



The experience of scaling up a decentralized, ambulatory model of care for management of multidrug-resistant tuberculosis in two regions of Ethiopia



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ABSTRACT

Strong strategies, including proven service delivery models, are needed to address the growing global threat of multidrug-resistant tuberculosis (MDR-TB) in low- and middle-income settings. The objective of this study was to assess the feasibility and effectiveness of the nationally approved ambulatory service delivery model for MDR-TB treatment in two regions of Ethiopia. We used routinely reported data to describe the process and outcomes of implementing an ambulatory model for MDR-TB services in a resource-limited setting. We compared percentage improvements in the number of MDR-TB diagnostic and treatment facilities, number of MDR-TB sputum samples processed per year, and MDR-TB cases ever enrolled in care between baseline and 2015. We also calculated interim and final treatment outcomes for patients who had completed at least 12 and 24 months of follow-up, respectively. Between 2012 and 2015, the number of MDR-TB treatment-initiating centers increased from 1 to 23. The number of sputum samples tested for MDR-TB increased 20-fold, from 662 to 14,361 per year. The backlog of patients on waiting lists was cleared. The cumulative number of MDR-TB patients put on treatment increased from 56 to 790, and the treatment success rate was 75%. Rapid expansion of the ambulatory model of MDR-TB care was feasible and achieved a high treatment success rate in two regions of Ethiopia. More effort is needed to sustain the gains and further decentralize services to the community level.

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Introduction

Multidrug resistant tuberculosis (MDR-TB) is a global public health challenge. In 2015, of over half a million people estimated to have developed MDR-TB, national TB control programs (NTPs) notified only 20% [1]. Moreover, only 52% of those treated successfully completed the recommended regimen. While these data suggest the presence of critical challenges in the scale-up of MDR-TB services, they also highlight a tripling in case detection and enrollment in care compared with the 2009 baseline [1].

Further scale-up of MDR-TB services in resource-limited settings requires consensus on the best model of service delivery, since the hospitalized model of care used in developed settings is not sustainable [2]. Cost-effectiveness studies suggest that MDR-TB treatment can be cost-effective, but the model of care is the main influencer of costs, with ambulatory care being more cost-effective [3]. There is also clear evidence from other infectious disease programs that decentralized service delivery improves treatment outcomes. Lessons from decentralized management of HIV programs are particularly relevant for scale-up of MDR-TB services, although important differences between the care needs of MDR-TB patients and those of HIV patients should be taken into consideration [4–6].

Earlier experience from resource-limited settings in Asia, Eastern Europe, and Latin America demonstrated the effectiveness of

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standardized MDR-TB treatment approaches, but treatment outcomes varied significantly among countries because of differences in the mode of service delivery. Higher loss-to-follow-up rates, for example, were reported from countries that provided services at a single centralized site compared with countries that implemented a more decentralized approach [7]. The degree of decentralization also varied considerably across countries and regions, with varying degrees of success in treatment outcomes [8–12]. More data are needed, especially from sub-Saharan Africa, to support the ongoing efforts to strengthen the decentralized ambulatory model of care for low- and middle-income settings.

Ethiopia is among the MDR-TB high-burden countries that have achieved an MDR-TB treatment success rate (TSR) exceeding 70% [13]. However, there is limited data on the TSR following the rapid expansion and decentralization of services. In this paper, we describe the processes and outcomes of a decentralized, ambulatory approach to MDR-TB treatment in two large regions of Ethiopia. The two regions cover over half of the country's population. Also, more than 50% of the country's MDR-TB treatment centers are located in these two regions. Our objective was therefore to describe how a decentralized, ambulatory model of MDR-TB treatment, if coupled with appropriate quality assurance strategies, could improve access to and quality of MDR-TB services without compromising treatment outcomes in a setting with limited resources. We also highlighted some of the challenges encountered during this progress and suggested practical solutions based on field-level implementation experience.

Methods

The setting

Ethiopia is located in the horn of Africa. The country is subdivided into nine administrative regional states and two city councils. Each regional state is further subdivided into administrative zones, which in turn comprise woredas (equivalent to districts). Oromia is the largest regional state, with an estimated population of over 34 million, followed by Amhara Region, which has a population of over 20 million [14]. The current national TB incidence and prevalence estimates per 100,000 population are 200 and 207, respectively [1]. The proportion of MDR-TB cases among new and previously treated cases is estimated to be 1.6% and 11.8%, respectively [15].

Under the guidance of the Ministry of Health of Ethiopia (FMOH) and the Regional Health Bureaus of Amhara and Oromia regions, the Help Ethiopia Address the Low Tuberculosis Performance (HEAL-TB) Project has provided comprehensive TB program support to the two regions since July 2011. HEAL-TB, funded by the United States Agency for International Development (USAID) and implemented by Management Sciences for Health, prioritized MDR-TB as one of the key technical areas for support. We selected the two HEAL-TB-supported regions for this analysis because we were able to obtain complete data through project activities, which allowed us to thoroughly document the processes and outcomes of the program.

Service delivery models

FMOH recommends two models of care for management of MDR TB patients [16,17]. In the **inpatient model of care**, all eligible patients that are ready to start treatment with second line drugs (SLDs) are admitted to treatment initiating centers (TICs) with designated MDRTB wards for four to eight weeks till the patient turns sputum smear negative. Upon discharge from the TICs, patients are referred to treatment follow up centers (TFCs) for outpatient follow up. Prior to 2011, only two tertiary hospitals pro-

vided MDR TB treatment to patients from all over the country using the inpatient model of care (Fig. 1). However, with the growing need to improve access to MDR-TB services, the FMOH developed a decentralized, ambulatory model of care for rapid expansion of the services [16].

In the **ambulatory model of care**, patients are treated at outpatient level at TFCs from day one. The multidisciplinary panel team at TICs may recommend temporary admission at TICs based on clinical or social criteria. At TFCs, patients received daily injections six times per week for the initial 8–9 months (intensive phase) and attended daily follow up during the continuation phase. The patients received their medications under direct observation and strict follow up by health workers both at TICs and TFCs. Table 1 describes the roles and responsibilities of TICs and TFCs in the ambulatory model of care.

All newly diagnosed MDR-TB patients received a standardized treatment regimen, per the national guidelines [18]. Accordingly, the recommended regimen of choice was eight months of Pyrazinamide (Z)-Capreomycin (Cm)-Levofloxacin (Lfx)-Prothionamide (Pto)-Cycloserine (Cs) for the intensive phase followed by 12 months of Pyrazinamide (Z)-Levofloxacin (Lfx)-Cycloserine (Cs) abbreviated as **8 Z-Cm₆-Lfx-Pto-Cs, 12 Z-Lfx-Cs**.

Interventions and innovative approaches

Some of the challenges identified at baseline and anticipated to be encountered in the longer-term necessitated prompt innovative interventions. Less organized clinic appointment systems and consequent poor adherence to treatment and follow up; limited experience of the clinical team; and irregularities in laboratory monitoring systems were some of the key challenges identified at baseline.

Strengthening the national and regional level program coordination capacity was the initial step in enabling the operationalization of the decentralized, ambulatory model of care. This was followed by specific capacity building efforts for health care providers and program managers through trainings on clinical and programmatic management of MDR-TB. To ensure ongoing learning and skills improvement we prepared, printed and distributed provider support tools including pocket guides, clinician desk references, cohort monitoring charts, and wall charts adapted from national guidelines. Since most health facilities did not have adequate space and were not infection control friendly, we supported renovation of three major MDR-TB treatment centers, and improved the functionality of facilities renovated through other projects by providing furniture and equipment. Strengthening the laboratory capacity was another area which required significant investment. This included supplying laboratory equipment and consumables and building human resource capacity on their use through training, on-site demonstration, and by providing job aids.

While clearing the backlog of patients in waiting list, we focused on improving case finding. As part of this effort and in addition to strengthening the overall human resource and laboratory capacity, we sensitized the community through mass communication by organizing orientation sessions for health program managers and community workers, with a focus on presumptive case identification and contact investigation.

Strengthening the monitoring and evaluation of the MDR TB program performance was a key component of the interventions. We supported the design and implementation of specific indicators for MDR-TB standards of care, for quarterly monitoring and reporting, and trained clinic staff on recording and reporting of MDR-TB data. To support more efficient recording and reporting, we provided desktop computers, an electronic patient data monitoring system, and access to mobile internet services.

At each TIC, MDR-TB panel teams, composed of a multidisciplinary group of personnel, guided patient-level decisions. Typi-

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