

18th National Laboratory Committee Meeting
12th February, 2010

Venue: New Delhi TB Centre, New Delhi

Time: 9.30 AM

Minutes of the Meeting

The 18th RNTCP National Laboratory committee was held at conference hall of New Delhi TB centre on 12th February, 2010. Agenda and the list of Participants are annexed at annexure-I and annexure-II respectively.

The meeting was chaired by Dr. V M Katoch, Secretary, Dept of Health Research and DG, ICMR. DDG (TB) welcomed the participants and appreciated the support to the programme from all National Reference Laboratories. The National Reference Laboratories were urged to be proactive in implementing the decisions of the laboratory committee, especially to ensure the uniform standards and methodology in Culture and DST.

As decided during the 17th National laboratory committee meeting, the following follow up points were discussed:

- NRLs were to make weekly telephonic calls to the respective IRL (Director/Microbiologist) and share the brief of the telephonic discussion with the STO and CTD. However it has been observed that the action on this recommendation was lacking. DDG-TB urged the NRLs to comply with this recommendation and submit the reports on the weekly follow ups on a monthly basis to CTD.
- It had been decided in the previous meeting that the labs which are accredited or in the process of accreditation were to implement the SOPs and report the performance indicators on a quarterly basis. Most of the labs have not submitted the quarterly report on the "RNTCP Standard Laboratory Performance Indicators for Mycobacterial Culture and Drug Susceptibility Testing". The Committee emphasized the importance of strengthening this mechanism. All IRLs are required to report quarterly on their culture and DST activities as per the recommended schedule.
- The Committee requested the NRLs to monitor the labs for submission of quarterly reports.

Dr Ranjani Ramachandran, MO(TB Labs), SEARO presented the recommendations of the WHO 2009 STAG meeting on the use of newer diagnostics in diagnosing TB and DR-TB, including the endorsement of LED FM and front loaded smear microscopy. Dr Katoch pointed out that there was a need to consider long-term radiation effects of LED light on microscopists, and suggested the constitution of an expert group to opine and guide regarding the safety of the using this technology. Meanwhile it was decided that the 12 sites of the validation study will continue as operational research sites and that FIND will continue to supply the consumables to these sites. Dr Fraser Wares, MO-TB, WHO-India emphasized that this technology being highly sensitive and with strong user preference, can be of value to the programme in high workload settings (DTCs and medical colleges), and

that LED light microscope can be of use in peripheral laboratories where electricity supply is erratic. It was suggested that there should be an operational research on the patient-centered outcomes of standard versus front loaded microscopy.

This was followed by the presentation by Dr Neeraj Raizada, MO, FIND India updating on the RNTCP-FIND projects in India.

Molecular Line probe assay and Liquid culture lab preparedness study

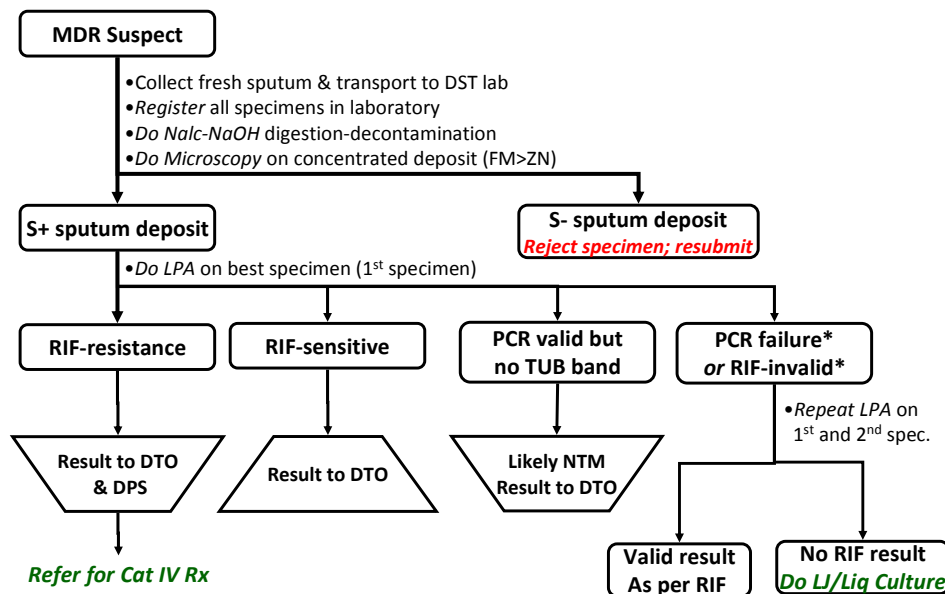
The findings of the demonstration phase which has been implemented in STDC Ahmedabad (10 districts) and STDC Nagpur (2 districts) were presented. The key achievements of the demonstration phase are

- Routine use of LPA in DOTS-Plus showed efficient testing and referral for treatment with low loss of patients before treatment
- Rapid sputum transportation mechanism functional for 10 districts (Ahmedabad) & 2 districts (Nagpur) with 100% of the specimens transported within 72 hours through courier or in-person by a district staff.
- Revised formats (revised sputum request forms, formats for LPA results in-lab, integrated LPA/culture/DST register results) smoothly implemented
- Laboratory database installed and automated email of results communicated to DTO & DOTS-Plus site.

As the next steps, the activities have to be initiated in other sites (AIIMS, SMS Jaipur, LRS, and STDC Hyderabad) and transition from special project mode to routine implementation as per the national lab scale-up plan. FIND was requested to continue the support for the projects sites till funding from Expand TB and TGF RD 9 projects is available later this year.

Dr Dewan, MO(TB), WHO SEARO presented the proposed revision in the diagnostic algorithm for diagnosis of DR-TB incorporating the use of LPA and Liquid culture (given below).

Proposed integrated diagnostic algorithm



***PCR Valid**

Y if both Amplification Control (AC) band & Conjugate Control (CC) band present

N if either AC or CC are missing; record no additional LPA results on this row. Record repeat LPA results in new row.

MTB Complex (TUB)

Y if *M. tuberculosis* (TUB) band on LPA strip confirming identity as *M. tuberculosis*

N if no TUB band on LPA strip

No DST result (NA) (DST invalid)

No locus control band on LPA strip for *rpo-B* (RIF), or for *inh-A* or *kat-G* (INH)

The laboratory committee endorsed this diagnostic algorithm for use nationwide; however, the committee suggested that the existing LPA demonstration sites continue the use of both LPA and Solid culture and DST in routine implementation in order to accumulate additional evidence for scale-up in programme settings.

Dr Neeraj Raizada, MO, FIND India, presented on the EXPAND-TB project and the lab strengthening components of the Global Fund Round 9. Under EXPAND-TB project, LPA equipments and consumables will be supplied to 40 labs and liquid culture equipments and consumables to 31 labs. The signing of the MoU between GoI and EXPAND-TB partners is underway. Under GFR9, the support the implementation of National laboratory scale-up plan comes in the form of additional HR support to 4 NRLs and 39 State labs for a period of 5 years, additional sputum processing equipment to 33 State labs to improve specimen throughput anticipating LPA and Up gradation of 20 State labs for liquid culture readiness. Other components in the project include

- Additional consumables for 39 State labs;
- Outsourced consultancies for Lab designing, bio-safety verification;
- Technical support for QA in coordination with NRLs and other FIND experts;
- IT agency for lab software development and maintenance; electronic transmission of reports from lab to districts and DOTS-Plus sites;
- Onsite trainings & technical support in coordination with NRLs; and
- One annual lab network meeting and annual regional lab meeting

As the next steps, coordinated efforts by all (NRLs, WHO, FIND) are required under leadership of CTD to ensure:

- Build capacity of NRLs for LPA and Liquid culture accreditation, conducting trainings, trouble-shooting, etc;
- Timely LJ accreditation for all Year one (April 1, 2010 to March 31, 2011 or year starting from the date of signing of the agreement) and Year two laboratories;
- Establishment of clean rooms for LPA
- Availability of adequate infrastructure and power supply;
- Availability of full contingent of trained lab staff;
- Coordinated efforts in HR development
- Lab MIS development - It was decided that FIND would take a leading role in the development of a comprehensive lab MIS which would link the lab data with the DOTS plus site data and streamline reporting to the districts. FIND would undertake the activity in close coordination with CTD and WHO.
- In case of delays at any given lab, identify next year labs at which activities could be initiated

- Additional 5 labs to be upgraded by NRHM/State funds. The labs will be identified in consultation with CTD.

The lab committee endorsed the routine use of Line probe assay, Liquid culture and Capilia-TB test in programme settings under Expand TB and TGF RD-9 project.

Dr Sheena George presented their activities on behalf of PATH. The important activities and recommendations of the committee are

- Up-gradation of IRL Hyderabad to BSL III-completed and handed over to state.
 - In future, there will be a committee of 3 persons (1 per NRL other than TRC) who will visit the lab in co-ordination with FIND/PATH to certify that it is a BSL-3 area.
 - Dr Neeraj shared that the power cables used in Gujarat lab was not capable of taking the load of the equipments, and the Air Handling Unit had been non-functional for last 6 months. This may become a problem in other laboratories as well and suggested that this should be part of the checklist in future.
- Equipments for IRL Nagpur-partially completed, problems with non-receipt of accessories being sorted out.
- On site training completed for Jharkhand & Uttarakhand. For IRL Haryana, it is scheduled from 15th February and for Raipur (Chhattisgarh) it has been planned in March /April 2010.
- Capacity building workshop undertaken on 6-7th Nov, 2009 at NTI (report sent to CTD & NRLs and participant IRLs)
- A preventive maintenance draft checklist for IRL equipments made with inputs from ASM. This will be circulated to NRL microbiologists and CTD for comments.
- It was reiterated that technical assistance will be provided by PATH to NE states.

A **National laboratory task force** mechanism has been recommended by JMM 2009 to expedite the process of establishment and accreditation of the labs in the country. USAID has agreed to consider funding this mechanism. Dr Ranjani informed that the proposal is being drafted by WHO and will be ready for submission by the end of February, 2010 after review by CTD.

In view of the planned scale up of laboratory capacity and introduction of LPA and Liquid culture besides the conventional solid culture and DST, the provision of quality training for the different technologies needs to be ensured. It was therefore proposed that a "**National Centre for Training**" be developed at one of the identified NRLs for this purpose. The committee approved the proposal in principle with a concern that a single centre may not be adequate for undertaking all training activities. It was clarified that in addition to the proposed training centre the other NRLs would continue with the training activities as has been decided earlier. The Committee suggested that CTD should take necessary steps for identification of the NRL and work out the expected costs and source of funding.

Status of DRS surveys

- AP - intake completed and the team has been invited to Delhi for discussions by the end of February, 2010.
- Orissa - pilot completed; main study yet to be started. It was decided that the culture will be done at IRL Orissa and culture isolates will be transported to NTI for DST.
- Western UP - Intake completed; data analysis to be done and presented. It was decided that the interim results will be presented to CTD by the end of February.

Dr Dewan suggested that to expand DRS among new patients to additional sites, future surveillance should perhaps be conducted with molecular technologies. This acknowledges that only information for RIF resistance would be available, hence this approach may be most useful in sites where surveillance information is not available.

NRLs presented the findings of their OSE visits to IRLs. Some of the recommendations of the committee during these presentations are as follows:

- DDG-TB urged all the NRLs to make every effort to meet the Health Secretary of the state and brief about the findings of the OSE visit.
- "Exposure Visits" of the state IRL teams (which are not yet established/accredited) may be permitted to learn from other states/NRLs.
- Binocular Microscopes (especially MLW) which are irreparable or where the cost of repair is more than 50% of the cost of the microscope, have to be replaced. CTD to replace such microscopes based on the report of the respective state IRL team.
- There should be more frequent OSE visits to some states like Bihar, UP, MP, J&K.
- LRS director informed that they have been receiving sputum samples from Dharampur district of Himachal Pradesh even though they are not under Plan-B of DOTS-Plus. It was decided that CTD will write an email to STO Himachal Pradesh to submit the appraisal form and following the appraisal visit and approval by CTD, the sputum samples may be transported to a designated C&DST Lab. **It was decided by the committee that sputum specimens will not be accepted for culture and DST from any district until the districts have been formally appraised and approved for DOTS-Plus.**
- DDG-TB requested the respective NRLs to expedite the accreditation of the IRL Jharkhand, SMS Jaipur, KGMU Lucknow and IRL Haryana which had already cleared the proficiency testing successfully.
- Dr Anand from NTI shared that the TA/DA provisioned for the IRL staff at Orissa was inadequate leading to fewer visits. CTD clarified that as per the recently revised financial guidelines, communicated to the States, the staff were entitled for TA/DA as per NRHM norms.
- Dr Anand also brought to the notice of the committee that the modules of LT and STLS need to be revisited. It was decided that the modules will be reviewed by NTI and shared with all the members by March 15 2010 for finalization.

Annexure I - Agenda
18th National Laboratory Committee Meeting
12th February, 2010

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Time: 9.30 AM

Objectives of the meeting

- To discuss the proposed diagnostic algorithm for the detection of DR-TB cases
- To endorse the new technologies to be used by RNTCP
- Discussion on the UNITAID support (EXPAND TB) and GF R9 to laboratory strengthening
- Update on the status of accreditation of C&DST labs - implementation of SOPs
- Update on EQA for sputum microscopy & DRS activities

AGENDA		
1	<ul style="list-style-type: none">• Presentation on STAG recommendations in relation to newer diagnostic technologies• Update on FIND projects (Liquid culture, LPA and LED-FM)	Dr Ranjani Ramachandran FIND
2	<p>Presentation of the proposed diagnostic algorithm for the detection of DR-TB</p> <ul style="list-style-type: none">• Discussion	Dr Puneet Dewan, WHO
3	Update on NRL EQA OSE Visits (Smear Microscopy) & RBRC activities in the states	NRLs
4	<p>Discussion</p> <ul style="list-style-type: none">• National Laboratory Task Force• Status and plans for 1st year Labs to be supported by UNITAID under EXPAND TB project	WHO, CTD, NRL, FIND
5	<p>Update on</p> <ul style="list-style-type: none">• Status of accreditation of IRLs, medical college and other sector labs• Status of DRS Surveys - AP, UP, Orissa• Plan B for states without C&DST facilities - Uttarakhand, Chattisgarh and Karnataka	NRLs
6	Update on PATH Laboratory technical assistance	PATH

Annexure II - List of participants

1. Dr V M Katoch, Secretary, Dept of Health research, Govt. of India, and DG ICMR
2. Dr L.S. Chauhan, DDG (TB)
3. Dr D. Behera, Director, LRS, New Delhi
4. Dr Kiran Katoch, Director in charge, NJIL & OMD
5. Dr. K S Sachdeva, CMO, CTD
6. Dr Niraj Kulshreshtha, CMO, CTD
7. Dr Selva Kumar, TRC Chennai
8. Dr V.P. Myneedu, LRS, New Delhi
9. Mr S. Anand, Consultant Microbiologist, NTI, Bangalore
10. Dr DS Chauhan, Scientist-C, NJIL & OMD
11. Dr. Fraser Wares, MO(TB), WHO India
12. Dr Ranjani Ramachandran, WHO-SEARO
13. Dr Puneet Dewan , MO(TB), WHO-SEARO
14. Dr Neeraj Raizada, Medical Officer, FIND
15. Dr Rahul Thakur, Medical Officer, FIND
16. Dr Sheena Susan George, Medical Officer, PATH
17. Dr Satish Kaipilyawar, Project Director, PATH
18. Dr Sarabjit Chadha, WHO-RNTCP Consultant, CTD
19. Dr Ajay Kumar MV, WHO-RNTCP Consultant, CTD