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Quality assessment of smear microscopy by stratified lot sampling of treatment follow-up slides

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SUMMARY

SETTING: Ten peripheral laboratories performing routine acid-fast bacilli (AFB) smear microscopy in Lima, Peru.

OBJECTIVES: To test whether external quality assessment (EQA) rechecking of AFB smears becomes more efficient with stratified lot sampling of treatment follow-up smears.

DESIGN: In 2 consecutive years, a stratified lot sample of 36 treatment follow-up slides and 24 diagnostic slides were randomly selected and blindly rechecked. A second controller determined the final result for discordant slides. Feedback was provided to laboratory technicians during supervisory visits.

RESULTS: More false-negative errors were found in the follow-up slides than in the tuberculosis suspect slides: 25 vs. 3. This represented a yield of 3.5% in 720 follow-up slides and only 0.6% in 480 diagnostic slides. Positive predictive values were high in both years. Respectively three and eight laboratories did not reach a relative sensitivity of >65% during the first and second year, and a clear improvement was seen in only one laboratory. Excessive workload seemed to preclude raising the level of routine performance.

CONCLUSIONS: EQA with stratified lot sampling of treatment follow-up slides proved very efficient and effective for identifying laboratories with substandard performance in a setting with low positivity rates in routine diagnostic smears.

KEY WORDS: tuberculosis; sputum smear microscopy; quality control; diagnosis

A STRONG LABORATORY NETWORK that provides reliable acid-fast bacilli (AFB) smear microscopy services is essential in the control of tuberculosis (TB).[1–3] In areas of high TB prevalence, routine reading of large numbers of slides overloads the scarce human resources, and maintenance of good quality performance becomes a challenge. Older guidelines for quality control recommended rechecking all positive and 10% of negative smears. This was highly inefficient in terms of sample size and composition, wasted efforts in laboratories with high workloads and focused excessively on positive slides. Moreover, the results were often not reliable, as the sample selected was not random, the rechecking not blinded and the final result—the 'gold standard'—relied on one controller only.[4]

In 2002, lot quality assurance sampling (LQAS) was recommended for external quality assessment (EQA) of AFB microscopy. LQAS leads to small, feasible sample sizes in large laboratories, especially those with high positivity rates in routine smears,[5] and has been successfully applied in different settings.[6–8] However, the sample size required is still too large for countries with decentralised services and moderate-to-low positive prevalence in routine smears, as the numerous small laboratories each require a large sample proportional to their volume of work. This is the case for various countries in South America, and one of the reasons why they continue to apply the old EQA recommendations reporting very low error rates for large numbers of rechecked slides.[9]

In this study, we tested a modification to the current EQA guidelines and LQAS. To keep rechecking effective but the sample size small despite a low prevalence of positive slides, the lots were stratified into treatment follow-up and diagnostic slides.

METHODS

Setting

The study was conducted between October 2003 and September 2005 in the District of San Juan de Lurigancho in Northeastern Lima, Peru. In 2005, the TB incidence in the district was 213 per 100 000

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population.[10] In 2008, the national human immunodeficiency virus prevalence rate in adults and children was estimated at 0.3%.[11] Ten first-level health centre laboratories in the district were selected for the study. Eight were performing only AFB smear microscopy, while the other two were also performing mycobacterial culture. The National Tuberculosis Programme (NTP) guidelines for AFB microscopy were followed using hot Ziehl-Neelsen (ZN) staining at 0.3% basic fuchsin concentration. Diagnostic smear microscopy was performed on two smears. One to two follow-up smears were examined after each month of the intensive treatment phase. For the study, slide rechecking by a first and second controller was done by two experienced biologists at the Instituto de Medicina Tropical Alexander von Humboldt, Universidad Peruana Cayetano Heredia, Lima, Peru.

Study procedures

The sample size for rechecking was determined for the subset of treatment follow-up smears. It was estimated to contain at least 10% positive and scanty positive results. Considering the generally low reproducibility of readings of follow-up smears (mostly 1+ and scanty positive), a minimum relative sensitivity (ability of the laboratory's technician to detect AFB relative to the controllers) of 65% and acceptance number zero (maximum number of false-negative errors allowed in the sample) were considered appropriate. These conditions resulted in a sample size of 36 follow-up smears per year to be rechecked for each laboratory. An arbitrary number of 24 diagnostic smears from TB suspects were added to each laboratory sample to prevent bias during routine reading.

The slides were stored in chronological order in the slide boxes rather than based on result. The laboratory coordinator selected nine follow-up and six suspect smears by stratified random sampling on a quarterly basis. During the second year of the study, positive slides were sampled randomly and added to the lot samples to avoid chance under-sampling of positives, as recommended in the global guidelines.[5] However, contrary to the instructions, the corresponding number of negative slides was randomly removed by mistake.

Selected slides were listed with their identification number, laboratory and type of sample (follow-up or TB suspect). The coordinator kept the sampling lists with the results obtained by the laboratories. The first controller received the sampled smears with a list showing slide identifiers only. All smears were restained prior to re-reading, which covered 100 fields, as also recommended by national guidelines for routine work. Discordant results between the peripheral laboratories and the first controller were identified by the coordinator. The second controller read the discordant smears, examining as many fields as needed to exclude the presence of AFB with the highest possible probability; reading was blinded only to the type of discordance, and this result was considered the 'gold standard'. The coordinator compiled all results, identifying the types of errors and their origin (laboratory or first controller). As feedback, and to improve performance, the potential causes of the errors were discussed with the health centre laboratory technicians during the routine supervisory visits of the local laboratory coordinator, and the error slides were reviewed.

Data analysis

All data were entered into an Excel spreadsheet (Microsoft, Redmonds, WA, USA) prepared for the study and double checked. The World Health Organization/International Union Against Tuberculosis and Lung Disease recommended quantification scale and corresponding classification of major and minor errors were used.[5,12]

To eliminate bias due to the considerably different routine prevalence of positives in the different peripheral laboratories and between these and the samples presented to the controllers, relative sensitivities were calculated by applying error rates found in the rechecking sample to the total positive and negative smear results reported in routine work. The relative sensitivity of the first controller's readings was calculated directly from his error rates in the samples rechecked, as explained elsewhere.[13] Furthermore, a ratio of the sensitivity of each laboratory to that of the first controller was calculated, with a value of 1.00 indicating equally sensitive detection by laboratory technicians and controller. Positive predictive values (PPVs) were calculated to provide discriminative power for false-positive error analysis.

Ethical considerations

The study was approved by the Ethics Committee at the Universidad Peruana Cayetano Heredia.

RESULTS

During the 2-year study period, 53 803 routine smears were read at the 10 laboratories (Table 1). The average rate of smear-positive/scanty results for the first and second year was respectively 6.7% and 8.2%, and follow-up smears represented respectively 28.6% and 27.4% of the total examined. A total of 600 slides were selected for rechecking per year, containing 63 (11%) smear-positive/scanty smears in the first and 182 (30%) in the second year.

The numbers of errors detected for TB suspect and treatment follow-up slides are shown in Table 2. The errors of the first controller for the samples from all laboratories taken together appear at the bottom. During the first year, there were three high false-positive (HFP) errors and 11 false-negative errors in the laboratories, of which nine were high false-negative (HFN);

Table 1 Numbers of slides examined routinely and numbers rechecked, by laboratory result and year, San Juan de Lurigancho, Lima, Peru

Year, laboratory no.	Positive		Scanty		Negative		Positive/ scanty in routine %	Positive/ scanty in rechecked sample %
	Routine	EQA	Routine	EQA	Routine	EQA		
October 2003–September 2004								
1	84	4	11	0	1 079	56	8	7
2	100	3	32	3	2 602	54	5	10
3	221	8	6	0	3 131	52	7	13
4	101	1	4	0	1 998	59	5	2
5	88	6	13	0	1 536	54	6	10
6	124	9	2	1	2 058	50	6	17
7	144	9	11	0	1 588	51	9	15
8	156	6	18	0	2 072	54	8	10
9	377	11	5	0	4 008	49	9	18
10	11	2	0	0	813	58	1	3
Total	1406	59	102	4	20 885	537	7	11
October 2004–September 2005								
1	63	12	29	0	1 799	48	5	20
2	142	16	65	0	2 999	44	6	27
3	320	24	46	1	5 457	35	6	42
4	153	20	13	0	2 769	40	6	33
5	94	14	22	0	2 115	46	5	23
6	188	20	9	0	2 678	40	7	33
7	158	21	23	0	1 969	39	8	35
8	148	23	27	0	1 748	37	9	38
9	1032	22	23	0	6 206	38	15	37
10	26	9	2	0	1 087	51	3	15
Total	2324	181	259	1	28 827	418	8	30

EQA = external quality assessment.

Table 2 Numbers of errors found in the rechecked slides, by type (suspect or follow-up) and year, San Juan de Lurigancho, Lima, Peru

Type of slide, laboratory no.	October 2003–September 2004					October 2004–September 2005				
	HFP	LFP	HFN	LFN	QE	HFP	LFP	HFN	LFN	QE
Suspect smears										
1	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0
3	1	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	1	0	0
5	0	0	1	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	1	0	0
7	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	1	0	0	0	0
Total	1	0	1	0	0	1	0	2	0	0
First controller	0	0	1	0	2	0	0	4	0	0
Follow-up smears										
1	0	0	1	2	0	0	0	1	0	0
2	0	0	4	0	0	0	0	2	1	0
3	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	3	1	0
5	1	0	2	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	2	0	0
7	0	0	0	0	0	0	0	2	0	1
8	0	0	1	0	0	1	0	1	0	0
9	1	0	0	0	0	0	0	0	1	0
10	0	0	0	0	0	0	0	0	1	0
Total	2	0	8	2	0	1	0	11	4	1
First controller	3	1	3	1	0	0	0	6	1	0

HFP = high false-positive; LFP = low false-positive; HFN = high false-negative; LFN = low false-negative; QE = quantification error.

during the second year, these figures were respectively 2 and 17 (13 HFNs). During the first year, three laboratories were identified with more than one false-negative error (mostly HFN), and four (all HFN) during the second year. There was thus no overall improvement in the laboratories during the second year, except for one laboratory (number 5) that went from 3 to 0 HFN. The first controller went from 3 to 0 HFP, but with an apparent deterioration for false-negatives (from 5 to 11, mostly HFN). Low false-positive and quantification errors were rare throughout the study period.

As also shown in Table 2, false-negative errors were far more frequent in the follow-up than in the suspect smears for both the laboratories (10/11 and 15/17 during first and second year) and the first controller (4/5 and 7/11). This represents, for the laboratories, a yield of 25 false-negative errors in 720 follow-up smears (3.5%) against only three such errors in 480 TB suspect smears (0.6%). It is also of note that in the second year at least one false-negative error was detected in the follow-up smears of 8/10 laboratories.

Table 3 converts the errors to relative sensitivities of the laboratories and to sensitivity ratios with the first controller. Relative sensitivity varied from 16% to 100% for follow-up smears, and from 58% to 100% for suspect smears. Considering suspect and follow-up smears separately, respectively one and three laboratories did not reach 65% relative sensitivity during the first year, vs. respectively two and eight during the second year. Relative sensitivity increased in only one laboratory. The average sensitivity also decreased slightly. The PPV was high for all laboratories in both years. The first controller scored 93% relative sensitivity in both years.

DISCUSSION

The application of EQA guidelines for AFB smear microscopy modified by stratified lot sampling of treatment follow-up slides was very efficient in screening laboratories for possible substandard performance. Far more false-negative errors were found in the follow-up slides than in the TB suspect slides.

Blinded rechecking of routine smears after LQAS is considered to be the best EQA method.[5] If correctly executed, it yields a realistic view of daily routine performance, allows identification of laboratories with problems that need to be solved and is highly motivating for the laboratory technicians. Its implementation is feasible in most countries with high TB incidence, but requires an excellent understanding of the procedure and good organisation.[14] However, where the cost of labour is high, the prevalence of positive smears is low and/or services are highly decentralised, its implementation remains problematic. The latter situation is typical in middle-income countries, where numerous laboratories detect a few cases each. In such

Table 3 Relative sensitivities of laboratories and sensitivity ratio to the first controller by year of study, San Juan de Lurigancho, Lima, Peru

	October 2003–September 2004			October 2004–September 2005		
Type of slide, laboratory no.	Relative sensitivity %	Sensitivity ratio to first controller	Positive predictive value %	Relative sensitivity %	Sensitivity ratio to first controller	Positive predictive value %
Suspect smears						
1	100	1.07	100	100	1.07	100
2	100	1.07	100	100	1.07	100
3	100	1.07	75	100	1.07	100
4	100	1.07	100	58	0.62	100
5	64	0.69	100	100	1.07	100
6	100	1.07	100	61	0.65	100
7	100	1.07	100	100	1.07	100
8	100	1.07	100	100	1.07	100
9	100	1.07	100	100	1.07	100
10	100	1.07	100	100	1.07	89
Total	94	1.01	96	91	0.98	99
Follow-up smears						
1	25	0.27	100	38	0.41	100
2	27	0.29	100	24	0.25	100
3	100	1.07	100	100	1.07	100
4	100	1.07	100	16	0.17	100
5	31	0.33	80	100	1.07	100
6	100	1.07	100	41	0.44	100
7	100	1.07	100	34	0.36	100
8	71	0.77	100	58	0.62	89
9	100	1.07	80	61	0.65	100
10	100	1.07	100	37	0.40	100
Total	62	0.67	95	43	0.46	98

a setting, sample sizes determined using the LQAS system turn out to be higher than those with the old '10% rule'. Although efficient in terms of detecting errors, the total number of slides to be rechecked becomes prohibitive.

In this study, we tried to circumvent this problem by stratified sampling, targeting treatment follow-up smears. The rationale for using follow-up smears from initially smear-positive cases is to minimise the sample size needed. A considerable proportion of TB patients continue to excrete (dead) bacilli during the first few months of treatment;[15] however, their sputum samples are generally scanty. Reading has lower inherent reproducibility, more errors can be allowed and the target sensitivity can be set lower. Both lower target sensitivity and higher prevalence of positive (and scanty) smears lead to smaller LQAS sample sizes. In all other respects, the rechecking technique applied here followed standard guidelines, including blinding of the first controller and a second controller for discordant slides.[5] Furthermore, we systematically restained before the control reading to also detect staining problems, which are common in situations of work overload, as was suspected in our laboratories.

Positive slides rarely present problems, and if errors occur they are systematic and easily detected with a small sample. They might nevertheless be missed where there is a low prevalence of positive smears. We therefore oversampled positive slides during the second year. Virtually no false-positives were detected, although three times more had been rechecked. This confirms that very small sample sizes would not hide a false-positive problem. This over-sampling of positives unintentionally resulted in slightly smaller sampling of negatives during the second year; however, the very high number of failing laboratories suggests that even so the statistical power had remained sufficient.

We used fixed sample sizes despite variability in the positivity rate between the laboratories and oversampling of positive slides in the second year. We compensated for this during analysis by applying the error rates detected to the total number of positive and negative slides registered in each laboratory over the year, thus calculating a relative sensitivity compared to the controllers. Likewise, the relative sensitivity for the first controller was calculated by applying his error rate to the total sample rechecked. It remained excellent for both years. This demonstrates that his increased false-negative error rate was explained by the far higher prevalence of positives in the samples rechecked during the second year and not by decreasing performance. In general, conversion to relative sensitivity can be recommended for identifying deficiencies.[13]

Follow-up smears were targeted because of their higher positive prevalence to reduce the necessary sample sizes, but also because they are more difficult to read correctly and a good indicator of quality in AFB microscopy laboratories.[16] It could be argued that sampling these smears was not fair and caused a distorted view of the laboratory's real performance. The large majority of false-negative errors were indeed found in the follow-up smears, and it is likely that the laboratories' overall performance is better than suggested by our results (or, alternatively, that they neglect follow-up smears). Notwithstanding, the relative sensitivity ratio still indicates large deficiencies in many laboratories compared to a controller with a good microscope and a good technique who follows the guidelines. For a rough but more objective view of case detection errors, calculations should include TB suspect smears only, but this is not really the point. In some of our laboratories, overall relative sensitivity did not even reach 50%, indicating that more than half of the positive smears had been missed, at least among follow-up smears. Our approach differentiates performance more clearly than a simple application of the pass/no pass rule that comes with the standard LQAS method, and the laboratories most in need of problem-solving supervision are more clearly identified.

In 2004, 152 577 AFB smears were rechecked in Peru (all positives and 10% negatives), and 99.7% agreement was observed.[9] It could be argued that the discordance rate was within the normal range of variation of the smear microscopy technique. However, our results, and those of other authors,[17,18] indicate that the rechecking system in place is not capable of identifying the problems that need to be addressed.

While our approach manifestly succeeded in efficiently identifying laboratories with unsatisfactory performance, the lack of improvement during the second year—in all but one laboratory—indicates a failure of follow-up and remedial action. The study included regular feedback and supervision, with error review and the occasional repair of a microscope. However, the excessive workload caused by tuberculosis programme policy could not be reduced. The NTP sets a performance target of TB suspects to be screened monthly. To reach this target, patients with <2 weeks of cough are screened, which leads to low smear positivity rates, overburdened laboratories and, as shown here, poor performance despite EQA and corrective measures.[19]

In line with current recommendations, NTPs should emphasise quality and not quantity of sputum smear examinations.[20,21] The introduction of methods that improve efficiency, such as the LED fluorescence microscopy,[22,23] could be worthwhile in the most overloaded laboratories. Finally, rechecking of routine slides should be made more efficient and effective by reducing sample size and ensuring excellent technical execution. Stratified LQAS of treatment follow-up smears permits efficient EQA of AFB smear microscopy in decentralised settings with a low prevalence of positives in laboratory routine, as in Peru.

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RÉSUMÉ

CONTEXTE : Dix laboratoires périphériques réalisant l'examen microscopique à la recherche de bacilles acido-résistants (BAAR) à Lima, Pérou.

OBJECTIFS : Vérifier si le recontrôle par evaluation externe de qualité (EQA) des frottis avec BAAR devient plus efficient grâce à un échantillonnage de lots stratifiés de frottis de suivi du traitement.

SCHÉMA : Au cours de 2 années consécutives, nous avons prélevé un échantillon stratifié de lots de 36 lames de suivi et de 24 lames de diagnostic. Les frottis ont été sélectionnés au hasard et recontrôlés à l'aveugle. Un second contrôleur a déterminé le résultat final en cas de discordance de la lecture des lames. Une rétro-information a été fournie aux techniciens des laboratoires au cours des visites de supervision.

RÉSULTATS : On a trouvé un plus grand nombre de faux négatifs dans les frottis de suivi que dans les frottis des suspects de tuberculose : 25 contre 3. Ceci représente un taux de 3,5% sur les 720 lames de suivi et seulement de 0,6% dans les 480 frottis de diagnostic. Les valeurs prédictives positives ont été élevées au cours des 2 années. Au cours de la première et de la deuxième année, respectivement trois et huit laboratoires n'ont pas atteint une sensibilité relative >65%. Une amélioration nette n'a été observée que dans un seul laboratoire. Une charge de travail excessive semble empêcher l'amélioration des performances de routine.

CONCLUSIONS : Une EQA avec un échantillonnage stratifié de lots de frottis de suivi de traitement s'est avérée très efficiente et efficace pour identifier les laboratoires dont les performances sont inférieures au standard dans un contexte où les taux de positivité sont faibles en routine dans les frottis de diagnostic.

RESUMEN

MARCO DE REFERENCIA: Diez laboratorios periféricos de Lima donde se lleva a cabo en forma rutinaria la baciloscopia (BAAR).

OBJETIVOS: Evaluar si una nueva verificación de las BAAR mediante evaluación externa de la calidad (EQA) es más eficiente con un muestreo estratificado por lotes de las baciloscopias de seguimiento del tratamiento antituberculoso.

MÉTODO: Durante 2 años consecutivos se tomó una muestra estratificada por lotes de 36 baciloscopias de seguimiento del tratamiento y 24 baciloscopias diagnósticas. Se escogieron en forma aleatoria los frotis y se verificaron de nuevo en forma anónima. Un segundo controlador definió el resultado final de las lecturas discordantes. Durante las visitas de supervisión se comunicaron los resultados a los técnicos de laboratorio.

RESULTADOS: Se encontró más resultados falsos negativos en los frotis de seguimiento que en las baciloscopias diagnóstico (25 contra 3). Esto representa un rendimiento de 3,5% en 720 frotis de seguimiento y de solo 0,6% en 480 baciloscopias diagnósticas. Los valores de predicción positiva fueron altos en ambos años. Tres laboratorios no alcanzaron una sensibilidad superior a 65% en el primer año y ocho laboratorios en el segundo año. Se observó una mejoría neta del rendimiento en un solo laboratorio. El volumen excesivo de trabajo parece impedir que se mejore el rendimiento rutinario de los laboratorios.

CONCLUSIÓN: La EQA con un muestreo estratificado por lotes de las baciloscopias de seguimiento del tratamiento antituberculoso dio muestras de eficiencia y eficacia en la detección de los laboratorios con un rendimiento inadecuado, en un medio con bajas tasas de positividad de las baciloscopias diagnósticas rutinaria.