

Commitment to ensure an effective quality assurance in diagnosis of tuberculosis

Sir,

India has been identified as one of the high burden countries accounting for almost one-quarter of tuberculosis (TB) cases of the entire global burden as per the recent estimates by the World Health Organization.^[1] Further, it has been estimated that, in India alone, every day almost 40,000 persons get infected with TB *Bacilli*, >5000 people develop TB disease and around 900 people die.^[2] These are quite enormous estimates from a public health point of view and thus it essentially requires sustained commitment of the policy makers and health authorities for curtailing the magnitude of the disease.^[1,2] Sputum microscopy has been regarded as the gold standard in diagnosing a case of smear positive pulmonary TB and hence an effective quality assurance (QA) system of sputum smear microscopy network is crucial in ensuring the reliability of data obtained from the diagnostic aspect (viz. laboratory network-national reference laboratory [NRLs], state TB training and demonstration centers [STDCs]/intermediate reference laboratory [IRLs], and designated microscopy centers [DMCs]) of the revised national TB control program (RNTCP).^[2-4] QA system in RNTCP comprises of three essential elements namely internal quality control, external quality assessment (EQA), and continuous efforts for quality improvement of laboratory services.^[4,5]

Internal quality control predominantly reflects the systematic process of monitoring the working practices internally and it usually includes technical procedures, instrument maintenance under annual maintenance contract, preparation and quality of reagents, smear preparation, grading of examined smear, equipment infection control measures, biomedical waste management etc.^[2]

External quality assessment itself comprises of three types/levels of check - on-site evaluation (OSE), panel testing (PT), and random blinded re-checking (RBRC). OSE provides a timely opportunity to the supervisor for immediate problem-solving, taking corrective action and giving on-site re-training, at the time of their scheduled visits to the respective laboratories. OSE is conducted by senior TB laboratory services in the DMC once a month; STDC/IRL laboratory supervisors in district TB centers (DTCs)/TB units once a year; and laboratory supervisors of NRLs in STDCs/IRLs once a year. The supervisors are expected to do a comprehensive assessment of safety procedures practiced in the laboratory, equipment status, inventory status of laboratory consumables, technical components of acid fast *Bacilli* smear microscopy, and un-blinded examination of five positive and five negative smears obtained from the laboratory register by systematic random sampling procedure to observe the quality of smear and staining. PT is employed to evaluate the efficiency of laboratory technicians (LTs) in performing smear microscopy, with no focus on other laboratory activities. Supervisory laboratory staff of STDCs/IRLs and DTCs (LTs of DMCs are exempted) are subjected to PT (viz. five unstained smears per technician), on an annual basis. It can also be used to assess the level of

performance or to quickly detect problems associated with very poor performance. However, since PT does not monitor the routine performance of LTs, it cannot be considered as a very effective component of EQA. RBRC of routine slides is a process of re-reading a sample of slides obtained using lot QA method of sampling, collected from a laboratory to assess the performance level of the laboratory. RBRC is performed once every month for every DMC and the role of the district TB officer is very much decisive in ensuring blinding.^[2,4]

Quality improvement is a comprehensive and a continuous process in which all integral components of smear microscopy are analyzed to identify the barriers that are limiting the effectiveness of the method. It includes identification of faults followed by implementation of corrective measures such as re-training, to prevent the recurrence of problems.^[3,4]

Altogether, the QA system under RNTCP is committed to enhance the credibility of laboratory results and simultaneously acts as a source of staff motivation for further betterment in their efficiency.

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