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Implementation of the national tuberculosis guidelines on culture and drug sensitivity testing in Guatemala, 2013

Maritza Samayoa-Peláez,[1] *Nancy Ayala,*[2] *Zaida E. Yadon,*[3] *and Einar Heldal*[4]

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ABSTRACT

Objective. *To assess whether the National Tuberculosis Program (NTP) guidelines for culture and drug sensitivity testing (DST) in Guatemala were successfully implemented, particularly in cases of smear-negative pulmonary tuberculosis (TB) or previously treated TB, by documenting notification rates by department (geographic area), disease type and category, and culture and DST results.*

Methods. *This was a cross-sectional, operational research study that merged and linked all patients registered by the NTP and the National Reference Laboratory in 2013, eliminating duplicates. The proportions with culture (for new smear negative pulmonary cases) and culture combined with DST (for previously treated patients) were estimated and analyzed by department. Data were analyzed using EpiData Analysis version 2.2.*

Results. *There were 3 074 patients registered with TB (all forms), for a case notification rate of 20/100 000 population. Of these, 2 842 had new TB, of which 2 167 (76%) were smear-positive pulmonary TB (PTB), 385 (14%) were smear-negative PTB, and 290 (10%) were extrapulmonary TB. There were 232 (8%) previously treated cases. Case notification rates (all forms) varied by department from 2–68 per 100 000 population, with the highest rates seen in the southwest and northeast part of Guatemala. Of new TB patients, 136 had a culture performed and 55 had DST of which the results were 33 fully sensitive, 9 monoresistant, 3 polyresistant, and 10 multidrug resistant TB (MDR-TB). Only 21 (5%) of new smear-negative PTB patients had cultures. Of 232 previously treated patients, 54 (23%) had a culture and 47 (20%) had DST, of which 29 were fully sensitive, 7 monoresistant, 2 polyresistant, and 9 MDR-TB. Of 22 departments (including the capital), culture and DST was performed in new smear-negative PTB in 7 departments (32%) and in previously treated TB in 13 departments (59%).*

Conclusions. *Despite national guidelines, only 5% of smear-negative PTB cases had a culture and only 20% of previously treated TB had a culture and DST. Several departments did not perform culture or DST. These short comings must be improved if Guatemala is to curtail the spread of drug resistant forms of TB, while striving to eliminate all TB.*

Key words Tuberculosis; diagnostic techniques, respiratory system; diagnostic techniques, standards; tuberculosis, multidrug-resistant; operations research; Guatemala; Latin America.

[1] National Tuberculosis Program, Ministry of Public Health and Welfare, Guatemala City, Guatemala. Send correspondence to Maritza Samayoa-Peláez, pelaezitza@gmail.com

[2] National Reference Laboratory, Amatilan, Guatemala.

[3] Communicable Diseases and Health Analysis Department, Pan American Health Organization (PAHO), Washington, DC, United States of America.

[4] Independent consultant, Oslo, Norway.

With an estimated 9 million new cases and 1.5 million deaths globally in 2013 (1), tuberculosis (TB) ranks second only to HIV / AIDS among the most important

infectious diseases that contribute to mortality. Multidrug resistant TB (MDR-TB)—resistant to both isoniazid and rifampicin—now constitutes a global public health crisis with an estimated 440 000 cases annually, or about 3.6% (95% Confidence Interval [95%CI]: 3.0–4.4) of all new TB cases globally. MDR-TB jeopardizes the progress made in TB control worldwide (1).

Since the National Tuberculosis Program (NTP) of Guatemala was established in 1978, its surveillance system has been collecting information on TB cases from each local and public center across the country. When Directly Observed Therapy Short-term (DOTS) was introduced in 1995, the surveillance system was further standardized. And since 2007, Guatemala has been receiving support from The Global Fund to Fight AIDS, Tuberculosis and Malaria (Geneva, Switzerland), which has further strengthened surveillance and improved its laboratory database. All of the country's TB data is collated, analyzed, and disseminated by the NTP.

Nevertheless, TB is a major health problem in Guatemala. In 2012, there were 3 442 registered TB cases (all forms), with a notification rate of 23 per 100 000 inhabitants. The World Health Organization (WHO) produces annual estimates of "real" TB incidence rates per country, working under the assumption that all cases are diagnosed and notified. For Guatemala, the WHO estimate was 60 per 100 000 in 2012; and the case detection rate, that is, the proportion of notified cases of the total estimate was only 38% (1, 2).

MDR-TB is also becoming a public health problem in Guatemala. A survey conducted in 2003 found that MDR-TB accounted for 3% of new and 26% of previously treated TB cases (3). For the 2006–2012 period, the country reported an annual average of 30 MDR-TB cases with an increasing trend, representing less than 35% of the 147 MDR-TB cases estimated for Guatemala by WHO for 2012 (4). Thus, despite the action taken to strengthen case management and laboratory diagnosis, Guatemala continues to face underdiagnosis and underreporting of TB cases, with "missed cases" both among new and drug-resistant TB. The number of cases reported by private centers is low, with only 11 cases (0.4%) in 2014, according to the NTP database.

The traditional method of diagnosing TB is by sputum smear microscopy, a simple, inexpensive, and rapid way of detecting the most infectious cases of pulmonary TB; however, this method also has low sensitivity and does not distinguish between *Mycobacterium tuberculosis* and non-tuberculous mycobacteria, nor between drug-sensitive and drug-resistant TB (5, 6). Therefore, mycobacteria culture is increasingly being used in Guatemala, and more recently, new diagnostic technology, such as Xpert® MTB/RIF (Cepheid Incorporated, Sunnyvale, California, United States) is preferred, particularly for sputum smear negative TB and previously treated TB (7).

According to the NTP guidelines of Guatemala, patients with sputum smear negative pulmonary TB should be offered sputum culture. All previously treated TB cases (and the contacts of MDR-TB cases) should have sputum culture and drug sensitivity testing (DST) in order to determine the presence or absence of drug resistance strains (8). Culture is carried out by seven regional laboratories that send the strains to the National Reference Laboratory for DST. In total, 329 and 279 samples were tested for resistancy to first-line drugs in 2012 and 2013, respectively. The NTP does not routinely receive laboratory results for all cultures and DST, so actual coverage by these techniques for new and previously treated patients is officially unknown. However, it is just such information that is key to identifying possible gaps in NTP guideline implementation and indicating the way forward.

Therefore, this study aimed to assess whether or not the NTP guidelines for culture and DST were successfully implemented in 2013, particularly in those cases of smear-negative pulmonary TB or previously treated TB. Specific objectives were: (i) to describe TB case notification rates by department (geographic area); (ii) to determine the number and proportion of cultures and DST performed by TB category (new versus previously treated); and (iii) to establish the profile of drug resistance (monoresistant, polyresistant, and MDR-TB) in relation to TB site and category, and department.

MATERIALS AND METHODS

Study design and setting

This was a cross-sectional study using program and laboratory data. The study included all TB cases registered in the NTP database during January–December 2013.

The land area of Guatemala is 108 889 km². In 2013, the country had 15.8 million inhabitants, making it the most populous country in Central America, with a density of 145 people/km². The country has 22 departments (geopolitical areas). Those in the southwest have the highest TB notification rates. In 2010–2012, the departments with the highest rates were Escuintla, Retalhuleu, Suchitepéquez, San Marcos, Izabal Quetzaltenango, and Zacapa. These departments reported the majority of all the country's TB cases (52% of the MDR-TB cases and 56% of the smear positive pulmonary TB cases).

In Guatemala, the public health system consists of a network of 4 875 health care facilities, of which 72% offer primary level care; 27%, secondary level; and 1%, tertiary level (9). TB patients diagnosed in private laboratories are referred to the public sector for diagnostic confirmation, treatment, and follow-up.

TB laboratories, culture, and drug sensitivity testing

Guatemala's laboratory network includes 288 laboratories that perform smear microscopy, and seven that perform culture. DST is done at the National Reference Laboratory in Guatemala City, and the results are registered only in its database. In addition, two public hospitals in Guatemala City do culture and DST for their admitted patients; the results are reported to the NTP. Culture and DST are not performed in the private sector.

The National Reference Laboratory uses the Löwenstein-Jensen method (10) for cultures and the Canetti proportions method for DST to four first-line drugs (rifampicin, isoniazid, ethambutol, and streptomycin) (11). Nitrate reductase assay is used for resistance screening for rifampicin and isoniazid, and Genotype® MTBC (HAIN Lifescience GmbH, Nehren, Germany) for species identification. The National Reference Laboratory participates in an annual external quality-control procedure with the Supranational Laboratory (*Instituto de Diagnóstico y Referencia Epidemiológicos*, Mexico City, Mexico) for DST for the four first-line drugs. The National Reference Laboratory met the required standards for DST in 2013.

Data collection and variables

Information related to the study objectives was collected from the registers of both the NTP and the National Reference Laboratory. The study variables included demographic data, information on site (pulmonary or extrapulmonary) and category (new or previously treated) of TB, and results of smear microscopy, culture, and DST. The data were entered into Microsoft Excel™ (Microsoft Corporation, Redmond, Washington, United States).

The NTP database is part of the National Health Management Information System (SIGSA). The main health facility in each department forwards its individual TB case registration forms for the month to NTP headquarters where the data is entered into Excel™.

For this study, cases registered with the NTP and by the National Reference Laboratory were merged and checked for duplication and incompleteness. Cases were linked using each patient's first and last names, and validated using sex, age, date of notification, site of TB registration, laboratory that sent the sputum samples, and date that the laboratory reported the result (within one month before or after TB registration date). Duplicate TB patient records were reviewed to determine if both were produced by the same or different disease episodes. Duplicate laboratory samples were also reviewed to determine if they were start or follow-up samples from the same episode or from another episode. If there were duplicate records from the same disease episode, only the first was kept.

Patients were classified according to the smear result (negative/positive) and previous treatment status in order to assess whether or not culture and DST had been performed according to the national guidelines.

Analysis and statistics

The analysis was done using EpiData Analysis software version 2.2 (EpiData Association, Odense, Denmark). TB notification rates by age group and department were standardized per 100 000 population. The proportion with culture (for new smear negative pulmonary cases) and culture combined with DST (for previously treated patients) were compared among departments. Data were analyzed separately for the first and second semesters to account for time delays in receiving results of culture and DST. Descriptive and summary statistics were used to express results.

Ethics

Authorization to conduct this study was obtained from the National Tuberculosis Program of Guatemala and the National Reference Laboratory (Guatemala City, Guatemala). Ethics approval was obtained from Ethics Advisory Committee of the International Union Against Tuberculosis and Lung Disease (Paris, France).

To protect patient identity, individual information was encoded and only the first author was authorized to see the patient's name, if required.

RESULTS

Case notification by department

In all, 3 074 cases of TB (all forms) were registered, for a case notification rate of 20 per 100 000 population. Of these, 2 842 were new cases, including 2 167 (76%) smear positive cases and 385 (14%) smear negative cases, and 290 (10%) extra pulmonary cases. There were 232 (8%) previously treated cases, of which 204 were smear positive, 20 smear negative, and 8 extrapulmonary (Table 1).

By department, the notification rate for all TB cases ranged from 2–68 per 100 000 population (Table 2), while the rate for new cases varied from 1–52 (Figure 1). The departments with the highest notification rates were in the southwest and northeast areas of the country. By department, the proportions of new pulmonary smear negative cases ranged from 0%–26%, and for those previously treated, from 0%–14%.

Culture and drug sensitivity testing by TB category

Of 405 smear negative cases, 385 (95%) were new and 20 (5%) had been treated previously. Only 21 (5%) of new smear negative cases had culture results (Table 1); 6% in the first semester and 3% in the second semester (data not shown). Of 232 pulmonary and extrapulmonary previously treated cases, 47 (20%) had results of DST (Table 1); 25% in the first semester and 17% in the second. Low coverage by culture and DST was seen in all departments (data not shown). Of 22 departments, 7 (32%) did culture testing in new smear negative patients. In previously treated TB, DST was done in 13 (59%) of all departments.

Profile of drug resistance by TB category

DST results were available for a total of 102 patients (Table 3). In 55 new TB cases, 16% of test results were monoresistant, 5% polyresistant, and 18% had MDR-TB. Of 47 previously treated cases, 14% of results were monoresistant, 4% were polyresistant, and 19% had MDR–TB.

TABLE 1. Results of culture and drug susceptibility testing (DST) by category of tuberculosis, site of disease, and smear results, Guatemala, 2013

Category, site of disease, and smear result	Total patients	With culture		With DST	
	No.	No.	%	No.	%
Pulmonary smear positive					
New	2 167	106	5	48	2
Previously treated	204	51	25	45	22
Total	2 371	157	7	93	4
Pulmonary smear negative					
New	385	21	5	7	2
Previously treated	20	3	15	2	10
Total	405	24	6	9	2
Extrapulmonary					
New	290	9	0	0	0
Previously treated	8	0	0	0	0
Total	298	9	0	0	0
All cases					
New	2 842	136	5	55	2
Previously treated	232	54	23	47	20
Total	3 074	190	6	102	3

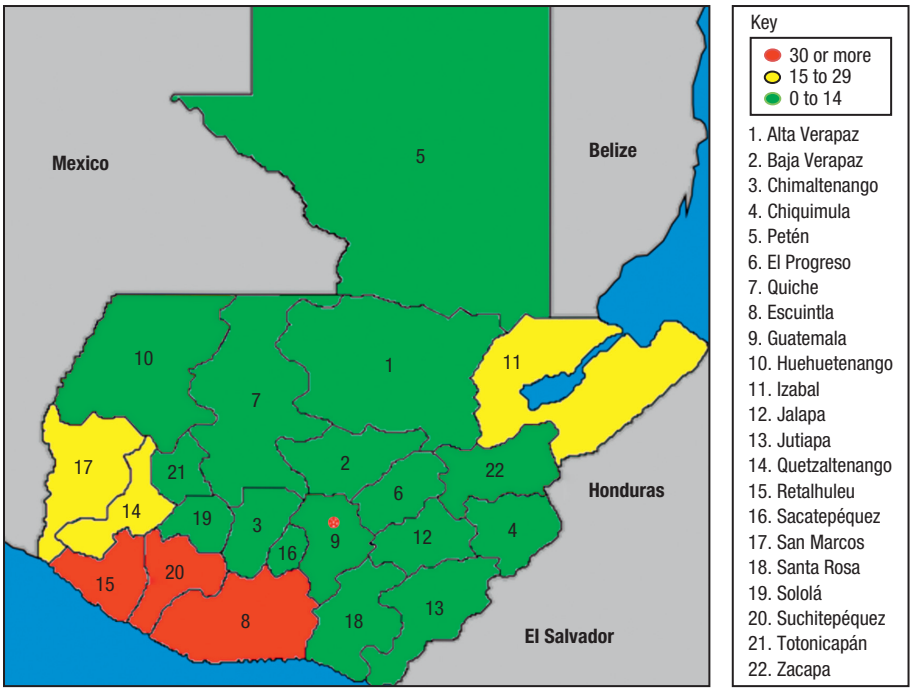
Source: prepared by the authors from the study data.

TABLE 2. Notification rates of all tuberculosis cases per 100 000 population, by department, Guatemala, 2013

Department	Population	Cases	Notification rate
Escuintla	731 326	497	68.0
Retalhuleu	318 319	166	52.1
Suchitepéquez	542 059	273	50.4
San Marcos	1 070 215	368	34.4
Izabal	434 378	116	26.7
Quetzaltenango	826 143	213	25.8
Zacapa	228 810	52	22.7
Huehuetenango	1 204 324	234	19.4
Guatemala	3 257 616	519	15.9
Sololá	464 005	66	14.2
Chiquimula	388 155	51	13.1
Petén	687 192	75	10.9
Sacatepéquez	329 947	36	10.9
Santa Rosa	360 288	37	10.3
Totonicapán	506 537	51	10.1
Alta Verapaz	1 183 241	118	10.0
Baja Verapaz	284 530	27	9.5
Quiche	1 019 290	93	9.1
Jutiapa	453 369	39	8.6
El Progreso	163 537	13	7.9
Jalapa	336 484	17	5.1
Chimaltenango	648 617	13	2.0
Total	15 438 382	3 074	19.9

Source: prepared by the authors from the study data. Population data provided by the National Statistics Institute of Guatemala.

FIGURE 1. New tuberculosis cases per 100 000 population, by department, Guatemala, 2013



Source: prepared by the authors from the study data.

DISCUSSION

This is the first countrywide study from Guatemala that assessed TB case notification by department, and determined adherence to national guidelines regarding TB cultures and DST. The national case notification rate for all TB cases was 20 per 100 000 population, ranging widely among departments (from 2–68 per 100 000) with the highest rates seen in the southwest and northeast. Coverage of culture and DST was very low among those considered eligible. Only 5% of smear negative pulmonary TB cases received a culture result, and only 1 of 10 previously treated TB patients received culture and DST. In previously treated patients, 19% had MDR-TB.

The large variation in TB notification rates among departments may be explained by both underreporting and underdiagnosis. Both of these deficiencies may be related to access to and use of health services, which may be linked to differences in socioeconomic vulnerability, education, and occupation. In the southwest (including the departments of Escuintla, Retalhuleu and Suchitepéquez), there are many seasonal migrant workers who cut sugar cane, live in overcrowded conditions, and suffer from inadequate nutrition. This situation can contribute to higher TB rates. Low rates in departments such as Chimaltenango and Jalapa may partly be explained by patients preferring to visit hospitals in the capital (12, 13).

The low coverage levels of culture and DST may have been related to shortcomings in sputum collection and/or issues with transportation to the seven centralized regional laboratories. There may also have been specific problems related to organizing the logistics of specimen transport, or under-trained health staff who were unaware of the importance of performing cultures and DST in particular cases. Finally, patients might have had problems with accessing health services or may have refused to provide a sputum sample.

TB notification rates usually vary among areas of a country, but most of the variation is usually related to programmatic issues, such as underreporting or underdiagnosis, not "real" differences in TB incidence unless strong risk factors (i.e., HIV) play an important role.

Globally, a topic of current discussion is how to reach the missing 3 million TB cases and eliminate TB (14). Transport of sputum specimens to centralized laboratories, as well as achieving a high culture and DST yield, are a global challenge. A countrywide survey in Malawi showed that in retreatment of TB patients, only 40% of specimens arrived at the National Reference Laboratory and less than 15% showed positive mycobacterial growth (15). Similarly, a study from China showed that less than one-third of patients who should have undergone DST actually did so (16). In Nepal, DST was

TABLE 3. Drug resistance stratified by tuberculosis (TB) category, Guatemala, 2013

Resistance type	Category of TB				Total	
	New case		Previously-treated			
	No.	%	No.	%	No.	%
Total	55	54	47	46	102	100
Sensitive to all	33	60	29	62	62	61
All resistant to:						
Isoniazid	16	29	12	26	28	27
Rifampicin	8	15	9	19	17	17
Ethambutol	16	29	11	23	27	26
Streptomicyn	11	20	5	11	16	16
Monoresistant to:						
Isoniazid	1	2	1	2	2	2
Rifampicin	0	0	0	0	0	0
Ethambutol	0	0	3	6	3	3
Streptomicyn	8	15	3	6	11	11
Polyresistant to:						
Isoniazid + streptomycin	3	5	2	4	5	5
MDR-TB[a] (isoniazid + rifampicin)	10	18	9	19	19	19

Source: prepared by the authors from the study data.
[a] Multidrug-resistant tuberculosis.

available for only 10% of previously treated patients (17).

The results of this study have a number of operational implications. First, the wide range in TB notification rates among departments raises questions of underreporting and underdiagnosis that need to be further assessed using the NTP routine notification system, including: completeness and quality of the notification system; rate of presumptive TB cases per 100 000 population; and proportion of presumptive cases with positive results. Specific research to further clarify these issues is needed.

Second, improving access to culture and DST in previously treated TB patients will require improved logistics for specimen collection and transportation, as well as resources to increase culture and DST yield at the laboratory level (18, 19).

Previously treated TB patients are known to have a higher prevalence of drug resistant TB and are considered a priority group for DST. The fact that only 20% of these patients had DST results indicates that many more with drug resistance may be on sub-standard treatment regimens, a situation that can promote community transmission of MDR-TB. In terms of the individual, an inappropriate regimen may compromise the possibility of a favorable treatment outcome. This situation has important public health implications for Guatemala and its efforts toward TB elimination.

On the other hand, new diagnostic technology, such as the Xpert® MTB/RIF, could facilitate rapid diagnosis of TB and rifampicin resistance, which would be an important step forward. The Xpert® MTB/RIF machine is a fully automated and commercially available nucleic acid amplification test that provides results in less than 2 hours. The test has high sensitivity and specificity for TB diagnosis and provides information on susceptibility to rifampicin (19). Patients in whom rifampicin resistance is found could be placed on an empirical MDR-TB treatment regimen, while awaiting results of culture and DST. In 2014, this machine was introduced in various parts of Guatemala; efforts to increase its use should be encouraged. Also, as rapid diagnosis detects more confirmed new and drug-resistant TB cases, the NTP will need to ramp up resources to ensure that the increased burden for treatment can be met.

The strengths of this study were that it was the first assessment of annual DST data since 2003; it was conducted on a national scale, which is more likely to reflect the operational reality on the ground; and it adhered to the Strengthening the Reporting of Observational Studies in Epidemiology guidelines (20) on reporting.

Limitations

The study also had some limitations that should be considered. Culture and DST results entered into the NTP register late in the year may have led to some underestimation. Moreover, while the level of drug resistancy and MDR-TB in previously treated patients was as expected, the level in new cases could not be assessed since only 2% underwent DST; so, selection bias is likely. Also, since the NTP and National Reference Laboratory use different patient identification numbers, there was a risk of errors (over- or underestimation). To minimize this risk, in addition to matching the first and last names, data was validated with other variables such age and sex.

Conclusions

This study shows that TB notification rates varied greatly among departments, which suggests underreporting and underdiagnosis. NTP guidelines on culture and DST were not well implemented, as shown by the small proportion of eligible patients who were tested. Data on drug resistance were not representative, but suggested an expected level (19%) of MDR-TB in previously treated patients.

To facilitate future comparisons and data analysis, it is imperative that the NTP and National Reference Laboratory come to an agreement on which variables to include in their registers; ideally, they would use the same TB patient identification number. This would also help match patient records, monitor the implementation of guidelines, and could serve as more reliable source for additional studies. The NTP and the National Reference Laboratory should regularly exchange information to ensure that TB patients have culture and DST done, and

that all TB patients diagnosed in the laboratory are registered in the NTP.

In addition, the NTP should further assess underreporting and underdiagnosis of TB, strengthen the surveillance system, improve the sputum sample transportation system, strengthen the quality of smear microscopy at the local level, increase coverage of culture and DST, and continue expanding the use of rapid diagnostic technology. Moving forward with these evidence-based recommendations, Guatemala may make great strides toward controlling drug resistant TB and reaching its goal of TB elimination.

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Ejecución de las directrices nacionales de tuberculosis sobre cultivo y antibiograma en Guatemala en el 2013

RESUMEN

Objetivo. Evaluar la eficacia de la ejecución de las directrices del Programa Nacional contra la Tuberculosis sobre cultivo y antibiograma en Guatemala, sobre todo en los casos de tuberculosis pulmonar con baciloscopia negativa o con antecedentes de tratamiento antituberculoso, mediante la investigación de las tasas de notificación por departamentos (o zonas geográficas), por tipos y categorías de la enfermedad y el examen de los resultados del cultivo y el antibiograma.

Métodos. Estudio transversal de investigación operativa en el cual se fusionaron y se vincularon todos los pacientes registrados en el Programa Nacional contra la Tuberculosis y el Laboratorio Nacional de Referencia en el 2013, tras la eliminación de los duplicados. Se calculó la proporción de casos con cultivo (en los casos nuevos de tuberculosis pulmonar con baciloscopia negativa) y de casos con cultivo y antibiograma (en los casos anteriormente tratados) y se analizaron por departamentos.

Resultados. Se registraron 3 074 pacientes con diagnóstico de tuberculosis (de todas las formas), lo cual representa una tasa de notificación de 20 casos por 100 000 habitantes. De estos pacientes, 2 842 fueron casos nuevos de tuberculosis, de los cuales 2 167 (76%) con diagnóstico de tuberculosis pulmonar y baciloscopia positiva, 385 (14%) con tuberculosis pulmonar y baciloscopia negativa y 290 casos (10%) con diagnóstico de tuberculosis extrapulmonar. Los casos con antecedentes de tratamiento antituberculoso fueron 232 (8%). Las tasas de notificación (de todas las formas) según el departamento oscilaron entre 2 y 68 casos por 100 000 habitantes y las tasas más altas se observaron en el suroeste y en parte del noreste de Guatemala. De los casos nuevos de tuberculosis, 136 contaban con cultivo y 55 con antibiograma; los resultados de estas pruebas revelaron 33 casos completamente sensibles, 9 casos monorresistentes, 3 casos polirresistentes y 10 casos de tuberculosis multirresistente (MR). Solo 21 (5%) de los casos nuevos de tuberculosis pulmonar y baciloscopia negativa contaban con cultivo. De los 232 pacientes anteriormente tratados, 54 (23%) contaban con cultivo y 47 (20%) con antibiograma, cuyos resultados fueron 29 casos completamente sensibles, 7 monorresistentes, 2 polirresistentes y 9 casos de tuberculosis MR. De 22 departamentos (incluida la capital), en 7 (32%) se efectuaba cultivo y antibiograma a los casos nuevos de tuberculosis pulmonar con baciloscopia negativa y en 13 departamentos (59%) a los casos de tuberculosis anteriormente tratada.

Conclusiones. Pese a la existencia de directrices nacionales, solo 5% de los casos de tuberculosis pulmonar con baciloscopia negativa contaba con cultivo y solo 20% de los casos de tuberculosis anteriormente tratada contaba con cultivo y antibiograma. En varios departamentos no se llevaban a cabo cultivos ni antibiogramas. Es preciso que se corrijan estas deficiencias en Guatemala si el país busca limitar la diseminación de la farmacorresistencia en su progreso hacia la eliminación total de la tuberculosis.

Palabras clave Tuberculosis; técnicas de diagnóstico del sistema respiratorio; técnicas de diagnóstico, normas; tuberculosis resistente a múltiples medicamentos; investigación operativa; Guatemala; América Latina.