

Minutes of 11th Lab committee meeting held on 06th June, 2007 at Nirman Bhawan

The eleventh Laboratory Committee of RNTCP was held in the resource centre, IV Floor, A wing, Nirman Bhawan, New Delhi on 06th June, 2007. List of participants who attended the meeting is annexed at Annexure-I.

DDG welcomed all the members and briefly highlighted the objectives and agenda for the meeting. The objectives of the meeting were:

- Discuss the XDR TB response plan
- Update the status of IRL strengthening in various states
- Discussion on the upcoming STAG meeting
- Capacity building of NRLs

XDR TB response plan

A draft version of XDR TB response plan of Central TB Division was presented to the committee by DDG(TB). DDG (TB) remarked that now that a few XDR-TB cases have reported from India by a tertiary care hospital, a response plan needs to be developed which gives the correct priority to the effective implementation of DOTS, as well as a phased introduction of DOTS-Plus activities into RNTCP in order to prevent the further development of MDR TB and XDR TB in the country. Also there is a need to evaluate the extent of second line drug resistance and XDR-TB in the country, as well as to review the supply and availability of second line anti-TB drugs. The draft version of the response plan was approved by the committee with minor modifications.

The committee suggested that all XDR-TB reported by any IRL should be validated by an NRL of the country and guidelines be developed for the reporting of such cases. A meeting of the DOTS-Plus committee will be held in the first week of July, 2007 for deciding on further course of action on this issue. It was also decided by the committee that a workshop will be held in TRC, Chennai in mid-August 2007 on 'Truths & Myths of MDR and XDR TB'. In addition to officers and technical experts of RNTCP, invitees to the workshop should include others such as officers from other Government departments, staff of NGOs, medical college and private health care providers, and social activists, legal advisers etc. In addition to providing a wide audience with factual information on MDR-TB and XDR-TB, the workshop can explore whether regulatory measures need to be undertaken to prevent the indiscriminate use of second line anti TB drugs in the country.

Proposed changes to diagnostic algorithm and case definition for WHO 2007 STAG

Presentations were made by Dr T Santha Devi on 2 versus 3 weeks cough and 2 versus 3 smears for diagnostic sputum smear microscopy, and by Dr Selvakumar on specificity and reproducibility of 2 versus 3 smears. These were discussed in view of the proposed changes in the definition of a smear positive pulmonary TB case and diagnostic algorithm in relation to number of smear examinations to be performed placed before the WHO Strategic Technical Advisory Group (STAG) in it's forthcoming meeting on 11-13 June 2007. The data presented from many studies highlighted the potential additional yield from a change to 2 weeks cough, 2 smears and change in the case definition. TRC study data also showed that there is no decrease in specificity, sensitivity and predictive values if 2 sputum smears are done for diagnosis against 3 smears, and 1 positive result is taken as a smear positive case. The other potential benefits for reducing the number of smears and

duration are early diagnosis, reduction of transmission of infection, and increased patient satisfaction. Data presented also showed good reproducibility with the proposed changes if a functional EQA system was in place. The committee agreed that the evidence presented to it demonstrated that it is technically appropriate to change from 3 smears to 2 smears for diagnostic examination and to change the smear positive PTB case definition to at least one positive result from at least two. However the committee strongly endorsed the recommendation that a prerequisite to any consideration of implementing the proposed changes was that a functional EQA system be in place. In addition, the committee strongly held the view the decision when to implement the proposed changes in the diagnostic algorithm and case definition be left up to the respective member country depending on each country's preparedness to meet the challenges posed by introduction of said changes.

However in the India specific setting, there are many operational difficulties to overcome such as the need to change records and registers, re-training of staff etc, prior to any implementation of such proposed changes in RNTCP. In addition, the workload of many microscopy centres will be reduced to a level where there is potential for loss of LT proficiency and the quality of smear microscopy services provided at these centres. To counter-balance the potential reduction of smears examined at a DMC if only 2 smears are examined for diagnosis, consideration should be given by RNTCP to a reduction in the duration of cough in the TB suspect definition from 3 weeks to 2 weeks.

Role of liquid culture in the programme setting

LRS and TRC shared their experiences with liquid culture techniques. The members pointed out that at present there is no reliable information on the use of liquid culture on a large scale in any TB control programme setting and that well designed field evaluation trials are required before liquid culture techniques be introduced into TB control programmes. It was noted that contamination is a major issue in the initial stages when liquid culture techniques are introduced into laboratories. It was also noted that good solid culture and DST facilities, with a good EQA system in place, are required before introducing liquid culture into any intermediate level laboratory. The committee recognized the advantages offered by liquid culture methodologies. However much more information and guidance on at what level in the health system to use liquid culture, what methodologies should be adopted, what these methodologies should be used for, is required and the issue of medium to long term sustainability needs to be discussed.

DRS activities

The intake of cases under the DRS survey in Maharashtra was completed in the month of November 2006, and the interim results have been analyzed by NTI. The interim results based on 75% of samples tested show the level of MDR-TB isolates amongst new cases at 3.6% and retreatment cases at 12.1% .

TRC informed the meeting that the pilot study on 100 MDR-TB suspects (200 samples) is now completed in Andhra Pradesh. The procedures for proficiency testing have been started.

Second line DST has also been initiated by TRC on the isolates found to be MDR-TB from the DRS survey in Gujarat. NTI also will be sending the MDR-TB isolates found in the Maharashtra DRS survey to TRC for second line DST.

In Orissa, the state needs to undertake collection of DMC-wise data on 'new' and 'retreatment cases' for the planning of the cluster sampling, and the data needs to be sent to NTI at the earliest. The DRS survey should be started at the earliest under the supervision of NTI.

The state of Uttar Pradesh has sent the DMC-wise data to TRC, Chennai for the planning of the cluster sampling, and the data is being analysed at present for the purpose of the DRS survey of western UP.

Accreditation of state designated IRLs

The culture and DST equipment is now installed in the IRLs of Andhra Pradesh, Delhi and Haryana. The pre-assessment visit to IRLs of Andhra Pradesh and Gujarat by TRC and to IRLs of Haryana and Delhi by LRS Institute will be conducted in the month of June 07. The pre-accreditation visit to IRL, Nagpur will be undertaken in July 07 by NTI. The states and their respective NRLs should ensure adherence to the timelines given in the activity plan of the 10th lab committee meeting so that the accreditation can be achieved as planned.

Capacity building of NRLs

The capacity of the NRLs needs to be strengthened in view of the increasing number of RNTCP related activities which are being assigned to the NRLs. These activities include EQA visits to their designated states, accreditation of IRLs and medical college laboratories applying for accreditation under RNTCP, second line drug sensitivity testing etc. The committee recommended that the NRLs may submit a detailed plan with justification for additional requirements for improving the human resources of their labs so that the issue can be taken with the authorities.

Technical evaluation of low cost LED adaptation of binocular microscopes

Irregular supply of electricity is a constraint for quality sputum microscopy in many parts of India. Based on the information available from the field (Bareilly district of UP), LED operated torches were found to be useful as an alternative source of light for the binocular microscopes. However there is a need to test the appropriateness of this proposed alternative. LRS will be undertaking a study to find out the feasibility of using LED battery operated torches for smear microscopy and a draft plan for the same was presented to the Committee. The Committee approved in principle the planned study, with a request that CTD, LRS and WHO finalize the study protocol at the earliest.

Review of EQA as per the recommendations of the JMM

As decided during the previous laboratory committee meeting, a two day workshop will be conducted in NTI in September 2007 to review the RNTCP EQA system, and to share the experiences of the reference laboratories and the field in implementing EQA in such a large TB control programme such as RNTCP.

Annexure-I

List of Participants of the 11th Lab Committee meeting of the RNTCP held in New Delhi on 06th June,2007

1. Dr. L. S. Chauhan, DDG (TB)
2. Dr.P.R.Narayanan, Director, TRC,Chennai
3. Dr.T.Santha Devi, TB expert, Chennai
4. Dr. Prahlad Kumar, Director, NTI, Bangalore
5. Dr.V.M. Katoch, JALMA Institute, Agra
6. Dr.Selva Kumar, TRC,Chennai
7. Dr. Vanaja Kumar, TRC, Chennai
8. Dr. Ranjini Ramachandran, TRC,Chennai
9. Dr.P.Vishalakshi, LRS Institute, New Delhi
10. Dr.Somasekhar, NTI, Bangalore
11. Ms. Reena, Microbiologist, NTI, Bangalore
12. Ms. Shyni San, NTI, Bangalore
13. Dr. Saxena, CMO, Central TB Division
14. Dr S. Sahu, NPO (TB), WHO India
15. Dr Fraser Wares, MO(TB), WHO India
16. Dr.S.N Rai, Consultant, Central TB Division
17. Dr.Yamuna Mundade, RNTCP Medical Consultant, Central TB Division
18. Dr. Sarabjit Chadha, RNTCP Medical Consultant, Central TB Division
19. Dr.Sai Kumar, RNTCP Medical Consultant, Central TB Division
20. Dr.Mala Srikanth, RNTCP Medical Consultant, Central TB Division
21. Dr.Reuben Swamickan, RNTCP Medical Consultant, Central TB Division
22. Dr.Srinath, RNTCP Medical Consultant , Central TB Division
23. Dr.Geetanjali, Sharma, RNTCP Medical Consultant, Central TB Division
24. Dr Sheena Susan George, RNTCP Medical Consultant, Central TB Division