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Quality control of smear microscopy for acid-fast bacilli: the case for blinded re-reading

Nguyen Thi Ngoc Lan,* C. D. Wells,† N. J. Binkin,‡ J. E. Becerra,‡ Pham Duy Linh,* Nguyen Viet Cô‡

***Pham Ngoc Thach TB and Lung Disease Centre, Ho Chi Minh City, Vietnam, †Division of Tuberculosis Elimination, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia, USA, ‡National Institute of Tuberculosis and Respiratory Diseases, Hanoi, Vietnam**

SUMMARY

SETTING: Quality control of sputum smear microscopy, which is essential for ensuring correct tuberculosis (TB) diagnosis, is often performed through the unblinded re-reading of all positive slides and a sample of negative slides.

OBJECTIVE: To assess misclassification error introduced by knowledge of prior results.

METHODS: The Southern Vietnam Regional TB Laboratory prepared three gold-standard sets of 750 slides: an unblinded set, an unblinded set in which 13% of negative slides were replaced by weakly positive slides purposefully mislabelled as negative, and a blinded set. Six provincial technicians who normally perform district quality control each reread 125 slides from each set.

RESULTS: In the three sets only one negative slide was misread as positive. In the unblinded set (referent), 2.9% (9/311) positive slides were misread as negative, compared with 18.7% (57/305) in the blinded set (prevalence ratio [PR] = 6.5; 95% confidence interval [CI] 3.3–12.8; $P < 0.001$), and 11.3% (33/293) in the unblinded set with mislabelled slides (PR = 3.9; 95%CI 1.9–8.0; $P < 0.001$).

CONCLUSIONS: False-negative error was more common than false-positive error. Knowledge of prior reading influences re-reading. Blinded re-reading of systematically selected slides would appear preferable, although this method requires high levels of proficiency among quality control technicians.

KEY WORDS: tuberculosis; acid-fast bacillus; microscopy; quality control; Vietnam

LABORATORY TESTS play an essential role in developing countries in the diagnosis of several major diseases, including tuberculosis and malaria. Because of the importance of initiating treatment in those who truly do have a disease, and of avoiding unnecessary and sometimes costly treatment among those who do not, quality assurance programs have been developed in an attempt to maintain high levels of diagnostic accuracy.

Sputum smear microscopy remains the basis of diagnosis for tuberculosis (TB) in most developing countries. The importance of correct reading of sputum smears at the local level, where the diagnosis is usually made, is critical. Therefore, the International Union Against Tuberculosis and Lung Disease (IUATLD) and the World Health Organization (WHO) recommend that quality control of smear microscopy be an essential part of an effective national TB control program.[1,2]

The purpose of quality control is to assure that those patients whose smears are reported as positive for acid-fast bacilli (AFB) are truly positive, and those whose smears are reported as negative for AFB are truly negative. The importance of the former, or identifying false-positive readings, is to minimize unnecessary treatment and the wasting of TB program resources; the importance of the latter, or identifying false-negative readings, is to ensure that the presence of TB is detected so that patient outcomes can be improved and community transmission of TB minimized.

The IUATLD currently recommends that a systematic sample of smear microscopy specimens be selected for review. The sample should include both positive and negative sputum specimen smears, and the slides should be re-read by a second individual who did not perform the initial specimen slide reading; this second individual should not know the results of the first reading (blinded re-reading).[1]

In practice, many TB control programs in developing countries continue to follow previous international recommendations on quality control.[3] In the previous system, technicians working at the local level (e.g., districts) periodically send all AFB positive and negative specimen slides to a more central laboratory (e.g., provincial or national) where all positive slides and a systematic sample of negative slides are

Correspondence to: Nancy Binkin, MD, MPH, Division of Tuberculosis Elimination, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, MSE10 Atlanta, GA 30333, USA. Tel: (+404) 639-8120. Fax: (+404) 639-8604.

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re-read in an unblinded fashion. These previous recommendations, developed in an era when supplies of antituberculosis drugs were limited, placed greater emphasis on detecting false-positive AFB smears; they were also based on the practical consideration of separating positive and negative smears so that the positive slides could be kept for a year and then destroyed and the negative slides cleaned and re-used if necessary.

A limited number of studies performed in India in the 1960s and Algeria in the 1970s have assessed agreement between peripheral and central readings of slides.[4,5] More recently, a study from Colombia in 1993 examined the concordance between initial slide readings at the local level and subsequent central laboratory blinded re-readings as a product of slide preparation technique and quality.[6] None of these studies, however, have specifically evaluated the performance of an established quality control system. Furthermore, none have evaluated the effect of unblinded re-reading on the results, which could bias the re-readings or could result in less diligent examination of the slides. We therefore undertook a study to compare blinded and unblinded quality control in southern Vietnam, where a comprehensive program of unblinded quality control has been in place for many years.

METHODS

The TB laboratory at Pham Ngoc Thach Hospital (PNTH) is responsible for quality assurance of smear microscopy for the southern Vietnam region. In this capacity, it performs quality control for the 19 districts in Ho Chi Minh City Province (HCMC), reviews quality control results for the other 18 provinces in the southern region of the country, and performs periodic proficiency testing and training for the provincial laboratories.

At the district level, technicians number each slide with a glass etching pencil, write the results of their reading for the slide on the slide itself using a waterproof marker, and place the slide in boxes marked 'positive' and 'negative', depending on the results. On a monthly basis, all slides read at district level in southern Vietnam are sent to provincial laboratories (or, in the case of HCMC Province, to the PNTH laboratory) for quality control purposes. At the provincial level, 100% of the positive and 1 in 3 of the negative slides are re-read. Feedback is given to the district laboratories and to the PNTH laboratory on a monthly basis.

To prepare the gold standard master set of slides for this study, 2250 slides from the 19 districts in HCMC that had been read by the PNTH laboratory as part of the quality control program were selected from the 'positive' and 'negative' boxes. The waterproof markings were removed, and the etched numbers covered over with tape. Each was given a randomly selected unique identification number between 1 and 2250 that could be matched back to the original slide number by the study coordinator. The 2250 slides included 1341 (60%) that had been re-read at PNTH as negative, and 909 (40%) re-read as positive; this negative:positive ratio approximates the 70:30 ratio resulting from the usual 1 in 3 sample of negative slides (or 34 543 out of 114 673 total negative slides for 1995) and the 100% sample of positive slides (15 732 for 1995). Each of the selected slides was re-stained using standard Ziehl-Neelsen techniques and then re-read by one of two technicians considered by the laboratory director to be highly proficient. Technicians examined 100 consecutive microscopic high-power fields using a binocular microscope with an electrical light source. If no organisms were observed in 100 fields, an additional 200 fields were examined before recording the slide as negative for AFB. If AFB were detected, the slides were recorded as positive and the number of organisms present were classified using WHO/IUATLD guidelines:[1,2] 1 to 9 AFB per 100 fields, exact figure recorded; 10 to 99 AFB per 100 fields recorded as 1+; 1 to 10 AFB per field recorded as 2+; and more than 10 AFB per field recorded as 3+.

After cleaning with xylene, the slides were then randomly assembled into three groups of 750 slides corresponding to the three study arms. The sample size per arm (n = 375 true positive slides) was calculated based on detecting an expected prevalence of false negative rates of 0.05 and 0.10 using blinded and unblinded readings, respectively, with a 95% level of confidence (alpha = 1.96) and a power of 80% (beta = 0.84). Similarly, 375 slides per arm were included to detect a similar difference in false positive rates. Therefore, the sample size of 750 slides per arm was established. The study was focused on false-negative reading error, rather than false-positive reading error, since data for 1995 from the PNTH quality control system had shown that false-negative error was 18-fold greater than false-positive error. During this period, the false-negative error among the 34 543 slides read by district technicians as AFB negative was 0.55%, while the false-positive error among the 15 732 slides read as AFB positive was 0.03%.

Three study arms were evaluated: an unblinded arm, an unblinded arm in which a fraction of the AFB-negative slides were replaced by slides that were weakly positive but deliberately mislabelled as negative (hereafter referred to as the unblinded/mislabelled arm), and a blinded arm. The slides for the three study arms were prepared in the following manner. For the slides to be used in the unblinded arm, the gold standard reading was recorded with each slide's identification number in the log to be used by each provincial technician for recording re-reading results. In the unblinded/mislabelled arm, the same method was followed, but 61/457 (13.3%) of the negatives were replaced by weakly positive slides (1 to 9 AFB per 100 fields) whose gold standard readings were deliberately recorded as negative in the technicians' study

log. Finally, in the blinded arm, the gold standard readings were not recorded in technician's study log; the log books contained only identification numbers.

Each group of 750 slides was further divided into six boxes of 125 slides, each of which contained a slightly different mix of positive, negative, and, in the case of the second study arm, mislabelled slides (Figure). Two technicians in each of three provinces were then given three boxes of 125 slides to re-read, one from each of the three study arms. Normally, each province has two technicians, who rotate between quality control and routine microscopy for the provincial hospital. The participating provinces were selected because their patient base was considered representative of TB patients identified in the region as a whole, and due to the high performance of their respective technicians. When the slides were delivered to the laboratories for reading, no details of the study

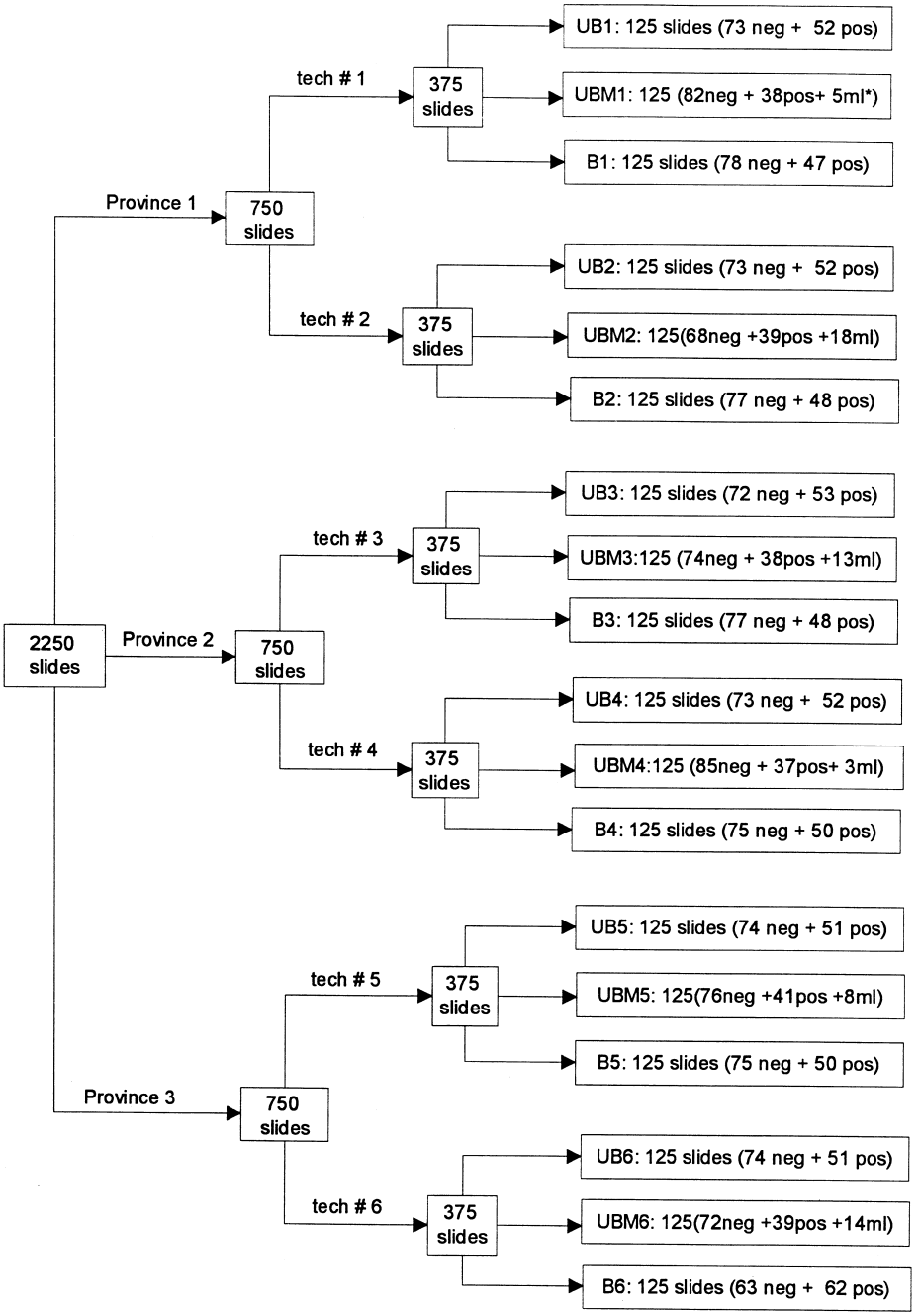

Figure Composition of slide sets read by the six provincial technicians. Each technician received one set of 125 slides from each of the three study arms (UB = unblinded, UBM = unblinded/misclassified, B = blinded). The numbers in parentheses show the number of positive (pos), negative (neg), and, in the case of the unblinded/mislabelled arm, the number of positive slides deliberately mislabelled as negative (ml). The mixture of type of slides was deliberately varied in the sets of 125.

design were provided, but the technicians were aware that the slides were being sent to them by PNTH laboratory. Slides were read using binocular microscopes with external light sources, using the same reading and scoring techniques outlined above for the PNTH technicians. Each technician read 5–10 slides daily in addition to their usual work until the slides were completed. The technician logs were then returned to PNTH laboratory for evaluation of the results.

Data entry and analyses, including calculation of prevalence ratios and exact binomial confidence intervals around each prevalence ratio, Kappa statistics, and Fisher's exact tests, were performed using the epidemiologic and statistical software package, Epi Info.[7]

RESULTS

Comparison of blinded and unblinded readings of district slides by PNTH laboratory

To compare the results of blinded and unblinded re-reading of the same slides sent from the district to PNTH, the unblinded re-readings that had been done as part of routine quality control were compared with the blinded re-reading done on the same 2250 slides, to establish the gold standard for the second portion of the study. With the initial unblinded quality control re-reading of the 2250 slides, all 896 slides read initially as positive at the district level were re-read as positive by PNTH technicians; likewise, all 1354 slides read initially as negative at the district level were re-read as negative. Table 1 compares the same initial district reading with the blinded reading performed by the PNTH technicians to establish the gold standard slide set. Of the 2250 slides, the 896 slides (39.8%) in the gold standard set initially read as positive at the district were again re-read as positive on blinded re-reading. Of the remaining 1354 slides (60.2%) identified as AFB negative at the district level, 13 (1.0%) were re-read as positive with blinded re-reading; this detection of false negative readings was significantly higher than in the initial quality control re-readings ($P = 0.0002$; Fisher's exact test, 2-tailed). Most of the slides that were re-read as positive on blinded re-reading had between 1 and 9 organisms per 100 microscopic fields.

Table 1 Concordance profile of tuberculosis smear microscopy results between district level readings and blinded quality control re-readings at Pham Ngoc Thach Hospital (PNTH), Ho Chi Minh City, Vietnam

	Blinded PNTH re-reading				
	Positive				
District reading	1+, 2+, 3+	4–9/100	1–3/100	Total	Negative
Positive*	700	180	16	896	0
1+, 2+, 3+	629	19	2	650	0
4/100–9/100	69	161	14	244	0
1/100–3/100	2	0	0	2	0
Negative	1	5	7	13	1341
False negatives detected (%)	0.1	2.7	30.4	1.4	—

*Concordance with/without negatives: 94.7%/88.2%; Kappa statistic with/without negatives 0.90 ± 0.03/0.69 ± 0.06.

Comparison of provincial level re-reading of unblinded, unblinded/mislabelled and blinded slide sets

Table 2 shows the concordance profile of the provincial technician slide readings for the three study arms compared to the gold standard. For the unblinded study arm, 311/750 (41.5%) of the slides were AFB positive according to the gold standard; of these 311, nine (2.9%) were subsequently read by provincial technicians as AFB negative (hereafter referred to as false-negative error). Among the 439/750 (58.5%) slides in this arm that were AFB negative according to the gold standard, 0/439 (0%) were read as positive by provincial technicians (hereafter referred to as false-positive error). For the unblinded/mislabelled arm, 293/750 (39.1%) of the slides were read as AFB positive for the gold standard, including 61/293 (20.8%) that were purposefully mislabelled as AFB negative. The false-negative error for this study arm was 33/293 (11.3%); the false-positive error was 1/457 (0.2%). In the blinded study arm, 305/750 (40.1%) were AFB positive according to the gold standard; the false-negative error was 57/305 (18.7%). No false-positive error was detected for this study arm. In all three study arms, false-negative rates increased as the number of organisms decreased. In the blinded arm, however, 23/242 (9.5%) of the slides that were 1+ to 3+ according to the gold standard were erroneously read as negative.

To assess the magnitude of the differences between the three groups, the prevalence ratios for false-negative and false-positive errors were compared, using the unblinded arm as the referent group. The false-negative error was significantly higher in the unblinded/mislabelled arm (prevalence ratio [PR] = 3.9, 95% confidence interval [CI] 1.9–8.0; $P < 0.001$) and the blinded arm (PR = 6.5, 95%CI 3.3–12.8; $P < 0.001$) compared to the unblinded arm. By contrast, differences in false-positive error among the three arms were not statistically significant.

To determine the influence of the deliberate mislabelling of AFB-positive slides as negative on the re-readings performed by the provincial technicians, the false negative error rate for the 61 mislabelled slides was compared with that observed in the unblinded arm (Table 3). The false-negative error for the mislabelled slides was 24/61 (39.3%), substantially greater than the 2.9% in the unblinded study arm (PR = 13.6, 95%CI 6.7–27.8; $P < 0.001$). In further comparison, the false negative reading error of the 61 mislabelled slides from the mislabelled/unblinded arm was still significantly higher than that among the subset of 61 weakly positive slides (9.8%) in the unblinded arm (PR = 6.0; 95%CI 2.1–19.1; $P < 0.001$).

Table 2 Concordance profile of tuberculosis smear microscopy results from a study of unblinded and blinded slide reading, Southern Vietnam, 1996–1997

Provincial technician reading results	PNTH gold standard reading				
	Positive				
	1+, 2+, 3+	4–9/100	1–3/100	Total	Negative
Unblinded*					
Positive	247	52	3	302	0
1+, 2+, 3+	224	9	0	233	0
4/100–9/100	20	32	2	54	0
1/100–3/100	3	11	1	15	0
Negative	3	3	3	9	439
False negative (%)	1.2	5.4	50.0	2.9	NA
Total	250	55	6	311	439
Unblinded/mislabelled†					
Positive	205	53	2	260	1
1+, 2+, 3+	170	7	0	177	1
4/100–9/100	30	31	2	63	0
1/100–3/100	5	15	0	20	0
Negative	4	23	6	33	456
False negative (%)	1.9	30.3	75.0	11.3	NA
Total	209	76	8	293	457
Blinded‡					
Positive	219	26	3	248	0
1+, 2+, 3+	192	3	0	195	0
4/100–9/100	23	18	1	42	0
1/100–3/100	4	5	2	11	0
Negative	23	28	6	57	445
False negative (%)	9.5	51.9	66.7	18.7	NA
Total	242	54	9	305	445

*Concordance with/without negatives: 92.8%/85.1%; Kappa statistic with/without negatives 0.87 ± 0.06/0.56 ± 0.10.
†Concordance with/without negatives: 87.6%/77.3%; Kappa statistic with/without negatives 0.76 ± 0.06/0.45 ± 0.10.
‡Concordance with/without negatives: 87.6%/85.5%; Kappa statistic with/without negatives 0.76 ± 0.06/0.49 ± 0.10.
PNTH = Pham Ngoc Thach Hospital.

In comparing the false negative reading errors for each of the six individual technicians participating in the study, there was little difference in the proportion of reading errors made among them in any of the three arms of the study; this was also the case in the subset of 61 slides that were purposefully mislabelled in the unblinded/mislabelled arm of the study.

DISCUSSION

Findings from this study have several implications for establishing a quality control system for TB smear microscopy. First, unblinded re-reading of slides for quality control may affect technicians' re-reading and may lower the yield for detecting false-negative error. Such errors may result in failure to detect infectious patients with AFB-positive smears who then continue to transmit TB in the community. In this study, PNTH technicians who performed blinded re-reading of district slides to establish the gold standard for the master slide set detected significantly more false negative error than when they performed general unblinded quality control re-readings of district slides.

Table 3 Results of provincial laboratory technician AFB-smear microscopy re-reading of positive slides deliberately mislabelled as negative

Provincial technician reading	Gold standard reading 4/100–9/100
Positive	37
1+, 2+, 3+	8
4/100–9/100	18
1/100–3/100	11
Negative	24
False negative (%)	39.3
Total	61

The influence of knowledge of prior results was also evident when provincial technicians re-read the unblinded slide sets sent from PNTH. Though provincial technicians were not told the exact nature of the study, they received all slides from the PNTH laboratory, which serves as the reference laboratory for the region, and thus may have been less likely to disagree with the known prior readings of slides. Results from the study arm that was unblinded but contained mislabelled slides underline this point; the provincial technicians misread 39.4% of the 61 AFB-positive slides that were purposefully mislabelled as AFB negative, while they misread only 2.9% of all AFB-negative slides in the unblinded study arm.

These findings were not unexpected, given the results of studies in social psychology. A large body of literature on the phenomenon known as expectancies, recently summarized by Olson et al.,[8] demonstrates that prior assumptions may influence the attention that is paid to the actual information at hand. In most situations, there is a tendency to rely on what is expected rather than carefully process new information. Furthermore, when information is discovered that is not in agreement with prior expectations, the consequences are often perceived as negative and threatening. Since district laboratories have performed well in the past, with a frequency of errors of <1%, it is likely that the quality control technicians expected to find few errors.

The results from this study also suggest that there is less need to focus on re-reading slides identified as AFB positive at district level. In general, the overall detection of false-positive error for the HCMC quality control system is very low (0.03% of 15 732 AFB slides in 1995). Furthermore, we found no significant difference in the levels of false-positive error detected between the PNTH blinded re-reading of the slides to create the gold standard set and the previous unblinded re-reading of these slides in the same laboratory. Additionally, among the three provincial study arms, false-positive error detection was also low and not significantly different. These findings are similar to those of previous studies in India and Algeria, where false-negative errors appear more common than false-positive errors.[4,5]

In our study, error rates were highest in smears with relatively low numbers of organisms. However, the number of organisms may vary between specimens from the same individual,[9] and persons with paucibacillary disease who do not receive treatment are likely to become more infectious over time, resulting in further community spread if they fail to return promptly for further evaluation and treatment. For this reason, the ability of district level technicians to detect even a low number of organisms is important for TB control efforts.

Based on results of the PNTH re-reading, blinded re-reading would appear preferable for detection of false-negative errors, and would be in keeping with the more recent recommendations on quality control of smear microscopy.[1] Systematic sampling in southern Vietnam would result in a ratio of positive:negative slides of approximately 1:3, increasing the relative proportion of AFB-negative slides being re-read. This advantage, combined with the greater diligence that is likely to occur when blinded re-reading is performed, would likely improve the overall detection of false-negative error, and thus serve to further reduce TB transmission in the community. For this to occur, however, additional training and ongoing quality assurance activities among the provincial technicians would also be needed. In the present study, the provincial technicians received a series of unknown slides from the central laboratory, a procedure similar to that which occurs during proficiency testing, and they may have spent greater time and care than usual examining the slides. Nearly 19% of the slides read as positive by the PNTH laboratory were nonetheless misclassified as negative at the provincial level, including a substantial proportion that were 1+ to 3+ positive.

Although this 19% false negative error is much lower than that for the 61 mislabelled slides (39.3%), it is still much higher than the 1.4% error detected for the Ho Chi Minh City district technicians with blinded re-reading by the PNTH technicians to establish the gold standard slide set. This difference is explained in part by the fact that the 1.4% error is an underestimate of the HCMC district technician reading error. In general in the quality control system, slides with errors detected are pulled from the slide sets for further assessment and are not stored with the slides in which the re-reading was in agreement with the district reading. Since standard quality control slides were pulled from storage for use in the study, slides previously identified with error were not included in the gold standard slide set. This difference in reading error also reflects a likely higher level of smear microscopy proficiency among Ho Chi Minh City district technicians compared to the provincial technicians. The district technicians from Ho Chi Minh City are directly supervised by PNTH technicians on a frequent basis and, because of their proximity to PNTH, they have better access to further training in microscopy skills. Furthermore, promotion opportunities are limited in Ho Chi Minh City, and many of the district technicians have chosen to remain in their posts in the city rather than seek promotion elsewhere. These findings suggest that additional efforts would be required to assure optimum performance by quality control technicians in the provinces if blinded re-reading were implemented.

Certain limitations are inherent in this study. First, in establishing the gold standard for the master slide set, we make the assumption that the central laboratory technicians from HCMC are highly proficient without independently evaluating their respective level of proficiency. We feel, however, that this assumption is reasonable since each technician re-reads a high volume of slides (~40/day), is directly supervised by the physician director of laboratory services for the region of Southern Vietnam, and frequently undergoes proficiency evaluations and participates in continuing education courses in laboratory science.

Another obvious limitation of the study was that slides re-read by the provinces came from the central rather than the district level, which may have increased the diligence with which the slides were read. However, although the magnitude of the effect might have been different had it been possible to send gold standard slides from the districts, our findings nonetheless demonstrate that blinded quality control may increase the yield for detecting false negative

error and that knowledge of prior readings may adversely influence the readers' performance.

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RÉSUMÉ

CADRE : Le contrôle de qualité de l'examen direct des étalements de crachats, qui est essentiel pour assurer un diagnostic correct de tuberculose (TB), est souvent pratiqué sous forme d'une relecture non aveugle de toutes les lames positives et d'un échantillon de lames négatives.
OBJECTIF : Etablir les erreurs de classifications introduites par la connaissance des résultats antérieurs.
MÉTHODES : Le laboratoire régional de tuberculose du Sud Vietnam a préparé trois séries de 750 lames servant d'étalon : une série non-aveugle, une série non-aveugle dans laquelle 13% des lames négatives avaient été remplacées par des lames légèrement positives, intentionnellement mal étiquetées comme négative, et une série aveugle. Six techniciens provinciaux, normalement en charge du contrôle de qualité des districts, ont relu chacun 125 lames de chaque série.
RÉSULTATS : Dans les trois séries, une seule lame négative a été lue erronément comme positive. Dans la série non-aveugle de référence, 9/311 lames positives ont été lues erronément comme négatives (2,9%), par comparaison avec 57/305 (18,7%) dans la série aveugle (ratio de prévalence [RP] 6,5 ; intervalle de confiance à 95% [IC] 3,3–12,8 ; $P < 0{,}001$) et avec 33/293 (11.3%) dans la série non-aveugle avec lames mal étiquetées (RP = 3,9 ; IC à 95% 1,9–8,0 ; $P < 0{,}001$).
CONCLUSION : Les faux négatifs sont plus fréquents que les faux positifs. Le fait de connaître le résultat antérieur influence la relecture. La recherche aveugle de lames sélectionnées systématiquement serait préférable, quoique cette méthode exige des niveaux élevés de compétence chez les techniciens du contrôle de qualité.

RESUMEN

MARCO DE REFERENCIA : El control de calidad de la baciloscopía del esputo, que es esencial para el diagnóstico correcto de la tuberculosis (TB), se efectúa a menudo a través de una relectura no ciega de todas las láminas positivas y un muestreo de las láminas negativas.
OBJETIVO : Evaluar los errores de clasificación introducidos por el conocimiento de resultados previos.
MÉTODOS : El Laboratorio Regional de TB de Vietnam del Sur preparó tres series estándares de 750 láminas : una serie no ciega, otra no ciega en la cual el 13% de las láminas negativas estaba reemplazado por láminas débilmente positivas expresamente catalogadas como negativas, y una serie ciega. Seis técnicos provinciales que normalmente efectúan un control de calidad distrital releyeron 125 láminas de cada serie.
RESULTADOS : En las tres series sólo una lámina negativa fue mal leída como positiva. En la serie no ciega (de referencia) el 2,9% (9/311) láminas positivas fueron releídas como negativas, comparado con el 18,7% (57/305) en la serie ciega (relación de prevalencia [RP] = 6,5 ; 95% intervalo de confianza [IC] 3,3–12,8 ; $P < 0{,}001$) y 11,3% (33/293) en la serie no ciega con láminas mal clasificadas (RP = 3,9 ; 95% IC 1,9–8,0 ; $P < 0{,}001$).
CONCLUSIÓN : El error de falso negativo era más común que el error de falso positivo. El conocimiento de la lectura previa influencia la nueva lectura. Sería preferible la relectura a ciegas de las láminas sistemáticamente seleccionadas, aunque este método requiere altos niveles de capacidad entre los técnicos de control de calidad.