

Completeness and consistency in recording information in the tuberculosis case register, Cambodia, China and Viet Nam

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SUMMARY

SETTING: Tuberculosis (TB) case registers in Cambodia, two provinces in China and in Viet Nam.

OBJECTIVE: To determine completeness and consistency of information for quarterly reports on case finding and treatment outcome.

METHODS: A representative sample of TB case registers was selected in Cambodia, in two provinces in China and in Viet Nam. Quarterly reports were reproduced from double-entered, validated data to determine completeness and consistency.

RESULTS: The dataset comprised 37 635 patient records in 2 calendar years. Only 0.2%, 3.6% and 1.1% of cases, respectively, in Cambodia, the two China provinces, and Viet Nam did not allow classification for the quarterly report on case finding. If the treatment outcome

was reported as cured, it was correct in 99.9%, 85.7%, and 98.5% of the respective three jurisdictions: errors were mostly due to misclassification of completion as cure. Under-reporting of failures was more frequent than over-reporting in Cambodia and Viet Nam, while in the two provinces in China 84% of reported failures did not actually meet the bacteriological criterion.

CONCLUSIONS: This evaluation demonstrates that recording essential information is exemplary in all three countries. It will be essential to carefully supervise the ability of staff to correctly define TB treatment outcome results in all three countries.

KEY WORDS: tuberculosis; tuberculosis case register; quarterly reports; completeness

THE TUBERCULOSIS (TB) case register is the data source for the quarterly reports submitted by the basic management units to the National TB Program (NTP). The information in the register is abstracted from the TB patient treatment cards, which in turn depends in part on the results from the TB laboratory register transcribed onto the request form for sputum examination.¹ The completeness and accuracy of the transcription process could only be ascertained if all forms and registers were linked electronically so that the information could be cross-checked, which is not usually the case. Nevertheless, the TB case register is accessible to determine to what extent the recorded information allows preparation of the two required quarterly reports on case finding and treatment outcome.

The purpose of our study was to capture electronically a representative sample of the physical paper records of TB case registers from Cambodia, from two provinces in China and from Viet Nam, to determine the completeness and consistency of information required for the preparation of quarterly reports

on case finding and treatment outcome according to international recommendations.¹

METHODS

Sampling

The three countries included in the study, Cambodia, China, and Viet Nam, elaborated a common research protocol to collect and analyze data from a representative sample of the paper records of the TB case registers in their respective jurisdictions.

In each participating country, the study jurisdiction for representative sampling was pre-determined, selecting the entire country in the case of Cambodia and Viet Nam, and two provinces, Hubei and Jiangsu, for China. Hubei, the 'Province of Lakes', has a large plain and mountains in its west and the peripheries, while Jiangsu is very flat and low-lying and borders the Yellow Sea. A random selection of 30 management units in each country was selected from the exhaustive list of all management units in the public (governmental) sector. From each of these units, the

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TB case register (henceforth the 'case register') for 2 full calendar years was to be taken. The earliest permissible registration date was 1 January 2003 and the latest 31 December 2005, to ensure that the study would not interfere with program activities for which the register would be required.

Study approval

Because of the retrospective, record-based nature of the study without capturing patient names, all participating countries decided to require only administrative approval from the Director of the NTP. Ethical approval for the study was obtained from the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease (The Union).

Data entry

The electronic data collection instrument was prepared using EpiData Entry (Version 3.1, EpiData Association, Odense, Denmark, freely available at <http://www.epidata.dk>). Data were double-entered and validated for any discordance by comparing the discordant values against the original physical case register and making corrections where appropriate.

Data analysis

All analyses were performed using EpiData Analysis (Version 2.2, <http://www.epidata.dk>). The 90 final datasets were combined into one single dataset for analysis.

The TB Register is a critical data source in the NTP's information system. Each registered patient is assigned one line with basic demographic information (age and sex), information relating to diagnosis and treatment (site of disease, category of patient, date treatment started, and initial regimen) and information on initial and follow-up bacteriological findings and treatment outcome.

Definitions for the quarterly report on case finding

The quarterly report on case finding requires five variables. These are:

- 1 disease site (pulmonary or extra-pulmonary);
- 2 microscopy result at diagnosis required for every registered patient;
- 3 category of patient, notably whether the patient is new, a relapse, return after default, a transfer in from another jurisdiction or belonging to another category. The latter two categories are not notifiable and were thus combined into a single group for the purpose of this analysis;
- 4 patient's age; and
- 5 patient's sex.

Definitions for the quarterly report on treatment outcome

The outcome of treatment is recorded with the date when the defining event occurs. Definitions have been provided for the six possible treatment outcomes for sputum smear-positive cases:²

- 1 Cure: a patient who is sputum smear-negative in the last month of treatment and on at least one previous occasion.
- 2 Treatment completed: a patient who has completed treatment but who does not meet the criteria to be classified as a cure or a failure.
- 3 Treatment failure: a patient who is sputum smear-positive at 5 months or later during treatment.
- 4 Died: a patient who dies for any reason during the course of treatment.
- 5 Defaulter: a patient whose treatment was interrupted for ≥ 2 consecutive months.
- 6 Transfer out: a patient who has been transferred to another recording and reporting unit and for whom the treatment outcome is unknown.

We applied these definitions, and expanded them to all other cases in whom only 'completion', but not 'cure' as defined above, was possible. We compared the outcome recorded in the register and the actual outcome defined by bacteriological recording of smear-positive cases (new, relapse, treatment after failure, return after default). For patients categorized as 'default', 'death', and 'transfer out', these outcome classifications were accepted as recorded.

Because different regimens were used (the majority of patients were on a 6-month regimen in China and an 8-month regimen in Viet Nam and Cambodia, with a transition to the 6-month regimen in some units), the regimen was taken into account in the definition of bacteriological cure. For sputum smear-positive cases receiving a 6-month regimen, cure was defined as a patient who had negative smear results at 2 and 5 months, while patients on an 8-month regimen had to have a negative smear examination at 7 months (or the end of treatment) and on at least one occasion at 2 or 5 months.

To qualify for the definition of a completed course, at least 150 days for the 8-month regimen and at least 120 days for the 6-month regimen between registration and last scheduled smear had to have elapsed. Failures were defined as any positive smear examination at 5 months or later.

Non-classifiable were cases that met the inclusion criteria but had insufficient information (initial microscopy result, site of disease, category of disease, follow-up examinations) to be unambiguously attributable to a defined outcome. Mis-classified cases belonged to a category other than the recorded category (e.g., a patient recorded as having extra-pulmonary TB but also having a positive sputum smear result, or a patient registered as a return after default but with a negative sputum smear examination).

RESULTS

In each jurisdiction it was possible to obtain the 30 randomly selected case registers. Each country collected information on patients registered during a 2-year period—Cambodia for the years 2003 and

2004, and China and Viet Nam for the years 2004 and 2005—with a total of 37 635 patients. A small number of cases in a few units in China and Viet Nam had been registered in December 2003 (153 cases), and in one unit in Jiangsu also during September through November (157 cases).

Information required for the quarterly report on case finding

Among the total of 37 635 patient records, 4215 (11.2%) were from Cambodia, 26 257 (69.7%) were from the two provinces Hubei and Jiangsu in China, and 7613 (20.2%) from Viet Nam (Table 1).

All patients in Cambodia had disease site recorded; this information was missing for some patients from China ($n = 106$, 0.4%) and in Viet Nam ($n = 6$, 0.1%). In China, only 1.2% of patients with extra-pulmonary TB were registered, while the respective percentages in Cambodia and Viet Nam were 18.5% and 15.7%.

For the purpose of this analysis, the sputum smear microscopy classification was based on the microscopy result recorded as the diagnostic result in the case register. The recording of at least one acid-fast

bacillus defined the patient as a sputum smear-positive case. Recording of the diagnostic microscopy result was poor in Cambodia (17.1% missing) and in Viet Nam (15.0% missing), but was much better in China (3.6% missing). This was almost exclusively attributable to the failure to record a sputum smear result among patients with extra-pulmonary TB. In Cambodia, 712 (91.2%) of the 781 cases with extra-pulmonary TB had no result recorded, and in Viet Nam 1027 (91.5%) of the 1122 cases did not.

One patient may be missing information on more than one of the five characteristics. Information on any of the characteristics was missing in 17.2% in Cambodia, 4.3% in China, and 15.5% in Viet Nam.

Quarterly report on case finding

Because the quarterly report consists of two parts that require different information, it is not necessary for all information on all variables used in either part to be simultaneously available to produce a complete report. The format we used for the quarterly report follows Union recommendations,¹ but was applied for the entire period and not for individual quarters.

Table 1 Completeness in recording of information on variables required to produce a quarterly report on tuberculosis case finding, Cambodia, China (Hubei and Jiangsu Provinces), and Viet Nam

Patient/disease characteristic	Cambodia		China		Viet Nam		Total	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Total	4215	100.0	26257	100.0	7163	100.0	37635	
Disease site								
Pulmonary	3434	81.5	25849	98.4	6035	84.3	35318	93.8
Extra-pulmonary	781	18.5	302	1.2	1122	15.7	2205	5.9
Not recorded	0	0.0	106	0.4	6	0.1	112	0.3
Microscopy diagnosis								
Smear-positive	2787	66.1	18768	71.5	5152	71.9	26707	71.0
Smear-negative	709	16.8	6537	24.9	939	13.1	8185	21.7
Not recorded	719	17.1	952	3.6	1072	15.0	2743	7.3
Patient category								
New case	3901	92.6	21913	83.5	6012	83.9	31826	84.6
Relapse	192	4.6	1845	7.0	523	7.3	2560	6.8
Treatment after failure	11	0.3	35	0.1	64	0.9	110	0.3
Treatment after default	5	0.1	454	1.7	26	0.4	485	1.3
Transfer in or other	95	2.3	1834	7.0	213	3.0	2142	5.7
Not recorded	11	0.3	176	0.7	325	4.5	512	1.4
Age group, years								
0–14	103	2.4	173	0.7	84	1.2	360	1.0
15–24	407	9.7	3601	13.7	737	10.3	4745	12.6
25–34	632	15.0	3906	14.9	1219	17.0	5757	15.3
35–44	974	23.1	4280	16.3	1330	18.6	6584	17.5
45–54	856	20.3	4351	16.6	1446	20.2	6653	17.7
55–64	709	16.8	4296	16.4	873	12.2	5878	15.6
≥65	533	12.6	5650	21.5	1472	20.6	7655	20.3
Not recorded	1	0.0	0	0.0	2	0.0	3	0.0
Sex								
Female	1981	47.0	7565	28.8	2200	30.7	11746	31.2
Male	2233	53.0	18686	71.2	4962	69.3	25881	68.8
Not recorded	1	0.0	6	0.0	1	0.0	8	0.0
Availability on any characteristic*								
Available	3489	82.8	25130	95.7	6053	84.5	34672	92.1
Missing	726	17.2	1127	4.3	1110	15.5	2963	7.9

*Total availability may be less than the sum of individual characteristics, as one patient may have information missing on several characteristics.

Table 2 All cases registered in quarter defined by initial findings in the register, using data from the entire 2-year period, Cambodia, China (Hubei and Jiangsu Provinces) and Viet Nam

	Cambodia		China		Viet Nam		Total	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Total	4120	100.0	24423	100.0	6950	100.0	35493	100.0
Total smear-positive	2757	66.9	17208	70.5	5021	72.2	24986	70.4
Total smear-negative/extra-pulmonary	1353	32.8	6324	25.9	1851	26.6	9528	26.8
Not fitting above categories	10	0.2	891	3.6	78	1.1	979	2.8
Smear-positive by type								
Smear-positive, new	2560	62.1	15369	62.9	4422	63.6	22351	63.0
Smear-positive, relapse	182	4.4	1548	6.3	512	7.4	2242	6.3
Smear-positive, after failure	10	0.2	32	0.1	64	0.9	106	0.3
Smear-positive, after default	5	0.1	259	1.1	23	0.3	287	0.8
Smear-negative/extra-pulmonary								
EPTB, smear-negative/unknown	740	18.0	296	1.2	1032	14.8	2068	5.8
Smear-negative <15 years	31	0.8	59	0.2	10	0.2	100	0.3
Smear-negative ≥15 years	582	14.1	5969	24.4	809	11.6	7360	20.7
Not fitting above categories								
Not classifiable	10	0.2	887	3.6	55	0.8	952	2.7
Misclassified	0	0.0	4	0.0	23	0.3	27	0.1

EPTB = extra-pulmonary tuberculosis.

The first part summarizes case finding by 1) four smear-positive reportable patient categories (new, treatment after relapse, failure, and return after default) which require the sputum smear result; 2) all sputum smear-negative patients, which also requires data on whether or not they were aged <15 years; and 3) any extra-pulmonary TB. The second part deals only with new sputum smear-positive patients, for whom data age and sex are necessary.

Non-reportable cases were 2142 patients who were either transferred in or categorized as 'other', leaving 35 493 (94.3%) cases subject to reporting. The first part in the quarterly report enumerates all reportable cases. The proportion of non-classifiable cases was 0.2% in Cambodia, 3.6% in China and 0.8% in Viet Nam. There were no misclassified cases in Cambodia and China and 0.3% in Viet Nam (Table 2).

The second part of the quarterly report on case finding provides detailed stratification by age and sex among new, sputum smear-positive cases (Table 3).

Quarterly report on treatment outcome

The second required quarterly report is the report on treatment outcome. In the Union recommendations,

outcome reporting is limited to sputum smear-positive cases,¹ while in the World Health Organization (WHO) recommendations, it should also include other than sputum smear-positive cases.³ For the purpose of this analysis, we included all smear-positive cases (new, relapse, start after failure, return after default).

Table 4 provides the cross-tabulation of the register-derived definitions based on bacteriological follow-up results vs. the recorded outcome of smear-positive cases. The under-reporting was calculated using bacteriological results as the denominator and determined the proportion missed. Over-reporting was calculated as the ratio of the falsely reported plus the correctly classified outcomes to that of the correctly classified outcomes. For cure, the proportions of under- and over-reported cases were respectively 1.9% and 0.1% in Cambodia, 3.3% and 16.1% in China, and 1.3% and 1.5% in Viet Nam. For treatment completion, the proportions of under- and over-reported cases were respectively 4.2% and 22.9% in Cambodia, 92.4% and 16.0% in China, and 26.7% and 30.0% in Viet Nam. For treatment failure, the proportions of under- and over-reported cases were respectively 27.3% and 9.1% in Cambodia,

Table 3 A quarterly report (using data from the entire 2-year period) on new sputum smear-positive cases only, stratified by age group and sex, Cambodia, China (Hubei and Jiangsu Provinces), and Viet Nam

Country	Age group, years														Total		Not classifiable			
	0-14		15-24		25-34		35-44		45-54		55-64		≥65		Total	Total	<i>n</i>	%	Total	
	F	M	F	M	F	M	F	M	F	M	F	M	F	M						
Cambodia	4	5	93	126	171	206	265	324	282	278	249	224	143	189	1207	1352	2559	1	0.04	2560
China	44	42	1028	1455	864	1603	794	1775	620	1853	546	1804	540	2397	4436	10929	15365	4	0.03	15369
Viet Nam	9	5	143	253	183	540	186	682	203	708	181	363	361	605	1266	3156	4422	0	0.00	4422
Total	57	52	1264	1834	1218	2349	1245	2781	1105	2839	976	2391	1044	3191	6909	15437	22346	5	0.02	22351

F = female; M = male.

Table 4 Accuracy of recorded outcome among smear-positive cases (new, relapse, start after failure, return after relapse) compared to outcome defined by bacteriological recording, Cambodia, China (Hubei and Jiangsu Provinces) and Viet Nam, 2003–2004*

Recorded outcome	Outcome defined by bacteriological recording								Column %
	Cure	Completion	Failure	Default	Death	Transfer out	Non-classifiable	Total	
Total number	20705	2717	197	188	479	335	365	24986	
Row %	82.9	10.9	0.8	0.8	1.9	1.3	1.5	100.0	
Cambodia									
Cure	2392	1	1	0	0	0	0	2394	86.8
Completion	10	46	1	0	0	0	0	57	2.1
Failure	0	1	8	0	0	0	0	9	0.3
Default	0	0	0	45	0	0	0	45	1.6
Death	0	0	0	0	118	0	0	118	4.3
Transfer out	0	0	0	0	0	83	0	83	3.0
Other non-specified outcome	0	0	0	0	0	0	0	0	0.0
No outcome recorded	37	0	1	0	0	0	13	51	1.8
Total	2439	48	11	45	118	83	13	2757	100.0
China									
Cure	13486	2225	8	0	0	0	16	15735	91.4
Completion	389	188	2	0	0	0	3	582	3.4
Failure	15	33	64	0	0	0	14	126	0.7
Default	0	0	0	70	0	0	0	70	0.4
Death	0	0	0	0	186	0	0	186	1.1
Transfer out	0	0	0	0	0	145	0	145	0.8
Other non-specified outcome	16	12	0	0	0	0	261	289	1.7
No outcome recorded	38	1	0	0	0	0	36	75	0.4
Total	13944	2459	74	70	186	145	330	17208	100.0
Viet Nam									
Cure	4267	50	13	0	0	0	0	4330	86.2
Completion	48	154	3	0	0	0	12	217	4.3
Failure	1	6	96	0	0	0	1	104	2.1
Default	0	0	0	73	0	0	0	73	1.5
Death	0	0	0	0	175	0	0	175	3.5
Transfer out	0	0	0	0	0	107	0	107	2.1
Other non-specified outcome	0	0	0	0	0	0	0	0	0.0
No outcome recorded	6	0	0	0	0	0	9	15	0.3
Total	4322	210	112	73	175	107	22	5021	100.0

*Default, death, and transfer were accepted as recorded.

13.5% and 83.8% in China, and 14.3% and 7.1% in Viet Nam.

Because the number of bacteriologically defined outcomes varied greatly between the three categories and the countries, the above point estimates are shown with 95% confidence intervals (CI) in the Figure.

DISCUSSION

To our knowledge, this is the largest study ever undertaken to assess in a representative fashion the routine work of case registration and the completeness and consistency of recording in NTPs in low-income countries. It is reassuring to note that in Cambodia, in Hubei and Jiangsu Provinces in China, and in Viet Nam, peripheral health care workers have an excellent understanding of the necessity of recording relevant information.

NTPs require two management reports on a quarterly basis. The first reports on cases registered in the quarter of interest, and the second summarizes the outcome of treatment after this cohort can be expected to have completed a full course of treatment. Despite

the increasing availability of computers, these reports are usually aggregated by hand⁴ from the TB case registers kept in the basic management units where the patients are treated, collected at intermediate level

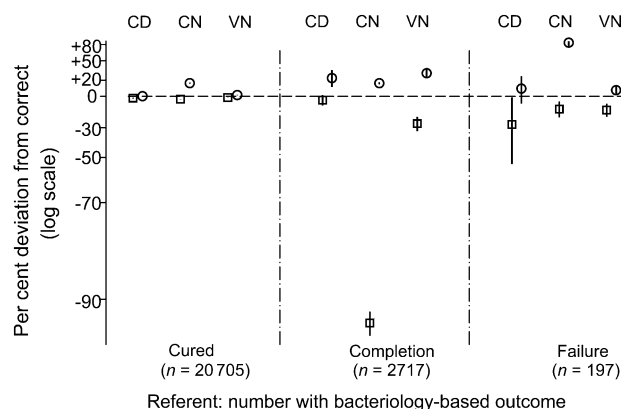


Figure Under- and over-recording of cure, completion, and failure relative to respective outcome derived from recorded bacteriological information, Cambodia (CD), China (CN; Hubei and Jiangsu provinces), and Viet Nam (VN). Squares indicate under-reporting, circles over-reporting.

and forwarded to the national level for collation of the data before being submitted to the WHO.

Experience with and evaluation of individual data collection at the periphery has remained limited. A critical evaluation of the experience has principally come from just one low-income country.^{5,6} While the advantages of a validated individual electronic database are obvious,⁴ errors accumulate over the sequence of transcription from one to the next paper record and from the latter to the electronic database. We ensured that our electronic database reproduced the paper-based case register as accurately as possible by double-entering and validating the data.

The analysis of the case registers in the three jurisdictions has demonstrated diligence in recording the essential information required for effective program management. Certain recommendations were not, or could not, be heeded, such as the requirement that each case presenting with extra-pulmonary TB should always have a sputum smear examination, not least because, in the case of a positive result, the patient is to be classified as having sputum smear-positive TB.^{1,2} The failure to actually record a negative sputum smear examination in cases of extra-pulmonary TB is likely attributable to the ambiguity in the recommendations made in the Union guide.¹

The low proportion of extra-pulmonary TB reported in China may be explained by the fact that treatment for extra-pulmonary TB is not offered free of charge, and patients may thus seek care outside the governmental clinics captured in this sample. The higher proportion of non-classifiable patients reported from China is partially explained by the policy to accept an ill-defined category of 'active TB' that is not necessarily based on sputum smear microscopy results.

Defining the treatment outcome is intrinsically more difficult than preparing a report on case finding. Patients tended to be all too readily declared as being cured when they in fact did not meet the criteria required for such a classification. This may, to some extent, be explained by a certain complacency at the international level, where both categories, cure and completion, are commonly summarized as 'success',⁷ and the distinction is thus accorded less significance than the originally defined targets emphasize.⁸

While, or perhaps because, failures were rare occurrences, all three countries experienced difficulties with this definition. In Cambodia and Viet Nam, failures tended to be more frequently not recognized as such, while in China, failure tended to be declared before the criterion was met. The latter may, in addition to not adhering to the standard definition by staff, be attributable to the emergence of multidrug-resistant TB in China,⁹⁻¹¹ and the perhaps associated concern of delaying the diagnosis of such a case.

CONCLUSIONS

This study has demonstrated that recording of essential information is exemplary in all three countries. Efforts may be required in Cambodia and Viet Nam to insist more on the need for sputum examinations, even in patients who present themselves primarily with an extra-pulmonary manifestation, to exclude the presence of sputum smear-positive pulmonary TB. This analysis calls for ambiguities to be removed from recording recommendations by international bodies. In all three countries it is essential to carefully supervise the ability of staff to correctly define TB treatment outcome results.

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R É S U M É

CONTEXTE : Les registres des cas de tuberculose (TB) au Cambodge, dans deux provinces de Chine et au Viet Nam. **OBJECTIF :** Déterminer le caractère complet et la cohérence des informations destinées aux rapports trimestriels sur le dépistage des cas et le résultat du traitement.

MÉTHODES : Un échantillon représentatif des registres des cas de TB a été sélectionné au Cambodge, dans deux provinces de Chine et au Viet Nam. Les rapports trimestriels ont été reproduits à partir de données à double entrée et validées pour déterminer leur caractère complet et leur cohérence.

RÉSULTATS : La base de données comporte 37 635 dossiers de patients au cours de deux années de calendrier. Au Cambodge 0,2% seulement des cas, dans les deux provinces de Chine 3,6% et au Viet Nam 1,1% des cas n'ont pas permis leur classification pour le rapport tri-

mestriel sur le dépistage. Lorsque le résultat du traitement est considéré comme guérison, il a été correct respectivement dans 99,9%, 85,7% et 98,5% des trois juridictions respectives, les erreurs étant le plus souvent dues à la classification erronée d'un achèvement du traitement comme guérison. La sous-estimation des échecs a été plus fréquente que la surestimation au Cambodge et au Viet Nam, alors que dans les deux provinces de Chine, 84% des échecs déclarés en fait ne répondaient pas aux critères bactériologiques.

CONCLUSIONS : Cette évaluation démontre que l'enregistrement des informations essentielles est exemplaire dans les trois pays. Il sera fondamental de superviser avec soin la capacité du personnel à définir correctement les résultats finaux du traitement de la TB dans les trois pays.

R E S U M E N

MARCO DE REFERENCIA: Los registros de casos de tuberculosis (TB) en Camboya, dos provincias de China y en Viet Nam.

OBJETIVOS: Determinar la exhaustividad y la coherencia de la información contenida en los informes trimestrales sobre la búsqueda de casos de TB y el desenlace terapéutico.

MÉTODOS: Se escogió una muestra representativa de registros de casos en Camboya, dos provincias de China y en Viet Nam. Se reprodujeron los informes trimestrales a partir de los datos introducidos en duplicado y validados, con el fin de determinar la exhaustividad y la coherencia.

RESULTADOS: El conjunto de datos comprendió 37 635 expedientes clínicos de pacientes en dos años civiles. Solo 0,2% de los casos de Camboya, 3,6% de las dos

provincias chinas y 1,1% de los casos en Viet Nam no se pudieron clasificar en el informe trimestral de búsqueda de casos. Cuando se notificó el desenlace como curación, fue correcto en 99,9% de los casos de Camboya, 85,7% en China y 98,5% en Viet Nam y los errores consistieron en su mayor parte en designar la compleción del tratamiento como curación. La deficiencia de notificación de fracasos fue más frecuente que la sobrenotificación en Camboya y Viet Nam, pero en las dos provincias de China el 84% de los fracasos notificados no cumplía con el criterio bacteriológico.

CONCLUSIÓN: La presente evaluación pone en evidencia que la consignación de la información esencial es ejemplar en los tres países. Es preciso supervisar con cuidado la capacidad del personal para definir correctamente los desenlaces terapéuticos en los tres países.