

**Minutes of 20<sup>th</sup> meeting on National Laboratory Committee, LRS Mehrauli, New Delhi**

**Date:** 13<sup>th</sup> July 2011

The Member Secretary of the National Laboratory Committee, Dr. Ashok Kumar, Deputy Director General – TB (DDG-TB) on behalf of Central TB Division and Lala Ram Swarup Institute of Respiratory Diseases welcomed all the participants, the Chair was welcomed by giving a floral bouquet by Dr. Behera, LRS Director. He said the 20<sup>th</sup> Committee was recently constituted in May and it is meeting immediately after that. He informed that the last meeting was held in the month of January and briefed about the composition of the new committee. The National Laboratory committee was constituted to provide technical guidelines and to provide support in monitoring the programme. The scope of work and terms of reference on National Laboratory committee are as follows.

1. To provide technical guidelines for diagnosis of TB, DR-TB and quality assurance mechanisms for the laboratory network.
2. Identify and recommend newer rapid diagnostic technologies for diagnosis of TB and DR-TB
3. Comment upon the infrastructure, resources available and forecast problems under National Laboratory Scale up and suggest possible solutions
4. Review programme laboratory scale up and consider alternative policy options based on scientific evidence.

He emphasized that tenure of committee is for three years and committee will meet every six months.

There was self introduction of all members (annexure -1).

DDG –TB briefed the Chair about the minutes of 19<sup>th</sup> National Laboratory committee and the agenda of the day's meeting, the Chair was also informed about the National DOTS Plus Committee meeting held on 11<sup>th</sup> and 12<sup>th</sup> July 2011.

The Chairman of the committee, Dr. RK Srivastava, Director General of Health Services, GoI in his opening remarks said that the meeting of the committee at this juncture is important as the programme is in the planning phase for next five years which addresses the forthcoming challenge of drug resistant tuberculosis. He said that accreditation of laboratories by the programme leads to development of laboratories that has accuracy in diagnosis and the newer diagnostic technologies which are endorsed by the committee are implemented in the laboratories, they are translated into investments in terms of capacity building which can also be useful for other programmes.

The Chairman expressed his intention of having more members in the committee especially from private sector and requested the committee members to discuss about it. He

advised the committee members to look at the issues in depth and critically analyze them before taking the decisions. He applauded the contributions made by WHO, PATH, FIND and other external partners in strengthening the programme.

He raised the concern, whether the present system of laboratory accreditations has to be empowered by involving other International partners who can assure us of quality in the process. The need of the hour is to involve private laboratories, medical colleges and laboratories developed by other sectors. The involvement of Medical college laboratory network was stressed.

He ended his remarks by wishing all the members a success in the meeting.

The Member Secretary, Dr.Ashok Kumar, DDG-TB thanked the Chair and assured that all the suggestions and advices made to the committee will be incorporated.

### **Analysis of State's IRL annual report on RBRC in India – Annexure G**

A presentation on the analysis of State's IRL annual report on RBRC – Annexure G was made. It highlighted the importance of sputum smear microscopy and the external quality assurance mechanism for microscopy in the programme. The calculation of sample size, recording and reporting formats dealt in routine random blinded re-checking of smears were discussed. The data analyzed from Annexure – G (2010) of 27 State IRLs involving 11,039 DMC's showed that the sensitivity of smear microscopy relative to the controller is at 98% with 100% specificity. Since, the existing recommended annual sample size for RBRC is based on 80% sensitivity and the programme data showed 98% sensitivity, it was proposed to raise the bar of sensitivity to 90%. *After discussions, the committee agreed upon and recommended that annual sample for RBRC should be based on 90% sensitivity, 100% specificity with d=0 (acceptance number)*

### **Phasing of LED based microscopes within the RNTCP - Discussion**

The WHO guidelines on phasing of LED microscopy was briefed by Dr.Ranjani and it was emphasized that they are user friendly, cheap, maintenance free, has long bulb hours, battery backup, increased sensitivity compared to conventional microscopy and extremely useful in settings where electricity is a concern. The programme, will consider phasing in of LED based microscopes when they are to be replaced after condemnation of conventional binocular microscopes. It was also informed to the committee that the proposal for providing LED microscopes to medical colleges by Union has been approved by TB reach wave 2 and there is a need to have specifications for the LED based FM microscopes. The members shared their experiences with LED based FM microscopes.

*The Vice-chair formed the CTD specifications committee to come up with the technical specifications for LED based microscopes with the following personnel's as members:*

- *Dr. KS Sachdeva (Chair)*
- *Dr. Myneedu, LRS microbiologist*
- *Dr. Selvakumar, TRC microbiologist*
- *Dr. Anand, NTI microbiologist*
- *Dr. Chauhan, JALMA microbiologist*
- *Dr. Urvashi Singh, AIIMS, microbiologist*
- *Dr. Haneef, NDTBC, microbiologist*

The specification committee was given the timeline of 6 weeks for coming up with the specifications. After the formal approval from DDG-TB, the specifications will be reviewed by the specification committee of the ministry and approval will be sought.

#### **Discussion and Decision: Need of stopping LJ back up cultures – Review of data from LPA-LJ backup demonstration sites in India**

The committee was briefed about the RNTCP – FIND LPA demonstration project, the project had three components, Initial proficiency testing phase, Validation phase and Demonstration phase. The duration of the project was from August 2008 to March 2011. The project was carried out at STDC Hyderabad, STDC Nagpur, STDC Ahmedabad, AIIMS Delhi, LRS Institute, JALMA Agra and SMS medical college, Jaipur. The in country LPA validation vs LJ culture and DST on direct sputum specimen and culture isolates has been completed and it has the approval of 17th meeting of National Laboratory committee meeting. After the approval, the demonstration project was initiated in which the DR-TB diagnosis and initiation of DOTS Plus based on LPA results. The duration of the phase was for 6 months but the scale up of the project was based on the availability of second line drugs. The project was implemented at STDC Ahmedabad (Oct 09), STDC Nagpur (Jan 10), STDC Hyderabad (July 10) till 31<sup>st</sup> March 2011. During these period, a total of 2433 MDR TB suspects were screened from 28 districts, out of which LPA results were available for 2253 (93%) suspects and both LPA and LJ results were available for 1521 (61%) suspects. 132 specimen which were having discordance with LPA and LJ results were sent to NRL for further evaluation of the specimens. Among the results available, the sensitivity and specificity of LPA results relative to LJ results were found to be 95% with Positive productive value of 93% and Negative predictive value of 96%. The median reporting time by LPA ranged from 0-1 day in three sites and the median time to treatment from LPA ranged from 29-37 days and by LJ DST ranged from 94-105 days in three sites. The cost for each LJ C&DST and LPA were found to be 32.66 USD and LPA 17.10 USD respectively as per the costing analysis done by the project.

The committee members flagged the issue of personnel's involved in the data analysis. *The Vice Chair was of the opinion that the raw data has to be shared with the 4 NRLs and CTD,*

*re-look into the data and analysis, the activity has to be completed by July end 2011 at NTI, Bangalore. The committee members agreed upon the decision.*

### **Review the progress on the Expand TB project – Laboratory wise status**

The four National reference laboratories presented the status of culture and DST laboratories coming under their jurisdiction and the activities carried out in the last six months. The following important issues were discussed.

- The LRS Microbiologist said that, despite the culture and DST laboratory being inaugurated at Manipur, the culture activity is not yet started in the laboratory due to non availability of Laboratory technicians. The issue of C&DST samples being sent from MSF Manipur to LRS institute was also raised and the committee proposed that the samples from MSF Manipur should not be accepted at LRS as they are not strictly complying with RNTCP treatment guidelines for drug resistant tuberculosis.
- The LRS Microbiologist informed the committee that All India Institute of Medical Sciences, Delhi had applied for accreditation of Culture and DST laboratories from three departments i.e., Dept of Laboratory Medicine, Medicine and Microbiology and it was unclear whether all three departments should be accredited as some of the applications were not endorsed by the Dean of the Institute. The committee asked LRS to go ahead with their accreditation process.
- It was reiterated that there has been considerable delay in receipt of funds at NRLs and CTD should look into the issue as the delay significantly hampers the NRL field activities.
- Dr. Kiran Katoch, Director JALMA, requested CTD to intervene in fastening the accreditation process of STDC Agra, UP and Tada Medical College, HP. CTD ensured that team visits along with other partners will be planned for these laboratories in July 2011.

### **Feasibility of Newer Diagnostic GeneXpert as TB diagnostic in India**

Dr. Camillia Rodrigues from Hinduja Hospitals, Mumbai and Dr. Meynedu from LRS Delhi shared their experiences of handling the newer diagnostic Genexpert as TB and DR-TB diagnostics in their institutions.

The CTD informed the committee that a feasibility study of rapid NAAT (GeneXpert) will be conducted at 18 TUs for in country evidence of this newer diagnostic.

*To decide upon the policy of GeneXpert as diagnostic tool for private sector and for positioning in diagnostic algorithm, the committee recommended Central TB Division to constitute a*

*Steering committee to suggest National Laboratory committee regarding the decisions to be made in this aspect.*

### **Evaluation study of Akonni Biosystems' TruArray Technology for Multi-Drug Resistant Tuberculosis.**

A presentation on the proposal of Akonni Biosystems Truarray technology for Multi drug resistant tuberculosis was made. The committee said that the technology is too preliminary to review at the National level instead it was suggested that it should come to Laboratory Committee only after being evaluated at the institutional levels.

*The Laboratory committee decided to constitute a sub - committee for setting up a minimum performance standards for TB diagnostics with the following persons as members in the committee:*

- 1. Member from DCGI*
- 2. Member from NIB*
- 3. Member from DBT*
- 4. Microbiologists from NTI,LRS,TRC and JALMA*
- 5. Dr. Madhukar Pai, Professor, McGill university*
- 6. Dr. Puneet Dewan, MO-TB, WHO SEARO*
- 7. Member from WHO*
- 8. Dr. Sandhya from NACO*

It was decided that the sub-committee will be presenting their recommendations in the next laboratory meeting.

### **Updates from FIND and PATH:**

The FIND and PATH provided the laboratory status updates, the activities carried out were as per the plan and within the stipulated time period.

On LPA laboratory accreditation, the committee recommended that in next three months all the NRLs should get their LPA laboratories accredited and later on the NRLs will be responsible for carrying out the proficiency testing for LPA accreditation to those labs falling under their purview, based on their recommendation the CTD will be issuing the Accreditation certificate for the LPA laboratories.

The committee felt that there are some co-ordination issues with FIND India and NTI. FIND India was asked not to communicate to NTI directly; any communication should happen through CTD or FIND Geneva.

The meeting ended with vote of thanks by Dr.Ashok Kumar, DDG-TB.

Government of India  
Central TB Division,  
DGHS/MoHFW/ New Delhi  
20<sup>th</sup> Meeting of the National Laboratory Committee, 13<sup>th</sup> July 2011  
Venue: LRS Institute of TB and Chest Diseases, Mehrauli, New Delhi

**Objectives of the meeting**

- Review of States report on Random blinded re-checking (RBRC) on External Quality Assurance(EQA) for sputum smear microscopy
- Discussion on introduction of LED based microscopy in high workload settings
- Review the data from Line probe assay (LPA)- Lowenstein Jensen (LJ) back up demonstration sites
- Review the progress on the Expand TB project – Laboratory wise status

Timings	Agenda	Presentations by
9000 - 9300	Registration	
9300-1000	Objectives of the meeting: Opening remarks and conduct of meeting	DDG-TB Chairman/DGHS/Gol
1000-1030	Analysis of State's IRL annual report on RBRC in India – Annexure G	Dr.Sharath, CTD
1030-1100	Issues for Discussions/Decisions Phasing of LED based microscopes within the RNTCP: - Light / FM - Formation of committee to review the LED Specifications for India	Dr.Ranjani Ramachandran,WHO
1100-1115	Tea break	
1115-1200	Discussion and Decision need of stopping LJ back up cultures Review of data from LPA-LJ back up demonstration sites in India	Dr. Neeraj, FIND
1200-1330	<ul style="list-style-type: none"> <li>• Review the progress on the Expand TB project – Laboratory wise status <ul style="list-style-type: none"> <li>○ LRS, Delhi</li> <li>○ NTI, Bangalore</li> <li>○ TRC, Chennai</li> <li>○ JALMA, Agra</li> </ul> </li> </ul>	Dr.Meynedu,LRS Dr.Anand, NTI Dr.Vanaja,TRC Dr.Chauhan,JALMA
1330-1415	Lunch break	
1415-1530	Feasibility of Newer Diagnostic GeneXpert as TB diagnostic in India - Positioning of GeneXpert in Diagnostic algorithm - Available country evidences <ul style="list-style-type: none"> <li>▪ LRS experience</li> <li>▪ Hinduja Hospital experience</li> </ul> - Policy on GeneXpert as diagnostic tool for private sector	Dr.Ranjani Ramachandran,WHO Dr.Meynedu,LRS Dr.Camillia, Hinduja
1530-1600	Evaluation study of Akonni Biosystems' TruArray Technology for Multi-Drug Resistant Tuberculosis	Dr.Sharath, CTD
1600-1615	Tea break	
1615-1645	Updates from FIND	Dr.Balasangameshwara, FIND
1645-1715	Updates from PATH	Dr.Mayank, PATH

**List of Participants:****(Annexure 1)**

1. Dr. RK Srivastava, DGHS, MohFW, GoI
2. Dr. Ira Ray, Former Addl.DGS/Dir. NIB
3. Dr. Ashok Kumar, DDG-TB
4. Dr. Behera, Director LRS
5. Dr. P Kumar, Director NTI
6. Dr. Kiran Katoch, Director JALMA
7. Dr.KS Sachdeva, CMO-SAG (TB)
8. Dr. Puneet Dewan, MO-TB, WHO SEARO
9. Dr.Ranjani Ramachandran, Lab Focal Point, WHO
10. Dr. Vanaja Kumar, Scientist TRC
11. Dr. Anand, Microbiologist NTI
12. Dr. Ichhpujani, Microbiologist, NCDC
13. Dr.Urvashi Singh, Microbiologist, AIIMS
14. Dr. Logani, Microbiologist, Delhi
15. Dr. Camillia Rodrigues, Microbiologist, Hinduja Hospitals
16. Dr. Meynedu, Microbiologist, LRS
17. Dr. Adhikaree, Microbiologist,PATH
18. Dr. Balasangameshwara V, FIND
19. Dr. Neeraj Raizada, FIND
20. Dr. Rahul Thakur,FIND
21. Dr.Ajay Kumar M, CTD Consultant
22. Dr. Malik Parmar, CTD Consultant
23. Dr. Sharath BN, CTD Consultant