



## Targeted active screening for tuberculosis in Zimbabwe: are field digital chest X-ray ratings reliable?

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**Setting:** Fifteen purposively selected districts in Zimbabwe in which targeted active screening for tuberculosis (Tas4TB) was conducted among TB high-risk groups (HRGs). There were 230 patients started on TB treatment on the basis of chest X-ray (CXR) results without corresponding bacteriological confirmation.

**Objectives:** To determine 1) the percentage of agreements in digital CXR ratings by medical officers against final ratings by radiologist(s), 2) inter-rater agreement in CXR ratings between medical officers and radiologists, and 3) number (and proportion) of patients belonging to HRGs who were over-treated during Tas4TB.

**Design:** This was a cross-sectional study using programme data.

**Results:** A total of 168 patients had their CXRs rated by two independent radiologists. Discordances among the radiologists were resolved by a third index radiologist, who provided the final rating.  $\kappa$  scores were 0.01 (field ratings vs. Radiologist A); 0.02 (field ratings vs. Radiologist B); 0.74 (Radiologists A vs. B). The percentage agreement for field and final radiologist rating was 70% (95%CI 64–78). Around 29% (95%CI 23–36) of the patients were potentially over-treated during Tas4TB.

**Conclusion:** Over a quarter of patients with presumptive TB are potentially over-treated during Tas4TB. Over-treatment is highest among those with previous contact with TB patients. Trainings of radiographers and medical officers may improve CXR ratings.

In 2016, the tuberculosis (TB) treatment coverage in Zimbabwe was 81%, suggesting that around a fifth of TB patients were not diagnosed and could be *foci* for community TB transmission.<sup>1</sup> These could be within high-risk groups (HRGs), who are less likely to utilise healthcare services. The inverse care law states that people who need medical services the most are least likely to utilise them.<sup>2</sup> Zimbabwe is a country in southern African and is among the 14 countries with a triple burden of TB, TB-HIV and multidrug-resistant TB (MDR-TB; defined as resistance to at least isoniazid and rifampicin, the two most potent first-line anti-TB drugs).<sup>3,4</sup> The 2014 Zimbabwe TB prevalence survey showed that around 67 (63%) individuals with no TB symptoms but with CXR suggestive of TB, had bacteriologically confirmed pulmonary TB.<sup>5</sup> The survey also recorded a similar crude prevalence of TB in rural and urban areas. However, under programme conditions, urban areas record higher prevalences of TB than rural areas. Like active case finding (ACF) strategies, the sur-

vey ensured equity of access by bringing healthcare services to the communities, especially the marginalised. Targeted active screening for TB (Tas4TB) is one example of an ACF strategy.

Following recommendations from the prevalence survey, and as part of the global effort to end TB, the first pillar of the End TB Strategy, which emphasises the need for early diagnosis of TB, the Zimbabwe National TB Control Programme (NTP) and partner institutions embarked on Tas4TB, targeting HRGs for TB to improve both yield and impact.<sup>6</sup> The groups comprise people living with human immunodeficiency virus (PLHIV), refugees, contacts of TB patients, miners and prison inmates.

Tas4TB is used to screen people in communities and has the potential to detect asymptomatic TB patients, especially in contexts characterised by delayed health-seeking behaviour. People delay seeking healthcare when they are asymptomatic, and do not recognise TB symptoms, or when barriers to accessing healthcare exist.<sup>7,8</sup> Such barriers may include cost of healthcare services and distance to health centres. Unlike patient-initiated passive case finding, Tas4TB systematically identifies people who are presumed to have active TB (usually outside health facilities) using reliable and rapid screening and diagnostic tests. The objective is to detect active TB early and to ensure early treatment. This reduces mortality, comorbidities, transmission of TB and the socio-economic burden due to TB.

The yield from ACF is a function of the reliability (sensitivity and specificity) of screening and diagnostic tests. Since a high yield of true-positives is required, the screening algorithm should have a high sensitivity.<sup>9</sup> According to the Zimbabwean programme, the Tas4TB algorithm comprises symptom inquiry and digital chest X-ray (CXR) as screening tools, and Xpert<sup>®</sup> MTB/RIF testing (Cepheid, Sunnyvale, CA, USA) as the diagnostic tool for bacteriological confirmation.

Tas4TB programme data for 2017 shows that a high proportion of patients is initiated into treatment on the basis of field CXR ratings and/or symptom screening. Of the 35 610 people who were screened, 11 213 (31%) had presumptive TB, and 705 (2%) were clinically diagnosed with TB (all forms) and initiated on treatment. Only 89/705 (13%) were bacteriologically confirmed. All the digital CXR images are retained by the Tas4TB programme. In 2017, there were 230 images for presumptive TB patients who were initiated on treatment but had sputum-negative results on

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Xpert or on Xpert plus smear microscopy. In the absence of bacteriological confirmation with smear microscopy or Xpert, clinical evaluation plus CXR has a sensitivity of just 24% (95% confidence interval [CI] 10–51).<sup>8</sup> It is feared that some patients are being overtreated during Tas4TB programmes since most patients do not get bacteriological confirmation. Over-treatment occurs when people without active TB are misdiagnosed with active TB, and are initiated on TB treatment.

It is imperative to note that the benefits/risk of TB overtreatment vary for different HRGs, depending on the incremental value of early treatment vs. the adverse consequences of overtreatment.<sup>9</sup> The risk of false-positives may be acceptable among PLHIV, where the potential to benefit from early treatment is high; however, which HRGs are receiving overtreatment remains unknown.

Proper identification of HRGs during Tas4TB is key, as this reduces false-positive results. Since identification of HRGs may be easy, a reliable ACF algorithm is crucial. The study algorithm comprised digital CXR and Xpert testing. While Xpert is automated and is subject to minimal human error, CXR ratings may be affected by high subjectivity. Variability in CXR scores have been reported to be common when CXRs are read by medical officers. However, where ratings were done by radiologists, studies have reported higher sensitivities and specificities than both medical officers and computer-aided diagnosis for TB (CAD4TB) (Delft Imaging Systems, Neenendaal, The Netherlands).<sup>10–12</sup> The reliability of field CXR scores is not known in Zimbabwe, as medical officers do not routinely undergo assessments for CXR competence. Accurate CXR interpretation is crucial as it acts as a ‘gatekeeper’, filtering patients who then proceed to Xpert testing or TB treatment.

We wanted to assess the reliability of field digital CXR ratings; specifically, we sought to determine 1) the percentage of agreements between digital CXR images scored by field officers and final ratings by radiologist(s), 2) the inter-rater agreement in CXR scores between field officers and radiologists, and 3) the number (and proportion) of HRGs that were overtreated among those screened under the Zimbabwe Tas4TB programme in 2017.

## METHODS

### Study design

This was a cross-sectional study.

### Specific setting

In 2017, Zimbabwe embarked on a Tas4TB programme in 15 districts with the aim of finding missing TB cases. The districts were purposively selected based on high TB notifications. The Tas4TB programme has mobile trucks equipped with digital CXRs and these travel around the districts with a team of nurses, radiographers, medical laboratory scientists and medical officers. Prior to TB screening, a health promotion team mobilises communities, identifies TB ‘hot-spots’ and schedules screening dates. The team sets up field clin-

ics where people from the community can get screened. Screening is provided free of charge and involves patient registration, symptom screening, HIV testing and counselling, CXR and sputum collection for those believed to have presumptive TB.<sup>13</sup> Presumptive TB patients are those who present with symptoms or signs that are suggestive of TB.<sup>14</sup> The Tas4TB team reaches even the most marginalised communities, thereby ensuring equity of access to early diagnosis and treatment.

The Zimbabwean Tas4TB algorithm uses symptom inquiry about cough of any duration, fever, night sweats, haemoptysis and weight loss, together with a digital CXR, as screening tools. Patients with positive symptoms, abnormal CXRs or both are presumed to have TB: they are asked to produce sputum specimens, which the Tas4TB team delivers to the nearest district laboratory for Xpert testing, or for smear microscopy where Xpert is not available. Patients with bacteriologically confirmed TB, and some with clinically diagnosed TB, are linked with their nearest health facilities so they can access free treatment and care according to national guidelines. A web application is used for real-time data entry and updates a central electronic database where patient-level data at each stage of the screening cascade are stored.

### Study population

All records of patients screened for pulmonary TB and initiated on treatment during Tas4TB in 2017 on the basis of CXR suggestive of TB but no bacteriological confirmation were included in the study.

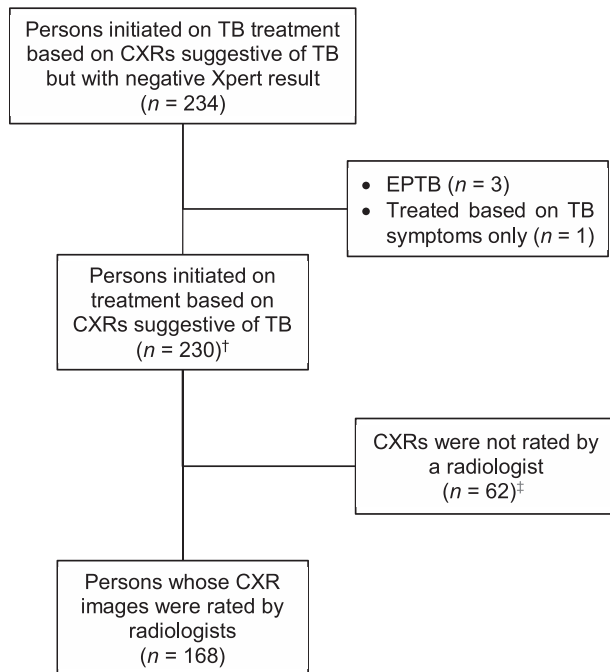
### Study procedure

All the 230 identification numbers (IDs) for patients who were initiated on treatment on the basis of CXR only or CXR plus symptoms were selected from the MS Excel database (Microsoft, Redmond, WA, USA). These patients had negative results on Xpert or on both Xpert and smear microscopy. Due to cost constraints, we consecutively sampled 168 images and stopped recruitment once the figure was reached. Four columns were added to the MS Excel file in order to capture ratings by Radiologist A, Radiologist B, Radiologist C and the final radiologist ratings. The digital CXR images together with a blank copy of the study proforma (with a filled out column for patient IDs, age and HIV status) were sent to Radiologists A and B for their scores. Both radiologists were blinded to the other’s scores, the study objectives, the Xpert results and the field CXR scores. Where the two radiologists were in agreement, the column for the final rating on the proforma was filled out appropriately. As part of quality control, we included five CXR images for patients who had bacteriological confirmation on Xpert. However, these images were not included in the analyses.

In case of discordant ratings between the first and second radiologist, the digital CXR images were sent to Radiologist C, an expert with vast experience, to provide the final interpretation of the CXR. Radiologist C interpreted the CXRs independently and was blinded to the interpretations of all other observers. If the final

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**FIGURE** Flow chart for people who were screened for active TB and had their CXR rated by radiologists during the targeted screening for TB, Zimbabwe, 2017. †All the 230 had CXR suggestive of TB but no bacteriological confirmation on either Xpert or Xpert + smear microscopy. ‡CXR were not rated because of financial constraints (radiologist's fees = US\$5/image). TB = tuberculosis; CXR = chest X-ray; EPTB = extra-pulmonary TB; US\$ = US dollar.

rating was not suggestive of TB, while the field rating was suggestive of TB, over-treatment was recorded.

### Selection of radiologists to provide CXR ratings

Radiologists were selected purposively on the basis of their experience in TB diagnosis using CXRs, especially digital CXRs. Previous experience in national surveys involving the scoring of digital CXRs was an added advantage.

### Data variables, sources of data and data collection

Data variables included patient ID, age, sex, HRG category (miner, prisoner), type of TB, field CXR rating (suggestive/not suggestive of TB), radiologist rating (suggestive/not suggestive of TB), and final radiologist rating. Sociodemographic data were obtained from the Excel database. Data on CXR ratings were obtained using a rating proforma.

### Analysis and statistics

Data on radiologist ratings were double-entered in two Microsoft Excel sheets (Microsoft). The formula = IF(EXACT(SHEET1!A2,SHEET2!A2),0,SHEET1!A2&"/"&SHEET2!A2) was used to compare the Excel sheets. The final database contents (sociodemographic and clinical data and CXR ratings) were imported to EpiData v2.2.2.186 (EpiData Association, Odense, Denmark) for analysis. Numbers (and proportions) were reported for patients who were over-treated.

Two-by-two tables in OpenEpi software (Dean AG, Sullivan KM, Soe MM. OpenEpi: Open Source Epidemiologic Statistics for Public Health; <http://www.openepi.com>) were used to compare frequencies of CXR ratings by field medical officers and the radiologists. Percentage agreements and their 95% confidence in-

**TABLE 1** Demographic and clinical characteristics of people who were screened for active TB during the targeted screening for TB and whose CXRs were rated by a radiologist, Zimbabwe, 2017

Characteristic	n	%
Total	168	100
Sex		
Male	102	61
Female	66	39
Age category, years		
<15	10	6
15–24	9	5
25–34	24	14
35–44	54	32
45–54	27	16
55–64	20	12
≥65	24	14
HIV status		
Positive	89	53
Negative	75	45
Not recorded	4	2
Type of TB		
Pulmonary clinically confirmed	127	76
Not recorded	41	24
Basis of TB treatment		
CXR and other symptoms	158	94
CXR only	10	6
Risk group*		
PLHIV	89	53
TB contacts and HCWs	20	12
Miners and refugees	34	20
Prison inmates	24	14
Not recorded	1	1

\*Risk groups are not mutually exclusive.

TB = tuberculosis; CXR = chest X-ray; HIV = human immunodeficiency virus; PLHIV = people living with HIV; HCW = health care worker.

tervals were calculated using sum concordances of 'suggestive of TB' and 'not suggestive of TB' as a fraction of total cell frequencies. κ scores were used to measure inter-rater agreement in digital CXR interpretation between field officers and each radiologist, and the final radiologist ratings. Levels of significance were set at 5%.

### Ethics

Ethics approval was obtained from the Ethics Advisory Group, International Union Against Tuberculosis and Lung Disease (The Union) (EAG-16/18) and the Medical Research Council of Zimbabwe (Harare, Zimbabwe; MRCZ/E/200). As the study involved reviews of existing patient records, the requirement for informed consent was waived.

## RESULTS

Of 234 participants eligible for the study, four were excluded because they had either extra-pulmonary TB or were initiated on TB treatment on the basis of symptoms alone (Figure). Sixty-two did not receive radiologist ratings as the CXRs were unavailable, resulting in a final sample size of 168 (sociodemographic and clinical characteristics shown in Table 1). The majority ( $n = 102$ ; 61%) of the patients were males. The mean age was 44.0 years (standard deviation 17.5). Just over half of the participants were HIV-posi-

**TABLE 2**  $\kappa$  agreement scores in the CXR ratings for high-risk groups that were screened during Tas4TB, Zimbabwe, 2017

	Medical Officers	Radiologist A	Radiologist B	Final rating
Medical Officers	—	0.01 (−0.03 to 0.10)	0.02 (−0.04 to 0.10)	0.02 (−0.03 to 0.10)
Radiologist A		—	0.74 (0.59 to 0.90)	0.87 (0.72 to 1.00)
Radiologist B			—	0.88 (0.73 to 1.00)

CXR = chest X-ray; Tas4TB = targeted active screening for tuberculosis.

tive. Most (94%) were initiated on treatment on the basis of CXRs suggestive of TB in combination with other TB symptoms, while the remainder were initiated on treatment on the basis of only CXRs suggestive of TB.

Inter-rater agreement between field ratings (by medical officers) and the radiologists are shown in Table 2.  $\kappa$  scores were 0.01 (medical officers vs. Radiologist A); 0.02 (medical officers vs. Radiologist B) and 0.02 (medical officers vs. final radiologist rating).  $\kappa$  scores between Radiologist A and B were 0.74 (95%CI 0.59–0.90). There were 17 discordant ratings between Radiologists A and B, which were resolved by Radiologist C.

The percentage agreements between field ratings; Radiologist A and Radiologist B ratings vs. the final ratings were respectively 70% (95%CI 64–78), 95% (95%CI 90–97) and 95% (95%CI 91–98) (Table 3). Overall, 49 (29%) patients were possibly over-treated during Tas4TB. The highest proportion was among TB contacts and health care workers (35%), followed by PLHIV (33%) and prison inmates (29%) (Table 4).

## DISCUSSION

We found out that a high proportion of patients who were screened for TB using digital CXR during Tas4TB may have been over-treated for TB. Our earlier assumption of possible overtreatment is thus justified. This assumption was based on the low proportion (13%) of bacteriologically confirmed pulmonary TB observed during Tas4TB compared with 58% of bacteriologically confirmed pulmonary TB recorded in routine programme settings.<sup>3</sup>

Second, agreement between field ratings and either of the radiologists was poor. This finding is not surprising. Studies have reported low  $\kappa$  scores in this group, especially in CXRs ratings among HIV patients, since HIV co-infection affects radiological presentation of TB.<sup>15</sup> By contrast, there was a moderate agreement in ratings between Radiologist A and Radiologist B, a finding that is consistent with most studies that suggest radiologist

**TABLE 3** Percentage agreement between Medical Officers and Radiologists ratings vs. final Radiologist CXR ratings in high-risk groups screened for TB during Tas4TB, Zimbabwe, 2017

	Total number of CXRs	Number in agreement <sup>†</sup>	Agreement* %	95% CI
Medical Officers	166	117	70	64–78
Radiologist A	166	157	95	90–97
Radiologist B	166	158	95	91–98

\*Diagnostic accuracy (sum of concordances for 'suggestive of TB' and 'not suggestive of TB' divided by the total number of CXR images that were rated).

<sup>†</sup>At least 11 (22%) of the 49 patients who were potentially over-treated were due to misclassification of any other abnormalities (fat deposits, cancers and pneumococcal infection) as CXRs that were suggestive of TB by Medical Officers.

CXR = chest X-ray; TB = tuberculosis; Tas4TB = targeted active screening for TB; CI = confidence interval.

ratings to be more reliable than those by medical officers and CAD4TB (Table 5).<sup>11,12</sup>

The strengths of this study lie in the fact that we purposively selected expert radiologists, based on their experience in rating CXRs; also, study radiologists were blinded to the scores of the other radiologists and independent ratings to ensure credibility and accuracy of results. We facilitated their ratings by providing information on HIV status on the rating proforma. Data transcription errors were greatly reduced in two ways: sociodemographic data were extracted from an electronic database (with check functions) and data double-entered to capture CXR ratings. Finally, as digital CXRs images were used, the images were of high quality and may have reduced inconsistencies in reporting due to poor quality images.<sup>16,17</sup>

Our main limitation was a lack of culture results, the gold standard for TB diagnosis. We were therefore not able to calculate sensitivity, specificity and predictive values of the field ratings. We relied on percentage of agreement, which is likely to lead to an overestimation of sensitivity. We also did not assess under-treatment, which would require CXRs of patients who were not treated to be independently examined by radiologists to see if active TB cases were missed during Tas4TB. Although we did not have a gold standard, we argue that radiologist ratings still provide useful insight into the field CXR ratings during Tas4TB. Studies have observed better correlation between culture and radiologist findings.<sup>10,11</sup> Thus, even without culture results, our findings raise several programmatic implications. First, almost a quarter of patients may be over-treated during Tas4TB. Overtreatment may have clinical, social and economic implications. First, patients may needlessly suffer from adverse drug events and stigma related to TB treatment. Second, TB treatment has lifelong implications since many countries require information on history of TB during visa applications, thereby impacting global travel and access to overseas opportunities. Third, overtreatment results in wastage of anti-TB medicines and has unnecessary non-medical costs, including transport costs to clinics.<sup>18,19</sup>

**TABLE 4** High-risk groups that were over-treated for TB during targeted screening for TB, Zimbabwe, 2017

High-risk group category*	Total treated for TB		Number possibly over-treated <sup>†</sup>	
	<i>n</i>	%	<i>n</i>	%
PLHIV	89	33	29	33
TB contacts and HCWs	20	35	7	35
Miners and refugees	34	18	6	18
Prison inmates	24	29	7	29
Total	167	29	49	29

\*Risk groups are not mutually exclusive and collectively exhaustive.

<sup>†</sup>At least 11 (22%) of the 49 patients who were potentially over-treated were due to misclassification of any other abnormalities (fat deposits, cancers and pneumococcal infection) as CXRs that were suggestive of TB by Medical Officers.

TB = tuberculosis; PLHIV = people living with human immunodeficiency virus; HCW = health care worker; CXR = chest X-ray

**TABLE 5** Consolidated ratings from three radiologists

Patient ID	Rating by:*				Final radiologist rating
	Medical Officer	Radiologist A	Radiologist B	Radiologist C	
1	1	1	1	—	1
2	1	0	1	0	0
3	1	1	0	1	1
4	1	0	0	—	0

\*1 = suggestive of TB; 0 = not suggestive of TB.  
HIV = human immunodeficiency virus; TB = tuberculosis.

Fourth, overtreatment may result in potential over-reporting of TB notifications submitted to NTPs and the WHO Global TB Department. Patients with abnormal CXRs and negative bacteriological confirmation need to be followed up.<sup>17</sup> However, overtreatment, especially among PLHIV, may be protective against tuberculous infection.<sup>20</sup>

Given the implications of overtreatment as evidenced in this study, NTPs need to prioritise the training of medical officers and radiographers in CXR interpretation to ensure double-reading at the time of examination. Studies have reported consistent and improved rating performance among trained medical officers and when TB reference images are used.<sup>16,21</sup> Electronic transmission of CXR images to expert radiologists needs to be explored as it ensures more accurate TB diagnosis, quality assurance of field CXR ratings, and savings on Xpert cartridges.

## CONCLUSION

At least one in four patients with presumptive TB are potentially over-treated during Tas4TB. Overtreatment is high among those with previous contact with TB patients. Training courses for medical officers and radiographers providing field assessment of CXRs in cases of suspected TB is crucial to improve performance.

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**Contexte :** Quinze districts sélectionnés de ce but au Zimbabwe dans lesquels un dépistage ciblé de la tuberculose (Tas4TB) a été réalisé parmi des groupes à risque élevé de TB (HRG). Sur la base des résultats d'une radiographie pulmonaire (CXR) 230 patients ont débuté un traitement de la TB sans confirmation bactériologique correspondante.

**Objectifs :** Déterminer 1) le pourcentage d'accords des scores des CXR numérisées lues par les responsables médicaux vis-à-vis des notes finales des radiologues, 2) l'accord inter évaluateurs de la CXR entre responsables médicaux et radiologues, et 3) nombre (et proportion) des HRG qui ont été sur traités pendant le Tas4TB.

**Schéma :** Ceci est une étude transversale basée sur les données du programme.

**Résultats :** Les CXR des 168 patients ont été notées par deux

radiologues indépendants. Les discordances entre les radiologues ont été résolues par un troisième radiologue index qui a constitué la note finale. Les scores  $\kappa$  ont été de 0,01 (notes sur le terrain contre radiologue A) ; de 0,02 (notes sur le terrain contre radiologue B) ; de 0,74 (radiologue A contre radiologue B). Le pourcentage d'accord des notes du terrain et du radiologue final a été de 70% (IC95% 64–78). Autour de 29% (IC95% 23–36) des patients ont été potentiellement sur traités pendant le Tas4TB.

**Conclusion :** Plus d'un quart des patients présumés atteints de TB sont potentiellement sur traités pendant le Tas4TB. Le sur traitement est le plus élevé parmi les patients qui ont eu un contact préalable avec des patients TB. La formation des radiologues et des responsables médicaux pourrait améliorer l'interprétation des CXR.

**Marco de referencia:** Quince distritos de Zimbabwe escogidos por muestreo intencional en los cuales se practicó una detección activa de la tuberculosis (Tas4TB) dirigida a los grupos de alto riesgo (HRG) de contraer la enfermedad y se inició el tratamiento antituberculoso en 230 pacientes a partir de las imágenes de la radiografía de tórax (CXR), sin la confirmación bacteriológica correspondiente.

**Objetivos:** Determinar 1) el porcentaje de concordancia entre la calificación de la CXR digital realizada por médicos en el terreno y la evaluación final por uno o varios radiólogos; 2) la concordancia entre observadores de la calificación de la CXR de los médicos y los radiólogos; 3) el número (y la proporción) de HRG tratados en exceso durante la Tas4TB.

**Método:** Fue este un estudio transversal a partir de los datos del programa.

**Resultados:** Hubo 168 pacientes cuyas CXR fueron calificadas por

dos radiólogos independientes. Un tercer radiólogo de referencia resolvió las discordancias entre los radiólogos y emitió la calificación final. Los índices  $\kappa$  de las calificaciones fueron como sigue: 0,01 entre la evaluación en el terreno y el radiólogo A; 0,02 entre la evaluación en el terreno y el radiólogo B; y 0,74 entre el radiólogo A y el radiólogo B. El porcentaje de concordancia entre la evaluación del terreno y la calificación final del radiólogo fue 70% (IC95% 64–78). Tal vez se administró sobretratamiento al 29% de los pacientes (IC95% 23–36) durante la Tas4TB.

**Conclusión:** Es posible que más de un cuarto de los pacientes con diagnóstico presuntivo de TB haya sido tratado por exceso durante la Tas4TB. La tasa más alta de sobretratamiento ocurrió en las personas con antecedente de contacto con pacientes tuberculosos. La capacitación de los radiólogos y los médicos del terreno puede mejorar la evaluación de la CXR.