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Making pragmatic sense of data in the tuberculosis laboratory register

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SUMMARY

SETTING: Tuberculosis (TB) microscopy network in Moldova, Mongolia, Uganda and Zimbabwe.

OBJECTIVE: To evaluate how scrutinising the information recorded in the TB Laboratory Register can assist in improving the performance of the microscopy laboratory network and TB case management.

METHODS: Review of records for completeness in registration of age, sex, reason for examination, analysis of variability patterns in serial smears and provision of exemplary statistical process charts of scanty positive results over time in the four countries.

RESULTS: A total of 128 808 records were analysed. A large proportion of examinees in Uganda (6.9%) and Zimbabwe (3.9%) had no information on sex. The reason for examination was unknown for 7.4%. Among suspects with three smear results with at least one positive result, 56.1% had no variation in the pattern. Statistical process control charts revealed considerable fluctuation in the frequency of scanty positive smears over a calendar year.

CONCLUSION: An analysis of information recorded in the TB Laboratory Register not only identifies strengths and weaknesses in the laboratory, it also reveals weaknesses on a much wider scale, in the entire case management system. TB laboratory data can thus demonstrate when, where and what action is indicated, and how performance might be monitored over time.

KEY WORDS: tuberculosis; laboratory; microscopy; statistical process control

INDIVIDUALS who present to health facilities with symptoms suggestive of pulmonary tuberculosis (TB) must undergo diagnostic sputum smear examinations, while patients on treatment undergo follow-up sputum smear examinations for acid-fast bacilli (AFB) to determine their response to chemotherapy. In countries that have implemented the DOTS strategy, all results are recorded in a standardised TB Laboratory Register,[1–4] which contains the following information about each examinee: name, age, sex, address, reason for examination and results of sputum smear examination. Our objective was to evaluate how scrutinising the information recorded in the register could assist in improving the performance of the microscopy laboratory network using data from Moldova, Mongolia, Uganda and Zimbabwe.

METHODS

This retrospective study used standard TB Laboratory Register records from at least one calendar year during the period January 1999–December 2003. From comprehensive national lists of laboratories in each country, 23 laboratories in Moldova, 30 in Uganda and 23 in Zimbabwe were randomly selected, whilst all 31 laboratories in Mongolia were selected.

All pertinent examinee data from these 107 laboratories were abstracted from their TB Laboratory Registers, as reported elsewhere.[5,6] A uniform EpiData (version 3.1, EpiData Association, Odense, Denmark, freely available at http://www.epidata.dk) data entry form was used. Data were entered twice and validated. Discordant records were examined against the original TB Laboratory Register and were corrected as needed to produce the final data file. The files from the laboratories were subsequently combined for analysis.

The data were analysed using EpiData Analysis (public release version 1.1 and test version 2.0) to generate frequencies, cross-tabulations and statistical process control charts. The main outcome measures were completeness of recording of age, sex and reason for

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Table 1 Recording of sex, age and reason for examination among examinees

	Moldova *n* (%)	Mongolia *n* (%)	Uganda *n* (%)	Zimbabwe *n* (%)	Total *n* (%)
Total	17 725	22 555	54 050	34 478	128 808
Sex					
Known	17 722 (100)	22 395 (99.3)	50 330 (93.1)	33 133 (96.1)	123 580 (95.9)
Unknown	3 (0.0)	160 (0.7)	3720 (6.9)	1345 (3.9)	5228 (4.1)
Age					
Known	17 628 (99.5)	22 069 (97.8)	42 463 (78.6)	26 997 (78.3)	109 157 (84.7)
Unknown	97 (0.5)	486 (2.2)	11 587 (21.4)	7481 (21.7)	19 651 (15.3)
Reason					
Known	17 696 (99.8)	22 497 (99.7)	48 609 (89.9)	30 410 (88.2)	119 212 (92.6)
Unknown	29 (0.2)	58 (0.3)	5441 (10.1)	4068 (11.8)	9596 (7.4)

examination; the frequency of scanty positive results over time was also assessed. To ascertain variability in the smear results, we selected only records with a diagnostic smear examination, among which only those with three quantified smear results with at least one positive result underwent further analysis. Smear results with no variations in pattern had the same grade of positivity for the three smears, e.g., '4/100 - 4/100 - 4/100' or '1+ - 1+ - 1+'.

For the purposes of this study, a case of smear-positive TB was defined as a suspect with at least one AFB in at least one of the sputum specimens examined. The unit of measurement was the examinee, and, where indicated, the individual smear examination. For certain indicators, such as reason for examination and frequency of scanty positive results, statistical process control charts were used to determine variability over the months of a given calendar year.

RESULTS

A total of 130 311 records from 107 laboratories were available from the four countries. After exclusion of 1503 (1.2%) examinees with nonsensical serial result patterns (e.g., no smear result followed by a valid smear result), the records of 128 808 examinees were analysed.

Recording of sex and age of examinees

While the age of the examinee is frequently unknown in some countries, there should never be difficulties in recognising and recording the sex of the examinee.

A large proportion of examinees in Uganda (6.9%) had no information on sex; this proportion was also high in Zimbabwe (3.9%). About a fifth of the examinees from Uganda (21.4%) and Zimbabwe (21.7%) did not have their age recorded (Table 1).

Figure 1 shows the age structure of the TB suspects in the four countries. 'Age heaping' is observed be-

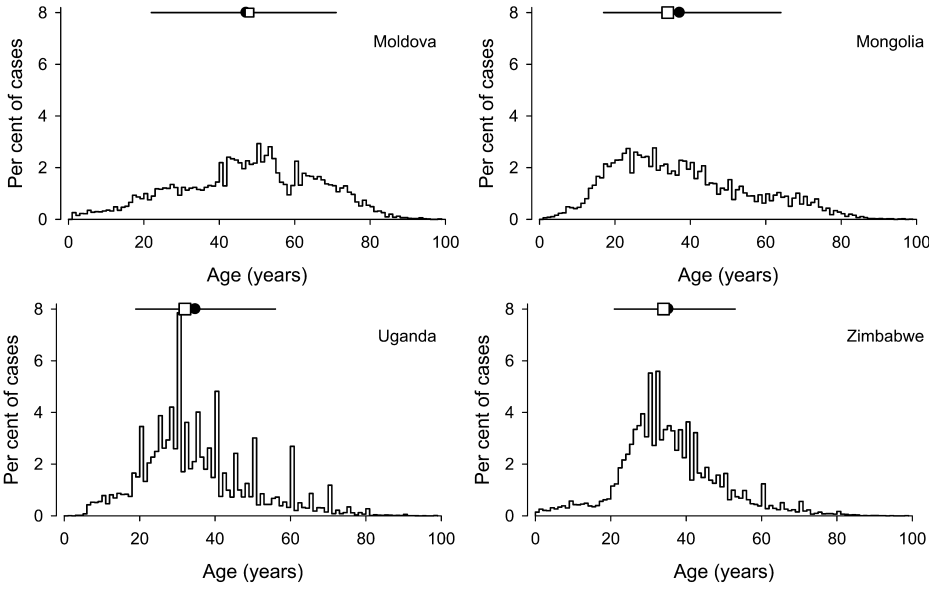

Figure 1 Age structure of tuberculosis suspects in Moldova, Mongolia, Uganda and Zimbabwe. The line above the histograms captures the range between the 10th and 90th percentile, the filled circle the mean, and the hollow square the median age in years.

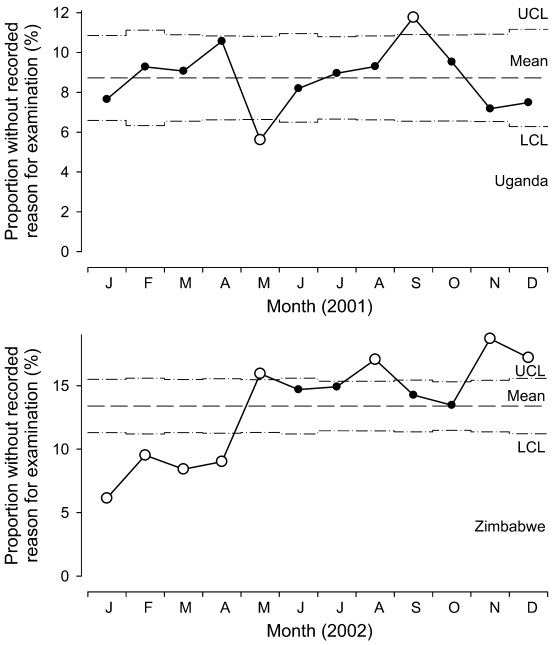

Figure 2 Statistical process control chart showing the frequency of examinees without a recorded reason for examination over one calendar year, Uganda 2001 and Zimbabwe 2002. Hollow circles show periods where respectively upper or lower limits were exceeded. UCL = upper control limit; LCL = lower control limit.

tween 20 and 50 years in Zimbabwe, and 'terminal digit preference' in Uganda, as shown by the peaks at multiples of 10, i.e., 20, 30, 40 years, etc.

Recording of the reason for examination

The reason for examination was not recorded for 9596 (7.4%) of the 128 808 examinees, with less than 1% for Moldova and Mongolia, and more than 10% for Uganda and Zimbabwe (Table 1).

Failure to record the reason for the examination was frequent for Uganda and Zimbabwe; fluctuations in the failure can be seen as a statistical process control chart (Figure 2). For Uganda, the fluctuation was unstable, whereas for Zimbabwe there was a clear deterioration in recording the reason for examination.

Recording the results

Among the suspects, 69.6% (62 178) had three smears examined, as recommended by the International Union Against Tuberculosis and Lung Disease (The Union) and World Health Organization (WHO) (if none is positive). Uganda had the lowest proportion, 51.4% (Table 2). Where a 'spot—early morning—spot' collection system is implemented, suspects should have either one or three examinations, and it should be rare for there to be two. This was the case only in Uganda.

Countries following the recommendations of The Union should examine one smear at each follow-up visit, and those following the WHO recommendations, two; none should have three examinations. Nevertheless, except in Moldova (14.8%), the results of three examinations were recorded for a quarter or more of patients on follow-up in Uganda and Zimbabwe, while in Mongolia almost all (95.7%) had three follow-up examinations at each visit.

To examine the extent of variation in serial examinations, only the 7900 suspects with three smear results recorded, at least one of which had AFB, were considered. In Moldova, 36.6% (318/870) had no variation in the quantification of serial smear results, compared to 63.8% (957/1499) in Mongolia, 53.6% (1857/3465) in Uganda, and 63.0% (1302/2066) in Zimbabwe.

For a more detailed analysis, the number of smear examinations was determined. The 128 808 examinees

Table 2 Number of smears examined per examinee by country and reason for examination*

	Moldova *n* (%)	Mongolia *n* (%)	Uganda *n* (%)	Zimbabwe *n* (%)	Total *n* (%)
Diagnosis					
1 smear	1 426 (11.4)	439 (2.9)	13 130 (36.4)	2 024 (7.9)	17 019 (19.0)
2 smears	1 761 (14.1)	897 (5.9)	4 410 (12.2)	3 097 (12.1)	10 165 (11.4)
3 smears	9 328 (74.5)	13 767 (91.2)	18 514 (51.4)	20 569 (80.1)	62 178 (69.6)
Total	12 515	15 103	36 054	25 690	89 362
Follow-up					
1 smear	255 (4.9)	64 (0.9)	8 022 (63.9)	1 212 (25.7)	9 553 (32.0)
2 smears	4 158 (80.3)	253 (3.4)	1 454 (11.6)	2 089 (44.3)	7 954 (26.6)
3 smears	768 (14.8)	7 077 (95.7)	3 079 (24.5)	1 419 (30.1)	12 343 (41.4)
Total	5 181	7 394	12 555	4 720	29 850
Reason not stated					
1 smear	21 (72.4)	2 (3.4)	2 937 (54)	345 (8.5)	3 305 (34.4)
2 smears	0	3 (5.2)	975 (17.9)	648 (15.9)	1 626 (16.9)
3 smears	8 (27.6)	53 (91.4)	1 529 (28.1)	3 075 (75.6)	4 665 (48.6)
Total	29	58	5 441	4 068	9 596
Total					
1 smear	1 702 (9.6)	505 (2.2)	24 089 (44.6)	3 581 (10.4)	29 877 (23.2)
2 smears	5 919 (33.4)	1 153 (5.1)	6 839 (12.7)	5 834 (16.9)	19 745 (15.3)
3 smears	10 104 (57.0)	20 897 (92.6)	23 122 (42.8)	25 063 (72.7)	79 186 (61.5)
Total	17 725	22 555	54 050	34 478	128 808

* Due to rounding, some percentages may not add up to 100.

Table 3 Proportion of scanty among positive examinees, Moldova, Mongolia, Uganda, Zimbabwe*

	Moldova smears *n* (%)	Mongolia smears *n* (%)	Uganda smears *n* (%)	Zimbabwe smears *n* (%)	Total smears *n* (%)
Diagnosis					
Negative	30 121 (91.5)	38 839 (89.2)	62 549 (80.7)	61 608 (88.1)	193 117 (86.3)
Positive	2 591 (7.9)	4 479 (10.3)	14 714 (19.0)	7 825 (11.2)	29 609 (13.2)
Scanty	220 (0.7)	216 (0.5)	229 (0.3)	492 (0.7)	1 157 (0.5)
Total	32 932	43 534	77 492	69 925	223 883
Scanty of positive+scanty, %	7.8	4.6	1.5	5.9	3.8
Follow-up					
Negative	8 969 (82.5)	19 711 (90.4)	17 551 (87.1)	8 943 (92.7)	55 174 (88.3)
Positive	1 636 (15.0)	1 891 (8.7)	2 441 (12.1)	627 (6.5)	6 595 (10.6)
Scanty	270 (2.5)	199 (0.9)	175 (0.9)	77 (0.8)	721 (1.2)
Total	10 875	21 801	20 167	9 647	62 490
Scanty of positive+scanty, %	14.2	9.5	6.7	10.9	9.9
Reason not stated					
Negative	45 (100.0)	157 (94.0)	8 051 (85.0)	9 462 (87.1)	17 715 (86.2)
Positive	0	9 (5.4)	1 417 (15.0)	1 374 (12.6)	2 800 (13.6)
Scanty	0	1 (0.6)	6 (0.1)	30 (0.3)	37 (0.2)
Total	45	167	9 476	10 866	20 552
Scanty of positive+scanty, %	NA	10	0.4	2.1	1.3
Total					
Negative	39 135 (89.2)	58 707 (89.6)	88 151 (82.3)	80 013 (88.5)	266 006 (86.7)
Positive	4 227 (9.6)	6 379 (9.7)	18 572 (17.3)	9 826 (10.9)	39 004 (12.7)
Scanty	490 (1.1)	416 (0.6)	410 (0.4)	599 (0.7)	1 915 (0.6)
Total	43 852	65 502	107 133	90 438	306 925
Scanty of positive+scanty, %	10.4	6.1	2.2	5.7	4.7

* Due to rounding, some percentages may not add up to 100.

underwent a total of 306 925 examinations (Table 3). Among suspects undergoing diagnostic examination, 13.2% (29 609/223 883) were positive and an additional 0.5% were scanty positive. The highest proportion of positives was in Uganda (19.0% positive plus 0.3% scanty positive) and the lowest in Moldova (7.9% positive and 0.7% scanty positive). Among the follow-up smear examinations, the proportion of positive and scanty positive examinations was respectively 10.5% and 1.2%, and was highest in Moldova (15.0% and 0.7%, respectively). The proportion of scanty results among the positive diagnostic smear examinations was 3.8%, compared to 9.9% among the smear-positive follow-up smear examinations. The proportion of scanty results among all positive results varied widely by country: the proportion among both newly diagnosed cases and follow-up examinees was highest in Moldova and lowest in Uganda.

The proportion of scanty positives among all positive smears was determined using a statistical process control chart for 2001 (Uganda), 2002 (Zimbabwe) and 2003 (Moldova and Mongolia). In these years, the proportions of scanty positives among scanty-positive plus positive smears were 9.8% (460/4687) in Moldova, 5.3% (358/6706) in Mongolia, 1.6% (100/6424) in Uganda and 4.9% (415/8467) in Zimbabwe. In all four countries, the threshold for unexpectedly low or high frequencies (determined by three standard deviations) was exceeded at one or more points in time, albeit at very different expected levels (note difference in scales). In Zimbabwe, for example, the extremes differed more than four-fold (Figure 3).

DISCUSSION

Sputum smear microscopy is a key examination in the diagnostic process for TB in any setting. Although generally a less sensitive diagnostic procedure in identifying pulmonary TB cases compared to state-of-the-art culture, it identifies those cases that are the most potent sources of infection in the community, with a sensitivity of approximately 90%.[2] We analysed the data of 107 laboratories in four countries recorded under routine conditions to see how the information could be utilised to improve programme performance.

About 1% of records from the 107 laboratories had nonsensical results, such as no smear result followed by a smear result. This could be due to errors on the request forms for sputum smear examination or recording errors by the laboratory technician. To minimise such errors, results should be entered in the TB laboratory register promptly after examination. If this is not done consistently, serious errors might occur: patients may be put on treatment erroneously or be denied treatment.

The diligence of recording is difficult to ascertain in retrospect. Nevertheless, certain indicators may as-

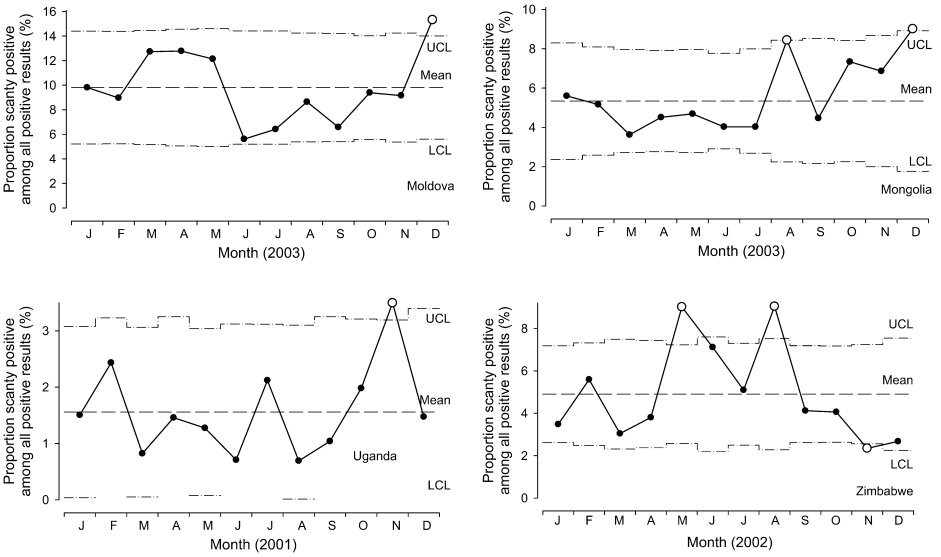

Figure 3 Statistical process control chart showing the frequency of scanty smears among all scanty and positive smears over one calendar year, Moldova 2003, Mongolia 2003, Uganda 2001 and Zimbabwe 2002. Hollow circles show months in which respectively upper or lower limits were exceeded. UCL = upper control limit; LCL = lower control limit.

sist in determining how well the request forms for sputum smear microscopy examination are filled out and/or how well the responsible technicians are recording such information. The main interest for the TB programme is the accuracy of results as they are recorded and reported to the requesting clinician. To what extent recorded results are accurate cannot be determined by such a retrospective study: this requires the implementation of systematic external quality assessment.[7]

Nevertheless, there are relatively direct indicators for the meticulousness with which a laboratory works and patterns that clearly highlight problems that need to be addressed. A good example is the recording of the examinee's sex. While this is not a variable of paramount interest to the technician or the clinician, as they have first-hand visual knowledge, failing to record the sex of an examinee might indicate that apparently small tasks are not taken very seriously, reflecting a general lack of diligence in laboratory work that requires simple but accurate recording of very few variables.

More specifically relevant for the TB programme is the recording of the reason for examination. Accurate determination of the proportion of cases among suspects hinges on the quality of recording of this variable. This proportion in itself has many useful applications for programme performance, including its role in the determination of laboratory requirements.[4] In three of the four countries studied (the exception being Mongolia), the reason for examination was only ticked as diagnosis or follow-up (data not shown). The failure to record the exact month of follow-up is attributable to a weakness in the design of the previous laboratory register. The revised recording and reporting forms and registers from the WHO and The Union now insist that the exact month be recorded at follow-up examination.[4,8] This additional information will allow the frequency of failures and a better assessment of the quality of laboratory services to be determined at virtually no additional labour cost.

A direct measure of adherence to policy is the number of smears examined per suspect and per patient on follow-up. Most countries recommend collecting the first specimen among suspects on the spot; the second should be produced early in the morning and brought to the laboratory by the examinee, whose third specimen is then collected on the spot. If this policy is strictly adhered to, only a small fraction of suspects should have two examinations recorded. In only one country in the present study was the proportion of suspects with two smears lower than that with one or three smears. Although no international organisations[1,9] recommend the examination of three smears at each follow-up visit, one of the countries in the study recorded three follow-up examinations in more than 95% of the examinees. If these examinations were in fact performed, a large amount of technician time had been wasted.

Perhaps the most direct indicator for the quality of examination is the pattern of grading sputum smear results in a series of examinations. Given the non-homogeneous character of sputum, the fact that there is a strategy to collect sputum of different quality,[10] and other factors, the quantitative grading of smears in a series of three is expected to differ to some extent. If the grading of positive smears is identical across a series in a large proportion of cases, there are good reasons to suspect that the results have been copied rather than being detected by careful examination. It is not known how frequently variations should be seen, but accumulated evidence now suggests that a figure

of around 60% variation might reasonably be expected in many settings. In an earlier study in four countries, the proportion of smears with some variation in grading was around 60% in three, while in the fourth it was only 15%.[11] In the present study, only one country had 60% variation, while in one country variation occurred only in about one third of suspects, and in the other two in around 45% of suspects. Of course, if it is suspected that results are copied from series with positive smears that are relatively easy to identify, the problem might be compounded in examinees who start off with a negative smear.

Follow-up examinations are a relatively sensitive tool for ascertaining the quality of sputum smear microscopy.[12] This is most likely linked to the more paucibacillary nature of smears that are positive and the expectation from experience that the prevalence of positive results is less frequent than among suspects in most high-burden settings. Nevertheless, follow-up smear examinations remain a difficult indicator if the revised laboratory registers, i.e., those that require the month of follow-up to be specified, are not widely implemented.

The study of scanty positive smears as a tool for quality assessment is fraught with complexities. While finding scanty results indicates thoroughness in examination, provided the technician disposes of a high quality microscope that is free from fungus in its optical system, variations in frequency also critically depend on the quality of the primary stain, notably basic fuchsin.[4] Where cases of TB are identified late, a shift from paucibacillary to multibacillary forms might be expected. The proportion of scanty positives among all positive smears thus might vary greatly from one setting to another without giving a clear indication of the quality of examination. In this study, the proportion of scanty positives varied widely, from less than 2% to almost 10%, in the four countries. Much more informative than the comparison between proportions among countries is the surveillance of the proportion over time within a given setting. Statistical process control charts provide a tool such as is exemplified here for the four countries as a whole. The unit of choice is nevertheless a single laboratory. A drop below expected values might indicate problems with stains, fungal infestation of the microscope or deterioration in the quality of examination. Changes above or below the expected values might also indicate changes in the policy of referring suspects. Among follow-up examinees, adherence to treatment or emergence of resistance might contribute to unexpected fluctuations or trends.

Statistical process control charts have been widely advocated, but are seldom used, partially perhaps because of computational difficulties.[13] The EpiData software used in the analysis of these laboratory data provides a free, readily accessible and simple to use interface for implementing the surveillance tool at any unit that has a computer. Surveillance of some basic laboratory indicators, as shown in the present study, could provide a simple and locally based adjunct to the improvement of the TB laboratory network, in addition to more formal external quality assessment schemes.

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RÉSUMÉ

OBJECTIF : Evaluer de quelle manière l'examen approfondi de l'information consignée dans le registre de laboratoire de tuberculose (TB) pourrait aider à améliorer la performance du réseau de laboratoires de microscopie et la prise en charge des cas de tuberculose.
CONTEXTE : Réseau de microscopie de TB en Moldavie, Mongolie, Ouganda et Zimbabwe.
MÉTHODES : Revue des enregistrements en ce qui concerne l'enregistrement complet de l'âge, du sexe, de la raison de l'examen, de l'analyse des types de variabilité des frottis en série et de disponibilité de dossiers constituant des exemples des processus statistiques pour les résultats très faiblement positifs au fil du temps dans les quatre pays.
RÉSULTATS : On a analysé au total 128 808 enregistrements. Les informations sur le sexe faisaient défaut dans une large proportion des sujets examinés en Ouganda (6,9%) et au Zimbabwe (3,9%). La raison de l'examen est inconnue pour 7,4%. Parmi les suspects dont les trois résultats de frottis comportaient au moins un résultat positif, il n'y avait pas de variation dans le type chez 56,1%. Les dossiers des processus de contrôle statistique ont révélé des fluctuations considérables dans la fréquence des frottis très faiblement positifs au cours d'une année calendrier.
CONCLUSION : L'analyse des informations présentes dans le registre de laboratoire de TB n'identifie pas seulement les forces et faiblesses des laboratoires mais révèle dans une beaucoup plus large mesure les faiblesses de l'ensemble du système de prise en charge des cas. Donc, les données de laboratoire de TB peuvent démontrer quand et où il fait agir, quel type d'action est indiqué et comment on pourrait suivre les performances au fil du temps.

RESUMEN

MARCO DE REFERENCIA : Red de laboratorios de microscopia en Moldavia, Mongolia, Uganda y Zimbabwe.
OBJETIVO : Evaluar en qué medida el examen de la información consignada en el registro de laboratorio de tuberculosis (TB) puede contribuir a mejorar el rendimiento de la red de laboratorios de microscopia y el manejo de casos de TB.
MÉTODOS : Revisión de los registros evaluando la integridad de los datos con respecto a la edad, el sexo y a la razón del examen, análisis de la variabilidad de la cuantificación en las muestras seriadas y suministro de modelos gráficos de control estadístico de los resultados débilmente positivos a lo largo del tiempo en los cuatro países.
RESULTADOS : Se analizaron 128 808 registros. Una proporción considerable carecía de datos sobre el sexo en Uganda (6,9%) y Zimbabwe (3,9%). Se desconoció la razón del examen en 7,4%. En aquellos casos con presunción diagnóstica y tres resultados de baciloscopia con por lo menos un resultado positivo, 56,1% no presentó variación en la cuantificación de la lectura. Los gráficos de control estadístico revelaron una fluctuación considerable en la frecuencia de baciloscopias débilmente positivas a lo largo de un año civil.
CONCLUSIÓN : El análisis de la información consignada en el registro del laboratorio de TB descubre los puntos fuertes y los puntos débiles, no solo del laboratorio mismo, sino también en forma más amplia, las deficiencias globales del sistema de manejo de casos. De esta forma, los datos del laboratorio de TB pueden demostrar el momento, el lugar y el tipo de acción que se precisa y la forma de realizar la supervisión de su eficacia en el tiempo.