

External quality assessment of smear microscopy by the National Reference Laboratory in nine states of India

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SUMMARY

The quality of sputum smear microscopy in nine Intermediate Reference Laboratories (IRLs) was assessed based on onsite evaluation conducted by the National Reference Laboratory (NRL) in India, which supervises the IRLs for external quality assessment. The IRLs were evaluated, problems were identified, causes were explored and remedial actions were suggested. The NRL reports and feedback from the states were evaluated. Of

the corrective actions recommended during the initial NRL evaluation visits, 65% were implemented within a month. Subsequent visits to seven IRLs showed 80% improvement. The NRL suggestions resulted in immediate corrective actions and had a sustained impact.

KEY WORDS: onsite evaluation; panel testing; random blinded rechecking; EQA

EFFECTIVE TUBERCULOSIS (TB) CONTROL is dependent on accurate and reliable diagnosis, treatment and monitoring. Serious deficiencies may be observed when insufficient attention is given to the quality of outcome, leading to underdiagnosis and increased rates of infection transmission.^{1,2} In 2003, efforts were made to develop a framework for the implementation of effective external quality activities in India.^{3,4} The objective of the present study was to assess the quality of the sputum smear microscopy centres and Intermediate Reference Laboratories (IRLs) of nine states based on National Reference Laboratory (NRL) onsite evaluation visits, followed by subsequent visits to seven states.

METHODS

Setting

India's Revised National Tuberculosis Control Programme (RNTCP) has established a system to monitor laboratory practices based on International Union Against Tuberculosis and Lung Disease and World Health Organization (WHO) guidelines.³ The NRL team makes onsite supervisory visits once a year to review activities in the IRLs.

Study area

The present study covered nine states of India: Gujarat, Andhra Pradesh, Chhattisgarh, Goa, Punjab, Kerala, Tamil Nadu, Uttar Pradesh and Sikkim.

Tools for data collection

The NRL onsite evaluation form designed by the RNTCP for assessment of laboratories was used for data collection and consisted of six sections: 1) general information, 2) actions required as per previous visit, 3) particulars about the current visit, 4) onsite panel checking, 5) review of onsite and panel testing results of District Tuberculosis Centres, and 6) summary of the current visit.³ Possible sources of errors were identified, remedial actions were suggested and summary reports were prepared. Reports on actions taken were obtained from the states within 1 month after the visit.

Panel testing

Panel testing was performed by microbiologists and laboratory technicians at the IRLs using a set of five unstained slides. Discordant results were verified before declaring errors.

The NRL onsite evaluation visits were conducted out between October 2005 and March 2008 for all nine states, of which seven were visited a second time. The data on the IRL facilities, observations made during the onsite evaluation visits and reports on actions taken submitted by the states were assessed.

RESULTS

Observations during the initial visits

In five states, the IRL director was the head of the organisation (Gujarat, Andhra Pradesh, Punjab, Goa

and Kerala); in the others the State TB Officers were in charge. The Goa and Punjab IRLs were based at the respective medical colleges. Five medical officers in Kerala, Gujarat, Andhra Pradesh and Chhattisgarh were trained in external quality assessment (EQA) and were helping in supervisory activities. In Kerala, Punjab and Goa, full-time microbiologists were posted for EQA. Only nine (42%) laboratory technicians in Gujarat, Andhra Pradesh, Punjab, Kerala, Sikkim and Uttar Pradesh were trained in EQA. In Chhattisgarh, no full-time staff had been recruited to perform EQA activities.

IRL performance during the initial visits

During the initial visits, only four IRLs were found to have well-equipped laboratories, adequate stocks of consumables and trained staff. Biomedical waste was properly disposed of in all except one state. Only Gujarat State was able to complete the first round of IRL onsite evaluation visits to the districts. Involvement of the IRL staff in clinical activities, non-availability of qualified microbiologists, lack of equipment for panel-slide preparations and lack of personnel trained in EQA activities compromised the supervisory activities in five states.

Onsite panel checking

A total of 86 laboratory personnel underwent panel testing using unstained smears, including 23 IRL laboratory personnel and 63 Senior TB Laboratory Supervisors (STLS). One IRL microbiologist and two laboratory technicians reported three high false-negative (HFN) and one low false-negative (LFN) errors and nine STLSs made six HFN, one low false-positive (LFP), two LFN and two quantification errors (QEs).

Suggestions made during the initial visits

The following recommendations were made: recruitment of full-time staff for EQA activities, discontinuation of clinical activities by staff recruited for EQA, procurement of equipment for panel-slide preparations, effective annual maintenance contracts for microscopes throughout the state, implementation of a proper EQA reporting system and training of IRL laboratory staff.

Observations made during the second visits

At the second visit, all of the IRLs were functioning optimally. The main corrective actions taken by the IRLs were: 1) initiation of IRL onsite evaluation visits to the districts, 2) discontinuation of other clinical activities, 3) appointment of microbiologists and laboratory technicians, 4) increase in the number of IRL technicians trained in EQA (from 42% to 55%), and 5) initiation of preparation of panel slides. There was an overall improvement in the checklist items of 80% (Figure). The post of the IRL director had fallen

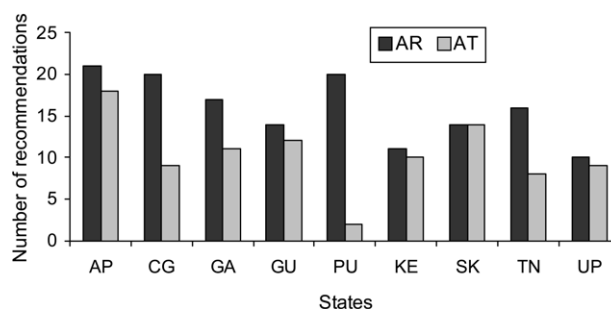


Figure Actions recommended during initial NRL onsite evaluation visits and feedback received from the respective states within a month. AR = actions recommended; AT = actions taken; AP = Andhra Pradesh; CG = Chhattisgarh; GA = Goa; GU = Gujarat; KE = Kerala; PU = Punjab; SK = Sikkim; TN = Tamil Nadu; UP = Uttar Pradesh; NRL = National Reference Laboratory.

vacant in Gujarat State. In Chhattisgarh, the IRL laboratory had been established and instruments had been procured. In the Goa IRL, the situation remained unchanged; although there was no separate functioning IRL, onsite evaluation visits were made by the chief of the Goa Medical College Microbiology Laboratory to both districts.

A total of 70 laboratory personnel, including 19 IRL laboratory personnel and 51 STLS, underwent panel testing using unstained smears. One IRL microbiologist and three laboratory technicians reported 4 LFN errors, while two STLS made 3 LFN errors.

DISCUSSION

Onsite supervision is a very effective method for assessing laboratory conditions. This point has been reiterated in the present study.

During the initial visits, seven of nine IRLs had already been established but only four were fully functional. The IRL buildings were just being made ready at Chhattisgarh and in Tamil Nadu, and the other five IRLs were at varying levels of functionality. Regular monitoring and supervision of primary health care centres was not being performed by these IRLs due to the fact that the posts of microbiologist and laboratory technician were vacant. Like India, many other countries are still struggling to expand effective EQA due to a lack of human resources.⁵

The limited errors (3%) in panel testing indicated that these technicians are well experienced. Laboratory supervisors are most likely to provide correct results because of their greater skill and experience.⁶

The first NRL visits focused on strengthening the IRLs. Suggestions were made to initiate onsite evaluation visits, to discontinue clinical activities by programme personnel, to procure equipment for panel slides and to take corrective measures for Designated Microscopy Centres with high false errors. About 66% (Figure) of the recommendations were implemented

within a month. During subsequent visits, a steady improvement was observed.

CONCLUSION

Improvements were noted in IRL facilities, infrastructure and human resources between the two NRL visits. To improve and sustain the quality of sputum microscopy throughout India, peripheral laboratories needed regular monitoring and close supervision.

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RÉSUMÉ

En Inde, la qualité de l'examen microscopique des frottis de crachats dans neuf laboratoires intermédiaires de référence (IRL) a été évaluée en se basant sur une évaluation sur site par le laboratoire national de référence (NRL), qui supervise les IRL pour le contrôle externe de qualité. L'évaluation des IRL a été menée, des problèmes ont pu être identifiés, les causes ont été explorées et des actions correctrices ont été suggérées. Les évaluations

du NRL et les renseignements provenant en retour des Etats ont été évalués. Parmi les actions correctrices recommandées au cours des visites initiales d'évaluation du NRL, 65% ont été mises en œuvre dans le mois. Les visites ultérieures à sept IRL ont montré une amélioration de 80%. Les suggestions du NRL ont entraîné des actions correctrices immédiates et ont eu un impact persistant.

RESUMEN

Se evaluó la calidad de la baciloscopia del esputo en nueve laboratorios intermedios de referencia (IRL) de tuberculosis en la India, durante las visitas de supervisión realizadas por el laboratorio nacional de referencia (NRL), el cual tiene a su cargo la evaluación externa de la calidad de los IRL. Durante la evaluación se detectaron los problemas, se examinaron sus causas y se pro-

pusieron medidas correctivas. Se analizaron los informes del NRL y las respectivas respuestas de los estados. El 65% de las medidas propuestas se ejecutaron en un lapso de un mes. En las siguientes visitas a los IRL se observó una mejoría del 80%. Las indicaciones del NRL dieron lugar a medidas correctivas que tuvieron un impacto sostenido.