EXECUTIVE SUMMARY
HELP ETHIOPIA ADDRESS LOW TB PERFORMANCE (HEAL TB) PROJECT 2011–2016
BACKGROUND

In 2010, when the United States Agency for International Development (USAID)-funded Help Ethiopia Address Low TB Performance (HEAL TB) project was designed, the population of Ethiopia was estimated to be 80 million, with more than half of Ethiopians living in the Amhara and Oromia Regions—18.1 and 29.6 million people respectively. Ethiopia was seventh among the 22 high-burden countries for tuberculosis (TB), with an estimated sputum-smear-positive rate of 163 per 100,000 population. Mortality was 92 per 100,000 population. The case detection rate was also very low, at 35.8% per the 2009–2010 report. The treatment success rate (TSR) was 84% and multidrug-resistant tuberculosis (MDR-TB) was a major concern, but there was no solid program. As for HIV, adult prevalence was 2.3% per the 2010 estimate.

The HEAL TB project supported 55 million people in five years. HEAL TB was a five-year, USAID-funded TB project implemented in the Amhara and Oromia Regions of Ethiopia. HEAL TB used a phased approach to provide comprehensive technical support, which encompassed case finding, universal DOTS, MDR-TB, TB/HIV, and health systems strengthening in 28 zones in the two regions. In Phase I, HEAL TB’s support was limited to 10 zones with an estimated population of 27 million. In the second phase, beginning in July 2014, the project expanded to 11 additional zones with a population of 16.6 million; seven more zones were added in August 2014, with a population of 10.9 million. The overall population coverage reached 55 million by Project Year (PY) 4. The initial cooperative agreement was designed to support only 15 zones, and many activities, such as MDR-TB, integrated sample transport, and capacity building of culture labs, were carried out without a budget increase. This report covers the period from July 15, 2011, through July 14, 2016.

CASES NOTIFIED, LIVES SAVED, AND NEW INFECTIONS AVERTED

A total of 265,842 new TB patients were treated. The project used several strategies to increase case notification. Among the main ones were screening all visitors to outpatient departments irrespective of the chief complaint that led them to seek medical attention; expanding the number of microscopic diagnostic health facilities; introducing TB contact screening (100,816 or 96.4% of contacts screened) and screening of diabetes patients, mining, pastoralist, and migratory workers; mapping high-TB-burden areas such as urban areas, mining areas, prisons, and pastoralist and commercial farm communities; and screening for TB at the community level using health extension workers (HEWs) and health development armies (HDAs). By implementing these complementary approaches, we were able to assist the two Regional Health Bureaus (RHBs) to enroll 265,842 new TB patients on treatment. Overall, there was a decline in the case notification rate by 8.2% from the baseline, while the decline in the rest of the country was 17.2%. The decline is compatible with the findings of the national survey. Although TB case notification is declining nationwide, prevalence is still 200 per 100,000, and some communities, such as mining, pastoralist, and commercial farm areas, have a high prevalence, which requires continuous surveillance to identify pockets with a high TB burden, and innovative case-finding strategies.

The overall project-level TSR has reached 94% from a baseline of 88%, and the cure rate has surpassed 88%, from an average baseline of 72% for the three phases. The achievement in the two regions was higher than the national averages of 92.5% TSR and 81.6% cure rate. If the high treatment outcome is sustained for a couple of years in the future, it is certain that the incidence of TB will decline further, the MDR-TB burden will decrease, and the country will be far along the path to achieve the End TB targets of the World Health Organization (WHO).
TB IN CHILDREN

Of the total number of new cases enrolled in treatment, 12% were children. Of all forms of TB notified from 2011 to 2016, children under 15 years of age constituted 12% of cases. Last year, the proportion of children diagnosed was also in the same range. This was achieved through health systems strengthening efforts, including the development of a pediatric TB roadmap, building the capacity of health workers through continuing medical education (CME), integrating TB screening into integrated management of newborn and childhood illnesses (IMNCI) clinics, and conducting contact investigation. Roll-out of GeneXpert has also contributed to improving the diagnosis of TB in children. Using TB household contact screening as an entry point, a total of 37,164 smear-positive TB index cases were registered, 10,584 children under the age of five were screened for TB, and 10,020 without TB symptoms were identified. Nearly four thousand (3,832, or 38.2%) were put on isoniazid preventive therapy (IPT), which is the highest number of children put on IPT in the country’s TB program history. Contact screening is an effective strategy for high TB case notification for both adults and children; it is also a very good entry point to put children on IPT. It has already become part of the national TB program strategy and the effort should be strengthened in the future. Although there was no national reporting system for the completion of IPT, HEAL TB followed a sample of health facilities and the completion rate was 80%.

CAPACITY STRENGTHENING OF TB LABORATORIES

More than 2,000 laboratories were supported in TB diagnosis. In support of the national TB laboratory system, HEAL TB focused on expanding the number of TB microscopic diagnostic centers, improving the quality of acid-fast bacillus (AFB) microscopy, introducing GeneXpert, improving culture and drug sensitivity testing (DST), and strengthening the sample transport system. In line with those goals, HEAL TB purchased 20 GeneXpert machines and 888 microscopes. An innovative strategy of creating decentralized external quality assurance (EQA) centers for Ziehl-Neelsen (ZN) microscopy covered 100% of the microscopic centers. Random blind rechecking was introduced as an innovation, and by the last year of the project, a total of 1,550 health facilities had regular quarterly EQA. A total of 102 EQA centers were established, up from a baseline of four, to serve the large number of health facilities. In the last year of the project, over 96% of the health facilities had a documented 95% and above concordance rate with that of the EQA center. The percentage agreement of positive slides with those of EQA readers was also 96%, and the percentage agreement of negative slides was 99.7%. The project’s experience with decentralized ZN microscopy was published in an international peer-reviewed journal. EQA for light-emitting diode (LED) microscopy using the blind rechecking method was piloted in the Amhara Region with the Regional Reference Laboratory (RRL) and Ethiopian Public Health Institute (EPHI), with results similar to those of ZN EQA. EPHI adopted the EQA approach after the pilot study and included it in the national guidelines to be implemented nationally.

Of 20,318 samples tested using GeneXpert, 21.3% were HIV-positive clients, while 13.1% were children below 15 years of age. Of the 18,227 tests with valid results, 17.9% were positive for Mycobacterium tuberculosis (MTB), and 296 (9.1%) of the MTB cases were rifampicin resistant (RR).

The performance of GeneXpert centers was variable, and the machines were not utilized to full capacity. The main reason is that most health facilities are distant from testing centers and transporting samples is difficult. To improve the sample referral linkages in the two regions, HEAL TB, in consultation with the EPHI and RRLs, purchased eight vehicles with cold-chain systems. A sample referral manual was developed; an e-health system for sample pickup and a system for delivering laboratory results via the web in real time were established; and couriers were employed. Full integrated sample transport for TB and HIV will be started soon.

To further enhance culture and DST services particularly for MDR-TB treatment follow-up cultures, HEAL TB procured five Mycobacterium Growth Indicator Tube (MGIT) liquid culture systems for the Adama, Harari, Hawassa, and Bahir Dar regional laboratories and Gondar University Hospital laboratory. Laboratory professionals from those institutions were also trained on culture and DST. All have started MGIT culture and DST services.

TB/HIV

Over 90% of TB patients were tested for HIV, and 89% of co-infected patients started antiretroviral treatment. In Phase I, II, and III zones, about 91%, 92%, and 92%, respectively, of TB patients were tested for HIV in Project Year 5 (PY5), whereas at baseline the testing rate was as low as 70%. Close to 89% of TB/HIV co-infected patients were also put on antiretroviral treatment (ART) in PY5, and uptake of cotrimoxazole preventive therapy (CPT) was 91.5%. IPT for HIV patients and screening of HIV/AIDS patients were part of the PEPFAR projects and HEAL TB collaborated with them, but did not directly report the achievements.
SUPPLY MANAGEMENT OF TB DRUGS

The rate of stock-outs of TB drugs dropped to 2%, and 2,186 TB drug kits were made available. The stock-out rate of TB drugs was as high as 20% at baseline and fell to 2% by the end of PY5. In year 1, it declined to 5%, in PY2 to 3%, and thereafter it was 2% for the remaining three years. The definition that we applied was “a health facility without a drug for one day for new patients,” but there were no stock-outs for patients who had started treatment. The implementation of Global Drug Facility (GDF) TB drug kits in the two regions contributed to the low rate of stock-outs of tracer drugs.

MDR-TB SERVICE EXPANSION AND IMPROVEMENTS IN QUALITY

Over 1,000 MDR-TB patients were identified and enrolled in treatment. Under the leadership of the Federal Ministry of Health (FMOH), HEAL TB worked with the two RHBs to apply the following strategies to identify MDR-TB cases: conducting conventional culture and DST as well as GeneXpert testing for all re-treatment and treatment failure cases and introducing strict smear conversion monitoring of pulmonary TB cases at the end of the second, third, fifth, and sixth months of treatment. For those who failed to convert, sputum was taken for GeneXpert or DST. The other strategy for case-finding was introducing contact screening of all MDR-TB contacts.

A challenge for the country was the existence of only two hospitals that could admit MDR-TB patients and initiate their treatment in 2011. With a mixed ambulatory and inpatient model designed by the FMOH, 23 treatment initiating centers (TICs) were established in the two regions, and more than 300 treatment follow-up centers were established for patients to get their DOT as close as possible to their homes. TICs are hospitals that have a physician qualified to initiate treatment and conduct monthly follow-ups. The treatment follow-up centers (TFCs) are health centers that are used only to administer DOT for patients who started their MDR-TB treatment in TICs and are referred to TFCs for their daily treatment. HEAL TB constructed three MDR-TB centers and equipped and trained staff of MDR-TB units in all 23 hospitals. A total of 1,005 MDR-TB patients started treatment in five years, an increase from a baseline of 50, in the two regions. The treatment success rates ranged from 76.5% to 84%, with variations in some quarters—as compared to a global average of 50%—and the cure rate was between 58.7% and 77% in different quarters, versus a national cure rate of 43.8%.

Training for health workers, continuing medical education for clinicians, and proper follow-up of patients were the major processes that contributed to improving the treatment outcomes of MDR-TB patients. Patients on follow-up take their DOT at nearby health centers, and one day per month they return to MDR-TB treatment initiating hospitals to receive their clinical checkup, give a sputum sample and other samples for treatment monitoring, and collect their supplementary food items. Their travel cost is also reimbursed on the same day. This arrangement helped the MDR-TB teams, including administrative staff, to dedicate the day to MDR-TB patients and save the remaining days for other hospital tasks. The laboratory professionals conduct the AFB smear microscopy locally, collect sputum for culture, and transport sputum samples to culture facilities in one batch. If a patient does not appear on the MDR-TB clinic day, a message is sent to the health center to trace the patient and send a health worker for follow-up. If the sputum AFB and culture do not convert at the expected time, treatment adherence is assessed. Contact screening of MDR-TB index cases is also done by the health center or the hospital.

CAPACITY BUILDING IN TB PROGRAM MANAGEMENT AND TECHNICAL SKILLS

Regions, zones, and woredas have full capacity in mentoring and supervision of health facilities. HEAL TB introduced an innovative strategy focused on zones and woredas, in line with the FMOH and woreda-led planning, implementation, monitoring, and evaluation, in order to support the system and create sustainability from the outset. More than 27,000 health workers were trained in five years’ time. Of those, more than 14,000 workers participated in short-term training, and the remaining 13,000 were trained using the nationally approved guidelines or under piloting for more than four days. These longer trainings include training of 1,500 woreda TB focal persons in TB program management and coordination. Furthermore, 6,152 health workers were trained in comprehensive TB, leprosy, and TB/HIV services. In both regions, a total of 2,614 laboratory professionals were trained on fluorescence microscopy (FM), ZN, and EQA, and 330 professionals were trained in laboratory quality management. Training on the integrated pharmaceutical logistics system was provided to 2,720 pharmacy professionals. Hands-on trainings for 106 health workers were held in model TB DOTS centers.

HEAL TB supported woreda health systems strengthening through improved supportive supervision and mentoring, supply of materials, strengthened mentoring and support on supply management, biomedical engineering, and TB infection control (IC). As of the last quarterly report, 70.4% of the health facilities had a TB IC plan, 72.5% had functional TB IC committees, and 72.6% were implementing priorit-
zation and triaging of coughing patients. HEAL TB worked with the zonal and woreda TB focal persons to conduct data quality assurance in health facilities, woreda health offices, and zonal health departments every quarter. The data quality in the two regions achieved a concordance rate ranging between 95.4% and 97.2% for different indicators, versus a baseline which was as low as 80.6% in the first year of the project.

INNOVATIONS AND OPERATIONAL RESEARCH

More than 70 abstracts were presented in national and international forums and 13 articles were published in peer-reviewed journals. Project researchers typically developed presentations and publications collaboratively with government counterparts. Operational research has been a major activity, and the project used research findings to revise or introduce new strategies and approaches and improve TB program implementation. HEAL TB disseminated the results of its innovative research both locally and in major international meetings and journals. A total of 70 abstracts were presented in international and national forums in five years’ time, and 13 articles were published in peer-reviewed journals, while another 13 are in the pipeline for publication. The project contributed 18 program implementation innovations to the National TB Program, and some have been adopted by other countries as well.

CONCLUSIONS AND WAY FORWARD

The USAID-funded HEAL TB project has contributed to significant improvements in TB program performance in Ethiopia, leading to the detection of more cases of TB, saving the lives of thousands of TB patients, and contributing to averting many new infections. The progress made in the areas of laboratory capacity building, supply management, MDR-TB, childhood TB, TB/HIV, community TB care, and operational research support was exemplary. Health systems strengthening was also a major achievement, including capacity building of human resources and strengthening of management capacity at all levels of the health care system, which are prerequisites for sustainability. The innovative and proven interventions implemented through HEAL TB’s support should be replicated in other regions of Ethiopia and other similar settings.
HEAL TB Partners:
Management Sciences for Health (MSH) (prime)
Program for Appropriate Technology in Health (PATH) (sub)
Kenya Association for the Prevention of Tuberculosis and Lung Diseases (KAPTLD) (sub)
All Africa Leprosy, Tuberculosis, Rehabilitation, Research, and Training Center (ALERT) (sub)

HEAL TB Country Office:
Management Sciences for Health – Ethiopia
Bole Sub City, Kebelle 02, House Number 708
PO Box 1157, Code 1250
Addis Ababa, Ethiopia

Contact information for this report:
Dr. Muluken Melese Aseresa
Project Director
+25 11 6 670 072
mmelese@msh.org