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Short Communication

Diagnosis of pulmonary tuberculosis in a pastoralist population in Ethiopia: are three sputum specimens needed?

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Abstract

OBJECTIVE To assess the number of sputum specimens necessary for a reliable diagnosis of pulmonary tuberculosis (PTB) in a pastoralist population in Ethiopia.

METHOD Using routine data from Ethiopia, where three sputum specimens are currently recommended for the diagnosis of PTB, we documented, (i) the proportion of persons with suspected, PTB who submitted a first, second and third sputum specimen for smear examination and (ii) the incremental smear-positive yield from the first, to the second and third specimens.

RESULTS Of 505 persons with suspected PTB, 107 (22%) failed to submit three samples. Of 60 patients who submitted three sputum samples with at least one smear-positive sample, the first sputum sample was smear positive in 56 (93%) cases; the second sputum sample was the first to be positive in 3 (5%) cases and in only one case was the third sample the first to be smear positive (additional yield 2%).

CONCLUSION In a pastoralist setting, a reliable diagnosis of PTB can be achieved with two sputum specimens and PTB diagnosis may be adequate with just one sputum specimen. However, if this more radical approach was adopted, ways of increasing diagnostic sensitivity should be explored.

keywords Ethiopia, tuberculosis, pastoralists, diagnostic yield, operational research

Introduction

Ethiopia has one of the highest burdens of tuberculosis (TB) in the world (WHO 2007), and this burden is disproportionately high in the Somali Regional State (SRS) (Barr & Menzies 1994; Agutu 1997; Waldman 2001; Coninx 2007). While weak TB control activities in the region may be to blame (Sheik-Mohamed & Velema 1999; Gele *et al.* 2009) – leading to many TB cases going undiagnosed and untreated – the situation is made more challenging by the type of population which lives there. Most of the inhabitants are pastoralists, and conventional TB management strategies are not well adapted to this mobile population (Tayler-Smith *et al.* 2011).

In 2010, Médecins Sans Frontiéres (MSF), in collaboration with the Somali Regional Health Bureau (SRHB), began providing TB care and treatment in Imey district in the SRS. Diagnosis of pulmonary TB (PTB) was based on light microscopy examination of three sputum specimens, each specimen submitted on three separate occasions. There has since been concern that this need for multiple visits, particularly in a pastoralist setting, may lead to high loss to follow-up, compounding delays in TB diagnosis and treatment. This has raised the question: is the current recommendation of three sputum specimens for the diagnosis of PTB appropriate in this setting?

Using routine data from the MSF TB programme in Imey, Ethiopia, we thus report on: i) the proportion of persons with suspected PTB who submitted a first, second and third sputum specimen for smear examination and ii) the incremental smear-positive yield going from the first, to the second and third specimen in those who submitted three sputum specimens.

Methods

Design

This was a retrospective cross-sectional study using routine programme data.

Setting and population

The study was conducted in Imey, a rural district in the eastern part of the SRS, where MSF, in collaboration with the SRHB, has been providing free comprehensive TB care since 2010. Integrated TB services are provided through a primary healthcare facility situated in Imey town serving a target population of about 65 000 and consisting mainly of pastoralists. This study included all adults ($\geq$15 years) with suspected PTB referred for sputum smear microscopy between December 2010 and March 2012.

TB diagnosis

Diagnosis of PTB was based on clinical examination and microscopic examination of smears made from three sputum specimens submitted on three occasions. PTB was only diagnosed if two or more sputum smears tested positive for acid-fast bacilli (AFB). Internal quality control measures are in place, and external quality control is performed quarterly in an external reference laboratory.

Data collection and statistical analysis

Data were sourced from the TB laboratory registers and double entered, by two independent encoders, into a data entry file created using EpiData Entry software version 3.1 (EpiData Association, Odense, Denmark). The two data files were compared and discordances resolved by cross-checking with the paper registers. The following variables were collected: laboratory serial number, age, sex, number of sputum samples submitted and AFB status (positive or negative) of each sputum sample submitted. To calculate the incremental smear-positive yield, only those who submitted three sputum specimens and were AFB positive on at least one of the specimens were included. Data were analysed using Epi Data analysis software version 2.2 (EpiData Association, Odense, Denmark).

Ethics approval

The study satisfied the criteria for analysis of routine data by the MSF Ethics Review Board, and formal approval was also obtained from the SRHB in Ethiopia.

Results

There were 505 persons with suspected PTB, of whom 278 (55%) were female. Median age was 38 years (interquartile range, 25–50 years). The number and proportion of persons with suspected PTB who submitted a first, second and third sputum specimen for smear examination are shown in Figure 1. There were losses at each stage, with a total of 107 (21%) patients failing to submit the three recommended sputum specimens. 398 (79%) patients submitted three samples, 69 (14%) submitted 2 and 31 (6%) submitted one sputum specimen. Seven patients submitted none.

Altogether, 72 (14%) of the 505 suspected patients with PTB were sputum smear positive. Of 398 patients who submitted three sputum specimens, 60 (15%) were sputum smear positive. The incremental yield of smear-positive results going from the first, to the second and the third sputum specimen is shown in the Table 1. The first

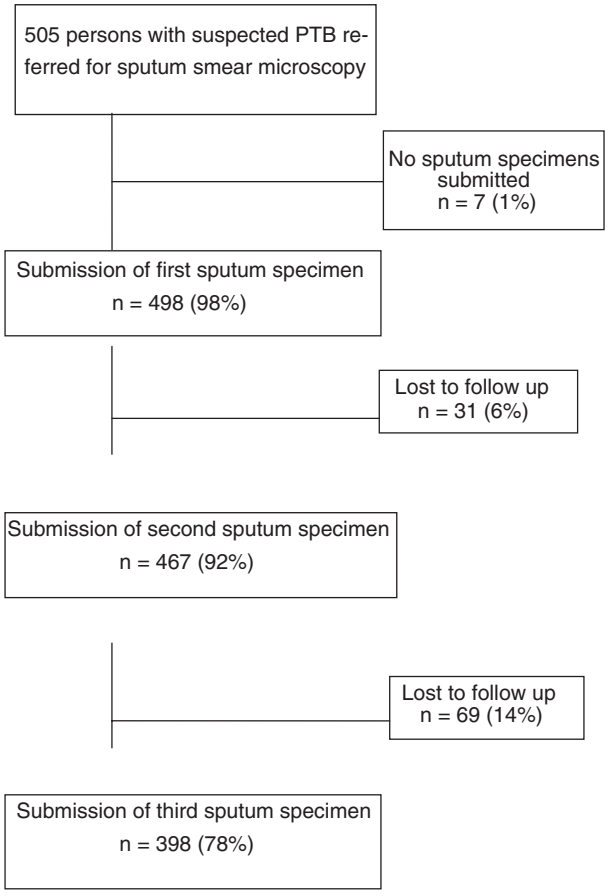

Figure 1 Submission of sputum specimens by persons with suspected pulmonary tuberculosis (PTB), Imey, Ethiopia.

Table 1 Incremental yield in smear positivity among patients submitting three sputum specimens with at least one smear positive for acid-fast bacilli (*n*–60), Imey, Ethiopia

	Incremental yield*	
Sputum sample	First AFB positive *n* (%)	95% CI
First	56 (93)	85–97
Second	3 (5)	2–14
Third	1 (2)	0.3–9
Total	60 (100)	–

AFB, acid-fast bacilli; CI, confidence interval.
*Defined as a positive AFB result on the second or the third specimen when the previous specimens were negative.

specimen identified 56 [93% (95% CI 84–97)] smear-positive patients, the second identified 3 [5% (95% CI 2–14)] and the third identified 1 patient [2% (95% CI 0.3–9)].

Discussion

This is one of the first studies assessing loss to follow-up (LTFU) related to a policy of requesting three sputum specimens for the diagnosis of PTB in a pastoralist setting in Ethiopia. The LTFU rates were unacceptably high. In those who submitted all three recommended sputum specimens, the incremental yield from the second and third smears was very low.

The study's strengths are that (i) the data come from a programme setting and thus are likely to reflect the operational reality on the ground, (ii) laboratory staff are well trained and supervised, (iii) quality control measures are in place and routinely performed and we believe that the results of the sputum microscopy are robust, and (iv) we adhered to the STROBE guidelines on the reporting of observational studies (Von Elm *et al.* 2007). The main study limitation is the relatively small sample size used to calculate diagnostic yield.

Our findings raise some important issues. First, while the majority of persons presenting with suspected PTB in our setting submit at least two sputum samples, more than one in five are lost to follow-up before submission of a third sample. This is a missed opportunity for diagnosing and treating potential cases of PTB.

Second, our findings suggest that the yield from the third sample is negligible considering that 98% of AFB-positive cases were identified by the first two specimens, which corroborates the findings from other studies (Ipuge *et al.* 1996; Mase *et al.* 2007). This finding is also in line with current WHO recommendations for submission of only two sputum specimens for the diagnosis of PTB (WHO 2010). However, the incremental yield gained from the second sputum sample in this setting was small. There are thus two operational options in this setting. The first is to rely on a single sputum smear and start TB treatment on the basis of one positive AFB smear – this recommendation for start of treatment is also in line with current WHO guidelines (WHO 2010). The second is to rely on more rapid, effective and advanced sputum screening techniques that would maximise diagnostic sensitivity with the first sputum submission. Results from a recent study suggest that PTB diagnosis using light emitting diode (LED) *fluorescence microscopy* (FM) for the examination of two smears prepared from one sputum sample may further improve the efficiency and accuracy of evaluation of patients with presumptive PTB (Cattamanchi *et al.* 2011). Such an approach would seem worthwhile in our setting, as it would not only help to reduce LTFU rates associated with additional visits for sputum submission, but would also reduce service and patient costs.

In conclusion, in a pastoralist setting in Ethiopia, our findings suggest that PTB diagnosis can be achieved with two sputum specimens and may be adequate with just one specimen. However, if this more radical approach was adopted, ways of increasing diagnostic sensitivity should be explored.

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