RESEARCH NOTE

EVALUATION OF A NEW QUALITY ASSESSMENT STRATEGY FOR BLINDED RECHECKING OF RANDOM SPUTUM SMEARS FOR TB IN DELHI, INDIA

Sonia Malik[1], M Hanif[1], KK Chopra[1], N Aggarwal[2] and RP Vashist[2]

[1]New Delhi Tuberculosis Center, New Delhi -2; [2]Delhi Government Dispensary, Gulabi Bagh, Delhi, India

Abstract. This study was conducted at the New Delhi Tuberculosis Center, Delhi, India, from 1 January 2006 to 31 December 2007 to assess the feasibility of implementing random blinded rechecking (RBRC), a quality assurance strategy, and its impact on the performance of tuberculosis smear microscopy in Delhi, RBRC activities are carried out monthly at District Tuberculosis Centers (DTCs). Forty thousand five hundred and six slides were rechecked during the study period. RBRC, as a method of quality assurance was found to be feasible for a large application. The quality of sputum microscopy improved, with a significant reduction in the number of false positive and false negative errors in 2007 compared to 2006. The number of microscopy centers reporting high false errors decreased significantly in 2007.

Keywords: RBRC, AFB microscopy, external quality assurance

INTRODUCTION

In most developing countries burdened with high rates of tuberculosis (TB) and access to culture and drug susceptibility testing being scarce to non-existent, sputum smear microscopy remains the mainstay of pulmonary tuberculosis case detection and treatment monitoring (Ridderhof *et al*, 2007).

To ensure reliable, high quality microscopy services, quality assurance of sputum smear microscopy is essential. This depends on a network of local laboratories and external quality assessment (EQA) of these laboratories under the supervision of reference laboratories to ensure smears are performed and interpreted correctly and that all microscopy centers achieve an acceptable level of performance.

The previous routine EQA method was rechecking all positives and 10% of negative slides reported by the technician in an unblinded fashion by senior tuberculosis lab supervisors (STLS) (RNTCP, 2000). This resulted in a large workload for the already burdened lab supervisors, making it unfeasible for operating conditions. In an effort to simplify EQA activities and to prioritize EQA of the

Correspondence: Dr KK Chopra, New Delhi Tuberculosis Center, JLN Marg, New Delhi -2, India.
Tel: 23234270
E-mail: ndtbc@yahoo.com

National TB Control Program, practical EQA guidelines were developed by an international working group (Aziz, 2002), which recommended three methods to evaluate laboratory performance: on-site evaluation (OSE) using a standardized questionnaire, panel testing of technician proficiency using centrally prepared slides, and random blinded rechecking (RBRC). RBRC is a process of rereading a statistically valid sample of routine slides based on lot quality assurance strategy (LQAS) in a blinded manner to assess whether the lab has an acceptable level of performance. To date, few countries have implemented the 2002 EQA guidelines and fewer studies have evaluated its field implementation, especially in high burden countries. The Revised National Tuberculosis Control Program (RNTCP) adopted the international guidelines to revise the existing quality control policy (RNTCP, 2005). This study was undertaken at the New Delhi Tuberculosis Center, the State Teaching and Demonstration Center (STDC) for Delhi and provides technical, managerial and training inputs to further the performance of the national tuberculosis program in terms of quality and quantity. The study objectives were: to assess the feasibility of implementing RBRC in the state of Delhi and to assess the impact of RBRC on the performance of smear microscopy in terms of number of errors. This study was conducted from January 2006-December 2007.

MATERIALS AND METHODS

To implement RNTCP, the state of Delhi was divided into 24 District Tuberculosis Centers (DTCs) each headed by a District TB Officer (DTO), who is responsible for the overall management and organization of RNTCP in his district. To provide people easy access to TB sputum smear microscopy, each district has one Designated Microscopy Center (DMC) for every 100,000 persons with competence in acid-fast staining. The state of Delhi has 183 DMCs catering to a population of 17,000,000. One trained lab technician (LT) is responsible for performing sputum AFB microscopy at each DMC. One trained STLS supervises the microscopy activities of 5 DMCs and is also responsible for quality assurance. The STLS conducts on-site visits to DMCs every month and collects slides for RBRC.

RBRC was initiated in Delhi in December 2005. The 24 DTCs were arranged into 5 groups. RBRC activities were carried out at one DTC each month. Utilizing revised EQA guidelines, the sample size of slides for rechecking was calculated using the LQAS method, which takes into account the slide positivity rate and the annual negative slide volume at a peripheral lab (RNTCP, 2005). To ensure a random, unbiased representative sample of slides, sample slides from each DMC were selected from the lab registery by the STLS and transferred each month to the District TB officer (DTO) responsible for conducting the RBRC of that particular group, who then coded the slides. The slides were rechecked by different STLS of the same group. The STLS were unaware of the original results. The original results and the results of the STLS were compared by the DTO and discrepant slides were sent for umpire reading to the STDC. The umpire reading results were considered final and reported back to the DTC.

RESULTS

All 183 state DMCs regularly participated in RBRC during the 2 year study period. Blinding procedures were ad-

Table 1
Random blinded rechecking of slides in Delhi state.

	2006	2007
Total slides stained	615,321	705,960
Positive slides	72,148	87,686
Slide positivity rate	11.7%	12.4%
No. of slides rechecked	20,015	20,491
No. of errors (%)[a]	257 (1.3%)	189 (0.9%)[b]
Major errors	111	109[b]
Minor errors	146	80[b]
No. of DMC with any error (major/minor)	174	178

[a] % of total slides rechecked; [b] $p<0.05$, fall is significant; DMC, District Microscopy Center

Table 2
Number and type of errors reported from District Microscopy Centers during RBRC in 2006 and 2007.

	2006	2007 (change from 2006)
Total no. of errors	257	189 (decrease by 24.5%)
Major errors (false positive)	29	11 (decrease by 64.3%)[a]
Major errors (false negative)	82	98 (increase by 19.5%)[a]
Minor errors (low false positive)	15	13 (decrease by 13.3%)
Minor errors (low false negative)	70	36 (decrease by 48.6%)[a]
Minor errors (quantitation errors)	61	31 (decrease by 47.5%)[a]

[a] $p<0.05$, significant change
Major error (false positive), false positive interpretation with >9 acid-fast bacilli/100 fields.
Major error (false negative), false negative interpretation with >9 acid-fast bacilli/100 fields.
Minor errors (low false positive), false positive interpretation with 1-9 acid-fast bacilli/100 fields.
Minor errors (low false negative), false negative interpretation with 1-9 acid-fast bacilli/100 fields.
Quantitation error, error in grading a positive slide.

equately followed. Monthly RBRC reports of DTCs were sent to the STDC. The RBRC report, consisting of feedback on the number and type of errors committed by the LT and suggestions to improve these, were sent to the DMCs. Major and minor errors in microscopy during RBRC were analysed per revised guidelines (RNTCP, 2005). Briefly, major errors were defined as: false positive or false negative results with >9 acid-fast bacilli/100 fields). Minor errors were defined as: false positive or false negative interpretation with 1-9 acid-fast bacilli/100 fields and a quantitation error or error in grading a positive slide (Table 2).

Forty thousand five hundred and six slides were rechecked during this period constituting 3% of the total of 1,321,281 smears read by LT during the study

Table 3
Performance of District Microscopy Centers (DMC) during RBRC in 2006 and 2007.

	No. of DMC in 2006	No. of DMC in 2007 (change from 2006)
Any major error	80	57 (decrease by 28.8%)[a]
DMC with major errors (false positive)	26	10 (decrease by 61.5%)[a]
DMC with major errors (false negative)	61	54 (decrease by 11.5%)

Total no. DMCs = 183; [a] $p<0.05$, significant decrease

period. A total of 446 errors were detected, comprising 2.2% of the slides rechecked (Table 1).

Compared to 2006, the number of errors (major and minor) in 2007 were significantly fewer ($p<0.05$) (Table 1, 2). This reduction was significant ($p<0.05$) in the number of HFP cases (64.3% reduction) in 2007 (Table 2). There was a slight increase in the number of false negative errors in 2007 due to repeated errors (15 HFN) reported from one private microscopy center. The number of DMC reporting major errors came down by 28.8% from 80 in 2006 to 57 in 2007 ($p<0.05$) (Table 3).

DISCUSSION

Similar to an earlier pilot study from a national reference laboratory in Chennai, India (Selvakumar *et al*, 2003), and in other studies (Van Rie *et al*, 2008; Martinez *et al*, 2005), we found this strategy was operationally feasible. All districts in Delhi regularly participated in the RBRC activities without exception, and all monthly reports were regularly sent to the STDC.

One of the major reasons for the fall in number of errors reported by DMC could be the reduced workload of rechecking of slides by the STLS, permitting them to allocate more time to supervision activities. Previous EQA guidelines mandated the STLS to recheck all positive results and 10% of all negative slides reported by the LT in an unblinded manner (original results of LT known to STLS) during their routine monthly visits. This resulted in high workloads for the STLS. After introducing RBRC, the use of the LQAS technique led to a smaller sample size, thus reducing the EQA workload. An STLS in Delhi, on an average, used to recheck 750 slides per quarter. This came down to 170 slides per quarter after implementation of LQAS based sampling. The relatively simple RBRC error report format leads to easy identification of faulty DMC, prompting quick corrective action by supervisory staff. Routine monthly rechecking as well as a RBRC feedback on the type of errors committed and suggestions for improvement was further motivation for improved quality of microscopy.

RBRC as a method of EQA is operationally feasible for large applications. It results in lower workloads, yields less biased estimates and allows direct assessment of laboratory performance of AFB smear microscopy prompting early corrective measures resulting in improved quality.

REFERENCES

Aziz M, Ba F, Becx-Bleumink, Bretzel G,

Humes R, Iademarco MF. External quality assessment for AFB smear microscopy. WHO, CDC, APHL, KNCV, RIT, and IUATLD. Washington: Association of Public Health Laboratories, 2002. [Cited 2010 Jan 7]. Available from: URL: http://www.tbrieder.org/publications/eqa_en.pdf

Martinez A, Balandrano S, Parissi A, *et al*. Evaluation of new external quality assessment guidelines involving random blinded rechecking of acid fast bacilli smears in a pilot project setting in Mexico. *Int J Tuberc Lung Dis* 2005; 9: 301-05.

Revised National Tuberculosis Control Program (RNTCP). Module for senior tuberculosis laboratory supervisor. New Delhi, India: Central Tuberculosis Division. Director General of Health Services, Ministry of Health and Family Welfare, 2000.

Revised National Tuberculosis Control Program (RNTCP). External quality assurance manual. New Delhi, India: Central Tuberculosis Division, Director General of Health Services, Ministry of Health and Family Welfare, 2005.

Ridderhof JC, Deun AV, Kam KM, Narayanan PR, Aziz MA. Roles of laboratories and laboratory systems in effective tuberculosis programmes. *Bull World Health Organ* 2007; 85: 325.

Selvakumar N, Prabhakaran E, Rahman F, *et al*. Blinded rechecking of sputum smears for acidfast bacilli to ensure the quality and usefulness of restaining smears to assess false positive errors. *Int J Tuberc Lung Dis* 2003; 7: 1077-82.

Van Rie A, Fitzgerald V, Cabuya G, *et al*. Sputum smear microscopy: evaluation of the impact of training, microscope distribution, and the use of External Quality Assessment Guidelines for resource poor settings. *J Clin Microbiol* 2008; 46: 897-01.