INT J TUBERC LUNG DIS 6(1):47–54

Quality assessment of sputum transportation, smear preparation and AFB microscopy in a rural district in Malawi

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SUMMARY

SETTING: Ntcheu District, Central Region of Malawi.

OBJECTIVES: To assess 1) the feasibility of introducing simple internal quality control procedures for acid-fast bacilli (AFB) microscopy, and 2) the quality of the district sputum smear microscopy service.

DESIGN: A simple internal quality control system was piloted in which district laboratory staff assessed: 1) specimen suitability, 2) time between sputum submission and smear examination, 3) smear preparation and staining, and 4) microscopy. Actual times for processing specimens were compared with recommended times. External quality validation was carried out.

RESULTS: Of 4805 sputum specimens: 1) documentation was complete in 95%, 2) 93% reached the laboratory within 7 days of collection, 3) 96% of smears were well prepared and stained, and 4) 97% concordance (96.4% smear-positive and 97.6% smear-negative) was demonstrated when 208 smears were re-examined by a second technician. The aggregate index of reliability was 86%. The mean time spent on microscopic examination was 3.8 minutes, compared with the recommended time of 10 minutes. When all smears from 164 patients were assessed externally, 98.2% concordance (98.1% smear-positive and 98.2% smear-negative) was demonstrated. False smear-negative and smear-positive rates were less than 2% each.

CONCLUSION: District laboratory staff were able to incorporate simple quality control procedures for AFB microscopy into their routine practice, resulting in a reliable service. The lessons learnt are widely relevant and potentially useful for implementation of a national quality assurance scheme.

KEY WORDS: tuberculosis; quality control; sputum smears; microscopy

SPUTUM SMEAR MICROSCOPY is the cornerstone of case finding and diagnosis in tuberculosis (TB) control. In sub-Saharan Africa, the advent of the human immunodeficiency virus (HIV) infection has been associated with a rise in the numbers of both TB suspects and registered TB cases.[1] In Malawi, new TB suspects submit three sputum specimens for smear microscopy. Smear-positive pulmonary TB patients on treatment submit a further two specimens each at 2, 5 and 8 months for the evaluation of treatment.[2] In 1998, 86 technicians in 45 hospital laboratories examined an estimated 204 350 sputum specimens from 88 304 TB suspects and TB patients on treatment (Source: Malawi National TB Control Programme [NTP]). Maintaining quality in the face of this burden is a considerable challenge.

The effective implementation of a sputum smear microscopy service in a district is a demanding process. It involves collection of sputum specimens at hospitals and health centres, storage of specimens prior to their transport to the hospital laboratory, preparation and staining of sputum smears, smear microscopy and reporting of results. Particulars about patients submitting sputum specimens and the results of smear microscopy are recorded in the laboratory sputum registers. There may be problems at each of the stages, which can compromise the reliability and quality of the sputum smear results. The International Union Against Tuberculosis and Lung Disease (IUATLD) has produced guidelines for external quality control.[3] These emphasise the re-reading of smears at a higher level of the laboratory service. However, these guidelines appear to be difficult to implement; few, if any, low-income African countries with high TB prevalence have functioning national quality control schemes for TB smear microscopy. This may be due, as is the case in Malawi, to financial and other resource constraints. Extending the responsibility for maintaining quality to laboratory staff working at grass roots level may comple-

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Article submitted 18 July 2000. Final version accepted 3 October 2001.

[A version in French of this article is available from the IUATLD Secretariat in Paris.]

ment elements of national higher level re-reading. We have therefore conducted a study in a rural district of Malawi to assess: 1) the feasibility of introducing simple internal procedures to enable district laboratory staff to monitor the quality of their own work, and 2) the quality of the district sputum smear microscopy service, once local quality control is in place.

This study was carried out as part of a major initiative to develop an essential laboratory package in Malawi.[4] Before this study, the only quality control procedure employed in the laboratory was the use of smears known to be positive and negative for acid-fast bacilli (AFB) each time a new batch of stain was prepared. Thus, the overall quality of the service was not known.

METHODS

Setting and routine process of sputum examination

The study was carried out in Ntcheu district in the Central Region of Malawi, which has an estimated catchment population of 500 000.[5] There is one district hospital with a laboratory which provides a basic range of services and is the only facility for AFB microscopy within the district. Of the sputum specimens examined in Ntcheu in 1997, 60% were from patients attending the hospital and 40% from patients attending one of the district's 32 rural health centres.

The laboratory was staffed by two laboratory technicians, who were responsible for carrying out the complete range of laboratory tests. They were assisted by two attendants, (ancillary staff without any formal laboratory training) who, in addition to their cleaning duties, routinely assisted with specimen collection and preparation. The existing laboratory practice of processing sputum specimens every Monday, Wednesday and Friday was continued during the study period. All smears were stained using the Ziehl Neelsen (ZN) method, and IUATLD-recommended protocols were followed.[6]

Staff from the central TB reference laboratory in Lilongwe made one supervisory visit each year. Although they were able to identify any major problems, there was insufficient time during their short visit for them to monitor routine performance, specimen suitability, or the process of smear preparation and staining.

Overall laboratory workload assessment

The number and type of all laboratory tests were recorded on a monthly basis. The Welcan unit system of workload measurement was used to determine the true activity of the laboratory and the relative demand of each test on staff time.[7] Information was collected on laboratory staff attendance and the actual time input was compared with the Welcan recommended time for the workload.

Piloting an internal quality control system

A simple internal quality control system for AFB microscopy was introduced in November 1997, in which the district laboratory staff themselves assessed specimen suitability, smear preparation and staining and the microscopic examination of the smears. A study was carried out concurrently to ascertain how much time they were taking to process specimens in comparison with recommended times. An external assessment of microscopy was carried out between October 1998 and March 1999. Records were also kept of numbers of patients, sputum specimens submitted, smear results and case detection rates. Before data collection commenced, the two microscopes were checked to ensure they were in proper working order. Instruction in the principles of quality control and practical training in test methodology were provided.

Specimen suitability and time between submission and examination

The laboratory attendant registering the specimens recorded information for 1) hospital specimens and 2) health centre specimens, on a daily worksheet immediately prior to processing the specimens. Results were collated monthly and compared with routine recording in the laboratory TB register. The following data were recorded: 1) numbers of patients submitting specimens and proportion of request forms completed with correct information, 2) total number of sputum specimens received and proportion labelled correctly, 3) number of specimens assessed macroscopically as mucopurulent, bloodstained or saliva, 4) number of empty containers received, and 5) number of days from specimen collection to smear preparation. There is debate about the time for which sputum specimens can be stored prior to smear preparation without significant deterioration.[8–11] However, some studies suggest that quality may deteriorate after 7 days in adverse conditions of temperature and humidity.[11] For this reason and for operational reasons, all specimens arriving in the laboratory within 7 days of collection were considered suitable for analysis. Older specimens were still processed.

Smear preparation and staining

Smears were prepared and stained, three mornings each week, by one of the laboratory attendants, each of whom carried out this activity alternately. In the afternoon, the second attendant prepared and stained another slide from every tenth specimen.

The laboratory technician reported the overall quality of preparation and staining on the basis of examination of the original preparation. In addition, so that potential differences in performance between laboratory attendants could be detected, comparative assessment was made of the quality of the preparation and staining between the original and duplicate smears. All assessments were made in accordance with IUATLD guidelines.[6]

Microscopy

Each technician reading a batch of smears randomly set aside 10% of the workload, to include both positive and negative slides. These were re-read by the second technician in the laboratory, who was unaware of the initial findings. Both results were recorded to compare the grading and identify discrepancies that could have affected the bacteriological classification of patients. All results were reported according to the IUATLD grading scheme.[6] As AFB are unevenly distributed in sputum, different microscopists can be expected to obtain a slightly different grading, depending on the part of the smear examined. Therefore, for the purposes of this study, discordant results were defined as positive smears (3+, 2+, 1+ or scanty) being recorded as negative, or negative smears being recorded as positive. Smears classified as scanty (4–9 bacilli per 100 high power fields) were included with the positives in line with local clinical practice, based on the likelihood of such cases being true cases in the setting of high HIV/TB prevalence.

Index of reliability

The proportion of 1) specimens arriving in the laboratory within 7 days of collection, 2) smears adequately prepared and stained, and 3) microscopy results which were concordant when examined by a second technician, were considered independent variables that could affect the quality of smear results. Therefore, they were combined to generate an overall index of reliability. This index is produced to highlight that microscopy results are not only dependent on the performance of the microscopist reading a slide, but also on the timely arrival of the specimen and adequate preparation and staining of the smear.

Time/workload study

On a daily basis, laboratory staff recorded time spent on: 1) registration of specimens, smear preparation and staining, 2) microscopic examination of the stained smears, and 3) recording and reporting of results. The total time taken to complete the whole AFB microscopy process from specimen registration to issue of report, and the time taken for microscopy alone, were calculated monthly. The total number of sputum specimens examined and the number of positive smears reported during this period were obtained from the laboratory TB register. This information was used to calculate the mean time to process each specimen and the mean microscopy time per smear. These were compared with the times recommended both by the Welcan Workload Measurement System for Pathology[7] for the complete processing of a sputum specimen, and by the IUATLD for the microscopic examination of smears.[6]

Welcan details that, using the ZN staining method, an average time of 15 minutes per sputum specimen is needed to complete all the required procedures. To classify a smear as negative, IUATLD recommend examination of 200 high power fields.[6] This normally requires 10 minutes. No formal recommendations exist for positive smears, although less time is required to examine smears with high concentrations of bacilli. Ntcheu laboratory staff considered that they needed an average of 2 minutes per positive smear. Based on the above, the total work times and deficits were determined.

External quality assessment

All the AFB slides examined in the laboratory between October 1998 and March 1999 were stored. From July 1998, Ntcheu district was involved in another study to assess a screening strategy for TB suspects using two, instead of three, sputum smears.[12] Therefore, two smears each from all positive suspects and 10% of randomly selected suspects who were smear-negative were sent to the Department of Mycobacteriology at the Statens Serum Institut (SSI) in Denmark for re-reading. Staff at SSI were blinded to the initial Malawi gradings. Patients submitting only one smear were excluded from the analysis. Findings were compared to identify discrepancies which would have resulted in a different patient classification. The same criteria used for internal quality control were applied to determine the concordance of smear results. Discrepant smears were re-read independently at the Liverpool School of Tropical Medicine (LSTM), UK, in order to obtain a consensus result. All results were compared and analysed to determine how many TB suspects had their smear status falsely reported positive or negative by Ntcheu laboratory. To facilitate the learning process, discrepant smears were returned to Ntcheu for re-examination by the laboratory staff.

Other performance indicators

Data were collected for 1997 and the first 6 months of 1998 on the numbers of patients submitting smears and the percentages of these with positive smears. The detection rate for new patients was calculated and compared with all district hospitals throughout Malawi.[13] Data on grading of positive smears were collected for 1998.

Data handling and statistical analysis

Epi Info 6.04 software (CDC, Atlanta, GA, USA) was used for the analyses. The χ^2 test with Yates correction was used to compare the percentage of smear-positive patients detected among those whose sputum was examined within 7 days of collection with those whose specimens were older than 7 days. The proportion of specimens arriving from health centres within 7 days of collection was compared with the equivalent proportion arriving after collection within the district hospital. The Ntcheu smear positivity rate was compared with all other district hospitals in Malawi.

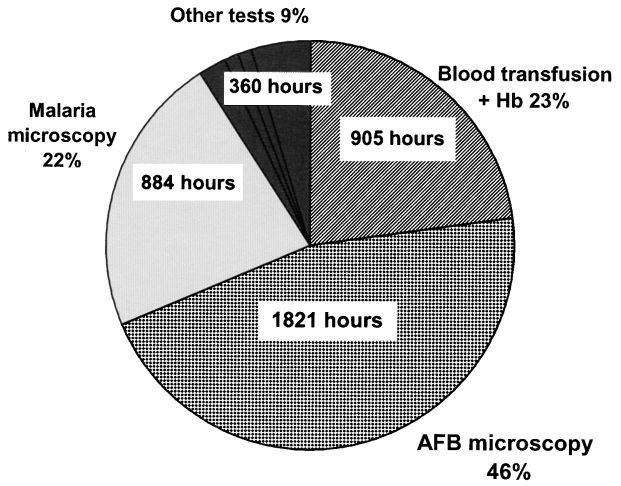

Figure Recommended time allocation required for 1997 laboratory workload. Hb = haemoglobin; AFB = acid-fast bacilli.

Differences at the 5% level ($P < 0.05$) were regarded as statistically significant.

RESULTS

Overall laboratory workload

In the study district, 7284 sputum specimens were examined in 1997, representing 23% of the total number of laboratory tests and demanding 46% of total staff working time. The Welcan-recommended time for the TB microscopy workload compared with other major areas of laboratory service provision is shown in the Figure. The recommended time for the total laboratory workload was 3970 hours. Actual technician input was 2479 hours, leaving a discrepancy of 1491 hours.

Internal quality control

It became clear that the establishment of quality reporting procedures instigated changes that improved the overall results as the study proceeded. For example, in the first month of the study, only 31% of specimens collected in health centres and 80% of those collected in the hospital were labelled with the patient's name. By June 1998, 100% of all specimens arriving in the laboratory were correctly labelled. Also, staining times were initially found to be variable and staff altered procedures as a result.

Sputum specimen suitability and time between submission and examination

Between November 1997 and June 1998, 1846 patients submitted 4805 sputum specimens. Data on suitability of specimens were obtained on 95% (4562) of these specimens submitted by 1775 patients. Results are shown in Table 1. More than 97% of the forms were completed correctly, 94% of specimens were correctly labelled with the patient's name and 95% of sputum samples appeared mucopurulent or blood stained on macroscopic examination. Forty empty sputum containers were received.

Data on the number of days from sputum submission to arrival in the laboratory were available on 1462 patients. Ninety-nine per cent of specimens collected from 817 patients attending the hospital arrived in the laboratory within 7 days of collection. In contrast, a significantly lower proportion of health centre specimens reached the laboratory within the same timeframe, with 84% of specimens from 645 patients arriving within 7 days, a further 12% within 8 to 14 days, and the remainder within 15 to 103 days ($\chi^2 = 115$, $P < 0.000001$). Overall, for all sputum submitted at the hospital or health centres, 93% of specimens arrived in the laboratory within 7 days of collection and were considered suitable for microscopy.

Statistically, the variation in time from sputum collection to arrival in the laboratory had no significant effect on the proportion of smear-positive patients detected. Of all patients whose sputum was examined within 7 days of collection, 15.5% had one or more smears reported as positive compared with 15.0% of those whose specimens were received in the laboratory more than 7 days after collection (Yates corrected $\chi^2 = 0.00$, $P = 0.99$). However, no positive smears were detected in the 10 new TB suspects whose specimens were older than 18 days.

Smear preparation and staining

Ninety-six per cent (69/72) of the original smears were judged by the technician carrying out the microscopy to be adequately prepared and stained.

Table 1 Specimen suitability, November 1997–June 1998

	Hospital *n* (%)	Health centre *n* (%)	Total *n* (%)
No. of patients recorded by laboratory attendant	1036	739	1775
No. of request forms with adequate patient information	1007 (97.0)	724 (98.0)	1731 (97.5)
Total no. of sputum samples recorded	2763	1797	4562
No. of sputum samples labelled with patient's name	2691 (97.0)	1594 (89.0)	4285 (94.0)

Table 2 Comparison of duplicate smear readings in Ntcheu

	Original smear reading	
Internal quality control	Smear-positive *n* (%)	Smear-negative *n* (%)
2nd smear reading		
Smear-positive	81 (96.4)	3 (2.4)
Smear-negative	3 (3.6)	121 (97.6)
Total	84 (100)	124 (100)

Table 3 Comparison of duplicate smear readings (Ntcheu vs. external)

	Ntcheu patient results	
External quality assessment	Smear-positive *n* (%)	Smear-negative *n* (%)
Final consensus result		
Smear-positive	106 (98.1)	1 (1.8)
Smear-negative	2 (1.9)	55 (98.2)
Total	108 (100)	56 (100)

When the duplicate smears were compared, 95% showed no difference in the quality of the preparation and 91.5% had consistent stain quality, regardless of which laboratory attendant had prepared them.

Microscopy

Results are summarised in Table 2: 208 patients each had one smear re-examined blind by a second technician. The concordance rate for positive smears was 96.4%, and for negative smears it was 97.6%. The overall agreement between the two technicians was 97%.

Overall reliability of reported smear results

The aggregate index of reliability for reported smear results was 86%. This figure is a combination of the key findings: the proportion of specimens arriving in the laboratory within 7 days of collection (93%), the proportion of smears adequately prepared and stained (96%), and the proportion of microscopy results concordant when examined by a second technician (97%).

Time/workload study

The mean time taken to fully process a sputum specimen to include all tasks from reception to issuing a report was 7.4 minutes compared with the Welcan recommended time of 15 minutes. A major part of this discrepancy is attributable to the time given to microscopic examination. The mean time for microscopy was 3.8 minutes per smear, compared with the IUATLD recommended time of 10 minutes for negative smears.

External quality assessment

One hundred and sixty-four patients each had two smears re-examined at the SSI. Possible discrepant results were initially found in 14 smears from 10 patients, which were counterchecked at the LSTM. This additional monitoring revealed that only three of the 164 patients actually had their smear status falsely reported by Ntcheu. Two 'false positive' patients each had one smear graded as scanty by Ntcheu; respectively four and five bacilli were seen per 100 high power fields for each patient. One 'false negative' patient had two smears graded as 3+ and 2+ by both the SSI and LSTM. This error had resulted in a new TB suspect who was clearly smear-positive being reported as smear-negative. Ntcheu findings compared with the final consensus result are shown in Table 3. In summary, 98.1% of suspects were correctly identified as smear-positive and 98.2% as smear-negative. Overall, 98.2% of TB suspects had their smear status correctly reported. The findings of the external quality assessment indicate that the Ntcheu false positive rate was 1.9% and the false negative rate was 1.8%.

Other performance indicators

The overall smear positivity rate, i.e., the percentage of new TB suspects found positive by the laboratory, was 14.3% in 1997 and 15.8% in the first 6 months of 1998. Both are significantly higher than the 1997 national rate of 11.9% ($P < 0.05$).[13]

Between January and June 1998, 3994 smears were examined in Ntcheu, with 523 reported as positive. Nineteen per cent of all positive smears and 40% of positive smears from follow-up patients were classified as scanty, suggesting that Ntcheu laboratory technicians are capable of detecting low concentrations of bacilli.

DISCUSSION

At district level in Malawi, sputum smear microscopy is a major area of laboratory service provision. This operational study shows that, with the introduction of internal quality control mechanisms, the reliability of the smear microscopy service in Ntcheu district could be documented. Eighty-six per cent of reported AFB microscopy results are now estimated to be reliable in an aggregate index, derived by combining key findings relating to specimen suitability, smear preparation and microscopy.

The overall process of specimen collection and labelling appears to be good. In the first month of the study, performance was poor, but this improved considerably as a result of the monitoring activities that were established. The majority (>90%) of sputum specimens arrived in the laboratory within one week of submission, although specimens collected in the rural health centres were significantly delayed. The time to smear examination has an important bearing on case detection, and therefore an improved mechanism for transport of specimens collected in health

centres is required. The study methodology did not allow us to identify those specimens that were collected but failed to reach the laboratory.

Sputum smear preparation and staining was consistently good, regardless of which worker prepared the slides, though there is still room for improvement. The overall concordance rate of 97% for repeat microscopy undertaken within the laboratory (positive smears 96.4% and negative smears 97.6%) indicates that results are reproducible, regardless of which microscopist performs the task. It was assumed that the capability and performance of both laboratory technicians was equivalent. The human resource limitations in Ntcheu, with only two laboratory technicians, did not permit local confirmation of the seemingly false positive rate of 3.6% and false negative rate of 2.4%. Although counterchecking of discrepant results by a third party from a higher level would have been desirable for determining the true false positive and negative rates, the infrequency of supervisory visits did not permit this. The counterchecking of discrepant smears by a third party in the external quality assessment exercise highlights the importance of including this second level of monitoring in order to ascertain the true false positive and negative smear rates. The false positive and false negative rates of just less than 2% are comparable with those obtained in other studies by experienced microscopists,[11,14] and were considered acceptable.

It is recognised that it may be difficult for technicians working in the same laboratory to be completely blinded in re-reading exercises. Similarly, there may be some bias in the selection of slides for re-reading. To minimise these problems, formal protocols for slide selection and blind reading were used. Overall, however, the main emphasis in this work has been on fostering a sense of mutual trust, integrity and responsibility within the laboratory. External supervision and quality control alone do not do this so readily.

Although the microscopy results were good, staff spent approximately 4 minutes examining each smear instead of the recommended 10 minutes for negative smears. Because of the overall high laboratory workload, it is not feasible for district laboratory staff in Malawi to spend 10 minutes examining 200 fields in every negative smear. We concluded that examination of 100 fields was adequate and formally reduced the recommended number of fields to 100 as a result of this study. The smear positivity rate remained around 15% throughout the first 6 months of 1998.

The studies also show that in Ntcheu it has been possible for district laboratory staff to incorporate simple procedures into everyday practice which allow them to take responsibility for assessing the quality of their own work. However, without basic training and support, they would not have been able to record data or analyse the results themselves. Thus, further training in quality control is currently in progress.

The laboratory staff themselves have continued with the internal quality control programme past the study period, and further assessment of their performance is in progress. However, because of the heavy laboratory workload, they decided that the attendants would only prepare duplicate smears one day a week instead of three. Duplicate microscopy of smears is maintained at the same level, and with the recent addition of a third laboratory technician a system for counterchecking of discordant results has been introduced. Staff motivation appears to have improved. For example, laboratory staff recently decided to improve the service by processing sputum every weekday instead of 3 days a week.

This system of internal quality monitoring, although well suited to Ntcheu, is not immediately generalisable for all district laboratories in Malawi. More than 50% of district hospital laboratories only have one staff member assigned and therefore duplicate testing within the laboratory would not be feasible. In addition, morale is often low among district laboratory staff because of heavy workloads, poor working conditions and inadequate remuneration. Despite these limitations, this study, carried out in a single but representative district, has provided detailed information on the efficiency of the current strategy for TB case detection at district level. It has highlighted the need to have a broad and flexible approach to quality monitoring, and several lessons have been learnt that are widely applicable.

For example, this study shows that in addition to making arrangements for microscopic re-reading of smears, a number of requirements are essential to implement an appropriate quality control scheme, internal or external, so that the results can be utilised in TB control activities. Each process relating to sputum smear microscopy needs attention, including the collection, storage, transport and preparation of specimens and reporting of results. The need for functioning microscopes and provision for their maintenance has previously been reported.[15] Moreover, sufficient numbers of highly motivated staff who have an appreciation and understanding of the principles of quality control are a pre-requisite for effective operation of any type of quality control system. In order to obtain a consensus microscopy result, provision must be made for counterchecking of discrepant smears. It is mandatory to have competent supervisors to assist with interpreting results, be available for counterchecking discrepancies, identifying problem areas and deciding on appropriate action to be taken. Ideally, quality control results would be reviewed during regular and frequent supervisory visits. In Malawi, the limiting factor for this process is the shortage of trained laboratory staff at regional and central levels with appropriate experience in supervision and quality control.

CONCLUSION

The internal system described is novel as it aims to monitor quality at each stage of the smear microscopy process. Most methods of quality control focus only on accuracy of grading of individual smears, with scores for over- and under-reading.[3,16] These ignore the important aspects of specimen collection and transport, and smear preparation, often carried out by unqualified staff. In the initial stages of implementing a quality control system, it is preferable, as we have done in Ntcheu, to employ a simple reporting system, focusing on gross errors relating to the accuracy of the bacteriological classification of patients. This has the advantage of motivating laboratory staff to relate their work to patient diagnosis and management. It also facilitates the quantification of new TB suspects who have their smear status correctly reported as positive or negative. This could potentially be used alongside other NTP targets in monitoring the effectiveness of TB diagnosis and control.

We have shown that implementation of a locally operated internal quality control system is feasible in a district laboratory in Malawi. Laboratory staff can be motivated to improve and monitor the quality of their own working practices. There is clearly a need to feed this experience into a system for assuring the quality of district AFB microscopy countrywide.

Since the study was carried out, there have been developments in Malawi towards implementing a national quality control system for AFB microscopy, whereby positive and negative smears will be re-read by regional staff and discrepant results counter-checked at central level. Although other workers have shown that this type of quality control is feasible under TB programme conditions,[16] such a task is a major challenge for Malawi, with its large and increasing smear microscopy workload. It will require careful integration with existing quality control mechanisms and investment in personnel and training.

Acknowledgements

This study was carried out as a collaborative initiative between the Malawi Essential Medical Laboratory Services Project and the National TB Control Programme. We thank the staff in Ntcheu district for their active participation and co-operation. We thank the staff of the Mycobacteriology Department at the Statens Serum Institut, Denmark, and the Clinical Diagnostic Laboratory of the Liverpool School of Tropical Medicine, UK, for re-reading smears as part of the external assessment.

Financial support was received from the Liverpool School of Tropical Medicine, UK, the Malawi National TB Control Programme, the Royal Netherlands Tuberculosis Association (KNCV) and the UK Department for International Development (DFID).

References

1 World Health Organization, Global Programme on AIDS. The current global situation of the HIV/AIDS pandemic. Weekly Epidemiological Record 1994; 69: 189–196.
2 Ministry of Health and Population. Manual of the National Tuberculosis Control Programme in Malawi. 4th ed. Malawi: Ministry of Health and Population, 1999.
3 Rieder H L, Chonde M L, Myking H, et al. The Public Health Service National Tuberculosis Reference Laboratory and the National Laboratory Network. Minimum requirements, role and operation in a low-income country. Paris: IUATLD, 1998: pp 25–55.
4 Floyd K, Gilks C F, Kadewele G, Mundy C J F, Nkhoma W, Squire S B. A baseline assessment of laboratory services in Ntcheu district, 1997. Report of the Essential Medical Laboratory Services Project–Phase 1. Malawi Ministry of Health and Population, Liverpool School of Tropical Medicine and UK Department for International Development. Liverpool, UK: LSTM, 1998.
5 Ntcheu District. Health Sector. Annual Report, 1996/97. Lilongwe, Malawi: Malawi Ministry of Health and Population, 1997.
6 Enarson D A, Rieder H L, Arnadottir T, Trébucq A. Tuberculosis Guide for Low Income Countries. Appendix 1: Technical guide for sputum examination for tuberculosis by direct microscopy. 4th ed. Paris: IUATLD 1996.
7 Welcan UK. Workload Measurement System for Pathology. Manual with schedule of units. Cardiff, UK: Welcan, 1990.
8 Mitchison D A. Bacteriology of tuberculosis. Tropical Doctor 1974; 4: 147–153.
9 Kamoto O, Mallewa M, Harries A D. Duration of sputum storage for diagnosis of tuberculosis. Malawi Medical J 1992; 8: 125–126.
10 Banda H T, Harries A D, Boeree M J, Nyirenda T E, Banerjee A, Salaniponi F M L. Viability of stored sputum specimens for smear microscopy and culture. Int J Tuberc Lung Dis 2000; 4: 272–274.
11 Toman K. Tuberculosis case finding and chemotherapy. Questions and answers. Geneva: World Health Organization, 1979: pp 14–22.
12 Harries A D, Mphasa N B, Mundy C, Banerjee A, Kwanjana J H, Salaniponi F M L. Screening pulmonary tuberculosis suspects using two sputum smears. Int J Tuberc Lung Dis, 2000; 4: 1–5.
13 Harries A D, Nyirenda T E, Banerjee A, Mundy C, Salaniponi F M. District sputum smear microscopy services in Malawi. Int J Tuberc Lung Dis 1998; 2: 914–918.
14 Boulahbal F, Coucke C, Aït-Mesbah H. Note sur le contrôle de la qualité des microscopistes. Arch Inst Pasteur Alger 1977; 52: 129–134.
15 Mundy C, Ngwira M, Kadewele G, Bates I, Squire B, Gilks C. Evaluation of microscope condition in Malawi. Trans Roy Soc Trop Med Hyg 2000; 94: 583–584.
16 Van Deun A, Portaels F. Limitations and requirements for quality control of sputum smear microscopy for acid-fast bacilli. Int J Tuberc Lung Dis 1998; 2: 756–765.

RÉSUMÉ

CADRE : District de Ntcheu, Région Centrale du Malawi.
OBJECTIFS : Apprécier 1) la faisabilité de l'introduction de procédures simples de contrôle interne de qualité pour l'examen microscopique des bacilles acido-résistants (AFB), et 2) la qualité du service de microscopie des frottis d'expectoration au niveau du district.
SCHEMA : On a fait un essai-pilote d'un système simple de contrôle interne de qualité dans lequel le personnel du

laboratoire de district a apprécié 1) le caractère adéquat des échantillons, 2) la durée séparant la production de l'expectoration et l'examen du frottis, 3) la préparation du frottis et sa coloration, et 4) l'examen microscopique. Les durées pour le traitement des échantillons ont été comparées avec les durées recommandées. On a pratiqué une validation externe de qualité.

RESULTATS : Sur 4.805 échantillons d'expectorations : 1) la documentation a été complète dans 95%, 2) 93% sont arrivés au laboratoire dans les 7 jours après le prélèvement, 3) 96% des frottis ont été correctement étalés et colorés, et 4) on a démontré une concordance dans 97% des cas lorsque les 208 frottis ont été réexaminés par un second technicien (96,4% pour les bacilloscopies positives et 97,6% pour les bacilloscopies négatives). L'index aggloméré de fiabilité est de 86%. La durée moyenne consacrée à l'examen microscopique a été de 3,8 minutes par comparaison avec la durée recommandée de 10 minutes. Un taux de concordance de 98,2% a été démontré quand tous les frottis provenant de 164 patients ont été réexaminé à l'extérieur (98,1% pour les bacilloscopies positives et 98,2% pour les bacilloscopies négatives). Tant les faux positifs que les faux négatifs ont été inférieurs à 2%.

CONCLUSION : Le personnel du laboratoire du district a été apte à introduire des procédés simples de contrôle de qualité pour la microscopie des bacilles acido-résistants au sein de sa pratique de routine, ce qui a permis un service fiable. Les leçons que l'on en a tiré sont largement significatives et potentiellement utiles pour la mise en œuvre d'un schéma national d'assurance de qualité.

RESUMEN

MARCO DE REFERENCIA : Distrito de Ntcheu, Región Central de Malawi.

OBJETIVOS : Evaluar 1) la factibilidad de introducir procedimientos simples de control interno de calidad para el examen microscópico de bacilos ácido-alcohol resistentes (BAAR) y 2) la calidad del servicio de baciloscopia del distrito.

MÉTODO : Se realizó un estudio piloto de un sistema simple de control interno en el cual el personal del laboratorio del distrito evaluaba 1) la conveniencia de las muestras, 2) el tiempo entre la toma de la muestra de esputo y el examen microscópico, 3) la preparación y la tinción de los frotis y 4) el examen microscópico. El tiempo de procesamiento de las muestras fue comparado con el tiempo recomendado. Se realizó una validación externa de calidad.

RESULTADOS : En 4805 muestras de esputo : 1) la documentación era completa en un 95% ; 2) el 93% de las muestras llegaron al laboratorio dentro de los 7 días después de la toma ; 3) el 96% de los frotis estaban bien preparados y teñidos y 4) se constató un 97% de concordancia (96,4% en los frotis positivos y 97,6% en los frotis negativos) cuando 208 frotis fueron examinados una segunda vez por otro técnico. El índice conjunto de fiabilidad fue de 86%. El tiempo promedio para la realización del examen microscópico fue de 3,8 minutos, en comparación con el tiempo recomendado de 10 minutos. Cuando la totalidad de los frotis de 164 pacientes fue sometido a una evaluación externa, se constató una concordancia de 98,2% (98,1 para los frotis positivos y 98,2 para los negativos). Las tasas de falsos positivos y falsos negativos fueron inferiores a 2%.

CONCLUSIÓN : El personal del laboratorio del distrito fue capaz de introducir procedimientos simples de control de calidad para el examen microscópico de BAAR en su práctica de rutina, lo que se traduce en la fiabilidad del servicio. La lección es ampliamente significativa y potencialmente útil para la implementación de un sistema nacional de control de calidad.