TB treatment in a chronic complex emergency: treatment outcomes and experiences in Somalia

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Received 15 July 2013; revised 16 August 2013; accepted 19 August 2013

Background: Médecins Sans Frontières (MSF) provides TB treatment in Galkayo and Marere in Somalia. MSF international supervisory staff withdrew in 2008 owing to insecurity but maintained daily communication with Somali staff. In this paper, we aimed to assess the feasibility of treating TB in a complex emergency setting and describe the programme adaptations implemented to facilitate acceptable treatment outcomes.

Methods: Routinely collected treatment data from 2005–2012 were retrospectively analysed. In multivariate analyses, factors associated with successful outcome (cure or completion versus failure, death and default) were assessed, including the presence of international supervisory staff. Informal interviews were conducted with Somali staff regarding programmatic factors affecting patient management and perceived reasons for default.

Results: In total, 6167 patients were admitted (34.8% female; median age 24.0 years [IQR 13.0–38.0 years]). Treatment success was 79% (programme range 69–87%). Presence of international staff did not improve outcomes (adjusted OR 0.85, 95% CI 0.66–1.09; p = 0.27). Perceived reasons for default included being away from family, nomadic group, insecurity, travel cost, need to return to grazing land or feeling better.

Conclusions: Despite the challenges, a high percentage of patients were successfully treated. Treatment outcomes were not adversely affected by withdrawal of international supervisory staff.

Keywords: Tuberculosis, Conflict, Complex emergency, Somalia, Humanitarian

Introduction

TB is a major cause of morbidity and mortality in complex emergencies.1,2 A complex emergency is defined by the Inter-Agency Standing Committee as ‘a humanitarian crisis in a country, region or society where there is total or considerable breakdown of authority resulting from internal or external conflict and which requires an international response that goes beyond the mandate or capacity of any single agency and/or the ongoing United Nations country programme’.3 The incidence and mortality of TB are thought to increase during times of conflict,4 although notification rates tend to decrease with increasing intensity of conflicts.5 Armed conflict disrupts health service delivery, diverts resources and contributes to delayed diagnosis and self-treatment (i.e. treatment without biomedical diagnosis and management, possibly using traditional medicines or inadequate anti-TB medicines), leading to increased TB transmission.6–10 Owing to the long duration of treatment, TB treatment is vulnerable to interruption in such settings, raising concerns over the potential emergence of drug resistance. Programme design must therefore be relevant for the setting to ensure that benefits outweigh risks.9,11

Despite these challenges, TB treatment programmes in complex emergencies in countries such as South Sudan, East Timor and Nicaragua have achieved outcomes in line with WHO target indicators.12–15 Similarly, the provision of antiretroviral therapy for HIV/AIDS patients in conflict settings has been shown to be feasible in carefully adapted programmes.16,17 Some of the challenges to TB programmes in insecure settings experienced by others2,7,9 as well as in our programme include destroyed infrastructure and limited financial resources; the absence of a good supervised programme and limited monitoring capacity; frequent evacuation of expatriate staff and limited availability of trained and dedicated local staff; knowledge and commitment of patients regarding diagnosis and treatment; sudden closure of programmes; continuous laboratory and drug supply and other logistical support; the potential for collaboration with other actors including Ministries of Health; attitude of local leaders and militant groups towards foreign aid agencies; insecurity causing displacement or limiting movement and access to...
In this paper, we describe the experience, innovative approaches and lessons learned in running TB programmes in three sites in South Central Somalia and Puntland. We also present a retrospective analysis of risk factors for poor treatment outcomes from 2005–2012, including the effect of the withdrawal of international supervisory staff on treatment success. We aimed to assess the feasibility of treating TB in a complex emergency setting and describe the programme adaptations implemented to facilitate acceptable treatment outcomes.

Methods

Treatment data routinely collected from 2005–2012 were analysed for treatment outcomes, which were allocated according to standard WHO outcome definitions. Characteristics of patients treated at different project sites were described and compared using a χ² test for proportions and one-way ANOVA for continuous variables with equal variances, or Kruskal–Wallis equality-of-populations rank test for those with unequal variances.

Multivariate multilevel logistic regression models estimated adjusted ORs for the outcomes of death or default (separately) and for success (cure or complete compared with failure, death and default), with the physical presence of international supervisory staff as a binary variable. Treatments started in 2007 and 2008 were potentially affected by the departure of international staff. Therefore, the analysis of the effect of the presence of international staff included only those patients who started treatment in 2005 and 2006 and thus had outcomes measured in 2006 and 2007 compared with those who started in 2009–2011 and had outcomes measured in 2010–2012. One site (Marere) was excluded from this model as the TB programme started in 2007, shortly before international staff were withdrawn. Models included variables significant at p<0.10 in unadjusted analyses or considered clinically or programmatically important. Transfer-in and transfer-out patients were excluded. Backward selection was used to choose prognostic variables for the final models, discarding those no longer associated (p>0.10) with the outcome after adjustment for other variables, aside from those clinically relevant. p-Values were calculated for the strength of association of each variable with the outcome using the Wald test, and the age categorical variable assessed as continuous to test for trend. Interaction was not considered plausible with the retained variables.

Informal interviews were conducted with Somali staff regarding programmatic factors affecting patient management and perceived reasons for default.

Programme settings

Galkayo is a town in the Mudug region with an estimated population of approximately 380,000 (http://www.somaliareport.com/index.php/post/3575), although this number can vary considerably as there are a large number of displaced people in the region. Chronic clan rivalry has created an invisible line dividing Galkayo into North and South; crossing the line is dangerous and disputes between clans erupt regularly. The two parts are under different governments: Galkayo North is part of Puntland, while Galkayo South is in South Central Somalia and thus under the Transitional Government of Somalia. MSF has run medical programmes in the area since 1997 and has been providing TB

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<th>Box 1. Security incidents</th>
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<td>Between January 2008 and December 2010, 160 security incidents were reported in the areas where Médecins Sans Frontières (MSF) works; not all involved MSF. Incidents included 56 shootings and 18 separate bomb attacks (hand grenades, remote-controlled improvised explosive device, land mine, mortar etc.). In 2008, 45 aid workers were killed in Somalia; 179 reported security incidents affected non-governmental organisations, 150 of them directly. Galkayo South: during a conflict at the end of 2009, patients residing in the TB village were clearly distressed and staff handed out 7–10 days of extra medication to those patients living near the conflict-affected area. This incident did not interrupt service provision by MSF staff. Marere area: from January 2008 to February 2011 there were 68 reported security incidents in this area alone, including 17 direct threats towards MSF and 2 robberies, 1 of which was by a militia faction that came to the hospital and demanded and took drugs. Despite the large number of incidents, they occurred continuously on a relatively small scale and did not cause sudden and massive displacement of the local population.</td>
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treatment since 2005 and 2006 in North and South Galkayo, respectively.

Marere is a village in the Middle Juba region of South Central Somalia. The population in and around Marere is approximately 75,000, but numbers fluctuate due to active fighting in the region. Currently (2013) the area is fairly stable because it is under the control of the Muslim faction Al-Shabaab (in Somali, ‘Harakat al-Shabaab al-Mujahideen’) who have imposed strict Sharia law. MSF is the only international organisation now in the region after other organisations were expelled or closed operations. MSF has worked in Marere since 2003, offering a range of medical services, which since 2007 have included TB treatment.

Programme description

Screening

TB screening is provided through MSF outpatient clinics and therapeutic feeding centres or specific TB clinics where there is no adult outpatient clinic. Very rarely, those presenting at a late stage are diagnosed while inpatients. TB diagnosis is mainly by sputum smear microscopy using Ziehl–Neelsen staining following collection of three sputum samples, including one early morning sample. Results are usually available within 48 h. Slides are selected monthly for external quality control, which is provided by the African Medical Research Foundation Laboratory in Nairobi every 2–3 months, depending on the availability of transport. Chest radiography and two antibiotic trial courses are used for the diagnosis of smear-negative pulmonary TB; in Marere, where chest radiography is not available, diagnosis is usually made clinically after two antibiotic trial courses. Well trained and experienced nurse clinicians diagnose most pulmonary cases; doctors diagnose and initiate treatment of more difficult cases such as TB meningitis or paediatric TB.

Treatment

Treatment is by WHO-recommended standardised short course chemotherapy (2HRZE+4HR; 2 months of isoniazid, rifampicin, pyrazinamide and ethambutol followed by 4 months of isoniazid and rifampicin) using fixed-dose combinations of drugs to improve adherence. Directly observed therapy (DOT) is provided throughout the intensive phase of treatment in all programme sites. In the continuation phase, self-administered treatment is used in Marere for patients who live close to the clinic and have demonstrated good adherence and ability to attend treatment centres monthly, while the remainder receive DOT.

Adherence

Adherence is promoted by DOT providers carrying out TB health education activities in the DOT centre, the TB village and the inpatient ward. A monthly nutrition package is provided for patients to support their health and to promote adherence. Before starting treatment, a TB patient must identify a treatment guarantor, such as a family member or community elder. The patient and guarantor are asked to sign a written agreement to complete treatment. The guarantor is given a dry food ration as an incentive to support the patient until treatment completion.

If treatment interruption occurs, patients are traced within 3 days using recorded residence location or contact telephone (belonging to the patient or a neighbour or guarantor). There are exceptions: some patients come from very far away and have no-one to be their treatment guarantor; and insecurity prevents staff travelling outside the project location to trace patients who cannot be reached by phone.

Infection control

The Somali population has good knowledge of TB signs and symptoms. However, there are mixed beliefs regarding disease transmission and treatment that include western biomedicine and traditional beliefs (David Citrin, personal communication; see also http://www.msf.org.uk/galcayo-somalia), other infection control measures such as cough triage, separation of coughing patients, or asking possible or confirmed TB cases to wear surgical masks in waiting areas are not implemented. However, the waiting areas in all health facilities are outdoors and infection control messages about cough hygiene are included in health education. Ensuring that staff wear high-filtration masks while attending potential or diagnosed TB cases has been challenging.

Adaptations for a conflict setting

Proximity of treatment: security for patients and staff

Owing to security constraints in Galkayo, patients are offered treatment only if they commit to stay in the project location for the full course. For patients without relatives in the area, MSF provides accommodation in a ‘TB village’ in the hospital compound. Strict DOT is followed for the whole treatment course in Galkayo because defaulter tracing is not feasible for security reasons. For patients living in Galkayo town there are two DOT ‘corners’ (small sites where a DOT provider sees TB patients for DOT between clinic appointments) in Galkayo North and one in Galkayo South so they can obtain treatment near their place of residence.

The MSF Marere project is the only available treatment centre for a large rural area that is particularly affected by instability. As a result, many patients come from very far away and present late; most are accommodated in the hospital for treatment. In all projects, mobile phone numbers provided by patients at initiation (phone number for patient, family member, neighbour or treatment guarantor) are used for defaulter tracing and follow-up, as staff are not allowed to travel outside the project location to trace patients owing to security risks, but have access to project mobile phones with adequate network coverage.

Remote control

Since the withdrawal of international staff, strategies have been developed to ensure the quality of care is maintained. For difficult cases there is daily communication between a medical referent in Nairobi and the key nurse and doctor in the Somali projects as well as routine weekly or biweekly case discussions between the medical teams in Nairobi and Somalia. This facilitates learning
and knowledge sharing for staff, enhanced by MSF-provided training for Somali staff at all levels. Programme performance monitoring includes review of weekly patient statistics and pharmacy consumption data, random checking of a copy of the TB registration book and patient medical records for diagnoses and treatment, monthly review of medical data with comparison with previous months and the same period in previous years, weekly telephone or internet conferences, ad-hoc telephone and e-mail support as needed, travel of key staff to meetings in Nairobi if conditions allow and very short visits of international staff from Nairobi to the project if possible.

Monitoring and contingency plans

Security and context changes are monitored daily. If increased tensions and insecurity cause patients to leave a project location, a contingency plan can be activated within hours. Patients are prepared for possible evacuation by intensive education. In addition, at treatment initiation each patient receives an ‘escape drugs package’ with 2 weeks supply of drugs to enable them to manage their treatment until the security situation is such that they can return to the clinic.

Acceptance

MSF has gained widespread acceptance and support for its TB programmes and has not had problems with local authorities or militia groups, including the Al-Shabaab groups in and around Marere. TB has long been recognised as one of the main health problems in Somalia and the importance of treatment for these patients is understood. MSF tries to keep the projects open unless staff are at significant risk.

Lessons learned

We have summarised the factors especially relevant for programmes in complex emergencies that contributed to the successful operation of the TB projects (Box 2).

Results

Patient characteristics and outcomes

Patients in Galkayo North were older than those at Galkayo South or Marere (median age 25.0, 23.0 and 22.0 years, respectively; p<0.001) and the proportion of females was low at all sites but was higher in Marere (38.5%; 329/855) (Table 1). There were approximately 2.5 times as many patients treated in Galkayo North as in the other sites in recent years (2010–2012). TB site and smear status differed between projects (p<0.001), with the greatest proportion of smear-positive pulmonary TB cases in Galkayo North (55.4%; 2092/3777) and the least in Marere (32.7%; 280/855); Marere had the most smear-negative or smear-not-done pulmonary cases (43.6%; 373/855).

Treatment outcomes were significantly better for Galkayo North and Marere compared with Galkayo South (81.6% [2687/3293], 87.0% [569/654] and 69.2% [921/1331] achieved cure or completion of treatment, respectively; overall 79.1% [4177/5278]); this difference remained clear when only the period when all sites were operating was compared (data not shown, but it does not account for other variables. In smear-positive patients only, the cure rate was 76.6% (2054/2683) and overall treatment success was 80.6% (2162/2683) for those commencing treatment in 2005–2011.

Most paediatric cases had smear-negative pulmonary TB. The proportion diagnosed with extrapulmonary TB increased with age until age 15 years (Figure 1). The proportion of successful outcomes was significantly lower for children younger than 1 year compared with older children and adults (63.7% [242/380]) for children younger than 1 year vs 79.7% [420/527] for 1 to <5 years old, 84.4% [341/404] for 5 to <15 years old and 80.0% [3174/3967] for ≥15 years; p<0.001). Admission of smear-positive patients significantly decreased over time (Figure 2), largely due to an increased proportion of children in later years; the proportion of adults who were smear-positive did not vary greatly (data not shown). The proportion of successful outcomes varied significantly over time for treatments commenced in 2005–2011 (p=0.006), but there was no clear trend, being highest in 2005 (84.5%; 328/388) and lowest in 2006 (75.1%; 368/490). The variation was not evident (p=0.65) if outcomes excluded transfer out, which were relatively high from 2006 (7–12%).

In multivariate analysis, risk factors for death compared with any other outcome (cure, completion, default or failure) included treatment site (p=0.011; Galkayo South adjusted OR 1.52, 95% CI 1.13–2.03 and Marere adjusted OR 1.44, 95% CI 0.99–2.08.

Box 2. Lessons learned

Factors considered to have contributed to the success of the TB programme:

- Trained and dedicated staff who have been with Médecins Sans Frontières (MSF) since the time when international staff were present in projects (before 2008).
- Continuous learning and training opportunities for national staff.
- Continuous and regular support provided to field staff by the remote project management team.
- Ensuring sufficient and working equipment for communication and feedback (telephone/internet, camera, copier machine, computer).
- Ensuring that patients coming from distant locations stay near the project, e.g. in a TB village, throughout the treatment course.
- Extra adherence support for those from distant locations—accommodation, food and non-food items.
- Adopting adherence strategy [ambulatory directly observed therapy (DOT) via DOT ‘corners’, and TB village DOT].
- Ensuring continuous laboratory and drug supplies and sufficient stocks in case of supply rupture.
- Regular and close monitoring of the programme.
- Regular monitoring of the security situation and adapting contingency plans.
- Obtaining the acceptance, trust and support of local community leaders.
- Sufficient resources and long commitment of the aid agency.
compared with Galkayo North); young age at start of treatment (adjusted OR 2.47, 95% CI 1.68–3.63 for children, 1 year compared with adults; test for trend across groups, p ¼ 0.001); smear-negative or smear-not-done pulmonary TB (adjusted OR 2.63, 95% CI 1.87–3.69) or extrapulmonary TB (adjusted OR 1.80, 95% CI 1.23–2.65) compared with smear-positive TB (p, 0.001); and re-treatment (adjusted OR 1.70, 95% CI 1.14–2.53) (Table 2).

Default rates varied from 3–10% across sites. The only factors associated with default compared with any other outcome (cure, complete, death or failure) were treatment site (Galkayo South adjusted OR 3.39, 95% CI 2.57–4.47 or Marere adjusted OR 1.49, 95% CI 0.97–2.31 compared with Galkayo North; p<0.001) and re-treatment (adjusted OR 1.71, 95% CI 1.17–2.49) (Table 2). In informal interviews, Somali staff suggested that the main factors for defaulting included: patients from nomadic groups; the strain of being away from the family (e.g., husband asked wife to come back); socioeconomic factors such as travel cost or needing to return to grazing land for farming and cattle raising; feeling better; or lack of belief in the treatment.

The physical presence of international supervisory staff in the Galkayo projects was not associated with successful treatment outcome (adjusted OR 0.56, 95% CI 0.39–0.81; p=0.002) (Table 3).

Discussion
These results show that treatment of TB is feasible and that relatively high rates of treatment success are possible in this extremely challenging setting if programmes are adaptable and flexible. Despite concerns over maintaining programme quality following the withdrawal of international staff, there was no measured effect on successful treatment outcomes. The remote
The management model used in this setting is feasible and should be considered in other settings where local expertise is lacking after years of infrastructure collapse and where international staff are at particular risk. Other adaptations described by staff as important in this setting included provision of local accommodation for patients who do not live near any treatment programme and emergency packs of drugs in case of increased insecurity.

The overall treatment success rate did not meet the WHO target of 85%. This target is for smear-positive cases, and fewer than one-half of our patients had smear-positive pulmonary TB, although overall success was only slightly better for smear-positive patients (81%) than all cases (79%). These rates are similar to those reported from other programmes in Somalia (success rates of 70–80%) and in conflict-affected East Timor (81%), but worse than those in Southern Sudan (85–95%) or Churachandpur, India (86–89%), yet markedly better than in Liberia (50–60%). Our outcomes surpassed the minimum threshold proposed by Biot et al. as beneficial in terms of public health in a risk–benefit analysis (≥4 months of treatment for 75% of patients). Despite the challenges, the benefits of providing treatment in these settings are clear, where the alternative of not treating TB can quickly lead to increased morbidity and

Figure 1. TB site and smear status by age category. PTB: pulmonary TB.

Figure 2. TB site and smear status by year of commencing treatment. PTB: pulmonary TB.
mortality as occurred in Bosnia and Herzegovina and in Somalia in the 1990s.22

There were substantial differences in outcomes between sites, with Galkayo South having the poorest outcomes. Possible reasons for this include weak management in Galkayo South despite various efforts to strengthen capacity, which may have reduced patient confidence and had a role in relatively high rates of transfer out (13%) and default (10%). Transfers were from or to a variety of locations (local and international) and for various reasons including insecurity, family or business needs, and nomadic lifestyle. Competition and clan issues between staff led to less team cohesion in Galkayo South, whereas in Galkayo North there was a stronger team. In addition, greater insecurity in Galkayo South than in Galkayo North meant that fewer short visits by international staff were possible to support and monitor treatment and record-keeping. In Marere, treatment outcomes were good, but adjusted ORs for death and default were both non-significantly raised compared with Galkayo North. One reason for this could be that levels of insecurity and lack of other regional treatment options and thus long distances for patients to attend for treatment in Marere resulted in late presentation, untreated co-morbidities or greater challenges to remaining on treatment than in Galkayo North.

Infants <1 year were less likely to have a successful outcome than other age groups, possibly due to poor diagnosis. It is challenging to obtain adequate sputum samples and diagnosis in this age group, which may have resulted in late treatment start or overdiagnosis of infant TB. In addition, there could have been a factor of late presentation of this age group owing to lack of knowledge of signs of TB in infants, who are challenging to diagnose in any setting.

It has been asserted that TB control programmes can function in fragile states such as Somalia with sufficient leadership, partnerships and funding.4 The key factors for success in conflict and post-conflict settings have been described as including visible leadership by one agency; effective partnerships and collaboration; strong and flexible management that is adapted locally; highly motivated individuals; facilitating social network system; and active community involvement.6 In Churachandpur, India, additional factors linked to success were reported to be selection of outreach workers from all ethnic groups to facilitate access to all areas and patients, and reducing DOT frequency to only three times per week, in some cases administered by outreach workers.9 Similarly, using community health workers to provide DOT in Southern Ethiopia, an area with low health service coverage but not a complex emergency, resulted in higher treatment success rates than areas without this intervention (89% vs 83%).24 Some of these factors have contributed to success in our treatment sites in Somalia, in particular commitment of the local staff and community; and some were challenges, such as clan issues among staff and weak leadership in Galkayo South. Owing to the level of insecurity, the use of

<p>| Table 2. Unadjusted and adjusted odds of death or default for patients commencing treatment from 2005–2011 (n=4788) |
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<th></th>
<th>Death</th>
<th>Adjusted OR (95% CI)</th>
<th>p-value</th>
<th>Default</th>
<th>Adjusted OR (95% CI)</th>
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<td>Programme site</td>
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<td>Galkayo North</td>
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<tr>
<td>Galkayo South</td>
<td>1.82 (1.38–2.41)</td>
<td>1.52 (1.13–2.03)</td>
<td>&lt;0.001</td>
<td>3.39 (2.59–4.45)</td>
<td>3.39 (2.57–4.47)</td>
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<td>Marere</td>
<td>1.72 (1.22–2.43)</td>
<td>1.44 (0.99–2.08)</td>
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<td>1.36 (0.90–2.06)</td>
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<td>Age at start of treatment (years)</td>
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<td>0 to &lt;1</td>
<td>4.56 (3.30–6.31)</td>
<td>2.47 (1.68–3.63)</td>
<td>&lt;0.001</td>
<td>1.62 (1.07–2.47)</td>
<td>1.36 (0.88–2.10)</td>
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<td>1 to &lt;5</td>
<td>1.30 (0.85–1.97)</td>
<td>0.73 (0.46–1.15)</td>
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<td>5 to &lt;15</td>
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<tr>
<td>PTB smear-positive</td>
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<tr>
<td>PTB smear-negative or not doneb</td>
<td>3.26 (2.45–4.34)</td>
<td>2.63 (1.87–3.69)</td>
<td>&lt;0.001</td>
<td>1.10 (0.82–1.47)</td>
<td>1.11 (0.79–1.55)</td>
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<td>Extrapulmonary</td>
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<td>1.80 (1.23–2.65)</td>
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<td>New</td>
<td>1.45 (0.99–2.12)</td>
<td>1.70 (1.14–2.53)</td>
<td>0.009</td>
<td>1.74 (1.21–2.50)</td>
<td>1.71 (1.17–2.49)</td>
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PTB: pulmonary TB, with or without extrapulmonary TB.

Table 2. Unadjusted and adjusted odds of death or default for patients commencing treatment from 2005–2011 (n=4788)

aAdditionally adjusted for year treatment started (not significant and not shown).
bSmear not done; reporting option introduced in 2011, previously classified as smear-negative.
outreach workers to administer DOT to support patient adherence was not feasible in our programmes, but we were able to provide DOT ‘corners’ to improve accessibility. In addition, in Marere some patients were permitted to have self-administered treatment, however a limitation of this study is that we have no data on the number of patients treated with this approach and thus cannot comment on it further. Retrospective review of routine programmatic treatment data also has inherent limitations, which may have been increased by remote supervision of programmes. However, this issue was recognised when this programme model was adopted and thus efforts were directed to improving monitoring and quality control of data. Finally, when international supervisory staff were withdrawn, it is possible that other programme and contextual changes occurred, however we are not aware of any potential confounding factors.

Conclusions
TB should not be ignored in chronic complex emergencies. With flexible and adapted programmes and investment in appropriate communication technology, acceptable treatment outcomes can be obtained. Useful adaptations include provision of accommodation near to treatment as well as emergency drug packs in case of increased instability. Remote management of programmes is feasible with sufficient resources and motivated and well supported local staff.

Authors’ contributions: KFL helped initiate the paper, helped clean and fill data gaps and wrote the sections on context; RE helped clean and fill data gaps, researched information and contributed to writing the paper; SST assisted in study conception, carried out interviews and contributed to writing the paper; JG conducted the analyses and contributed to writing the paper; SV assisted in study conception and writing and editing the paper. All authors read and approved the final paper. KFL and JG are guarantors of the paper.

Acknowledgements: The authors thank the staff and patients of the Somalia projects.

Funding: This study was funded by Médecins Sans Frontières (MSF).

Competing interests: None declared.
Ethical approval: This study met the standards set by the Médecins Sans Frontières (MSF) Ethics Review Board for retrospective analyses of routinely collected programme data.25

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