

## A clinical prediction rule for pulmonary tuberculosis in emergency departments

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### SUMMARY

**SETTING:** University-affiliated hospital located in an area with a high incidence of pulmonary tuberculosis (PTB).

**OBJECTIVE:** To develop a clinical prediction rule (CPR) based on information obtainable on admission, to permit rapid identification of patients with PTB.

**DESIGN:** Information from patients with respiratory symptoms who attended the emergency department of Cayetano Heredia Hospital, Lima, Peru, was collected prospectively. Clinical symptoms, past medical history, demographic data and results of chest X-rays (CXRs), sputum smear and culture in Löwenstein-Jensen media were obtained. Based on logistic regression, we constructed a scoring system to predict PTB.

**RESULTS:** A total of 345 patients were enrolled in the study, including 109 (31%) culture-proven PTB cases. In

logistic regression analysis, we found age, previous history of PTB, weight loss, presence of cavities, upper lobe infiltrate and miliary pattern on CXR as independent predictors of PTB. We designed a scoring system with these variables, taking into account their statistical weight. The score attained 93% sensitivity and 42% specificity. **CONCLUSION:** The CPR that was developed performed well in our population. It merits further validation in other settings. It should not, however, replace, but should complement sputum microscopy when deciding on isolation, and it does not preclude microbiology in making a definitive diagnosis.

**KEY WORDS:** pulmonary tuberculosis; clinical prediction rule; isolation; score; emergency department

CLINICAL PREDICTION RULES (CPRs) are tools that help clinicians reach a diagnosis or predict the probability of a health event.<sup>1-3</sup> They quantify the joint predictive value of previously identified signs and symptoms that are normally easy to obtain from patient history, physical examination or simple diagnostic tests through algorithms or scoring systems. Their aim is to optimize the utilization of resources by identifying those patients who are at low or high risk of having a disease and by suggesting courses of action to achieve satisfactory levels of care.<sup>4,5</sup>

Pulmonary tuberculosis (PTB) is a disease frequently seen in medical wards and emergency rooms,<sup>6,7</sup> especially in developing countries.<sup>8</sup> Due to its infectiousness, the transmission of *Mycobacterium tuberculosis* from unidentified cases to other patients and health care workers, sometimes leading to nosocomial outbreaks, has become a major problem.<sup>9-11</sup> This can be potentiated by overcrowding and lack of ventilation in emergency rooms. The Centers for Disease Control

and Prevention (CDC, Atlanta, GA, USA) emphasizes the need for isolation of all patients suspected of PTB,<sup>12</sup> but the low specificity of this policy<sup>13</sup> (92 patients are unnecessarily isolated for every patient correctly isolated) considerably elevates its costs,<sup>14,15</sup> and makes this recommendation difficult to apply, particularly in resource-constrained settings. Given the highly infectious potential of air in emergency rooms,<sup>16</sup> the fact that a PTB patient can produce up to 44 quanta per hour (one quantum is defined as the infectious dose)<sup>17</sup> and that sputum smear can attain 70% sensitivity at best, diagnostic alternatives are urgently needed to base isolation decisions and simultaneously optimize resources.

A CPR could be a useful tool to this end. We therefore conducted a prospective study in the emergency department of a public hospital in Lima, Peru, to develop a CPR that could guide clinicians in their decision to isolate patients with pulmonary complaints suggestive of PTB.

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## METHODS

### Setting

The study was conducted at the Internal Medicine Emergency Department of Cayetano Heredia Hospital, a tertiary level, university-affiliated hospital located in the north of Lima. The incidence of PTB is 178 per 100 000 population, and human immunodeficiency virus (HIV) infection prevalence 1%. The Emergency Department has an average of 100 consultations per day.

The study protocol was revised and approved by the Ethics Committee of Cayetano Heredia Hospital.

### Patients

From 1 August 2002 to 31 August 2003, we included all patients aged >18 years with respiratory symptoms suggestive of PTB who attended the emergency department. Patients who attended outside normal duty hours (Sundays, public holidays or between 6 pm and 7 am) were not investigated in detail for logistic reasons. Respiratory symptoms suggestive of PTB were defined as productive cough for >7 days, cough of any duration accompanied by constitutional symptoms (fever for at least 3 days, night sweats or weight loss of at least 3 kg in the previous month), hemoptysis or a differential diagnosis of PTB from the attending physician. We excluded patients with a confirmed diagnosis of PTB and those who were too critically ill to produce a sputum sample.

### Data collection

After obtaining informed consent, we performed face-to-face interviews to obtain demographic data and clinical information on signs, symptoms and past medical history (HIV infection, alcoholism, drug use, previous episode of PTB and comorbidities related to PTB).<sup>18</sup> For each patient, at least two sputum samples were sent for acid-fast bacilli (AFB) smear and another for culture in Löwenstein-Jensen (LJ) media. Chest X-rays (CXRs) were also taken and read by the practitioner in charge of the study and by the resident in charge of the patient. Abnormalities were classified according to the location (upper, middle or lower lobe) and the type of lesion (cavities, alveolar, reticular, miliary). Other findings, such as pneumothorax or pleural effusion, were also reported as such. Additional pre-test counseling and informed consent were obtained from those who accepted an enzyme-linked immunosorbent assay (ELISA) HIV test (Biotest Anti HIV Tetra ELISA, BioTest AG, Dreieich, Germany). Positive results were confirmed by Western Blot. Patients with PTB confirmed by AFB smear or culture and patients with HIV infection were included in the National Tuberculosis and STD/AIDS (sexually transmitted diseases/acquired immune-deficiency syndrome) Control Programs, respectively, and treated according to national guidelines.

### Statistical analysis

To develop the CPR, PTB was defined as a positive culture for *M. tuberculosis*. We calculated odds ratios to quantify the association between categorical variables and the final diagnosis of PTB. For continuous variables, we used Spearman's correlation coefficient. Variables found to be significant in univariate analysis ( $P < 0.25$ ) and those considered clinically relevant (even if not significant) were included in a multivariate logistic regression model. In case of high correlation (>50%) between covariates, the variable with the lowest  $P$  value was included to avoid multicollinearity. The logistic regression model was reduced by backward stepwise elimination until all variables retained had  $P$  values  $\leq 0.05$ .

Based on the final model, we developed a scoring system by multiplying the  $\beta$  regression coefficient of each variable by 10 and rounding it up to the next integer. We calculated sensitivities and specificities, and constructed a receiver operating characteristic (ROC) curve to choose the best cut-off point for the score. All analyses were performed using SAS Software version 3.0 (Statistical Analysis Software Institute, Cary, NC, USA).

## RESULTS

During the study period, 3122 patients attended the emergency department at Cayetano Heredia Hospital. Of these, 487 fulfilled our criteria for respiratory symptoms suggestive of PTB. Of the 487, 133 attended the Emergency Department outside normal duty hours and were not investigated in detail. According to their medical records, there were no significant differences between these patients and those who were fully investigated in terms of age, sex, symptoms and prevalence of known HIV infection. Of the 354 patients who were fully investigated, eight were excluded from the analysis due to incomplete data: two because no CXRs were available, five due to contaminated sputum culture, and one because the culture result was unavailable. Another patient, who had an AFB-positive smear and negative culture, was also excluded from the analysis. Our final sample population was thus composed of 345 patients, 109 (31.59%) of whom had a positive culture for *M. tuberculosis*. Of these, 82 (78%) also had a positive AFB smear, 45 (13%) were HIV-positive and 113 (32.8%) had a history of previous PTB. In the bivariate analysis (Table 1), clinical and demographic variables positively associated with PTB were longer duration of cough, younger age, fever, weight loss, loss of appetite and lack of history of previous episode of PTB. Radiographic variables positively associated with PTB (Table 2) were: presence of cavities, upper lobe infiltrate, miliary pattern and alveolar infiltrate. A diffuse reticular pattern was negatively associated with PTB. When association between covariates was evaluated, a previous episode of TB was

**Table 1** Clinical symptoms and demographic characteristics in emergency department PTB suspects

Characteristic	Total (N = 345) n (%)	PTB patients (n = 109) n (%)	Non-PTB patients (n = 236) n (%)	OR (95%CI)	P value
Age, median	33	27	36	NA*	<0.001
Sex, males	222 (64.4)	74 (67.9)	148 (62.7)	1.26 (0.78–2.03)	0.351
<b>Symptoms</b>					
Cough, median number of days	21	26.5	21	NA†	<0.001
Fever	180 (52.2)	67 (61.5)	113 (47.9)	1.74 (1.09–2.76)	0.02
Night sweats	76 (22.0)	24 (22.0)	52 (22.0)	1.05 (0.56–1.99)	0.88
Hemoptysis	154 (44.6)	52 (47.7)	102 (43.2)	1.20 (0.76–1.89)	0.44
Productive cough	278 (80.6)	83 (76.1)	195 (82.6)	0.67 (0.39–1.08)	0.18
Hyporexia	121 (35.1)	44 (40.4)	77 (32.6)	2.04 (1.05–3.97)	0.04
Weight loss	229 (66.4)	88 (80.7)	141 (59.7)	2.82 (1.64–4.86)	<0.001
Dyspnea	187 (54.2)	51 (46.8)	136 (57.6)	0.65 (0.41–1.02)	0.06
Chest pain	144 (41.7)	45 (41.3)	99 (41.9)	0.97 (0.61–1.54)	0.91
History of past episode of PTB	113 (32.8)	26 (23.9)	87 (36.9)	0.54 (0.32–0.90)	0.017
History of close contact with a PTB patient	127 (36.8)	38 (34.9)	89 (37.7)	0.87 (0.54–1.40)	0.57
HIV infection	45 (13.0)	16 (14.7)	29 (12.3)	1.41 (0.72–2.77)	0.32
Alcohol consumption	68 (29.7)	21 (19.3)	47 (19.9)	0.96 (0.54–1.70)	0.87
Drug use	29 (8.4)	8 (7.3)	21 (8.9)	0.81 (0.35–1.89)	0.62
Comorbidities	17 (4.9)	5 (4.6)	12 (5.1)	0.90 (0.31–2.61)	0.84

\* Spearman's correlation coefficient: -0.23

† Spearman's correlation coefficient: 0.02

PTB = pulmonary tuberculosis; OR = odds ratio; CI = confidence interval; NA = not available.

**Table 2** Radiographic patterns in PTB suspects

Radiographic finding	Total (N = 345) n (%)	PTB patients (n = 109) n (%)	Non-PTB patients (n = 236) n (%)	P value
Diffuse reticular pattern	123 (35.7)	25 (22.9)	98 (41.5)	0.001
Lower lobe infiltrate	71 (20.6)	16 (14.7)	55 (23.3)	0.071
Cavity	96 (27.8)	42 (38.5)	54 (22.9)	0.003
Upper lobe infiltrate	103 (29.9)	59 (54.1)	44 (18.6)	<0.001
Miliary pattern	20 (5.8)	13 (11.9)	7 (3.0)	0.001
Pneumothorax	11 (3.2)	3 (2.75)	8 (3.39)	0.754
Pleural effusion	19 (5.5)	4 (3.7)	15 (6.4)	0.309
Alveolar infiltrate	161 (4.7)	61 (56)	100 (42.4)	0.019
Athelectasis	11 (3.2)	1 (0.92)	10 (4.2)	0.103

PTB = pulmonary tuberculosis.

strongly associated with hemoptysis and with presence of cavities in the CXR ( $P < 0.001$ ). These results show that symptoms alone are not accurately predictive of PTB, and that radiographic findings are more useful.

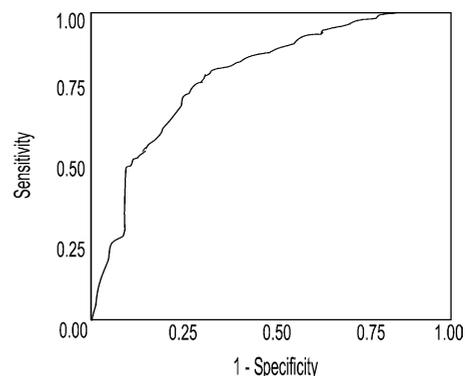
*Model development*

All the predictors were evaluated in a logistic regression model. Due to their clinical importance, HIV status and hemoptysis were also considered in the analysis, even when they were not found to be significant in the bivariate analysis. Six variables were retained in the final model (Table 3). With these predictors, the scoring system was constructed using the weights given in Table 3. The score ranged between -5 up to 29 points and radiographic variables were the most important contributors. The area under the ROC curve was 0.809 (95% confidence interval [CI] 0.762–0.856), as shown in the Figure. When a positive score was defined as a total of 3 or more points, the performance of the score was as follows: sensitivity 93%,

**Table 3** Independent predictors for PTB in PTB suspects and weights used in the scoring system

Variable	OR (95%CI)	Score points
Age, years	0.97 (0.96–0.99)	
<35		0
35–60		-1
≥61		-2
Weight loss	2.79 (1.51–5.18)	5
History of PTB	0.51 (0.28–0.95)	-3
Miliary pattern	8.04 (2.79–23.16)	10
Cavities	2.54 (1.40–4.62)	5
Upper lobe infiltrate	5.64 (3.20–9.93)	9

PTB = pulmonary tuberculosis; OR = odds ratio; CI = confidence interval.



**Figure** ROC curve of the scoring system for identifying PTB patients in emergency departments. ROC = receiver operating characteristic; PTB = pulmonary tuberculosis.

specificity 42%, positive predictive value (PPV) 43% and negative predictive value (NPV) 93%. Hence, if all patients from our derivation cohort with ≥3 points had been isolated, eight (7%) of the 109 PTB patients

**Table 4** Independent predictors for PTB among different subpopulations of PTB suspects

Variable	Patients without a previous history of PTB (n = 232) OR (95%CI)	Patients with a previous history of PTB (n = 113) OR (95%CI)	HIV-negative patients (n = 300) OR (95%CI)
Age, years	0.97 (0.95–0.99)	Not included	0.97 (0.96–0.99)
Weight loss	3.25 (1.50–7.03)	Not included	2.67 (1.38–5.18)
History of PTB	NA	NA	0.52 (0.28–1.01)
Miliary pattern	9.49 (2.92–30.86)	8.34 (0.67–104.54)	14.83 (3.39–64.92)
Cavities	3.19 (1.48–6.91)	2.13 (0.83–5.44)	2.99 (1.56–5.73)
Upper lobe infiltrate	7.18 (3.55–14.55)	3.61 (1.40–9.32)	6.36 (3.44–11.76)

PTB = pulmonary tuberculosis; OR = odds ratio; CI = confidence interval; HIV = human immunodeficiency virus; NA = not available.

would have been missed, while 101 (43%) of 238 isolated patients would have been confirmed afterwards as PTB. With a cut-off point of  $\geq 2$ , the sensitivity of the score increased to 95.4%, but the specificity dropped to 36%, and the PPV and NPV became respectively 41% and 94.4%. Although the score can miss some patients with PTB, including AFB smear as a predictive variable would increase the sensitivity to 98%, with a specificity of 42%.

We evaluated the performance of our score in various subpopulations: HIV-positive and -negative patients and patients with and without a previous episode of PTB. We constructed logistic regressions models for each subpopulation (Table 4). Most of the independent predictors were the same as in the general model, but cavities and upper lobe infiltrate associations were weaker in patients with a previous episode of PTB. We were not able to perform this analysis among HIV patients due to the small sample size (45 patients).

## DISCUSSION

We developed a CPR for PTB in patients with respiratory symptoms that could help clinicians decide when to isolate patients with suspicion of PTB attending an emergency department. It attains a sensitivity of 93% and specificity of 42%, which leads in our population to high predictive values. However, despite our low rate of false negatives (7%), some cases were missed, which could have implications for other patients and health care personnel, as well-documented outbreaks of nosocomial TB have originated from a single index case.<sup>9</sup>

Including the AFB smear results as a predictive variable would improve the performance of our score (sensitivity 98% without affecting specificity). AFB smear is cheap, rapid and highly feasible even in resource-constrained settings; however, when used alone for deciding isolation, its sensitivity (78% in this study) is insufficient, as recent evidence suggests efficient TB transmission from smear-negative patients.<sup>16</sup> In addition, AFB smear testing is not widely available in all emergency rooms;<sup>19</sup> this is the case in our hospital and many health care facilities in developing countries. We therefore did not use it in the score, as our primary aim was to create a CPR based on predictors that were easily obtained on admission. Nevertheless, in set-

tings where it can be readily performed, AFB smear microscopy gives valuable information and should always be performed to help to make a decision. We therefore consider the two tools to be complementary rather than mutually exclusive. Cost-effectiveness analysis should be performed to determine if improving the availability of AFB smear in emergency departments would be worthwhile in diminishing nosocomial transmission of PTB.

Several CPRs to avoid nosocomial transmission of TB have been proposed,<sup>20–26</sup> but hardly any of these have been externally validated. Furthermore, most of them have been developed in areas with high resources and low or moderate TB prevalence. We therefore decided to do a CPR in our own setting, which is the epidemiological opposite. The high prevalence of PTB (31%) among PTB suspects found in our study was also noted by other investigators in Lima.<sup>27</sup> The well-recognized changes in the clinical and radiographic manifestations of PTB associated with HIV infection<sup>28</sup> could have altered the performance of our score, but 14 of 15 patients with HIV infection and PTB in our cohort had a positive score (sensitivity 93%), suggesting a good performance in this subgroup of patients. Nevertheless, as the sample size for HIV was small, our conclusions cannot be extended to this subgroup, and the performance of this CPR will probably be affected. Overall, the CPR presented performs comparably or better than CPRs in other studies<sup>20–26</sup> that report sensitivities of between 77% and 100% and specificities of between 14% and 94%.

According to our results, weight loss and radiographic findings are independent predictors of PTB; these variables were also identified by other investigators,<sup>20,25,26</sup> but lower risk at older ages and with a previous episode of PTB seem to be specific to our population. Although changes in the immune system during aging lead to increased susceptibility to mycobacterial infections and reactivation of latent foci, TB is still associated with younger ages in developing countries, independently of HIV status.<sup>29</sup> This may be explained by the higher proportion of young people, a higher annual risk of infection and shorter life expectancies in comparison to industrialized countries. The negative association with a previous episode of PTB could be explained by the pulmonary complications in this

group of patients that can mimic PTB;<sup>30</sup> for example, residual cavities in the lung may produce hemoptysis when there is infection due to common bacteria or fungi. Our analysis of covariates shows that patients with previous episodes of PTB are more likely to present hemoptysis and cavities on the CXR even in the absence of PTB. As a consequence, our score did not perform as well in this subgroup of patients as in the whole sample population.

All CPRs referred to use findings from history, physical examination or test results, quantify their relative importance and predict an outcome, such as the need to isolate PTB suspects. In general scores are used, but alternatives include decision trees,<sup>22</sup> neural network<sup>21</sup> or list of variables.<sup>20</sup> CPRs should ideally be derived in settings with high nosocomial risk for PTB to optimize isolation, but this is costly. Another alternative is validation and impact analysis of existing CPRs in different settings.

Although our score has high internal validity and may attain a similar level of performance in settings that share these epidemiological characteristics, further studies are needed to verify this assumption and assess its external validity, its acceptance and implementation by clinicians and its eventual impact on the decision to isolate PTB patients.

This study has the following limitations: for logistic reasons, patients who attended the emergency department at night, on Sundays or on public holidays were not investigated in detail and were not included in the analysis. Potentially, this may have induced a selection bias, but given the similarity in terms of demographic characteristics, symptoms and known HIV status between those who were fully enrolled and those who were not, such a bias, if any, should be small. Although culture on LJ media was used as the standard of reference to define PTB, it should also be kept in mind that culture-negative PTB cases can occur.<sup>31,32</sup> Current evidence indicates increased sensitivity of new liquid phase media and BACTEC (BD Diagnostic Systems, Sparks, MD, USA);<sup>33–35</sup> nevertheless, culture in LJ media remains the most widely used method for diagnosing PTB in resource-constrained settings.

In conclusion, the clinical prediction rule that we developed, designed as a scoring system, composed of age, weight loss, history of PTB, miliary pattern, cavities and upper lobe infiltrate, performed well in our population and may be used to complement smear microscopy to define respiratory isolation. Given its simplicity and efficacy we plan to train our emergency physicians to implement it in routine practice. Future studies should assess its performance in different settings and evaluate its impact and cost-effectiveness when used to prevent TB transmission among inpatients and health personnel.

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## R É S U M É

**CONTEXTE :** Un hôpital affilié à l'Université situé dans une zone à forte incidence de tuberculose pulmonaire (TBP).

**OBJECTIF :** Développer une règle de prediction clinique (CPR) basée sur les informations recueillies à l'admission afin de permettre une identification rapide des patients atteints de TBP.

**SCHÉMA :** Nous avons colligé de façon prospective les informations chez les patients ayant des symptômes respiratoires et qui fréquentaient le département d'urgence de l'hôpital Cayetano Heredia à Lima, Pérou. On a recueilli les symptômes cliniques, les antécédents médicaux, les données démographiques et les résultats des clichés thoraciques (CXR), des frottis de crachats et des cultures sur milieu de Löwenstein-Jensen. On a construit un système de scores prédictifs de la TBP en se basant sur la régression logistique.

**RÉSULTATS :** On a pu inclure 345 patients, dont 109 (31%) étaient atteints d'une TBP démontrée par la culture. L'analyse de régression logistique a montré comme facteurs prédictifs indépendants de la TBP : l'âge, les antécédents de TBP, la chute du poids, la présence de cavités, l'infiltrat des lobes supérieurs et une miliaire au CXR. Nous avons élaboré un système de scores basé sur ces variables et prenant en compte leur poids statistique relatif. Le score a une sensibilité de 93% et une spécificité de 42%.

**CONCLUSION :** La CPR que nous avons élaborée a une bonne performance dans notre population. Elle mérite d'être validée dans d'autres contextes. Toutefois, elle ne peut pas remplacer mais doit compléter l'examen microscopique des crachats lors de la décision d'isolement et n'enlève pas à l'examen microbiologique son rôle pour le diagnostic définitif.

## R E S U M E N

**UBICACION :** Hospital Universitario ubicado en un área de alta incidencia de tuberculosis pulmonar (TBP).

**OBJETIVO :** Desarrollar una regla de predicción clínica (CPR), usando información obtenida en la admisión, para permitir una rápida identificación de pacientes con TBP.

**DISEÑO :** Se obtuvo información prospectivamente de pacientes con síntomas respiratorios que acudieron al departamento de emergencia del Hospital Cayetano Heredia en Lima, Perú. Síntomas, historia médica, información demográfica y resultados de radiografía de tórax (CXR), examen de esputo y cultivo en medio Löwenstein-Jensen fueron obtenidos. Usando análisis de regresión logística se construyó un score predictivo para TBP.

**RESULTADOS :** Hemos incluido 345 pacientes, de los cuales 109 (31%) tuvieron TBP cultivo positivo. Usando regresión logística se encontró que : edad, historia previa de TB, pérdida de peso, presencia de cavernas, infiltrado apical y patrón miliar en la CXR fueron predictores independientes de TBP. Con estas variables se construyó un score predictivo. El score alcanza una sensibilidad de 93% y especificidad de 42%.

**CONCLUSIÓN :** La CPR tuvo una buena performance en nuestra población y amerita ser validada en otras poblaciones. Sin embargo no debe reemplazar sino complementar al examen de esputo para definir aislamiento respiratorio y no reemplaza al examen microbiológico para obtener un diagnóstico definitivo.