NOTES FROM THE FIELD

Did successfully treated pulmonary tuberculosis patients undergo all follow-up sputum smear examinations?

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To assess response to anti-tuberculosis treatment as per national guidelines, a retrospective record review was undertaken in four districts of Andhra Pradesh, India, in December 2009 to determine whether pulmonary tuberculosis (PTB) patients reported as successfully treated (cured or treatment completed) underwent all scheduled follow-up sputum smear examinations. In a quarterly cohort of 3000 PTB patients reported as successfully treated, 1847 (61.5%) underwent all follow-up sputum examinations, with a higher proportion of new cases (65%) than retreatment cases (45%). The mid-continuation phase follow-up sputum examinations were commonly missed, and 11% patients had not undergone end-of-treatment follow-up sputum examinations.

Follow-up sputum smear examinations are performed during anti-tuberculosis treatment to monitor progress: sputum smears negative for acid-fast bacilli (AFB) indicate a good response, while AFB-positive smears indicate poor adherence or non-response to anti-tuberculosis treatment, necessitating appropriate corrective measures.¹ Large numbers of pulmonary tuberculosis (PTB) patients worldwide are reported as successfully treated (cured or treatment completed).² However, information on whether these patients undergo all follow-up sputum smear examinations is limited.

In December 2009, to assess response to anti-tuberculosis treatment as per national guidelines, we performed a retrospective record review study in four districts of Andhra Pradesh State, Southern India, to determine whether PTB patients reported as successfully treated underwent all scheduled follow-up sputum smear examinations.

METHODS

Study setting

The four districts included in the study were Hyderabad, Rangareddy, Nalgonda and Medak, which have a combined population of 14.4 million.

India's Revised National Tuberculosis Control Programme (RNTCP) follows World Health Organization definitions for classifying TB patients and declaring treatment outcomes.³ Under the RNTCP, new TB patients are treated for 6 months and retreatment TB cases for 8 months.

The follow-up sputum examination schedule is as follows: smear-positive PTB patients should submit

two sputum samples (early morning and spot) on three occasions—at the end of the intensive phase of treatment (at 2 months for new TB and 3 months for retreatment TB), 2 months into the continuation phase (at 4 months for new TB and 5 months for retreatment TB) and at the end of treatment. If the smear is positive at the end of the intensive phase, the intensive phase is extended by a month and the patients undergo follow-up sputum examination again 1 month later. Patients with smear-negative PTB submit two sputum samples on two occasions: at the end of the intensive phase and at the end of treatment.³ Patients who complete treatment with negative sputum smears are recorded as successfully treated ('cured' in the case of sputum smear-positive cases and 'treatment completed' in the case of sputum smear-negative cases).

All TB patients are treated according to the principles of directly observed treatment (DOT), whereby a trained paramedical worker or community member provides anti-tuberculosis drugs to the patient under direct observation. It is the responsibility of the DOT provider to remind patients to undergo all follow-up sputum examinations. A Senior Treatment Supervisor supervises DOT providers, maintains a TB register and documents treatment progress, including follow-up sputum examinations.³ The accuracy of recording is verified during routine supervision.⁴

Study population

The cohort of all new and retreatment PTB patients registered for treatment between October and December 2008 in the four districts was used for the study, which was conducted in December 2009, when final treatment outcomes were available. PTB patients with successful treatment outcomes (cured + treatment completed) were included in the study.

Data sources and variables

Data collected from TB registers and treatment cards included TB registration number, type of TB, and whether the follow-up sputum examination was performed at the end of the intensive phase, during the continuation phase and at the end of anti-tuberculosis treatment.

Data management and analysis

Data were extracted to a structured proforma by two study investigators, cross-checked for consistency and all discrepancies resolved by referring to the original records. The EpiData statistical software package

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KEY WORDS

follow-up sputum examinations; tuberculosis; treatment; programmes; India; RNTCP

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FIGURE Follow-up sputum smear examination status of a cohort of pulmonary TB patients with successful treatment outcomes in Andhra Pradesh, India. TB = tuberculosis.

(version 3.1, EpiData Association, Odense, Denmark) was used for data entry and analysis. Comparisons between groups were made using the χ^2 test.

Ethical issues

The study was approved by the state and national level RNTCP programme managers and by the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease (The Union).

RESULTS

Of 3000 PTB patients reported with successful treatment outcomes, 1847 (61.5%) had undergone all follow-up sputum smear examinations (Figure). The proportion of patients with all follow-up examinations was higher among new cases than in retreatment cases (65% vs. 45%, $P < 0.01$). The follow-up examination in the middle of the continuation phase was most commonly

missed, followed by the examinations at the end of treatment and at the end of the initial phase (Table).

DISCUSSION

In this study, nearly 62% of the successfully treated PTB patients underwent all follow-up sputum smear examination according to RNTCP guidelines. These findings are similar to a previous study conducted in Malawi.⁵ Nearly 11% of the patients did not undergo the end-of-treatment follow-up examination.

The findings have the following implications for TB control in India. First, the consequences of missing follow-up sputum examinations include delayed or non-identification of patients who are not adherent or not responding to treatment. This may result in ongoing TB transmission, including drug-resistant TB and progression of disease, thereby significantly increasing morbidity and mortality in patients and the community. More attempts need to be made to improve follow-up sputum smear examinations, especially among retreatment patients, as these are more likely to harbour drug-resistant organisms and have poorer treatment outcomes.⁶

Second, there is a need to understand why sputum smear examinations are missed: possible reasons include lack of cough or expectoration by patients, incomplete or inadequate information given to the patients by DOT providers on the need for follow-up sputum examinations, non-availability of decentralised laboratory facilities and inadequate monitoring and supervision by programme staff.

Third, in India, multidrug-resistant TB (MDR-TB) suspects include patients who are smear-positive on follow-up sputum smear examinations during the course of treatment.⁷ If patients do not undergo follow-up sputum examinations regularly, this may impair early detection of MDR-TB.

Programme implications

As a result of this study, measures such as sensitisation of DOT providers and more regular and detailed supervision and monitoring were initiated at state and district levels to ensure that patients undergo all follow-up sputum smear examinations.

CONCLUSIONS

The study shows that nearly a third of PTB patients reported as successfully treated in the study districts did not undergo all follow-up sputum smear examinations. Further research is needed in other parts of India and globally to assess whether similar situations exist, identify bottlenecks for the implementation of guidelines on follow-up sputum smear examination and undertake appropriate corrective measures.

TABLE Follow-up sputum smear examination status in a cohort of successfully treated pulmonary tuberculosis patients in Andhra Pradesh, India

	Overall (n = 3000) n (%) [*]	New pulmonary tuberculosis		Retreatment	
		Smear-positive (n = 1518) n (%) [*]	Smear-negative (n = 851) n (%)	Smear-positive (n = 496) n (%) [*]	Smear-negative (n = 135) n (%) [*]
Follow-up sputum smear examination					
Underwent all examinations	1847 (62)	926 (61)	619 (73)	243 (49)	59 (44)
Missed end of intensive phase examination	222 (7)	48 (3)	87 (10)	74 (15)	13 (10)
Missed mid-continuation phase examination	880 (41) [†]	574 (38)	Not expected [‡]	236 (47)	70 (52)
Missed end-of-treatment examination	346 (11)	59 (4)	149 (17)	109 (22)	29 (21)

^{*}Percentages may add up to more than 100% as follow-up sputum smear examination may be 'missed' on more than one occasion.

[†]The denominator for the percentage is 2149; excludes new smear-negative patients.

[‡]New sputum smear-negative patients are not expected to undergo the mid-continuation phase follow-up examination.

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On a entrepris en décembre 2009 une revue rétrospective des enregistrements dans quatre districts d'Andhra Pradesh en Inde afin de déterminer dans quelle mesure les patients atteints de tuberculose pulmonaire (TBP) signalés comme traités avec succès (guérison ou achèvement du traitement) avaient subi tous les examens de frottis de crachats prévus dans le suivi pour évaluer la réponse au traitement TB conformément aux directives nationales. Dans une cohorte trime-

strielle de 3000 patients TBP signalés comme traités avec succès, 1847 (61,5%) avaient subi des examens de crachats du suivi, la proportion étant plus élevée parmi les nouveaux cas (65%) que parmi les retraitements (45%). Les examens de crachats du suivi au milieu de la phase de continuation ont manqué régulièrement et l'examen de crachats du suivi à la fin du traitement n'a pas été appliqué chez 11% des patients.

En diciembre 2009 se llevó a cabo una revisión retrospectiva de los registros de tuberculosis (TB) en cuatro distritos de Andhra Pradesh en la India, con el fin de determinar si todos los pacientes con TB pulmonar (TBP) cuyo desenlace terapéutico se había notificado como exitoso (curación o tratamiento completo) habían cumplido con las baciloscopias de seguimiento programadas para evaluar la respuesta al tratamiento antituberculoso de conformidad con lo estipulado en las directrices nacionales. En una cohorte trimestral de 3000 pacientes

con TBP cuyo tratamiento se registró como exitoso, 1847 pacientes (61,5%) contaban con todas las baciloscopias de seguimiento; esta proporción fue más alta en los casos nuevos (65%) que en los casos de retratamiento (45%). Con frecuencia faltaron las baciloscopias previstas en la mitad de la fase de continuación y 11% de los pacientes carecía del examen de esputo correspondiente a la finalización del tratamiento.