

Laboratories and DR-TB

Meeting WG on MDR-TB

Tbilisi, September 2007

Questions to the WG on MDR-TB

1. Key factors to be addressed to build sufficient lab-capacity for scale up?
2. Role of new diagnostic tools?
3. How to expand capacity for SL-DST?
4. Implications of decentralizing
5. Which methodologies need further research and/or consensus-building?

Key factors to be addressed to build lab-capacity for scale up?

- Need for coherent plans to scale up quality controlled lab. networks – informed by international policy guidelines
- Technical assistance (long term and consistent) crucial for implementing new tools; consultant capacity (quality and quantity)
- International technical consensus - EQA (SOP, QC, supportive supervision)
- Human resources (quality and quantity)
- Explicit linkage between NTP and laboratory; link with the private labs and hospitals
- Coordination of efforts (multiple donors and partners, sometimes bringing contradicting messages)
- Minimal requirements for starting MDR-TB programme
- Linking SRNL network with more than 1 lab at national level (especially in large countries)

Role of new diagnostic tools?

- Rapid targeted diagnosis of rifampicin resistance (several options) and MDR-TB (HAIN-test)
 - FIND's led project: PCR based rapid screening test for R and H resistance directly from SS+ specimens
- Distinguish diagnosis and monitoring
- Cost effectiveness / decentralization
 - Need to re-emphasize "low tech" methods applicable at intermediate level
 - Use of LED fluorescent microscopy, especially for detection of SS- in high HIV prevalence setting
- How to implement new tools in routine programme conditions.

How to expand capacity for SL-DST?

- First of all consensus among experts on methodologies and clinical relevance for each of the drugs
 - WHO and Lab. subgroup are finalizing interim policy guidelines on SLD DST and technical manual for lab personnel (based on consensus among experts);
 - Aminoglycosides and fluoroquinolones;
 - other SLD – lack of standards; regimens should be based on history of drugs used in country and individual patient
- Need to implement proficiency testing for SLD
- Explicit linkage between laboratory, NTP and clinicians: make them understand importance and consequences of lab results (especially SLD DST and their *in vitro* reliability)
- Human resource development

Implications of decentralizing

- Minimal specimen-load to maintain quality
 - not less than 200 DST per year to maintain proficiency (may be other consideration, such as geographic, staff number and their qualifications, etc.)
- SLD DST still to be centralized
- Only in a functional and rational network, with appropriate responsibilities, transport of specimens, infrastructure
- In high HIV prevalence settings – maximal specimen load should also be recommended – to maintain quality

Which methodologies need further research and/or consensus-building?

- SL-DST ?
- Operational research to evaluate feasibility and reliability of rapid DST-methods
- Monitor with smear instead of culture (repeated, several smears, especially after culture conversion)?