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Sputum smear examination and time to diagnosis in patients with smear-negative pulmonary tuberculosis in the Pacific

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Setting: National tuberculosis programmes (NTPs) in Kiribati and the Marshall Islands, 2006–2010.

Objective: To determine the proportion of all tuberculosis (TB) cases that were pulmonary smear-negative, and for these patients to determine how many sputum smears were examined and the time from sputum smear examination to registration.

Design: A retrospective cross-sectional study involving a record review of national TB and laboratory registers.

Results: Of 2420 TB cases identified, 709 (29%) were registered as smear-negative pulmonary TB. Of the 695 (98%) with information on smear examination, 222 (32%) had no smear recorded, 61 (9%) had one smear, 86 (12%) two smears and 326 (47%) three smears. Among the 473 patients who had at least one smear, 238 (50%) were registered before sputum examination, 131 (28%) within 1 week, 72 (15%) between 1 and 4 weeks, and 34 (7%) >4 weeks after sputum examination.

Conclusion: NTPs in Kiribati and the Marshall Islands are diagnosing 29% of all TB patients as smear-negative pulmonary TB. Many patients do not have smears done or are registered before undergoing smear examination. Corrective measures are needed.

uberculosis (TB) rates in the Pacific vary greatly between Pacific Island countries and territories. In 2010, the highest rates of TB in the Western Pacific Region of the World Health Organization (WHO) were reported by the Republic of the Marshall Islands (352 per 100 000 population) and the Republic of Kiribati (287/100 000). These countries, in the Pacific subregion of Micronesia, have consistently reported high rates of TB in recent years.

In national TB programmes (NTPs) with a functional laboratory system and applied diagnostic algorithms, the proportion of all TB patients registered with smear-negative pulmonary TB (PTB) is expected to be approximately 35% of all pulmonary cases.3 This figure can be higher in countries with a high background prevalence of human immunodeficiency virus (HIV) infection.3 However, in some Pacific countries, the proportion of patients registered with smear-negative PTB is higher than one third of all pulmonary cases,⁴ and because the reported prevalence of HIV appears to be low in these countries,5 the reasons for the high proportion of smear-negative PTB are not clear. Another important consideration is the time taken to diagnose smear-negative PTB, as various steps are required after receipt of negative sputum smears, which include undergoing a chest radiograph (CXR), which is performed, read and interpreted by a clinician, and a clinical assessment. This may result in delays in diagnosis,⁶ which in turn can be associated with progression of disease, worse treatment outcome and spread of TB in the community.^{7–9}

To our knowledge, there is little local or published evidence about the practice of or time taken for diagnosing smear-negative PTB in the Pacific Islands, although TB surveillance data are reported annually. These data report the proportion of all TB cases diagnosed as PTB (both smear-positive and smear-negative) and extra-pulmonary TB, but do not report the number of smears for each case, how this relates to the age and sex of the patients or the time taken for diagnosis. Furthermore, one possible reason for an overdiagnosis of smear-negative PTB is that sputum smear examinations are not performed according to national guidelines. Patients may be being diagnosed without laboratory investigation, with the diagnosis based instead only on clinical criteria and CXR findings.

We therefore decided to investigate the practice of sputum smear examination in the Pacific Islands, focusing on two countries in the subregion of Micronesia where the TB burden is highest. The aim of this study was to determine the practice of sputum smear examination in patients registered with smear-negative PTB over a 5-year period in Kiribati and the Marshall Islands. Specific objectives were to determine: 1) the number and proportion of all TB patients registered with smear-negative PTB; 2) in patients registered with smear-negative PTB, whether or not smears were performed and the number of sputum smear examinations performed in relation to age and sex; and 3) the time taken between smear examination in the laboratory and recording the patient as smear-negative PTB in the TB patient register.

METHODS

Desian

This study was a retrospective, cross-sectional study involving a record review of TB patient registers and TB laboratory registers.

Setting

The setting is two Micronesian Pacific Island countries, Kiribati and the Marshall Islands. Kiribati is an equatorial country, located about halfway between Australia and Hawaii, while the Marshall Islands are located in the northern Pacific. Kiribati is an independent nation, while the Marshall Islands are affiliated with the United States under a Compact of Free Association.

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KEY WORDS

smear-negative; pulmonary tuberculosis; operational research; Pacific

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PHA 2012; 2(4): 133–137 © 2012 The Union Both are classified as lower middle-income countries according to the World Bank method of income classification, with a gross national income of US\$1006–3975 per capita. Their combined population is approximately 125 000: 92 000 in Kiribati and 33 000 in the Marshall Islands. Both countries are made up of many islands, and both are experiencing urbanisation, with people from the outer islands moving to urban centres. The urban areas have consequently become crowded, and in two urban centres—South Tarawa (Kiribati) and Ebeye (Marshall Islands)—the population density is >2000/km². 12

Both countries adopted the DOTS strategy as their TB control strategy in 2000. In addition, in the Marshall Islands, the US Centers for Disease Control and Prevention (CDC) TB control policies are applied. Health services in both countries are provided by national governments that have committed to providing a minimum package of funding and services for TB control. This funding is supplemented by funds from technical partners such as the CDC and the WHO, and donors such as the Global Fund to Fight AIDS, TB and Malaria (for both countries); in the case of Kiribati, additional funds are provided by the Australian Agency for International Development.

In both countries, people with presumptive TB are identified by passive case finding if they cough for more than 2 weeks, and diagnostic services are free for patients. According to national TB guidelines, 13,14 which are in line with WHO 2003 guidelines (third edition),3 all people with presumptive TB should submit three sputum specimens for smear examination in one of the recognised laboratories; this is done by Ziehl-Neelsen staining of sputum smears using light microscopy. Patients who are found to have acid-fast bacilli (AFB) in at least one sputum specimen are diagnosed as smear-positive PTB. Those whose sputum smears are negative for AFB are referred to a clinician for a CXR and clinical assessment. Based on findings from these examinations, a diagnosis of smear-negative PTB may be made. Such patients are referred to a DOTS centre where they are registered and treated for smear-negative PTB with a standardised regimen. 13,14 Registration and treatment often occur simultaneously due to the centralised nature of the TB services. The sputum smear examination results are recorded in the subnational TB patient registers and TB laboratory registers, and are later collated by the central unit of the NTP.

Patient sample

Study participants were all TB patients notified to the NTP in Kiribati and the Marshall Islands from 1 January 2006 to 31 December 2010 (5 years).

Data variables, data source and data collection

The data collection instrument was a questionnaire designed for the study in EpiData Entry (EpiData, Odense, Denmark). Variables collected from the TB patient register and TB laboratory register were as follows: 1) the total number of TB patients registered, stratified by type of TB, year of registration and country of registration; 2) in those with smear-negative PTB: age, sex, number of sputum smears submitted for TB diagnosis (0, 1, 2 or 3), and date of registration of smear-negative PTB; and 3) in patients for whom sputum smears were submitted, the date of sputum smear examination as recorded in the laboratory register, and date of registration in the TB register.

Data sources for this study were the national TB patient registers and TB laboratory registers in Tarawa (Kiribati) and Majuro (Marshall Islands). Data were entered from paper registers into the electronic data questionnaire in EpiData Entry.

Data analysis

Analysis was conducted using EpiData Analysis. We determined: 1) the proportion of patients registered each year with smearnegative PTB; 2) the proportion of patients registered with smearnegative PTB who did not have a smear examination, who were assessed in relation to sex and age (stratified by mutually exclusive age groups); 3) the number of smears examined, again stratified by sex and age group; and 4) the time taken from smear examination to registration of smear-negative PTB, as a proxy for diagnostic delays, in relation to sex and age. Categorical variables were compared in relation to the main outcomes using the χ^2 test and relative risks with 95% confidence intervals. Levels of significance were set at 5%.

Ethics approval was provided by the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease, Paris, France and the national Ministries of Health in both countries.

RESULTS

Over the 5-year period 2006–2010, 2420 cases of TB were registered in Kiribati and the Marshall Islands, 1628 in Kiribati (67%) and 792 (23%) in the Marshall Islands (Table 1). Of these, 1678 were PTB cases, 741 were extra-pulmonary TB cases, and 1 case did not have type of TB recorded. Of all TB cases, 876 (36%) were smear-positive PTB, 709 (29%) were smear-negative PTB, and 93 (4%) were reported as PTB 'smear not done'. Of all PTB cases, 709 (42%) were smear-negative.

Of the 709 cases of smear-negative PTB, 362 (54%) were male; 440 (62%) were from Kiribati and 269 (38%) were from the Marshall Islands. The mean age (standard deviation) of the smearnegative PTB cases was 35 years (±22); 138 (19%) were children aged <15 years. The sputum smear examination results and results stratified by age and sex are shown in Table 2. A small number of patients (n = 14) had no information recorded about their sputum smear status. Of those with information, 222 (32%) classified as smear-negative PTB had no smear recorded, 61 (9%) had one recorded, 86 (12%) had two recorded, and 326 (47%) had the required three smears recorded. Smear examinations were not performed more frequently in children aged <15 years (67%) compared with adults (23%, P < 0.001), and there were no differences between males and females. For those with smears done, the proportion with one, two or three smears was no different in relation to age and sex.

Time from first sputum smear examination to TB registration was accurately recorded for all 473 smear-negative PTB patients for whom smears were examined (Table 3). Of these patients, 238 (50%) were registered before they had sputum smears examined in the laboratory, 131 (28%) within 1 week of sputum examination, 72 (15%) between 1 and 4 weeks after sputum examination, and 34 (7%) > 4 weeks after the first sputum was examined. There

TABLE 1 Tuberculosis cases stratified by type of tuberculosis in Kiribati and the Marshall Islands, 2006–2010

Type of tuberculosis	Kiribati	Marshall Islands	Total
	n (%)	n (%)	n (%)
Smear-positive pulmonary	665 (41)	211 (27)	876 (36)
Smear-negative pulmonary	440 (27)	269 (34)	709 (29)
Pulmonary, smear not done	0	93 (12)	93 (4)
Extra-pulmonary	523 (32)	218 (28)	741 (31)
Not recorded	0	1 (0)	1 (0)
Total	1628 (100)	792 (100)	2420 (100)

TABLE 2 Number of sputum smears for sputum smear-negative pulmonary tuberculosis cases in Kiribati and the Marshall Islands, by age group and sex, 2006–2010

	0 smears n (%)	1 smear <i>n</i> (%)	2 smears n (%)	3 smears n (%)	Not recorded n (%)	Total n
Age group, years						
0–4	39 (100)	0	0	0	0	39
5–14	52 (53)	9 (9)	13 (13)	23 (23)	2 (2)	99
15-49	92 (25)	36 (10)	43 (12)	193 (53)	1 (0)	365
≥50	37 (19)	16 (8)	30 (16)	109 (57)	1 (1)	193
Age not						
recorded	2 (15)	0	0	1 (8)	10 (77)	13
Sex						
Male	108 (30)	32 (9)	52 (14)	168 (46)	2 (1)	362
Female	114 (35)	29 (9)	34 (10)	150 (46)	2 (1)	329
Sex not	,	` '	` ,	` ,	` '	
recorded	0	0	0	8 (44)	10 (56)	18
Total	222	61	86	326	14	709

was no difference in the time taken for smear examination to TB registration in relation to age and sex.

DISCUSSION

This is the first study on the practice of diagnosing smear-negative PTB in the Pacific. Our study confirms our hypothesis that Kiribati and the Marshall Islands are reporting more smear-negative PTB than the expected 35% of all pulmonary cases. Our study found that just under half of all pulmonary cases were smearnegative and an additional number of cases were reported as pulmonary 'smear not recorded'. These cases may also have been smear-negative, although we cannot ascertain this from our data. A lower proportion of smear-negative cases was reported in Kiribati (27%) than in the Marshall Islands (34%, P < 0.001).

About one third of smear-negative PTB patients had no sputum specimens collected and examined for diagnosis, and just under half had the required number of three smears assessed in the laboratory according to national guidelines. Furthermore, of those smear-negative patients who had accurate information recorded, many were registered and had commenced treatment before the first smear was examined, suggesting significant deviation from recommended practice. We were pleased to see that the time taken to diagnose smear-negative PTB was not excessive, and that

fewer than 10% were diagnosed more than 4 weeks from first sputum submission. Conversely, many patients were registered too early, with no smears done, although national guidelines recommend a diagnostic algorithm with at least two sputum smear examinations.

This study collected national data for both countries and is therefore representative of the situation in Kiribati and the Marshall Islands. All registered TB patients were assessed, and TB patient registers were cross-checked, where necessary, against TB laboratory registers to ensure completeness of data.

There may be several reasons why smear-negative PTB is being overdiagnosed in Kiribati and the Marshall Islands. Smear-negative PTB is more common in children, the elderly and HIV co-infected patients. In addition, programmatic factors may affect the diagnosis of smear-negative PTB. For example, patients may not submit high quality sputum specimens, the correct number of specimens may not be submitted, staining of sputum specimens for diagnosis in the laboratory may be suboptimal, clinicians may rely on CXR and symptoms to make a diagnosis, and errors in recording and reporting may be made.

In the Pacific, where the prevalence of HIV is generally low,5 co-infection with HIV is not thought to be associated with high rates of smear-negative PTB. In our population, as one fifth of the patients were aged <15 years, this may be one reason why smearnegative PTB was common. However, it is likely that programmatic factors played a large part. In our study, many patients did not have the required number of sputum specimens examined, which may have led to an overdiagnosis of smear-negative PTB. Furthermore, it is possible that clinicians relied on the patient's CXR and clinical presentation for diagnosis, and sputum induction was not used to aid diagnosis. Another possible reason may be the relatively high background prevalence of diabetes mellitus in these two countries. The prevalence of diabetes in adults is 28% in Kiribati and 41% in the Marshall Islands. 19,20 The association between diabetes mellitus and TB has been well documented, and some studies report that smear-negative PTB is more common in people with diabetes, although this association may require rigorous studies to prove an association.^{21–23} Information on diabetes mellitus was not collected during the study, and the association may warrant further research. In addition, knowledge, attitudes and behaviour of programmatic staff may influence the practice of diagnosing smear-negative PTB.

To our knowledge, no previous studies on the practice of diagnosing smear-negative PTB have been undertaken in the Pacific.

TABLE 3 Time from first sputum smear to registration for sputum smear-negative pulmonary tuberculosis cases in Kiribati and the Marshall Islands, by age group and sex

	Tuberculosis registration before smear examination n (%)	<7 days n (%)	7–13 days n (%)	14–20 days n (%)	21–27 days n (%)	≥28 days n (%)	Unknown n (%)	Total n
Age group, years								
0–4	0	0	0	0	0	0	39 (100)	13
5–14	22 (22)	13 (13)	3 (3)	1 (1)	2 (2)	5 (5)	53 (54)	193
15–49	129 (35)	79 (22)	27 (7)	7 (2)	4 (1)	21 (6)	98 (27)	365
≥50	78 (40)	38 (20)	13 (7)	8 (4)	7 (4)	8 (4)	41 (21)	99
Age not recorded	9 (69)	1 (8)	0	0	0	0	3 (23)	39
Sex								
Male	113 (31)	73 (20)	30 (8)	6 (2)	8 (2)	20 (6)	112 (31)	362
Female	110 (33)	56 (17)	13 (4)	10 (3)	5 (2)	14 (4)	121 (37)	329
Sex not recorded	15 (83)	2 (11)	0 `	0 `	0 `	0 `	1 (6)	18
Total	238	131	43	16	13	34	234	709

Studies in other settings show that people with smear-negative PTB may not have the adequate number of sputum specimens submitted to a laboratory, and clinicians may make incorrect diagnoses based on radiographic and clinical findings.^{15,24}

The study has some limitations. A number of TB cases were recorded as pulmonary 'smear not done'. These cases may have been misclassified and may be smear-negative PTB. In addition, a systematic enquiry about diagnostic practices, which might have identified how and why smear-negative pulmonary cases are diagnosed, providing potentially useful insights into the practice of diagnosis, was not undertaken.

CONCLUSION

This study has revealed that smear-negative PTB is overdiagnosed in Kiribati and the Marshall Islands, and that there are deficiencies in the practice of sputum smear examination. Many smearnegative PTB patients do not have smear information recorded and many are registered before having sputum smears examined in the laboratory. We believe that these issues can be corrected through training and appropriate follow-up and supervision. A similar operational research study should then be conducted to determine if improvements have been made.

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Contexte: Les Programmes Nationaux de la Tuberculose (PNT) à Kiribarti et aux lles Marshall, 2006–2010.

Objectif: Déterminer la proportion des cas de tuberculose (TB) pulmonaire à bacilloscopie négative sur l'ensemble des cas, et pour ces patients, déterminer le nombre de frottis de crachats examinés ainsi que la durée entre l'examen du frottis de crachats et l'enregistrement.

Schéma: Etude transversale rétrospective impliquant une révision des dossiers des registres nationaux de la TB et des laboratoires.

Résultats: On a identifié 2420 cas de TB dont 709 (29%) ont été enregistrés comme TB pulmonaire à bacilloscopie négative. Des 695 cas (98%) où les informations existent sur l'examen des frottis, aucun frottis n'a été enregistré pour 222 (32%), 61 (9%) ont eu un frottis,

86 (12%) deux frottis, et 326 (47%) trois frottis. Chez les 473 patients chez qui au moins un frottis avait été obtenu, 238 (50%) ont été enregistrés avant l'examen des crachats, 131 (28%) au cours de la première semaine après l'examen des crachats, 72 (15%) entre 1 et 4 semaines après l'examen des crachats et 34 (7%) >4 semaines après l'examen des crachats.

Conclusion: A Kiribati et aux lles Marshall, les PNT diagnostiquent comme TB pulmonaire à bacilloscopie négative 29% de l'ensemble des patients TB. Chez beaucoup de patients aucun frottis n'est exécuté ou l'enregistrement a lieu avant l'examen des frottis. Des mesures correctrices s'imposent.

Marco de referencia: Los Programas Nacional contra la Tuberculosis (PNT) de Kiribati y las Islas Marshall entre el 2006 y el 2010.

Objetivo: Determinar la proporción de todos los casos de tuberculosis (TB) registrados con baciloscopia negativa y en estos casos, definir el número de muestras de esputo analizadas y el lapso entre la baciloscopia y la notificación en el registro de TB.

Método: Fue este un estudio transversal retrospectivo en el cual se consultaron el registro nacional de TB y los registros de los laboratorios.

Resultados: De 2420 casos de TB, 709 (29%) estaban diagnosticados como TB pulmonar con baciloscopia negativa. De los 695 (98%) casos con información diagnóstica sobre la baciloscopia, 222 (32%) no tenían datos sobre este examen, 61 (9%) tenían consignada una

baciloscopia, 86 casos (12%) tenían dos y en 326 casos (47%) se encontraron consignados tres exámenes microscópicos del esputo. De los 473 pacientes que contaban al menos con una baciloscopia, 238 (50%) se registraron antes del examen del esputo, 131 (28%) en la primera semana después de la baciloscopia, 72 (15%) se registraron entre 1 y 4 semanas después y 34 pacientes (7%) se registraron >4 semanas después del examen microscópico del esputo.

Conclusión: En los PNT de Kiribati y las Islas Marshall 29% de todos los pacientes tuberculosos se registran como casos de TB pulmonar con baciloscopia negativa. En muchos pacientes no se practica el examen microscópico del esputo o se registran antes de realizar el examen. Es preciso aplicar medidas que corrijan esta anomalía.

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