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ORIGINAL ARTICLE

# Self-administered treatment for tuberculosis among pastoralists in rural Ethiopia: how well does it work?

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**Objectives:** In the Somali Regional State, Ethiopia, where most of the population are pastoralists, conventional TB treatment strategies based on directly observed treatment (DOT) at health facilities are not adapted to the mobile pastoralist lifestyle and treatment adherence is poor. From a rural district, we report on treatment outcomes of a modified self-administered treatment (SAT) strategy for pastoralists with TB.

**Methods:** A descriptive cohort study was carried out between May 2010 and March 2012. The modified DOT strategy comprised a shorter intensive phase at the health facility (2 weeks for new patients, 8 weeks in the event of re-treatment), followed by self-administered TB treatment.

**Results:** A total of 390 patients started TB treatment. The overall treatment success rate was 81.2% (317/390); the rates of death, loss-to-follow up and treatment failure were 6.7% (26/390), 9.2% (36/390) and 0.3% (1/390) respectively. A considerable proportion (10/26, 38%) of deaths occurred during the first month of treatment.

**Conclusion:** In a pastoralist setting, a modified SAT strategy resulted in good treatment outcomes. If the global plan to eliminate TB by 2050 is to become a reality, it will be necessary to adapt TB services to client needs to ensure that all TB patients (including pastoralists) have access to TB treatment.

**Keywords:** Ethiopia, Tuberculosis, Pastoralists, SAT, Operational research

## Introduction

Pastoralists live by a social and economic system based mainly on the raising and herding of livestock. They often move with their animals from one geographic area to another in search of fresh pastures and water.[1] Two groups of pastoralists are identified in the Somali Regional State (SRS), Ethiopia. The first group are agro-pastoralists whose basic livelihood is from livestock, but who also practise nonpastoral activities such as farming. The second group are nomadic pastoralists whose economy relies exclusively on livestock rearing. They do not practise agriculture, nor do they have any permanent places of residence.[1]

Ethiopia has the world's seventh highest TB burden,[2] and this burden is higher in the SRS, where the population is predominately pastoralist. This is most probably attributable to the region's long history of armed conflict, which has weakened social services delivery to most of its population. People in the region are extremely poor and bear a disproportionately high burden of TB.[3] In addition, poor health infrastructure in the areas where pastoralists live and poor compliance with treatment related to patients' mobile lifestyle contribute to the spread of infection.[4]

The WHO recommends direct observation of TB treatment (DOT) for all patients (including pastoralists), as it is believed that this will ensure treatment compliance and limit the development of drug resistance.[5] The DOT strategy, which relies on patients returning daily for supervised treatment (pill swallowing) to a health facility, is not adapted to the mobile lifestyle of pastoralists[6] and poor adherence to treatment has been previously reported in such populations.[1] A study from Kenya, for example, reported a lost-to-follow-up rate of 21% among 996 new smear-positive TB patients treated in two nomadic districts.[7] Traditionally, DOT entails an intensive phase of observed treatment of at least 4 weeks for new patients and 12 weeks for patients requiring re-treatment. On the basis of comments from patients during counselling sessions at the Médecins Sans Frontières (MSF) health center in Imey, SRS, and from nursing and clinical staff administering DOT, this phase of observed treatment was considered to be too long.

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It was necessary to increase uptake and acceptability of TB treatment in this relatively vulnerable and excluded group. To make the intensive phase of DOT more suited to the lifestyle of pastoralists and reduce the need to travel long distances to health facilities, MSF, in collaboration with the Somali Regional Health Bureau, modified and shortened the duration of health facility-based DOT. Tayler-Smith et al.[8] have reported on outcomes of the self-administered treatment (SAT) strategy for pastoralists within the context of a 'TB village', where free accommodation near the treatment centre was provided to all TB patients for the entire period of treatment.[8] However, in that setting, distances did not pose a barrier to treatment adherence. There is no other published information on the treatment outcomes of a modified approach to the intensive phase of treatment that includes self-administration of drugs among pastoralists.

WHO sets a target of 85% treatment success in all TB programmes, irrespective of population type.[5] This implies that the rate of adverse outcomes (death, treatment failure and loss to follow-up) should be <15%. Meeting this target among difficult-to-reach populations such as pastoralists is one of the six key operations of the WHO Stop TB Strategy to eliminate TB by 2050. TB elimination is defined as an annual incidence of <1 new case per million population, a rate that is expected to prevent sustained transmission of *Mycobacterium tuberculosis*.[5]

From Imey in rural Ethiopia, we describe a modified approach to TB treatment with a shortened intensive phase and the use of SAT, and report on the treatment outcomes in relation to the stated WHO target for treatment success.

## Methods

This was a descriptive cohort study using routine programme data. The study was conducted in Imey, a rural district in the eastern part of the Somali Regional State, Ethiopia, where MSF, in collaboration with the Somali Regional Health Bureau, 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 that consists mainly of pastoralists. Although there is no active conflict at present, the SRS has had a long history of conflict, which has severely weakened the health infrastructure and TB control activities. These circumstances might have negatively influenced TB treatment outcomes.[9–13] The study population consisted of all TB patients who were recorded in the TB treatment register between May 2010 and March 2012.

### Diagnosis of TB

All patients presenting with a productive cough for 3 weeks or more were examined for TB. Three sputum specimens were submitted for light microscopy examination using Ziehl–Neelsen staining methods. If acid-fast bacilli (AFB) were identified on two of three smear examinations, the patient was recorded as a case of smear-positive pulmonary TB (PTB). For patients with initial negative smear microscopy and no response to a course of broad-spectrum antibiotics, smear microscopy was repeated; if it was still negative, the patient was classified as having smear-negative pulmonary TB.[14] Extrapulmonary TB (EPTB) was diagnosed on the basis of clinical evidence and a decision by the TB doctor.[14] TB diagnosis in children was based on the Edwards Score Chart.[15] Patients were further categorised into new and re-treatment cases.[14] There was no access to radiographs, cultures or nucleic acid amplification technology such as GeneXpert MTB/RIF.

Internal quality control for sputum smear diagnosis was assured by a qualified Belgian laboratory technician and an Ethiopian laboratory technician who worked in tandem. External quality control of sputum smears was performed every 3 months in the regional reference laboratory at Jijiga, the capital of the Somali region of Ethiopia.[14]

### Definitions of TB treatment outcomes

We used the WHO definitions of TB treatment outcomes, as set out in Table 1.

### Study population

Inclusion criteria for our study of the SAT strategy of the Imey TB programme: patients were eligible if they were diagnosed with TB, were from Imey district, and had a place to stay at Imey town during the intensive phase of treatment. Additionally, each patient had to have a guarantor and a contact person to facilitate tracing in the event of being lost to follow-up.

Exclusion criteria: patients from other districts were not eligible for enrolment into the Imey TB programme, as it would have been logistically difficult to ensure their adherence and to trace any patients who did not return for scheduled follow-up visits. These patients were referred to the national TB programme at their nearby medical facilities.

**Table 1.** WHO definitions of TB treatment outcomes.

| |
|---|
| **Cured:** a patient who was initially smear-positive and who was smear-negative in the last month of treatment and on at least one previous occasion. |
| **Completed treatment:** a patient who completed treatment, but who did not meet the criteria for cure or failure. This definition applies to smear-positive and smear-negative patients and to patients with extrapulmonary TB. |
| **Died:** a patient who died from any cause during the course of treatment. |
| **Failed:** a patient who was initially smear-positive and who remained smear positive at month 5 of treatment or later during treatment. |
| **Lost to follow-up:** a patient whose treatment was interrupted for 2 consecutive months or longer. |
| **Transferred out:** a patient who transferred to another reporting unit and for whom treatment outcome is unknown. |
| **Successfully treated:** a patient who was cured or who completed treatment. |

Source: http://www.who.int/tb/publications/global_report/2007/table_5/en/index1.html.

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**Table 2.** TB treatment regimens and indications, Imey, Ethiopia (May 2010–March 2012)

| Treatment regimen | Drugs and duration[a] | Indication |
|---|---|---|
| 8-month regimen | 2HRZE/6EH | Adult with new smear-positive PTB, new smear-negative PTB and EPTB |
| 6-month regimen | 2HRZE/4RH | Adult with new smear-positive PTB, new smear-negative PTB and EPTB |
| Re-treatment regimen | 2HRZES/1HRZE/5HRE | All forms of re-treatment TB |
| Meningitis regimen | 2HRZS/4RH | TB meningitis in adult or child |
| Paediatric regimen | 2HRZE/4RH | New TB in child |

[a] A regimen has two phases: intensive and continuation. The number before a regimen is the duration of that phase in months.
H: isoniazid; R: rifampicin; Z: pyrazinamide; E: ethambutol; PTB: pulmonary TB; EPTB: extrapulmonary TB; S: streptomycin.

### Strategy for management of TB

The treatment strategy used for the study population was a modified DOT strategy that included self-administered treatment (SAT). The intensive phase of treatment lasted 2 months for newly diagnosed patients and 3 months for those requiring re-treatment). Initially patients took a combination of drugs daily under the direct supervision of a health worker (health-facility-based DOT), for 2 weeks if newly diagnosed and for 8 weeks if receiving re-treatment. After this period, medications were collected weekly by the patient from the health facility and self-administered until the end of the intensive phase. During the continuation phase of treatment (4 months for newly diagnosed patients and 5 months for those receiving re-treatment), drugs were collected monthly by the patient from the health facility and self-administered. Fixed-dose combinations were used throughout the treatment period. TB treatment was offered on an ambulatory basis, except for severely ill patients requiring admission for medical reasons. The different TB treatment regimens used in Imey and their indications are described in Table 2.

### Follow-up visits and patient tracing

In line with the drug collection schedule, follow-up visits to the TB doctor at the health facility were every 2 weeks during the intensive phase and once a month during the continuation phase. The purpose of these visits was to check for weight gain, adjust drug dosage according to weight, and assess the patient for side-effects and clinical progress. Patients were classified as absent if they missed an appointment date, and did not appear within 3 subsequent days. The patient's contact person was informed and a health extension worker (a community outreach worker) visited the patient's residence. A maximum of three such visits were conducted on separate occasions. One member of the counselling team (health extension worker), together with the contact person, would search for the absentee. Patients who did not return to care after 2 months following their appointment date were classified as 'lost to follow-up'.

Follow-up AFB sputum examination was performed at 2, 5 and 6 months for new smear-positive PTB, and at 3, 5 and 8 months for re-treatment patients.

### Adherence counselling

Adherence counselling sessions were provided for all patients on the day of diagnosis and on the first day of treatment. Thereafter, counselling sessions were conducted at each scheduled follow-up visit during the intensive and continuation phase of treatment. Special counselling sessions were organised for patients who returned after being lost to follow-up and for any patient deemed by the treating doctor to need additional counselling. All counselling sessions were conducted by a trained MSF counsellor according to MSF TB guidelines.

### Data collection, variables and statistical analysis

Variables related to the study objectives were sourced from patients' record cards and the TB treatment register. They included: registration number, TB treatment start date, age, sex, type and category of TB, TB treatment regimen, treatment outcome and date of outcome. Data were transferred from patient's cards to the TB treatment register by a trained data officer and this activity was supervised by the TB doctor every month. Data were cross-checked and double entered, by two independent encoders, into a data entry file created using EpiData Entry software V.3.1 (EpiData Association, Odense, Denmark). The two data files were compared and discordances resolved by cross-checking with paper registers. Treatment outcomes were expressed in proportions (%) and the cumulative incidence of death over time was calculated. Data were analysed using EpiData analysis software V.2.2.1.171 (EpiData Association).

## Results

Between May 2010 and March 2012, a total of 390 patients started TB treatment, of whom 189 (48.5%) were women. Most patients (369, 94.5%) were newly diagnosed with TB while 21 (5.5%) needed re-treatment. The median age of all patients was 24 years (IQR 8–39). Of the 369 new TB patients, 129 (35.0%) had smear-positive pulmonary TB (PTB), 92 (2.0%) had smear-negative PTB and 148 (40.0%) had extra-pulmonary TB. Table 3 shows the demographic and clinical characteristics of all patients included in the study.

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Treatment outcomes by type and category of TB and by TB treatment regimen are shown in Table 4. The overall treatment success rate for all new cases was 317/390 (81.2%), while the rates for death, loss-to-follow-up and failure were 26/390 (6.7%), 36/390 (9.2%) and 1/390 (0.3%) respectively. A considerable proportion of deaths (10/26, 38%) occurred early in the first month of starting anti-TB treatment (Figure 1).

**Table 3.** Characteristics of pastoralists with TB placed on self-administered treatment in Imey, Ethiopia (May 2010–March 2012)

| Variable | n (%) |
|---|---|
| Total | 390 |
| Sex | |
| Female | 189 (48) |
| Male | 201 (52) |
| Age (years) | |
| <15 | 149 (38) |
| 5–34 | 120 (31) |
| ≥35 | 121 (31) |
| Median (IQR) | 24 (8–39) |
| TB type | |
| New patients | |
| Smear-positive PTB | 129 (35) |
| Smear-negative PTB | 92 (25) |
| EPTB | 148 (40) |
| Re-treatment patients | |
| Smear-positive PTB | 3 (14) |
| Smear-negative PTB | 14 (67) |
| EPTB | 4 (19) |

PTB: pulmonary TB; EPTB: extrapulmonary TB.

## Discussion

This is one the first studies to assess TB treatment outcomes following implementation of a modified DOT strategy with SAT in a rural pastoralist setting. It proved feasible to implement this strategy, and it was associated with a satisfactory rate of treatment success and relatively low levels of adverse outcomes (e.g. lost-to-follow-up and death) when compared to the WHO target. There has been a tendency to avoid offering TB treatment to mobile populations because of the fear that treatment adherence may be poor.[16] Our experience is encouraging, as it shows that modification of the treatment strategy to allow for mobile lifestyles can allay such fears. It is also important, because it shows a way forward towards providing universal access to TB treatment and thus bringing us closer to the internationally agreed target of TB elimination by 2050.[17,18] Achieving this target will require that all populations at risk, including those in unstable situations and those who are mobile, receive TB treatment in an effective manner.

The study strengths are threefold. 1. The data came from a routine programme setting and therefore are likely to reflect operational reality. 2. Data encoders were well trained and supervised, and we therefore believe the data were robust. 3. We adhered to the STROBE guidelines for reporting of observational studies.[19]

Although treatment success did not meet the stated WHO target of 85%, it is higher than the nationally reported global treatment success Rate for Ethiopia as a whole (77%).[2] Tayler-

**Table 4.** TB treatment outcomes for pastoralists in Imey, Ethiopia (May 2010–March 2012)

| | Treatment success[a] n (%) | Died n (%) | Lost to follow-up n (%) | Transferred out n (%) | Treatment failure n (%) | Not recorded n (%) | Total n (%) |
|---|---|---|---|---|---|---|---|
| All patients | 317 (81.2) | 26 (6.7) | 36 (9.2) | 6 (1.5) | 1 (0.3) | 4 (1.0) | 390 (100) |
| TB type | | | | | | | |
| Smear-positive | 110 (83.3) | 7 (5.3) | 11 (8.3) | 1 (0.8) | 1 (0.8) | 2 (1.5) | 132 (34) |
| Smear-negative | 78 (73.5) | 15 (14.2) | 12 (11.3) | 1 (0.9) | 0 | 0 | 106 (27) |
| EPTB | 129 (85.0) | 4 (2.6) | 13 (8.6) | 4 (2.6) | 0 | 2 (1.3) | 152 (39) |
| TB category | | | | | | | |
| New TB cases | 298 (81.0) | 25 (6.8) | 35 (9.5) | 6 (1.6) | 1 (0.3) | 4 (1.08) | 369 (94.6) |
| Re-treatment TB[b] | 17 (90.5) | 1 (4.8) | 1 (4.8) | 0 | 0 | 0 | 21 (5.4) |
| TB treatment | | | | | | | |
| Short course (6 months) | 128 (81.5) | 9 (5.7) | 13 (8.3) | 5 (3.2) | 0 | 2 (1.3) | 157 (40.3) |
| Short course (8 months) | 189 (81.1) | 17 (7.3) | 23 (9.9) | 1 (0.4) | 1 (0.4) | 2 (0.9) | 233 (59.7) |
| Paediatric | 124 (83.2) | 7 (4.7) | 13 (8.7) | 4 (2.7) | 0 | 1 (0.7) | 149 (38.2) |
| Meningitis | 2 (66.7) | 1 (33.3) | 0 | 0 | 0 | 0 | 3 (76) |

[a] Includes patients who were cured and those who completed TB treatment.
[b] Includes relapse, re-treatment after lost to follow-up, re-treatment after failure and re-treatment others.

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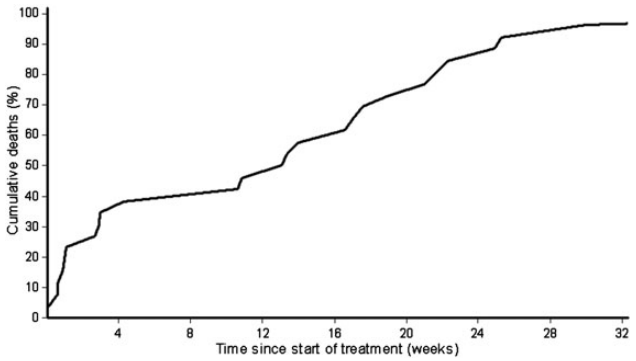


**Figure 1.** Cumulative incidence of death among patients with TB included in a study of the effectiveness of a modified DOT (directly observed treatment) strategy in Imey, Ethiopia, May 2010–March 2012 (n=26).

Smith et al. reported a high rate of treatment success (91%) following implementation of the SAT strategy within the context of a 'TB village' in a similar population in the Cherrati district of SRS.[8] However, in that project, patients were provided with food and housing for the entire period of the treatment, which helped to minimise the rate of lost-to-follow-up to 3%. Our lost-to-follow-up rate was 9%, and this may be a result of circular and internal migration within this group. A possible way forward may be to introduce decentralised DOT centres linked to recognised migration routes to ensure treatment continuation. However, varying migration patterns might make this practically difficult.[1]

We believe that there may be several reasons for the success achieved in our Imey study. First, this was a selected population that was likely to have better outcomes. Patients were included from Imey district only if they had a place to stay in the town, and had available a guarantor and a contact person who would facilitate tracing in the event of them being lost to follow-up. Both the guarantor and the contact person were members of the patient's family and participated on a voluntary basis; this is an advantage when considering financial sustainability after MSF hands over the project to the Somali Regional Health Bureau. There might have been other social factors that favoured treatment success, but they merit further research. Second, regular adherence counselling, considered one of the most effective strategies to prevent treatment interruption, was offered throughout the treatment period.[20] Third, we believe modification of the DOT strategy, to reduce the health-facility-based DOT period, may have been perceived as being a more patient-friendly approach. However, as we have no direct comparison, our data cannot support this claim. An added consideration is that this strategy may have reduced financial and physical barriers for patients. This is also an example of how health services can adapt to client needs without compromising on the quality of care. Fourth, regular monitoring and follow-up of patients' clinical condition allowed for prompt detection and management of adverse drug reactions.[20] Fifth, hospital services were always available for severely ill patients, especially during the intensive phase of the SAT strategy and in the event of side-effects. Finally, in a resource-poor country like Ethiopia, it is challenging to run a TB project in a remote area such as Imey with a long-standing history of conflict, mainly because of the lack of trained and skilled health workers. The presence of a non-governmental organisation (NGO), in this case MSF, alleviated human resources shortages, ensured a regular drug supply and provided support for counselling and patient-tracing activities. In addition, the project was run in close collaboration with the Somali Regional Health Bureau, with a component of training for national staff. Where national TB control programmes lack resources in these difficult conditions, building partnerships with NGOs is a possible way forward.

A considerable proportion of deaths occurred early during the first month of treatment. Possible reasons are that patients presented late, with severe illness and possible co-infection with HIV. A previous study conducted among pastoralists in SRS showed a median patient delay of 60 days between onset of symptoms and diagnosis.[13] Enhancing community awareness and involving community leaders (religious leaders, traditional healers and clan leaders) to disseminate knowledge about TB may be one way forward. TB patients in our setting did not have access to HIV testing and the next step would be integration of provider-initiated HIV testing for all patients with presumptive TB, and initiation of co-trimoxazole and antiretroviral treatment (ART) for HIV-positive patients.[21] There might be other factors associated with early death in this type of population, but this needs further research.

The study limitations are that: 1. Diagnosis of other types of mycobacteria such as *Mycobacterium bovis* was not feasible because sputum culture services were not available; 2. We were unable to do a before-and-after intervention comparison of TB treatment outcomes in Imey district as no prior treatment programme existed and therefore no data were available; and 3. The study did not nvestigate the specific reasons for death or loss to follow-up, as this was beyond the scope of the stated objectives.

In conclusion, we have shown that, for pastoralists in the Somali region of Ethiopia, a modified DOT strategy for the treatment of TB that included SAT produced satisfactory results. The strategy's success demonstrates a way forward to improve access to TB treatment and treatment outcomes in a difficult-to-access population. If the global goal to eliminate TB by 2050 is to be achieved, innovative approaches are needed to ensure that all populations, including pastoralists, have access to TB treatment.

**Authors' contributions:** MK, RZ and TR conceived and designed the study. MK wrote the study protocol, which was improved by RZ and TR. SCA, MG, SZ and TW implented and supervised the study. MK did the initial analysis of the data, with the support of TR and RZ. MK wrote the first draft of the paper, which was reviewed by RZ, TR and ADH. MK dealt with revisions of the paper, and all authors read and approved the final version. MK is guarantor of the paper.

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**Competing interests:** None declared.

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**Ethical approval:** This study met the approved criteria of the Médecins Sans Frontières Ethics Review Board, Geneva, Switzerland, for analysis of routinely collected programme data, and was approved by the Somali Regional Health Bureau, Ethiopia.

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