Eligibility and inclusion criteria for the SRLN

Christopher Gilpin

Global Consultation of the
TB Supranational Reference Laboratory Network

14-15th April 2010
WHO Geneva
Content

• Laboratory network and level of service
• Eligibility criteria
• Exercise
Laboratory Networks

• Core elements of laboratory services

– Laboratory infrastructure and maintenance;
– Equipment validation and maintenance;
– Specimen transport and referral mechanisms;
– Management of laboratory commodities and supplies;
– Laboratory information and data management systems;
– Laboratory quality management systems;
– Appropriate, adequate strategies and funding for laboratory human resource development.
Functions at the different levels of laboratory Services

- **Supranational Reference Labs**
  - Quality assurance DST
  - Reference methods for Culture and DST

- **Central (often National) Reference Laboratory**
  - Reference methods
  - First line DST
  - Network supervision

- **Regional Level**
  - Microscopy
  - Specimen processing
  - Training

- **District Level**
  - AFB microscopy

- **Peripheral Level**
Eligibility criteria for new candidate SRLs

- Officially recognized by the country health authority/MoH

- National Level Reference Laboratory supervising the national or sub-national network of lower level laboratories.

- Sufficient staffing, expertise, biosafety and equipment to perform AFB microscopy, culture, identification and susceptibility testing of MTB using phenotypic and molecular methods.

- Accredited to a National or International standard to perform TB testing

- Proven DST proficiency and sufficient workload levels (participated in at least 2 rounds of SRLN proficiency testing)

- Extra capacity (HR + equipment base) to support laboratories in other country/ies (as per new SRL TOR)

- Established or capacity to establish working relationships with the NRL in another country/ies through formal links
Issues to consider in linking SRLs with NRLs?

- Political implications / Political history
- Religious differences
- Country size and disease burden
- Appropriate geographical linkages
- Experience of the Head of the SRL

- MoU established between candidate SRL with ministry of Health of the supported country
Key messages

• Laboratories must develop DST proficiency for INH and Rif as a minimum

• Laboratories should develop DST capacity for fluoroquinolones and second-line injectables

• Appropriate biosafety measures needed for the different levels of testing.

• Quality assurance is critical
Scenario

A National TB Reference Laboratory Manager has requested a WHO Regional Office to be designated as an SRL.

The Regional Office says that your lab is NOT ready.

How can the NRL convince WHO that it is ready?
Analysis

Diagnostic methods and algorithms defined at different level of laboratory services (SOP)

DR-TB and TB/HIV Risk Group country algorithm for diagnosis and referral is defined

Correct tests

HR development Training Records

Correct training

Correct supplies

Culture /DST Molecular/ Microscopy consumables

Facility with Equipment Maintenance Biosafety

Correct facility and equipment

Linkage with technical assistance from an SRL

SRL Ready

Correct patient

Correct results

Correct quality

EQA 1\textsuperscript{st} / 2\textsuperscript{nd} line DST Internal QC Performance indicators

Functional QA laboratory network