SRL München-Gauting

Institute of Microbiology & Laboratory Medicine

IML red
(Dpt of research, education and development)

Kuratorium against Tuberculosis in the World

Achievements & Challenges
Safar N., 34 J, Tadschikistan
Support...  

- providing prompt and accurate results to patients  
- national TB laboratory strategy  
- laboratory worker protection / biosafety  
- quality management systems  
- human capacity building

Collaboration Agreement

1. Coordinate and prospectively communicate with Stop TB Partnership’s workgroup, the Global Laboratory Initiative (GLI) and its technical partners, National TB Reference Laboratories (NRLs) and National TB Programmes (NTPs) to facilitate implementation of WHO policy guidance on TB diagnostics and laboratory norms and standards, while respecting relevant national laws and regulations.
2. Support the integration of quality TB diagnostic testing for the purpose of providing prompt and accurate results to patients according to the International Standard of Care with national laboratory strategic laboratory plans incorporating cross cutting laboratory issues including supply management, specimen transport, and referral and human resource development.
4. Support development of monitoring and evaluation indicators starting with a good data management system
5. Provide guidance on and build capacity in quality management systems for a process towards NRLs achieving accreditation, nationally, internationally, or both.

Serve as the focal point for coordination of technical assistance to NRLs to enable:

1. Proficiency monitoring of the NRL performing drug susceptibility testing of *M. tuberculosis*
2. The provision of guidance to NRL microscopy networks on implementation of quality assured AFB microscopy
3. Support to countries with technical assistance to develop capacity and proficiency performing conventional and new WHO endorsed techniques including:
   a. Microscopy methods
   b. Culture and identification methods
   c. Drug susceptibility testing (phenotypic and molecular methods)
4. Assist and collaborate in the development drug resistance survey (DRS) protocols, data analysis, and quality assurance as required
5. Provision of testing against second-line drugs (for both patient management and surveillance purposes) as NRLs establish capacity
6. On-site technical training or in-house training of NRL staff as needed
7. Provision of operational research, if relevant, on the introduction of new laboratory tools
Established SRL-NRL partnerships

- Republic of Uzbekistan (MoH & NRL)
- Republic of Tajikistan (MoH & NRL)
- Republic of Kyrgyzstan (MoH & NRL)
- Republic of Turkmenistan (new partnership, LoA pending)
- Nepal
  - GENETUP (German Nepalese Tuberculosis Project)
  - NTC (National TB Center Thimi, Bhaktapur)
- Bolivia, Santa Cruz de la Sierra
  - Regional TB Center (Centro Bronchopulmonar I & II)
  - International Committee Of the Red Cross
SRL ToR TA providing prompt and accurate results to patients

Achievements

- Fully functional diagnostic service in all NRLs
- Increase of specimen throughput up to 6-fold
- EQA & certification of microscopy, culture, DST of FLD & SLD
SRL ToR

TA providing prompt and accurate results to patients

Challenges

- High staff turn-over
- Lack of functional logistical & communication systems
- Technical challenges e.g.
  - Interruptions of electricity supply
  - Water quality
  - Dust
National strategic laboratory plans

Achievements

- Kyrgyzstan: provision of TA with drafting national lab plan (collaboration project with KNCV / USAID)
  - Draft submitted in 09/2013 to KNCV for further review
  - Revised version under discussion with local partners (NRL, NTP)

- Tajikistan:
  - New diagnostic algorithm incl. new tools and forms (collaboration with FIND / USAID). Endorsed by NTP / MoH in 2013
  - Strategic plan for Xpert MTB / RIF implementation (collaboration with FIND). Endorsed by NTP / MoH in 2013

- Uzbekistan: updated assessment of laboratory network including review of national guidelines and standards in 2012
  - Systematic report with recommendations as guidance for strategic plan submitted to NTP / MoH in 2013
  - Draft of QMH for TB lab network submitted to WHO / MoH in 02/2014
Approval of drafted NLSP pending

Implementation challenged by
- unclear funding
- geographic / political heterogeneity of countries

Poor political commitment in two countries

Implementation of QMH in UZB challenged by
- Lack of approval by MoH
- Only 4 culture laboratories functional
SRL ToR
Biosafety
Achievements

- NRLs: BSL-3 containment areas established in all NRLs

- RRLs: Start of construction of new BSL-3 unit in Santa-Cruz de la Sierra, Bolivia, funded by
  - Kuratorium (80 TEUR)
  - German Ministry of International Collaboration (320 TEUR)
Example: New NRL of Kyrgyzstan in Modular Design

New modular design TB laboratory in Kyrgyzstan commissioned in 2013.
Example: New NRL of Kyrgyzstan in Modular Design

Example: New NRL of Kyrgyzstan in Modular Design
SRL ToR
Biosafety
Challenges

- Maintenance – Maintenance - Maintenance !!!!!!!!
  - Lack of political commitment
  - Lack of budget
  - Lack on in-country expertise
  - Lack of commitment of international partners to support maintenance
SRL ToR
Quality management system
Achievements

- SOPs implemented in NRLs of KGZ / TJK and UZB for
  - Diagnostic tests and methods including internal controls
    (~35 SOPs plus ~ 50 forms per lab)
  - Equipment including maintenance
    (~ 40 SOPs plus ~ 80 forms & electronic database)
  - Biosafety
    (2 SOPs plus 5 forms per lab)
  - HR capacity building and management
    (SOP plus 5 forms per lab)
  - Warehouse management
    (SOP plus electronic database)

- Quality management handbook developed for Uzbekistan
Quality management system

Challenges

- Lack of experience with QMS in partner countries on all levels
- Experienced internal / external auditors
- Lack of human / financial capacities for effective role out in the networks
- Lack of funding for accreditation process
Human capacity building by on-site visits / trainings

Achievements

Tajikistan: NRL & Culture Labs Trainings and WHO NTP Review

Uzbekistan: NRL & Samarkand Trainings and Assessment

Kyrgyzstan: new NRL Final inspection, Commissioning, Training

Bolivia: Starting construction of BSL Lab, new diagnostic algorithm, training, management supervision

Nepal: Management review, Biosafety QMS
Investing in our future

The Global Fund
To Fight AIDS, Tuberculosis and Malaria

UNITAID
Together to heal

TB CARE 1

Stop TB Partnership
TB REACH

KNCV
Tuberculosis Foundation
To eliminate TB

ICRC

MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

UNDP

UN

KFW
Entwicklungsbank

GLI
Rakhmat
Спасибо
Dhaanyabaad
धन्यबाद
Gracias
Thank you
Danke