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Cured MDR-TB patient with his care team at Yirgalem TIC.
Photo credit: Jennifer Gardella

TECHNICAL BRIEF

IMPROVING ACCESS TO PATIENT-CENTERED DRUG-RESISTANT TUBERCULOSIS MANAGEMENT SERVICES IN ETHIOPIA

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July 2023

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BACKGROUND

According to the Global Tuberculosis (TB) Report 2021, an estimated 3–4% of newly diagnosed TB cases and 18–21% of previously treated TB were rifampicin-resistant/multidrug-resistant (RR/MDR)-TB. Close to half a million cases of RR/MDR-TB were reported in 2020.(1,2)

Ethiopia is one of 30 countries designated as high TB-burdened and high TB/HIV-burdened, but it moved off the list of high RR/MDR-TB-burdened countries in 2020. Among the notified TB cases in 2019, 1.1% of new cases and 7.5% of previously treated cases were estimated to be RR/MDR-TB. In 2020, RR/MDR-TB treatment coverage was 46% and treatment success was above 75%.

The five-year US Agency for International Development (USAID) Eliminate TB Project implemented by Management Science for Health (MSH) aims to support the National TB and Leprosy Program, Government of Ethiopia, and other stakeholders in building, through targeted investment, programmatic and leadership capabilities to reduce the incidence and mortality of TB and eliminate catastrophic costs for patients.

PROBLEM STATEMENT

Despite the progress made so far, drug-resistant TB (DR-TB) case finding remains inadequate and low. One of the main enduring challenges is the insufficient implementation of first-line and second-line drug susceptibility testing. Therefore, the number of DR-TB patients that are detected and enrolled in treatment is consistently below the expected number of DR-TB cases (figure 1).

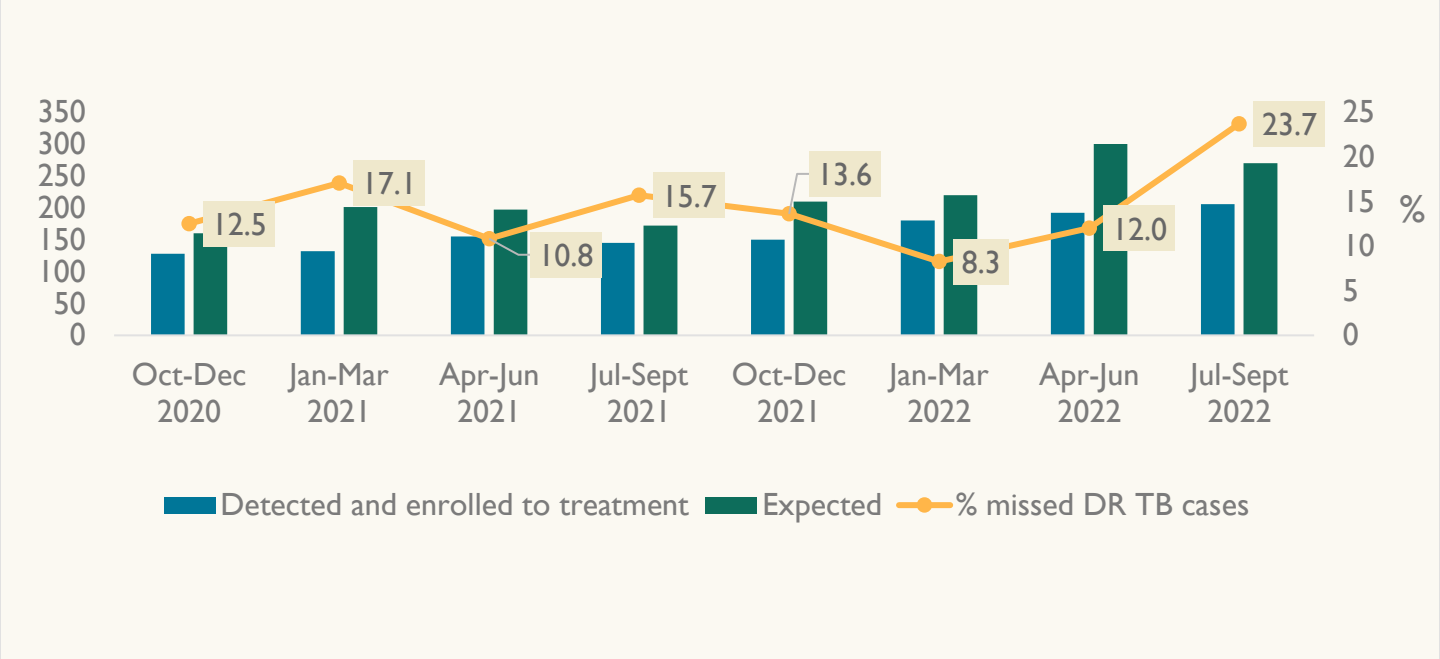

Figure 1: Gap between expected and detected/enrolled DR-TB cases, national level

Moreover, despite clearly stated national policy, implementation of second-line line probe assays and second-line phenotypic drug susceptibility testing is low. This causes patients with additional resistance, such as pre-extensive drug-resistant (pre-XDR)-TB and extensive drug-resistant (XDR)-TB, to be missed.

Other significant challenges include:

- Delayed roll-out and scale-up of new regimens recommended by the World Health Organization (WHO)
- Intermittent interruptions of second-line drugs
- Interruptions in monitoring of and follow-up tests for DR-TB patients

- Sub-optimal communication between DR-TB treatment initiation centers (TICs) and DR-TB treatment follow-up centers (TFCs)
- Limited access to critical care services for DR-TB patients

In addition, the COVID-19 pandemic and continuing conflict throughout the country have inhibited the scale-up of programmatic management of drug-resistant TB (PMDT) services.

According to national health management information system data, the missed DR-TB cases increased from 12.5% in October 2020 to 23.7% in September 2022 (figure 1). DR-TB case-finding efforts need further strengthening, and implementation of new drugs and novel regimens should be prioritized to improve treatment outcomes for RR/MDR-TB, pre-XDR-TB, and XDR-TB cases.

STRATEGIC APPROACH

The USAID Eliminate TB Project has annual targets with detailed activities to increase the rate of TB case detection to 90%, DR-TB treatment success to 85%, and DR-TB case notification to 5,673 individuals by the end of the project. Areas of support include strengthening the capacity of health care workers, improving the quality of the DR-TB care cascade, and establishing DR-TB centers of excellence (COEs) to serve as referral sites.

Developed, reviewed, and updated the national guidelines and training materials

The project senior advisors provided technical support to the National TB and Leprosy Program on February 22–25, 2021, to develop, review, and update the national comprehensive training materials on TB, TB/HIV, and DR-TB. Major global and national TB-related updates have been released since the last edition of the national DR-TB guideline of Ethiopia was finalized. In collaboration with the National TB and Leprosy Program, Ethiopian Public Health Institute, Ethiopian Pharmaceutical Supply Agency, and other non-governmental partners, the USAID Eliminate TB Project facilitated the revision of the guidelines and training materials. The project also supported the printing of these documents and their distribution to health facilities.

Health care provider capacity strengthening on early identification of DR-TB cases, improving treatment initiation center/treatment follow-up center linkage, and strengthening the clinical review committee

Health care workers from the national to the facility level were trained to implement molecular WHO-recommended rapid diagnostics, mainly GeneXpert, as a primary test for presumptive DR-TB cases and second-line drug susceptibility tests for all RR/MDR cases to ensure universal drug susceptibility test implementation. Eight rounds of national training sessions on clinical and programmatic management of drug-resistant TB were delivered to 464 health care providers from September to December of 2020. In addition, those health care providers were trained to follow the national guidelines in their clinical practices to ensure that:

- Patients are put on effective treatment regimens in treatment initiation centers
- Strong linkage between treatment initiation centers and treatment follow-up centers is established
- Regular mentoring of follow-up centers by initiation centers is conducted
- Job aids are developed
- Regular DR-TB contact investigations at treatment initiation centers and treatment follow-up centers, per the guideline policy, are implemented

Health care workers regularly undertook clinical consultations with clinical review committee experts and subsequently applied the experts' recommendations.

Improving quality of patient care at health facilities (centers of excellence)

Since the second quarter of project year 1, the USAID Eliminate TB Project has been providing technical support to establish centers of excellence for DR-TB services and to make ALERT and St. Peter Hospitals into referral centers. The support included training of health care workers and regular clinical mentoring, along with supportive supervision to the centers of excellence and to all treatment initiation centers in the project-supported regions. The project also helped reduce interruptions in availability of second-line and ancillary drugs through regular monitoring of requests, distribution, and supplies.

Clinical and laboratory monitoring was conducted to improve the care of DR-TB patients. TICs and TFCs conduct regular monthly clinical evaluations of patients, which include nutritional assessments, counseling, and psychosocial support. TICs have also conducted quarterly site mentorship and supervision activities. DR-TB survivors and experts have been brought in to talk with TB patients and stress the importance of adhering to treatment plans.

Technical support for smooth roll-out of full-oral bedaquiline-containing short treatment regimen

The project supported the roll-out of an all-oral bedaquiline-containing short treatment regimen for RR/MDR-TB in all DR-TB treatment initiation centers, starting in February 2021. The training on the short treatment regimen roll-out was included in the comprehensive TB/HIV and DR-TB guidelines and training materials. After comprehensive training has been provided, quarterly supportive supervision and clinical mentoring onsite visits are conducted regularly for smooth implementation.

Workshop launching all-oral bedaquiline-containing short RR/MDR-TB treatment regimen, held in Adama, February 1, 2021. Photo credit: Brehan Teklehymanot, USAID Eliminate TB Project public relations professional

Strengthening active drug safety monitoring and management (aDSM) and pharmacovigilance

The project worked with the Ethiopian Food and Drug Authority (EFDA) to strengthen the national DR-TB drugs pharmacovigilance and aDSM system on appropriate prevention, detection, management, causality assessment, and reporting of drug side effects. This was accomplished through training, onsite orientation, and supportive supervision. The first two trainings were delivered in April 2021, followed by an additional two trainings in 2022. The National aDSM Committee was established by the EFDA in August 2021 as part of the effort to strengthen the national DR-TB drugs pharmacovigilance system.

The USAID Eliminate TB Project Senior PMDT Advisor is a member of the National aDSM Committee and contributed to the "clinical management of adverse events of interest and serious adverse events (SAE) during DR-TB treatment," which is part of the aDSM standard operating procedures developed by the EFDA. The first National aDSM Committee meeting was conducted in August 2021, during which draft terms of reference were discussed and finalized. In addition, causality assessments for three severe adverse events were conducted. From the time the aDSM system was implemented in 2017 through August 2021, treatment initiation centers made 480 reports of adverse drug events. Seventeen treatment initiation centers have been regularly reporting adverse events to EFDA.

Technical support to clinical review committees

Clinical review committees support the management of DR-TB patients at treatment initiation centers and treatment follow-up centers. The committees contain, at a minimum, pulmonologists, internists, psychiatrists, surgeons, and pediatricians. The project technically supports the establishment and revitalization of the national and regional clinical review committees and supports those committees in facilitating case consultations with treatment initiation centers and treatment follow-up centers. For instance, six clinical seminars—which included updates on topics such as new WHO recommendations, second-line drugs grouping, adverse drug event management, and management of extra-pulmonary DR-TB—were conducted several months apart at national and regional levels in the last two project years. Complicated DR-TB cases were discussed, and senior experts from clinical review committees made recommendations on those cases to health care providers, which had a significant impact on patient progress (figure 2).

Sub-agreement is made between Management Sciences for Health and the Ethiopian Thoracic Society to provide support on DR-TB patient care, strengthen clinical review committees, expand DR-TB case consultation, and provide support to centers of excellence

The Ethiopian Thoracic Society, as a local implementing partner of MSH, was engaged in supporting the DR-TB services improvement activities in 2022. The Ethiopian Thoracic Society's contribution includes:

- Providing technical support to establish and strengthen critical-care units
- Developing standard operating procedures for critical-care services
- Training health care workers on critical-care service delivery
- Developing training modules
- Strengthening the national and regional clinical review committees
- Organizing and facilitating virtual case consultations

National and regional joint supportive supervision to health facilities

To improve the quality of care provided to TB/DR-TB patients, the TB program is regularly monitored. Regular supportive supervision to regional health bureaus and health facilities was conducted every six months to improve DR-TB program implementation, identify programmatic gaps and challenges, and develop action plans.

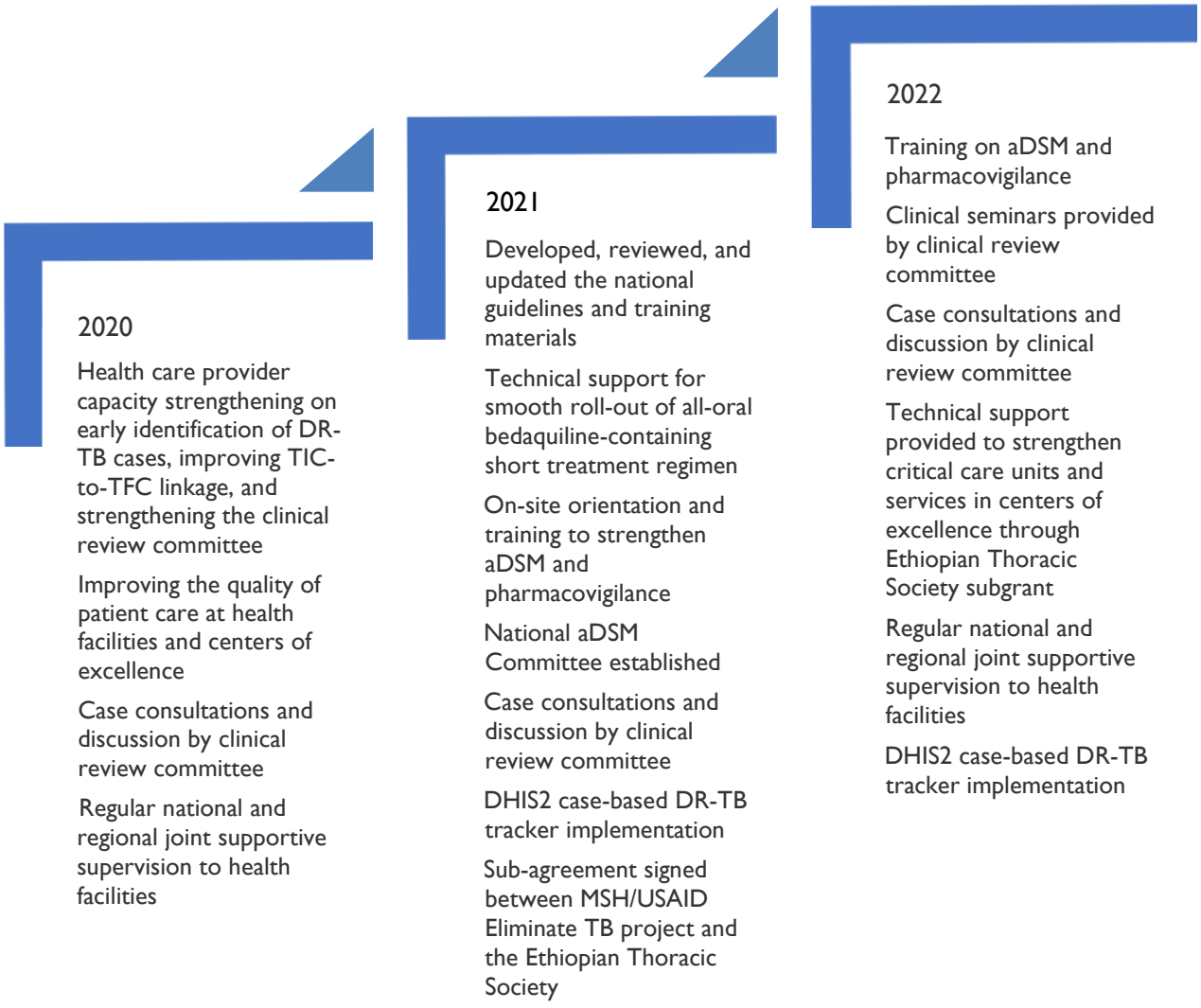

Figure 2: PMDT strategic approaches followed by the USAID Eliminate TB Project, 2020–2022

RESULTS AND ACHIEVEMENTS

Roll-out and scale-up of bedaquiline-containing short treatment regimen

Significant improvement has been achieved in the roll-out and scale-up of the bedaquiline-containing full-oral DR-TB short treatment regimen. Currently, almost all treatment initiation centers are implementing the short treatment regimen. The number of patients enrolled in care increased from time to time, and, as of March 2022, around 342 out of 696 eligible patients had been put on the all-oral short treatment regimen since its introduction in five regions (Oromia; Amhara; Southern Nations, Nationalities, and People [SNNP]; Sidama; and Addis Ababa [AA] [St. Peter and ALERT]). Stockouts of second-line line probe assay kits continue to be the main challenge for implementation scale-up.

Nationally, 591 of the 700 targeted patients (84.4%) were detected and enrolled for RR/MDR-TB treatment in October 2020–September 2021. National RR/MDR-TB coverage has reached 59%, compared to a baseline of 46% in 2019. In addition, 12 (60% of the project target) pre-XDR-TB and XDR-TB patients were detected and enrolled in treatment, and 72% of bacteriologically confirmed pulmonary TB cases had a documented first-line drug susceptibility test result. Moreover, 90% of patients with DR-TB were successfully linked to care. During October 2020–September 2021, 57% of RR/MDR-TB patients had access to second-line drug susceptibility testing.

Oromia, Amhara, SNNP, Sidama, and AA represented 84% of the national DR-TB detection from October 2020 to September 2021. DR-TB case detection in these regions improved by 45% from October 2020 to June 2022 (figure 3). Enrollment in RR/MDR-TB treatment also increased in this time, with the greatest increase seen in Amhara where enrollment more than doubled (24 to 49), followed by SNNP (14 to 23) and Oromia (34 to 48) (figure 4).

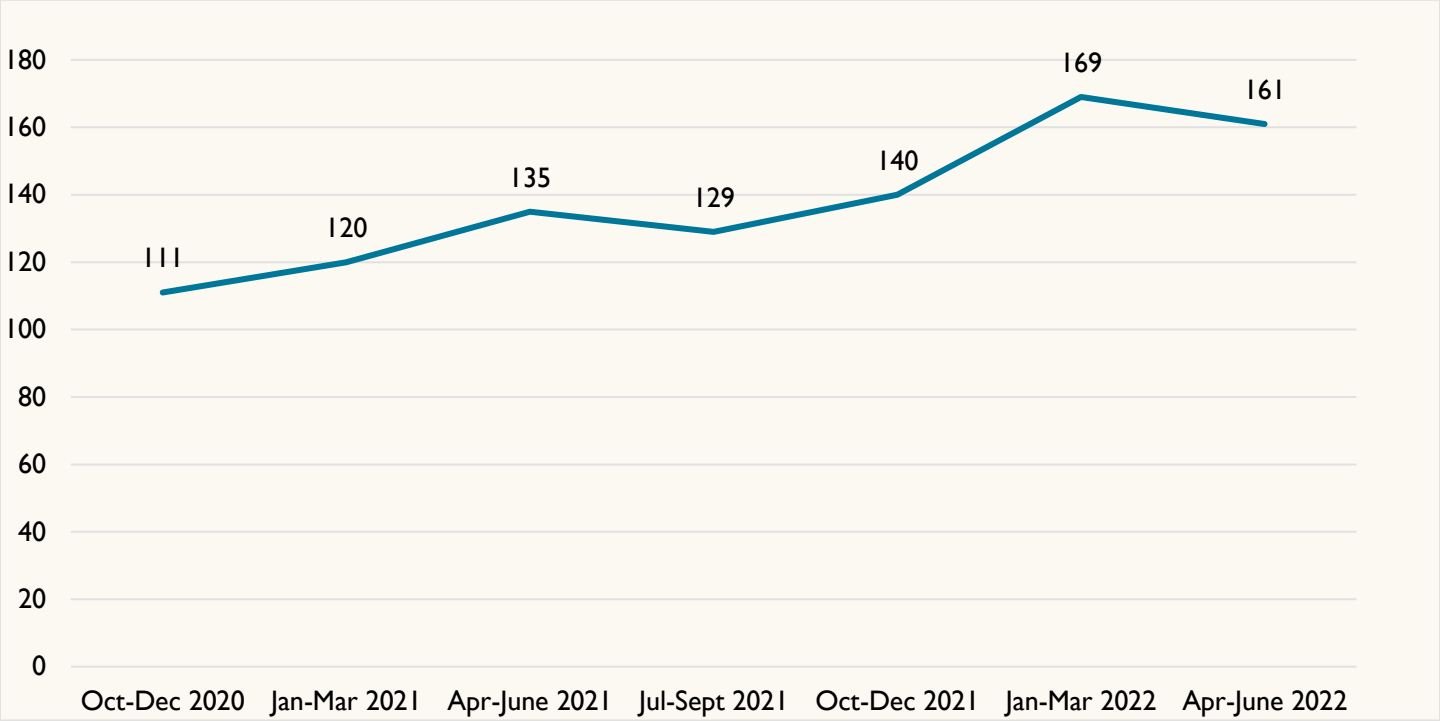

Figure 3: Increasing trend of RR/MDR-TB detected in five regions (Oromia, Amhara, SNNP, Sidama, and AA), October 2020–June 2022

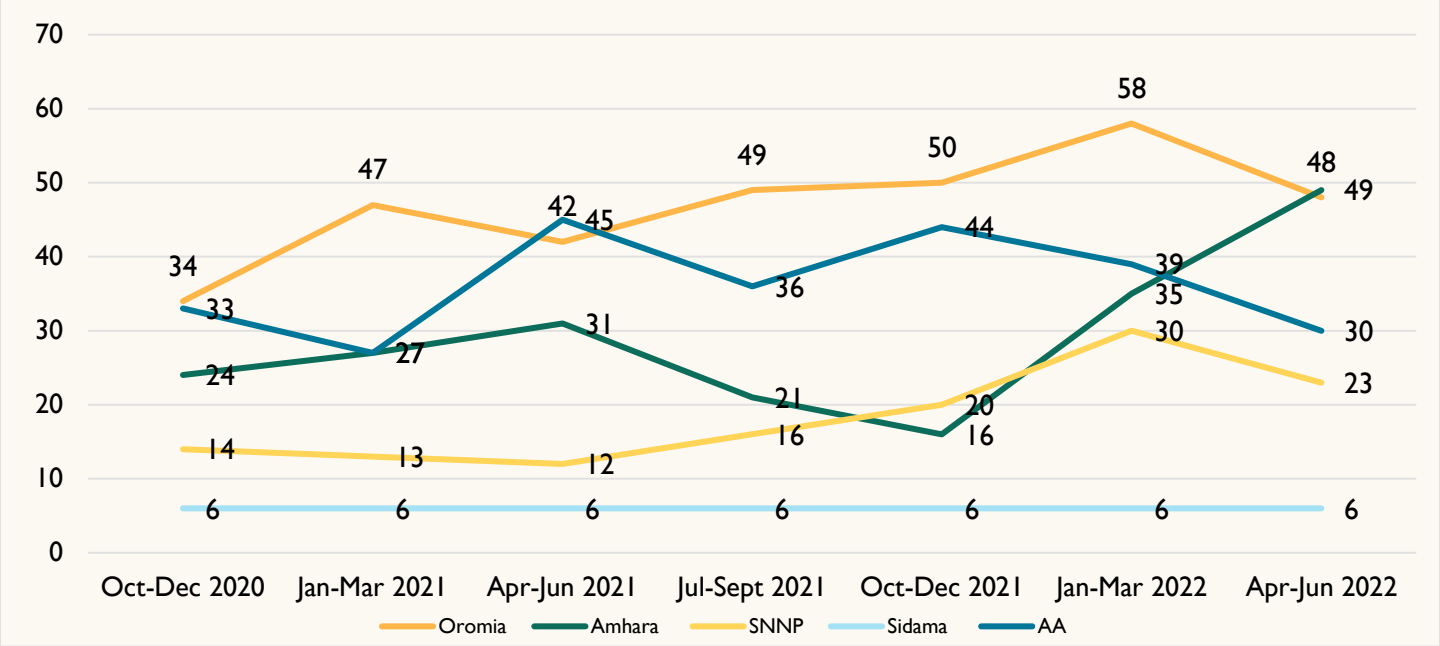

Figure 4: Increasing trend of RR/MDR-TB enrollment by region, October 2020–June 2022

Patient-centered adherence, care, support, and treatment outcomes of DR-TB patients

The average treatment success rate (TSR) for the five regions for project year 1 was over 75%, which is within the range of the national targets in the past two quarters (figure 5).

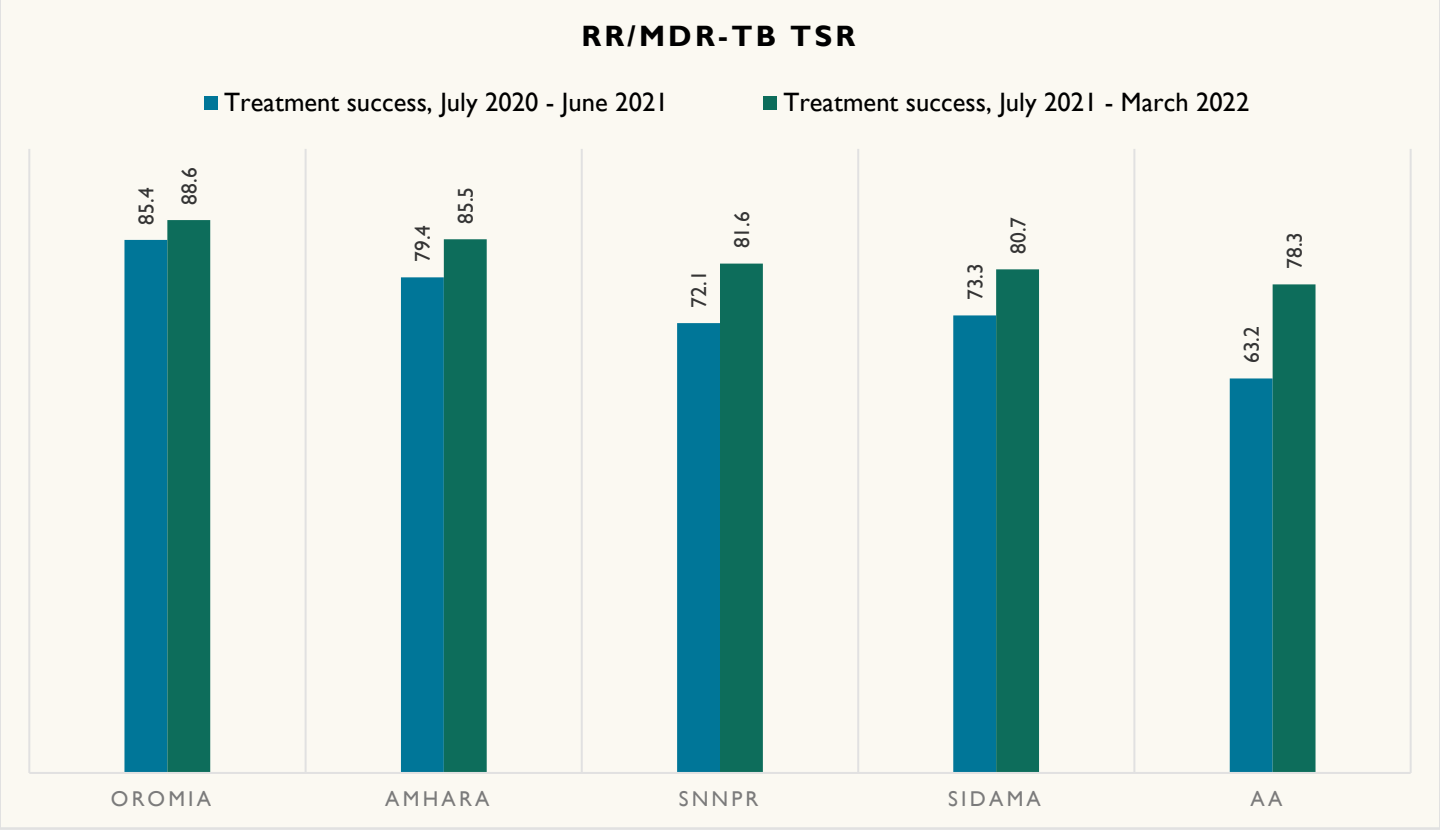

Figure 5: Treatment success rate of RR/MDR-TB treatment by region, July 2021–March 2022

MDR-TB tracker implementation and scale-up progress

Most TICs have started addressing data entry backlogs and the work is progressing well. They have also begun active live-case data entry for current patients. For the patient-level DR-TB case-monitoring system, the project collaborated with the USAID Digital Health Activity project for implementing the DR-TB tracker to conduct case-based registration and reporting of DR-TB patients. The project provided technical and financial support to conduct two rounds of performance reviews for 67 treatment initiation centers and 12 regional health bureaus, revise the tool to make it user-friendly, and cover airtime to ensure internet connectivity. So far, 1,789 DR-TB patients have been registered on the DR tracker (figure 6).

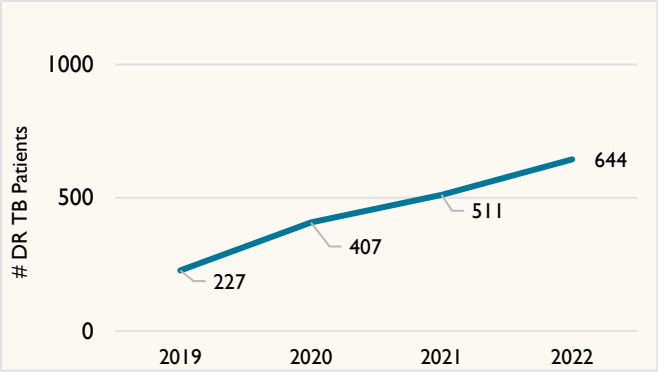

Figure 6: Increasing trend of DR-TB patients registered on DHIS2-based DR tracker, 2019–2022, national level

CHALLENGES

The main challenges have been stagnant DR-TB detection, presumptive case identification, inefficient specimen referral, low drug susceptibility test coverage, the impact of ongoing conflict on DR-TB case finding and treatment adherence, poor data quality, and suboptimal recording and reporting of adverse drug events. Reagent stockouts have limited the use of line probe assays, which in turn has hindered the enrollment of patients on the short treatment regimen.

Major bottlenecks associated with the implementation of the national DR-TB tracker include incompleteness of entered data, internet connection disruptions, turnover of trained staff, and a bulky and time-intensive tool. Moreover, the tool was not quite user friendly—it was difficult to edit, and generating reports was complicated. To overcome the challenges, the tool has been simplified and made more user friendly.

To deal with the challenges and gaps, several discussions were held with the National TB and Leprosy and other Lung Diseases Program and other stakeholders. Action plans were developed for subsequent follow-up and monitoring.

LESSONS LEARNED AND WAY FORWARD

RR/MDR-TB case detection and drug susceptibility test coverage were improved by:

- Strengthening contact investigation
- Screening high-risk populations for TB
- Advocating for the use of GeneXpert as an initial diagnostic test
- Regular mentoring of health care workers, supportive supervision, and onsite orientation
- Active case finding through targeted interventions at high-load health facilities.

Accelerated support of health care workers by national and regional senior clinical experts, facilitation of case consultations, support to national centers of excellence, technical meetings, and discussions with central and regional RR/MDR-TB experts could all enhance the quality of DR-TB services. These activities improve the quality of patient management by implementing senior experts' recommendations for complicated and advanced diseases. These activities must become routine practice in order to achieve successful patient treatment outcomes. Strengthening local non-governmental organization networking and partnerships and expediting the scale-up for implementation of the DR-TB tracker could further improve DR-TB case detection, care, and data quality.

REFERENCES

1. World Health Organization | Global tuberculosis report 2021. Geneva, Switzerland: World Health Organization, 2021. https://www.who.int/tb/publications/global_report/en/

2. Guidelines for Clinical and Programmatic Management of TB, TB/HIV, DR-TB and Leprosy in Ethiopia, 7th edition, August 2021, Addis Ababa, Ethiopia. http://dataverse.nipn.ephi.gov.et/bitstream/handle/123456789/1662/Guidelines_for_Clinical_and_Programmatic_Management_of_TB_TBHIV.pdf?sequence=1

Acknowledgements:
We thank Rachael Church, Mayssa el Khazen, Sara Harris, Pedro G. Suarez, and Veronica Triana at Management Sciences for Health for their contributions to this technical brief, as well as Mulatu Biru and Asfawesen Gebreyohannes at KNCV.

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This document is made possible by the generous support of the American people through the US Agency for International Development (USAID) cooperative agreement no. 72066320CA00009. The contents are the responsibility of Management Sciences for Health (MSH) and do not necessarily reflect the views of USAID or the United States Government.

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