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Challenges in TB diagnosis and treatment: the Kavieng Provincial Hospital experience, Papua New Guinea

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Setting: The Tuberculosis (TB) Basic Management Unit at Kavieng Provincial Hospital, New Ireland Province, Papua New Guinea.

Objective: To assess the linkage between laboratory diagnosis and treatment initiation and describe the characteristics and treatment outcomes of TB patients.

Design: This was a retrospective cohort study of 1) sputum smear-positive TB patients recorded in the laboratory register, and 2) TB patients recorded in the treatment register in 2015 and 2016.

Results: Of the 221 patients registered for TB treatment, 173 (78%) were clinically diagnosed; extrapulmonary TB was common (36% of all patients). Unfavourable treatment outcomes were seen in more than 40% of patients, including death (10%) and loss to follow-up (26%), and were significantly more common in smear-negative vs. smear-positive pulmonary TB patients (RR 1.69 [95%CI 1.02–2.80]). Only 4 (<2%) TB patients had undergone testing for HIV. Twelve (21%) of 58 sputum smear-positive TB patients were not registered as undergoing treatment for TB.

Conclusion: This study identifies diagnostic and treatment gaps in the TB treatment cascade at the Kavieng Basic Management Unit. The TB programme requires strengthening to address the high proportions of clinically diagnosed TB, of patients not tested for HIV and of loss to follow-up.

Tuberculosis (TB) is the most common infectious cause of death globally and a major public health challenge for many resource-limited countries. In 2016, the World Health Organization (WHO) estimated that there were 10.4 million new patients with TB, with approximately 1.3 million deaths among human immunodeficiency virus (HIV) negative cases and an additional 374000 deaths among HIV-positive cases.[1] The WHO's End TB Strategy highlights the need for patient-centred care to achieve a high coverage of TB case detection and high rates of treatment success.[2] Access to quality diagnosis and treatment for individuals with presumptive TB is critical. It is therefore important to improve the pre-treatment TB cascade to ensure timely diagnosis and linkages to care for all individuals who present to the health facility with TB.[3]

Papua New Guinea (PNG) is a high-burden TB country in the Western Pacific region with an estimated TB incidence rate of 432 patients per 100000 population in 2016.[1] The national surveillance system for TB has been strengthened in PNG since 2008 with an increase in TB case notification each year until 2014.[4] However, the recently reported case detection rate of 333/100000 for 2016 suggests that many TB patients remain undetected. The case notification rate for New Ireland Province was reported to be 105/100000, with 26% being new smear-positive TB patients.[4] The treatment success rate for all TB patients in PNG in 2016 was 64%,[4] indicating major challenges and deficiencies in the quality of care provided to TB patients undergoing treatment. 'Loss to follow-up' (LTFU) and 'not evaluated' were the major categories contributing to a low treatment success rate in all regions of PNG, and the proportion of LTFU was highest in the Islands region (27% in 2016).[4]

We aimed to assess the linkage between laboratory diagnosis and treatment initiation, and the characteristics and treatment outcomes of all patients registered in the basic management unit (BMU) at Kavieng Provincial Hospital in New Ireland Province during a 2-year period.

METHODS

Study setting

New Ireland, one of the 22 provinces of PNG, is an island province located in north-eastern PNG, approximately 850 km (by air travel) from the capital, Port Moresby. The province covers a land area of approximately 9557 km^2 and has an estimated population of 194067 inhabitants (2011 Census). Under the recently established New Ireland Provincial Health Authority, there are 17 health facilities, 10 of which function as TB BMUs.

Kavieng Provincial Hospital is the main referral hospital in New Ireland Province and has a total bed capacity of 104. It is the largest BMU in the province, diagnosing and treating TB patients from a catchment of approximately 69000 population. The only diagnostic service for TB at the hospital is smear microscopy for acid fast bacilli using Ziehl-Neelsen staining. Radiology services are also available. The hospital's laboratory officers undergo regular external quality assurance under the supervision of the Central Public Health Laboratory (Port Moresby, PNG), the sole reference laboratory for the country.

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Study design and population

This was a retrospective cohort analysis involving two cohorts. The first population consisted of sputum smear-positive pulmonary TB (PTB) patients registered in the TB laboratory register between 1 January 2015 and 31 December 2016 and residing in the catchment area of Kavieng Hospital's BMU. Patients from other BMUs with smear-positive PTB registered in the hospital's TB laboratory register were excluded. The second study population consisted of all TB patients who registered for treatment in the Kavieng Hospital BMU TB treatment register between 1 January 2015 and 31 December 2016.

Data collection and data variables

The data were collected on two separate standardised data collection forms: one for the TB laboratory register and the other for the BMU TB treatment register. De-identified data were then double-entered into EpiData v.3.1 (EpiData Association, Odense, Denmark) with no names, addresses or other personal identifiers. The data collected from the TB laboratory register included demographic information and laboratory registration number, estimated travel time from residence to the facility, date of sputum examination, sputum smear result and grade, and date of treatment initiation. For the treatment initiation, in the absence of a unique identifier (presumptive TB number or laboratory number), registers for the BMU and the TB laboratory were placed adjacently to each other and the patients' demographic data (name, sex, age and place of residence) were matched to ensure it was the same patient from the laboratory register in the BMU register.

Data from the TB treatment register included serial number, registration date, distance in km from residence, distance in time from residence, age, sex, the date sputum was examined, date of treatment initiation, type of patient, site of TB (categorised as PTB or extrapulmonary TB [EPTB]), diagnostic classification of TB, sputum grading, HIV status, treatment outcome, and end of treatment date.

Outcomes at the end of treatment were defined according to the PNG National Tuberculosis Management Protocol.[5] Outcomes were categorised as favourable (cured and treatment completed) or unfavourable (death, LTFU, failure or missing). Patients categorised with an outcome of 'not evaluated' were excluded from the analysis as the majority transferred out to other BMUs.

Data analysis and statistics

The data were analysed using Stata v.15 (StataCorp, College Station, TX, USA). Categorical data were reported as frequencies and proportions and continuous data as medians and interquartile ranges [IQR]. Factors associated with an unfavourable outcome were summarised using relative risks (RR) with a P value (calculated using the χ^2 test); $P < 0.05$ was considered significant. For variables with more than 10% missing values, a 'missing' category was included in the analysis. All other missing values were excluded from the analysis.

Ethics approval

Ethical approval to conduct this study was obtained from PNG Medical Research Advisory Council (Port Moresby, PNG) and the Alfred Hospital Ethics Committee (Melbourne, VIC, Australia). As the study involved secondary data, waiver for informed consent was sought and approved by the ethics committees.

RESULTS

Of the 221 TB patients registered for treatment (Table 1), there was an equal distribution of males and females; 51% (113/221) were aged 15–44 years; 78% (173) resided within a distance of 30 min from the hospital, and 98% (217) did not undergo testing for the human immunodeficiency virus (HIV). The majority of TB patients were clinically diagnosed (78%, 173/221). There were 41% (91/221) with sputum smear-negative PTB and 37% (82/221) with EPTB. Only 21% (47/221) had bacteriologically confirmed PTB and only 9% (19/221) of patients were retreatment patients.

There were 58 bacteriologically confirmed patients recorded in the laboratory register (Table 2), predominantly aged 15–44 years (83%). Of these 58, 21% (12) were lost to follow-up in the pre-treatment phase. The

TABLE 1 Characteristics of all TB patients registered for treatment in Kavieng Provincial Hospital, New Ireland Province, Papua New Guinea (2015–2016)

Characteristic	*n* (%)
Total	221
Age, years	
<15	57 (26)
15–44	113 (51)
⩾45	51 (23)
Sex	
Male	111 (50)
Female	110 (50)
Travel time from residence to facility, mins	
0–30	173 (78)
31–60	27 (12)
>60	0 (0)
Missing	21 (10)
HIV status	
Uninfected	1 (1)
Infected	3 (1)
Missing	217 (98)
Type of TB	
Smear-positive PTB	47 (21)
Smear-negative PTB	91 (41)
EPTB	82 (37)
Missing	1 (0)
Patient type	
New	192 (87)
Treatment after LTFU	13 (6)
Treatment after relapse	6 (3)
Missing	10 (5)

TB = tuberculosis; HIV = human immunodeficiency virus; PTB = pulmonary TB; EPTB= extrapulmonary TB; LTFU= loss to follow-up.

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Conflicts of interest: none declared.

TABLE 2 Characteristics of patients with bacteriologically confirmed pulmonary TB, including those with pre-treatment loss to follow-up, in Kavieng Provincial Hospital, New Ireland Province, Papua New Guinea (2015–2016)

Characteristic	Total *n* (%)	Pre-treatment LTFU *n* (%)	Treatment initiated *n* (%)
Total	58 (100)	12 (100)	46 (100)
Age, years			
<15	4 (7)	0 (0)	4 (9)
15–44	40 (69)	10 (83)	30 (65)
⩾45	14 (24)	2 (17)	12 (26)
Sex			
Male	26 (45)	5 (42)	21 (46)
Female	32 (55)	7 (58)	25 (54)
Travel time from residence to facility, mins			
0–30	47 (81)	8 (67)	39 (85)
31–60	4 (7)	1 (8)	3 (7)
Missing	7 (12)	3 (25)	4 (5)

TB = tuberculosis, LTFU = loss to follow-up.

TABLE 3 Treatment outcomes among TB patients registered for treatment, overall and by TB type, in Kavieng Provincial Hospital, New Ireland Province, Papua New Guinea (2015–2016)

Treatment outcomes	All TB *n* (%)	Sputum smear-positive PTB *n* (%)	Sputum smear-negative PTB *n* (%)	EPTB *n* (%)
Total	221 (100)	47 (100)	91 (100)	82 (100)
Cured	32 (14)	32 (68)	—	—
Treatment completed	95 (43)	—	46 (51)	49 (60)
Death	23 (10)*	2 (4)	9 (10)	11 (13)
LTFU	58 (26)	10 (21)	31 (34)	17 (21)
Not evaluated	5 (2)	2 (4)	1 (1)	2 (2)
Missing	8 (4)	1 (2)	4 (4)	3 (4)

*One death had no TB site recorded.
TB = tuberculosis; PTB = pulmonary TB; EPTB = extrapulmonary TB; LTFU = loss to follow-up.

pre-treatment LTFU TB cases were 58% (7/12) female and 67% (8/12) resided within a 30-min distance from the hospital.

Favourable treatment outcomes occurred in 57% (127/221) of patients. Among the unfavourable outcomes, 10% (23/221) were deaths, 26% (58/221) were LTFU; no treatment failure patients were recorded (Table 3).

Of the 221 patients registered for treatment, 2% (5) transferred out from the BMU and were considered as not evaluated. The treatment success rate differed by treatment site and bacteriological confirmation: 68% (32/47) for clinically diagnosed PTB, sputum 51% (46/91) for smear-negative PTB and 60% (49/82) for EPTB. Mortality was higher in the clinically diagnosed categories: 10% (9/91) in cases of sputum smear-negative PTB and 13% (11/82) in cases of EPTB. The only significant association with an unfavourable outcome was smear-negative PTB, RR 1.69, 95% confidence interval (CI) 1.02–2.80, $P = 0.04$ (Table 4).

DISCUSSION

This retrospective analysis of TB treatment outcomes from the largest TB BMU in New Ireland Province highlights a number of challenges throughout the TB treatment cascade. There were a low proportion of TB patients bacteriologically confirmed and approximately one fifth of these patients were not initiated on treatment. Over two fifths of patients had an unfavourable outcome, with outcomes significantly worse in smear-negative PTB patients. Few patients were tested for HIV, despite the fact that HIV is a major risk factor for TB and for poor treatment outcome. These findings are similar to those recently reported from national surveillance data[4] and highlight the importance of ongoing programme evaluation at Kavieng Hospital to identify key areas for programme improvement.

The high proportion of patients diagnosed clinically likely relates in part to the minimal diagnostic facilities available at Kavieng Hospital. Kavieng Hospital relies on smear microscopy for confirming TB. Rapid diagnostic tests such as GeneXpert® (Cepheid, Sunnyvale, CA, USA) could potentially increase the diagnostic yield and lead to a decrease in empiric TB treatment, if supported by adequate training and resources. There are now 30 Xpert machines in PNG but only one in New Ireland Province, at Lihir Mining Hospital, requiring air transport for specimens from Kavieng to Lihir. The implementation of rapid diagnostics may not necessarily result in improvements in TB-related mortality and morbidity, especially if there is no improvement in linking diagnosed patients to TB treatment.

Even though the majority of the patients in this study had easy access to the hospital, over 20% of bacteriologically confirmed patients were not registered for TB treatment. Failure to treat confirmed patients has significant individual health consequences in addition to contributing to the ongoing spread of TB within the community. In a systematic review, pre-treatment LTFU was reported to vary 4–38% between programmes; the main reason for pre-treatment LTFU was death, although the majority of publications were from high HIV-TB settings.[6] There were difficulties in linking patients from the laboratory register to the BMU treatment register in the current study, as we did not have a unique identifier (presumptive TB number or laboratory number) consistently recorded in both registers.

The PNG National TB Management Protocol recommends that every presumptive TB case and every TB patient be offered HIV counselling, testing and care.[5] Despite this directive, 98% of the registered TB patients in this study did not undergo testing for HIV, a finding similar to that from recent surveillance by the National TB Programme.[4] Based on our experience in PNG, we speculate that there could be two reasons for this. First, and probably the most significant, is that staff at the TB clinic are not referring patients for HIV testing. Second, despite performing HIV testing on presumptive or confirmed TB cases, the staff is not entering the results in the appropriate TB registers; thus the column regarding HIV testing status remains blank.

The treatment success rate for TB patients at the national level remains low compared to global targets.[1,4] LTFU remains a major issue for PNG, with the highest rate found in the Islands; 27% in 2016 compared to a national LTFU rate of around 19% in 2016.[4] Similar to the national data, the proportion of successful outcomes in this study for both bacteriologically confirmed and clinically diagnosed TB patients was low in comparison to the global targets. The number of patients lost to follow-up was significant, with sputum smear-negative patients comprising the largest proportion. Multiple factors have been associated with LTFU, including socioeconomic, geographical, behavioural, and even traditional beliefs. Other factors include a lack of communication

TABLE 4 Risk factors associated with unfavourable treatment outcomes among TB patients in Kavieng Provincial Hospital, New Ireland Province, Papua New Guinea (2015–2016)

Characteristic	Total *n* = 216*	Favourable outcome† *n* = 127	Unfavourable outcome *n* = 89	RR‡ (95% CI)	*P* value
Age, years					
<15	57	33 (58)	24 (42)	Reference	
15–44	110	64 (58)	46 (42)	0.99 (0.68–1.44)	1.00
⩾45	49	30 (61)	19 (39)	0.92 (0.58–1.47)	0.88
Sex					
Male	108	66 (61)	42 (39)	Reference	
Female	108	61 (56)	47 (44)	1.12 (0.81–1.54)	0.58
Travel time from residence to facility, mins					
0–30	169	106 (63)	63(37)	Reference	
31–60	26	13 (50)	13 (50)	1.34 (0.87–2.06)	0.31
Missing	21	8 (38)	13 (62)	1.66 (1.13–2.45)	0.05
HIV status					
Negative	1	0 (0)	1(100)	—	
Positive	3	0 (0)	3 (100)	—	
Missing	212	127 (60)	85 (40)	—	
Type of Patient					
New	187	109 (58)	78 (42)	Reference	
Treatment after LTFU	13	7 (54)	6 (46)	1.13 (0.61–2.09)	0.92
Treatment after relapse	6	6 (100)	0 (0)	—	
Missing	10	5 (50)	5 (50)	—	
Type of TB					
Smear-positive PTB	45	32 (71)	13 (29)	Reference	
Smear-negative PTB	90	46 (51)	44 (49)	1.69 (1.02–2.80)	0.04§
EPTB	80	49 (61)	31 (39)	1.34 (0.79–2.29)	0.36
Missing	1	0 (0)	1 (100)	—	–
Baseline weight, kg					
<45	64	40 (63)	24 (38)	Reference	
45–59	46	30 (65)	16 (34)	0.93 (0.56–1.54)	0.93
⩾60	26	20 (77)	6 (23)	0.62 (0.29–1.33)	0.29
Missing	80	37 (46)	43 (54)	1.43 (0.98–2.08)	0.08

*Five 'not evaluated' outcomes were not considered as unfavourable outcomes and therefore were excluded from the total cohort.
†Favourable outcome included treatment outcomes of 'cured' and 'treatment completed'.
‡Relative risk for unfavourable outcome.
§Statistically significant.
TB = tuberculosis; RR = relative risk; HIV = human immunodeficiency virus; LTFU = loss to follow up; PTB = pulmonary TB; EPTB = extrapulmonary TB.

between health workers and patients, inadequate management of adverse drug reactions, inadequate diagnostic and treatment services (including for HIV), concomitant use of harmful drugs during treatment, and a lack of basic knowledge on TB and its complications. Interventions reported to reduce LTFU include patient education and counselling, and the strengthening of TB implementation, such as community-based treatment support and financial incentives.[7,8]

The outcomes for sputum smear-negative PTB were significantly worse than for sputum smear-positive PTB patients. This could be related to the over-diagnosis of PTB with unnecessary trial and cessation of TB treatment, a lack of response to treatment due to drug resistance, or the unknown presence and inadequate management of co-morbidities, including HIV and diabetes. Higher mortality rates for sputum smear-negative PTB have been reported in settings with a high incidence of TB and HIV.[9] Increasing access to rapid molecular diagnostic tests combined with increased training and supervision is likely to help improve TB diagnosis. Screening for HIV and diabetes should be offered to all patients.

This study is limited by its retrospective design with reliance on routinely collected programmatic data, with data missing for some variables, and a relatively small sample size. In addition, there were difficulties with linking patients between the laboratory and BMU registers. This highlights the need for a unique registration number that can be used to link patients in both registries.

Although previous studies suggest multiple interventions are needed to achieve the global TB targets in settings such as Kavieng Hospital, there are a number of key interventions that could be implemented in the short term to improve outcomes. The introduction of Xpert, in combination with the automated electronic notification system GxAlert (SystemOne, Boston, MA, USA), is being rolled out throughout PNG and its introduction in Kavieng Hospital would likely decrease pre-treatment LTFU and increase microbiological confirmation of both drug-sensitive and drug-resistant TB. Furthermore, an increased focus on improving the coverage of HIV testing and care is a priority given that PNG is a high HIV-TB burden country. The implementation of a unique identifier to link laboratory and treatment registers, regular monitoring and evaluation to ensure TB register completion and strengthened processes for tracing presumptive TB patients may help to reduce pre-treatment LTFU. Finally, capacity building of the TB programme team in Kavieng Hospital in the components

of the End TB Strategy, combined with quality supervision, will be essential to improving outcomes.

CONCLUSION

This study has identified several key areas for improvement in programme functioning in New Ireland's largest BMU. The challenges in the areas of diagnostics, treatment and LTFU are complex and will likely require multiple interventions to improve. This study shows how the analysis of linkage between laboratory diagnosis and treatment initiation in the BMU can help provide insight into where limited resources should be focussed to improve TB diagnosis and outcomes.

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CONTEXTE: L'unité de base de la prise en charge de la tuberculose (TB) à l'hôpital provincial de Kavieng, province de Nouvelle Irlande, Papouasie Nouvelle Guinée.
OBJECTIF: Evaluer l'articulation entre le diagnostic de laboratoire et la mise en route du traitement et décrire les caractéristiques et les résultats du traitement des patients TB.
SCHÉMA: Une étude rétrospective de cohorte de 1) patients TB à frottis de crachats positif enregistrés au laboratoire, et 2) patients TB enregistrés en traitement en 2015 et 2016.
RÉSULTATS: Sur les 221 patients enregistrés en traitement de TB, 173 (78%) ont eu un diagnostic clinique et la TB extra pulmonaire a été fréquente (36% des patients). Plus de 40% des patients ont eu un résultat défavorable du traitement, notamment un décès (10%) et une perte de vue (26%) ; ces résultats ont été significativement plus fréquents chez les patients atteints de TB pulmonaire à frottis négatif que chez ceux ayant un frottis positif (RR 1,69 [IC95% 1,02–2,80]). Seuls 4 (<2%) patients avaient eu un test VIH. Douze (21%) sur 58 patients TB à frottis de crachats positif n'ont pas été enregistrés comme étant traités pour TB.
CONCLUSION: Cette étude identifie les lacunes en matière de diagnostic et de traitement de la cascade de prise en charge de la TB dans l'unité de base de Kavieng. Le programme TB doit être renforcé pour affronter les problèmes de la proportion élevée de diagnostics purement cliniques de la TB, d'absence de test VIH et de taux élevé de perte de vue.

MARCO DE REFERENCIA: Una unidad básica de manejo de la tuberculosis (TB) en el Hospital Provincial de Kavieng de la provincia de Nueva Irlanda en Papúa Nueva Guinea
OBJETIVO: Evaluar el vínculo entre el diagnóstico de laboratorio y el inicio del tratamiento y describir las características y los desenlaces terapéuticos de los pacientes con TB.
METODO: Fue este un estudio retrospectivo de cohortes de pacientes con TB y baciloscopia positiva anotados en el registro de laboratorio y los pacientes con TB anotados en el registro de tratamiento en el 2015 y el 2016.
RESULTADOS: De los 221 pacientes registrados para tratamiento antituberculoso, 173 (78%) tenían un diagnóstico clínico y fue frecuente la tuberculosis extrapulmonar (36% de todos los pacientes). Más de 40% de los pacientes alcanzó desenlaces terapéuticos desfavorables, incluida la muerte (10%) y la pérdida durante el seguimiento (26%) y estos resultados fueron significativamente más frecuentes en los casos con baciloscopia negativa, que en los casos con baciloscopia positiva (riesgo relativo: 1,69; intervalo de confianza del 95%: de 1,02 a 2,80). Solo en cuatro pacientes (<2%) se había practicado la prueba diagnóstica de infección por el virus de la inmunodeficiencia humana (VIH). Doce de 58 pacientes (21%) con TB y baciloscopia positiva no estaban registrados en el programa de tratamiento.
CONCLUSION: En el presente estudio se reconocieron deficiencias en el diagnóstico y el tratamiento de la secuencia asistencial de la TB en la unidad básica de tratamiento de la TB de Kavieng. Es preciso fortalecer el programa contra la TB con el fin abordar la alta proporción de diagnósticos clínicos, la falta de pruebas del VIH y las tasas altas de pérdida durante el seguimiento.

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