

Minutes of 13th Lab committee meeting held on 16th February, 2008 at New Delhi

The 13th meeting of National Laboratory Committee of RNTCP was held at New Delhi TB Centre on 16th February, 2008. List of participants is annexed at Annexure-I.

DDG (TB) welcomed the participants and briefly highlighted the objectives and agenda for the meeting. The objectives of the meeting were to:

- Update the status of IRL strengthening in various states
- Review of DRS & DOTS-Plus activities
- Progress of SLD DST at NRLs
- Update on EQA activities

Review of accreditation process of 13 IRLs (The revised action plan for 13 IRLs is at Annexure II)

The status of accreditation process of 13 IRLs (Andhra Pradesh, Gujarat, Maharashtra, Kerala, Orissa, Tamil Nadu, West Bengal, Rajasthan, Uttaranchal, Chhattisgarh, Jharkhand, Haryana and Delhi) and status of other proposed state level IRLs were reviewed in detail by the committee.

CTD informed the committee that Bihar and Goa have not yet finalized the site for their IRLs and the matter has been taken up with STOs & Director, Health Services.

Status of accreditation process:

The culture and DST equipments are installed in 13 IRLs (Andhra Pradesh, Gujarat, Maharashtra, Kerala, Orissa, Tamil Nadu, West Bengal, Rajasthan, Uttaranchal, Chhattisgarh, Jharkhand, Haryana and Delhi) and the microbiologists are in place in these IRLs. The IRLs of Chhattisgarh & Uttarakhand are having one LT each and Jharkhand has not yet appointed LTs for their IRL.

Proficiency testing of the IRLs of Gujarat, Delhi and Andhra Pradesh with their respective NRLs are almost completed and the results will be available by March 2008. IRL, Nagpur (Maharashtra) had undertaken the proficiency testing with NTI and achieved more than 90% concordance for rifampicin and isoniazid susceptibility testing. However, the accreditation of this laboratory was delayed due to the transfer of trained LTs and the delay in complying with recommendations of the central team during the pre-accreditation visit in October 2007. It was informed by the microbiologist of IRL, Nagpur that the three transferred LTs are being deputed back to the IRL and also that the state has initiated action on the other recommendations.

The members felt that frequent transfer of trained technical staff from the IRLs may affect the proficiency of the laboratory as the accreditation process also tests the proficiency of the staff and therefore any change in the staffing pattern may affect this process.

IRL, Karnal (Haryana) has undertaken more than 100 cultures and 64 DST results are now available. The IRLs of Rajasthan, Tamil Nadu and Kerala have also started the culture & DST activities. The pre assessment visit to West Bengal was undertaken by the central team and culture & DST activities will be initiated soon.

Frequent and long power failures are an issue in many IRLs as noted during the pre-assessment visits.

It was informed by the microbiologist that all the four LTs at IRL, Chennai (Tamil Nadu) have resigned and now the IRL is functioning with two technicians from TRC.

Recommendations by the committee

- Accreditation of the laboratories should be reviewed if there is any change in the pattern of the trained staff and the states must ensure that once in place, trained laboratory staff at the IRL must remain in post for at least 3 years to ensure stability and proficiency of the laboratory.
- The accreditation of IRL, Nagpur can be restarted after the recommendations of the central team are complied with. However a second set of 20 panel cultures is to be sent to IRL, Nagpur by NTI , Bangalore to undertake a repeat panel testing in view of the recent staff reshuffling.
- All states which are now under the accreditation process must adhere to the time lines as given in the action plan(Annexure II). In addition to the 13 labs reviewed in this meeting, the 14th lab committee meeting should also review progress of the culture and DST labs in Punjab, Himachal Pradesh, Karnataka and Uttar Pradesh (Lucknow).
- The microbiologists of the IRLs should ensure that the procurement of consumables and reagents for the second year of culture and DST activities should be completed in a timely manner. The procurement will be done utilizing RNTCP funds with the respective state and should follow the World Bank procurement guidelines. In addition any required glassware should be procured by the state in a similar manner. The norms for this are at the rate of Rs 0.15 lakh per million population per year. The technical specifications of the required consumables and glassware are available on the RNTCP website at <http://www.tbcindia.org/Procurementnotices.asp>. These specifications should be strictly adhered to. The requirements for the IRL activities must be mentioned in the annual action plan. Once procured, the consumables need to be stored as per guidelines and that guidelines are adhered to while undertaking C&DST.
- Completion of walk in incubator room and cold room to be expedited at IRLs of West Bengal(Kolkata) and Rajasthan(Ajmer).
- The other states which are preparing for the establishment of IRLs should ensure to complete the civil works including electrical and water connections, walk in cold room and incubator room immediately so as to receive the C& DST equipments. The essential staff for the IRL also must be in place in all the proposed IRLs
- All states whose IRLs are in the process of accreditation as well as those who are preparing for receipt of equipments at their proposed IRLs must ensure to have backup electricity/generator and this requirement must be met from the funds available through the 'Additionalities Head' under NRHM during the preparation of state NRHM PIP.
- The process of exchange of cultures between IRL, Haryana and LRS Institute needs to be expedited once the requisite number of culture and DST isolates are available at the IRL. The IRL may send the list of cultures (with DST results available) to LRS Institute for selecting the strains and LRS also should send a set of 20 panel cultures to Karnal at the earliest.
- DRS for Orissa is an important activity under GFATM and if the state does not initiate the process soon, the Grant-in-Aid to the state may be affected. The central team visiting the state for pre-assessment must meet the Health Secretary and DHS and apprise them of this situation and draw a definite timeline for future activities.
- Regular supervisory visits must be undertaken by NTI, Bangalore for expediting the accreditation and DRS Survey in Orissa.

- Lack of LTs at IRL, Chennai will affect the progress of accreditation process and hence Director TRC, Chennai may discuss with Principal Secretary, Health, Tamil Nadu to resolve this issue at the earliest
- Frequent supervisory visits should be undertaken by the NRLs to their respective IRLs for giving technical guidance to the IRL staff during the accreditation process.
- Weekly follow up of the IRLs of Jharkhand, Uttarakhand and Chhattisgarh needs to be done by the NRL and CTD in view of the delay in establishment of IRLs in these states
- The committee also agreed that if any medical College in the state gets accredited, they may be utilized for undertaking culture & DST activities for DOTS plus treatment.
- Accreditation of PGI, Chandigarh, AIIMS & MGIMS, Wardha to be expedited as they are undertaking TB prevalence surveys under the programme
- All NRLs must adhere to the procedures for accreditation as laid out in the RNTCP accreditation documents.

DRS activities

- JALMA Institute, Agra is undertaking training for the district level staff at present and the pilot study for the DRS survey in western Uttar Pradesh is expected to start in March 08.
- CTD has received the draft protocol of the DRS study of Orissa which will be finalized after incorporating the comments given by CTD. However if the state laboratory is not accredited in the near future, as this being a time-bound GFATM activity, the use of the lab at NTI, Bangalore may be considered in order to complete this survey in the required timeframe.
- It was informed by NTI that the statistical validation of Maharashtra DRS study is being undertaken at TRC and the results will be available by April 08.
- New Clinical Information forms (CIF) sent by CTD should be used for the DRS surveys of AP, Orissa and Western UP.
- As highlighted by the Maharashtra DRS survey results, immediate action should be taken by the IRL microbiologists and NRLs to find out the reasons for high contamination and negativity in the culture examinations and to undertake corrective action as soon as possible.
- The laboratory experts opined that delay in transport of CPC specimens to the laboratories from the districts should be avoided and it should reach the lab within 7 days of collection of specimens.

Scheme for purchase of C&DST services from NGO/Private sector labs

In view of the challenges faced by RNTCP in establishing the network of culture and DST labs in public sector facilities and also to provide wider access to RNTCP diagnostic services for the large number of MDR-TB cases in the country, CTD has proposed to involve well equipped, functioning and quality assured culture and DST labs existing in the non-governmental sector (NGO and private) through a new RNTCP scheme. CTD informed the committee that this proposal was discussed and approved in the recent workshop on 'revision of NGO/PP Guidelines' and the recent meeting of the RNTCP National DOTS-Plus Committee.

Any well functioning mycobacterial culture & DST laboratory with adequate infrastructure, equipment and staff can apply under this proposed scheme. The lab should be willing to be accredited under the existing RNTCP accreditation mechanism and also must undergo routine

quality assurance (QA) and annual proficiency testing (PT) with RNTCP National reference laboratories.

The group felt that this proposal is a viable option for the programme. But adequate human resources should be made available in the NRLs to undertake the task of accreditation, provision for technical support etc. The committee also opined that the programme should explore the possibility of utilizing other WHO-SNRLs for conducting the proficiency testing.

Accreditation of Medical college mycobacterial culture and DST laboratories

To date the following medical colleges have applied for accreditation under RNTCP are: AIIMS, PGI Chandigarh, SMS Jaipur, CMC Vellore, and KGMU Lucknow. The respective NRLs have started the process for accreditation and AIIMS, PGI, CMC & SMS Jaipur have been requested to send a list of 100 cultures (with DST results) at the earliest.

The committee members opined that the accreditation of these medical colleges should be based on their support to programme related activities including treatment of MDR TB patients as per DOTS Plus guidelines.

Update on renewal of accreditation of LRS & JALMA with TRC

As per the minutes of the previous lab committee meetings, JALMA Institute and LRS Institute have initiated the process of accreditation with TRC (WHO-supranational laboratory). TRC has sent a set of 20 cultures to these two institutes for panel testing and the results will be available by May 08. TRC is also retesting the 10 cultures sent by JALMA as part of the proficiency testing.

Update on second line drug sensitivity testing

Dr. Ranjani from TRC presented the data on second line drug susceptibility testing on those isolates identified as MDR-TB during the state-representative DRS survey in Gujarat. The results showed 4% XDR-TB (7 out of 179) amongst previously treated TB cases. However no case of XDR-TB was found amongst the new cases. But the results also showed high fluoroquinolone resistance (any ofloxacin resistance of 26%) overall amongst the MDR-TB isolates. This was found amongst both new (20%, 7 / 37) and previously treated cases (28%, 45 / 179). Extremely high levels of ethionamide resistance were found again amongst both new and previously treated cases. However the lab experts noted that in vitro ethionamide resistance does not necessarily correlate well with in vivo resistance and also that it may be a cross resistance with isoniazid. The committee welcomed the further work being done by TRC on the matter of the ethionamide resistance in co-ordination with the WHO SNRL at Borstel, Germany.

Progress on capacity building of other NRLs in Second line DST

Two laboratory technicians from NTI, Bangalore have undertaken training at TRC in SLD DST. DDG advised that two lab technicians and one microbiologist from LRS and JALMA also to be sent to TRC for training.

It has been decided by the committee that a separate meeting of all NRLs with CTD may be called in April to discuss and review the accreditation process/proficiency testing of first line and second line DST, training methods etc.

Update on Dr Hilleman's visit to TRC

A brief update on the visit of Dr Hilleman from Borstel laboratory in Germany (another WHO supranational laboratory) to TRC was presented by Dr Fraser. The purpose of this visit was

- to assist the culture and drug susceptibility testing laboratory at TRC, Chennai and review and update existing SOP for Drug Susceptibility Testing;
- To assist TRC in the finalization of critical concentrations, resistance definitions and reporting for second-line anti-tuberculosis drug (SLD) sensitivity testing in line with existing international recommendations; and
- To assist in reviewing, and updating if necessary, the QC and QAP procedures for SLD sensitivity testing.

It is hoped that Dr Hilleman will return for a second visit to India in June 2008. It is planned that in addition to revisiting TRC, Dr Hilleman will also visit the other 3 NRLs.

Use of liquid culture in the programme

DDG informed the group that, in collaboration with FIND, RNTCP evaluation studies on liquid culture (MGIT) are being done at three sites -AP, Gujarat and LRS, and only after detailed analyses of the evaluation study results from these sites, would CTD consider expansion of the same technique to other sites. It was opined by the laboratory experts that liquid culture methods have various technical and operational difficulties, and is to be recommended only for labs which are already having well established solid media C&DST facility.

Dr. Narayanan opined that whether liquid culture is to be used under the programme is to be decided at the National level. To look into the many operational and technical challenges, multi-centric field level evaluation studies are very much required. A common protocol may be developed for these evaluation studies at different sites.

The group felt that at present solid media culture technique (LJ) remains the gold standard for MDR-TB diagnosis. Though molecular tests, such as Hains test, may be shown to be a feasible option for rapid diagnosis of MDR cases at state level labs, liquid culture is feasible only at reference labs where BSL-III facilities are available. The committee felt that RNTCP should also look into the operational feasibility of other liquid culture methods currently available internationally. For example the MODS test is faster than MGIT, but again is a relatively complex test, at present is not standardized and needs to be handled carefully in for bio-safety.

New Diagnostic methodologies

The committee requested that CTD in co-ordination with the RNTCP laboratory network, may organize a 1 or 2 day consensus building workshop on the evaluation and demonstration of new diagnostic methodologies.

Culture and DST Laboratory Performance Indicators

Dr. Dewan made a presentation on the draft document on 'Culture and DST laboratory performance indicators'. These proposed standardized indicators can help in the supervision and monitoring of laboratory quality, and inform on required improvements in quality over time. Systematic assessment of laboratory quality should be in-built into the system, and quality should resistant to changes in personnel. Culture and DST lab staff should understand that their service quality will be subject to ongoing monitoring, in the form of quarterly reports and an annual round of proficiency evaluation. Indicators proposed include:

- The percentage of samples inoculated in one quarter reported as *Mtb.* Complex
- The correlation between positive smears and positive cultures in one quarter
- The percentage of cultures contaminated in one quarter [culture system specific]
- The percentage of cultures reported as non-tuberculous mycobacterium (NTM) in one quarter
- Performance on Proficiency Testing (PT) in Drug Susceptibility Testing (DST)
- Performance on Drug Susceptibility Testing (DST) by re-testing of randomly selected isolates

The committee finalized the document with minor changes and suggested that NRLs may pilot test these indicators.

Update on EQA activities

The NRLs presented the status of EQA activities on the EQA reporting format. The status of EQA implementation by states allotted to NTI, TRC and LRS Institute are appended at Annexures-III, IV and V respectively. During the quarter, NTI, Bangalore visited Rajasthan, Pondicherry & West Bengal, LRS Institute, Delhi visited Mizoram, Haryana & Assam and TRC, Chennai made visits to Chhattisgarh, Goa & Kerala as part of annual NRL EQA onsite evaluation. Presentations were made by the respective NRLs regarding their field visits and other activities undertaken during the previous quarter.

Defective microscopes are a problem in many DMCs as observed during the NRL OSE visits. DDG reiterated that the responsibility of maintenance of microscopes rests with the LTs and MO-DMC.

Officials from TRC informed that Chhattisgarh has not sent the action taken report on the recommendations of the NRL-OSE visit conducted by TRC team in October 2007 inspite of repeated reminders to them. DDG requested Director, TRC, Chennai to send a letter to Director Health Services/Health Secretary, Chhattisgarh regarding this issue.

Protocol for usage of patient wise smears for panel testing

Dr.Selvakumar presented a protocol for using patients' smears for panel testing instead of manufactured smears. The process for preparing panel slides required a high degree of technical proficiency and a reference laboratory with appropriate equipment including a biosafety cabinet. If the laboratory has insufficient technical expertise to prepare manufactured slides using NALC procedure, patients' samples may be used for this purpose. Advantage of this method includes low workload, no requirement for special equipments and the panel sets can be prepared easily. Disadvantage of this process is the lack of consistency in panel sets and the slides with discrepant result will need to be reviewed in order to ensure the initial reading of the patient smear was correct.

The committee approved the protocol and suggested that this may be sent to the IRLs for usage (protocol attached at Annexure VI).

Indicators for EQA data analysis

NTI, Bangalore has presented a preliminary draft on the 'proposed indicators for EQA data analysis and interpretation' and 'analysis on currently available EQA data'. The committee appreciated the efforts taken by the NTI & TRC for developing these indicators. The committee suggested that further modifications would be required for developing these

indicators for National, state and district level usage and more detailed analysis and interpretation of the data may be possible after receiving the EQA data of 2007 from the states.

Revised STLS OSE Checklist

As per the decision in the previous lab committee to simplify the STLS OSE checklist of EQA protocol, a revised/simplified OSE checklist was presented by TRC. The committee suggested that this checklist may be pilot tested at Tiruvallur district, TN by TRC.

List of Participants

1. Dr. L. S. Chauhan, DDG (TB)
2. Dr.P.R.Narayanan, Director, TRC, Chennai
3. Dr. Prahlad Kumar, Director, NTI, Bangalore
4. Dr.Vishwa Mohan Katoch, JALMA,Agra
5. Dr.Saxena,CMO(TB),CTD
6. Dr.S.K.Chaturvedi, CMO,CTD
7. Dr.Selva Kumar, TRC,Chennai
8. Dr. Ranjani Ramachandran, TRC Chennai
9. D.V.K.Dhiman,CMO,CTD
10. Mr. Anand, NTI, Bangalore
11. Ms.Hema Sundaram, NTI, Bangalore
12. Ms. Reena, NTI, Bangalore
13. Dr.Sandeep Meharwal, LRS, New Delhi
14. Dr S. Sahu, NPO (TB), WHO India
15. Dr Fraser Wares, MO(TB), WHO India
16. Dr.Puneet Dewan , MO(TB), WHO-SEARO
17. Dr.Sonia Mallik, Microbiologist, NDTB Centre
18. Dr.Mrs.Dongre, Microbiologist, IRL, Nagpur
19. Dr.Praveen Shanker, Microbiologist, STDC, Trivandrum
20. Dr.N.Joshi, Microbiologist, STDC, Ahmedabad
21. Dr.Sant Lal Verma, Microbiologist, IRL, Karnal
22. Dr.Ashok Gupta, Microbiologist, Karnal
23. Dr.Madhumati, Mmicrobiologist,IRL, Chennai
24. Dr.Tarun Tapni, Microbiologist, IRL,,Ajmer
25. Dr.Somthirta B.Ganguly, Microbiologist, IRL, West Bengal
26. Dr. Sarabjit Chadha, WHO-RNTCP Consultant, Central TB Division
27. Dr.Geetanjali Sharma, WHO-RNTCP Consultant, Central TB Division
28. Dr.Mala Srikanth, WHO-RNTCP Consultant, Central TB Division
29. Dr Sheena Susan George, WHO-RNTCP Consultant, Central TB Division

Update& Revised Action Plan for Accreditation of culture labs

State(Establishment of IRL as per PIP)	NR L	Activities/ Remarks	Timeline (As per May 2006)	Timeline(as on 31 st March, 2007)	Revised action plan(28 th September 2007)	Revised as on 16 th Feb 08)
Gujarat (2005)	TR C	1. Training of Microbiologist & LTs in C&DST		April 2007		
		2.Bio-safety certification of equipments	May 2006	April 2007		
		3.Fill up the application form & send to NRL& CTD	Sep 2006	April 2007		
		4.NRL pre assessment visit to IRL	Sep 2006	May 2007		
		5.Starting of cultures(Pilot study)	----	May 2007		
		6. Send cultures / Exchange of strains with NRL(NRL ↔ IRL)	May 2006	July-August 2007	September/October 07	November 07
		7. Results of proficiency testing	Aug-Sept 06	October 2007	December 2007	March 08
		8. Accreditation visit by NRL	Sept 2006	November 2007	January 2008	March 2008
		9. Time for corrective actions	Oct-Nov 2006	December 2007	Jan-Feb 2008	April 2008
		10. Accreditation	Nov 2006	Dec 07/Jan08	Feb-march 2008	April 2008
		11. Intake of first MDR suspect	Nov 2006	March 2007 (at NRL)		March 07
		12. First MDR-TB patient registered for Cat IV treatment	Jan 07	May/June 2007		August 07
Mahara	NT	1. Bio safety Certification of the	May 06	April-May	October 2007	October 2007

shtra (2005)	I	equipments		2007		
		2.Fill up the application form & send to NRL& CTD	Nov 06	May 2007		
		3.NRL pre assessment visit to IRL	Nov 06	June 2007		
		4.Pilot study started		Feb 2007		
		5. Send existing cultures / Exchange of strains with NRL(NRL ↔ IRL)	July 06	February 2007		
		6. Results of proficiency testing	Sept-Nov 06	May 2007		December 07
		7. Accreditation visit	Nov 06	June 2007	October 2007	October 2007
		8. Time for corrective actions	Dec 06-Jan 07	June 2007	November 2007	Nov –Feb 08
		9. Accreditation	Jan 07	July 2007	December 2007	March 08
		10. Intake of first MDR suspect	Jan 07	March 2007 (at NRL)		March 07
		11. First MDR-TB patient registered for Cat IV treatment	April 07	May/June 2007		September 07
Andhra Pradesh (2005-2006)	TR C	1. Installation of equipments	June 06	April 2007		May 2007
		2.Biosafety certification of equipments		April 2007		May 2007
		3.Fill up the application form & send to NRL& CTD	Dec 06	April 2007		June 2007
		4.NRL pre assessment visit to IRL	Dec 06	May 2007		June 2007
		5. Pilot study started (on existing BS Cabinet)	?	Jan 2007		
		6. Send existing cultures / Exchange of strains with NRL(NRL ↔ IRL)	Sept 06	April/may 2007	October 2007	Nov 2007
		7. Results of proficiency testing	Nov-Dec06	July 2007	December 2007	Feb 2008
		8. Accreditation visit	Dec 06	August 2007	December 2007	March 08
		9. Time for corrective actions	Jan-Feb 07	September	Dec-Jan 2008	March 08

				2007		
		10. Accreditation	March 07	October 2007	Dec-January 2008	April 08
		11. Intake of first MDR suspect	April 07	November 2007	January 2008	April 08
		12. First MDR-TB patient registered for Cat IV treatment	July 07	January 2008	March 2008	June 08
Kerala(2005-2006)	TR C	1. Training for the untrained LTs in C& DST		April/May 2007	October 2007	
		2. Installation of equipments	June 06	April 2007	June 07	
		3. Bio safety certification of equipments		May 2007	June 07	
		4. Fill up the application form & send to NRL& CTD		May 2007	June 07	
		5.NRL pre assessment visit to IRL	Dec 06	June 2007	August 07	
		6.Starting of cultures(Pilot study)		June 2007	November 2007	January 08
		7. Send cultures / Exchange of strains with NRL(NRL↔IRL)	Sept 06	September 2007	January 2008	May 08
		8. Results of proficiency testing	Nov 06	November 2007	April 2008	August 08
		9. Accreditation visit	Dec 06	December 2007	April-May 2008	September 08
		10. Time for corrective actions	Jan-Feb 07	January 2008	May 2008	
		11. Accreditation	March 07	February 2008	May-June 2008	October 08
		12. Intake of first MDR suspect	April 07	March 2008	June 2008	Aug/Sept 08
		13. First MDR-TB patient registered for Cat IV treatment	July 07	June 2008	August 2008	Nov/Dec08

Haryana(2006-2007)	LRS	1. Training of untrained LTs in C&DST	July 06	May 2007	October 2007	
		2. Installation of equipments	August 06	April 2007	May 07	
		3.Bio safety certification of		April 2007	October 07	

		equipments				
		4. Fill up the application form & send to NRL& CTD	March 07	May 2007	Yes	
		5.NRL pre assessment visit to IRL	Mar 07	June 2007	June 07	
		6.starting of cultures(Pilot study)		June 2007	September 07	Cultures ongoing from Sept 07
		7. Send cultures / Exchange of strains with NRL(NRL↔IRL)	Dec 2006	September 2007	Jan 2008	March 08
		8. Results of proficiency testing	Feb-Mar 07	November 2007	April 08	June08
		9. Accreditation visit	April 07	December 2007	April-may 08	July 08
		10. Time for corrective actions	May-June 07	January 2008	May 08	
		11.Accreditation	June 07	February 2008	May-June 2008	August 08
		12. Intake of first MDR suspect	July 07	March 2008	Jan 08(samples to be send to LRS)	April 2008
		13. First MDR-TB patient registered for Cat IV treatment	October 07	June 2008	March-April 2008	June 2008
Delhi(2005-2006)	LRS	1. Training of Microbiologist & LTs in C&DST		April 2007	Yes	
		2.Bio-safety certification of equipments		April 2007	Yes	
		3.Fill up the application form & send to NRL& CTD		May 2007	Yes	
		4.NRL pre assessment visit to IRL		June 2007		
		5.Starting of cultures (pilot study)		June 2007	Yes	
		6. Send cultures / Exchange of strains with NRL(NRL ↔ IRL)		September 2007	September 2007(October)	Under Proficiency testing with LRS
		7. Results of proficiency testing		November 2007	December 2007	Feb 08
		8. Accreditation visit by NRL		December	Dec-Jan 2008	March 08

				2007		
		9. Time for corrective actions		January 2008	Jan 08	
		10. Accreditation		February 2008	Feb 2008	April 08
		11. Intake of first MDR suspect		March 2008	March 2008	April 08
		12. First MDR-TB patient registered for Cat IV treatment		June 2008	June 2008	June/July 08
Rajasthan (2005-2006)	NTI	1. Training of Microbiologists & LTs in C& DST		April 2007	Yes	
		2. Installation of equipments		April 2007	August	
		3. Bio safety Certification of the equipments		May 2007	Yes	
		4. Fill up the application form & send to NRL& CTD		June 2007	Yes (September 07)	
		5. NRL pre assessment visit to IRL		July 2007	October 2007	October 07
		6. Starting of cultures (pilot study)		July 2007	November 07	November 07
		7. Send cultures / Exchange of strains with NRL (NRL ↔ IRL)		October 2007	Feb 2008	April 08
		8. Results of proficiency testing		January 2008	May 2008	July 08
		9. Accreditation visit		February 2008	June 2008	August 08
		10. Time for corrective actions		March 2008	July 2008	September 08
		11. Accreditation		April 2008	August 2008	October 08
		12. Intake of first MDR suspect		May 2008	September 2008	May 08
		13. First MDR-TB patient registered for Cat IV treatment		August 2008	December 2008	Aug/Sept 08
Tamil Nadu (2005-2006)	TRC	1. appointment of 3 LTs & their training		June 2007	October 2007	
		2. Installation of equipments		April 2007	June 07	
		3. Biosafety certification of equipments		April 2007	Yes	
		4. Fill up the application form & send to NRL& CTD		May 2007	September 07	

		5.NRL pre assessment visit to IRL		June 2007	October 2007	November 07
		6. Starting of cultures(Pilot study)		June 2007	November 07	December 07
		7. Send cultures / Exchange of strains with NRL(NRL ↔ IRL)		September 2007	Feb 08	April 08
		8. Results of proficiency testing		October 2007	June 2008	July 08
		9. Accreditation visit		November 2007	July 2008	August 08
		10. Time for corrective actions		Dec 2007	August 2008	September 08
		11. Accreditation		Jan 2008	September 08	October 08
		12. Intake of first MDR suspect		Feb 2008	September 08	October 08
		13. First MDR-TB patient registered for Cat IV treatment		May 2008	December 2008	Jan 09
Orissa a (2005 - 2006)	NTI	1. Installation of equipments	August 2006	April 2007	October 2007	November 2007
		2. Bio safety certification of equipments	DRS plan was made in May 06	May 2007	October 2007	November 2007
		3. Fill up the application form & send to NRL& CTD		May 2007	November 2007	January 2008
		4.NRL pre assessment visit to IRL		June 2007	December 2007	Feb 2008
		5.Starting of cultures(Pilot study)	Sept 06	June 2007	January 08	March 08
		6. Send cultures / Exchange of strains with NRL(NRL↔IRL)		September 2007	April 08	June 08
		7. Results of proficiency testing		November 2007	June 08	September 08
		8. Accreditation visit		December 2007	July 08	October 08
		9. Time for corrective actions		January 2008	August 08	
		10. Accreditation		February 2008	September 08	November 08
		11. Intake of first MDR suspect		March 2008	October 08	December 08
		12. First MDR-TB patient registered for Cat IV treatment		June 2008	Jan 09	March 09
	NTI	1.Posting of Microbiologist		May 2007	July 07	

West Bengal (2005 - 2006)	NTI	1.Posting of Microbiologist		May 2007	July 07	
		2.Training of microbiologist & LTs		June 2007	September07	
		3. Installation of equipments		May 2007		November 2007
		4.Bio safety certification of equipments		May 2007	yes	Nov 07
		5. Fill up the application form & send to NRL& CTD		July 2007	October 07	December 07
		6.NRL pre assessment visit to IRL		August2007	November 07	Jan 08
		7.starting of cultures(Pilot study)		September 2007	November 07	Feb 08
		8. Send cultures / Exchange of strains with NRL(NRL↔IRL)		December 2007	March 08	June 08
		9. Results of proficiency testing		February 2008	June 08	September 08
		10. Accreditation visit		March 2008	July08	October 08
		11.Time for corrective actions		April 2008	August 08	
		12.Accreditation		May 2008	September 08	November 08
		13. Intake of first MDR suspect		June 2008	September 08	October 08
		14. First MDR-TB patient registered for Cat IV treatment		September 2008	December 08	Dec 08/Jan 09

			Time line(as on March 07)	Revised(Sept 07)	Revised on 16 th Feb 08
Jharkhand (2005-2006)	NTI	1. Posting of LTs in IRL	April/May 2007	October07	Not yet
		2.Training of Microbiologists& LTs in C& DST	May /June 2007	(September-MB)	
		3.Installation of equipments	May 2007	October 07	Feb 08
		4.Bio-safety certification of equipments	May 2007	November 07	Feb 08
		5.Fill up the application form & send to NRL& CTD	July 2007	December 07	April 08
		6.NRL pre assessment visit to IRL	August 2007	January 08	
		7.Starting of cultures (pilot study)	September 2007	January 08	To be decided depend on the

					posting of LTs
		8. Send cultures / Exchange of strains with NRL(NRL ↔ IRL)	December 2007	April 08	
		9. Results of proficiency testing	March 2008	July08	
		10. Accreditation visit by NRL	April 2008	August 08	
		11. Time for corrective actions	May 2008	September 08	
		12. Accreditation	June 2008	October 08	
		13. Intake of first MDR suspect	July 2008	October08	
		14. First MDR-TB patient registered for Cat IV treatment	October 2008	Jan 09	
Uttaran chal (2005- 2006)	LR S	1. Appointment of Microbiologist& LTs in IRL	??June 2007	October 07	January 2008(MB+1LT)
		2.Training of Microbiologists & LTs in C& DST	?August 2007	November 07	Feb-March 08
		3.Completion of civil works	May 2007	June 07	
		4.Installation of equipments	June 2007	Yes	
		5.Bio safety Certification of the equipments	June 2007	Yes	
		6.Fill up the application form & send to NRL& CTD	?August 2007	December07	April 08
		7.NRL pre assessment visit to IRL	September 2007	January 08	April 08
		8.Starting of cultures(pilot study)	October 2007	February 08	May 08
		9. Send cultures / Exchange of strains with NRL(NRL ↔ IRL)	January 2008	May 08	August 08
		10. Results of proficiency testing	April 2008	August 08	November 08
		11. Accreditation visit	May 2008	September 08	December 08
		12. Time for corrective actions	June 2008	October 08	
		13. Accreditation	July 2008	November 08	Jan09
		14. Intake of first MDR suspect	August 2008	November08	Jan 09
		15. First MDR-TB patient registered for Cat IV treatment	November 2008	Feb 09	April 09
Chhatti	TR C	1. appointment of Microbiologist & LTs	??June 2007	December07	Microbiologist& 1 LT

sgarh (2005- 2006)	2. Training of the staff	??July 2007	October 07	Feb 08-march 08
	3.Installation of equipments	April/May 2007	Yes	
	4.Biosafety certification of equipments	May 2007	Yes	
	5.Fill up the application form & send to NRL& CTD	August 2007	November 07	April 08
	6.NRL pre assessment visit to IRL	September 2007	December 07	May 08
	7. Starting of cultures(Pilot study)	October 2007	December07	May 08
	8. Send cultures / Exchange of strains with NRL(NRL ↔ IRL)	January 2008	April 08	August 08
	9. Results of proficiency testing	April 2008	July 08	December 08
	10. Accreditation visit	May 2008	August 08	Jan 09
	11. Time for corrective actions	June 2008	September 08	
	12.Accreditation	July 2008	October 08	Feb09
	13 Intake of first MDR suspect	August 2008	November 08	Feb 09
	14. First MDR-TB patient registered for Cat IV treatment	November 2008	Feb 09	May 09

EQA Status in the Country at the end of 4th Quarter 2007

States							EQA Training status				Panel test slides preparation	Reporting - district to IRL						Date
	STDC Director		Microbiologist		LTs at IRL/STDC		DTOs		STLS			Annex E		Annex M		Annex G		
	In place	Trained in EQA	In place	Trained in EQA	No. in place	Trained in EQA	No. in place	Trained in EQA	No. in place	Trained in EQA	Yes/No	No. recd last qtr	No. expected	No. recd last qtr	No. expected	No. recd	No. expected	
Bihar	1	no	1	1	2	2	38	21	170	142	Yes	31	31	31	31		1	
Jammu Kashmir	1	no	1	1	3	2	8	5	22	22	No	20	24	248	261		1	
Jharkhand	1	1	1	1	nil	nil	20	12	62	59	No	48	66	48	66		1	
Karnataka	1	1	1	1	4	3	30	28	124	120	Yes	84	84	84	84		1	
Madhya Pradesh	1	1	1	1	5	5	45	39	142	136	Yes	45	135	45	135		1	
Maharashtra	1	1	1	1	4	4	48	48	209	209	Yes	106	144	106	144		1	
Orissa	1	Yes	1	1	3	3	30	27	100	97	Yes	49	93	13	31		1	
Pondicherry	1	1	1	1	4	4	4	4	5	5	Yes	3	3	3	3		1	
Rajasthan	1	1	1	1	3	2	31	31	140	133	Yes	31	32	32	32		1	
West Bengal	1	1	1	no	3	2	19	19	185	178	Yes	57	57	57	57		1	
Total	10	7	10	9	31	27	273	234	1159	1101		474	669	667	844		10	

Annexure III-NTI

Annexure VI-Protocol for using patients' samples for panel testing

Introduction

Panel testing is one of the components of external quality assessment (EQA) that can be used to determine whether a laboratory technician is proficient to perform AFB smear microscopy. The result of panel testing will help to identify if poor performance problems are due to the quality of the stains and staining procedure or actual reading of the smears or microscopes. The revised EQA guidelines recommended NALC method for preparing panel testing slides. The process for preparing panel slides required a high degree of technical proficiency and a reference laboratory with appropriate equipment including a biosafety cabinet. If the laboratory has insufficient technical expertise to prepare manufactured slides using NALC procedure, patients' samples may be used for this purpose. Advantage of this method includes low workload, no requirement for special equipments and the panel sets can be prepared easily. Disadvantage of this process is the lack of consistency in panel sets and the slides with discrepant result will need to be reviewed in order to ensure the initial reading of the patient smear was correct.

Method

Collection of samples:

Collect samples from the nearest DMCs. Select samples of all grades (3+, 2+, 1+ and scanty). Prepare smears and stain by ZN method to confirm the results. Fresh specimens, not more than 2days old are preferred. Prepare the smears as quickly as possible to retain the pus cells.

Positive specimens: 3+, 2+, 1+and Scanty

Amount: 3ml or more, Colour: should be white to green (avoid specimen, which are blood stained) thickness: less mucous specimen are preferred to increase consistency.

Negative specimen:

Amount: 3ml or more, Colour: should be white to green, (avoid specimen which are blood stained) Thickness: less mucous. An AFB negative specimen with 20 or more pus cells per field is preferred.

Selected specimen should have AFB quantification as follows:

3+: >10 AFB/field in minimum of 20 fields

2+: 1-10 AFB/field in minimum of 50 fields

1+: 10-99 AFB/ minimum of 100 fields

'Scanty': 1-9 AFB/100 fields

Negative: 0 AFB/100 fields

Preparation of smear:

Prepare smears (size of 2x3 cm), dry and heat fix for 10-15 min over a hot plate maintained at 85°C. Prepare 50-100 smears using these samples. These panel slides should be kept in slide boxes and stored under ambient conditions in a closed cupboard.

Log for AFB panel testing slides:

Number of slides made: It is recommended that the laboratories prepare 50-100 slides per batch (in each grade) so that sufficient slides are available in panel slide sets.

Date of slide made: This is the date that the test slides were produced.

Document the procedure followed during the panel slide preparation. A logbook of Panel test slide sets should be maintained which can also be used to select slide sets.

Evaluation and interpretation of result:

A panel consisting of 5 pre-fixed unstained slides, which includes slides with different grades of positivity should be given to each technician. It represents $\frac{1}{4}$ of the maximum slides that a technician can examine per working day without losing quality. An approximate time of 25 to 35

minutes for five slides should be allowed. The reference laboratory team should review the discordant slides immediately to ensure the correct results.

References:

External quality assessments for AFB smear microscopy. PHL, CDC, IUALTD, KNCV, RIT, and WHO, Washington DC: Association of Public Health Laboratories, 2002.

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