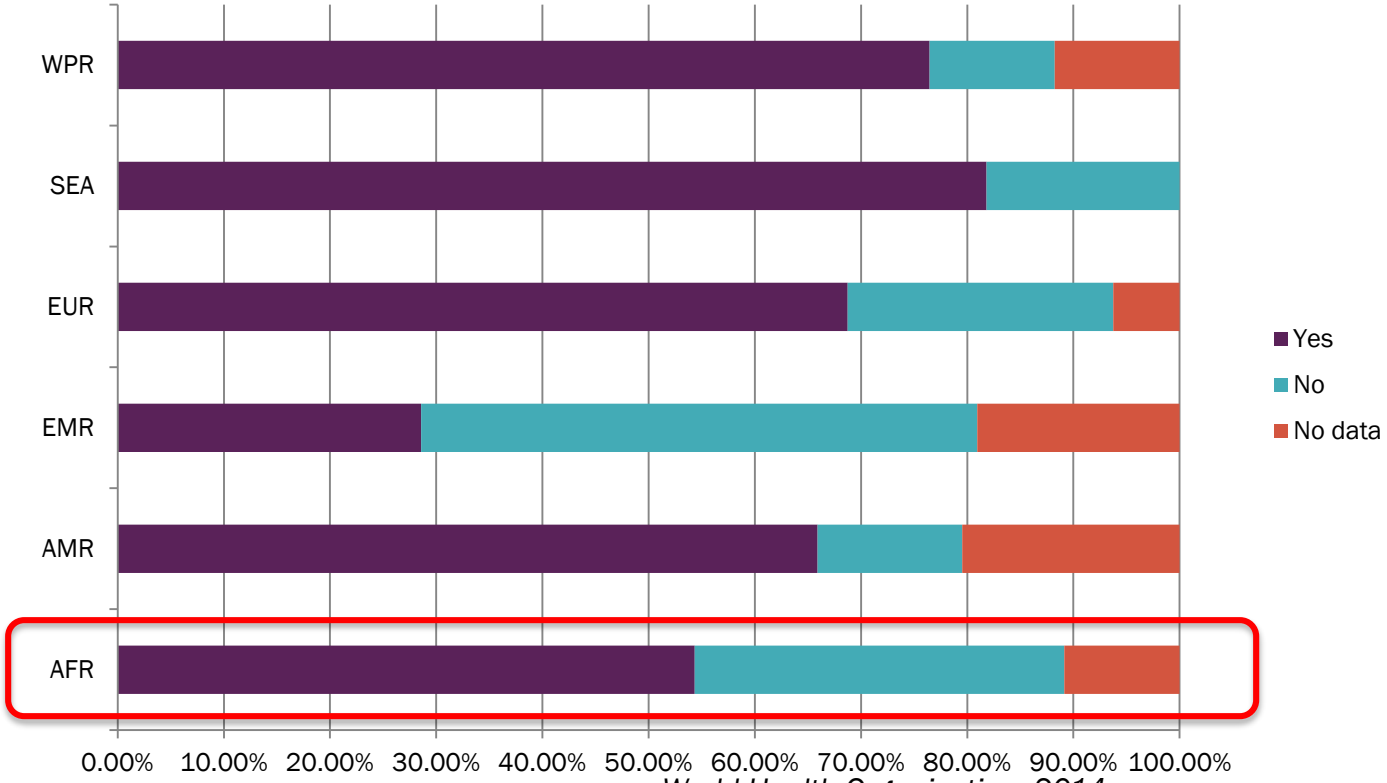
- Every laboratory conducting culture, LPA or phenotypic DST should be implementing a quality management system that aims to achieve accreditation according to international standards*
- NTRLs and regional referral labs
- National laboratory strategic plans should articulate the goals for TB diagnostic network quality improvement

**Target: 50% of labs by 2020, 100% of labs by 2025.*

WHO Framework of indicators and targets for laboratory strengthening under the End TB Strategy.

The status of laboratory quality systems at NTRLs

Has a formal quality management system towards achieving laboratory accreditation been implemented at the National Reference Laboratory?



World Health Organisation, 2014.
http://www.who.int/tb/country/data/download/en/

Why TB SLMTA?

Demonstrated impact of SLMTA approach

Limited participation of TB labs

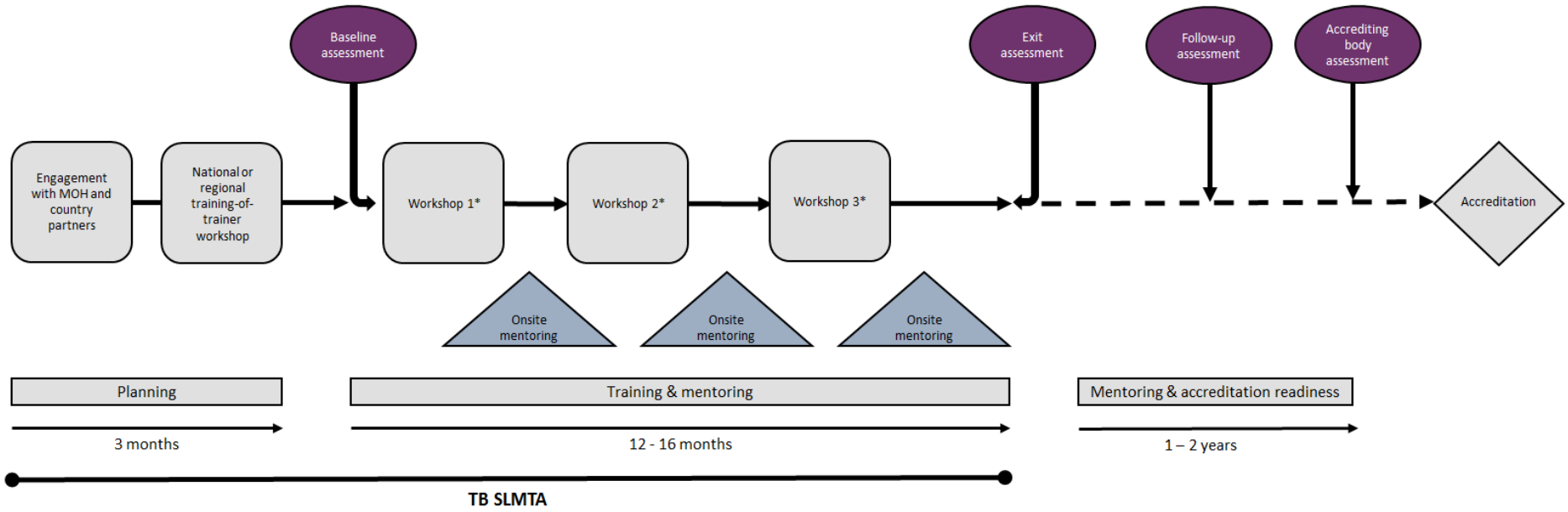
Identified need for focus on TB labs

Critical areas for QMS are different in TB labs e.g. biosafety, QA

Specialized TB mentoring to ensure success

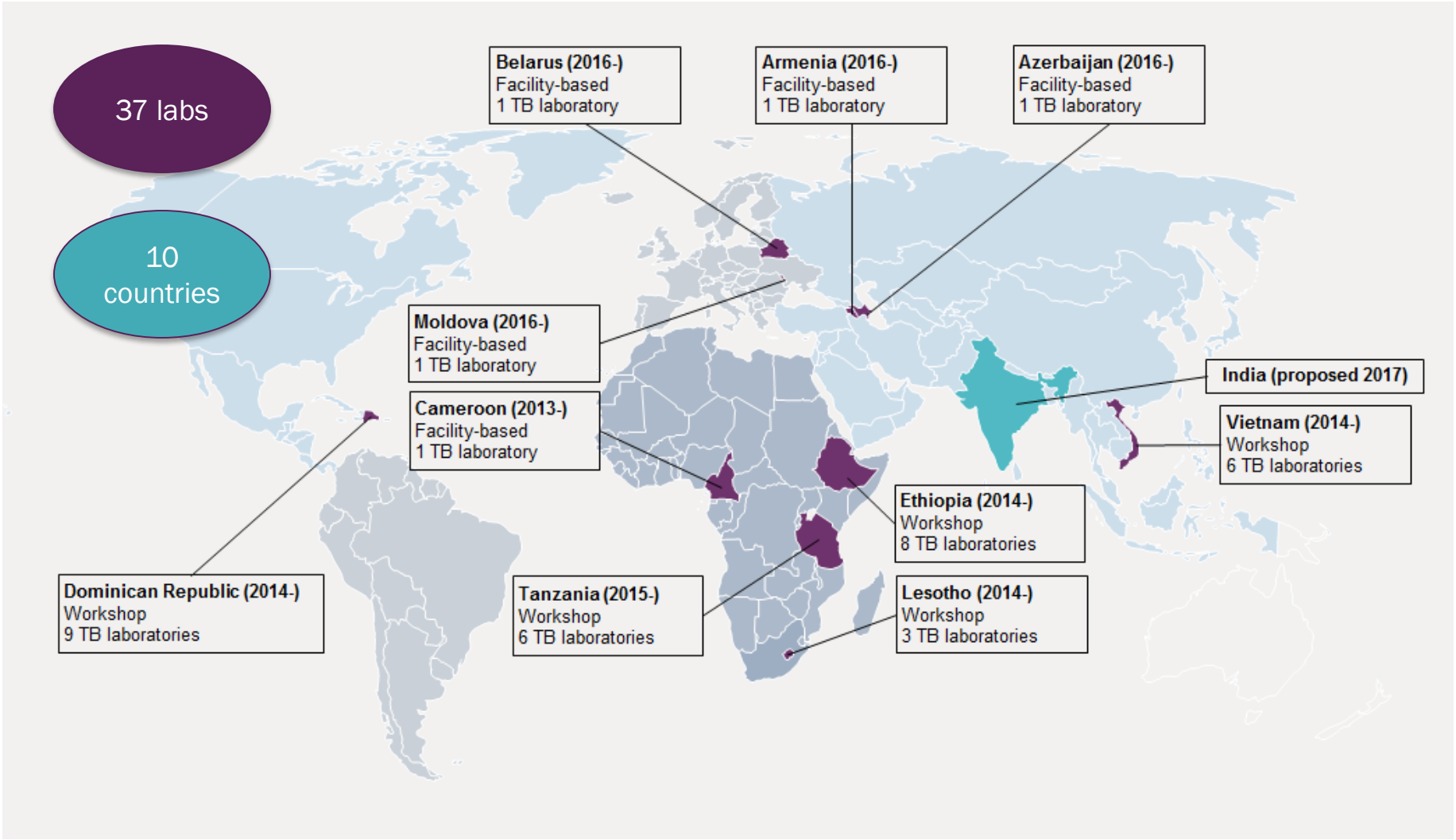
GLI Online tool available but no training and mentoring approach

Programme overview



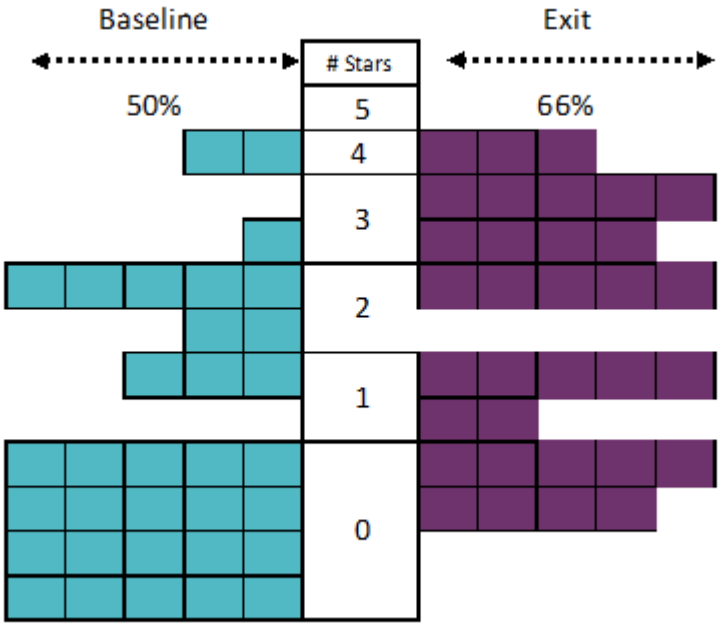
* Training block in facility-based model

TB SLMTA Implementation



TB SLMTA Impact

Comparing baseline and exit assessment star rating



- 37 labs in 10 countries enrolled
- 33 labs in 6 countries completed TB SLMTA
- Increase in average assessment score from 50% at baseline to 66% at exit **(+16%)**
- **34% reduction in labs scoring 0%**
- **27% increase in labs scoring 3 or more stars**

TB SLMTA Impact

Measurable improvement in all checklist sections

Success factors

- Motivated lab staff with sufficient time to focus on implementing QMS
- Strong support of senior management
- Mentoring is a critical component; mentors must have knowledge of implementing QMS and be trained in effective mentoring skills
- Trained assessors with TB lab expertise
- Integration with country SLMTA and other QMS activities for sustained support
- Adequate planning and budgeting: reaching accreditation is a multi-year process; careful planning and alignment of partners and funding will help to reach the end goal
- Although adequate resources are important to reach accreditation, many labs have made substantial quality improvements through hard work and dedication even with limited resources.

TB laboratory worker screening as part of the TB SLMTA Programme in Lesotho

- "I *worked in the TB Laboratory at National TB Reference Laboratory, Lesotho as Laboratory Technologist since 2007 and in the TB Culture section since 2008. I was diagnosed with TB in January 2015 through TB screening of all National TB Reference Laboratory (NTRL) staff. The NTRL was participating in TB SLMTA and the* ***TB Laboratory Quality Management Towards Accreditation Harmonized Checklist, that has a question on whether TB screening of laboratory staff was conducted, was being used to audit the laboratory.***

- ***The NTRL Biosafety guidelines also had a requirement that laboratory staff be screened for TB****. Before I was diagnosed I did not have TB symptoms. Although I knew that health care workers are at risk of TB infection more than anyone else as they are exposed to TB over long periods of time in the clinic and laboratory setting, my diagnosis with TB came as a shock to me and my colleagues.* ***This emphasizes the need for laboratories to plan for screening of their staff*** *and to screen the laboratory as scheduled.*

- *I also recommend that TB screening be conducted in 6 months as sputum sample is easy to collect. To other countries, TB laboratories and health care workers who have not started medical screening, I say act now. Prevention is better than cure. Treatment has also side effects especially during intensive phase*."

Mr. Lebohang Marai, medical technologist, CTRL

Resources

- 3 Master Trainers and 2 candidate Master Trainers available (based in Caribbean, Africa and SE Asia)
- 59 certified trainers, half of whom are actively implementing TB SLMTA
- TB SLMTA-trained staff at 3 WHO Supranational TB Reference Laboratories
- TB lab specialists with auditing training and experience
- Training materials in English, Spanish, Russian, Vietnamese
- Online or face-to-face training in TB lab biosafety and Introduction to quality management systems are available to complement TB SLMTA curriculum

Lessons learned and next steps

- Substantial quality improvement is possible in relatively short time frame from low baseline

- With well-targeted investment, accreditation of TB labs is an achievable goal
  - Support needed all the way to accreditation
  - Partnerships to expand support to other high burden countries
  - Strengthen and better coordinate mentoring and country level support
  - Focus on measuring impact of quality improvement on patient care – needed for government and donor advocacy

- With or without the specific target of accreditation, quality improvement of diagnostic services is the goal

Acknowledgements

- National Tuberculosis Programs and National Reference Laboratories
- Lab staff and management from participating TB labs
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- CDC country office staff: Dominican Republic, Lesotho, Viet Nam, Tanzania
- Heather Alexander, Katy Yao, CDC

World Health Organization

UKaid from the British people

Australian Aid

Australian Government Department of Foreign Affairs and Trade

EXPAND-TB

UNITAID

CDC Centers for Disease Control and Prevention

For more information on TB lab strengthening

TB Laboratory Accreditation

A training & mentoring programme

Quality-assured TB laboratory services are critical to provide timely, accurate and reliable results to support TB diagnosis, drug resistance testing, treatment monitoring and surveillance. Weak laboratory systems result in high levels of laboratory error that impact patient care and undermine confidence in laboratory services.

Implementation of a Quality Management System (QMS) leads to improved quality of diagnostic tests and better patient care. Reaching the End TB Strategy targets will rely on strengthening TB diagnostic networks, with a first essential step being strengthening quality systems of national TB reference laboratories (NTRLs) and regional referral laboratories that provide oversight of the whole laboratory network.

Recognizing the unique needs of TB laboratories, FIND developed a training and mentoring programme - Strengthening TB Laboratory Quality Management Towards Accreditation (TB SLMTA). The programme is based on the SLMTA approach developed by the U.S. Centers for Disease Control and Prevention (CDC), and incorporates TB-specific aspects of the Global Laboratory Initiative (GLI) Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) online tool.

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1

GLI-Africa and FIND symposium. Evolving partnerships for TB: diagnostic network strengthening in Africa. Mon 5 Dec, 8.00-10.00, Room 1.61-1.62.

GLI Africa symposium. Strengthening diagnostic networks in Africa. Wed 7 Dec, 15.30-16.30, Room 2.6.

Strengthening quality management systems in Africa (Poster), Thurs 8 Dec, 12.30-13.30, East/West Ballroom.

Contribution of online training to safety training in TB laboratories. Thurs 8 Dec, Room 2.6.

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