

Minutes of 15th Lab committee meeting held on 18th October, 2008 at New Delhi

The 15th meeting of National Laboratory Committee of RNTCP was held at New Delhi TB Centre on 18th October, 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:

- Discuss the new International technical guidelines
- Update the status of strengthening of C&DST labs
- Discuss the progress of SLD DST at NRLs
- Update on EQA activities

The first agenda item for discussion was on the proposed change of i) TB suspect definition to 2 weeks history of cough, ii) diagnostic algorithm to 2 smear examinations and iii) change to case definition of smear positive Pulmonary TB of 1 positive smear result. This is in accordance with the new international guidelines recommended by WHO.

The RNTCP national laboratory committee considered the WHO STAG 2007 recommendations and the evidence supporting it, including additional evidence from TRC Chennai as well as monitoring and evaluation of programme data. The committee discussed the new evidence, recent changes in international guidelines, the progress made by RNTCP on EQA and the need for early diagnosis of pulmonary TB and increase of case detection rate over 70% of estimated cases.

Recommendations:

- After careful consideration of all issues related to case detection and quality assurance in laboratories under programmatic setting, the committee strongly recommends that RNTCP changes the diagnostic criteria of smear positive TB as listed below:
 - TB suspect is any person with cough for two weeks, or more
 - Number of sputum specimen required for diagnosis is 2, with one of them being a morning sputum
 - One specimen positive out of the two is enough to declare a patient as smear positive TB
- In view of this change, the laboratory committee also strongly recommends that CTD, along with the NRLs and IRLs, take adequate steps to maintain the full range of EQA activities in all the RNTCP designated microscopy centres across all states and districts.

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

4 IRLs (Gujarat, Maharashtra (Nagpur), Andhra Pradesh & Delhi) were accredited under RNTCP to carry out quality assured mycobacterium culture & DST activities.

The Status of other IRLs under each NRL is as follows:

NTI

- Rajasthan: Under proficiency testing
- WB, Orissa: Undertaking C&DST activities and proficiency testing will be initiated soon
- Jharkhand : Started C&DST activities
- Bihar has not started the civil works for the IRL

- Madhya Pradesh has not completed the civil works
- Civil works ongoing in Srinagar, Pune and completed in Jammu
- Karnataka : Civil work was completed, but now the site has been shifted out by the state

TRC

- Kerala and Tamil Nadu are under proficiency testing
- Chhattisgarh : Microbiologist resigned, LTs not posted yet
- Goa has not started the civil works
- Civil works ongoing in Sikkim, and completed in Punjab and Uttar Pradesh.

LRS

- Haryana: under proficiency testing
- Uttarakhand: Initiated culture activities in the lab
- Civil works completed in HP, Assam and Manipur
- Arunachal Pradesh: Civil works and appointment of staff to be completed

The committee was informed that some of the C&DST equipments at IRL, Karnal are not working and there is no AMC for the equipments in place. Though the equipments are installed in IRL, Chhattisgarh, C&DST activities cannot be carried out without the staff (microbiologist, LTs, lab attendants) in place. CTD had requested the state to expedite the process, but so far there is no progress.

Recommendations of the Committee:

- NRLs should communicate and discuss the technical issues regularly with the IRLs so that the microbiologist and technicians follow proper technique and bio-safety practices in the lab
- A person from JALMA Institute, Agra may visit IRL, Karnal immediately to see if they are following appropriate maintenance methods taught to them during the training conducted at JALMA Institute on 'Routine maintenance and bio-safety practices to be observed while handling C&DST equipments'
- The state of Haryana should ensure to have AMC in place for all the C&DST equipments at IRL, Karnal and necessary support may be taken from LRS&JALMA in this regard
- Appointment of microbiologist and other staff for the IRL, Chhattisgarh to be expedited by the state. As the state is in the phase of Election, CTD to take up the matter with Election Commissioner to see that the selection and appointment of contractual microbiologist and lab technicians for the IRL has not affected
- An accreditation request may be sought from the Director, NEIGRIHMS, by CTD for undertaking mycobacterium C&DST activities by their microbiology lab for the state of Meghalaya
- The possibility of utilizing the services of mycobacteriology lab at a Private Medical College, Bhopal and ICMR, Jabalpur for C&DST activities for the state of Madhya Pradesh to be explored by CTD.
- NTI has been requested to collect the status of IRL, Karnataka immediately and inform CTD so that the issues can be taken up with Secretary (Health), Govt. of Karnataka
- Addition of Generator/power back up for IRLs to be included in all PIPs under 'additionalities Head'

DOTS Plus activities

At present, the states of Kerala, West Bengal and Haryana are sending the sputum samples of MDR TB suspects to their respective NRLs so as to start the DOTS Plus activities in these states. It was informed by the NRLs that the following deficiencies are observed while receiving the sputum samples of MDR TB suspects from the state/districts at the NRLs

1. The C&DST request form is not complete
2. States/districts are not sending the electronic copy of the request form
3. Only one form is being sent for 2 samples

Recommendations

- All states/districts sending the samples for C&DST to NRLs/IRL should ensure that
 - The request form for C&DST is complete with all details clearly written with ball point pen and preferably in English (or Hindi)
 - They should also send the filled in electronic copy of the request form for all samples so that the NRLs will be able to cross verify as well as enter the results without retyping the whole format again
 - Each sample should be accompanied by a separate request form (2 forms for 2 samples). A communication in this regard will be sent from CTD and nodal person will also speak to the concerned microbiologist and local RNTCP consultant to ensure this
- The C& DST services for MDR TB patients from TN may be initiated by TRC (Plan B) till the IRL is accredited. The districts for DOTS plus project to be decided after discussion with STO, TN, including the 4 districts be taken up by CMC Vellore for C&DST of MDR TB suspects
- If IRL at Ajmer is not accredited till December, plan B (C&DST at NTI) may be initiated.
- DOTS Plus training for HP,UP and TN to be planned at the earliest by CTD(not later than November 08)
- The committee agreed that C&DST services for MDR TB suspects from Himachal Pradesh may be undertaken at LRS Institute/New Delhi TB Centre and as decided earlier, for patients from UP, these services to be offered at JALMA Institute till their labs are accredited .Both UP and HP be informed immediately to identify the master trainers, to have the plan ready for districts to be included in the DOTS Plus, training etc
- A meeting of STO, Haryana, Microbiologist and Director ,IRL, Karnal with LRS &CTD to be convened immediately to discuss the DOTS Plus project and related issues
- The C&DST results of MDR TB suspects to be communicated to IRL, Karnal by LRS Institute
- DOTS Plus districts for AIIMS to be identified after discussion with STO
- States of Jharkhand, Chhattisgarh and Uttarakhand to be included for procurement of second line drugs under GLC. The revised proposal for procurement of these drugs for about 500 patients to be submitted

Infection control methods in TB Labs

A presentation was made by Mr. Shashi Sinha, Bio-Medical Engineer, Crown agents on infection control techniques required in a TB laboratory. It is noted that maintenance of equipments and biomedical waste management is an issue in all the newly established C&DST labs.

- JALMA Institute, Agra was requested to draft a document on guidelines on biomedical waste management in culture labs and maintenance and disinfection of equipments and send the draft to CTD within one month.
- A meeting of lab committee with FIND and PATH to be undertaken at the end of November 08 to finalize these guidelines
- Procurement of new equipments used for automatic disinfection also may be considered under the programme.
- An Institution Bio-safety committee may be constituted in all the IRLs once these guidelines are finalized
- Mr.Shashi Sinha was asked to prepare a handbook/manual for maintenance of laboratory equipments

DRS activities

- The state of Andhra Pradesh has initiated the DRS study from September 2008
- JALMA Institute, Agra has completed the pilot study for the DRS survey in western Uttar Pradesh and actual study will be initiated soon.
- Orissa: Training for the STDC & STC staff and DTOs of pilot districts were undertaken by the NRL in September 08. It is to be followed up on a day to day basis
- NTI to submit the final report of DRS study conducted in Maharashtra to CTD.

Accreditation of Medical college/other sector C & DST laboratories

Status

- Under Proficiency testing
 - CMC, KGMU, AIIMS, SMS, BPRC, PGI
- Asked for list of 100 C&DST results
 - Bhopal Memorial Hospital, BJ Medical college, Pune
- Forms received, not having enough capacity at present
 - KEM ,Mumbai, DY Patil's MC, Kolhapur, MGR University, Tamil Nadu
 - GMC, Chandigarh
 - To undertake assessment visit- JN MC, Aligarh
- Ranbaxy-Process to be initiated

Recommendations

- NRLs should visit the medical colleges to assess the microbiology lab when they go for OSE visits to states and give suggestions to enhance the capacity so as to enable them to undertake mycobacterium C&DST as per programme requirements
- The programme envisages that each accredited TB laboratory should be able to deliver public health services by offering at least 5000 cultures per year and be able to meet the increased workload as demanded by the programme
- The committee approved the draft guidance document on setting up TB labs in medical colleges and other sectors prepared by CTD, WHO & NRLs .

Update on renewal of accreditation of LRS & JALMA with TRC

JALMA Institute, Agra has completed the proficiency testing with TRC, Chennai and achieved concordance in DST as per guidelines. LRS Institute has completed the panel testing with WHO-SNRL at Antwerp, Belgium and achieved desired concordance. They have also completed the proficiency testing with TRC

Progress on capacity building of other NRLs in Second line DST

NTI, Bangalore has initiated second line DST since September 2008 and also undertaking proficiency testing with Belgium lab. Microbiologist and LT from LRS will

be attending the training at TRC in November 2008. Culture isolates from JALMA will be sent to TRC for SLDST proficiency testing by end of October 2008

Recommendations to IRLs of Gujarat & Nagpur

As communicated earlier, in order to estimate the prevalence of XDR-TB amongst the MDR-TB cases the culture isolates from identified MDR TB patients at IRLs of Gujarat and Nagpur should be sent to TRC for second line DST. However, the second line DST will be done for surveillance purposes only.

Update on RNTCP/FIND project

A presentation was made by FIND on the status of various ongoing FIND projects to promote rapid and newer diagnostics in the country. The three projects presently undertaken by FIND are Line probe assay, Led Fluorescent Microscope and Liquid culture.

The sites for Line probe Assay are: JALMA, Agra (for Validation only) SMS Jaipur , IRL Ahmedabad, IRL Hyderabad, GHTM Tambaram, AIIMS

The Study structure is

1. Initial Pilot and proficiency phase (IPPP)
 - 50 patients; two samples per patient tested ;
 - Concordance between A & B sample evaluated
 - 20 randomly selected DNA extracts sent to different lab for intra lab concordance
2. Validation phase
 - Sample size –Sputum sample of 250 patients; One 'blinded' line probe test/patient; results compared to LJ media results
 - Results of line probe assay not used for patient management
 - Additional 100 culture isolates per site to be tested on line probe assay
3. Demonstration phase
 - Duration: 6 months
 - Diagnosis based on Line probe test

SMS Jaipur has completed IPPP and validation phase initiated from September 2008. In view of the pending accreditation of LJ-Culture, culture isolates being sent to JALMA for DST. The other sites are yet to initiate the activities.

The main objective of **LED Fluorescent Microscopy** study is to assess the feasibility of implementing Primostar iLED FM for TB diagnosis at microscopy centers. The supervisory sites for this study are New Delhi TB Centre, JALMA Institute, Agra and CMC, Vellore.

Status

- 14 LED microscopes, stains & consumables delivered to supervisory sites
- Project staff appointed at all three sites- 2 supervisors each
- Training conducted from at CMC Vellore

The study sites for **liquid culture** and their status are

- LRS Institute: lab upgraded, awaiting certification
- SMS Jaipur: study will start once the accreditation for solid media done
- IRLs of Ahmedabad and Hyderabad: Awaiting for lab up gradation

Recommendations

- The IPPP by JALMA to be completed by November 2008
- Validation of all sites to be completed by March 2009 and demonstration phase by November 2009
- FIND has been requested to make a time line accordingly and share with CTD which should be discussed in the next DOTS Plus committee meeting

Quality Assurance for Fluorescent Microscopy

The laboratory experts opined that the fluorescent stains usually fade within 24 hours and therefore RBRC of these slides will be difficult. At present there is no EQA for FM anywhere and only IQC is being used for this purpose. Panel testing (using unstained slides) and Onsite Evaluation can be undertaken by the supervisors.

Recommendations

- TRC has been requested to develop a document on guidelines for IQC, panel testing, training methods, certification process etc
- All the STOs and consultants may be requested to provide a list of sites using FM to CTD

Accepting Gastric lavage smear microscopy

The committee agreed that smear microscopy results of gastric lavage in paediatric patients can be registered under the programme provided the microscopy centre is under the RNTCP EQA mechanism

Accreditation of labs using liquid cultures

It was informed to the committee that CTD has received accreditation application forms from labs which are mainly using liquid culture methods. The lab experts opined that accreditation can be granted provided there is concordance between the two labs as per guidelines irrespective of the methods being used in the lab and also the NRL which is accrediting these labs should be handling/ should have been accredited for the liquid culture system.

Recommendations

- NTI, JALMA &LRS may initiate proficiency testing of liquid culture with WHO-SNRL at Antwerp, Belgium
- The accreditation application from Ranbaxy lab to be taken up by TRC, Chennai
- Necessary amendment to be made in the RNTCP accreditation application format to include the liquid culture methods as part of the accreditation process
- The costing under NGO/PP scheme for purchase of C&DST services is applicable for whichever method used by the lab (solid or liquid culture methods)
- All labs should continue to process DST for all four drugs, but accreditation can be granted if there is concordance for Isoniazid and Rifampicin

Culture and DST Laboratory Performance Indicators

NTI & LRS presented the data for one quarter on C&DST lab performance indicators. The committee agreed that these indicators are useful in regular monitoring of the performance of TB laboratories. The committee recommended that IRLs of Nagpur and Delhi may be requested to collect the required data for assessment of these Indicators

Update on EQA activities

The NRLs presented the status of EQA activities on the EQA reporting format. During the quarter, NTI, Bangalore visited Jharkhand and Orissa, LRS Institute, Delhi visited Manipur and Nagaland and TRC, Chennai visited the state of Andhra Pradesh 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.

Recommendations

- All states should ensure that their IRLs conduct OSE visits to the districts regularly and also that EQA protocol is being implemented in all the districts as per guidelines.
- All efforts should be taken to implement EQA in all districts of Orissa in view of the soon to be initiated DRS study in the state.
- The states of Bihar, Chhattisgarh, Orissa, Himachal Pradesh, Uttarakhand and Madhya Pradesh, needs more attention and any team visiting these states should give more emphasis on the implementation of EQA.

States allotted to JALMA

The states designated under JALMA are

- Uttar Pradesh
- Uttarakhand
- Himachal Pradesh
- Assam

Annexure-I

List of Participants

1. Dr. L. S. Chauhan, DDG (TB)
2. Dr. Prahlad Kumar, Director, NTI, Bangalore
3. Dr.S.K.Chaturvedi, CMO,CTD
4. Dr.Saxena,CMO,CTD
5. Dr.N.Selva Kumar, TRC,Chennai
6. Dr.P. Vishalakshi, LRS, New Delhi
7. Dr. Ranjani Ramachandran, TRC Chennai
8. Dr.Devesh Gupta,CMO,CTD
9. Mr. Anand, NTI, Bangalore
10. Ms.Hema Sundaram, NTI, Bangalore
11. Ms. Reena, NTI, Bangalore
12. Dr.D.S.Chauhan,JALMA Institute,Agra
13. Dr.V.D. Sharma JALMA Institute,Agra
14. Mr.S.B.Sinha, EPW,MOHFW(Special invitee)
15. Dr S. Sahu, NPO (TB), WHO India
16. Dr Fraser Wares, MO(TB), WHO India
17. Dr. Puneet Dewan , MO(TB), WHO-SEARO
18. Dr.Neeraj Raizada, Medical Officer,FIND
19. Dr. Sarabjit Chadha, WHO-RNTCP Consultant, Central TB Division
20. Dr.Geetanjali Sharma, WHO-RNTCP Consultant, Central TB Division
21. Dr Sheena Susan George, WHO-RNTCP Consultant, Central TB Division

Activities	Kerala	Haryana	Rajasthan	West Bengal	Tamil Nadu
1 Completion of civil works	Jan 07	April 07	June 07	July 07	March 07
2. Installation & bio-safety certification of equipments	June 07	May 07	August 07	August 07	June 07
3. Posting of microbiologist & LTs	2006/Nov07(LTs)	2006/Jan 07	Feb 07	2006/July 07(MB)	Feb07/Oct 07(LT)
4. Training of Microbiologist & LTs in C&DST	Dec2006(MB)/Dec 07(LT)	March 07	March 07	September 08	March/Nov 07
5. Fill up the application form & send to NRL & CTD	June 07	May 07	September 07	December 07	Sept07
6. NRL pre assessment visit to IRL	August 07	June 07	October 07	Jan 08	November 07
7. Starting of cultures (Pilot study)	January 08	Sept 07	Dec 07	Feb 08	December 07
8. Send cultures / Exchange of strains with NRL (NRL ↔ IRL)	May 08	March 08	May 08	November 08	July 08
9. Results of proficiency testing	August 08	July 08	November 08	Jan 09	October 08
10. Accreditation visit by NRL	November 08	December 08	November 08	Jan 09	November 08
11. Time for corrective actions			November 08		November 08
12. Accreditation	November 08	December 08	December 08	Feb 09	November 08
13. Intake of first MDR suspect	July 08(TRC)	July 08(LRS)	November/December (Plan B-NTI)	August 08 (NTI)	October 08(TRC)
14. First MDR-TB patient registered for Cat IV treatment	October 08	October 08	March 09	November 08	Jan 09

Activities	Orissa	Jharkhand	Uttarakhand	Chhattisgarh
1 Completion of civil works	October 07	Jan 08(*CR-)	May 07(*CR-)	July 07
2. Installation & bio-safety certification of equipments	November 07	Feb 08	June 07	October 07
3. Posting of microbiologist & LTs	Jan 07	2006(MB)/No LTs	Jan 08(MB+1 LT)	Resigned
4. Training of Microbiologist & LTs in C&DST	March 07	Sept07(MB)	Feb-March 08	??
5. Fill up the application form & send to NRL & CTD	Jan 08	June 08	April 08/June 08	
6. NRL pre assessment visit to IRL	Feb 08	July 08	July 08	
7. Starting of cultures (Pilot study)	March 08	July 08	July 08	
8. Send cultures / Exchange of strains with NRL (NRL ↔ IRL)	October 08	Feb 09	December 08	
9. Results of proficiency testing	Jan 09	May 09	March 09	
10. Accreditation visit by NRL	Jan 09	June 09	/March 09	
11. Time for corrective actions				
12. Accreditation	Feb 09	June 09	June 09	??
13. Intake of first MDR suspect	Feb 09	June 09	April 09	
14. First MDR-TB patient registered for Cat IV treatment	April 09	September 09	July 09	

